CHAPTER 3

The legislation applicable to radiation protection can be found in chapter III of part II of book II of the first part of the Public Health Code, the provisions of which are taken mainly from ordinance 2001-270 of 28 March 2001 concerning the transposition of community directives dealing with protection against ionising radiations.

This legislation is based on internationally adopted rules, whether community regulations or directives such as Council Directive 96/29/Euratom dated 13 May 1996 and setting basic standards for health protection of the population and workers against the dangers of ionising radiations. It is also based on a variety of norms, standards and recommendations, such as the recommendations from the International Commission on Radiation Protection (ICRP) or the standards issued by the International Atomic Energy Agency (IAEA), in particular the International Basic Safety Standards for Protection against Ionising Radiations and for the Safety of Radiation Sources (Safety Series n° 115).

Legislative requirements concerning nuclear safety were contained in law 61-842 of 2 August 1961 concerning the reduction of atmospheric pollution and odours, in decree 63-1228 of 11 December 1963 concerning nuclear installations and in decree 95-540 of 4 May 1995 concerning liquid and gaseous effluents discharges and water intake by BNIs. The 13 June 2006 Nuclear Transparency and Security Act 2006-686, which created ASN, defined a new system of authorisations for basic nuclear installations (BNI) and introduced new requirements concerning information. It will be supplemented by various implementing texts.

Following on from the 30 December 1991 Act, Act 2006-739 of 28 June 2006 concerning long-term management of radioactive materials and waste, defined three main areas of research: separation/transmutation, deep geological disposal and long-term storage.

This chapter presents the current regulations applicable to radiation protection, nuclear safety and the transport of radioactive materials.

1 REGULATION OF RADIATION PROTECTION

1 | 1 The regulatory basis

1 | 1 | 1 The international reference framework (ICRP, IAEA, Euratom)

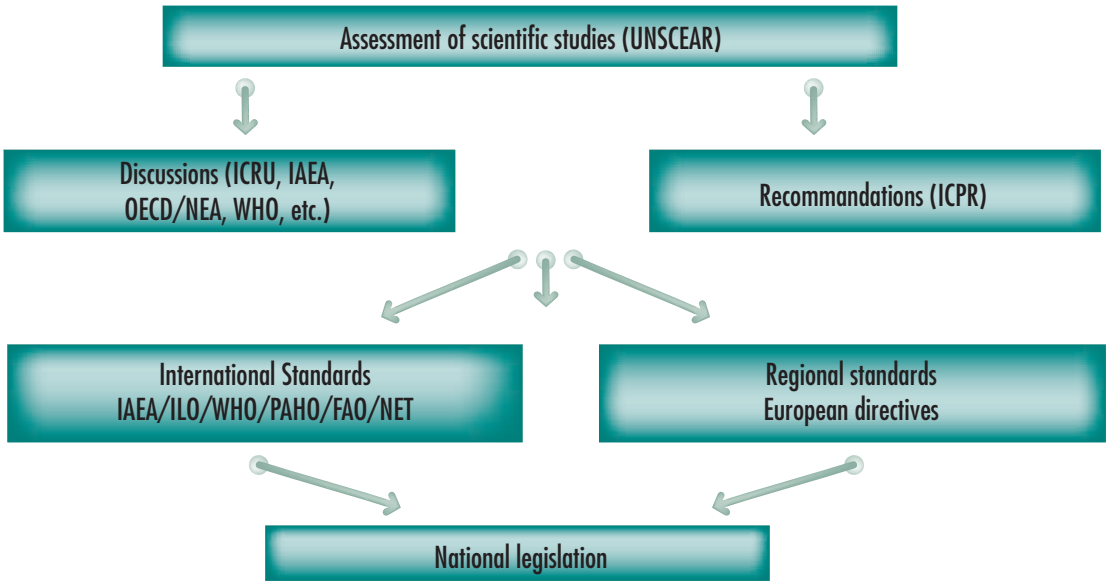
The specific legal requirements for radiation protection are based on various norms, standards and recommendations issued internationally by various organisations. The following in particular should be mentioned:

– the International Commission on Radiation Protection (ICRP), a non-governmental organisation comprising experts in various fields from around the world. It publishes recommendations concerning the protection of workers, the population and patients against ionising radiations, based on an analysis of the available scientific and technical knowledge. The latest recommendations from the ICRP are to be found in ICRP Publication 103, which came out in 2007.

– the International Atomic Energy Agency (IAEA) which regularly publishes and revises standards in the fields of nuclear safety and radiation protection. The International Basic Safety Standards for Protection against Ionising Radiations and for the Safety of Radiation Sources (Safety Series n° 115), based on the ICRP 60 recommendations, were published in 1996, in partnership with the United Nations Food and Agriculture Organisation (FAO), the International Labour Organisation (ILO), the OECD Nuclear Energy Agency (NEA), the Pan-American Health Organisation (PAHO) and the World Health Organisation (WHO). In 2008, IAEA initiated a process to revise the basic requirements, in order to take account of the new recommendations from the ICRP (Publication 103), while a new standard for the fundamental safety principles was published by IAEA at the end of 2006;

– the International Standards Organisation (ISO) which publishes international technical standards. These are a key element in the radiation protection of individuals and are the cornerstone between the principles, concepts and units, and the body of regulatory texts for which they guarantee harmonised implementation.

At a European level, the Euratom Treaty, in particular its Articles 30 to 33, defines the procedures for drafting of European Community requirements 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



Drafting of radiation protection policy

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 existing Euratom directives and overhaul them in order to incorporate the experience acquired by the member States and the changes in international texts (ICRP, IAEA).

1 | 1 | 2 The Public Health Code and the Labour Code

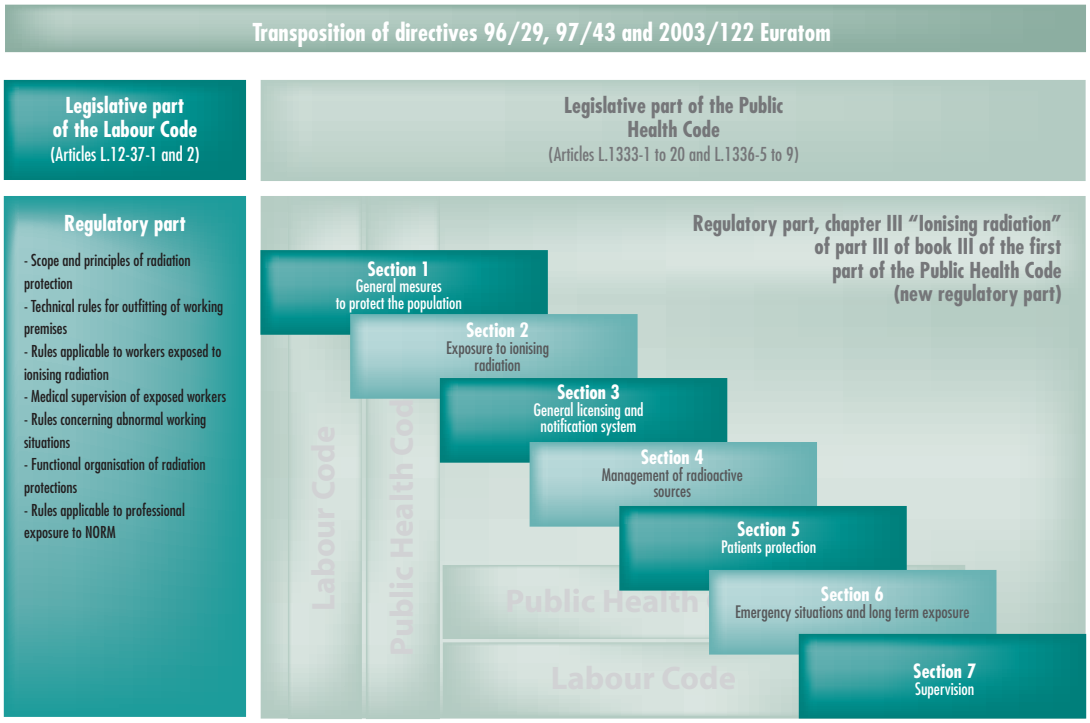
Since the publication of directives Euratom 96/29 of 13 May 1996 and Euratom 97/43 of 30 June 1997, a complete update of the legislative and regulatory radiation protection provisions of the Public Health Code and Labour Code has been undertaken.

The update of the legislative part was completed with publication of the above-mentioned ordinance of 28 March 2001 and Act 2004-806 of 9 August 2004 concerning public health policy, with the introduction of new articles concerning the radiation protection inspectorate and an update to take account of the creation of ASN (Act of 13 June 2006).

The regulatory part was updated with the publication of the following decrees:

- decree 2001-1154 of 5 December 2001 concerning mandatory maintenance and quality control of medical devices;
- decree 2002-460 of 4 April 2002 concerning the protection of individuals against the dangers arising from ionising radiations;
- decree 2003-270 of 24 March 2003 concerning the protection of individuals exposed to ionising radiations for medical and medico-legal purposes;
- decree 2003-295 of 31 March 2003 concerning intervention in a radiological emergency and in the event of long-term exposure;
- decree 2003-296 of 31 March 2003 concerning worker protection against the hazards of ionising radiations.
- decree 2006-694 of 13 June 2006 setting the procedures for designating, approving and swearing-in radiation protection inspectors and modifying the Public Health Code.

The decrees 2002-460 of 4 April 2002, 2003-270 of 24 March 2003, 2003-295 of 31 March and 2006-294 of 13 June 2006, mentioned above, are codified in chapter 3 "Ionising Radiations" of part III of book III of the new regulatory part of the Public Health Code (Articles R.1333-1 to R.1333-92). Decree 2003-296 of 31 March 2003 is codified in section 8 "Prevention of the risk of exposure to ionising radiations" in chapter I of part III of book II of the second part of the Labour Code.



Legislative and regulatory architecture of radiation protection

The above general architecture was adopted for updating of these legislative and regulatory requirements.

An initial update of chapter 3 "Ionising Radiations" of the Public Health Code, was carried out in 2005, with additions to section 7 "Emergency situations and long-term exposure" by decree 2005-1179 of 13 September 2005 concerning radiological emergencies, in order to complete the transposition of Council Directive 89/618/Euratom of 27 November 1989 concerning information of the population about applicable heath protection measures and what to do in the event of a radiological emergency.

A second update was carried out in 2007 (decree 2007-1582 of 7 November 2007 concerning protection of individuals against the dangers arising from ionising radiations and modifying the Public Health Code and decree 2007-1570 of 5 November 2007 concerning worker protection against the dangers arising from ionising radiations and modifying the Labour Code) in order to meet the following objectives:

– to transpose Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources;
– to introduce administrative simplification measures, particularly with regard to the ionising radiations source licensing and notification procedures, incorporating the experience acquired in application of the new regulations;
– to supplement requirements concerning regulation of radiation protection;
– to take account of the prerogatives granted to ASN by the Act of 13 June 2006.

In 2008, the Labour Code was revised (decree 2008-244 of 7 March 2008).

The actual implementation of the new regulatory requirements was dependent on the publication of a number of orders (27 were published between July 2003 and September 2006, 8 are still to be published) and a large number of ASN technical decisions (42 decisions are mentioned in the Public Health Code and the Labour Code). However, transposition of the above-mentioned directives 96/29/Euratom, 97/43/Euratom and 89/618/Euratom is considered to be complete. The list of decisions adopted by ASN is presented in appendix B.

The Public Health Code

The principles of radiation protection

Chapter III "Ionising Radiations" of part III of book III 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 radiations, emanating either from an artificial source, whether a material or a device, or from a natural source when the natural radionuclides are or have been treated owing to their fissile or fertile radioactive properties. It also includes "interventions" aimed at preventing or mitigating a radiological risk following an accident, due to environmental contamination.

The general principles of radiation protection (justification, optimisation, limitation), established internationally (ICRP) and incorporated in the above-mentioned Directive 96/29/Euratom, are enshrined in the Public Health Code (Article L. 1333-1). They constitute guidelines for the regulatory action for which ASN is responsible.

1. The principle of justification
"A nuclear activity or intervention may only be undertaken or carried out if justified by the advantages it procures, particularly in health, social, economic or scientific terms, with respect to the risks inherent in the exposure to ionising radiations to which the individuals are likely to be subjected".

Depending on the type of activity, the justification decision lies with various levels of authority: it lies with the government for issues of general interest, as in the case of whether or not to resort to nuclear energy; it lies with ASN in the case of sources used for medical, industrial and research purposes; it lies with the AFSSAPS for release to the market of a new irradiating medical device and with the physicians for prescribing and carrying out a diagnostic or therapeutic procedure. Assessment of the expected benefit of a nuclear activity and the corresponding health drawbacks may lead to prohibition of an activity for which the benefit would not seem to outweigh the risk. This prohibition is either generic (for example: ban on the intentional addition of radioactive materials in consumer goods), or the licence required with regard to radiation protection will be refused or will not be renewed. For existing activities, justification may be reassessed if current know-how and technology so warrants.

2. The principle of optimisation
"Human exposure to ionising radiations as a result of a nuclear activity or medical procedure must be kept as low as reasonably achievable, given the current technological, economic and social factors and, as applicable, the medical purpose involved".

This principle, referred to as the ALARA principle, for example leads to a reduction in the discharge licences of the quantities of radionuclides present in the radioactive effluents from nuclear installations, to monitoring of exposure at the workstation in order to reduce it to the strict minimum, and to ensure that medical exposure as a result of diagnostic procedures remains close to the predetermined reference levels.

3. The principle of limitation
"Exposure of a person to ionising radiations as a result of a nuclear activity, cannot raise the sum of the doses received beyond limits set by the regulations, unless this person is exposed for medical purposes or for biomedical research".

The exposure of the general population or of workers as a result of nuclear activities is subject to strict limits. These limits comprise significant safety margins to prevent the appearance of deterministic effects. They are also far below the doses at which probabilistic effects (cancers) have begun to be observed (100 to 200 mSv). Exceeding these limits is considered to be unacceptable and in France, can lead to administrative or legal sanctions.

In the case of medical exposure, no strict dose limit is set in that this voluntary exposure is justified by the expected health benefits to the person exposed.

The notification and licensing system
The new legislative base introduced into the Public Health Code means that decrees of the *Conseil d'Etat*[1] can be used to lay down general rules concerning the conditions for prohibition, licensing and notification of uses of ionising radiations (Article L. 1333-2 and 4), as well as rules for artificial or natural radionuclides management (Articles L. 1333-6 to L. 1333-9). These licences and notifications concern all applications of ionising radiations generated by radionuclides or by electrical X-ray generators, whether for medical, industrial or research purposes.

Exposure to technologically-enhanced naturally occurring radioactive materials (TENORM)
The transposition of Directive 96/29/Euratom of 13 May 1996 also led to new provisions being defined to assess and reduce exposure to naturally-occurring radioactive materials (NORM), in particular exposure to radon, when human activities contribute to enhancing this exposure (Article L. 1333- 10 of the Public Health Code).

Inspection of radiation protection
In 2004, new provisions were introduced, creating the new radiation protection inspectorate (Articles L. 1333-17 to L. 1333-19), oversight of which is entrusted to ASN. The implementing decree of 13 June 2006 set the procedures for designating, approving and swearing-in the radiation protection inspectors. The law of 13 June 2006

1. France's highest administrative Court.

now gives the ASN Chairman the powers to designate radiation protection inspectors, chosen mainly from among ASN personnel. The administrative and judicial police powers of the radiation protection inspectors were also defined (Article L. 1337-1-1).

Finally, a new system of legal sanctions accompanies these provisions (Articles L. 1337-5 to L. 1337-9).

The Labour Code

The new provisions of the Labour Code (Articles L.4451-1 and L.4121-4 7°) introduce a legislative base specific to the protection of workers, whether or not salaried employees, with a view to transposition of Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiations during their activities in controlled areas, and the above-mentioned Directive 96/29/Euratom. They bring French legislation into line with Directive 90/641/Euratom concerning non-salaried workers exposed to ionising radiations.

The link with the three principles of radiation protection published in the Public Health Code is established in the Labour Code; the rules concerning worker protection were the subject of a specific decree (decree 2003-296 of 31 March 2003 amended by above-mentioned decree 2007-1570 of 5 November 2007 and revised by decree 2008-244 of 7 March 2008).

1 | 2 Protection of individuals against the dangers of ionising radiations from nuclear activities

Appendix 2 to this chapter gives the various levels and exposure limits set by the regulations.

1 | 2 | 1 General protection of workers

Articles R. 4451-1 to R. 4457-14 of the Labour Code (formerly R. 231-71 to R. 231-116) create a single radiation protection system for all workers (whether or not salaried) liable to be exposed to ionising radiations 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 (Article R. 4451-7 to 11), which will lead 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;

Signs indicating ionising radiation work at the Henri Mondor university hospital in Créteil (Val-de-Marne *département*)

– the dose limits (Article 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 child to be born (1 mSv for the period from the declaration of pregnancy up until birth).

The publication of implementing orders offers the clarification necessary for these new measures to be put into place.

Zoning

New provisions concerning the boundaries of monitored zones, controlled zones and specially regulated zones (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 marking out the regulated zones, three levels of protection are now taken into account. They are the effective dose for external and, as applicable, internal exposure of the whole organism, the equivalent doses for external exposure of the extremities and, as applicable, the dose rates for the whole organism. The order sets reference values that the head of the establishment is required to compare with the external and internal exposure levels encountered at the workstations, when determining the zones. A DGT/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. 4456-10).

The 26 October 2005 order 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 medico-legal examinations - dentistry, medical biology and biomedical research, as well as veterinary medicine;
– the "BNI - ICPE" sector, covering establishments containing one or more basic nuclear installations and those which comprise an installation subject to licensing as a classified facility, 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.

Training comprises a theory module - common to all the options - and a practical module specific to each sector, comprising two options ("sealed sources and electric generators of ionising radiations" and "unsealed sources"). The duration and content of the PCR training programme therefore differ according to the activity sector in which the person is to work and the type of sources used. The instructor must be certified by an organisation accredited by the French Accreditation Committee (COFRAC).

Dosimetry

The new arrangements for approval of organisations responsible for worker dosimetry have also been published (order of 6 December 2003 as amended); the arrangements for worker medical surveillance and transmission of information on individual dosimetry were published in the order of 30 December 2004. ASN is now in charge of examining the approval applications submitted by the dosimetry organisations and laboratories.

Radiation protection supervision

Technical supervision of sources a nd devices emitting ionising radiations, 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. 1333-44 62 of the Public Health Code. The supervision procedures were published in the order of 26 October 2005.

This order defines the nature and frequency of the radiation protection technical checks. These concern sources and devices emitting ionising radiations, the ambient environment, measuring instruments and protection and alarm devices, management of sources and of any waste and effluents produced. This supervision is partly carried out 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 now responsible for examining approval applications submitted by the organisations.

The list of approved organisations is available from the ASN website, www.asn.fr.

Radon in the workplace (see point 1|4|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 radiations.

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, except with respect to foodstuffs and materials placed in contact with them, cosmetic products, toys and personal ornaments. This new range of prohibitions 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 in principle prohibited, when they are contaminated or likely to have been contaminated by radionuclides as a result of this activity.

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 (average value for any 1 cm surface of skin). 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.

A national network for collection of environmental radioactivity measurements is currently being set up (Article R. 1333-11 of the Public Health Code) and the data collected will help estimate the doses received by the population. This network collates the results of the various environmental impact assessments required by the regulations, and those of analyses performed by the various government departments and its public institutions, by local authorities and by associations who so request. These results will be made available to the public. Management of this monitoring network has been entrusted to IRSN, with guidelines being defined by ASN (order of 27 June 2005 organising the national network for environmental radioactivity measurements and setting the procedures for laboratory accreditation).

So that the quality of the measurements taken can be guaranteed, the laboratories in this network must meet approval criteria, which in particular include intercomparison benchmarking tests. The list of approved organisations is available from the ASN website, www.asn.fr.

Old advertising poster for the now prohibited uses of radionuclides in consumer goods

Old advertising poster for agricultural fertiliser containing radium

Management of waste and effluents from BNIs and ICPEs is subject to the provisions of the special arrangements concerning these installations (see point 2 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 issued in an ASN decision (ASN decision 2008-DC-0095 of 29 January 2008). This 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, waste and effluents disposal is monitored on a case by case basis when the activities which generate them are subject to licensing (as is the case of BNIs and installations classified on environmental protection grounds). The regulations also do not include the notion of "trivial dose", in other words the dose below which no radiation protection action is felt to be necessary. This notion appears however in above-mentioned Directive 96/29/Euratom (10 µSv/year).

1 | 2 | 3 The licensing and notification procedures for sources of ionising radiations

The system of licensing or notification, which covers all sources of ionising radiations, is described in section 3 of chapter III of part III of book III of the Public Health Code. This section was updated in 2007 to take account of the experience acquired by ASN since 2002 and the new prerogatives granted to it by the 13 June 2006 Act.

All licences will from now on be issued by ASN and notifications will be filed with ASN regional departments. Medical, industrial and research applications which do not benefit from an exemption 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.

It should be noted that the licensing system applies irrespectively to companies or facilities which have radionuclides on-site, as well as to those which trade in them without directly possessing them. From the public health and safety viewpoint, this obligation is essential to close monitoring of source movements and to the prevention of accidents as a result of orphan sources.

It should be remembered that, in accordance with Article L. 1333-4 of the Public Health Code, licences for industries subject to the Mining Code, for BNIs and for ICPEs, replace the radiation protection licence.

Finally, X-ray installations used for medico-legal procedures are subject to a system of licensing or notification applicable to medical installations, whenever their operation involves exposing individuals to ionising radiations.

The ASN license, now issued for a maximum renewable period of 10 years, is granted to the individual practitioner, who remains responsible for it.

The licence application or notification is made with a form (that can be downloaded from www.asn.fr or obtained from the ASN regional divisions). The application dossiers, plus the backup items requested, are to be returned to the respective regional divisions with responsibility for examination.

Activities requiring notification

The list of activities requiring notification should be published in early 2009 in an ASN decision. In the same way as for low-intensity medical radiology, veterinary radiology should now be included in the activities requiring notification.

In each establishment using electric generators of X rays for medical or dental diagnostic purposes, a single

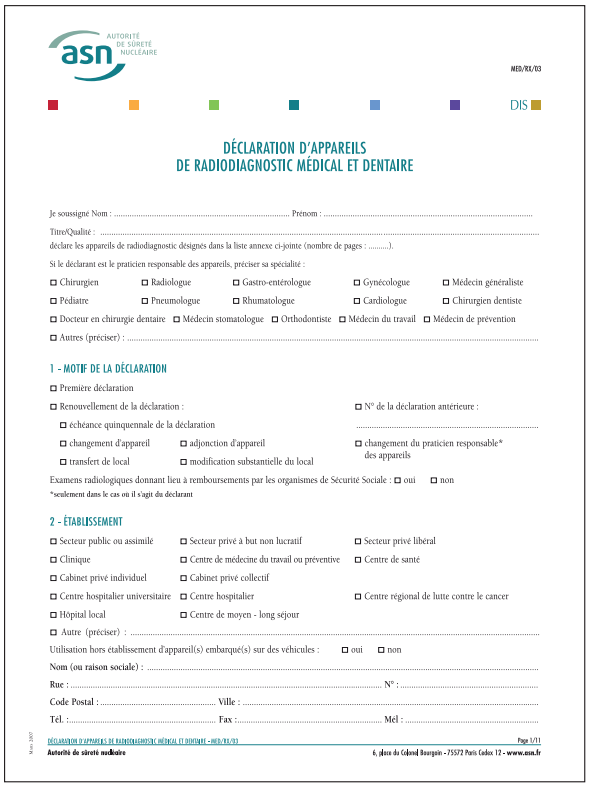
The new general system of licensing and notification for small-scale nuclear activities

Section 3 of chapter III (part III, book III) of the Public Health Code concerning the general system of licensing and notification has been completely reorganised and supplemented, in order to simplify the licensing and notification system set up in 2002 and include ASN's new prerogatives with regard to individual decisions.

The main changes made involve sources being transferred from the licensing to the notification category, cancellation of the 5-year licence validity period, it now being possible for ASN to set such a limit on a case by case basis if necessary, but with a maximum of 10 years, and the possibility of issuing the individual licence to a corporate body rather than an individual person. For implementation of this section, several ASN decisions will be required, in particular to:
– exempt certain electrical devices from licensing or notification, as their design confers effective protection;
– draw up the list of installations subject to notification;
– clarify the list of the information to be included with the notification and the licensing application;
– indicate the elements which can be covered by the licence issued by ASN;
– set the particular conditions for use of certain ionising radiations sources;
– lay down minimum technical rules for the design, operation and maintenance of the installations.

notification mentioning all the radiological installations is to be presented.

When the dossier is considered by the ASN competent regional division to be complete, an acknowledgement of receipt of notification of a radiodiagnosis installation is sent by ASN to the declaring party. As the maximum 5-year validity of the notification has been abolished, a new notification becomes necessary only if significant changes have been made to the installation (change in or addition of an appliance, transfer or substantial modification of the room or change in the practitioner in charge).



asn AUTORITÉ DE SÛRETÉ NUCLÉAIRE

MED/RX/03

DIS

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 : .....

DÉCLARATION D'APPAREILS DE RADIODIAGNOSTIC MÉDICAL ET DENTAIRE - MED/RX/03 Page 1/11

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

Medical and dental radiodiagnostic equipment notification form available on www.asn.fr

In 2008, ASN acknowledged about 4000 notifications for medical and dental radiodiagnosis appliances.

Licences in the medical, biomedical research and medico-legal field

For medical and biomedical research applications, the licensing system contains no exemptions:
– the licences required for the manufacture of radionuclides, or products and devices containing them, as well as for their distribution, import or export, are issued by ASN and no longer by the French Health Products Safety Agency (AFSSAPS);
– 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.

In 2008, ASN issued about 600 decisions of this type (commissioning or renewal licences or revocations).

The industrial and non-medical research fields

ASN is also in charge of issuing licences for non-medical industrial and research applications, and for receiving the notifications. For these areas, this concerns:
– the import, export and distribution of radionuclides and products or devices containing them;
– the manufacture of radionuclides, products or devices containing them, the use of devices emitting X-rays or

Computed tomography appliance

of 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 criteria for licensing exemption adopted by Directive 96/29/Euratom (Appendix 1, table A) have been introduced into and appended to the Public Health Code (table A, appendix 13-8) and values for supplementary radionuclides introduced by the order of 2 December 2003 have been added to it.

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.

For this latter criterion, a mass limitation was introduced (the mass of material used must be less than 1 ton), which is the reference criterion used when preparing the scenarios on which the exemption values were based. The transposition into French law is thus stricter than Directive 96/29/Euratom which does not introduce this mass limit. Introduction of this restrictive criterion should avoid the risk of the radioactive material being diluted in order to fall below the exemption threshold.

Transport of radioactive materials

Notwithstanding the regulations concerning the transport of hazardous materials, companies transporting radioactive materials are now required to either notify ASN or obtain a licence from it for all transport on the national territory (an ASN decision clarifying the licensing and notification system procedures is pending).

Approval of radiation protection technical supervision 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 (R. 1333-97 of the Public Health Code). The list of approved organisations is available from 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.

1|2|4 Licensing of suppliers of ionising radiations sources intended for medical purposes

The new provisions of the Public Health Code published in November 2007 broaden ASN's scope of competence with regard to the issue of licences for nuclear activities. This now in particular includes the manufacture, distribution, import and export of health products containing radionuclides. Two ASN technical decisions published in 2008 clarify the content of the licensing application files:

asn AUTORITÉ DE SÛRETÉ NUCLÉAIRE

MED/MR/04

DIS

DEMANDE D'AUTORISATION DE DÉTENTION ET D'UTILISATION
DE RADIONUCLÉIDES EN MÉDECINE NUCLÉAIRE ET EN RECHERCHE BIOMÉDICALE

Je soussigné Nom..... Prénom .....
sollicite l'autorisation de détenir et d'utiliser des radioéléments artificiels à des fins de médecine nucléaire ou de recherche biomédicale au sens de l'article L.1121-1 et suivants du code de la santé publique.

Le signataire, responsable de l'installation doit obligatoirement disposer des titres et diplômes mentionnés à l'arrêté du 26 mars 1974 modifié :
- Applications in vivo : docteurs en médecine possédant l'un des titres mentionnés à l'article 1,
- Applications in vitro : personnes possédant l'un des titres mentionnés aux articles 1 et 3.

1 - MOTIF DE LA DEMANDE

☐ Nouvelle demande — Date d'achèvement des installations : .....
☐ Renouvellement — Référence et date de l'autorisation à renouveler .....
☐ Participation à un protocole de recherche biomédicale
Référence et date de l'autorisation couvant le fonctionnement habituel du service : .....

Motif du renouvellement de l'autorisation :
☐ Échéance de l'autorisation — ☐ Modification des installations
☐ Changement de responsable — ☐ Mise en œuvre d'une nouvelle technique médicale

Cocher la case correspondante. En cas de demande d'extension à une nouvelle technique, préciser dans un document annexe sa nature, les locaux utilisés à cet effet, joindre le plan de ces locaux et les notes de calcul associées en annexe.

2 - ÉTABLISSEMENT

☐ Secteur public — ☐ Secteur privé à but non lucratif — ☐ GIE
☐ Secteur privé libéral — ☐ Association public-libéral — ☐ Hôpital
☐ Centre hospitalier régional — ☐ Centre hospitalier — ☐ Clinique
☐ Centre de lutte contre le cancer — ☐ Autre (préciser) : .....

Nom : .....
Rue : ..... N° : .....
Code Postal : ..... Ville : .....
Tél. : ..... Fax : ..... Mél : .....

3 - SERVICE

Dénomination
Tél. : ..... Fax : ..... Mél : .....
Implantation des installations
Bâtiment : ..... Étage : .....
Surface : .....m² Nombre de pièces de l'installation : .....
Nombre de lits réservés aux malades traités : ..... dont ..... en chambres protégées
(préciser l'implantation : .....)

Janvier 2007

DEMANDE D'AUTORISATION DE DÉTENTION ET D'UTILISATION DE RADIONUCLÉIDES EN MÉDECINE NUCLÉAIRE ET EN RECHERCHE BIOMÉDICALE - MED/MR/04 Page 1/10

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

Radionuclides possession and utilisation licence application form for nuclear medicine and biomedical research available on www.asn.fr

– 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, for which the ASN examination procedures are not significantly modified, 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.

The decision concerning the use of radionuclides and appliances emitting ionising radiations in the medical, industrial, research and health fields, should be published in the first half of 2009.

1 | 2 | 5 Radioactive source management rules

Chapter III "Ionising radiations" (part III, book III) of the Public Health Code was modified in order to transpose Directive 2003/122/Euratom of 22 December 2003 concerning the supervision of high-level sealed radioactive sources and orphan sources, which are defined in appendix 13-7.

The general radioactive source management rules are contained in section 4 of chapter III of part III of book III 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). These general rules are as follows:

– no person may distribute or acquire sources without a license;
– prior registration with IRSN is mandatory for the acquisition, distribution, import and export of radionuclides in the form of sealed or unsealed sources, or products or devices containing them. This prior registration is necessary so that monitoring of the sources and control by the customs services can be organised;
– traceability of radionuclides in the form of sealed or unsealed sources, or products or devices containing them, is required in each institution, and a quarterly record of deliveries must be sent to IRSN by the suppliers;
– any loss or theft of radioactive sources must be declared;
– all users of sealed sources are required to recover sources that have expired, are damaged, or have reached the end of their operational life, at their own expense (except when a waiver is granted for decay in-situ);
– simply at the request of the user, the supplier is required unconditionally to recover any source no longer needed or which has expired.

Identification and marking of high-level sealed sources

An ASN decision will define the procedures for implementation of the measures concerning the identification and marking of high-level sealed sources, as well as the type of information concerning these sources that the person in possession will be required to provide.
A new requirement is introduced for the control of orphan radioactive sources: the préfet is asked to determine how they are to be dealt with as well as the steps to be taken in the event of such a source being discovered.

The conditions for the use of gammagraph appliances were updated in an order of 2 March 2004.

The methods for calculating the financial guarantees required from the source suppliers were introduced into the Public Health Code (Article R. 1333.53 and 54-2). The national table of charges, established for each family of sources, will be specified by order of the ministers responsible for health and finance, on recommendations from ASN, IRSN and ANDRA, along with the procedures for implementation and payment of this guarantee.

1 | 2 | 6 Protection of individuals during a radiological emergency

The population is protected against the hazards of ionising radiations 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 applicable to basic nuclear installations, by expressing response levels in terms of doses. These levels constitute reference points for the public authorities (*préfets*[2]) who have to decide locally, on a case by case basis, on what action is to be taken. These actions 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 100 mSv.

Types of sealed gamma sources

These response levels were included in the order of 13 October 2003 concerning response levels in a radiological emergency situation, implementing Article R. 1333-80 of the Public Health Code. The reference exposure levels for persons intervening in a radiological emergency situation are also defined in the regulations (Article R. 1333-86 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 community directive (Directive 89/618/Euratom of 27 November 1989 concerning public information about health protection measures and how to act in the event of a radiological emergency). This directive was transposed into French law by:

– decree 2001-470 of 28 May 2001 concerning public information and modifying decree 88-622 of 6 May 1988 dealing with emergency plans and two implementing orders (order of 30 November 2001 concerning the creation of an emergency alert system around a basic nuclear installation with its own off-site emergency plan (PPI) and the order of 21 February 2002 concerning information to the populations);
– decree 2005-1179 of 13 September 2005 concerning radiological emergency situations.

Two implementing orders were published:

– the order of 4 November 2005 concerning public

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

Definition of a radiological emergency situation (Article R. 1333-76 of the Public Health Code)

"There is a radiological emergency when an event is likely to lead to the emission of radioactive materials or to a level of radioactivity such as to constitute a hazard for public health, in particular with reference to the limits and response levels set in Articles R. 1333-8 and R. 1333-80 respectively. This event may be the result of:

1°) an incident or accident occurring during the performance of a nuclear activity defined in Article L. 1333-1, including the transport of radioactive materials;

2°) a malicious act;

3°) environmental contamination detected by the environmental radioactivity measurement network mentioned in Article R. 1333-11;

4°) environmental contamination made known to the competent authority as defined by international conventions or agreements, or decisions taken by the European Community on the subject of information in the event of a radiological emergency."

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.

National guide for medical intervention in the case of a nuclear or radiological event – ASN 2008

1 | 2 | 7 Protection of the population in a long-term exposure situation

In recent years, and on a case by case basis, the General Directorate for Health (Ministry for Health) set clean-up thresholds for sites contaminated by radioactive materials. These were 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.

This approach has today been abandoned in favour of a complete methodological approach defined in the IPSN guide (methodology guide for sites contaminated by radioactive materials, version 0, December 2000), produced at the request of the ministries for Health and the Environment, and distributed to the *préfets* (DRIRE and DDASS/DRASS).

Based on the current and future uses of the land and premises, this guide proposes a number of steps for local definition of rehabilitation targets expressed in terms of doses. The parties concerned (owners of the site, local elected representatives, local residents, associations) are involved in the process. Operational values for decontamination can then be set for each case.

This new approach now has a regulatory framework in Article R. 1333-90 of the Public Health Code.

Radiology appliance

1 | 3 Protection of individuals 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 radiations and the practitioners carrying out these procedures. These principles cover all the diagnostic and therapeutic applications of ionising radiations, including radiological examinations requested for screening, occupational health, sports medicine and in a medico-legal setting.

1 | 3 | 1 Justification of procedures

A written exchange of information between the prescribing practitioner and the practitioner carrying out the procedure exposing the patient should justify the benefit of the exposure for each procedure. This "individual" justification is required for each procedure. It will nonetheless be based on a more general justification of medical procedures using ionising radiations, described in good practice guides.

Articles R. 1333-70 and R. 1333-71 of the Public Health Code respectively refer to the publication of "prescription of routine procedures and examinations" guides (also called "indication guides") and "performance of procedures involving exposure to ionising radiations" guides (called "procedure guides"). Under the impetus of the departments reporting to the Ministry for Health (DGSNR since 2002), the professionals represented by their learned societies, including the French Radiotherapy and Oncology Society (SFRO), the French Radiology Society (SFR), the French Nuclear Medicine and Molecular Imaging Society (SFMN), the French medical Radio-physics Society (SFPM), and various organisations representing dental practitioners, have set up the necessary working frameworks for drafting these guides.

The Nuclear Safety Authority (ASN), the Institute for Radiation Protection and Nuclear Safety (IRSN), the High Health Authority (HAS) and the National Cancer Institute (INCa) are also involved in this approach.

1 | 3 | 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

Table 1: list of Indication and Procedure Guides for the performance of medical procedures entailing exposure to ionising radiations

Speciality	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

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.

The optimisation approach is thus a pledge of the quality of the procedures conducted. Standardised guides for conducting procedures using ionising radiations have been prepared and updated by health professionals, or are currently being prepared, to make optimisation easier in practice (table 1).

External radiotherapy procedures guide produced by SFRO in 2007

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 IRSN survey of the readings taken by the professionals between 2004 and 2006 indicates a very low level of participation. Based on these findings, ASN carried out a campaign to raise the awareness of all those who declared radiology appliances and all those holding a nuclear medicine, computed tomography or digital vascular imaging license.

Dose constraints

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

Medical radiological physics

Special medical physics skills are called for in optimising the dose delivered to patients. The employment of a specialised medical radiological physicist (PSRPM), formerly called a "radiophysicist", has been extended to radiology, having already been compulsory in radiotherapy and nuclear medicine.

In order to become qualified, the PSRPM must first obtain a Master's degree (the list of the 4 Master's degrees was published in an order of 7 February 2005) followed by specialist training given by the French National Institute for Nuclear Science and Technology (INSTN). This training programme includes hospital internships.

Candidates holding another Master's degree may exceptionally be admitted for the specialist training entrance examination (order to be published in early 2009).

The duties of the PSRPM have been clarified and broadened (order of 19 November 2004). Thus medical radiological 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 radiations. 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. Finally they contribute to teaching and training the medical and paramedical personnel in medical radiological physics.

As part of the new measures, heads of establishments will have to draw up plans for medical radiological physics as of the year 2005, defining the resources allocated, primarily in terms of staffing, in the light of the medical practices 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

In order to improve the radiation protection of patients, in particular following the radiotherapy accident in Épinal, ASN wished to tighten up the regulations and clarify the quality assurance obligations of the radiotherapy centres, as stipulated in Article R.1333-59 of the Public Health Code. After discussion with the health professionals, decision 2008-DC-0103 was published on 1st July 2008 and 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 organisation, human factors or equipment related.

Following a specific schedule, these obligations will enter into force over a two and a half year period, specified in the decision, after approval by the Minister for Health. Although not yet approved by the Minister for Health, this decision is already binding, given the fact that the approval deadline has already passed (Article R. 1333-112).

Maintenance and quality control of medical devices

Maintenance and quality control, both internal and external, of medical devices using ionising radiations (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 who is responsible for issuing a decision to define the acceptability criteria, the monitoring parameters and the frequency of the inspections on the medical devices concerned.

The following decisions were published:
- decision of 2 March 2004 concerning external quality control of external radiotherapy installations, modified by a decision of 27 July 2007;
- decision of 20 April 2005 setting the quality control procedures for bone mineral density test devices using ionising radiations;
- decision of 7 October 2005 concerning quality control procedures for analog mammography installations, amended by a decision of 16 December 2005;
- decision of 30 January 2006 concerning quality

The shortage of specialised medical radiological physicists (PSRPM)

The inspections carried out in 2007 and 2008 highlighted the lack of specialised medical radiological physicists in certain radiotherapy centres. Furthermore, there are not enough of these PSRPM in the nuclear medicine departments and radiology departments.

ASN considers that a period of transition is inevitable before the number of medical radiological physicists and dosimetrists reaches a satisfactory level. ASN thus considers that from 5 to 10 years will be needed before sufficient levels of medical radiological physicists are reached. The new approval criteria published by INCa will become binding as of 2012 only.

During this transitional period, ASN asks that interim operating criteria be defined for the radiotherapy centres, to ensure an acceptable level of safety, along with an appropriate regulations incorporating these interim criteria.

control procedures for digital mammography installations;
– decision of 27 July 2007 setting the external quality control procedures for external radiotherapy installations;
– decision of 27 July 2007 setting the internal quality control procedures for external radiotherapy installations abrogating the decision of 2 March 2004 concerning electron accelerators used for medical applications and tele-cobalt therapy devices;
– decision of 24 September 2007 setting the quality control procedures for certain radiodiagnosis installations, abrogating the decision of 20 November 2006;
– decision of 22 November 2007 setting the quality control procedures for computed tomography scanners.
– decision of 25 November 2008 setting the quality control procedures for nuclear medicine installations used for diagnostic purposes.

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 radiations, or who assist in these procedures, were defined in the order of 18 May 2004. This patient radiation protection training is already part of initial medical training programmes and extends to other medical professions involved in these procedures; on-the-job training, currently being devised by learned societies and professional bodies, will also be offered to working practitioners.

As regards the traceability of the data on the 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 and 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, 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 therapeutically-oriented nuclear medicine procedure, 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.

1 | 3 | 3 Medico-legal applications of ionising radiations

In the medico-legal field, ionising radiations is used in a wide variety of sectors such as occupational medicine, sports medicine or for investigative procedures required

Approval criteria for external radiotherapy activities

Decree 2007-388 of 21 March 2007 defines the layout conditions for "cancer treatment" health care activities. The licence issued by the regional hospitalisation agency is granted for one or more therapies: surgery, external radiotherapy and brachytherapy, therapeutic use of unsealed source radionuclides and chemotherapy.

In the field of external radiotherapy, this licence takes the place of the previous heavy equipment license. The conditions for issue of the licence include:
– *the presence of a technical area which on the same site comprises at least two particle accelerators, one of which has an energy level in excess of 15 MeV;*
– *compliance with the approval criteria defined by the National Cancer Institute (deliberations of the board of the INCa of 20 December 2007). These criteria were defined with the participation of ASN and representatives of professional organisations as well as the regional hospitalisation agencies. The criteria defined in particular include:*
  • *the use of 3-dimensional imaging on a scanner dedicated to treatment preparation;*
  • *the recording and verification of the treatment parameters by means of a dedicated IT system;*
  • *the use of in vivo dosimetry;*
  • *periodic verification of the position of the patients and the geometrical properties of the beams;*
  • *the presence of a radiation therapist and a radiological physicist for the duration of patient treatment.*

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 radiations is used for medical supervision of workers (whether or not professionally exposed to ionising radiations, for example workers exposed to asbestos). A working group set up by ASN is examining the justification and optimisation of various procedures currently conducted, some of which are required by the regulations. The conclusions of this work will be published in 2009.

1 | 4 Protection of individuals exposed to technologically-enhanced naturally occurring radioactive materials (TENORM)

1 | 4 | 1 Protection of individuals exposed to radon

The regulations applicable to management of the radon-related risk in premises open to the public (Article R. 1333-15 of the Public Health Code) introduce the following clarifications:

– the radon monitoring obligation applies in geographical areas in which radon of natural origin is likely to be measured in high concentrations and in premises in which the public is likely to stay for extended periods;
– the measurements are made by organisations approved by the Minister for Health, 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 1000 Bq/m³, the implementing order of 22 July 2004 concerning management of the radon risk in premises open to the public defined geographical areas and premises open to the public for which radon measurements are now mandatory: the geographical areas correspond to the 31 *départements*[3] 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 penitentiaries.

The obligations of the owner of the facility are also specified when the action trigger levels are found to have been exceeded.

3. Administrative region headed by a *Préfet*.

The conditions for accreditation of the organisations authorised to carry out activity concentration measurements were defined in the order of 14 July 2006 concerning the accreditation of organisations responsible for measuring radon. The list of approved organisations was published in the ASN Official Bulletin, after obtaining the opinion of the approval commission consisting of representatives of the Ministries concerned, technical organisations (IRSN, Scientific and Technical Centre for the Building Industries, French High Public Health Council), building professionals and professionals involved in radon measurements.

The order of 22 July 2004 was accompanied by publication in the Official Gazette of an opinion defining the standards applicable to radon measurement (O.G. of 12 August 2004) and an opinion concerning the definition of actions and work required in the event of the action trigger levels of 400 and 1000 Bq/m³ being exceeded (O.G. of 22 February 2005).

In the residential field, the National health and environment plan has defined a number of priorities which include regulatory action to deal with the radon risk:

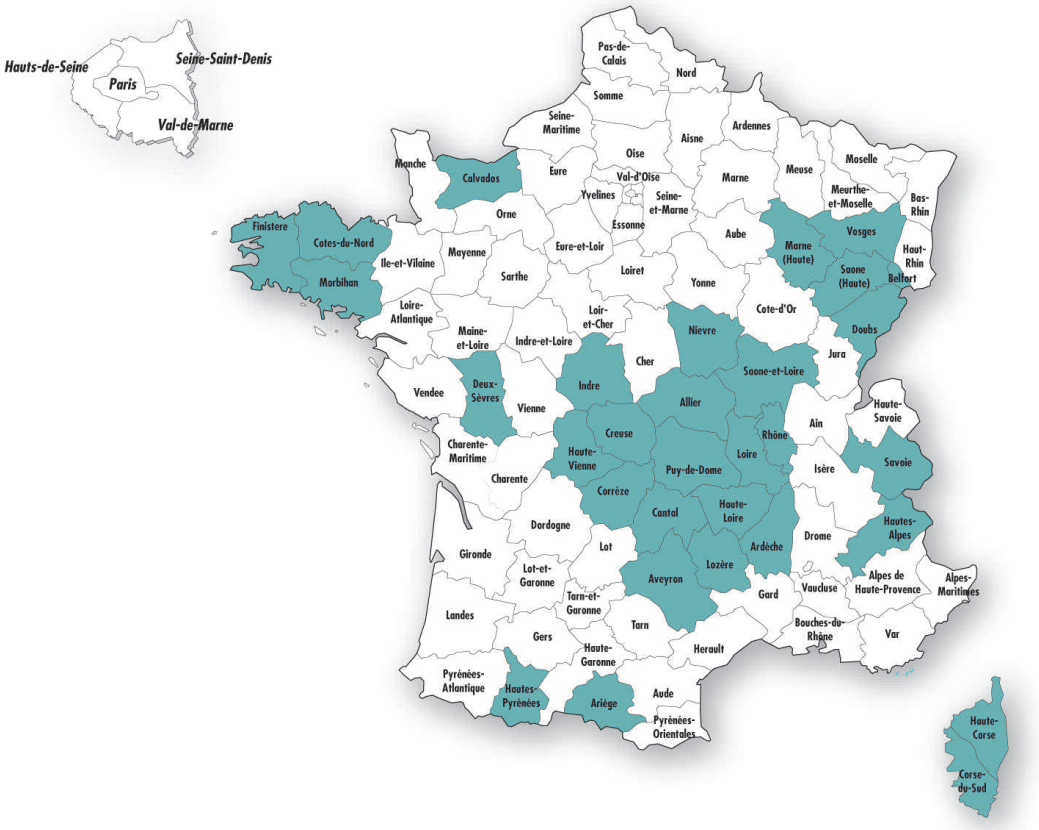
– setting up a radon diagnosis to improve information made available to future real estate buyers and tenants;
– definition of construction rules for newly built accommodation located in the priority areas.

Finally, in the workplace, the new Article R. 4457-6 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.

1 | 4 | 2 Other sources of exposure to TENORM

Professional activities which use materials which naturally contain radionuclides not used for their intrinsic radioactive properties but which are likely to create exposure such as to harm the health of workers and the public ("enhanced" natural exposure) are subject to the provisions of the Labour Code (Articles R. 4457-1 to 5) 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.



Map of the 31 priority *départements* for radon measurement

The following are therefore concerned:
1. coal combustion in thermal power plants;
2. processing of tin, aluminium, copper, titanium, niobium, bismuth and thorium ores;
3. the production of refractory ceramics as well as glass-making, foundry, steelmaking and metallurgical activities employing them;
4. the production or use of compounds comprising thorium;
5. the production of zircon and baddeleyite, and foundry and metallurgical activities employing them;
6. the production of phosphated fertilisers and the manufacture of phosphoric acid;
7. processing of titanium dioxide;
8. processing of rare earths and production of pigments containing them;
9. treatment of underground water by filtration intended for the production of:
– water intended for human consumption
– mineral waters;
10. Spas.

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. The Minister for Health may also implement measures to protect the public against ionising radiations, should this prove necessary in the light of the estimations made. When these activities fall into the category of classified installations, these measures will be defined by the corresponding applicable regulations.

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 measure complements the ban on the intentional addition of radioactive materials to consumer goods.

For the professional 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 clarification of the technical measurement procedures for evaluating the doses received by the workers.

Finally, the Labour Code (Article R. 4457-10) stipulates that for aircrews likely to be exposed to more than 1 mSv/year, the employer must evaluate the exposure,

Exposure to technologically-enhanced naturally occurring radioactive materials (TENORM)

Implementation of the regulations on professional activities employing materials containing naturally occurring radionuclides, but not used for their radioactive properties, led the industries concerned to provide 79 studies as required by the Public Health and Labour Codes. These studies allow assessment of the radiological risk to both workers and the population, broken down as follows (a particular study can concern two sectors):
– coal combustion in thermal power plants: 14
– processing of tin, aluminium, copper, titanium, niobium, bismuth and thorium ores;
– the production of refractory ceramics as well as glassmaking, foundry, steelmaking and metallurgical activities employing them: 38
– production or use of compounds containing thorium: 1
– the production of zircon and baddeleyite, glassmaking and metallurgical activities employing them: 12
– production of phosphated fertilisers and the manufacture of phosphoric acid: 5
– processing of titanium dioxide: 3
– processing of rare earths and production of pigments containing them: 2
– treatment of underground water by filtration: 1
– Spas: 1
– Others: 3

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.

1 | 5 Radiological quality of water intended for human consumption and foodstuffs

1 | 5 | 1 Radiological quality of water intended for human consumption

Since 1st January 2005, pursuant to the order of 12 May 2004, a health check on the radiological quality of water is a mandatory part of the health checks carried out by the Departmental Health and Social Action Directorates (DDASS), which are the regional services of the Ministry for Health.

The order of 11 January 2007 concerning water quality limits and references introduces four radiological quality indicators for water intended for human consumption.

These four indicators are:
– the total alpha activity, set at 0.1 Bq/L^{-1};
– the total residual beta activity, set at 1 Bq/L^{-1};
– the tritium activity (in Bq/L^{-1}), set at 100 Bq/L^{-1};
– the total indicative dose (or TID), set at 0.1 $mSv \cdot year^{-1}$.

Tritium is considered to be an indicator capable of revealing the presence of other artificial radionuclides, while the TID covers both natural radioactivity and radioactivity due to the presence of artificial radionuclides. It is calculated using the methods and dose coefficients defined in the order of 1 September 2003. This evaluation can be used to estimate the share of ionising radiations exposure attributable to drinking water. The dose can only be calculated once the radionuclides present have been identified and the concentrations, quantified. This is only necessary if warranted by the total alpha and residual total beta or tritium measurement results[4].

The circular from the General Directorate for Health (DGS) dated 13 June 2007, accompanied by recommendations from ASN, specifies the policy underpinning this new regulation.

1 | 5 | 2 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 (Euratom) regulation 3954/87 of 22 December 1987, modified by Council (EEC) regulation 2219/89 of 18 July 1989, setting the maximum allowable levels (MAL) of radioactive contamination for foodstuffs and animal

4. Order of 12 May 2004, Article 3; also see appendix 1 on analytical methodology.

feedingstuffs. The MAL were defined to "safeguard the health of the population while maintaining the unified nature of the market".

A list of foodstuffs said to be of "lesser importance" has also been drawn up (foodstuffs which are not consumed in quantities exceeding 10 kg/year). For these items, levels ten times higher are set. This concerns thyme, garlic, cocoa paste, etc.(tables 7 and 8 in appendix 2).

Foodstuffs or feedingstuffs in which contamination exceeds these MAL, may not be sold or exported.

In the event of a confirmed nuclear accident, "automatic" application of this requirement cannot exceed a period of three months, after which it will be superseded by specific measures (see the regulations specific to the Chernobyl accident)[5].

At the international level, exchanges with third-party countries (outside the EU) are governed by the harmonised standards of the Codex Alimentarius Commission, a joint body of the FAO and WHO, 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. European regulations should be updated to take account of the new values in the Codex (see table in Appendix 2 to this chapter).

5. EEC regulation 737/90 of 22/03/90 on the governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station, has been modified on several occasions (regulations 686/95 of 28/03/95 and 616-2000 of 20/03/2000): the maximum radioactivity for caesium 134 and 137 was set at 370 Bq/kg for milk and dairy products, and at 600 Bq/kg for other products.

2 BNI REGULATORY PROVISIONS

2|1 The regulatory basis

2|1|1 International conventions and standards

The regulations applicable to basic nuclear installations (BNIs) is to a very large extent derived from the international conventions and standards laid down by IAEA.

The Convention on Nuclear Safety (see chapter 7, point 4|1) concerns civil nuclear power generating reactors. It defines a certain number of 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 the Safety of Radioactive Waste Management (see chapter 7, point 4|2).

IAEA publishes reference texts, called "Basic Safety Standards", describing the safety principles and practices that can be used by States as the foundation for their own national regulations. These documents are not binding. They concern installation safety and radiation protection, the safety of waste management and the safety of radioactive materials transportation.

2|1|2 Community texts

At a Community level, the only two texts dealing with nuclear safety are Council resolutions of 22 July 1975 and 18 June 1992 concerning technological nuclear safety problems and asking the member States and the Commission to reinforce cooperation through significant joint actions to tackle fundamental safety issues.

The members of WENRA (see chapter 7, point 2|1|4) have for a number of years been conducting a programme to harmonise technical rules concerning the safety of nuclear installations and the management of spent fuel and radioactive waste.

2|1|3 National texts

The "TSN" Act and its implementing decrees

Act 2006-686 of 13 June 2006 on Nuclear Transparency and Security, known as the TSN Act, lays the legislative foundations for the system of licensing and regulating basic nuclear installations, as well as the rules concerning transparency in the field of nuclear security and radiation protection. It creates ASN, an independent administrative authority in charge of regulating these sectors.

Fifteen decrees have been planned for implementation of the TSN Act, ten of which were urgently needed because they concern requirements of the Act that cannot be implemented without them, or at least not in full. These decrees were all published between May 2007 and March 2008.

Of these decrees, the following directly concern the BNI system:
– decree 2007-830 of 11 May 2007 concerning the list of basic nuclear installations (decree clarifying the definition of the various BNI categories);
– decree 2007-1557 of 2 November 2007 concerning basic nuclear installations and nuclear safety regulation of the transport of radioactive materials (see below);
– decree 2007-831 of 11 May 2007 determining the procedures for designating and approving nuclear safety inspectors;
– decree 2008-251 of 12 March 2008 concerning the local information committees of basic nuclear installations.

The BNI system, which dates back to 1963, was thus completely overhauled. As a result of these decrees, ASN now has the legal tools it needs to play its full role as a nuclear activities regulatory authority.

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.

Ten of the twelve decrees implementing the "Waste" Act have been published, with the remaining two not being immediately necessary.

Decrees concerning national waste management policy:
– decree of 5 April 2007 nominating the French national commission for the evaluation of research and studies into the management of radioactive materials and wastes;
– decree 2008-209 of 3 March 2008 concerning the procedures applicable to the reprocessing of foreign spent fuel and radioactive waste;
– decree 2008-257 of 16 April 2008 setting the requirements for the French National Radioactive Materials and Waste Management Plan (PNGMDR);
– decree 2008-875 of 29 August 2008 determining the nature of the information to be submitted by the persons responsible for nuclear activities, for production of the national waste inventory and supervision of the PNGMDR.

A final decree will update the ANDRA decree in order to take account of its changing roles and duties.

Decrees linked to research into deep geological disposal of long-lived high and intermediate level waste:
– decree 2006-1606 of 14 December 2006 concerning public interest groupings;
– decree 2007-150 of 5 February 2007 defining the outer perimeter of the Meuse and Haute-Marne underground laboratory;
– decree 2007-720 of 7 May 2007 concerning the composition and working procedures of the local information and supervision committees of the radioactive waste management underground research laboratories;
– decree 2007-721 of 7 May 2007 determining the fraction of the support tax paid back to those communes a part of which is less than 10 kilometres from the main access to the Bure (Meuse) underground research laboratory installations;
– decree 2007-1870 of 26 December 2007 determining the coefficients of the taxes supplementing the basic nuclear installations tax and modifying decree 2000-361 of 26 April 2000.

The last decree in this category will specify the scope of the area to be consulted when creating a repository.

Decrees concerning the secure financing of nuclear costs:
– decree 2007-243 of 23 February 2007 concerning the secure financing of nuclear costs.

This decree was clarified by the order of 21 March 2007 concerning the secure financing of nuclear costs.

"BNI procedures" decree of 2 November 2007

Nationally, BNI regulations are now governed by decree 2007-1557 of 2 November 2007 concerning basic nuclear installations and the 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 abrogated decree 63-1228 of 11 December 1963 concerning nuclear installations and decree 95-540 of 4 May 1995 concerning BNI discharges of liquid and gaseous effluents and water intake. It defines the new regulations henceforth 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 established the CCINB (see chapter 2, point 2|2|4), a new consultative body for debate on the regulatory texts and major individual decisions concerning BNIs; it specifies the applicable procedures for adoption of the general regulations and for individual decisions concerning BNIs. It defines how the Act is to be implemented with regard to inspection and to administrative or criminal penalties. It finally defines the particular conditions for implementing certain regimes within the perimeter of BNIs.

2|2 General technical regulations

The general technical regulations comprise all general texts laying down technical rules for nuclear safety, whether regulatory (orders) as specified in Article 30 of the "TSN" Act, or related (circulars, basic safety rules, guides).

2|2|1 Ministerial and government orders

Pressure vessels

BNIs comprise two types of pressure vessels: those which are specifically nuclear, in other words those which contain radioactive materials, and those which are more conventional and which are not specific to nuclear facilities.

Quality organisation

The order of 10 August 1984 concerning the quality of the design, construction and operation of basic nuclear installations ("quality order") specifies the steps to be taken by a BNI licensee for defining, obtaining and maintaining the necessary quality of its installations and operating conditions, in order to guarantee its 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 appropriate 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 compliance with procedures adopted to guarantee quality.

Experience feedback from incidents and accidents occurring in BNIs and the findings of the inspections conducted, enable ASN to analyse the various problems in order to assess the application of the abovementioned order of 10 August 1984.

A draft revision of the quality order has been produced, aiming to bring it into line with the WENRA reference levels. This order should be replaced by one dealing with BNI safety policy and management.

Table 2: regulation of pressure vessels

	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 • RFS II.3.8 of 8 June 1990(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 vessels, except for the operational aspects of the main primary and main secondary systems of pressurised water reactors.

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

BNI operation can entail detrimental effects and hazards for the environment in the broadest sense, that is for the surrounding installations and their workers, but also for the public and the environment off the site. The policy conducted by ASN with respect to environmental protection is described in Chapter 5. It aims to prevent and minimise the risks for the installations by ensuring that the following are applied:

– the order of 31 December 1999 stipulating the general technical regulations designed to prevent and mitigate the harmful effects and external hazards resulting from operation of basic nuclear installations,
– ICPE legislation for installations of this type within the BNI perimeter.

The order by the ministers for the Environment and Industry of 31 December 1999, as amended by the above-mentioned order of 31 January 2006, sets the general technical regulations for preventing and mitigating off-site detrimental effects and hazards resulting from BNI operation, with the exception of water intake and discharge of effluents. More specifically, and in addition to the on-site emergency 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 (water and atmosphere). 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.

It is supplemented by the requirements specific to each installation.

The order of 31 December 1999 led to progress in the way that detrimental effects and off-site risks resulting from BNI operations are dealt with. It represented an innovative breakthrough in 1999, and contained a number of intrinsic limits, concerning both the subjects it covered and the nature of its requirements.

The order of 31 January 2006 amending the order of 31 December 1999 led to adaptation of this order as follows:

– the procedures applying to fires were reformulated to concentrate on specific objectives;
– a special section was created for installations and equipment which do not significantly differ from classified installations and to which general rules can be applied;
– the possibility of calling in an expert third-party at the expense of the licensee was introduced;
– a system of waivers to the resource deployment obligations contained in the order was introduced in order to deal with certain particular situations, although the objectives to be reached naturally remain unchanged.

Application of this text ensures that environmental protection concerns are taken into account by the licensees at a level comparable with that required for non-nuclear industrial installations.

2|2|2 Documents produced by ASN

Technical regulatory decisions

Pursuant to Article 4 of the TSN Act, ASN issues decisions to supplement the implementation procedures for the decrees and orders issued concerning nuclear safety or radiation protection, except for those dealing with occupational medicine.

They require approval by the ministers responsible for nuclear safety when they concern nuclear safety, or by the ministers responsible for radiation protection when they concern radiation protection.

These ASN decisions, as well as the mandatory opinions it is required to issue concerning draft decrees, are published in its Official Bulletin, available on-line from its website.

The following section presents decisions of this nature.

Basic safety rules and ASN guides

On a variety of technical subjects, concerning both PWRs and other BNIs, ASN has drafted basic safety rules (RFS). These are recommendations which specify safety objectives and describe practices ASN considers to be adequate for compliance with them.

They are not, strictly speaking, regulatory documents. A Licensee may decide not to follow the specifications of an RFS if it can demonstrate that the alternatives it proposes employing enable the stipulated safety objectives to be met.

In the light of the overhaul of the general technical regulations, the RFS will be transformed into guides.

There are currently about forty RFS and other technical rules issued by ASN, which can be consulted on the ASN website (www.asn.fr).

2|2|3 Overhaul of the general technical regulations

The "BNI system" draft order

Pursuant to the TSN Act and following adoption of the decree of 2 November 2007, ASN started work on overhauling the orders presented above (see point 2|2|1) in 2008.

A new "BNI system" order will incorporate the fundamental requirements of the orders today in force, while implementing the adaptations made necessary by the 13 June 2006 Act and the decree of 2 November 2007 and ensuring that the regulations take into account the reference levels defined by the Western European Nuclear Regulators' Association (WENRA). Following the requisite discussions and consultations, this order should be adopted in 2009.

"BNI" decisions

Pursuant to the Act, ASN regulatory decisions will specify the implementation procedures for the decree of 2 November 2007 and this new order.

ASN has defined a programme of decisions, which will be gradually adopted until 2010.

The first ASN decision implementing the decree of 2 November 2007 is decision 2008-DC-106 of 11 July 2008 concerning procedures for the use of internal authorisations within basic nuclear installations, approved by the ministers responsible for nuclear safety and radiation protection in the order of 26 September 2008. This decision concerns operations which entail significant nuclear safety and radiation protection issues, but which do not compromise the safety scenarios used for BNI operation and decommissioning. The licensee assumes direct responsibility, provided that it sets up a system of enhanced and systematic internal supervision, offering sufficient guarantees of quality, independence and transparency. The decision on whether or not to carry out the operations concerned must be formally authorised by the qualified members of the licensee's staff. The corresponding system is referred to as the "internal authorisations system".

2|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, thus facilitating contractual relations between customers and suppliers.

In the particular field of nuclear safety, the industrial codes used by the manufacturers and nuclear licensees 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 Framatome Areva NP are members. The RCC codes of design and construction rules were drafted for the design, manufacture and commissioning of electrical equipment (RCC-E, 4th edition), civil engineering (RCC-G) and mechanical equipment (RCC-M, 2000 edition).

As of 1990, a code of in-service surveillance rules for mechanical equipment (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 RFS, a guide or a decision, recognising the overall acceptability on the date of the edition concerned.

The new version of the RCC-E code was accepted by ASN in 2003. ASN in particular checked that this fourth edition of the code was consistent with RFS II.4.1.a of 15 May 2000 concerning software in PWR safety-classified electrical systems.

In the field of nuclear pressure vessels, these requirements changed with the publication of the 12 December 2005 order implementing the 13 December 1999 decree on pressure vessels. The use of a code is now dependent on a demonstration of its conformity with the essential safety requirements defined in these texts. This arrangement thus enables the use of other construction codes to be envisaged.

With regard to the RCC-M code, AFCEN made a number of changes to bring it into conformity with the above-mentioned requirements, leading to the 2007 version of the code.

The RSE-M code changed in October 2005, in particular to ensure conformity with the 10 November 1999 order concerning supervision of the operation of PWR reactor main primary system and main secondary systems. ASN carried out an overall analysis of these changes. This analysis concluded that the 2005 version of the code could be applied today, provided that modifications were made to establish its conformity with the regulations.

2 | 3 Installation authorisation decree and commissioning license

Part IV of the "TSN Act" contains an authorisation decree procedure followed by a series of licences issued throughout the life of a BNI: creation, commissioning, possible modification of the installation, final shutdown and decommissioning.

2 | 3 | 1 Siting

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

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.

This analysis deals with socio-economic aspects and safety. For its part, ASN analyses the safety-related characteristics of the sites: seismicity, hydrogeology, industrial environment, cold water sources, etc.

Furthermore, pursuant to Articles L.121-1 and following of the Environment Code, BNI creation entails the holding of a public debate:
– systematically, in all cases when dealing with a new electricity generating site or a new site not generating electricity and costing more than €300 millions;
– possibly, when dealing with a new site not generating electricity from nuclear power and costing between €150 millions and €300 millions.

Public debates were held in 2006 to discuss the building of an EPR type nuclear reactor at Flamanville and location of the ITER research reactor in Cadarache.

2 | 3 | 2 Safety options

Anyone 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 of 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.

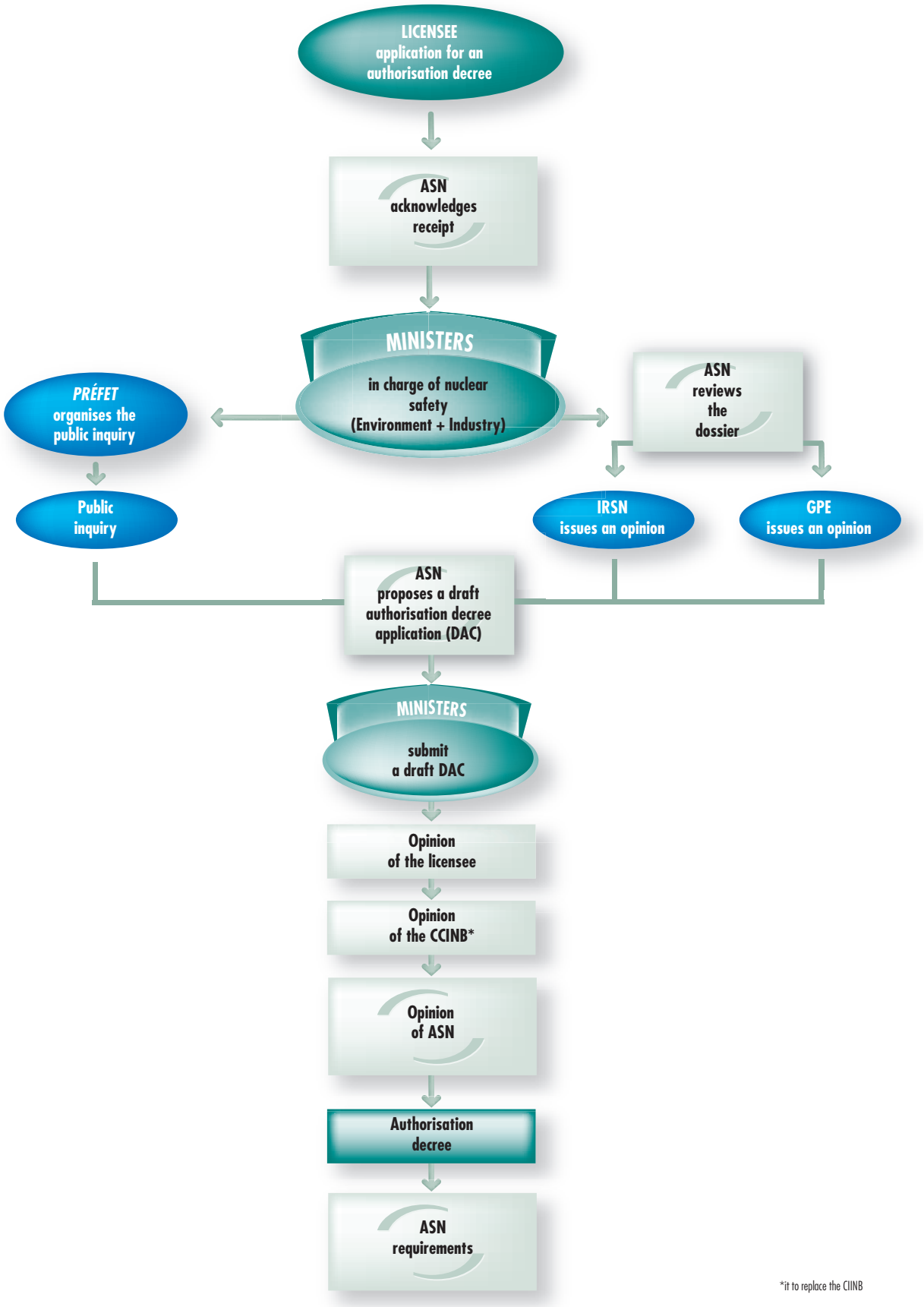
The safety options will then be presented in the authorisation application file, in the form of a preliminary safety case.

ASN generally asks a competent Advisory Committee of experts (GPE) to review the project. Their report is then sent to the licensee so that it can familiarise itself with the issues which will need to be addressed in its authorisation decree application.

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

2 | 3 | 3 Plant authorisation decrees

A BNI authorisation decree application is submitted by the person in charge of operating the installation, who thus acquires the status of licensee, to the ministers responsible for nuclear safety. The application is accompanied by a file comprising several items, including the detailed drawing of the installation, the impact assessment, the preliminary



Basic nuclear installations authorisation decree procedure under the law of 13 June 2006

safety case, the risk management study and the decommissioning plan.

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

The public inquiry

The authorisation decree can only be issued after a public inquiry as provided for in section I of Article 29 of the TSN Act.

The authorisation decree application and its corresponding file are submitted to a public inquiry by the *préfet*.

The public inquiry is opened at least in each of the communes which is situated, at least in part, less than five kilometres from the perimeter of the installation. The file submitted to the public inquiry must notably include the authorisation application, specify the identity of the applicant, the purpose of the inquiry, the nature and basic characteristics of the installation and comprise a plan of it, a map of the region, a hazard analysis and an environmental impact assessment.

A copy of the file submitted to the public inquiry is sent for information to the mayor of each of those communes in the area in which the operation is to be carried out, but the town hall of which is not selected for holding the inquiry.

In addition to the *préfecture* concerned, a descriptive file and an inquiry register are made available in all communes completely or partially within a 5 km radius around the planned installation. If this radius encompasses the territory of several départements, a joint order of the *préfets* concerned organises the inquiry in each département, with the *préfet* of the main site of the operation coordinating the procedure.

In accordance with general provisions in this respect, the public inquiry shall proceed for a minimum period of one month and a maximum period of two months, with the possibility of a two week extension in the event of a well-founded decision in this matter on the part of the Inquiry Commissioner.

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 competent authority with all the elements necessary for its own information. So any interested person, whatever his nationality or place of residence, is invited to express his opinion.

An Inquiry Commissioner (or an Inquiry Committee, depending on the nature or extent of the operations) is nominated by the President of the competent Administrative Court. He may receive any document, visit the site, arrange to meet all people wishing to make statements, organise public meetings and request extension of the inquiry period.

When the inquiry is over, he examines the observations of the public entered into the inquiry register or sent to him directly. Within the month following the end of the inquiry, he sends a report containing his recommendations to the *préfet*.

In each département concerned by the public enquiry, the *préfet* also consults the General Council and the Local Councils in those communes where the public enquiry is taking place, as well as the State regional offices he feels to be concerned by the application.

No later than fifteen days following receipt of the report and the conclusions of the enquiry commissioner, the *préfet* forwards them to the ministers responsible for nuclear safety and to ASN, with his opinion, along with the results of all the consultations carried out.

The creation of a local information committee (CLI)

By giving them a legislative basis, the TSN Act has strengthened the role of the CLIs (see chapter 6 point 3|1).

Provision is made for the creation of a CLI for any site comprising one or more BNIs. Its role is a general one of supervision, information and consultation concerning nuclear safety, radiation protection and the impact of nuclear activities on people and the environment. It comprises representatives from the general councils, local councils or joint council assemblies and the regional councils concerned, elected members of Parliament from the region, representatives of environmental protection associations, economic interests and pertinent employee trade unions and the medical professions, as well as qualified personalities. Representatives of ASN and other State departments concerned, as well as representatives of the licensee, may attend the sessions of the local information committee on a consultative basis.

The CLI may forward to ASN and the ministers responsible for nuclear safety or radiation protection all questions concerning nuclear safety and radiation protection as related to the site.

It can obtain from the licensee, ASN and other State departments all documents and information it may need to perform its duties.

Consultation of technical organisations

The preliminary safety case appended to the authorisation decree application is transmitted to ASN, which submits it

for examination to one of the Advisory Committees of Experts 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 proposal for drafting of a decree either authorising or rejecting creation of the installation.

Authorisation decree

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.

After consulting the licensee, the ministers responsible for nuclear safety finalise the draft decree and forward this draft and the file submitted to the public inquiry to the CCINB for its opinion.

The CCINB is required to submit its opinion within two months. The ministers responsible for nuclear safety ask ASN for its opinion concerning the draft authorisation or rejection decree, possibly as amended to take account of the opinion of the CIINB.

ASN's opinion is deemed to be favourable if not returned within two months.

The authorisation decree for a BNI is issued by the Prime Minister, 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 sets the duration of the licence and the time by which the installation must be commissioned. 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 requirements concerning the design, construction and operation of the BNI that it considers to be necessary to protect public health and safety, or to protect nature and the environment.

These requirements may in particular concern the quality of the design, construction and operation of the installation, its protection and security systems, emergency resources, the ventilation and discharge systems, protection against earthquakes, radiological protection of the environment and workers, transport of radioactive materials, installation modifications, final shutdown and decommissioning.

As and when necessary, ASN in particular specifies the requirements concerning BNI water intake and the radioactive materials discharged from the BNI. The specific requirements setting limits on the discharges from the BNI into the environment must be approved by the ministers responsible for nuclear safety.

Water intake and effluents discharge

Regulations for water intake and the discharge of effluents are built around a regulatory system which involves three successive stages. Schematically, this entails:
– an authorisation procedure (by decree);
– general requirements (by ministerial order);
– individual decisions.

Previously, radioactive discharge licences were based on two decrees of 1974[6], on two ministerial orders of 10 August 1976 concerning the general rules applicable to determining the limits and procedures for the discharge of radioactive effluents (gaseous and liquid) from nuclear installations, the choice of environmental monitoring measures and their means of regulation by the Central Service for Protection against Ionising Radiations (SCPRI) and on the *Conseil d'État* opinion of 27 January 1987.

The discharge licence comprised three parts:
– a ministerial order regulating gaseous radioactive discharges;
– a ministerial order regulating liquid radioactive discharges and the associated chemical discharges;
– an order of the préfet for the other chemical discharges and for water intake.

With the publication of decree 95-540 of 4 May 1995, all of these licences were grouped under a single ministerial order issued on behalf of the ministers responsible for health, the environment and industry. The ministerial order of 26 November 1999 setting the general technical requirements concerning the limits and procedures involved in water intake and discharges subject to licensing and carried out by basic nuclear installations, specified the provisions to be contained in the authorisation orders.

The ministerial order of 26 November 1999 made a number of improvements, in particular:
– concerning the regulation of issues concerning water intake, effluents discharge, environmental surveillance

6. Decree 74-945 of 6 November 1974 concerning discharges of gaseous radioactive effluents from basic nuclear installations and other installations located on the same site, and decree 74-1181 of 31 December 1974 concerning discharges of liquid radioactive effluents from basic nuclear installations.

and information of the public and of the State departments responsible for oversight;
– incorporating the regulatory principles applicable to installations classified on environmental protection grounds, in particular setting discharge limits based on the use of the best available techniques at an economically acceptable cost.

Decree 2007-1557 of 2 November 2007 abrogates decree 95-540 of 4 May 1995 while making provision for interim measures to deal with applications currently being processed. The order of 26 November 1999 is among the texts which are being rewritten, as described in point 2|3 of this chapter.

Installation modifications

The licensee advises ASN of any modifications to the installation entailing an updating of the general operating rules or the on-site emergency plan.

A new authorisation decree, examined as previously described for the authorisation decree, must be obtained if there is a change in licensee, a modification of the perimeter or a significant change to the installation.

A modification is considered to be significant if:
– there is a change in the nature of the installation or an increase in its maximum capacity;
– there is a change in the key elements regarding protection of the interests mentioned in section I of Article 28 of the 13 June 2006 Act, mentioned in the authorisation decree;
– a new BNI mentioned in section III of Article 28 of the above-mentioned 13 June 2006 Act is added within the perimeter of the installation and its operation is linked to that of the installation in question.

The other installations located within a BNI perimeter

Two types of installation exist side by side within a BNI perimeter:
– equipment and installations which are part of a BNI: these are elements of this installation which are necessary for it to operate; depending on its type, this equipment can in technical terms be compared to classified installations but, as a part of the BNI, it is subject to the procedure applicable to BNIs;
– classified equipment and installations which are not necessarily linked to the BNI: this equipment and these installations are subject to the legislation applicable to installations classified on environmental protection grounds (ICPE) as specified in part I of Book V of the Environment Code.

The equipment necessary for BNI operation is fully covered by the BNI regime 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.

2|3|4 Operating licences

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

Prior to commissioning, the licensee sends ASN a file comprising the safety case, 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.

ASN's authorisation decision is mentioned in its Official Bulletin. ASN notifies the licensee of its decision and communicates it to the ministers responsible for nuclear safety and to the *préfet*. It may also forward it to the local information committee.

Prior to or on completion of the authorisation procedure, partial commissioning may however be authorised by decision of ASN, published in its Official Bulletin, for a limited period and with regard to one of the following categories:
– performance of particular installation operating tests requiring that radioactive materials be brought into it;
– arrival of nuclear fuel within the perimeter of a reactor, prior to first loading of fuel into this reactor.

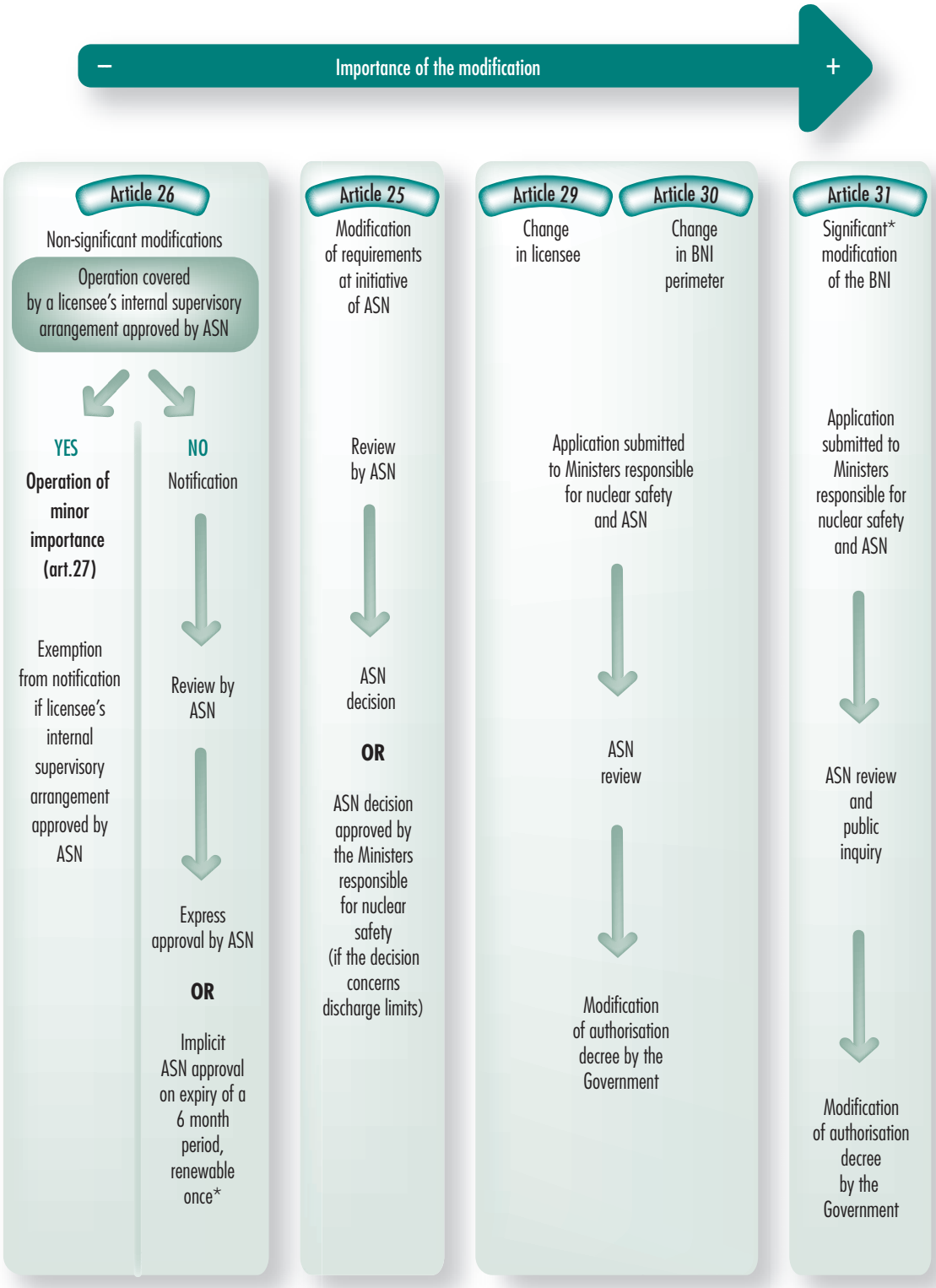
2|4 Radioactive waste and decommissioning regulations

2|4|1 Radioactive waste management

Production of radioactive waste in basic nuclear installations

Management of radioactive waste from basic nuclear installations is structured within strict regulations, defined by a ministerial order of 31 December 1999 stipulating the general technical regulations intended to prevent and limit the detrimental effects and external hazards resulting from the operation of basic nuclear installations. This order recalls the need for the licensee to take all necessary steps in the design and operation of its installations to

Types of BNI modifications covered 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.

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 basic nuclear installations is to be managed. One part of this study is submitted to ASN for approval. Following the overhaul of the BNI regulations, further to the "TSN" Act, this order will soon be revised and the requirements concerning waste management in BNIs will be grouped in a new order. An ASN decision will supplement the requirements concerning management of the waste produced in BNIs.

Production of radioactive waste in other activities using radioactive materials

The provisions mentioned in the decree of 4 April 2002 concerning the general protection of individuals against ionising radiations have been incorporated into the Public Health Code. Article R. 1333-12 of this code states that the management of effluents and waste contaminated by radioactive materials originating from all nuclear activities intended for medicine, human biology or biomedical research, entailing a risk of exposure to ionising radiations, must be examined and approved by the public authorities. The Nuclear Safety Authority's decision dated 29 January 2008, approved by the ministers responsible for the environment and health, implementing the provisions of Article R. 1333-12 of the Public Health Code, set the technical rules for the disposal of effluents and waste contaminated by radionuclides, or liable to be contaminated as a result of a nuclear activity.

2 | 4 | 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 radiations, the production of radioactive waste, discharge to the environment of effluents and measures designed to reduce the risk of accidents and mitigate their consequences. Safety issues, in other words protection of individuals and the environment, can be significant, during active clean-out or decommissioning 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 regulations 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, issued on the advice of ASN.

A 2003 ASN guide specified the regulations for basic nuclear installation decommissioning operations, following major work designed to clarify and simplify the administrative procedure 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 2008. This guide is intended for nuclear licensees and its main objectives are:

– to explain in detail the regulatory procedure laid down by the decree implementing the TSN Act;
– to clarify ASN's expectations with regard to the content of certain documents in the final shutdown and decommissioning authorisation application, and in particular the decommissioning plan;
– to explain the technical and regulatory aspects of the various phases of decommissioning (preparation for final shutdown, decommissioning, delicensing).

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 file 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 license is granted by decree, subject to the opinion of ASN, setting the dismantling 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 file 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[7] 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…

Installation delicensing

Following decommissioning, a nuclear installation can be delicensed. It is then removed from the list of basic nuclear installations and no longer has BNI status. To support its delicensing application, the licensee must provide a file 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 basic nuclear installation dependent on the implementation of such restrictions.

2|4|3 Financing of decommissioning and radioactive waste management

Article 20 of Programme Act 2006-739 of 28 June 2006 on the sustainable management of radioactive materials and waste, creates a system for securing the expenses involved in the decommissioning of nuclear installations and management of radioactive waste. This article is clarified by decree 2007-243 of 23 February 2007 concerning the secure financing of nuclear costs and the order of 21 March 2007 concerning the secure financing of nuclear costs. These two texts were approved by ASN on 1 February 2007 (opinions 2007-AV-0013 and 2007-AV-0014).

The legal framework 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 take charge of 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 expenses.

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 closure, maintenance and surveillance 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.

7. Formerly called "final cessation of operation".

3 REGULATIONS FOR THE TRANSPORT OF RADIOACTIVE MATERIALS

Unlike the technical safety regulations for installations, which are specific to each State, the International Atomic Energy Agency (IAEA) has laid down an international basis for transport safety and this constitutes the regulations for the transport of radioactive materials, known as TS-R-1.

3|1 International regulations

This basis is used in the drafting of the transport safety regulations in force: 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. These transport 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 Directorate 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).

Transport safety is based on three main factors:
– first and foremost, on the engineered toughness of the packages;
– on transport reliability and certain specially equipped vehicles;
– on an efficient emergency response in the event of an accident.

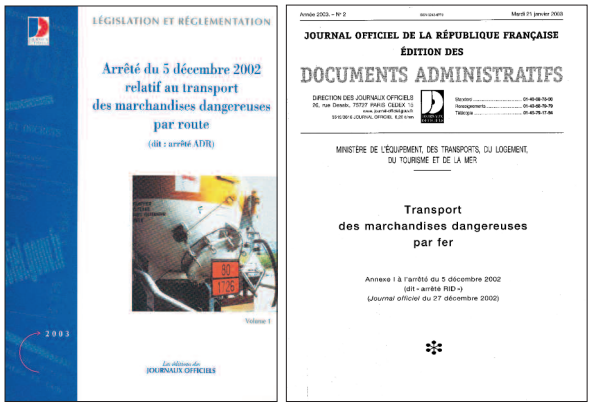
Regulations are based on IAEA recommendations, which specify package performance criteria. The safety functions to be assured are containment, radiation protection, prevention of thermal hazards and criticality.

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 associated safety requirements and testing criteria (see chapter 11, point 1|1).

ASN aims to intervene as early as possible in the drafting of the regulations, jointly with IRSN, in particular by taking part in the various international or multinational working groups that exist to deal with the transport of hazardous or radioactive goods.

In this context, ASN is a member of the IAEA TRANSSC Committee (Transport Safety Standards Committee) and is represented as an expert in many working groups, organised according to transport mode, in cases where radioactive material transport is at issue. An ASN representative thus took part in the meetings of the TRANSSC group held from 3 to 7 March and from 7 to 10 October 2008 in Vienna. It also participates in the Club of European authorities with competence for the transport of radioactive materials, a grouping of the authorities from several countries in Europe. The latest meeting took place on 1 and 2 December 2008 in London.

ASN is also a member of the safety of radioactive material transport standing working group of the DG Energy and Transport of the European Commission. In this capacity, it took part in the meetings of this group on 25 and 26 June 2008.



ADR and RID transport regulations

3 | 2 National regulations

The orders applicable to each mode of radioactive material transport are as follows:

– the order of 1 June 2001 as modified concerning the transport of dangerous goods by road (known as the "ADR order");
– the order of 5 June 2001 as modified, concerning the transportation of dangerous goods by rail (known as the "RID order");
– the order of 5 December 2002 as modified, concerning the transportation of dangerous goods by inland waterway (known as the "ADNR order");
– 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 regulations for the safety of ships (RSN);
– the order of 18 July 2000 as modified, regulating the transport and handling of dangerous goods in sea ports.

These orders transpose in full the requirements of the international agreements and regulations in force.

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

4 OUTLOOK

Radiation protection

ASN is continuing to publish the technical decisions required by the Public Health Code and the Labour Code, updated at the end of 2007. A large number of technical decisions are expected in 2009, including those concerning updating of the response levels in an emergency situation, the list of small-scale nuclear activities requiring notification, the content of the notification and authorisation application files for users of ionising radiations sources, the system of authorisation or notification for source transporters, the conditions for outsourcing the duties of the person with competence for radiation protection, the extension of source lifetimes, registration, monitoring, recovery and disposal of sources, and the identification and marking of high-level sealed sources.

In the medical field, ASN will be particularly insistent in its efforts to ensure the definition of appropriate regulations for the operating criteria of radiotherapy departments, in terms of the numbers of medical radiological physicists needed to ensure an acceptable level of safety in all the centres.

ASN is also participating actively in the work being done to update IAEA standards and European Community directives, in particular with a view to incorporating the recommendations published by the International Commission on Radiological Protection at the end of 2007.

BNIs

The 13 June 2006 Nuclear Transparency and Security Act brought about an in-depth overhaul of the regulations concerning BNI safety. Pursuant to this Act, a number of decrees were adopted to determine the new regime applicable to BNIs. These decrees abrogated the decree of 11 December 1963 concerning nuclear installations and the decree of 4 May 1995 concerning BNI liquid and gaseous effluents discharges and water intake.

An order from the ministers responsible for nuclear safety and a regulatory decision from ASN should be published in 2009 in order to complete the overhaul of the BNI procedures.

The implementation of these new regulatory requirements, plus the process of European harmonisation, will lead to a major revision and development of the general technical regulations applicable to BNIs. Preparatory work continued on a number of government orders and regulatory decisions along these lines in 2008 and they should be adopted in 2009.

With regard to individual decisions, if the main authorisations concerning the life of a BNI (creation, final shutdown and decommissioning) remain within the remit of the Government, it is up to ASN to authorise BNI commissioning and define the requirements regarding its design, construction and operation pursuant to the decrees. It is in this respect that ASN defines the requirements concerning water intake into and liquid and gaseous discharge of materials from the installation, whether or not radioactive.

Transport

As part of the transposition of Directive 96/29/Euratom, transport companies carrying radioactive materials on the national territory should soon be bound by a system of notification to or licensing by ASN. A decision by ASN, approved by the ministers responsible for nuclear safety and transport, will specify the characteristics of the radioactive materials requiring either notification or licensing, the composition of the licensing application file and the items to be enclosed with the notification, the review procedures and the conditions for renewal, revocation or suspension.

In 2008, ASN was asked for an opinion by the General Directorate for the Prevention of Risks, on the basis of Article 62 of the "BNI Procedures" decree, with regard to the draft orders amending the orders concerning the transportation of dangerous goods by road, by rail, by inland waterway, in sea ports and concerning the safety of ships. In the field of transportation of nuclear materials, ASN should thus see its role as regulatory authority strengthened. In the case of incidents or accidents, events concerning the transportation of class 7 dangerous goods, that is radioactive materials, must be declared to ASN. This declaration must reach ASN within two working days of detection of the event and will constitute the accident declaration.

APPENDIX 1
VALUES AND UNITS USED IN RADIATION PROTECTION

1 The main values used in radiation protection

The implementation of radiation protection rules is impossible without metrology. The exposure indicators that are most important for radiation protection are the doses received by man. The transposition of Council Directive Euratom 96/29 of 13 May 1996 setting basic standards for health protection of the population and workers against the hazards resulting from ionising radiations, led to the definitions of the main values used in radiation protection being updated (appendix 13-7, regulatory part of the Public Health Code).

Activity and becquerel

Activity (A) : the activity A of an amount of a radionuclide in a particular energy state at a given time is the quotient of dN by dt, where dN is the expectation value of the number of spontaneous nuclear transitions with emission of ionising radiation from that energy state in the time interval dt.

$$A = \frac{dN}{dt}$$

The unit of activity of a radioactive source is the becquerel (Bq).

Absorbed dose and gray

Absorbed dose (D) : energy absorbed per unit mass

$$D = \frac{dE}{dm}$$

where:
dE is the mean energy communicated by the ionising radiation to the matter in a volume element;
dm is the mass of the matter in this volume element.
The term “absorbed dose” designates the mean dose received by a tissue or an organ.

L'unité de dose absorbée est le gray (Gy).

The absorbed dose D represents the quantity of energy absorbed per unit mass of tissue. 1 gray (Gy) corresponds to the absorption of 1 joule per kilogram. This quantity designates the mean dose absorbed by a tissue, organ or the whole body. However, the absorbed dose cannot be directly used in radiation protection because it does not take account of the fact that the biological effects of the energy intake depend on a number of parameters:

– the quality of the radiation, in other words how it loses its energy in the micro-volumes along its path. This depends on its nature, whether electromagnetic (X or gamma rays) or electrically charged or uncharged particle (alpha, beta or neutrons);
– the characteristics of the organ or tissue into which the energy is taken, as not all tissues have the same sensitivity to radiation;
– the dose rate, that is the inclusion of the time factor in the energy intake.

A large number of experiments have analysed the importance of each of these factors with regard to the biological effects of irradiation. To manage all the doses received by an individual, equivalent doses must be used which take account of these exposure parameters. Weighting factors are thus applied to the “absorbed dose” when one wishes to define the “equivalent dose” which takes account of the nature of the radiation and the “effective dose” which concerns the whole body.

Equivalent dose, committed equivalent dose and sievert

Equivalent dose (H_T): dose absorbed by the tissue or organ T, weighted according to the type and energy of the radiation R. It is given by the following formula:

$$H_{T,R} = w_R \, D_{T,R}$$

where:
$D_{T,R}$ is the mean for the organ or tissue T of the absorbed dose of radiation R;
w_R is the weighting factor for the radiation R.

When the radiation field comprises radiation of types and energies corresponding to different values of w_R, the total equivalent dose H_T is given by the formula:

$$H_T = \sum w_R \, D_{T,R}$$

The equivalent dose unit is the sievert (Sv).

The ICRP w_R values, published in the order of 1 September 2003, are given in the following table. For the types of radiation which do not appear in the table, an approximate w_R value is obtained from the mean quality factor determined by the ICRU.

Type of radiation and energy range	w_R
Photons all energies	1
Electrons and muons all energies	1
Neutrons of less than 10 keV	5
Neutrons from 10 to 100 keV	10
Neutrons from 100 keV to 2 MeV	20
Neutrons de 2 MeV à 20 MeV	10
Neutrons of more than 20 MeV	5
Protons of more than MeV	5
Alpha particles	20

Committed equivalent dose [$H_T(\boldsymbol{\tau})$]: integral over time ($\boldsymbol{\tau}$) of the equivalent dose rate in the tissue or organ T to be received by an individual following the intake of radioactive material. For an intake or activity at time t_o, it is defined by the formula:

$$H_T(\boldsymbol{\tau}) = \int_{to}^{to+\boldsymbol{\tau}} H_T\,(t)\,dt$$

where:

$H_T\,(t)$ is the equivalent dose rate in the organ or tissue T at time t;
$\boldsymbol{\tau}$ the period over which intake is carried out.

In $H_T(\boldsymbol{\tau})$, $\boldsymbol{\tau}$ is given in years. If the value of $\boldsymbol{\tau}$ is not given, for adults it is implicitly taken at fifty years and for children as the number of years remaining until the age of 70.

The committed equivalent dose unit is the sievert (Sv).

Effective dose, committed effective dose and sievert

Effective dose (E): sum of the weighted equivalent doses delivered by internal and external exposure to the various tissues and organs of the body. It is defined by the formla:

$$E = \sum_{T} w_T H_T = \sum_{T} w_T \sum_{R} w_R D_{T,R}$$

where:

$D_{T,R}$ is the mean for the organ or tissue T of the absorbed dose of radiation R;
w_R is the weighting factor for the radiation R;
w_T is the weighting factor for the tissue or organ T.

The effective dose unit is the sievert (Sv).

Committed effective dose [$E(\tau)$] : sum of the equivalent doses in the various tissues or organs [$H_T(\tau)$] following integration, each multiplied by the appropriate weighting factor w_T. It is given by the formula:

$$E(\tau) = \sum_{T} w_T H_T(\tau)$$

In $E(\tau)$, τ is the number of years of integration

The committed effective dose unit is the sievert (Sv).

The choice made in 1990 by the International Commission on Radiological Protection (ICRP) is to express doses by the effective dose, which is the result of an equivalence calculated in terms of a belated risk of radiation-induced fatal cancers and serious genetic consequences. The effective dose E is the result of a second weighting by a factor describing the relative importance of the effects on the tissues in which the dose is distributed. It is thus already the result of a modelling of the risk. The values of w_T are given in the following table.

Tissue or organ	w_T
Gonads	0.20
Red marrow	0.12
Colon	0.12
Lungs	0.12
Stomach	0.12
Bladder	0.05
Breasts	0.05
Oesophagus	0.05
Thyroid	0.05
Liver	0.05
Skin	0.01
Bone surface	0.01
Others[1]	0.05

Comments - The choice of the same unit to express the equivalent dose, defined in an organ, and the effective dose which takes account of all irradiated organs, is frequently a source of confusion.

1. For the calculations, the "other" organs are represented by a list of 12 organs for which selective irradiation may occur through internal contamination. If one of them concentrates most of the radionuclides, it is given a w_T of 0.025 and a factor of 0.025 is given to the average dose received by the other 11 organs. The sum of the different w_T values is equal to 1, which corresponds to uniform irradiation of the whole body. The w_T values are suitable for expressing internal contamination.

The effective dose can be used to compare irradiations of different types, with regard to both the nature of the radiation and whether irradiation is overall or partial. On the other hand, the effective dose comprises a weakness: that of not being a measurable value. In the case of external exposure, measurable operational values are defined (ambient equivalent dose, directional equivalent dose, etc.), which will be used to calculate the dose in variable volumes, according to whether or not the radiation is penetrating and according to the effects (dose on the eye, dose on the skin).

The means of calculating the effective dose also has the drawback of having varied with time, in line with the changes made by the ICRP to the w_R and w_T coefficients, which were reviewed in the light of fresh data as it became available. Comparing the effective doses calculated at intervals of several years means that the weighting coefficients used in the calculations must be known for each period.

In the case of internal contamination from a long-lived radionuclide, we use the committed dose (committed equivalent dose or committed effective dose). At the time of contamination, it expresses integration of all the tissue doses, up to complete elimination of the radionuclide or for 50 years in workers and up to the age of 70 in children. The committed effective dose is calculated using the dose coefficients of Directive 96/29/Euratom published in France in the order of 1 September 2003 defining the methods for calculating effective and equivalent doses resulting from exposure of individuals to ionising radiations. Radionuclide by radionuclide, these coefficients give the effective dose (in sieverts) committed per unit of activity taken in, expressed in becquerels.

Collective dose and man.sieverts

The collective dose for a given population or group is the sum of the individual doses in a given population; it is obtained by the formula:

$$S = \sum H_i P_i$$

Hi is the mean of the total doses or the doses in a given organ of the Pi members of the ith subgroup of the population or group.

The collective dose unit is the man.sievert.

Commentary – For the ICRP, the advantage of the collective dose is that it can allow optimisation of collective exposure to a level that is as low as possible. This value, little used in France, was not included in the European and national regulations.

2 Uncertainties

The values recognised for the various weighting factors (w_R and w_T) were chosen from a relatively wide range of values. These are approximations designed to provide a tool for risk management.

The w_R values are taken from physical measurements describing the intensity of ionisation per unit volume, a value which varies with the residual energy along the path. When choosing a single value for a given radiation, account is therefore only taken of the direct biological observations, comparing the effects of this radiation with those of a reference radiation. Depending on the dose level and the biological effects considered, the relative biological effectiveness (RBE) can vary widely.

The w_T were also chosen with a view to compromise and simplification. A few numerical values alone characterise them. Some are of debatable scientific value. Thus, the value of 0.2 for the gonads implies the existence of genetic effects which have not been observed and the animal experimentation data used are probably highly overvalued. Finally, the breakdown of the risk between the various organs is primarily the result of epidemiological observations in Hiroshima and Nagasaki and we do not know exactly on what bases these risks should be transposed to a human group with significantly different ways of life.

APPENDIX 2
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 (Public Health Code)	• Effective doses for the body • Equivalent doses for the lens of the eye • Equivalent doses for the skin (average dose over any area of 1 cm^2 of skin, regardless of the area exposed)	1 mSv/year 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 trigger levels in cases of radiological emergencies

References	Definition	Values	Observation
Protection of the general public			
Intervention trigger 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 100 mSv	☞ The *préfet* can make adjustments to take account of local factors.
Protection of participants			
Reference levels Art. R.1333-86	These levels are expressed as effective dose: • for the special teams for technical or medical intervention • for the other participants	100 mSv 10 mSv	☞ This level is raised to 300 mSv when the intervention is designed to prevent or reduce exposure of a large number of people.

Source: The Public Health Code

Action levels (Public Health Code and Labour Code) and activity or dose levels above which action 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 1000 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	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…*	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 ALLOWABLE 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 radionuclide with a radioactive half life of longer than 10 days, in particular ^{134}Cs and ^{137}Cs	400	1,000	1,250	1,000

Source: EURATOM regulation 2218-89 of 18 July 1989 modifying regulation 3954-87 of 22 December 1987

Maximum allowable 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: EURATOM regulation 770-90 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
Tritium, carbon 14, technetium 99	10000	1000

Source: Codex alimentarius, July 2006