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 Act of 13 June 2006 relative to nuclear transparency and security (known as the "TSN" act) has profoundly modernized the BNI legal system. 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 REGULATORY REQUIREMENTS 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.

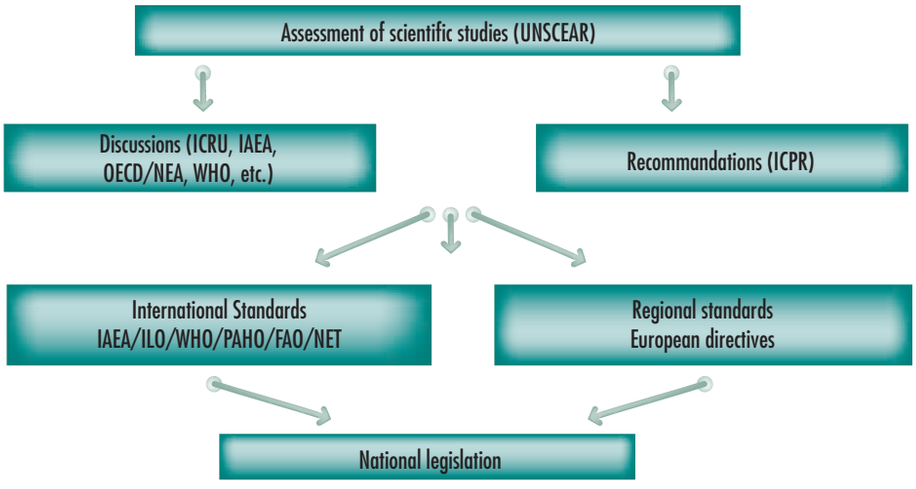
1|1 The regulatory basis

1|1|1 The international radiation protection framework (ICRP, IAEA, EURATOM)

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 diverse disciplines, which publishes recommendations concerning the protection of workers, the population 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. In 2008, IAEA initiated a process to revise the basic requirements, in order to take account of the new recommendations from ICRP (Publication 103), while a new standard for the basic safety principles was published by IAEA at the end of 2006;



Drafting of radiation protection policy

– 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 13 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 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure; and directive 2003/122/Euratom of 22 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 draft directive has been issued for review by the Member States since March 2010.

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 and the TSN Act

The most general requirements are contained in the Public Health Code and in the first sections of act 2006-686 of 13 June 2006 concerning transparency and security in the nuclear field (TSN Act). This act is currently being incorporated in 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.

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 benches of the Sénat

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.

As for the TSN Act, its part I defines various concepts:

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"*.

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"*.

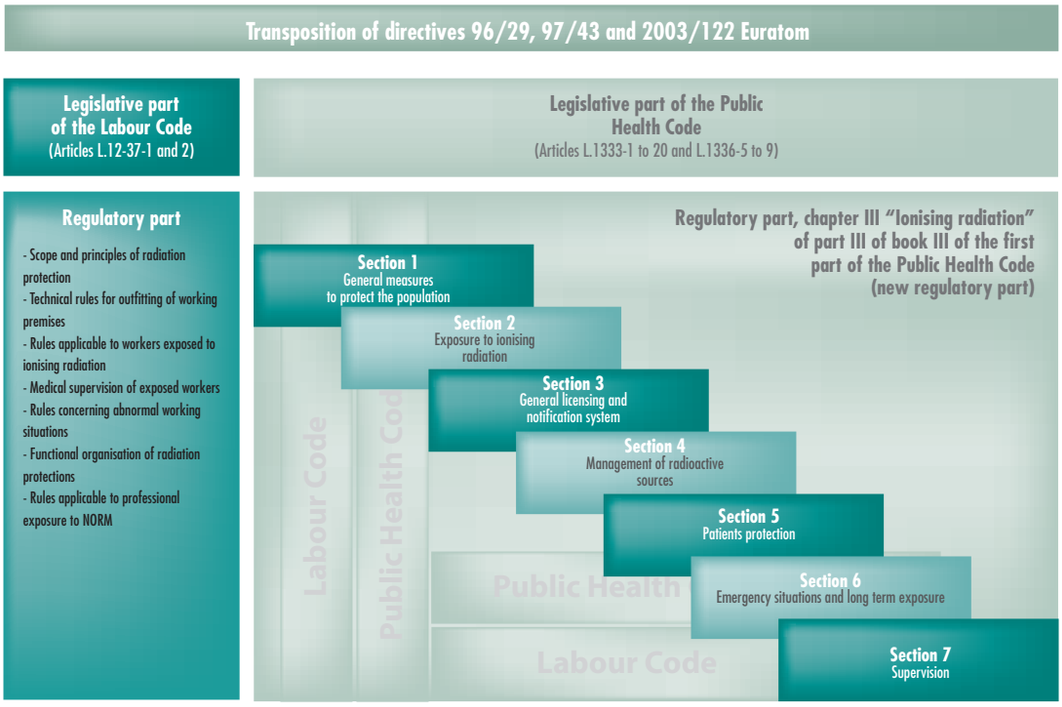
Nuclear transparency is defined as *"the set of provisions adopted to ensure the public's right to reliable and accessible information on nuclear security"*.

Part I of the TSN Act also defines the role of the state with regard to nuclear safety: it *"defines the regulations on nuclear security and implements controls to apply these regulations. It ensures the public is informed of the risks related to nuclear activities and their impact on personal health and security as well as on the environment"*.

Part I of the TSN Act also lays down the general principles applicable to nuclear activities. These principles are presented in point 1 of chapter 2.

Part III of the TSN Act creates the ASN, defines its roles and clarifies its organisation. These aspects are presented in point 2|3|1 of chapter 2.

Part III of the TSN Act deals with public information about nuclear safety. Its main requirements are mentioned in chapter 6.



Legislative and regulatory architecture of radiation protection

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 28 June 2006 on the sustainable management of radioactive materials and waste, called the "Waste" Act, part of which is incorporated into 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.

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

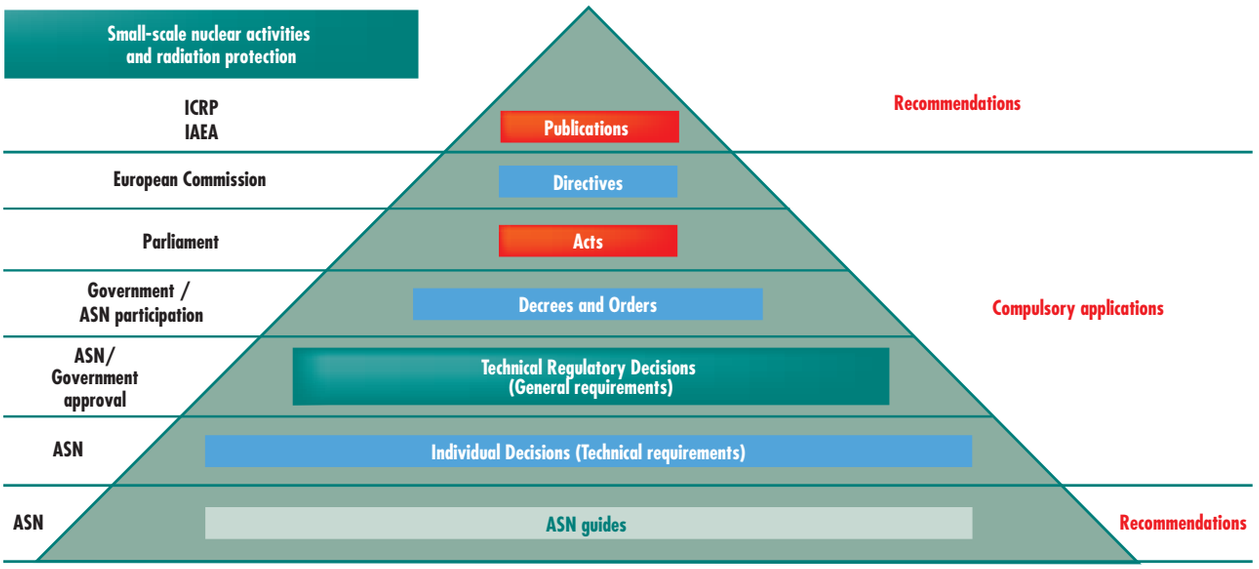
Appendix 1 to this chapter gives the various dose levels and exposure limits set by the regulations.

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 ionizing 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 2 July 2010 relative to the protection of workers against risks due to artificial optical radiation.

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

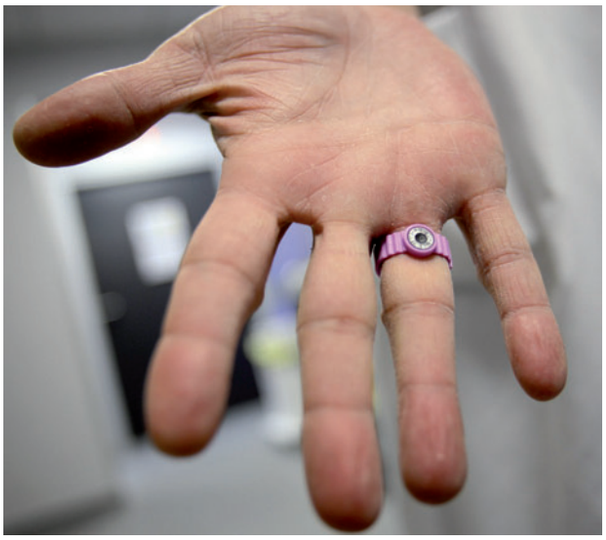


Schematic of the different levels of regulation in the small-scale nuclear sector in France

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;
– the dose limits (articles R. 4451-12 to 15) were reduced to 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).

These requirements are clarified by the implementing orders.



Dosimetric finger ring used by the nuclear medicine unit personnel in the North Saint-Denis Cardiology Centre

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 15 May 2006 (O.G. of 15 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 joint General Directorate for Labour/ASN circular of 18 January 2008 specifies the implementation procedures.

The person with competence for radiation protection (PCR)

The duties of the person with competence for radiation protection (PCR) were extended to marking out 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 26 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 "BNI - ICPE" sector, covering establishments containing one or more BNI(s) and those which comprise an installation subject to licensing as an installation classified on environmental protection grounds, with the exception of the nuclear activities in the medical sector 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 16 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.

Dosimetry

The procedures for approval of the organisations responsible for worker dosimetry are defined by the order of 6 December 2003 as amended; the procedures for medical monitoring of workers and the transmission of individual dosimetry data are specified in the order of 30 December 2004. ASN is in charge of examining the approval applications submitted by the dosimetry organisations and laboratories.

Radiation protection supervision

Technical control 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 radiation 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 4 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. The controls are carried out partly as part of the licensee's in-house inspection processes and partly 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). The approval procedures for these organisations were defined in the order of 9 January 2004. ASN is responsible for examining approval applications submitted by the organisations.

The list of approved organisations is available on the ASN website: *www.asn.fr*.

Radon in the working environment

(See point 2 | 3 | 1).

1 | 2 | 2 General protection of the population

Apart from the special radiation protection measures included in individual nuclear activity licences for the benefit of the population as a whole 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 15 mSv/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 1 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 5 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 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.

Taking plant samples in the vicinity of the Marcoule power plant

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.

Radioactivity and the environment

A national network for the measurement of environmental radioactivity 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 population. The network's orientations are defined by ASN and it is managed by IRSN (order of 27 June 2005 on the organisation of a national network for the measurement of environmental radioactivity and setting the conditions of 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.

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

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 12 May 2004. They form part of the sanitary inspections carried out by the Regional Health Agencies (ARS). The order of 11 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 (0.1 Bq/L), the total residual beta activity (1 Bq/L), the tritium activity (100 Bq/L) and the total indicative dose – TID (0.1 mSv/year). The circular from the General Directorate for Health (DGS) dated 13 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 3954/87/Euratom of 22 December 1987, modified by Council Regulation no. 2219/89/EEC of 18 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 appendix 1).

At the international level, exchanges with non-EU countries are governed by the harmonised standards of the Codex Alimentarius Commission, a joint body of the FAO (Food and Agriculture Organisation of the United Nations) and WHO (World Health Organisation), which in July 2006 revised the Guideline Levels (GL) for radionuclides in foodstuffs contaminated as a result of a nuclear accident or a radiological event, for use in international trade. The EU regulation should be updated to take account of the new values in the Codex (see table in Appendix 1 to this chapter).

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 (ASN decision 2008-DC-0095 of 29 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 (10 µSv/year).

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

The population is 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 10 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

Intervention levels were updated in 2009 by ASN regulatory decision 2009-DC-0153 of 18 August 2009, approved by order of the Minister for Health and Sports, dated 20 November 2009, with a reduction in the level concerning exposure of the thyroid. Henceforth, the protection measures to be taken in an

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

emergency situation, and the corresponding intervention levels, are:
– sheltering, if the predicted effective dose exceeds 10 mSv;
– evacuation, if the predicted effective dose exceeds 50 mSv;
– 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.

Public information in a radiological emergency

The ways in which the population is informed in a radiological emergency situation are covered by a specific EU directive (Directive 89/618/Euratom of 27 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 13 September 2005 concerning the off-site emergency plans for certain fixed structures or installations, implementing article 15 of Act 2004-811 of 13 August 2004 on the modernisation of civil security.

Two implementing orders were published:
– the order of 4 November 2005 *concerning public information in the event of a radiological emergency situation;*
– the order of 8 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 population in a long-term exposure situation

Sites contaminated by radioactive materials are sites which had 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.

The approach for determining clean-out thresholds for these sites is defined in the IRSN guide (methodology guide for sites contaminated by radioactive materials). A new version of this guide, produced under the supervision of ASN and the Ministry of Ecology, was the subject of prior consultation on the ASN website in 2010.

Emergency exercise simulating an accident involving the transport of radioactive material – October 2010

2 REGULATORY REQUIREMENTS APPLICABLE TO SMALL-SCALE NUCLEAR ACTIVITIES

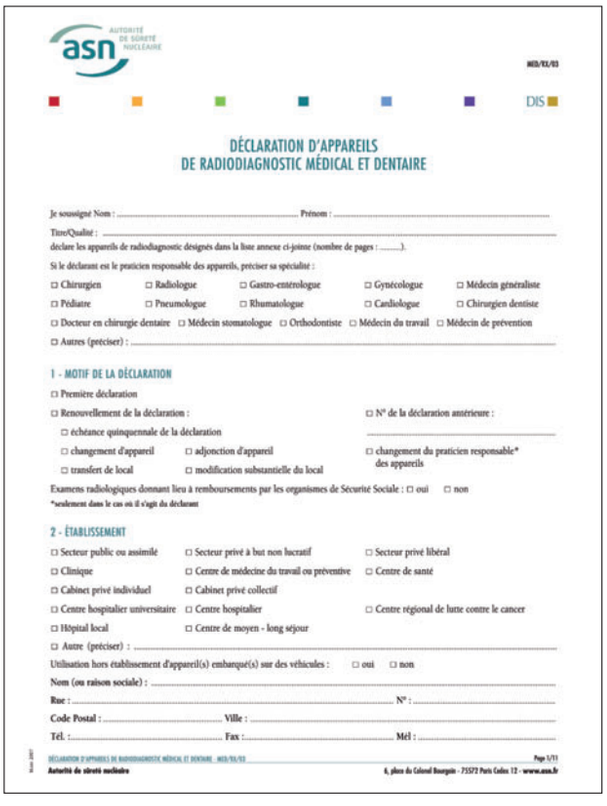
2|1 The small-scale nuclear activities licensing and notification system

2|1|1 Licensing and notification 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 it is planned to subject individuals to ionising radiation (see point 2|2).



DÉCLARATION D'APPAREILS
DE RADIODIAGNOSTIC MÉDICAL ET DENTAIRE

Je soussigné Nom : ..... Prénom : .....
Titre/Qualité : .....
déclare les appareils de radiodiagnostic désignés dans la liste annexe ci-jointe (nombre de pages : .....).
Si le déclarant est le praticien responsable des appareils, préciser sa spécialité :
☐ Chirurgien ☐ Radiologue ☐ Gastro-entérologue ☐ Gynécologue ☐ Médecin généraliste
☐ Pédiatre ☐ Pneumologue ☐ Rhumatologue ☐ Cardiologue ☐ Chirurgien dentiste
☐ Docteur en chirurgie dentaire ☐ Médecin stomatologue ☐ Orthodontiste ☐ Médecin du travail ☐ Médecin de prévention
☐ Autres (préciser) : .....

1 - MOTIF DE LA DÉCLARATION
☐ Première déclaration
☐ Renouvellement de la déclaration : ☐ N° de la déclaration antérieure : .....
☐ échéance quinquennale de la déclaration
☐ changement d'appareil ☐ adjonction d'appareil ☐ changement du praticien responsable* des appareils
☐ transfert de local ☐ modification substantielle du local
Examens radiologiques donnant lieu à remboursements par les organismes de Sécurité Sociale : ☐ oui ☐ non
*seulement dans le cas où il s'agit du déclarant

2 - ÉTABLISSEMENT
☐ Secteur public ou assimilé ☐ Secteur privé à but non lucratif ☐ Secteur privé libéral
☐ Clinique ☐ Centre de médecine du travail ou préventive ☐ Centre de santé
☐ Cabinet privé individuel ☐ Cabinet privé collectif
☐ Centre hospitalier universitaire ☐ Centre hospitalier ☐ Centre régional de lutte contre le cancer
☐ Hôpital local ☐ Centre de moyen - long séjour
☐ Autre (préciser) : .....
Utilisation hors établissement d'appareil(s) embarqué(s) sur des véhicules : ☐ oui ☐ non
Nom (ou raison sociale) : .....
Rue : ..... N° : .....
Code Postal : ..... Ville : .....
Tél. : ..... Fax : ..... Mél : .....

Autorité de sûreté nucléaire — 6, place du Colonel Bourgoin - 75572 Paris Cedex 12 - www.asn.fr

Medical and dental radiodiagnosis appliance declaration form, available on *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 2010-DC-192 of 22 July 2010, approved by the order of 22 September 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 16 July 2009, supplemented by ASN decision 2009-DC-0162 of 20 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.

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 of the notification has been abolished, a new notification for regularly notified activities only becomes necessary if significant changes have been made to the installation (change in or addition of an appliance, transfer or substantial modification of the premises or change in the licence holder).

Licencing 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.

Licencing 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 licence exemption criteria adopted in Directive 96/29/Euratom (appendix 1, table A) were introduced into an appendix of the Public Health Code (table A, appendix 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 control organisations

Technical supervision of the radiation protection organisation, including supervision of the management of radioactive sources and any associated waste, is entrusted to approved organisations (article R. 1333-97 of the Public Health Code). The list of approved organisations is available on the ASN website (*www.asn.fr*). The type and frequency of the inspections were defined by the order of 26 October 2005, mentioned in point 1|2|1.

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

Decision 2008-DC-0109 of 19 August 2008 concerns the licensing system for the distribution, import and/or export of radionuclides 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 radio-immunology assay).

Decision 2008-DC-0108 of 19 August 2008 in particular concerns the licence to possess and use a particle accelerator (cyclotron) and the manufacture of radiopharmaceuticals containing a positon 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 inventory of sources is given to IRSN (article L. 1333-9 of the Public Health Code).

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 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.

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

2|2 Protection of persons exposed for medical and medico-legal 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 procedures

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 procedure and examinations*" guide (also called "*indication 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 (NRD) are one of the tools used for dose optimisation. The NRD are stipulated in article R. 1333-68 of the Public Health Code and were defined by the order of 12 February 2004. 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. These reference levels will be updated by conducting regular measurements or readings in line with the type of examination in each radiology and nuclear medicine department and centralising them at IRSN. The NRDs will be updated in 2010 by order of the Minister of Health.

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 19 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 of presence of radiation physicists in radiotherapy centres have been defined by decree (decree 2009-959 of 29 July 2009). They are applicable until the end of the interim period provided for in the health-care activities licensing system (decree 2007-388 of 21 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.

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 1 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 will be brought progressively into force before 26 September 2011 following a schedule specified in the decision.

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 3 March 2003. External quality control is entrusted to organisations approved by the Director General of the AFSSAPS (French Health Product Safety Agency)

Table 1 : list of Indication 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**	**Indication guide**	**Indication and procedure guide**	**External radiotherapy procedure guide**	**Indication 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

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 informing 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 18 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 22 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.

2|2|3 Forensic applications of ionising radiation

In the forensic field, ionising radiation are 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 are 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.

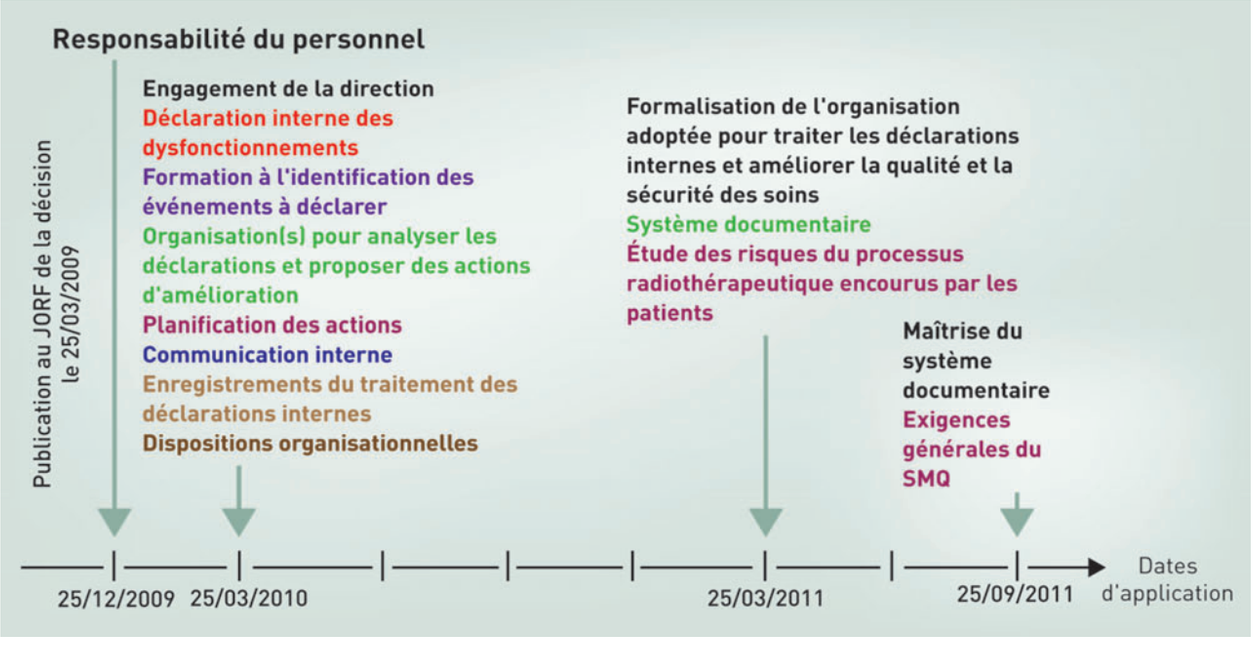
2|3 Protection of individuals exposed to enhanced natural ionising radiation

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;

Application calendar for ASN decision 2008-103 of 1 July 2008



– 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/m³, the implementing order of 22 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*[2] classified as having priority for radon measurement (see map below) ;
– 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 22 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 levels of 400 and 1,000 Bq/m³ were to be exceeded (O.G. of 22 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 7 April 2009, amended by decision 2010-DC-0181 of 15 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*.

Act 2009-879 of 21 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 7 August 2008 defined the workplaces in which these measurements are required and ASN decision 2008-DC-0110, approved by the order of 8 December 2008, specifies the reference levels above which the radon concentration must be reduced.

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

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

Professional activities that 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 25 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 population or of workers.

For these activities, the Public Health Code requires an estimation of the doses to which the population 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 will also be 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 offers

Aerial view of Le Havre thermal power plant

clarification of the technical measurement procedures for evaluating the doses received by the workers[3].

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 the exposure (particularly in the event of a declared pregnancy) and inform the personnel of the health risks. The order of 7 February 2004 defines the procedures for implementing these measures.

Map of the 31 *départements* prioritised for radon monitoring

3. 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.

3 THE LEGAL RULES AND REQUIREMENTS 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 population and the environment.

3|1 The legal bases

3|1|1 International conventions and standards

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 defines the main safety objectives and appropriate measures. Its counterpart 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).

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. These documents are not binding.

3|1|2 European texts

The Euratom Treaty

The Euratom Treaty, which was signed in 1957 and came into force in 1958, aimed at developing nuclear power while protecting the population 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 the informing of the Commission were incorporated into the decree of 2 November 2007. The decrees authorising creation of a BNI, or a modification leading to an increase in the discharge limit values, or final shutdown, can now only be issued after obtaining the opinion of the Commission.

The Directive of 25 June 2009

Directive 2009/71/Euratom of 25 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.

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).

Previously, only two resolutions of the Council in 1975 and 1992 concerning nuclear safety technology-related issues had asked the Member States to work more closely together on addressing basic safety issues.

3|1|3 National texts

The "TSN" Act and its implementing decrees

Part IV of the TSN Act creates the BNI authorisation and inspection system.

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.

Of the fifteen TSN Act implementing decrees, the following specifically concern BNIs:
- decree 2007-830 of 11 May 2007 concerning the list of BNIs;
- decree 2007-831 of 11 May 2007 determining the procedures for designating and approving nuclear safety inspectors;
- decree 2007-1557 of 2 November 2007 (amended) concerning BNIs and nuclear safety aspects of the transport of radioactive materials;
- decree 2010-882 of 27 July 2010 thus abolished the BNI Consultative Committee and transferred its consultative remit regarding certain regulatory texts relating to BNIs to the CSPRT (High Council for Technological Risk Prevention).
- decree 2008-251 of 12 March 2008 concerning the local information committees of BNIs.

The "Waste" Act and its implementing decrees

Act 2006-739 of 28 June 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.

The "BNI procedures" decree

BNI regulations are governed by decree 2007-1557 of 2 November 2007 concerning BNIs and the regulation of nuclear safety aspects of the transport of radioactive materials, known as the "BNI procedures" decree, implementing Article 36 of the "TSN" Act.

The "BNI procedures" decree 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 30 of the TSN Act, comprise all the general texts laying down the technical rules concerning nuclear safety, whether regulatory (ministerial orders and ASN regulatory decisions) or related (circulars, basic safety rules, ASN guides).

3|2|1 Ministerial and government orders

Quality organisation

The order of 10 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 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 public and the environment off the site.

The order of 31 December 1999 amended by the order of 31 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, 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 26 November 1999 order lays out the general technical

Public consultation regarding the planned recasting of the general technical regulations

In the framework of the planned recasting of the general technical regulations applicable to BNIs, several draft regulatory texts (a draft order and ten draft ASN decisions) were submitted to public consultation in 2010.

This broad consultation was addressed to licensees, experts, environmental protection associations, union organisations and European safety authorities. The draft order was moreover posted on line on the MEDDTL (Ministry of Ecology, Sustainable Development, Transport and Housing) and ASN web sites for three months in order to collect comments from the public at large. ASN also posted the ten draft decisions on its web site.

TO BE NOTED

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.

Pressure equipment

The general technical regulations concerning pressure equipment are presented in point 3|6.

3|2|2 Overhaul of the general technical regulations

Pursuant to the publication of the TSN Act 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 new technical regulations shall comprise:

– an order from the ministers responsible for nuclear safety establishing the essential requirements applicable to all BNIs to protect persons and the environment against the risks of accidents, chronic pollution or other detrimental factors;
– some twenty ASN decisions.

The "BNI system" draft order

A "BNI system" order will include in the basic provisions in effect today and integrate the reference levels defined by WENRA. Following the requisite discussions and consultations, this order should be adopted in 2011.

Regulatory decisions

Pursuant to article 4 of the TSN Act, ASN may issue decisions to clarify the decrees and orders in the field of nuclear safety or radiation protection. These decisions have to be approved by the Government.

ASN has defined a programme of regulatory decisions which will clarify the decree of 2 November 2007 and the new "BNI system" order.

The first ASN decision issued for application of the decree of 2 November 2007 is decision 2008-DC-106 of 11 July 2008 relating to the implementation of the BNI internal authorisations system.

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.

They are not, strictly speaking, regulatory documents. A licensee may decide not to follow the specifications of a BSR if it can demonstrate that the alternatives it will employ enable the same safety objectives to be met.

As part of the ongoing reorganisation of the general technical regulations, the BSRs are gradually being replaced by "ASN guides".

There are currently about forty BSRs and other technical rules issued by ASN, available on its website.

UNDERSTAND

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 exchange of experience and 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 to examine 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.

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

Part IV of the TSN Act makes provision for an authorisation decree for the creation of a BNI followed by any necessary licenses during its operation, from commissioning through to final shutdown and decommissioning, and including any modifications to the installation.

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. The review then focuses in particular on the socio-economic and safety aspects. 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.

Public debates were held in 2006 for the construction of an EPR nuclear reactor at Flamanville and for the siting of the ITER research reactor at Cadarache, and in 2010 for the construction of an EPR nuclear reactor at Penly. Smaller-scale projects can also give rise to a "local debate" initiatives. 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 by the industrial concern in charge of operating the installation, which thus acquires the status of licensee, to the ministers responsible for nuclear safety. The application is accompanied by a dossier comprising several items, including the detailed drawing of the installation, the impact assessment study, the preliminary safety analysis report, the risk management study and the decommissioning plan.

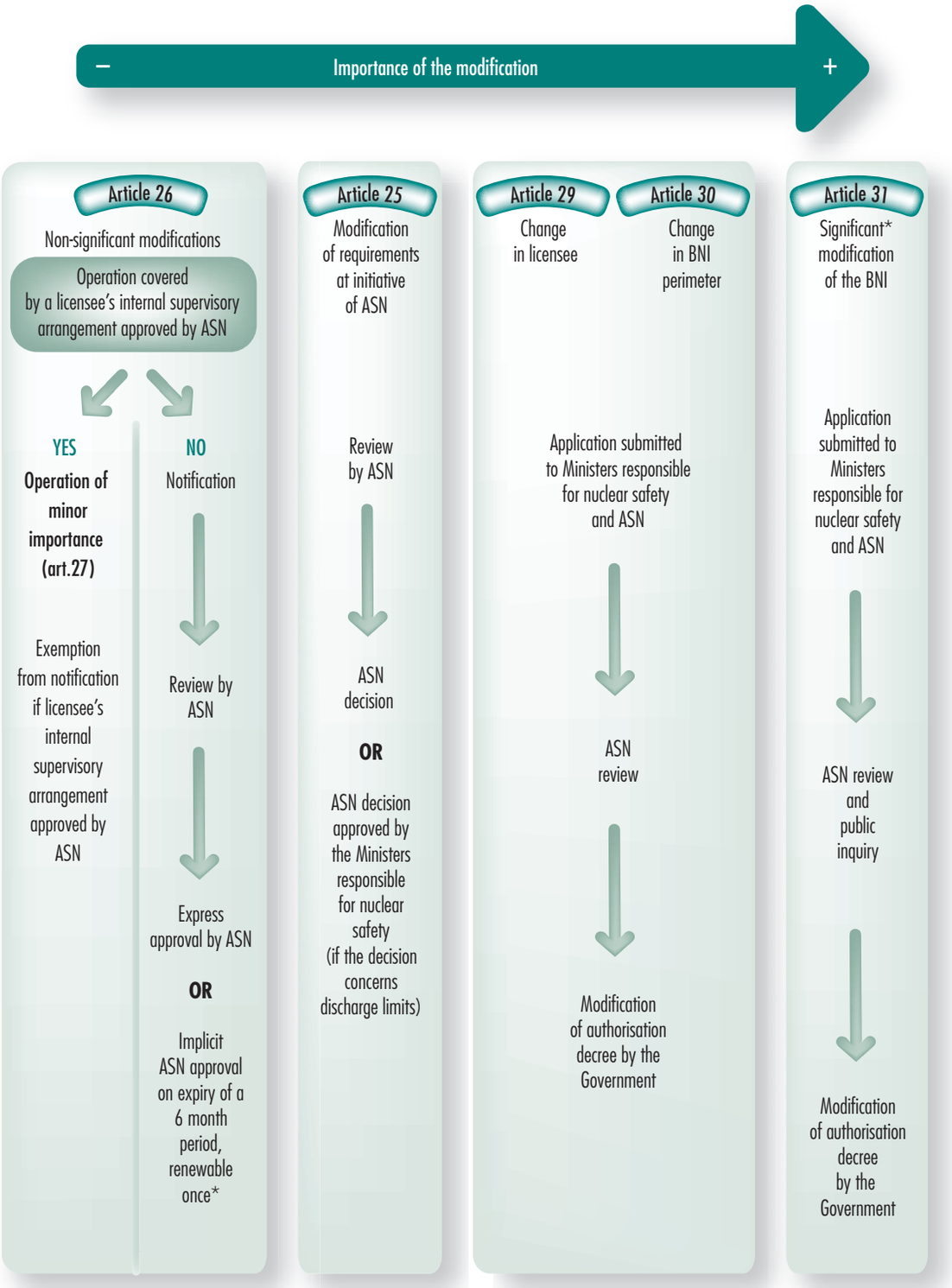
ASN is responsible for reviewing the dossier, jointly with the ministers responsible for nuclear safety. This is followed by a period of parallel consultation of the public and technical experts.

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

The public inquiry

The authorisation can only be given after a public inquiry as provided for in Article 29 of the TSN Act. The purpose of the inquiry is to inform the public and collect opinions, suggestions and counter-proposals, in such a way as to provide the

Diagram 1: 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.

competent authority with all the elements necessary for its own information before any decisions are made.

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.

The creation of a local information committee (CLI)

Article 22 of the TSN Act gave a formal status to the BNI local information committees (CLIs). 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

In application of article 37 of the treaty instituting the European Atomic Energy Community and the TSN Act, the authorisation decree for an installation that could discharge radioactive effluents into the environment can only be granted after consulting the Commission of the European Communities in application of article 37 of the treaty instituting the European Atomic Energy Community.

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 2)

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 13 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 authorisation decree sets the perimeter and characteristics of the installation and the particular rules by which the licensee is bound. The authorisation decree 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 II bis of article 29 of the TSN Act, created by the "Grenelle II" Act 2010-788 of 12 July 2010 providing for the French environmental commitment, information on BNI modification projects that could lead to a significant increase in water intakes or effluent discharges into the environment will now be made available to the public.

Modification of a BNI

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

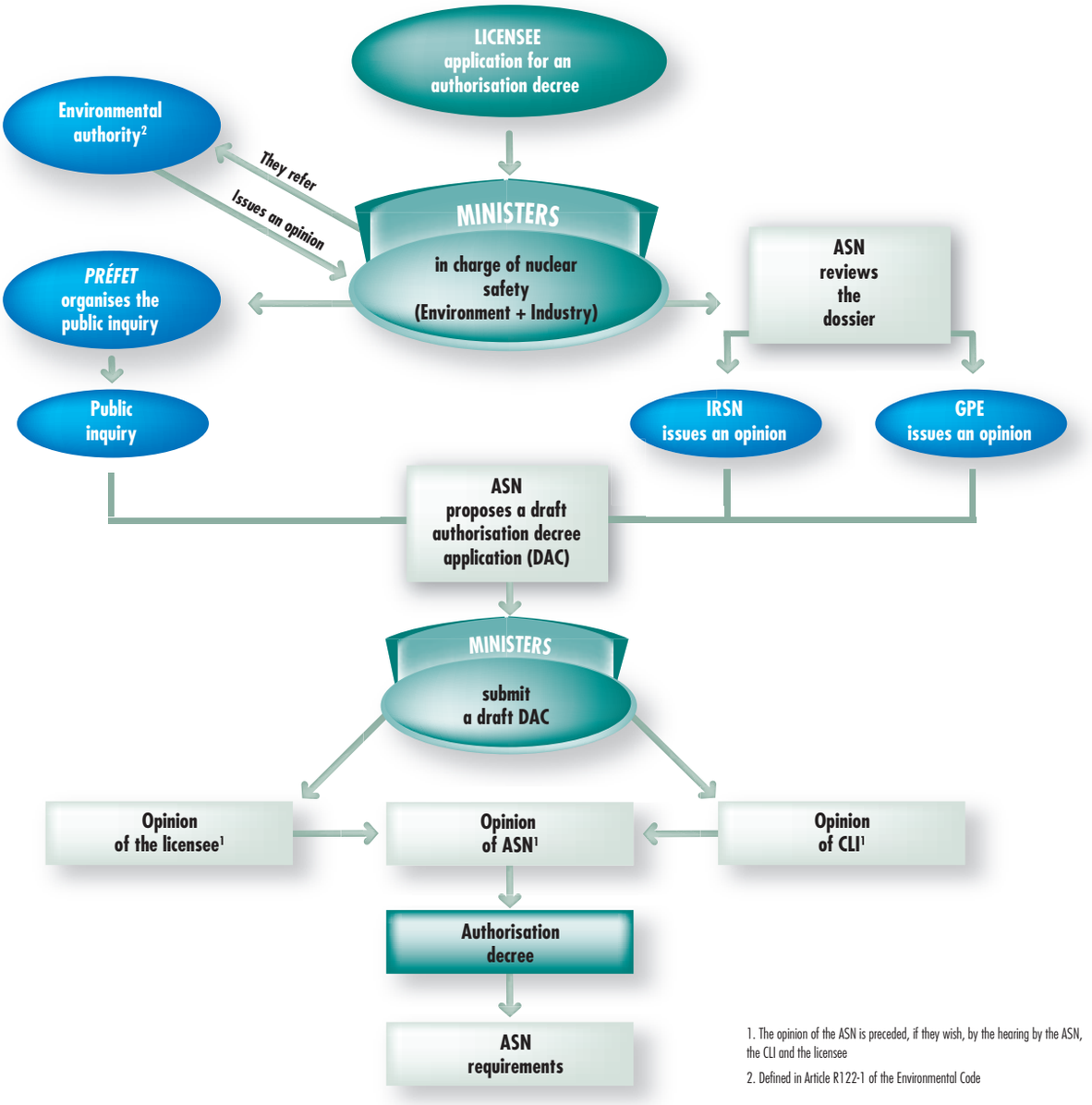
A modification is considered to be significant in the cases mentioned in article 31 of decree 2007-1557 of 2 November 2007, the "procedures" decree:
– a change in the nature of the installation or an increase in its maximum capacity;
– a change in the key elements regarding protection of the interests mentioned in section I of article 28 of the TSN Act, mentioned in the authorisation decree;
– a new BNI mentioned in section III of article 28 of the TSN Act is added within the perimeter of the installation and its operation is linked to that of the installation 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 period of at least six months, renewable once, has expired, unless ASN gives its express agreement. If it deems necessary, ASN can order that the planned modifications be reviewed or be accompanied by complementary measures to guarantee protection of the interests provided for by law.

The other installations located within a BNI perimeter

Two types of installation coexist within a BNI perimeter (TSN Act - article 28-V):
– 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.

Diagram 2: 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

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 (TSN Act - Articles 20 and 21)

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 communicates it to the local information committee.

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. In 2010, France presented a report on the application of the best available techniques for optimising discharges from BNIs.

3|4|2 BNI discharges

BNI discharges management policy

Like all industries, nuclear activities (nuclear industry, nuclear medicine, research installations, etc.) create by-products, which may or may not be radioactive. Steps are being taken to 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 functioning" - 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, and more generally the technical regulations relative to discharges and the environment, take this matter into account. 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.

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.

IRSN technicians taking grass samples in the vicinity of the Tricastin nuclear power plant

The measures taken following the 2003 heat wave and drought meant that the 2006 drought episode was dealt with in good conditions, in particular ensuring full compliance with the discharge licences applicable. The summer of 2010 did not lead to any severe low-water situations or any very high temperatures in the watercourses concerned by the BNIs.

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.

As part of the revision of the general regulations applicable to BNIs, the requirements of the order of 31 December 1999 shall be taken up both in the "BNI system" order and in several of the decisions developing it, and notably the "environment decision" which was submitted to public consultation from 19 July 2010 to 15 October 2010.

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.

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 in 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 Management of BNI radioactive waste

The management of radioactive waste in BNIs is based more particularly on the provisions of the order of 31 December 1999 which establishes the general technical regulations for preventing and limiting nuisance factors and off-site risks resulting from operation of the BNIs. This order recalls the need for the licensee to take all necessary steps in the design and operation of its installations to ensure optimum management of the waste produced, taking account of the subsequent management solutions. This order requires drafting of a study specifying how the waste produced in BNIs is to be managed. One part of this study is submitted to ASN for approval. In the revision of the technical regulations applicable to BNIs, certain requirements relative to waste management in the BNIs will be integrated in the "BNI system" order. An ASN decision will supplement the requirements concerning management of the waste produced in BNIs. ASN submitted the draft decision to public consultation from 26 May to 31 August 2010.

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

Cleaning out a tank in the vitrification shop of Marcoule – August 2007

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 the TSN Act, final shutdown, followed by decommissioning of a nuclear installation, is authorised by a new decree, subject to the opinion 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 2 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;
– 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 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

Article 20 of the "Waste" Act provides for the securing of the costs associated with the decommissioning of nuclear installations and the management of radioactive waste. This Article is clarified by decree 2007-243 of 23 February 2007 and the order of 21 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 must also evaluate the cost of managing their spent fuels and radioactive waste (section I of article 20 of the Act of 28 June 2006). 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 28 October 1943 concerning pressure equipment used on land and gas pressure equipment used on land or on-board inland waterway boats, and those of the decree of 2 April 1926 as amended regulating pressure equipment other than that installed on-board ships, decree 63 of 18 January 1943 as amended, regulating gas pressure equipment, or decree 99-1046 of 13 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 13 December 1999 and specific orders. The "BNI system" order, of which the draft is mentioned in point 3|2|2, will replace these orders and will be clarified by ASN regulatory decisions.

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 12 May 2009 simplifying and clarifying the law and relaxing procedures, modified the Act of 28 October 1943, giving ASN additional competence for verification 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 2 April 1926 • Order of 26 February 1974(1)	• Decree of 2 April 1926 • BSR II.3.8 of 8 June 1905(1)	• Decree of 2 April 1926 • Decree of 18 January 1943 or decree 99-1046 of 13 December 1999	• Decree 99-1046 of 13 December 1999
	or Order of 12 December 2005			
Operation	• Order of 10 November 1999		• Decree of 2 April 1926 • Decree of 18 January 1943(1)	• Decree 99-1046 of 13 December 1999 • Order of 30 March 2005

(1) As of 2011, the order of 12 December 2005 will apply 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 24 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 have been fully transposed into French law and have been implemented by government orders. For this purpose, ASN is in contact with the administrations in charge of the various modes of transport (Directorate General for Infrastructure, Transport and the Sea – DGITM – General Directorate for risk prevention – DGPR and General Directorate for Civil Aviation – DGAC) and sits on the French Interministerial Commission for the Carriage of Dangerous Goods (CITMD).

The directive of 24 September 2008 is transposed into French law by a single order covering all land transport on the national territory. This is the order of 29 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.

Other orders specific to a mode of transport are applicable to the transport of radioactive materials:
– the order of 12 May 1997 as modified, concerning the technical conditions for the operation of aircraft by a public air transport operator (OPS1);
– the order of 23 November 1987 as modified, division 411 of the regulation concerning the safety of ships (RSN);
– the order of 18 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

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

subject to either notification 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 transport regulations

5 REQUIREMENTS APPLICABLE TO CERTAIN RISKS OR CERTAIN PARTICULAR ACTIVITIES

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

The ICPE system 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, manufacture, transformation, packaging, utilisation, accumulation, storage or disposal of radioactive substances. These activities are subject to notification or licensing, depending on the quantity of radionuclides used. However, these activities are only covered by the ICPE system if the establishment in which they are used is subject to licensing under this system 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 28 of the TSN Act, an installation covered by the list of ICPEs which is also covered by the BNI system would in fact only be subject to the latter system.

By virtue of article L.1333-4 of the Public Health Code, the licences issued to ICPEs in accordance with the Environment Code for the possession or use of radioactive sources act as the licences required under the Public Health Code. However, except with respect to procedures, the regulatory requirements of the Public Health Code apply to them.

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

The systems mentioned above often take account of the fight against malicious acts, at least in part. For example, in the BNI system, the licensee must in its report present a safety analysis of the accidents liable to occur in the installation, regardless of the cause of the accident, even 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 and 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 must be licensed;

– 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 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 population". 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 others, 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 III of Article 2 of the TSN Act, other requirements are specific to defence-related nuclear activities and installations: they are for example subject to particular information rules to take account of the specific requirements of the defence sector. 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 to publish the technical decisions required by the Public Health Code and the Labour Code. Numerous technical decisions are still expected in 2011, including those concerning the design and operation rules for medical facilities using ionising radiation, the recording, monitoring, recovery and disposal of sources, and the identification and marking of high-activity sealed sources.

ASN will moreover assist the Government in the forthcoming consultations on the draft Euratom directive and the subsequent work to transpose this new directive into national law.

As regards BNIs, ASN will continue its revising of the general technical regulations in 2011, in collaboration with the Ministry of Ecology, Sustainable Development, Transport and Housing. Publication of the "BNI system" ministerial order will be followed in the course of the year by the publication of some twenty regulatory decisions clarifying the provisions of decree 2007-1557 of 2 November 2007 and the above order. Several draft decisions were submitted to the stakeholders for consultation along with the "BNI system" draft order in 2010. After analysing their observations, the draft text will be modified as and where necessary and proposed to the ministers responsible for nuclear safety. Entry into force of these decisions will mark the completion of the transposition into French law of the "reference levels" adopted by WENRA.

ASN will also help to produce the implementing decrees for the provisions of the Grenelle II Act relative to impact studies and public inquiries.

Working groups will be set up in 2011 for the forthcoming revision of the radioactive material transport regulations (future 2012/2013 edition). 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, the study into the setting up of a system to control the "security of sources", which began several months ago, should be able to be concluded in 2011. This system will aim at guaranteeing the application of measures to protect the most dangerous sources of ionising radiation against malicious acts, from production through to disposal. If these measures are adopted, they should be incorporated in the legislative part of 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 whole 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 5 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 cm2 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 Article 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 medico-legal 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 14 October 2003, circular of 10 March 2000	Expressed in effective dose (except for iodine), these levels are designed to assist with the relevant response decision to protect the population: • 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

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Action levels (Public Health Code and Labour Code) and activity or dose levels above which actions 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/m^3 1.000 Bq/m^3	☞ 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/m^3	
Enhanced natural exposure (other than radon)			
Protection of the general public Article 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 Article 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	Dairy products	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, in particular ^{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 18 July 1989 amending Regulation 3954/87/Euratom of 22 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 29 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	1000	1000
Sulphur 35, cobalt 60, strontium 89, ruthenium 103, caesium 134, caesium 137, cerium 144, iridium 192		
Tritium, carbon 14, technetium 99	10000	1000

Source: Codex alimentarius, July 2006