REGULATIONS

CHAPTER 3

Nuclear activities are highly diverse, covering any activity relating to the preparation or utilisation of radioactive substances or ionising radiation. Nuclear activities are covered by a legal framework that aims to guarantee that, depending on the nature of the activity and the associated risks, it will not be likely to be detrimental to safety, public health or the protection of nature and the environment.

This legal framework is adapted to the type of nuclear activity. Consequently, medical or industrial activities that involve ionising radiation or radioactive sources are regulated by the French Public Health Code (CSP). Beyond a given threshold of radioactive substances contained or used in an installation, that installation falls within the system of basic nuclear installations (BNI).

The 13th June 2006 Act concerning transparency and security in the nuclear field (now codified in books I and V of the Environment Code by ordinance 2012-6 of 5th January 2012) extensively overhauled the BNI legal regime. It has in particular given this system an "integrated" nature, that is to say that it seeks to prevent the hazards and detrimental effects of any type that the BNIs could create: accidents - whether nuclear or not, pollution - whether radioactive or not, waste - whether radioactive or not, noise, etc.

1 THE GENERAL LEGAL FRAMEWORK APPLICABLE TO NUCLEAR ACTIVITIES

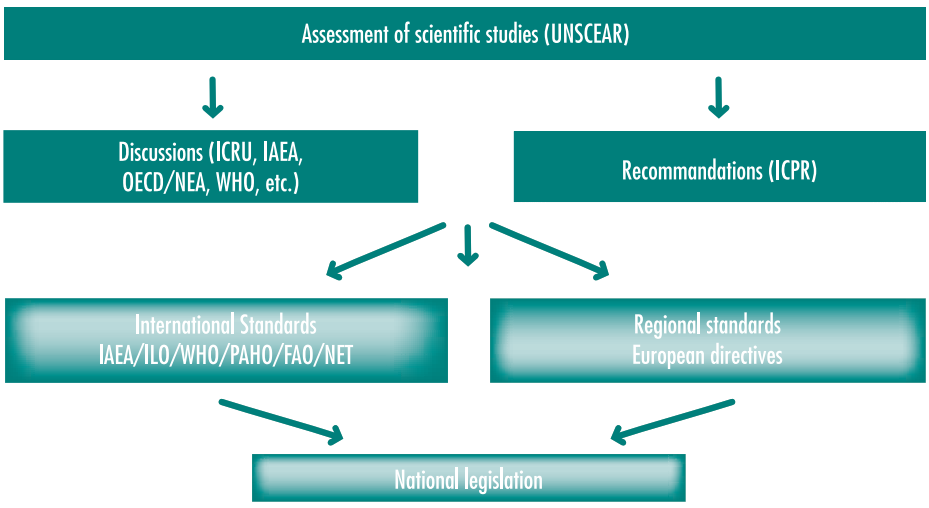
Nuclear activities are defined in article L. 1333-1 of the CSP (Public Health Code). As nuclear activities, they are subject to various specific requirements designed to protect individuals and the environment and applying either to all these activities, or only to certain categories. This set of regulations is described in this chapter.

1|1 The regulatory basis of nuclear activities

1|1|1 Radiation protection international baseline requirements

The specific legal requirements for radiation protection are based on various standards and recommendations issued internationally by various organisations. The following in particular can be mentioned:

– the International Commission on Radiation Protection (ICRP), a non-governmental organisation comprising international experts in various disciplines, which publishes recommendations concerning the protection of workers, the general public and patients against ionising radiation, based on an analysis of the available scientific and technical knowledge. The latest ICRP recommendations were published in 2007 in ICRP publication 103;
– the international atomic energy agency (IAEA) which regularly publishes and revises standards in the fields of nuclear safety and radiation protection. The basic requirements concerning protection against ionising radiation and the safety of radiation sources (basic safety standard no.115), based on the recommendations of ICRP 60, were published in 1996.



Drafting of radiation protection doctrine

A new standard on fundamental safety principles was published by the IAEA at the end of 2006 and, to take account of the new recommendations in ICRP 103, the basic safety standards (BSS) were updated in 2011 (Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards - Interim Edition);

– the International Standards Organisation (ISO) which publishes international technical standards which are a key part of the radiation protection system: they provide a bridge between the principles, concepts and units, and the body of regulatory texts for which they guarantee harmonised application.

At European level, the EURATOM treaty, in particular its Articles 30 to 33, defines the procedures for drafting EU provisions concerning protection against radiation and specifies the powers and obligations of the European Commission with respect to their enforcement. The corresponding EURATOM directives are binding on the various countries, such as directive 96/29/Euratom of 13th May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation; directive 97/43/Euratom of 30th June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure; and directive 2003/122/Euratom of 22nd December 2003 on the control of high-activity sealed radioactive sources and orphan sources.

In 2008, the European Commission initiated a process to merge and revise existing Euratom directives in order to incorporate the experience acquired by the Member States and the changes in international texts (ICRP, IAEA). A directive proposal, adopted in September 2011, is currently being reviewed at the European level, with publication scheduled for the end of 2012.

1|1|2 The codes and the main Acts applicable to the regulation of nuclear activities in France

The legal and regulatory requirements covering nuclear activities in France have been extensively revised in recent years. The legislative arsenal is now relatively complete and the publication of the implementing texts is well-advanced, even if not yet totally complete.

The Public Health Code (CSP) and the TSN Act (codified in books I and V of the Environment Code)

Chapter III ("ionising radiation") of part III of book III of the first part of the legislative part of the Public Health Code aims to cover all "nuclear activities", that is all activities involving a risk of human exposure to ionising radiation, emanating either from an artificial source, whether a substance or a device, or from a natural source when the natural radionuclides are or have been treated owing to their fissile or fertile radioactive properties. It also includes "interventions" aimed at preventing or mitigating a radiological risk following an accident, due to environmental contamination.

The European Parliament

Article L.1333-1 of the Public Health Code defines the general principles of radiation protection (justification, optimisation, limitation), established at international level (ICRP) and taken up in the requirements of the IAEA and directive 96/29/Euratom. These principles, described in chapter 2, constitute guidelines for the regulatory actions for which ASN is responsible.

The Public Health Code also institutes the radiation protection inspectorate, in charge of verifying compliance with its radiation protection requirements. This inspectorate, created and coordinated by ASN, is presented in chapter 4. The code also defines a system of administrative or criminal sanctions, described in the same chapter.

The Environment Code defines various notions

According to article L.591-1 of the Environment Code, nuclear security is a global concept encompassing "nuclear safety, radiation protection, the prevention and fight against malicious acts, and also civil security actions in the event of an accident". In some texts, however, the expression "nuclear security" remains limited to the prevention and mitigation of malicious acts.

Nuclear safety is "the set of technical provisions and organisational measures - related to the design, construction, operation, shut-down and decommissioning of basic nuclear installations (BNIs), as well as the transport of radioactive substances - which are adopted with a view to preventing accidents or limiting their effects".[1]

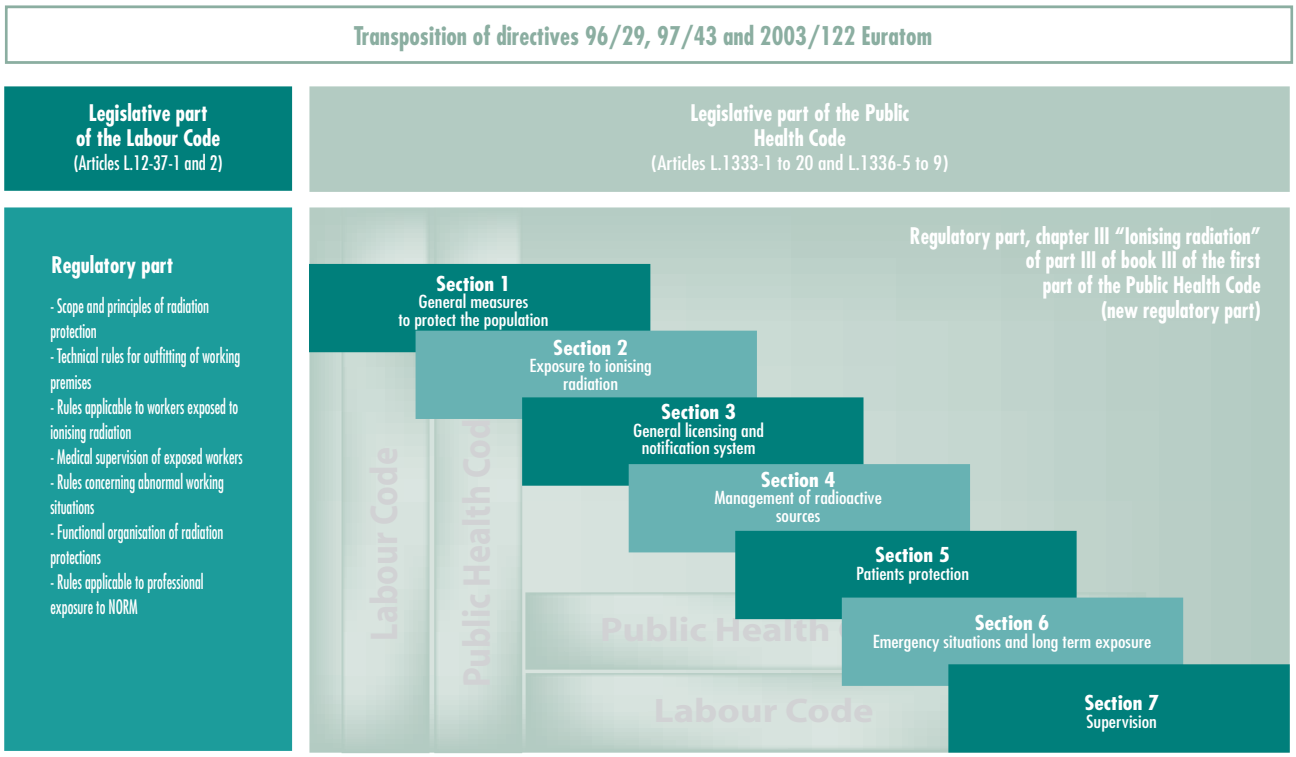
Radiation protection is defined as "the set of rules, procedures and prevention and surveillance means aimed at preventing or mitigating the direct or indirect harmful effects of ionising radiation on individuals, including in situations of environmental contamination".

Nuclear transparency is defined as "the set of provisions adopted to ensure the public's right to reliable and accessible information on nuclear security as defined in article L.591-1".

Article L. 591-2 of the Environment Code, stipulates the State's role in nuclear security: it "defines the nuclear security

1. Nuclear safety, as defined in the TSN Act, is thus a more limited concept than that of the objectives of the BNI regime as described in point 3 of this chapter.

Diagram 1: legislative and regulatory architecture of radiation protection



regulations and implements the checks necessary for their application". In accordance with Article L. 125-13 of the Environment Code, "the State is responsible for informing the public about the risks linked to nuclear activities defined in the first section of article L. 1333-1 of the Public Health Code and their impact on the health and safety of individuals and on the environment".

The general principles applicable to nuclear activities are mentioned in turn in Articles L. 591-3, L. 125-14 and L. 591-4 of the Environment Code (previously in article 2 of the TSN Act). These principles are presented in point 1 of chapter 2 of this report.

Chapter II of part IX of book V of the Environment Code (previously section II of the TSN Act) creates the ASN, defines its general duties and rights and specifies its composition and operation. Its missions are presented in points 2|3|1 et 2|3|2 of chapter 2.

The former part III of the TSN Act deals with public information about nuclear safety. This subject is detailed in chapter 6 of this report.

The TSN Act also contains measures specific to certain activities. They are presented in point 2|1|4 of this chapter.

Other codes or Acts containing requirements specific to nuclear activities

The Labour Code defines specific requirements for the protection of workers, whether or not salaried, exposed to ionising radiation. They are presented in point 1|2|1 of this chapter.

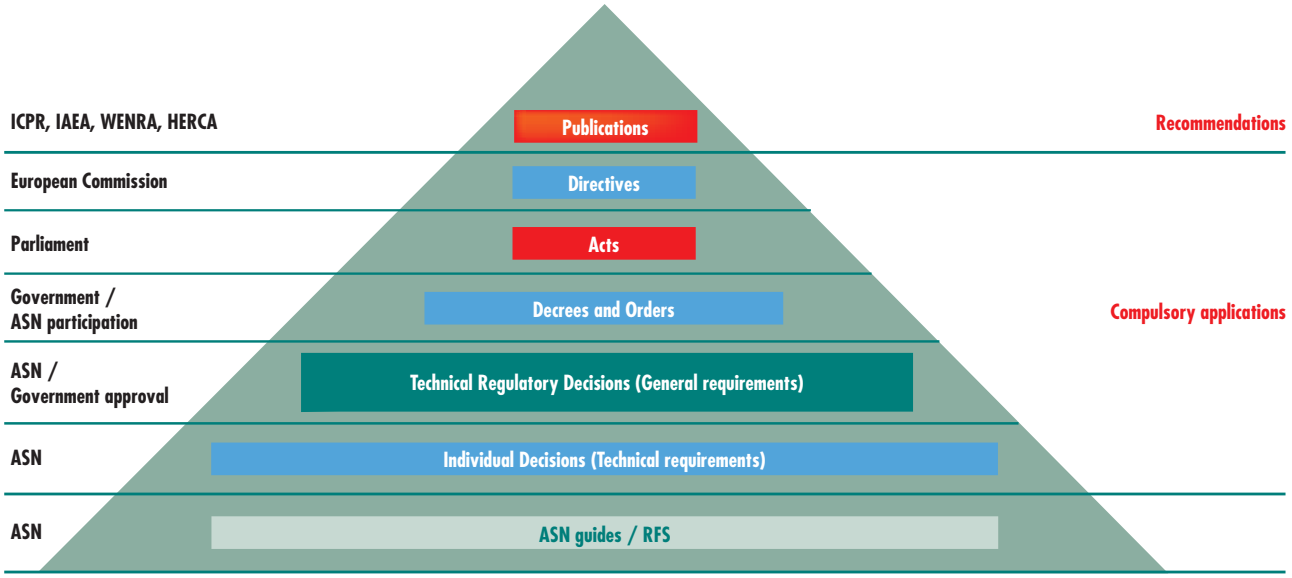
Programme Act 2006-739 of 28th June 2006 on the sustainable management of radioactive materials and waste, called the "Waste" Act, codified in books I and V of the Environment Code, sets the legal requirements for the management of radioactive materials and waste. It also requires that BNI licensees make provision for the cost of managing their waste and spent fuel, or the decommissioning of their installations Chapter 16 describes certain aspects of this Act in detail.

Finally, the Defence Code contains various measures concerning the fight against malicious acts in the nuclear field, or the regulation of defence-related nuclear activities and installations. They are presented further on in this chapter.

The other regulations concerning nuclear activities

Some nuclear activities are subject to a variety of rules with the same goal of protecting individuals and the environment as the above-mentioned regulations, but with a scope that is not limited to nuclear aspects alone. This for example includes European or Environment Code requirements concerning impact assessments, public information and consultation, the regulations governing the transport of hazardous materials or the regulations governing pressure equipment. The applicability of some of these rules to nuclear activities is mentioned during the course of this report.

Diagram 2: various levels of regulation in the field of small-scale nuclear activities in France (orientations, recommendations): legally binding or non-binding nature



1|2 The regulations applicable to the various categories of individuals and the various situations involving exposure to ionising radiation

The appendix to this chapter gives the various levels and exposure limits set by the regulations.

1|2|1 General protection of workers

The Labour Code contains a number of requirements specific to the protection of workers, whether or not salaried, exposed to ionising radiation. It transposes into French law two Euratom directives, namely 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas, and the above-mentioned directive 96/29/Euratom.

The Labour Code establishes a link with the three radiation protection principles contained in the Public Health Code. The regulatory articles of this code concerning radiation protection were reclassified by decree 2010-750 of 2nd July 2010 relative to the protection of workers against risks due to artificial optical radiation.

A General Directorate for Labour/ASN joint Circular no. 4 of 21st April 2010 indicates the conditions of application of the provisions of the Labour Code concerning the radiation protection of workers.

Articles R. 4451-1 to R. 4451-144 of the Labour Code create a single radiation protection system for all workers (whether or not salaried) liable to be exposed to ionising radiation during the course of their professional activities.

Of these requirements, the following should be mentioned:
– application of the optimisation principle to the equipment, processes and work organisation (Articles R. 4451-7 to 11), which leads to clarification of where responsibilities lie and how information is circulated between the head of the facility, the employer, in particular when he or she is not the head of the facility, and the person with competence for radiation protection;

TO BE NOTED

The Euratom directive setting the basic radiation protection standards

The new Euratom directive proposal, setting the basic radiation protection standards, currently being discussed at the European level, sets an effective dose limit of 20 mSv per year, in place of the value of 100 mSv for five consecutive years (provided that this effective dose does not exceed 50 mSv in any one year). The Labour Code anticipated this change as early as 2003 and, as it stands, it is already in compliance with this future European requirement.

Moreover, and in accordance with the latest recommendations from the International Commission on Radiological Protection (ICRP), dating from 21st April 2011, this new draft European text proposes a significant reduction in the equivalent dose limit for the lens of the eye, to 20 mSv over a one-year period. French regulations currently state an equivalent dose limit for workers of 150 mSv over 12 consecutive months for the lens of the eye.

– the annual dose limit (articles R. 4451-12 to 15) set at 20 mSv for 12 consecutive months, barring waivers resulting from exceptional exposure levels justified in advance, or emergency occupational exposure levels;
– the dose limits for pregnant women (article D. 4152-5) or more accurately for the unborn child (1mSv for the period from the declaration of pregnancy up until birth).

Zoning

Provisions concerning the boundaries of supervised areas, controlled areas and specially regulated areas (subject to special checks) were issued, regardless of the activity sector, by the order of 15th May 2006 (O.G. of 15th June 2006). This order also defines the health, safety and maintenance rules to be observed in these zones.

When defining the regulated zones, different levels of protection are taken into account: the effective dose for external exposure and, as applicable, internal exposure of the whole body; the equivalent doses for external exposure of the extremities and, as applicable, the dose rates for the whole body. A General Directorate for Labour/ASN joint circular of 18th January 2008 specifies the implementation procedures.

Check on zoning signage during an inspection of the nuclear medicine unit of the Oscar Lambret centre in Lille – November 2011

The person with competence for radiation protection (PCR)

The duties of the person with competence for radiation protection (PCR) were extended to delineating the areas in which radiation work is being carried out, to assessing the exposed workstations and to taking measures such as to reduce exposure (optimisation). For the performance of these duties, the PCR will have access to passive dosimetry and operational dosimetry data (article R. 4451-112 of the Labour Code).

The order of 26th October 2005 concerning training of the person with competence for radiation protection and certification of the instructor distinguishes between three different activity sectors:
– the "medical" sector, comprising nuclear and radiological activities intended for preventive and curative medicine - including forensic examinations - dentistry, medical biology and biomedical research, as well as veterinary medicine;
– the "Basic nuclear installation – BNI / Installation classified on environment protection grounds – ICPE" sector, comprising establishments containing one or more BNIs, as well as those comprising a facility requiring licensing as a classified installation, with the exception of medical sector nuclear activities as defined above;
– the "industry and research" sector, covering the nuclear activities defined in article R. 4451-1 of the Labour Code, with the exception of the activities in the "medical" and "BNI - ICPE" sectors defined above.

The instructor must be certified by an organisation accredited by the French accreditation committee (COFRAC).

ASN decision 2009-DC-0147 of 16th July 2009 defines the conditions to be met by a PCR who is not an employee of the company in which the nuclear activity is carried out. This option of calling on an outside PCR is limited to those nuclear activities that require notification to ASN. On the basis of the opinion issued by the Advisory Committee for radiation protection (GPRAD), an update of the order of 26th October 2005 is currently being examined, with publication scheduled in 2012.

UNDERSTAND

The role of the "Radiation Protection Expert"

On the basis of the work done by EUTERP (European Training and Education on Radiation Protection Platform), the proposed Euratom directive currently being examined at the European level, intends to change the concept of "qualified expert" stipulated by directive 96/29 (PCR in France), by introducing an advisory function for the RPE (radiation protection expert) and a more operational role for the RPO (radiation protection officer).

The RPE will be responsible for issuing an opinion to the head of the company or the employer on questions concerning exposure of the workers and the general public. This opinion will in particular concern new facilities, the delineation of regulated zones, worker classifications, the content of monitoring and inspection programmes, the optimisation and definition of appropriate dose constraints, training programmes for exposed workers, and so on.

Operational radiation protection tasks will be entrusted to the RPO: they include monitoring the effective implementation of the inspection programme, individual dosimetric surveillance and the creation of adequate source registers.

Dosimetry

The approval procedures for organisations tasked with worker dosimetry are defined by the order of 6th December 2003 as amended; the procedures for medical monitoring of workers and the transmission of individual dosimetry data are specified in the order of 30th December 2004 (the order of 30th December 2004 is currently being updated and should be completed in 2012). ASN is in charge of examining the approval applications submitted by the dosimetry organisations and laboratories.

Radiation protection checks

Technical controls on of sources and devices emitting ionising radiation, protection and alarm devices and measuring instruments, as well as ambient environment checks, can be entrusted to the French institute for radiation protection and nuclear safety (IRSN), to the department with competence for radiation protection or to organisations approved under application of Article R. 1333-97 of the Public Health Code. The nature and frequency of the radiation protection technical controls are defined by ASN decision no. 2010-DC-0175 of 4th February 2010.

These technical controls concern sources and devices emitting ionising radiation, the ambient environment, measuring instruments and protection and alarm devices, management of sources and of any waste and effluents produced. Some of these controls are carried out as part of the licensee's in-house inspection processes and some by outside organisations (the outside checks must be performed by IRSN or an organisation approved under article R. 1333-97 of the Public Health Code – see point 2|1|2).

Radon in the workplace

(see point 2|3|1).

1|2|2 General protection of the general public

Apart from the special radiation protection measures included in individual nuclear activity licences for the benefit of the general public and the workers, a number of general measures included in the Public Health Code help to protect the public against the dangers of ionising radiation.

Public dose limits

The annual effective dose limit (article R. 1333-8 of the Public Health Code) received by a member of the public as a result of nuclear activities, is set at 1mSv; the equivalent dose limits for the lens of the eye and the skin are set at 15mSv/year and 50 mSv/year respectively. The calculation method for the effective and equivalent dose rates and the methods used to estimate the dosimetric impact on a population are defined by ministerial order of 1st September 2003.

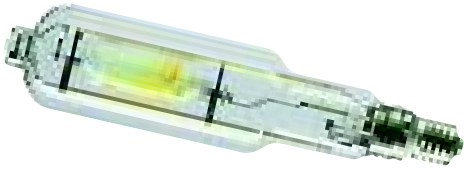
Radioactivity in consumer goods and construction materials

The intentional addition of natural or artificial radionuclides in all consumer goods and construction materials is prohibited (article R. 1333-2 of the Public Health Code). Waivers may however be granted by the minister for health after receiving the opinion of the French high public health council (HCSP) and ASN, except with respect to foodstuffs and materials placed in contact with them, cosmetic products, toys and personal ornaments. The Government order of 5th May 2009 specifies the content of the waiver application file and the consumer information procedures stipulated in Article R. 1333-5 of the Public Health Code. This waiver arrangement was used for the first time in 2011 to cover the gradual phase-out of ionization smoke detectors (see chapter 10). This prohibition principle does not concern the radionuclides naturally present in the initial components or in the additives used to prepare foodstuffs (for example potassium 40 in milk) or for the manufacture of materials used in the production of consumer goods or construction materials.

Furthermore, the use of materials or waste from a nuclear activity is also prohibited, when they are contaminated or likely to have been contaminated by radionuclides as a result of this activity.

At present, there are no regulations limiting the natural radioactivity of construction materials, when this is naturally present in the components used in their manufacture.

The proposed Euratom directive currently being examined at European level introduces a new regulatory framework to limit natural radioactivity in construction materials. Regulations such as these do not exist in France. It will require that manufacturers carry out tests to measure the potential emissions of gamma radiation.



Very high-intensity gas discharge lamp

Radioactivity and the environment

A national network for the collection of environmental radioactivity measurements was set up in 2009 (Article R. 1333-11 of the Public Health Code) and the data collected will help estimate the doses received by the general public. The network's orientations are defined by ASN and it is managed by IRSN (order of 27th June 2005 on the organisation of a national network for the measurement of environmental radioactivity and setting the conditions for laboratory approval).

To guarantee the quality of the measurements, the laboratories in this network must meet approval criteria, which in particular include intercomparison benchmarking tests.

New-generation IRSN Téléray network monitor designed to monitor ambient gamma radiation in France, installed on the roof of the Navy headquarters in Paris.

A detailed presentation of the national measurement network is given in chapter 5.

The radiological quality of water intended for human consumption

Pursuant to article R. 1321-3 of the Public Health Code, water intended for human consumption is subject to radiological quality inspection. The inspection procedures are specified in the order of 12th May 2004. They form part of the sanitary inspections carried out by the Regional Health Agencies (ARS). The order of 11th January 2007 concerning water quality limits and benchmarks introduces four radiological quality indicators for water intended for human consumption. These indicators and the corresponding limits are the total alpha activity (0.1Bq/L), the total residual beta activity (1Bq/L), the tritium activity (100Bq/L) and the total indicative dose – TID (0.1mSv/year). The circular from the General Directorate for Health (DGS) dated 13th June 2007, accompanied by recommendations from ASN, specifies the policy underpinning this regulation.

Radiological quality of foodstuffs

Restrictions on the consumption or sale of foodstuffs may be necessary in the event of an accident or of any other radiological emergency situation.

In Europe, these restrictions are determined by Council Regulation 3959/87/Euratom of 22nd December 1987, modified by Council Regulation no.2219/89/EEC of 18th July 1989, laying down maximum permitted levels of radioactive contamination of foodstuffs and of feeding-stuffs. The maximum permitted levels were defined to "safeguard the health of the population while maintaining the unified nature of the market".

In the event of a confirmed nuclear accident, "automatic"application of this regulation cannot exceed a period of three months, after which it will be superseded by specific measures (see the regulation specific to the Chernobyl accident, the values of which are given in the appendix.

Following the events which affected the Fukushima nuclear power plant, as of 11th March 2011, contamination analyses on certain foodstuffs produced around the plant have revealed radioactive contamination levels higher than those accepted by commercial sale standards. European regulation (EU) 297/2011, amended by regulations 351/2011, 506/2011 and 657/2011, stipulated harmonised implementation of contamination checks on food products imported from Japan. These European provisions stipulate a two-level process, with the first checks prior to export being conducted under the responsibility of the Japanese authorities, and then further checks being performed on arrival in European territory, in all the Member States of the European Union. Two inspection levels were defined by the European regulation, depending on the geographical proximity of the area of origin of the foodstuffs to the Fukushima plant.

This measure enables each Member State to adapt the level of control to that it wishes to use. To maximise consumer safety, the French authorities decided first of all to run 100% checks on all foodstuffs of animal origin produced after 11th March and all fresh produce. This level of inspection is changing in line with the clearer picture being obtained of the contamination of foodstuffs in Japan.

The results of these checks should be compared first of all with the MPL set by regulation 3459/87/Euratom and, since 11th April, with the MPL set by appendix II to regulation 351/2011 (these levels correspond to the MPL applied by the Japanese authorities and are more restrictive than those set by regulation 3954/87/Euratom). The radioactive substances measured are iodine 131 and radioactive caesium. The analyses are carried out by the network of laboratories of the Ministry responsible for agriculture (nine laboratories reporting to the General Councils) and by the laboratories reporting to the customs and consumer affairs services (joint laboratories service).

Radioactive waste and effluents

Management of waste and effluents from BNIs and ICPEs is subject to the provisions of the special regulations concerning these installations (for BNIs, see point 3|5 of this chapter). For the management of waste and effluents from other establishments, including hospitals (article R. 1333-12 of the Public Health Code), general rules are established in an ASN decision 2008-DC-0095 of 29th January 2008. These waste and effluents must be disposed of in duly authorised facilities, unless there are special provisions for on-site organisation and monitoring of their radioactive decay (this concerns radionuclides with a radioactive half-life of less than 100 days).

Although above-mentioned Directive 96/29/Euratom so allows, French regulations have not adopted the notion of discharge threshold, in other words, the generic level of radioactivity below which the effluents and waste from a nuclear activity can be disposed of without supervision. In practice, the disposal of waste and effluents is regulated on a case by case basis when the activities that produce them are subject to licensing (the case of BNIs and ICPEs) or can be covered by technical requirements when these activities simply require notification. Similarly, French regulations do not use the notion of "trivial dose" as contained in Directive 96/29/Euratom, in other words, a dose below which no radiation protection action is considered to be necessary (10µSv/year).

1|2|3 Protection of persons in a radiological emergency situation

The general public are protected against the hazards of ionising radiation in the event of an accident or of radiological emergency situations through the implementation of specific actions (or countermeasures) appropriate to the nature and scale of the exposure. In the particular case of nuclear accidents, these actions were defined in the government circular of 10th March 2000 which amended the off-site emergency plans (PPI) applicable to BNIs, by expressing intervention levels in terms of doses. These levels constitute reference points for the public authorities (*préfets*[1]) who have to decide locally, on a case by case basis, on what action is to be taken.

Reference and intervention levels

The intervention levels were updated in 2009 by ASN regulatory decision 2009-DC-0153 of 18th August 2009, with a reduction of the level concerning exposure of the thyroid. Henceforth, the protection measures to be taken in an emergency situation, and the corresponding intervention levels, are:
– sheltering, if the predicted effective dose exceeds 10mSv;
– evacuation, if the predicted effective dose exceeds 50mSv;
– administration of stable iodine, when the predicted thyroid dose is liable to exceed 50 mSv.

The reference exposure levels for persons intervening in a radiological emergency situation are also defined in the regulations (Articles R. 1333-84 and 86 of the Public Health Code) and two groups of response personnel are thus defined:
– the first group comprises the personnel making up the special technical or medical response teams set up to deal with a radiological emergency. These personnel benefit from radiological surveillance, a medical aptitude check-up, special training and equipment appropriate to the nature of the radiological risk;
– the second group comprises personnel who are not members of the special response teams but who are called in on the basis of their expertise. They are given appropriate information.

The reference individual exposure levels for the participants, expressed in terms of effective dose, should be set as follows:
– the effective dose which may be received by personnel in group 1 is 100 mSv. It is set at 300 millisieverts when the intervention measure is aimed at protecting other people;
– the effective dose which may be received by personnel in group 2 is 10 millisieverts. In exceptional circumstances, volunteers informed of the risks involved in their acts may exceed the reference levels, in order to save human life.

Emergency exercise in the off-site emergency plan zone of the Chinon nuclear power plant – June 2011

Public information in a radiological emergency

The ways in which the general public is informed in a radiological emergency situation are covered by a specific EU directive (Directive 89/618/Euratom of 27th November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency). This directive was transposed into French law by decree 2005-1158 of 13th September 2005 concerning the off-site emergency plans for certain fixed structures or installations, implementing article 15 of Act 2004-811 of 13th August 2004 on the modernisation of civil security.

Two implementing orders were published:
– the order of 4th November 2005 concerning public information in the event of a radiological emergency situation;
– the order of 8th December 2005 concerning the medical aptitude check-up, radiological surveillance and training or information to the personnel involved in managing a radiological emergency situation.

1|2|4 Protection of the general public in a long-term exposure situation

Sites contaminated by radioactive materials are sites which have been contaminated by a nuclear activity in the recent or more distant past (use of unsealed sources, radium industry, etc.) or an industrial activity using raw materials containing significant quantities of natural radionuclides (uranium and thorium families). Most of these sites are listed in the inventory distributed and periodically updated by ANDRA.

A new guide for the management of potentially contaminated sites, which was drafted under the supervision of ASN and the Ministry for ecology has, since December 2011, replaced the IRSN guide published in October 2000. It describes how to deal with the various situations liable to be encountered when rehabilitating sites (potentially) contaminated by radioactive substances.

2. In a *département*, representative of the State appointed by the President.

2 REGULATORY REQUIREMENTS APPLICABLE TO SMALL-SCALE NUCLEAR ACTIVITIES

2|1 The small-scale nuclear activities licensing and notification system

2|1|1 Licensing and declaration procedures for sources of ionising radiation

The system of licensing or notification, which covers all sources of ionising radiation, is described in section 3 of chapter III of part III of book III of the first part of the Public Health Code. Licences are issued by ASN and notifications are filed with the ASN regional divisions. Medical, industrial and research applications which do not benefit from a waiver are concerned by these procedures. This more specifically concerns the manufacture, possession, distribution – including import and export – and use of radionuclides or products and devices containing them.

The licensing system applies both to companies or facilities which have radionuclides on-site, and to those which trade in them or use them without directly possessing them. However, the licences issued under the licensing system for industries covered by the mining code, BNIs and ICPEs, constitute authorisation to produce or possess sources of ionising radiation.

Finally, the X-ray facilities used for forensic procedures (for example, radiological examination to determine the age of an individual, use of X-rays to detect objects hidden within the human body, etc.), are regulated by the licensing or notification system applicable to facilities designed for medical uses, given that individuals will be intentionally exposed to ionising radiation (see point 2|2).

Licence application form updated in 2011, available from *www.asn.fr*

The renewable ASN licence is delivered for a period that cannot exceed 10 years. The licence application or notification is made with a form that can be downloaded from the *www.asn.fr* website or obtained from the ASN regional divisions. The conditions for filing licence applications, established by Articles R. 1333-23 and following of the Public Health Code, are set out by ASN decision 10-DC-192 of 22nd July 2010, which establishes the content of the dossiers enclosed with the licence application. During the preparation of these texts, the requirements applicable to the various medical and non-medical fields were harmonised. The new forms integrating the above decisions will be available in the course of 2011.

Activities requiring notification

The list of activities requiring notification pursuant to article R.1333-19-1 of the Public Health Code was updated in 2009 by ASN decision 2009-DC-0146 of 16th July 2009, supplemented by ASN decision 2009-DC-0162 of 20th October 2009. As in low-intensity medical radiology, radiology in veterinary practices is now included in the activities requiring notification. It is added to the list of non-medical activities requiring notification, pursuant to Article R.1333-19-3 of the Public Health Code.

When the dossier is considered by ASN to be complete, an acknowledgement of receipt of notification of the installations is sent by ASN to the notifying party. As the maximum validity period for a notification has been abolished, a new notification for regularly notified activities only becomes necessary if significant changes have been made to the installation (replacement or addition of an appliance, transfer or substantial modification of the premises or change in the licence holder).

Licensing of medical applications and biomedical research

ASN issues licences for the use of radionuclides, or products and devices containing them, used in nuclear medicine and brachytherapy, for the use of particle accelerators in external radiotherapy, tomography appliances and blood product irradiators. For medical and biomedical research applications, the licensing system contains no exemptions.

Licensing of non-medical activities

ASN is responsible for issuing licences for industrial and non-medical research applications. This concerns:
– the import, export and distribution of radionuclides and products or devices containing them;
– the manufacture, possession and use of radionuclides, products or devices containing them, devices emitting ionising radiation or radioactive sources, the use of accelerators other than electron microscopes and the irradiation of products of whatsoever nature, including foodstuffs, with the exception of

activities which are licensed under the terms of the mining code, the BNI system or that applicable to ICPEs.

The license exemption criteria adopted by directive 96/29/Euratom (Annex 1, table A) are appended to the Public Health Code (table A, annex 13-8).

Exemption will be possible if one of the following conditions is met:
– the total quantity of radionuclides possessed is less than the exemption values in Bq;
– the radionuclide concentrations are less than the exemption values in Bq/kg.

2|1|2 Approval of radiation protection technical supervision organisations

Technical monitoring of the radiation protection organisation, including monitoring of the management of radioactive sources and any associated waste, is entrusted to approved organisations (article R. 1333-97 to of the Public Health Code). The conditions and procedures for approval of these organisations are set by ASN decision 2010-DC-0191 of 22nd July 2010. ASN is responsible for issuing these approvals. The list of approved organisations is available on the ASN website (*www.asn.fr*). The nature and frequency of the radiation protection technical checks are defined in ASN decision 2010-DC-0175 mentioned in point 1|2|1.

2|1|3 Licensing the suppliers of ionising radiation sources

ASN decision 2008-DC-0109 of 19th August 2008 concerns the licensing system for the distribution, import and/or export of radionuclides and products or devices containing them. This decision covers products intended for industrial and research purposes, but also health products: drugs containing radionuclides (radiopharmaceutical drugs, precursors and generators), medical devices (gamma-ray teletherapy devices, brachytherapy sources and associated applicators, blood product irradiators, etc.) and *in vitro* diagnosis medical devices (for radioimmunology assay).

ASN decision 2008-DC-0108 of 19th August 2008 in particular concerns the licence to possess and use a particle accelerator (cyclotron) and the manufacture of radiopharmaceuticals containing a positron emitter.

During the preparation of these texts, the requirements applicable to the various medical and non-medical fields were harmonised. The new forms incorporating the above decisions reflect this harmonisation. They are available on the ASN website, along with guides to help applicants put together their dossiers.

2|1|4 Radioactive source management rules

The general radioactive source management rules are contained in section 4 of chapter III of part III of book III of the first part of the Public Health Code. Responsibility for keeping the national inventory of sources is given to IRSN (Article L. 1333-9 of the Public Health Code).

Packaging of sealed sources, nuclear medicine unit in Nancy university hospital

The national table of financial guarantees required from source suppliers, and the implementation and payment procedures, must be defined in an order from the ministers responsible for Health and for Finance (Articles R. 1333.53 and R. 1333-54-2 of the Public Health Code). Pending publication of this order, the particular licensing conditions established by the CIREA (French Interministerial Commission for Artificial Radionuclides) in 1990 are reiterated as requirements in the licences, which allows their validity to be extended.

2|2 Protection of persons exposed for medical and forensic purposes

Radiation protection for individuals exposed for medical purposes is now based on two regulatory principles: justification of the procedures and optimisation of exposure, which are under the responsibility of both the practitioners prescribing medical imaging examinations entailing exposure to ionising radiation and the practitioners carrying out these procedures. Ultimate responsibility for exposure lies with the practitioners carrying out the procedures. These principles cover all the diagnostic and therapeutic applications of ionising radiation, including radiological examinations requested for screening, occupational health, sports medicine and forensic purposes.

2|2|1 Justification of practices

A written exchange of information between the prescribing practitioner and the practitioner carrying out the procedure

exposing the patient should provide justification of the benefit of the exposure for each procedure. This "individual" justification is required for each procedure. Articles R. 1333-70 and R. 1333-71 of the Public Health Code respectively require the publication of "prescription of routine procedures and examinations" guides (also called "referral criteria for imaging guides") and "performance of procedures" guides (called "procedure guides").

2|2|2 Optimisation of exposure

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

Standardised guides for conducting procedures using ionising radiation have been prepared and are regularly updated by health professionals, or are currently being prepared, to facilitate optimisation in practice (table 1).

Diagnostic reference levels

The diagnostic reference levels (DRL) are one of the tools used for dose optimisation. As required in article R. 1333-68 of the Public Health Code, the DRL are defined in the order of 24th October concerning diagnostic reference levels in radiology and nuclear medicine. For radiology, this consists of dose values, while for nuclear medicine it consists of activity levels administered in the course of the most common or most heavily irradiating examinations. Depending on the type of examination, periodic measurements or readings shall be taken in each radiology and nuclear medicine unit.

Dose constraints

In the field of biomedical research, where exposure to ionising radiation is of no direct benefit to the persons exposed, dose constraints designed to limit the doses delivered must be established by the physician.

Medical radiation physics

The safety of radiotherapy and optimisation of the doses delivered to the patients in medical imaging require particular expertise in the field of medical physics. The employment of a specialised medical radiation physicist (PSRPM), formerly called a "radiophysicist", has been extended to radiology, having already been compulsory in radiotherapy and nuclear medicine.

The duties of the PSRPM were clarified and broadened by the order of 19th November 2004. Thus medical radiation physics specialists must ensure the appropriateness of the equipment, data and computing processes for determining and delivering the doses and activity levels administered to the patient in any procedure involving ionising radiation. In the field of radiotherapy, they guarantee that the radiation dose received by the tissues due to be irradiated matches that prescribed by the prescribing physician.

Furthermore, they estimate the dose received by the patient during diagnostic procedures and play a part in quality assurance including inspecting the quality of the medical devices.

Temporary criteria determining the conditions for the presence of radiation physicists in radiotherapy centres have been defined by decree (decree no.2009-959 of 29th July 2009. They are applicable until the end of the interim period provided for in the health-care activities licensing system (decree no.2007-388 of 21st March 2007), i.e. May 2012 at the latest.

Since 2005, heads of facilities have had to draw up plans for medical radiation physics, defining the resources allocated, primarily in terms of staffing, in the light of the medical procedures carried out in the establishment, the actual or probable patient numbers, existing dosimetry skills and resources allocated to quality assurance and control.

The PSRPM training procedures were updated by an order of 28th February 2011 and a further update is expected in early 2012.

Radiotherapy quality assurance

The quality assurance obligations of radiotherapy centres, provided for in article R.1333-59 of the Public Health Code, were specified by decision 2008-DC-0103 dated 1st July 2008, which mainly concerns the quality management system (SMQ), the management's commitments as stipulated in the SMQ, the documentary system, staff responsibility, the analysis of the risks run by the patients during the radiotherapy process, and the identification and handling of undesirable situations or malfunctions, whether organisational, human or equipment-related.

These obligations entered into force in September 2011.

Quality control of a CT installation by a medical physicist at the Pitié Salpêtrière Hospital in Paris

Table 1 : list of Referral Criteria for Imaging and Procedure Guides for the performance of medical procedures entailing exposure to ionising radiation

Specialty	Medical radiology		Nuclear medicine	Radiology	Dental Radiology
Documents	Procedure guide	Referral criteria for imaging guide	Referral criteria for imaging and procedure guide	External radiotherapy procedure guide	Referral criteria for imaging and procedure guide
Availability	www.sfrnet.org www.irsn.org	www.sfrnet.org www.irsn.org	www.sfmm.org	www.sfro.org	www.adf.asso.fr www.has-sante.fr

TO BE NOTED

The proposed Euratom directive currently being examined at European level makes it mandatory to carry out a risk analysis and record and analyse undesirable events, along with their notification to the authorities (already required in France).

Maintenance and quality control of medical devices

Maintenance and quality control, both internal and external, of medical devices using ionising radiation (Articles R. 5211-5 to R. 5211-35 of the Public Health Code) have been mandatory since publication of the order of 3rd March 2003. External quality control is entrusted to organisations approved by the Director General of the AFSSAPS (French Health Product Safety Agency) who is responsible for issuing a decision defining the acceptability criteria, the monitoring parameters and the frequency of the inspections on the medical devices concerned. The published decisions are posted on the AFSSAPS web site.

Training and information

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

Thus the objectives and content of training programmes for practitioners conducting procedures using ionising radiation, or who assist in these procedures, were defined in the order of 18th May 2004. To ensure the traceability of the data on application of the justification and optimisation principles, the report on the procedure, written by the medical practitioner carrying out the examination, must provide information justifying the procedures and the operations carried out as well as the data used to estimate the dose received by the patient (order of 22nd September 2006).

Finally, before carrying out a diagnostic or therapeutic procedure using radionuclides (nuclear medicine), the physician must give the patient oral and written guidelines on radiation protection that are of use to him/herself, his/her relations, the public and the environment. In the event of a nuclear medicine procedure for therapeutic purposes, this information, issued in a written document, provides lifestyle hints to enable potential contamination to be minimised and states, for example, for how many days contacts with the spouse and children should be reduced. Recommendations (French High Public Health Council, learned societies) were distributed by ASN (January 2007) to enable the content of the information already sent out to be harmonised.

The proposed Euratom directive currently under review at European level introduces a new regime concerning forensic applications of ionising radiation. It in particular clarifies the conditions for identification and authorisation of these practices, thus improving the existing "forensic exposure" situation (directive 97/34/Euratom).

TO BE NOTED

2|2|3 Forensic applications of ionising radiation

In the forensic field, ionising radiation is used in a wide variety of sectors such as occupational medicine, sports medicine or for investigative procedures required by the courts or insurance companies. The principles of justification and optimisation defined apply both to the person requesting the examinations and to the person performing them.

In occupational medicine, ionising radiation is used for medical supervision of workers (whether or not professionally exposed to ionising radiation, for example workers exposed to asbestos). ASN transmitted proposals in early 2010 to the General Labour Directorate, to the French Agency for Environmental and Occupational Health Safety (AFSSET), and to the French National Authority for Health (HAS), to have the examinations

that today are considered unjustified removed from the regulations in force. In 2012, ASN will be consulting the stakeholders in order to reach a final decision on this subject.

2|3 Protection of persons exposed to "enhanced" natural radiation

2|3|1 Protection of persons exposed to radon

The regulations applicable to management of the radon-related risk in premises open to the public (Article R. 1333-15 of the Public Health Code) introduce the following clarifications:
– the radon monitoring obligation applies in geographical areas in which radon of natural origin is likely to be measured in high concentrations and in premises in which the public is likely to stay for extended periods;
– the measurements are made by organisations approved by ASN, these measurements being repeated every 10 years and whenever work is carried out to modify the ventilation or the radon tightness of the building.

In addition to introducing action trigger levels of 400 and 1,000 Bq/m^3, the implementing order of 22nd July 2004 concerning management of the radon risk in premises open to the public defined geographical zones and premises open to the public for which radon measurements are now mandatory:
– the geographical areas correspond to the 31 *départements* classified as having priority for radon measurement (see map p. 81);

2011-2015 national action plan for management of the radon risk

Map of 31 priority *départements* for radon monitoring

– the categories of premises open to the public cover teaching institutions, health and social institutions, spas and prisons.

The obligations of the owner of the facility are also specified when the action levels are found to have been exceeded. The order of 22nd July 2004 was accompanied by the publication in the *Official Gazette* of a notice defining the action and work to be carried out if the action trigger levels of 400 and 1,000 Bq/m^3 were to be exceeded (O.G. of 22nd February 2005). The conditions for approval of organisations qualified to measure an activity concentration, and the measurement conditions, were updated by three ASN decisions:
– decision 2009-DC-0134 of 7th April 2009, amended by decision 2010-DC-0181 of 15th April 2010, sets the approval criteria, provides the detailed list of information to be enclosed with the approval application, and specifies the conditions of issue, verification and withdrawal of approval;
– decision 2009-DC-0135 specifies the conditions in which the radon activity concentration is measured;
– decision 2009-DC-0136 concerns the objectives, duration and content of the training programmes for the individuals carrying out radon activity concentration measurements.

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

Act 2009-879 of 21st July 2009 reforming the hospital system and concerning patients, health and the regions, introduced new requirements concerning radon into the Public Health Code (Article L.1333-10). A radon measurement will therefore be taken in residential buildings every 10 years. The corresponding implementing decree is currently being prepared.

Finally, in the workplace, Article R. 4451-136 of the Labour Code requires the employer to carry out radon activity measurements and take the necessary steps to reduce exposure when the results of the measurements reveal an average radon concentration higher than the levels set in an ASN decision. The order of 7th August 2008 defined the workplaces in which these measurements are required and ASN decision 2008-DC-0110, approved by the order of 8th December 2008, specifies the reference levels above which the radon concentration must be reduced.

2|3|2 Other sources of exposure to "enhanced" natural radiation

Professional activities which use materials which naturally contain radionuclides not used for their intrinsic radioactive properties but which are likely to create exposure such as to harm the health of workers and the public ("enhanced" natural exposure) are subject to the provisions of the Labour Code (Articles R. 4451-131 to 135) and the Public Health Code (Article R. 1333-13).

The order of 25th May 2005 defines the list of professional activities using raw materials naturally containing radionuclides, the handling of which can lead to significant exposure of the general public or of workers.

For these activities, the Public Health Code requires an estimation of the doses to which the general public is exposed owing to the installation, or owing to the production of consumer goods or construction products by these activities (see chapter 1). In addition, and if protection of the public so warrants, it is also possible to set radioactivity limits for the construction materials and consumer goods produced by some of these industries (Article R. 1333-14 of the Public Health Code). This latter measure complements the ban on the intentional addition of radioactive materials to consumer goods.

For the occupational exposure resulting from these activities, the Labour Code requires a dose assessment to be carried out under the responsibility of the employer. Should the dose limit of 1 mSv/year be exceeded, steps to reduce exposure should be taken. The above-mentioned order of 25 May 2005

TO BE NOTED

The proposed Euratom directive currently under review at European level defines the list of industries and activities concerned by exposure to enhanced natural radioactivity (in force in France) and introduces exemption values.

TO BE NOTED

The proposed Euratom directive currently under review at European level requires that the Member States define a national action plan to reduce radon exposure and introduce a maximum reference level for the general public of 300 Bq/m. The second national action plan for radon was published on 15th December 2011.

Aircrew

offers clarification of the technical measurement procedures for evaluating the doses received by the workers[2].

Finally, the Labour Code (Article R. 4451-140) stipulates that for aircrews likely to be exposed to more than 1 mSv/year, the employer must evaluate the exposure, take steps to reduce it (particularly in the event of a declared pregnancy) and inform the personnel of the health risks. The order of 7th February 2004 defines the procedures for implementing these measures.

3 THE LEGAL SYSTEM APPLICABLE TO BASIC NUCLEAR INSTALLATIONS (BNIs)

Basic nuclear installations (BNI) are installations which, due to their nature or to the quantity or activity of the radioactive substances they contain, are subject to particular provisions in order to protect the general public and the environment.

3|1 The legal bases

3|1|1 International conventions and standards

IAEA publishes reference texts, called "Basic Safety Standards", which describe safety principles and practices. They concern installation safety and radiation protection, the safety of waste management and the safety of radioactive materials transportation. Although these documents are not binding, they do nonetheless constitute references which are widely drawn on in the drafting of national regulations.

Several legislative and regulatory provisions relative to BNIs are derived from or take up international conventions and standards, and notably those of the IAEA.

The Convention on Nuclear Safety (see chapter 7, point 4|1) concerns civil nuclear power generating reactors. It aims to propose binding international obligations concerning nuclear safety. France has voluntarily decided to include the steps taken with regard to research reactors.

The counterpart of the Convention on Nuclear Safety in the field of spent fuel and radioactive waste management is the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (see chapter 7, point 4|2).

For France, these conventions are a tool to be used to reinforce nuclear safety, periodically presenting the international community with the status of the facilities concerned and the steps taken to ensure their safety.

3|1|2 European texts

Several European community texts apply to BNIs. The more important ones are described below.

The Euratom Treaty

The Euratom Treaty, which was signed in 1957 and came into force in 1958, aimed to develop nuclear power while protecting the general public and workers from the harmful effects of ionising radiation.

Chapter III of part II of the Euratom Treaty deals with health protection as linked to ionising radiation.

Articles 35 (implementation of means for checking compliance with standards), 36 (information to the Commission on environmental radioactivity levels) and 37 (information to the Commission on planned effluent discharges) deal with the issues of discharges and environmental protection.

Requirements regarding information of the Commission were incorporated into the decree n°2007-1557 of 2 November 2007. The BNI creation authorisation or final shutdown decrees, as well as significant modifications to the facilities leading to an increase in discharge limit values, are only issued once the opinion of the Commission has been obtained.

The Directive of 25 June 2009

Directive 2009/71/Euratom of 25th June 2009 creates an EU framework for nuclear safety and paves the way for the creation of common legal requirements for nuclear safety among all Member States.

This directive defines basic obligations and general principles in this field. It strengthens the role of the national regulatory organisations, contributes to harmonising the safety requirements between the Member States in order to develop a high level of safety in the installations and guarantees a high level of transparency on these issues.

2. This concerns: the combustion of coal in coal-fired power stations; the treatment of tin, aluminium, copper, titanium, niobium, bismuth and thorium ores; the production of refractory ceramics and the glassworks, foundries, iron and steel and metallurgy plants that use them; the production or use of compounds containing thorium; the production of zircon and baddaleyite, and the foundry and metallurgy activities that use them; the production of phosphated fertilizers and phosphoric acid; the treatment of titanium dioxide; the treatment of rare earths and the production of pigments containing them; the treatment of underground water by filtration for the production of water for human consumption and mineral waters and spas.

The directive comprises stipulations regarding cooperation between nuclear regulators, in particular the creation of a peer review mechanism, personnel training, regulation and inspection of nuclear installations and public transparency. In this respect, it reinforces cooperation between the Member States.

Finally, it creates a framework for the harmonisation work carried out by the Western European Nuclear Regulators' Association (WENRA) (see chapter 7, point 2|1|5).

France transposed this directive (22nd July 2011) within the allotted time. Certain provisions were already applied in France, for example the requirements of the TSN Act 2006-686 of 13th June 2006, decree 2007-1557 of 2nd November 2007 concerning BNIs and the regulation of the nuclear safety of the transport of radioactive materials, decree 2007-831 of 11th May 2007 determining the designation and qualification of nuclear safety inspectors, and the orders of 10/08/84 on the quality of the design, construction and operation of BNIs, the order of 31/12/99 setting out the general technical regulations for preventing and limiting detrimental effects and off-site hazards arising from the operation of BNIs, the order of 26/11/99 setting out the general technical requirements concerning the limits and procedures for BNI water intake and discharge subject to licensing and, with regard to pressure equipment, the order of 10/11/99 concerning surveillance of the operation of the main primary system and the main secondary systems of pressurised water reactors, plus the order of 12/12/2005 concerning nuclear pressure equipment.

The signing of the order setting the general rules concerning basic nuclear installations (see point 3|2|2) constitutes an improvement of the national frameworkconcerning the safety of nuclear facilities, as stipulated in the directive.

The directive of 19th July 2011

Directive 2011/70/Euratom of 19th July 2011 establishes a European framework for the safe and responsible management of spent fuel and radioactive waste. It applies to the management of spent fuel and the management of radioactive waste, from production to disposal, when this waste is the result of civil activities. In a manner similar to the directive of 25th June 2009, it calls for each Member State to set up a coherent and appropriate national framework and sets various requirements for the States, the safety regulators and the licensees. Several of the requirements of this directive, which should in any case be fully transposed before August 2013, are already in force in France, for example through the provisions of the Environment Code concerning waste, the waste Act 2006-739 of 28th June 2006 and the TSN Act 2006-686 of 13th June 2006. ASN took part in the work involved in the transposition of this directive.

3|1|3 National texts

The TSN Act (now codified in books I and V of the Environment Code) and its implementing degrees

The provisions of chapters III and V of part IX of book V of the Environment Code (previously section IV of the TSN Act) underpin the BNI authorisation and regulation regime.

The legal regime applicable to BNIs is said to be "integrated" because it aims to cover the prevention or control of all the risks and detrimental effects, whether radioactive or not, that a BNI could create for man and the environment.

About fifteen decrees implement the legislative provisions of book V of the Environment Code, in particular decree 2007-830 of11th May 2007 concerning the list of BNIs and decree 2007-1557 of 2nd November 2007 as amended, concerning BNIs and the regulation of the nuclear safety of the transport of radioactive materials, known as the "BNI procedures" decree (see below).

The "Waste" Act and its implementing decrees

Act 2006-739 of 28th June 2006 on the Sustainable Management of Radioactive Materials and Wastes, known as the "Waste" Act, creates a coherent, exhaustive legislative framework for managing all radioactive waste. It is now codified in chapter II of part IV of book V of the Environment Code.

TO BE NOTED IN 2011

The codification of the "Nuclear Acts"

Pursuant to the authorisation granted by the 10th July 2010 Act constituting the national environmental undertaking, referred to as the "Grenelle II" Act, the Government - with the assistance of ASN - undertook to codify the TSN Act, the "Waste" Act and Act 68-943 of 30th October 1968 on civil liability in the field of nuclear energy, in the Environment Code, but without changing the legislative content. Certain provisions of Act 571 of 28th October 1943 as amended, concerning steam pressure equipment employed on land and gas pressure equipment employed on land and on board seagoing vessels are also codified, with regard to the monitoring and inspection of equipment in a BNI by ASN inspectors. The codification of these provisions, since the publication of ordinance 2012-6 of 5th January 2012 amending books I and V of the Environment Code, leads in particular to the creation of a part IX within book V of the Environment Code, entitled "Nuclear security and basic nuclear installations". Additions have also been made to chapter V of part II of book I, to include provisions specific to information and transparency with regard to nuclear activities.

The "BNI procedures" decree

Decree 2007-1557 of 2nd November 2007 concerning BNIs and the regulation of the nuclear safety of the transport of radioactive materials, known as the "BNI procedures" degree, implements article L. 593-38 of the Environment Code.

It defines the requirements applicable to BNI procedures and deals with the entire lifecycle of a BNI, from its authorisation decree to commissioning, to final shutdown and decommissioning. Finally, it explains the relations between the ministers responsible for nuclear safety and ASN in the field of BNI safety.

The decree clarifies the applicable procedures for adoption of the general regulations and for taking individual decisions concerning BNIs. It defines how the Act is implemented with regard to inspections and administrative or criminal sanctions. Finally, it defines the particular conditions for application of certain regimes within a BNI.

3|2 General technical regulations

The general technical regulations stipulated by Article L.593-4 of the Environment Code, comprise all the general texts laying down the technical rules concerning nuclear safety, whether binding (ministerial orders and ASN regulatory decisions) or non-binding (circulars, basic safety rules, ASN guides).

3|2|1 Ministerial and government orders

Quality organisation

The order of 10th August 1984 concerning the quality of the design, construction and operation of BNIs, known as the "quality order", specifies the steps to be taken by a BNI licensee for defining, obtaining and maintaining the quality of its installations and the conditions necessary to guarantee its operational safety.

It thus stipulates that the licensee must define quality requirements for each activity concerned, employ the appropriate skills and methods for meeting these quality requirements and finally, guarantee quality by checking compliance with these requirements.

It also specifies:
– that detected discrepancies and incidents be thoroughly corrected and that preventive action be taken;
– that suitable documents testify to the results obtained;
– that the licensee supervise the service companies used and check satisfactory operation of the procedures adopted to guarantee quality.

Operating experience feedback from events that have occurred in BNIs, plus the observations made during inspections, enable ASN to assess the application of the "quality" order.

This order is one of the texts undergoing revision, as described in point 3|2|2 of this chapter.

Prevention of off-site detrimental effects and hazards resulting from BNI operation

BNI operation can entail detrimental effects and risks for the environment, that is to say for the surrounding installations and their workers, but also for the general public and the environment off the site.

The order of 31st December 1999 amended by the order of 31st January 2006 contains the general technical regulations intended, except for water intake and discharge of effluents, to prevent and mitigate off-site detrimental effects and risks resulting from BNI operation. More specifically, and in addition to the general incident and accident prevention rules (staff training,

UNDERSTAND

The planned overhaul of the general technical regulations applicable to BNIs

The planned overhaul of the general technical regulations applicable to BNIs aims to publish several texts implementing the TSN Act and some of its application decrees; one order and about twenty regulatory decisions, as well as guides. The draft texts are written and reviewed by all the ASN entities concerned and its technical support organisation (IRSN). For the draft order, ASN proposed a preliminary version of the text to the Ministry for Ecology, Sustainable Development, Transport and Housing (MEDDTL). In 2010, the draft order and ten decisions were submitted to the stakeholders and made available for consultation by the general public.

This broad consultation was addressed to licensees, experts, environmental protection associations, union organisations and European safety authorities. The draft order was also placed on-line on the MEDDTL and ASN websites for three months, in order to obtain comments from all interested parties. Similarly, ASN also posted the drafts of the ten decisions mentioned above on its own website.

The stakeholders expressed particularly keen interest in the draft order, for which several hundred comments were processed. As a result, the draft was extensively modified. Following a further public consultation of this new version, the draft order was submitted in January 2012 to the high council for the prevention of technological risks (CSPRT). The ASN issued its opinion on the draft on 24th January 2012. The order was signed on 7th February 2012.

safety instructions, maintenance of installations, etc.), the order specifies objectives for protection against fire, lightning, noise, or the risks of accidental pollution of the environment. It introduces principles concerning waste management, prevention of accidental pollution, fire, lightning, criticality and radiolysis applicable to all nuclear equipment, including that which is situated outside the sensitive parts of the BNIs.

The various provisions of the order are detailed in point 3|4 of this chapter.

Regulation of BNI water intake and effluent discharges

The 26th November 1999 order lays out the general technical requirements concerning the limits and procedures applicable to BNI water intake and effluent discharges requiring licensing.

This order also introduced improvements:
– concerning the regulation of issues regarding water intake, effluents discharge, environmental monitoring and information of the public and of the Government departments responsible for oversight;
– concerning the incorporation of the regulatory principles applicable to ICPEs, in particular setting discharge limits based on the use of the best available techniques at an economically acceptable cost.

3|2|2 Overhaul of the general technical regulations

Pursuant to the publication of the TSN Act in 2006 and its implementing decrees, ASN wished to completely revise the general technical regulations applicable to BNIs. This initiative moreover ties in with a drive for European harmonisation of nuclear safety, by integrating in the new regulations the principles ("reference levels") developed by WENRA, the Western European Nuclear Regulators' Association, which has worked for several years on defining a baseline of common requirements. WENRA's work results from a review of existing reactors and experience feedback on their operation and inspection.

The order of 7th February 2012 setting out the general rules for BNIs

An order setting out the general rules for BNIs reuses the basic provisions in force and incorporates the "reference levels" developed by the Western European Nuclear Regulators' Association (WENRA). Most of the provisions of this order, published in the Official Gazette on 8th February 2012, will come into force on 1st July 2013, on which date the orders of 10th August 1984, 26th November 1999 and 31st December 1999 previously mentioned will be abrogated.

This order represents a significant reinforcement of the regulatory framework applicable to BNIs, as it specifies numerous requirements and formalises a number of ASN practices which hitherto had no regulatory underpinning. It also offers a solid basis for several requirements expressed by ASN, following the analysis of the complementary safety assessments (CSA) requested in the wake of the Fukushima accident.

Regulatory decisions

Pursuant to Article L.592-19 of the Environment Code, ASN may issue regulatory decisions to clarify decrees and orders in the field of nuclear safety or radiation protection, which have to be approved by the Government.

ASN defined a programme of regulatory decisions which will clarify decree 2007-1557 of 2nd November 2007 and the order of 7th February 2012 setting out the general rules applicable to BNIs.

The first ASN decision issued for application of the decree of 2nd November 2007 was decision 2008-DC-106 of 11th July 2008 relating to the implementation of the BNI internal authorisations system. Several decisions should be issued in 2012 following the publication of the order setting out the general rules applicable to BNIs. They will need to be approved by the ministers responsible for nuclear safety.

3|2|3 Basic safety rules and ASN guides

ASN has drafted basic safety rules (BSR) on a variety of technical subjects concerning BNIs. These are recommendations which specify safety objectives and describe practices ASN considers satisfactory. As part of the ongoing reorganisation of the general technical regulations, the BSRs are gradually being replaced by "ASN guides".

The "ASN guides" collection was created as an educational tool for professionals. In 2011, it comprises 17 purely advisory guides. These documents present ASN doctrine, stipulate recommendations, propose methods for achieving the objectives presented in the texts and share methods and good practices derived from experience feedback from significant events.

3|2|4 French nuclear industry professional codes and standards

The nuclear industry produces detailed rules dealing with the state of the art and industrial practices. It groups these rules in "Industrial codes". These rules allow concrete transposition of the requirements of the general technical regulations, while reflecting good industrial practice. They thus facilitate contractual relations between customers and suppliers.

In the particular field of nuclear safety, the industrial codes are drafted by the French association for NSSS equipment construction rules (Association française pour les règles de conception, de construction, et de surveillance en exploitation des matériels des chaudières électronucléaires - AFCEN), of which EDF and AREVA are members. The RCC codes of design and construction rules were drafted for the design, manufacture and commissioning of electrical equipment (RCC-E), civil engineering (RCC-G) and mechanical equipment (RCC-M). A code of mechanical equipment in-service monitoring rules (RSE-M) was drafted to deal with this subject.

Production of these documents is the responsibility of industry rather than ASN, which is nonetheless tasked with examining them to ensure their conformity with the general technical

regulations, in most cases leading to drafting of a BSR, a guide or a decision, recognising the overall acceptability on the date of the edition concerned.

3|3 Plant authorisation decree and commissioning licence

Chapter III of part IX of book V of the Environment Code contains a creation authorisation procedure, which may be followed by a number of licensing operations throughout the life of a BNI, from its commissioning up to final shutdown and decommissioning, including any modifications made to the facility.

3|3|1 Siting

Well before applying for a BNI authorisation decree, the licensee informs the administration of the site(s) on which it plans to build this installation. For its part, ASN analyses the safety-related characteristics of the sites: seismicity, hydrogeology, industrial environment, cold water sources, etc.

Construction of a BNI requires issue of a building permit by the préfet, according to procedures specified in Articles R.421-1 and following and Article R.422-2 of the Town Planning Code.

3|3|2 Safety options

Any industrial concern intending to operate a BNI may, even before starting the licensing procedure, ask ASN for an opinion on all or part of the safety options it intends to adopt for its installation. The applicant is notified of the ASN opinion and will produce any additional studies and justifications as necessary for a possible authorisation decree application. ASN generally asks a competent Advisory Committee to review the project.

The safety options must then be presented in the authorisation application dossier in the form of a preliminary safety analysis report (PSAR).

This preparatory procedure in no way exempts the applicant from the subsequent regulatory examinations but simply facilitates them.

3|3|3 Public debate

Pursuant to articles L.121-1 and following of the Environment Code, creation of a BNI must be preceded by a public debate when dealing with a new nuclear power plant site or a new site with a cost in excess of €300 million and, in certain cases, when dealing with a new site costing between €150 million and €300 million.

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

For example, a public debate was held in 2010 prior to the decision to build an EPR type nuclear reactor in Penly. Smaller-scale projects can also give rise to a "local debate" initiative. This was the case for example in 2005 for the Jules Horowitz reactor project on the CEA (French Atomic Energy and Alternative Energy Commission) site at Cadarache.

3|3|4 Plant authorisation decrees

A BNI authorisation decree application is submitted to the ministers responsible for nuclear safety by the industrial concern intending to operate the facility, which thus acquires the status of licensee. The application is accompanied by a dossier comprising several items, including the detailed drawing of the installation, the impact assessment, the preliminary safety analysis report, the risk management study and the decommissioning plan.

ASN is responsible for reviewing the dossier, jointly with the ministers responsible for nuclear safety. This is followed by a period of parallel consultation of the public and technical experts.

The impact assessment is submitted for its opinion to the environmental authority created within the Departmental Council for the Environment and Sustainable Development (CGEDD).

TO BE NOTED

The WENRA reference levels

The Western European Nuclear Regulator's Association (WENRA) was created with the following aims:
- *to establish and coordinate a network of the chief nuclear safety regulators in Europe;*
- *to promote the sharing of experience and take mutual advantage of best practices;*
- *to develop a harmonised approach to subjects relating to nuclear safety and radiation protection, and to their regulation, particularly within the European Union;*
- *to give the European Union an independent capability for examining nuclear safety and its regulation in candidate countries for EU membership.*

WENRA has produced some 300 common "reference levels" concerning the safety of nuclear reactors, the safety of decommissioning operations and the safety of radioactive waste and irradiated fuel management facilities. These "reference levels", which are agreed upon at European level, cover subjects such as safety management, installation design and operation, the verification of safety, and emergency situations.

The collection of ASN guides

No.1	Disposal of radioactive waste in deep geological formations
No.2	Transport of radioactive materials in airports
No.3	Recommendations for drafting annual information reports for the public concerning basic nuclear installations
No.4	Auto-assessment of potential risks to patients receiving external radiotherapy
No.5	Management of radiotherapy safety and quality of treatment
No.6	Final shutdown, decommissioning and delicensing of basic nuclear installations in France
No.7	Applications for shipment authorisation and approval of package models or radioactive materials for civil use transported on the public highway
No.8	Assessment of nuclear pressure equipment conformity
No.9	Definition of a BNI perimeter (to be published in 2012)
No.10	Local involvement of CLIs in the 3rd ten-year inspections of the 900 MWe reactors
No.11	Notification and codification of criteria related to significant radiation protection events (excluding BNIs and radioactive material transport operations)
No.12	Notification and codification of criteria related to significant safety, radiation protection or environmental events applicable to BNIs and radioactive material transport operations
No.13	Protection of BNIs against off-site flooding
No.14	Acceptable complete clean-out methodologies in basic nuclear installations in France
No.15	Safety management policy within BNIs
No.16	Significant radiation protection event affecting a radiotherapy patient: declaration and classification on the ASN-SFRO scale
No.17	Studying hazards in transport infrastructures concerned by the transport of radioactive material
No.18	Disposal of effluents and waste contaminated by radionuclides, produced in facilities licensed under the Public Health Code

The public inquiry

The authorisation can only be granted after a public inquiry, as stipulated in Article L. 593-8 of the Environment Code. Publication of decree 2011-2018 of 29th December 2011 reforming the public inquiry process for operations liable to affect the environment, led to harmonisation of the public inquiry regime, which meant that the procedure applicable to BNIs was no longer an exception but was incorporated into the general regime. The purpose of the inquiry is to inform the public and collect their opinions, suggestions and counter-proposals, in such a way as to provide the competent authority with all the elements necessary for it then to make an informed decision.

The inquiry is carried out in accordance with the provisions of Articles L. 123-1 to L. 123-19 and R. 123-1 to R. 123-27 of this code. The préfet opens the public inquiry at least in each of the communes which is situated, at least in part, less than five kilometres from the perimeter of the installation. This inquiry lasts between a minimum of one month and a maximum of two months. The dossier submitted by the licensee in support of its authorisation application is made available in the public inquiry dossier. However, the safety analysis report (document containing the inventory of installation risks, an analysis of the measures taken to prevent these risks and a description of the measures designed to limit the probability and effects of accidents) is a large document that is difficult for non-specialists to understand, therefore it is supplemented by a risk control study.

Furthermore, the procedures concerning BNIs subject to an inquiry are concerned by decree 2011-2021 of 29th December, determining the list of projects, plans and programmes to be communicated electronically to the general public under the experiment specified in II of article L. 123-10 of the Environment Code. This states that the Authority responsible for opening and holding the public inquiry shall communicate the main documents in the inquiry dossier to the general public in electronic format. This approach aims to make it easier for the public to understand the projects, in particular those who do not live where the inquiry is being held. Using this means of providing access to information and the possibility of also submitting observations in electronic format, as stipulated in article R. 123-9 of the Environment Code, since the publication of decree 2011-2018 of 29th December 2011 reforming the public inquiry process for operations liable to affect the environment, should make it considerably easier for the public to express their opinions. These provisions will enter into force for those projects for which the order opening the public inquiry is published as of 1st June 2012.

Creation of a local information committee

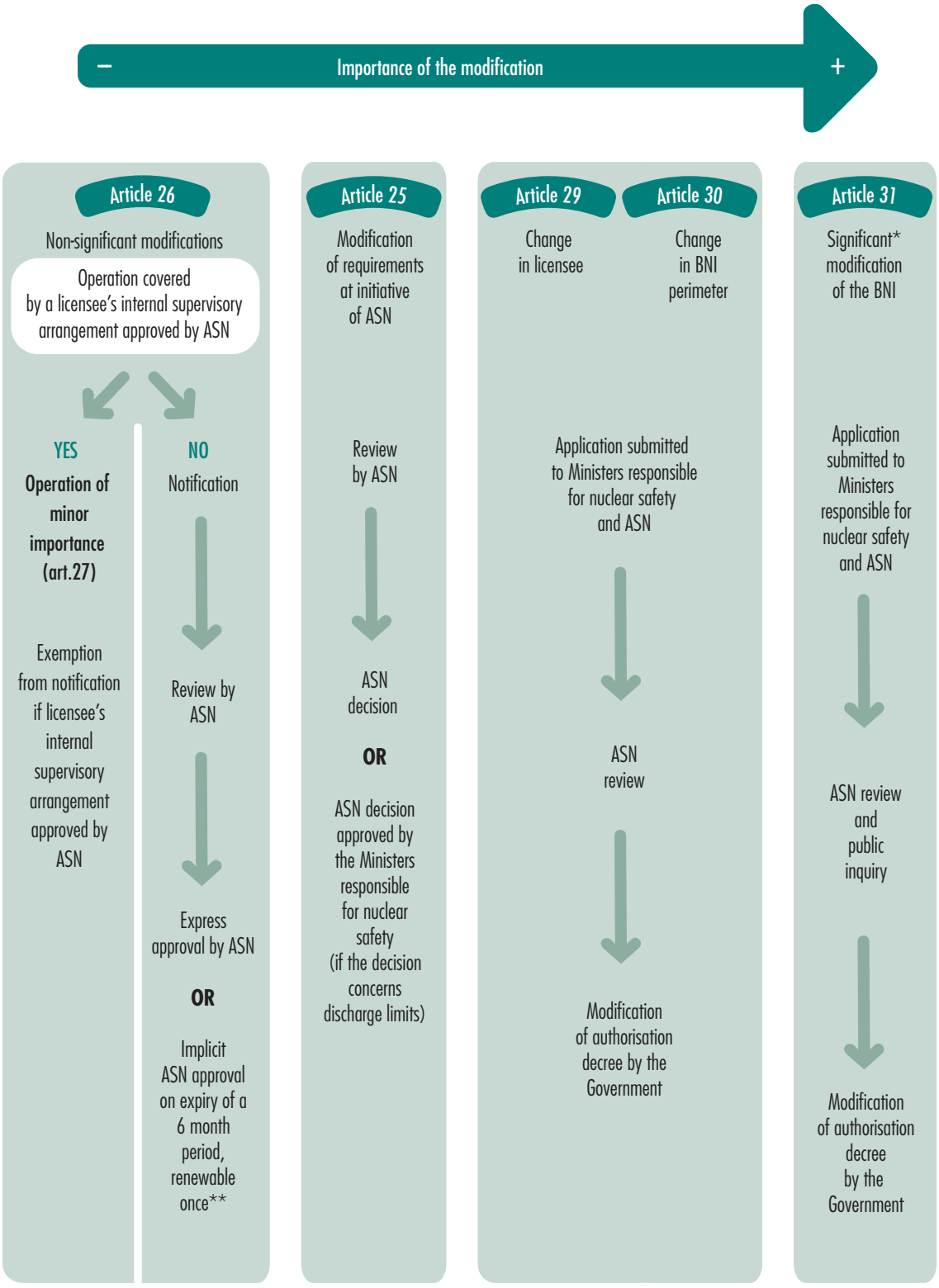
The TSN Act formally defined the status of the BNI local information committees (CLI). The corresponding provisions can be found in sub-section 3 of section 2 of chapter V of part II of book 1 of the Environment Code. The CLI can be created as soon as the BNI authorisation decree application is made. Whatever the case, it must be constituted once the authorisation decree has been issued.

The CLIs are presented in chapter 6.

Consultation of other European Union countries

Pursuant to article 37 of the treaty instituting the European atomic energy community and the TSN Act, it is only possible to authorise the creation of a facility liable to discharge radioactive effluent into the environment after consulting the European Commission.

Diagram 3: types of BNI modification provided for by the "BNI procedures" decree



* Definition of significant modification of a BNI: a change in its nature or rise in its capacity, a change in the key aspects regarding the protection of public health and safety, nature and the environment, the addition of a new BNI within the perimeter of the initial BNI.
** This time allows ASN to proceed with a new review or issue additional requirements.

Consultation of technical organisations

The preliminary safety analysis report appended to the authorisation decree application is transmitted to ASN, which submits it for examination to one of the Advisory Committees reporting to it, following a report from IRSN.

Further to its investigation and the results of the consultations, ASN sends the ministers responsible for nuclear safety a draft decree proposal authorising or rejecting creation of the installation.

The authorisation decree (DAC, see diagram 4)

The ministers responsible for nuclear safety send the licensee a draft decree granting or rejecting authorisation. The licensee has a period of two months in which to present its observations. The ministers then solicit the opinion of the ASN. Decision 2010-DC-0179 of 13th April 2010, which came into force in July 2010, gives licensees and the CLIs the possibility of being heard by the ASN college before it gives its opinion.

The authorisation decree for a BNI is delivered by a decree from the Prime Minister and countersigned by the ministers responsible for nuclear safety.

The DAC establishes the perimeter and characteristics of the facility. It also specifies the duration of the authorisation, if applicable, and the installation commissioning deadline. It also specifies the essential elements required to protect public health and safety, or to protect nature and the environment.

The requirements defined by ASN for application of the authorisation decree

For application of the authorisation decree, ASN defines the requirements regarding the design, construction and operation of the BNI that it considers to be necessary for nuclear safety.

ASN defines the requirements regarding the BNI water intakes and effluent discharges. The specific requirements setting limits on the discharges from the BNI into the environment are subject to approval by the ministers responsible for nuclear safety. In application of Article L.593-15 of the Environment Code (previously paragraph IIbis of Article 29 of the TSN Act) created by the "Grenelle II" Act 2010-788 of 12th July 2010 constituting the French environmental commitment), information on BNI modification projects that could lead to a significant increase in water intake or effluent discharge into the environment will now be made available to the public. This arrangement will enter into force on 1st July 2012 (6 months after publication of the decree specified in Article L. 122-3 of the Environment Code, which stipulates certain legislative requirements concerning the impact assessments). ASN has nonetheless required this of the licensees since 2008 and it has been implemented on several occasions, for example the revision of the discharge license provisions for the Cadarache site in 2010.

Modification of a BNI

Any significant modification to an installation is subject to a procedure similar to the authorisation decree application.

A modification is considered to be significant in the cases mentioned in article 31 of decree 2007-1557 of 2nd November 2007, known as the "procedures" decree:
– a change in the nature of the installation or an increase in its maximum capacity;
– a modification of the key elements protecting the interests mentioned in the first paragraph of article L. 593-1 of the environment code, which appear in the authorisation decree;
– the addition, within the perimeter of the facility, of a new BNI, the operation of which is linked to that of the facility in question.

Furthermore, if a BNI licensee envisages making modifications to its operating arrangements or to its installation that would not be considered significant under the above criteria, it must declare them to the ASN beforehand. It cannot make the modifications until a renewable period of at least six months has expired, unless ASN gives its express agreement. If it so considers necessary, ASN may stipulate requirements so that the envisaged modifications are reviewed or accompanied by additional measures to guarantee the protection of the interests mentioned in the 1st paragraph of article L. 593-1 of the Environment Code.

The other installations located within a BNI perimeter

The following co-exist within the perimeter of a BNI:
– equipment and installations which are part of a BNI: these are elements of this installation which are necessary for it to operate; depending on their type, they can in technical terms be compared to classified installations but, as a part of the BNI, they are subject to the regulations applicable to BNIs;
– classified equipment and installations which are not necessarily linked to the BNI.

The equipment necessary for BNI operation is fully covered by the BNI system specified in the "BNI procedures" decree. The other equipment subject to another regime (water or ICPE) but located within the perimeter of the BNI remains subject to this regime, but with a change in competent party, as individual measures are no longer taken by the préfet, but by ASN.

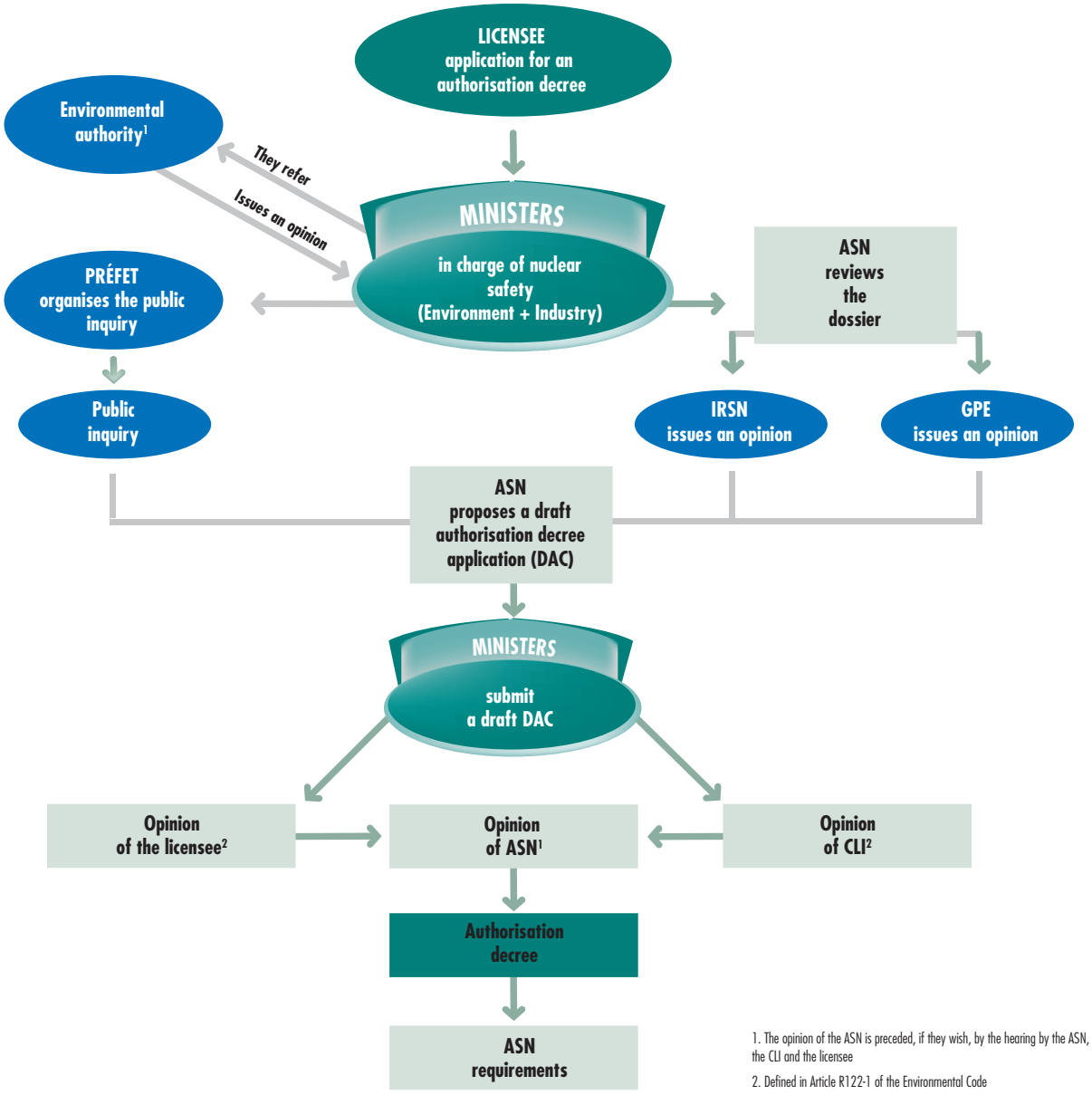
3|3|5 Commissioning licences

Commissioning corresponds to first utilisation of radioactive materials in the installation or the first operation of a particle beam.

Prior to commissioning, the licensee sends ASN a dossier comprising the updated safety analysis report of the "as-built" installation, the general operating rules, a waste management study, the on-site emergency plan and the decommissioning plan.

After checking that the installation complies with the objectives and rules defined by the TSN Act and its implementing texts, ASN authorises commissioning of the installation and communicates this decision to the ministers responsible for nuclear safety and to the préfet. It also forwards it to the CLI.

Diagram 4: basic nuclear installation authorisation decree in accordance with the Act of 13 June 2006



1. The opinion of the ASN is preceded, if they wish, by the hearing by the ASN, the CLI and the licensee

2. Defined in Article R122-1 of the Environmental Code

3|4 Particular requirements for the prevention of pollution and detrimental effects

3|4|1 The OSPAR convention

The international OSPAR Convention (the result of the merger between the Oslo and Paris conventions) is the mechanism whereby the European Commission and fifteen States, including France, cooperate to protect the marine environment of the North-East Atlantic. In 2010, through the Bergen declaration, the ministers of each contracting party renewed and reaffirmed their commitments with respect to OSPAR. They approved the general report on the quality of the environment and adopted the new strategic orientations. With regard to radioactive materials, the strategic objectives are to "prevent pollution of the maritime area by ionising radiation through progressive and substantial reductions in discharges, emissions and losses of radioactive substances, with the

ultimate aim of achieving concentrations in the environment approaching the background values for naturally occurring radioactive substances and approaching zero for artificial radioactive substances". To achieve these objectives, the following are taken into account:
– the radiological impacts on man and biota;
– the legitimate uses of the sea;
– technical feasibility.

Within the French delegation, ASN takes part in the work of the committee tasked with assessing application of this strategy.

3|4|2 Discharges from basic nuclear installations

BNI discharges management policy

Like all industries, nuclear activities (nuclear industry, nuclear medicine, research installations, etc.) create by-products, which may or may not be radioactive. Steps are being taken to reduce their quantity through reduction at source.

The radioactivity discharged in effluents represents a marginal fraction of that which is confined in the waste.

Opting for discharge of effluents (liquid or gaseous) is part of a more general approach aimed at minimising the overall impact of the installation.

ASN makes sure that the BNI authorisation decree application explains the licensee's choices, in particular the reduction at source measures, the decisions taken between confinement, treatment or dispersal of substances, based on safety and radiation protection considerations.

The optimisation efforts required by the authorities and made by the licensees have - for "equivalent operation" - resulted in these emissions being constantly and sometimes considerably reduced. ASN hopes that setting discharge limit values will encourage the licensees to maintain their discharge optimisation and management efforts. It ensures that discharges are kept to the minimum possible by using the best techniques available, and has undertaken a revision of the discharge limits in recent years.

The impact of BNI chemical discharges

The substances discharged can have an impact on the environment and the population owing to their chemical characteristics.

ASN considers that BNI discharges should be regulated in the same way as those of other industrial facilities. The TSN Act, now codified in the Environment Code, and more broadly the general technical regulations concerning discharges and the environment, takes account of this issue. This integrated approach is little used abroad, where chemical discharges are often regulated by an authority different from that in charge of radiological issues.

ASN wants to ensure that the impact of chemical discharges on the populations and the environment is as low as possible, in the same way as for radioactive materials.

ASN "environmental" inspection at the Flamanville nuclear power plant – November 2011

The impact of BNI thermal discharges

Some BNIs, especially nuclear power plants, discharge cooling water into watercourses or the sea, either directly or after cooling in cooling towers. Thermal discharges lead to a temperature rise in the watercourse around and downstream of the discharge point, which can reach several degrees.

The regulatory limits aim to prevent a modification of the receiving environment, in particular fish life, and to ensure acceptable health conditions if water is taken for human consumption downstream. These limits can thus differ according to the environment and the technical characteristics of each installation.

3|4|3 Prevention of accidental pollution

The order of 31 December 1999 sets measures designed to prevent or, in the event of an accident, to minimise direct or indirect release of toxic, radioactive, flammable, corrosive or explosive liquids into the natural environment and the sewers.

On the occasion of the overhaul of the general regulations applicable to BNIs, the requirements of the order of 31st December 1999 are taken up by the order of 7th February 2012 setting the general rules for BNIs, some of which will be subsequently clarified in the relevant ASN regulatory decisions, for example the "detrimental effects and impact" decision.

3|4|4 Protection against noise

The 31 December 1999 order sets allowable limits for noise and requires verification of compliance with the stipulated noise limits. Protection against noise is among the requirements of the order of 7th February 2012 setting the general rules applicable to BNIs.

3|4|5 Protection against the microbiological risk (legionella, amoebae)

Most natural surface waters (lakes, rivers) naturally contain high levels of bacteria, whose presence is linked to the existence of the nutrients and minerals essential for their growth and to temperature conditions conducive to this growth.

Micro-organisms can therefore be found in various installations: sanitary installations, air-conditioning installations and cooling systems (cooling towers, industrial cooling circuits), ponds and fountains, spa waters and medical equipment producing aerosols.

Some of these bacteria are pathogenic, which is why special measures are required. This is in particular the case with legionella and amoebae such as Naegleria Fowleri.

The requirements relative to the prevention and limitation of the risks of development of legionella are similar to those adopted for ICPEs, while taking into account the specifics of BNIs. The characteristics of the cooling towers and nuclear power plant cooling systems justified the adoption of particular measures. They are presented in chapter 12.

3|5 Requirements concerning radioactive waste and decommissioning

3|5|1 Radioactive waste management in basic nuclear installations

The regulations, whether the requirements of the order of 31st December 1999 setting the general technical regulations designed to prevent and limit off-site detrimental effects and hazards resulting from the operation of basic nuclear installations, or the order of 7th February 2012 setting the general rules concerning basic nuclear installations and applicable in 2013, determine requirements concerning waste management in BNIs, whether conventional or radioactive.

The licensees must for example conduct a study comprising an analysis of the waste produced or to be produced in the facility, as well as of the waste zoning plan, which specifies the measures taken by the licensee for waste management. An ASN decision will supplement the requirements concerning management of the waste produced in BNIs. ASN submitted the draft decision to public consultation from 26th May to 31st August 2010. Following incorporation of the comments and observations received, it will be published in 2012 after publication of the order of 7th February 2012 setting the general rules applicable to BNIs and it will enter into force in 2013.

3|5|2 Decommissioning

The technical provisions applicable to installations a licensee wishes to shut down and decommission must be in compliance with general safety and radiation protection regulations, notably regarding worker external and internal exposure to ionising radiation, the production of radioactive waste, discharge of effluents to the environment and measures designed to reduce the risk of accidents and mitigate their consequences. Safety issues can be significant during active clean-out or dismantling operations and must never be neglected, including during passive surveillance phases.

Once the licensee has decided to cease operations in its installation in order to proceed with final shutdown and decommissioning, it is no longer covered by the framework set by the licensing decree nor the safety reference system associated with the operating phase. In accordance with the provisions of chapter III of section IX of book V of the Environment Code, final shutdown and then decommissioning of a nuclear facility are authorised by a further decree, issued on the advice of ASN.

ASN has specified the regulations for BNI decommissioning operations in a guide, following major work designed to clarify and simplify the administrative procedures while at the same time improving the importance given to safety and radiation protection. A completely revised version of this guide, produced to include the regulatory changes resulting from the publication of the TSN Act and decree 2007-1557 of 2nd November 2007, as well as the work done by WENRA, was finalised in 2009.

The final shutdown and decommissioning authorisation procedure

At least one year before the date scheduled for final shutdown, the licensee submits the authorisation request to the ministers responsible for nuclear safety. The licensee sends ASN a copy of its application along with the dossier necessary for its examination.

The final shutdown and decommissioning authorisation application is in the same way subject to the consultations and inquiries applicable to the BNI authorisation decree applications.

Two licensing systems coexist, one for general cases and one for radioactive waste disposal facilities:

General case:
– the licence application contains requirements concerning the shutdown conditions, the decommissioning and fuel management procedures, and the surveillance and subsequent maintenance of the installation site;

Bugey 1 dismantling worksite – UNGG gas-cooled reactor fuel loading zone – August 2011

– the licence is granted by decree, subject to the opinion of ASN, setting the decommissioning characteristics, the time allotted for decommissioning and the types of operations for which the licensee is responsible after decommissioning.

Radioactive waste disposal facilities:
– the licence application contains requirements concerning final shutdown and the subsequent maintenance and surveillance of the site;
– the licence is issued by decree, subject to the opinion of ASN, setting the types of operations for which the licensee is responsible after final shutdown.

Performance of final shutdown and decommissioning operations

In order to avoid fragmentation of the decommissioning projects and improve their overall consistency, the dossier submitted to support the final shutdown and decommissioning application must explicitly describe all the planned work, from final shutdown to attainment of the target final condition and, for each step, must explain the nature and scale of the risks presented by the installation as well as the envisaged means of managing these risks. The final shutdown and decommissioning phase may be preceded by a final shutdown preparation stage, provided for in the initial operating licence. This preparatory phase in particular allows removal of all or part of the source term, as well as preparation for the decommissioning operations (readying of premises, preparation of worksites, training of staff, etc.). It is also during this preparatory phase that installation characterisation operations can be carried out: production of radiological maps, collection of pertinent data (operating history) with a view to decommissioning, etc.

Installation delicensing

Following decommissioning, a nuclear installation can be delicensed. It is then removed from the list of BNIs and no longer has BNI status. To support its delicensing application, the licensee must provide a dossier demonstrating that the envisaged final state has indeed been reached and describing the state of the site after decommissioning (analysis of the state of the soil and remaining buildings or equipment, etc.). Depending on the final state reached, public protection restrictions may be implemented, depending on the intended subsequent use of the site and/or buildings. These may contain a certain number of restrictions on use (only to be used for industrial applications for example) or precautionary measures (radiological measurements to be taken in the event of excavation, etc.). ASN may make delicensing of a BNI dependent on the implementation of such restrictions.

3|5|3 The financing of decommissioning and radioactive waste management

Sections 1 and 2 of chapter IV of part IX of book V of the Environment Code (previously Article 20 of the "Waste" Act) create an arrangement for ring-fencing funds to meet the costs of decommissioning nuclear facilities and managing radioactive waste. These arrangements are clarified by decree 2007-243 of 23rd February 2007 and the order of 21st March 2007 concerning the secure financing of nuclear costs. The legal system created by these texts aims to secure the financing of nuclear costs, through implementation of the "polluter-pays" principle. It is therefore up to the nuclear licensees to ensure this financing, by setting up a portfolio of assets dedicated to the expected costs. This is done under the direct control of the State, which analyses the situation of the licensees and can prescribe measures, should it be seen to be insufficient or inadequate. In any case, the nuclear licensees remain responsible for the satisfactory financing of their long-term costs.

It stipulates that the licensees must make a prudent assessment of the cost of decommissioning their installations or, for radioactive waste disposal installations, their final shutdown, maintenance and monitoring costs. They also evaluate the cost of managing their spent fuel and radioactive waste, according to Article L. 594-1 of the Environment Code. Pursuant to the decree of 23 February 2007, ASN issues an opinion on the consistency of the decommissioning and spent fuel and radioactive waste management strategy presented by the licensee with regard to nuclear safety.

3|6 Particular requirements for pressure equipment

Pressure equipment is subject to the requirements of Act 571 of 28th October 1943 as amended, concerning steam pressure equipment used on land and gas pressure equipment used on land or on-board seagoing ships, and those of the decree of 2nd April 1926 as amended regulating steam pressure equipment other than that installed on-board ships, decree 63 of 18th January 1943 as amended, regulating gas pressure equipment, or decree 99-1046 of 13th December 1999 concerning pressure equipment.

Pressure equipment specifically designed for BNIs is subject to special requirements entailing monitoring and inspection by ASN. These requirements are covered by both the BNI system and that applicable to pressure equipment. They are in particular defined in the decree of 13th December 1999 and specific orders.

The principles of these regulations are those of the new approach pursuant to the European pressure equipment directive. The equipment is designed and produced by the manufacturer under its own responsibility. It is required to comply with the main safety and radiation protection requirements and to have the conformity of its equipment assessed by an independent, competent third-party organisation approved by ASN. The equipment in operation must be monitored and maintained by the licensee under ASN control and must undergo periodic technical inspections by ASN-approved organisations.

ASN will monitor the organisations.

Article 50 of Act 2009-526 of 12th May 2009 simplifying and clarifying the law and relaxing procedures, modified the Act of 28th October 1943, giving ASN additional competence for regulation of the other ("conventional") pressure equipment present in a BNI.

Table 2 summarises the texts applicable to the pressure equipment present in BNIs.

Table 2 : regulations applicable to pressure equipment

	Nuclear			Conventional
	Main primary system of pressurised water reactors	Main secondary systems of pressurised water reactors	Other equipment	
Construction	• Decree of 2nd April 1926; • Order of 26th February 1974(1)	• Decree of 2nd April 1926; • RFS II.3.8 of 8th June 1990(1)	• Decree of 2nd April 1926; • Decree of 18th January 1943(1) or; • Decree 99-1046 of 13th December 1999	• Decree 99-1046 of 13th December 1999
	or Order of 12th December 2005			
Operation	• Order of 10th November 1999		• Decree of 2nd April 1926 • Decree of 18th January 1943(1)	• Decree 99-1046 of 13th December 1999 • Order of 30th March 2005

(1) Since 2011, the order of 12th December 2005 applies to the construction and operation of nuclear pressure equipment, except for the operational aspects of the main primary and main secondary systems of pressurised water reactors.

4 REGULATIONS GOVERNING THE TRANSPORT OF RADIOACTIVE MATERIALS

4|1 International regulations

For the safe transport of radioactive materials, the International Atomic Energy Agency (IAEA) has issued basic rules called "Regulations for the Safe Transport of Radioactive Material" (TS-R-1). ASN is a participant in IAEA's work.

This basis specific to radioactive materials is used in the drafting of the "modal" transport safety regulations in force for dangerous goods: the ADR agreement (European agreement on the international transport of dangerous goods by road) for road transport, the regulations concerning international rail transport of dangerous goods (RID) for rail transport, the regulations for the transport of dangerous goods on the Rhine (ADNR) for river transport, the international maritime dangerous goods code (IMDG) for maritime transport and the technical instructions of the ICAO (International Civil Aviation Organisation) for air transport.

Directive 2008/68/EC of 24th September 2008 sets out a common framework for all aspects of goods transport by road, rail and inland waterway, within the European Union.

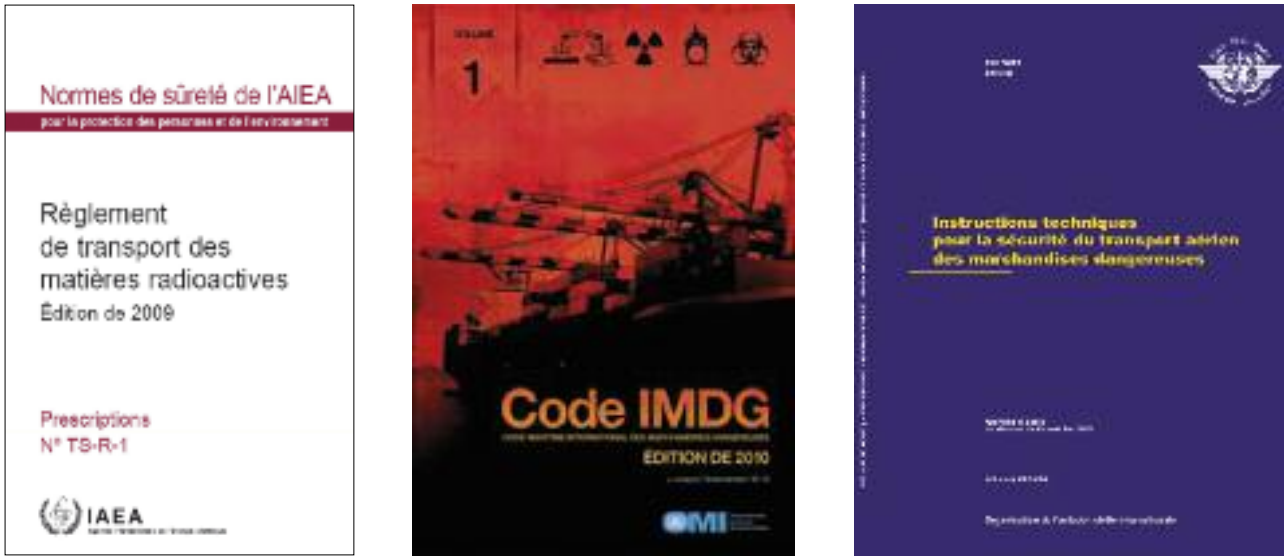
The regulations derived from IAEA recommendations specify the package performance criteria. The safety functions to be assured are containment, radiation protection, prevention of thermal hazards and criticality.

The degree of safety of the packages is adapted to the potential harmfulness of the material transported. For each type of package, the regulations define the scope of intervention of the public authorities, the associated safety requirements and the criteria to be met for successful testing (see chapter 11, point 2).

4|2 National regulations

The "modal" regulations are transposed in full into French law and are made applicable by interministerial orders based on the provisions of the transport code, especially its Articles L. 1252-1 and following. ASN is in direct contact with the Administrations responsible for the various modes of transport (General Directorate for Infrastructure, Transport and the Sea (DGITM), General Directorate for Risk Prevention (DGPR) and General Directorate for Civil Aviation (DGAC)) and attends the French Interministerial Commission for the Carriage of Dangerous Goods (CITMD).

The directive of 24th September 2008 is transposed into French law by a single order covering all land transport on the national territory. This is the order of 29th May 2009 concerning the transport of dangerous goods by land, known as the "TMD order". This text replaced the previous "ADR", "RID" and "ADNR" modal orders as of 1st July 2009.



IAEA TS-R-1 regulations and maritime (IMDG) and air (IT ICAO) transport regulations

Other orders specific to a mode of transport apply to the transport of radioactive materials:

– the order of 12th May 1997 as modified, concerning the technical conditions for the operation of aircraft by a public air transport operator (OPS1);
– the order of 23rd November 1987 as modified, division 411 of the regulation concerning the safety of ships (RSN);
– the order of 18th July 2000 as modified, regulating the transport and handling of dangerous goods in sea ports.

The regulations in particular require approval of the package models for certain radioactive material transport operations (see chapter 11). These approvals are issued by ASN.

Article R. 1333-44 of the Public Health Code also requires that companies transporting radioactive materials in France be subject to either notification of or licensing by ASN. The procedures for implementation of this requirement are to be clarified by an ASN regulatory decision, publication of which is currently suspended pending a possible European regulation covering these activities.

Implementation of the regulations on the safe transport of radioactive materials is checked by nuclear safety inspectors duly appointed by ASN.

ADR and RID regulations

5 REQUIREMENTS APPLICABLE TO CERTAIN RISKS OR CERTAIN PARTICULAR ACTIVITIES

5|1 Installations classified on environmental protection grounds (ICPE) using radioactive materials

The ICPE regime comprises objectives that are similar to those for BNIs, but it is not specialised and applies to a large number of installations involving risks or detrimental effects of all types.

Depending on the scale of the hazards they represent, ICPEs require authorisation by the préfet, or registration, or simple notification.

For installations requiring licensing, this licence is issued by order of the préfet following a public inquiry. The licence comprises requirements which may be subsequently modified by a further order.

The list of ICPEs is given in column A of the appendix to Article R. 511-9 of the Environment Code. It defines the types of installations subject to the system and the applicable thresholds.

Two headings in the list of ICPEs concern radioactive materials:
– heading 1715 concerns the preparation, fabrication, transformation, packaging, utilisation, deposit, storage or disposal of radioactive materials. These activities require notification or authorisation, depending on the quantity of radionuclides used. However, these activities are only subject to the ICPE regime if the establishment in which they take place is subject to authorisation under the terms of this regime for another of its activities;
– heading 1735 requires licensing of repositories, storage or disposal facilities for solid residues of uranium, thorium or radium ore, as well as their by-products not containing uranium enriched with isotope 235 and for which the total quantity exceeds one ton.

Pursuant to article L.593-3 of the Environment Code, an installation covered by the list of ICPEs which is also covered by the BNI regime would in fact only be subject to the latter regime.

Similarly, by virtue of Article L. 1333-4 of the Public Health Code, the authorisations issued to ICPEs under the Environment Code for the possession or utilisation of radioactive sources take the place of the authorisation required under the Public Health Code. However, except for the provisions concerning procedures, the regulatory provisions of the Public Health Code apply to them.

5|2 The regulations designed to combat malicious acts in nuclear activities

The regimes mentioned above often take account of the fight against malicious acts, at least in part. For example, in the BNI regime, the licensee must in its safety analysis report present an analysis of the accidents liable to occur in the installation, regardless of the cause of the accident, including in the event of a malicious act. This analysis mentions the effects of the accidents and the steps taken to prevent or minimise these effects. It is taken into account when assessing whether or not the authorisation decree can be issued. The most important risk prevention or mitigation measures can be the subject of ASN requirements.

The threats to be considered when examining malicious acts are defined by the Government (General Secretariat for Defence and National Security).

There are also procedures specific to the fight against malicious acts. Two systems created by the Defence Code concern certain nuclear activities:
– chapter III of part III of book III of the first part of the Defence Code defines the measures to protect and monitor nuclear materials. This concerns the following fusible, fissile or fertile materials: plutonium, uranium, thorium, deuterium, tritium, lithium 6, as well as chemical compounds comprising one of these elements, except ores. To prevent the dissemination of these nuclear materials, their import, export, production, possession, transfer, use and transport are subject to licensing;
– chapter II of part III of book III of the first part of the Defence Code defines a system for protection of establishments which "if unavailable, would risk significantly compromising the nation's combat or economic potential, its security or its capacity for survival". The TSN Act, particularly its article 2, supplemented Article L. 1333-2 of the Defence Code in order to enable the administrative authority to apply this system to establishments comprising a BNI "when the destruction of or damage to (this BNI) could constitute a serious danger for the general public". This protection system requires that the licensees take the protective measures stipulated in a particular protection plan prepared by itself and approved by the administrative authority. These measures in particular include effective surveillance, alarm and material protection measures. If the plan is not approved and in the event of a persistent disagreement, the decision is taken by the administrative authority.

With regard to nuclear activities outside the scope of national defence, these systems are monitored at national level by the Defence High Official at the Ministry responsible for Energy.

5|3 The particular system applicable to defence-related nuclear activities and installations

Defence-related nuclear installations and activities are mentioned in point III of Article 2 of the TSN Act. Pursuant to Article R. 1333-37 of the Defence Code, these are:
– secret basic nuclear installations (INBS);
– military nuclear systems;
– defence-related nuclear experimentation sites and installations;
– the former nuclear experimentation sites in the Pacific;
– transport of fissile or radioactive materials involved in the nuclear weapons and naval nuclear propulsion activities.

A large number of the requirements applicable to nuclear activities governed by ordinary law also apply to defence-related nuclear activities and installations; for example, they are subject to the same general principles as all nuclear activities and the requirements of the Public Health Code, including the system of licensing and notification of small-scale nuclear activities, and they concern defence-related nuclear activities in the same conditions as the ordinary law activities, except for the fact that the licences are granted by the Delegate for Nuclear Safety and Radiation Protection for National Defence Installations and Activities (DSND), reporting to the Minister for Defence and the Minister for Industry. These activities and installations are regulated and inspected by the personnel of the Defence Nuclear Safety Authority (ASND) headed by the Delegate.

Pursuant to point III of article 2 of the TSN Act, other provisions are specific to defence-related nuclear activities and facilities. They are subject to particular information rules in order to comply with specific defence requirements. Similarly, the installations on the list of BNIs, but which are classified as INBS by order of the Prime Minister, are not subject to the BNI system but to a special system defined by the Defence Code and implemented by the ASND (see section 2 of chapter III of book III of the first part of the Defence Code).

ASN and ASND maintain very close relations to ensure consistency between the systems for which they are responsible.

6 OUTLOOK

ASN is continuing with the publication of technical regulatory decisions required by the Public Health Code and the Labour Code. A number of decisions should therefore be issued in 2012, including those concerning the design and operating rules for medical facilities using ionising radiation, the minimum technical design rules applicable to facilities using X-rays, the design rules applicable to electrical devices emitting X-rays, the registration, monitoring, recovery and disposal of sources, and the identification and marking of high-level sealed sources.

ASN will also be assisting the Government with coming work on the transposition into French law of the new Euratom directives, whether the directive concerning radiation protection, or that concerning the management of waste and spent fuel.

With regard to the new radiation protection directive and in order to prepare for the transposition, ASN will in 2012 be conducting an analysis of the legislative modifications that will probably be necessary and will then start specific work on medical physics, the radiation protection expert (RPE), the radiological emergency and post-accident response teams and natural radioactivity in construction materials.

With regard to BNIs, ASN will in 2012 continue its work to overhaul the general technical regulations. The order setting out the BNI general rules has already been issued on 7th February 2012 (published on 8th February 2012). 2012 should also be marked by the publication of regulatory decisions, some of which have already been through the public consultation process. The publication of these texts is a new and significant step in the project to overhaul the regulations. The order of 7th February 2012 supplements and clarifies the framework created by the TSN Act and the "BNI procedures" decree, by formally stipulating the requirements based on experience feedback from several years of regulating nuclear facilities, thus giving them an appropriate legal underpinning. The publication of the order of 7th February 2012 is also a means of ensuring that the requirements ASN considers to be essential, and which were generally specified individually subsequent to periodic safety reviews, can now be applied clearly and uniformly to all facilities. Entry into force of regulatory decisions will mark the completion of the transposition into French law of the "reference levels" adopted by WENRA. As this entry into force is scheduled for 1st July 2013, 2012 could be devoted to disseminating and assimilating the provisions of the order of 7th February 2012, for instance by the licensees.

ASN will propose to the ministers responsible for nuclear safety modifications to decree 2007-1557 of 2nd November 2007 concerning BNIs and the regulation of the nuclear safety of the transport of radioactive materials, known as the "BNI procedures" decree, on the basis of the feedback gathered with respect to its implementation.

ASN will assist the Ministry for Ecology, Sustainable Development, Transport and Housing with integrating the regulatory requirements in force into the Environment Code.

Working groups will continue their work on drafting the next revision of the regulations concerning the transport of radioactive materials. They will in particular deal with fissile exceptions, the acceleration levels to be considered for package tie-down, and the interim measures and requirements.

Lastly, ASN hopes in 2012 to see the completion of the study into setting up a system to control "source security", which began several months ago. This control system will aim to guarantee the application of measures to protect the most dangerous sources of ionising radiation against malicious acts, from production through to disposal. ASN is thus working on drafting the corresponding legislative and regulatory requirements to be included in the bill ratifying ordinance 2012-6 of 5th January 2012 amending books I and V of the Environment Code. Following discussion by the Cabinet on 21st March 2012, this bill was tabled before the Senate. If adopted, these requirements should be incorporated into the Public Health Code.

APPENDIX 1
REGULATION EXPOSURE LIMITS AND DOSE LEVELS

Annual exposure limits contained in the Public Health Code (CSP) and in the Labour Code (CT)

References	Definition	Values	Observation
	Annual limits for the general public		
Art. R.1333-8 of the CSP	• Effective doses for the body • Equivalent doses for the lens of the eye • Equivalent doses for the skin (average dose over any area of 1 cm^2 of skin, regardless of the area exposed)	1 mSv/year 15 mSv/year 50 mSv/year	☞ These limits comprise the sum of effective or equivalent doses received as a result of nuclear activities. These are limits that must not be exceeded.
	Worker limits for 12 consecutive months		
Art. R. 4451-13 of the CT	Adults: • Effective doses for the body • Equivalent doses for the hands, forearms, feet and ankles • Equivalent doses for the skin (average dose over any area of 1 cm^2 of skin, regardless of the area exposed) • Equivalent doses for the lens of the eye Pregnant women • Exposure of the child to be born Young people from 16 to 18 years old*: • Effective doses for the body • Equivalent doses for the hands, forearms, feet and ankles • Equivalent doses for the skin • Equivalent doses for the lens of the eye	 20 mSv 500 mSv 500 mSv 150 mSv 1 mSv 6 mSv 150 mSv 150 mSv 50 mSv	☞ These limits comprise the sum of effective or equivalent doses received. These are limits that must not be exceeded. ☞ Exceptional waivers are accepted: • when justified beforehand, they are scheduled in certain working areas and for a limited period, subject to special authorisation. These individual exposure levels are planned according to a ceiling limit which is no more than twice the annual exposure limit value; • emergency occupational exposure is possible in an emergency situation, in particular to save human life.

* Only if covered by waivers, such as for apprentices.

Optimisation levels for patient protection (Public Health Code)

References	Definition	Values	Observation
Diagnostic examinations			
Diagnostic reference levels Art. R.1333-68, order of 16 February 2004	Dose levels for standard diagnostic examinations	E.g. : entry level of 0.3 mGy for an X-ray of the thorax	☞ The diagnostic reference levels, the dose constraints and the dose target levels are used by applying the principle of optimisation. They are simply guidelines. ☞ The reference levels are defined for standard patients by dose levels for standard radiological examinations and by radioactivity levels for radiopharmaceutical products used in diagnostic nuclear medicine.
Dose constraint Art. R.1333-65, order expected in 2006	Used when exposure offers no direct medical benefit to the person exposed		☞ The dose constraint can be a fraction of a diagnostic reference level, in particular for exposure in the context of biomedical research or forensic procedures.
Radiology			
Target dose level Art. R.1333-63	Dose necessary for the target organ or tissue (target organ or target-tissue) during radiotherapy (experimentation)		☞ The target dose level (specialists talk of a target volume in radiotherapy) is used to adjust the equipment.

Intervention levels in cases of radiological emergencies

References	Definition	Values	Observation
Protection of the general public			
Intervention levels Art. R.1333-80, order of 14th October 2003, circular of 10th March 2000	Expressed in effective dose (except for iodine), these levels are designed to assist with the relevant response decision to protect the general public: • sheltering • evacuation • administration of a stable iodine tablet (equivalent dose for the thyroid)	10 mSv 50 mSv 50 mSv	☞ The *préfet* can make adjustments to take account of local factors.
Protection of participants			
Reference levels Art. R.1333-86	These levels are expressed as effective dose: • for the special teams for technical or medical intervention • for the other participants	100 mSv 10 mSv	☞ This level is raised to 300 mSv when the intervention is designed to prevent or reduce exposure of a large number of people.

Source: The Public Health Code

Action levels (Public Health Code and Labour Code) and activity or dose levels above which steps must be taken to reduce exposure

References	Definition	Values	Observation
Lasting exposure (contaminated sites)			
Art. R.1333-89 of the CSP IRSN Guide 2000	Selection level: individual dose above which the need for rehabilitation must be examined	Not defined	☞ The notion of selection level is introduced by the IRSN guide for management of industrial sites potentially contaminated by radioactive materials.
Exposure to radon			
Protection of the general public Art. R.1333-15 and R.1333-16 of the CSP, order of 22 July 2004	Premises open to the public	400 Bq/m³ 1,000 Bq/m³	☞ See recommendation published in Official Gazette of 11 August 2004 defining the radon measurement methods. ☞ See recommendation published in Official Gazette of 22 February 2005 defining corrective action to be taken in the event of an overexposure.
Lasting exposure (contaminated sites)			
Worker protection	Working environments	400 Bq/m³	
Enhanced natural exposure (other than radon)			
Protection of the general public Art. R.1333-13 and R.1333-16 of the CSP	Effective dose	None	☞ Any population protection action to be taken will be defined on a case-by-case basis.
Worker protection Art. R.4457-6 to 9 Order of 7 August 2008		1 mSv/year	
Water intended for human consumption			
Order of 11 January 2007	Annual total indicative dose (TID), calculated based on the radionuclides present in the water, except for tritium, potassium 40, radon and daughter products Tritium Total alpha activity Total residual beta activity	0.1 mSv/an 100 Bq/L 0.1 Bq/L 1 Bq/L	☞ The TID can be used to estimate the exposure attributable to the radiological quality of the water. Any corrective measures to be taken if the TID is exceeded depend on the value of the TID and the radionuclides in question. ☞ Tritium is a contamination indicator.
Foodstuffs (emergency situation)			
European regulations *Codex alimentarius,* etc.	Sale restrictions (MAL and GL)	See following table	

Limit values for the consumption and sale of foodstuffs contaminated in the event of a nuclear accident

MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION FOR FOODSTUFFS (Bq/kg or Bq/L)		Baby food	Other foodstuffs except those of lesser importance	Liquids intended for consumption
Isotopes of strontium, in particular ^{90}Sr	75	125	750	125
Isotopes of iodine, in particular ^{131}I	150	500	2,000	500
Isotopes of plutonium and alpha-emitting transuranic elements, especially ^{239}Pu and ^{241}Am	1	20	80	20
Any other element with a half-life of more than 10 days, in particular ^{134}Cs and ^{137}Cs	400	1,000	1,250	1,000

Source: Council Regulation 2218/89/Euratom of 18th July 1989 amending Regulation 3954/87/Euratom of 22nd December 1987

Maximum permitted levels of radioactive contamination in feedingstuffs (caesium 134 and caesium 137)

Animal categories	Bq/kg
Pork	1,250
Poultry, lamb, veal	2,500
Others	5,000

Source: Regulation 770/90/Euratom of 29th March 1990

Guideline levels in Bq/kg

Radionuclides	Foodstuffs intended for general consumption	Baby food
Plutonium 238, plutonium 239, plutonium 240, americium 241	10	1
Strontium 90, ruthenium 106, iodine 129, iodine 131, uranium 235	100	100
Sulphur 35, cobalt 60, strontium 89, ruthenium 103, caesium 134, caesium 137, cerium 144, iridium 192	1,000	1,000
Tritium, carbon 14, technetium 99	10,000	1,000

Source: Codex alimentarius, July 2006