

## MEDICAL USES OF IONISING RADIATION

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For more than a century now, and for both diagnostic and therapeutic purposes, medicine has made use of a variety of ionising radiation sources, produced either by electric generators, or by artificial radionuclides. Even if their benefits and usefulness have long been medically proven, these techniques do however make a significant contribution to exposing the population to ionising radiation. Behind exposure to natural radiation (NORM), they represent the second source of exposure for the population and the leading source of artificial exposure (see chapter 1).

Protection of the staff working in installations using ionising radiation for medical purposes is regulated by the provisions of the Labour Code. This text was recently updated with the publication in 2006 of new rules for marking out controlled and monitored areas in which X-ray generators or sealed or unsealed radioactive sources are used.

The installations themselves are required to comply with specific technical rules, while the use of radioactive sources is subject to the specific management rules contained in the Public Health Code.

In recent years, the technical regulations have been considerably strengthened with the creation of a new body of regulations dedicated to patient radiation protection (see point 3|1|3|2). The principles of justification of procedures and optimisation of the doses delivered are the foundation of these new regulations. However, unlike the other applications of ionising radiation, the principle of limitation of the dose delivered to the patient does not apply, owing to the anticipated health benefits.

In 2006, the Nuclear Safety Authority (ASN) published the latest text, thereby completing these new regulations. It also incorporated supervision of patient radiation protection into its inspection programme. In addition, it is working on assessing radiation protection in the medical field via the indicators announced in the 2005 report. The initial results are presented in this chapter and are taken from the observations made during the course of about 110 inspections. ASN also initiated the creation of an incidents declaration procedure designed to improve radiation protection, in particular for patients. This new procedure revealed a number of serious incidents in recent months, particularly in radiotherapy, and led to action being undertaken with the professionals to ensure that greater account be taken of human and organisational factors in the daily exercise of their activities.

## 1 MEDICAL AND DENTAL RADIODIAGNOSIS INSTALLATIONS

### 1 | 1

#### **Presentation of the equipment inventory**

Radiology is based on the principle of differential attenuation of X-rays by the organs and tissues of the human body. The information is gathered either on radiological film or more and more often on digital media allowing computer processing of the images obtained.

Radiodiagnosis, which is the oldest of the medical applications of radiation, is a discipline containing all the techniques for morphological exploration of the human body using X-rays produced by electric generators. It enjoys pride of place in the medical imaging field and comprises various specialities (conventional or interventional radiology, computed tomography, angiography and mammography) and a wide variety of examinations (radiography of the thorax, the abdomen, and so on).

Prescription of a radiological examination by the physician must be part of a diagnostic strategy taking account of the relevance of the information to be looked for, the expected benefit for the patient, the anticipated exposure level and the possibility of using other non-irradiating investigative techniques (see medical imaging good practices guide, chapter 3).



W. Roentgen



Stamp representing A. Béclère, father of French radiology

## 1 | 1 | 1

### Medical radiodiagnosis

In the medical field, apart from conventional radiology, more specialised techniques allowing a broader field of investigation are also used.

#### Conventional radiology

This uses the principle of conventional radiography and covers the vast majority of radiological examinations carried out. The main subjects are the skeleton, thorax and abdomen. Conventional radiology can be split into three main families:

- radiodiagnosis performed in fixed installations specifically built for the purpose;



Conventional radiology room

- radiodiagnosis carried out using mobile appliances, especially by the patient's bedside. This practice is however restricted to those patients who cannot be transported;
- radiodiagnosis in the operating theatre as a tool contributing to the satisfactory performance of interventional procedures. In this case mobile X-ray generators fitted with a light intensifier are used, outputting images on a screen (radioscopy) that can be used in real time to guide the surgeon's hand.

The use of radioscopy appliances without image intensification (simple radioscopy) was banned in July 2003.

### Interventional radiology

These techniques use radioscopy with image intensification and radiography and require special equipment for the performance of operations which are either diagnostic (examination of coronary arteries, etc.) or therapeutic (dilation of coronary arteries, etc.). They often require long-term exposure of the patients, who then receive high doses which can sometimes lead to radiation deterministic effects (cutaneous lesions, etc.). The interventional staff usually working in the immediate vicinity of the patient are also exposed to higher levels than during other radiological practices. Then, given the risk of external exposure for the operator and the patient, interventional radiology must be justified by clearly determined medical need and its practice must be optimised in order to improve the radiation protection of both operators and patients.



**Operating theatre radiology appliance**

### Digital angiography

This technique, which is used to explore the blood vessels, is based on digitisation of images before and after injecting a contrast medium. Computer processing masks the bone structures around the vessels by subtracting two series of images.

### Mammography

Given the composition of the mammary gland and the degree of detail sought for the diagnostic, high definition and perfect contrast are required for the radiological examination. This can only be achieved by special appliances working with low voltage. These generators are also used for breast cancer screening campaigns.



**Mammography appliance**

### **Computed tomography**

Using a closely collimated X-ray beam, emitted by a generating tube rotating around the patient and a computerised image acquisition system, tomography appliances give a three-dimensional picture of the organs with image quality higher than that of conventional equipment, providing a more detailed picture of the organ structure.

When first used, this technique revolutionised the world of radiology, in particular in the neurological exploration area, but is today being rivalled by magnetic resonance imaging (MRI) for certain investigations. However, the new generation of appliances (multi-slice scanners) enable the scope of investigation of computer tomography to be expanded, with easier and faster investigation. The counterpart can be a greater number of images being taken, which runs contrary to the principle of optimisation, thus leading to a significant rise in the doses of radiation delivered to the patients.



**Tomography appliance**

1 | 1 | 2

### Dental radiodiagnosis

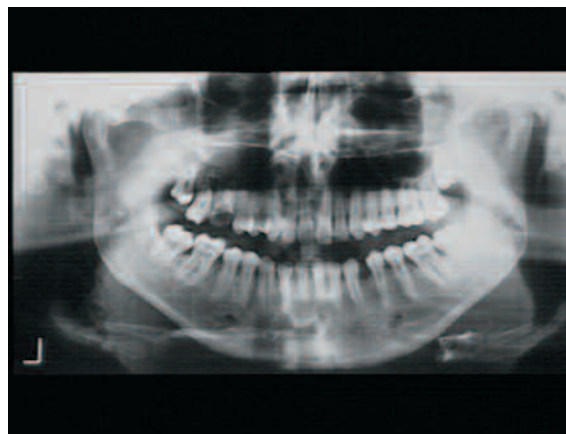
Dental radiodiagnosis equipment are among the most common of radiological installations. Three techniques are used:

#### Intra-oral radiography

Intra-oral type radiography generators are generally mounted on an articulated arm, to provide localised images of the teeth. They operate with relatively low voltage and current and a very short exposure time, of about a few hundredths of a second. This technique is increasingly frequently combined with a system for digital processing of the radiographic image which is displayed on a monitor.

#### Panoramic dental radiography

Primarily used by dental specialists (orthodontists, stomatologists) and radiologists, panoramic radiography gives a single picture showing both jaws, by rotating the radiation generating tube around the patient's head for about ten seconds.



Panoramic dental radiography appliance and panoramic dental radiography image

#### Cranial tele radiology

These generators are more rarely used by practitioners. They operate with a focus - film length of 4 metres, and are mainly used to take radiographic images for orthodontic diagnosis.

1 | 2

### Key figures: several tens of thousands of installations

Table 1 presents the inventory of medical and dental radiology installations in operation in 2005. It was drawn up on the basis of notifications made to ASN by users of this type of equipment.

According to the information collected by ASN, the radiology installations counted in this way and the computer tomography installations dealt with below, are distributed among 4,000 radiology departments in which about 7,000 radiologists are working. The radiologists call on the services of

	Medical radiodiagnosis	Dental radiodiagnosis	Total
Private sector	8 470	31 880	40 350
Mammography	2 005		
Public and related sector	7 503	1 420	8 923
Mammography	505		
Total	15 973	33 300	49 273

**Table 1: breakdown of dental medical radiodiagnosis installations per sector**

more than 22,500 radiology operators or similar. In the field of dental radiology, 40,000 dentists in 28,600 facilities share the use of the appliances listed above.

### Tomography appliances

The French radiological inventory comprises 754 tomography installations. It should be noted that this count includes appliances intended for radiotherapy simulation and that there are almost twice as many appliances in the public sector as in the private.

## 1 | 3

### Installations requiring notification or licensing

#### 1 | 3 | 1

#### Technical rules for fitting out radiology and tomography installations

##### Radiology installations

A conventional radiological installation comprises a generator (high-voltage unit, radiation generating tube and control unit), a stand for moving the tube and an examination table or chair. The general standard NFC 15-160, published by the *Union technique de l'électricité* (UTE), defines the conditions in which the installations must be fitted out to ensure human safety against the risks resulting from the action of ionising radiation and electrical current. It is supplemented by specific rules applicable to medical radiodiagnosis (NFC 15-161) and dental radiodiagnosis (NFC 15-163). These standards stipulate that the walls of radiology rooms must be sufficiently opaque to radiation and may require the installation of reinforced lead protection. In the light of the changes to the radiation protection regulations, which have in particular led to a reduction in the exposure limits for both the general public and workers, a revision of these standards was initiated by the UTE in 2005. ASN is a participant in this work, in partnership with the Institute for Radiation Protection and Nuclear Safety (IRSN) and the representatives of the professionals concerned. The revision of standard NFC 15-160 in particular aims to replace the analytical method it uses to assess the opacity of the walls of the radiology room by a more operational and simple method.

In addition to complying with the above-mentioned standards, the installations must be equipped with a generator less than 25 years old (medical appliances used for medical care) and carrying the CE marking. This certifies appliance conformity with the essential health and safety requirements mentioned in articles R. 5511-21 to 24 of the Public Health Code. The CE marking is mandatory for appliances which have entered service since June 1998.



### Tomography installations

Tomography installations must be fitted out in accordance with the requirements of special standard NFC 15-161, which sets rules primarily for the dimensions of the examination room and for the radiological safety measures to be taken. A tomography appliance cannot therefore be installed in a room with a surface area of less than 20 m<sup>2</sup> and in which no linear dimension is less than 4 metres. The opacity of the walls (including floor and ceiling) of the room must correspond to an equivalent thickness of 0.2 to 1.5 mm of lead, depending on the purposes for which the adjoining rooms are used. In addition, tomography equipment more than 25 years old must not be used.

## 1 | 3 | 2

### Notification of medical or dental diagnostic appliances

The use of electrical appliances generating X-rays for medical and dental diagnostic purposes - other than installations classified as heavy - requires that ASN be notified (article R. 1333-22 of the Public Health Code, chapter 3|1). Notification is by means of a form (that can be downloaded from [www.asn.fr](http://www.asn.fr) or obtained from the ASN regional divisions) plus the backup items specified in the regulations. For each establishment, a single notification mentioning all the radiological installations needs 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.

After a five-year period, a further notification must be submitted. If, prior to expiry of the period of validity, significant modifications are made to the notification (change in or addition of appliance, transfer or substantial modification of the premises or change in the practitioner responsible), ASN must be immediately notified accordingly.

Notification form for medical and dental radiodiagnostic equipments

During the course of 2006, theASN regional divisions received about 3,600 medical or dental radiodiagnosis appliance notifications.

## 1 | 3 | 3

### Tomography installation operating license

Tomography installations require prior licensing by ASN (article R. 1333-24 of the Public Health Code), for a renewable period of no more than 5 years. This license is issued to the practitioners, who then bear responsibility

The license application is made with a form (that can be downloaded from [www.asn.fr](http://www.asn.fr) or obtained from theASN regional divisions). The application dossiers, plus the backup items requested, are to be returned to the respective regional divisions with responsibility for examination.

The licence is granted on the basis of criteria concerning necessity (in particular the case of installations classified as sophisticated equipment), the competence of the practitioner in charge, and conformity with the installation technical arrangement and layout rules and the radiation protection organisation.

In 2006, ASN issued 203 decisions concerning the use of scanners (commissioning or renewal licenses, license revocation notices).

## 2 NUCLEAR MEDICINE

### 2 | 1

#### Presentation of nuclear medicine activities

Nuclear medicine includes all uses of unsealed source radionuclides for diagnostic or therapeutic purposes. Diagnostic uses can be divided into in-vivo techniques, based on administration of radiopharmaceuticals to a patient, and exclusively in-vitro applications.

### 2 | 1 | 1

#### In-vivo diagnosis

This technique consists in examining the metabolism of an organ with a specific radioactive material - called a radiopharmaceutical - administered to a patient. The nature of the radiopharmaceutical, which is classified as a drug, will depend on the organ being examined. The radionuclide can be used directly, or fixed to a carrier (molecule, hormone, antibody, etc.). For example, table 2 presents some of the main radionuclides used in the various investigations.

Technetium 99m, delivered to nuclear medicine departments in the form of a generator, is by far the most commonly used radionuclide. Its short radioactive half-life of 6 hours and its limited gamma radiation energy (140 keV) enable the dose received by the patient to be optimised. The activity administered to a patient for an examination is a few hundred megabecquerels (MBq). The radioactive material administered is located in the organism by a specific detector - a scintillation camera or gamma-camera - which consists of a crystal of sodium iodide coupled with a computer-controlled acquisition and analysis system. This equipment is used to obtain images of how the investigated



Scintillation camera

organs are functioning (scintigraphy). As these images are digitised, the physiological processes can be quantified, along with a three-dimensional reconstruction of the organs, using the same principle as for the X-ray scanner.

Fluorine 18 is a radionuclide that emits positrons (511 keV, 110 minutes half-life) and is increasingly widely used in nuclear medicine units for cancerology examinations. Fluorine 18 requires the use of a scintillation camera appropriate for detecting positrons, called a positron emission tomograph (PET), now coupled with a scanner to form a hybrid device called a PETSCAN.

Nuclear medicine is used to produce functional images and therefore complements the purely morphological pictures obtained with the other imaging techniques: conventional radiology, X-ray scanner, echography or magnetic resonance imaging (MRI).



**Positron emission tomograph**

Type of exploration	Type of radionuclide
Thyroid metabolism	Iodine 123, technetium 99m
Myocardial perfusion	Thallium 201, technetium 99m
Pulmonary perfusion	Technetium 99m
Pulmonary ventilation	Xenon 133, krypton 81m, technetium 99m
Osteo-articular process	Technetium 99m
Oncology - search for metastasis	Fluorine 18

**Table 2: some of the main radionuclides used in the various forms of nuclear medicine explorations**

## 2 | 1 | 2

### **In-vitro diagnosis**

This is a medical biology analysis technique - without administration of radionuclides to the patients - for assaying certain compounds contained in the biological fluids, particularly in blood samples taken from the patient: hormones, drugs, tumour markers, etc. This technique uses assay methods based on immunological reactions (antibody - antigen reactions marked with iodine 125), hence the name RIA (RadioImmunoAssay). The activity levels present in the analysis kits designed for a series of assays do not exceed a few kBq. Radioimmunoassay is currently being strongly challenged by techniques which make no use of radioactivity, such as immuno-enzymology.

## 2 | 1 | 3

### **Metabolic radiotherapy**

Metabolic radiotherapy aims to administer a radiopharmaceutical emitting ionising radiation, which delivers a high dose to a target organ for curative or palliative purposes.

Some therapies require limited administration of radionuclides (< 740 MBq). They are for example designed to treat hyperthyroidism by administration of iodine 131, painful bone metastases by strontium 89 or samarium 153, and polyglobulia by phosphorus 32. Joints can also be treated using colloids marked with yttrium 90 or rhenium 186. As a general rule, these treatments do not require hospitalisation of the patient in the nuclear medicine department.

Other therapies require the use of far higher activity levels. This is the case with treatment of certain thyroid cancers after surgery. This is done by administering about 4,000 MBq of iodine 131 and the patients have to be hospitalised for several days in a special room in the nuclear medicine ward, until urinary evacuation of most of the radionuclide administered. The radiological protection of these rooms must be appropriate to the type of radiation emitted by the radionuclides.

## 2 | 1 | 4

### **The new nuclear medicine tracers**

The routine use in nuclear medicine of fluorine 18, in the form of fluorodeoxyglucose (18FDG), for cancerology diagnosis purposes, has opened the door to research into development of new radioactive tracers intended for both diagnosis and internal radiotherapy. Other than fluorine 18 marking on new vectors, current work in progress concerns the use of other positron-emitting radionuclides such as rubidium 82, copper 64 or iodine 124 for diagnostic applications. In the field of internal radiotherapy, research is looking at new beta-emitting (copper 67 or lutetium 177) or alpha-emitting (astatine 211, bismuth 213, radium 223 or actinium 225) radionuclides, as well as new vectors in association with radionuclides already in use (antibodies marked with yttrium 90 in radio-immunotherapy). During the course of 2006, and for the first time in France, an alpha-emitting radionuclide - radium 223 - was used for nuclear medicine purposes as part of a clinical trial designed to assess its effectiveness in treating painful bone metastasis.

At least with regard to some of them and even if their medical benefit is proven, their use in nuclear medicine will require that the radiation protection requirements associated with their use be taken into account as far upstream as possible. This is because the activity levels which could be involved (usually far higher than those normal in nuclear medicine), the characteristics of the radionuclides and of the known preparation and administration protocols, operator exposure (particularly the hands) could reach or exceed the dose limits set in the regulations. In these conditions and pending the initial licensing applications, ASN is combining a reminder of regulatory requirements with

awareness raising programmes, in particular by encouraging the development of automated systems for preparation and/or injection of these radioactive products.

## 2 | 2

### Key figures: nearly 300 nuclear medicine departments

This sector comprises a total of 288 operational nuclear medicine units, containing both in vivo and in vitro installations (2005 figures). The public/private split between nuclear medicine units is 220 and 68 respectively. In 2005, 48 nuclear medicine units were equipped with positron emission tomography installations (PETSCAN cameras - PET camera coupled with a tomograph) mainly using fluorine 18 in the form of fluorodeoxyglucose (18FDG).

Nuclear medicine involves about 550 specialist practitioners in this field, to which must be added 1,000 physicians working in the nuclear medicine units (interns, cardiologists, endocrinologists, etc.).

## 2 | 3

### Installations subject to licensing and fitted out to prevent the risk of radioactive contamination

#### 2 | 3 | 1

### Nuclear medicine department organisation and operating rules

Given the radiation protection constraints involved in the use of unsealed source radionuclides, nuclear medicine departments must be designed and laid out so that they can receive, store, prepare and then administer unsealed radioactive sources to patients or handle them in laboratories (radioimmunology for instance). Arrangements also need to be made for collection, interim storage and disposal of radioactive waste and effluent produced in the installation.

From the radiological viewpoint, the personnel are subjected to an external exposure hazard, in particular on the fingers, owing to handling of sometimes highly active solutions (the case with fluorine 18 and iodine 131), along with an internal exposure hazard through accidental intake of radioactive materials. As the patients eliminate the administered radioactivity through their urine, special treatment of it is required in order to limit discharges into the public domain. In these conditions, the nuclear medicine departments have to comply with specific layout rules, the main provisions of which are described below.



Source in a lead-shielded syringe protector ready for administration to the patient



## Location and layout of premises

The premises of a nuclear medicine unit must be located away from the general circulation areas, clearly separated from premises intended for ordinary use, grouped so that they form a single unit allowing easy marking out of a controlled area, and categorised in descending order of radioactive activity levels. The controlled area comprises at least the following:

- a changing area airlock for the staff, separating normal clothing from work clothing;
- examination and measurement rooms and waiting rooms for the patients prior to examination;
- areas for storage and preparation of unsealed sources (hot laboratory);
- an injection room adjoining the hot laboratory;
- installation for delivery of radionuclides and storage of radioactive waste and effluent.

## Fitting out the controlled area

The thickness of the hot laboratory and injection room walls must be at least equivalent to 15 cm of ordinary concrete. The floors, walls and worktop surfaces must be made of smooth, impermeable, seamless and easily decontaminable materials. The washbasin taps must not be hand-operated. The changing area airlock must be equipped with washbasins and a shower and the sanitary facilities for the patients who have received an injection must be connected to a septic tank, itself directly connected to the establishment's main sewer. The hot laboratory must be fitted with one or more shielded chambers for storing and handling radioactive sources, offering protection against the risks of internal exposure and dispersal of radioactive materials.



**Shielded chamber for handling unsealed radioactive sources**

## Ventilation of the controlled area

The ventilation system must keep the premises at negative pressure, with air renewed at least five times per hour. It must be independent of the building's general ventilation system and foul air must be extracted with no possibility of recycling. The shielded compartments for storage and handling of radioactive materials in the hot laboratory must be connected to independent extraction ducts fitted with filters.

## Collection and storage of radioactive solid waste and liquid effluent

A room intended solely for storage of radioactive waste pending disposal must be provided. Similarly, liquid radioactive effluent must be sent from a small number of dedicated drainage points to buffer tanks which operate alternately as filling tanks and decay storage tanks. These tanks, of which there must be at least two, must be positioned above a safety leak tank.

The management of radioactive sources in nuclear medicine units must comply with the rules stipulated by the Public Health Code (chapter 3|1).

## 2 | 3 | 2

### Nuclear medicine licenses

The use of radioactive sources in nuclear medicine and in the associated biomedical research field, is subject to prior licensing by ASN (article R. 1333-24 of the Public Health Code), for a maximum renewable period of 5 years. The license is issued to the practitioner, who is then responsible.

The license application dossiers are based on a form that can be downloaded from [www.asn.fr](http://www.asn.fr) plus backup items as listed in the regulations. Particular attention must be paid to the procedures for collecting and disposing of the radioactive waste and effluent produced. The dossier must therefore comprise a waste and effluent management plan for the entire establishment within which the nuclear medicine unit is located.

In 2006, ASN issued 129 decisions concerning nuclear medicine (commissioning and renewal licenses, license revocation notices, etc.).

Form for requesting authorisation to possess and use radionuclides for nuclear medicine or biomedical research

### 3 RADIOTHERAPY

#### 3 | 1

#### Presentation of radiotherapy techniques

With surgery and chemotherapy, radiotherapy is one of the key techniques employed to treat cancerous tumours. 180,000 patients are treated every year, including about 140,000 in the early stages of their illness. Radiotherapy uses ionising radiation to destroy malignant cells. The ionising radiation necessary for treatment is either produced by an electric generator, or emitted by artificial radionuclides in the form of a sealed source. A distinction must be made between external (or transcuteaneous) radiotherapy, in which the radiation source is placed outside the patient and brachytherapy, in which the source is positioned in direct contact with the patient, either in or close to the area to be treated.

#### 3 | 1 | 1

#### External radiotherapy

Before the irradiation sessions take place, a treatment plan is always drawn up. For each patient, and in addition to the dose to be delivered, this plan defines the target volume to be treated, the ballistics of the irradiation beams and the dose distribution (dosimetry), as well as the duration of each treatment session. Preparation of this plan, which aims to set conditions for achieving a high, uniform dose in the target volume while protecting sound tissues, requires close cooperation between the radiotherapy specialist and the person specialising in medical radiophysics (PSRPM), previously known as the radiophysicist.

Irradiation is performed either using particle accelerators producing photon or electron beams with an energy of between 4 and 25 MeV and delivering dose rates varying between 2 and 6 Gy/mn, or - albeit now to a lesser extent - telegermatherapy appliances equipped with a cobalt 60 source, the activity of which is about 200 terabecquerels (TBq). The number of these



Cobalt 60 source for telegermatherapy



Radiotherapy particle accelerator



Telegammatherapy appliance

latter appliances has significantly declined in France, where they are being gradually replaced by particle accelerators whose superior performance offers a wider range of treatments.

### 3 | 1 | 2

## Brachytherapy

Brachytherapy allows specific or complementary treatment of cancerous tumours, specifically in the ENT field, as well as of the skin, the breast or the genitals.

The main radionuclides used in brachytherapy, in the form of sealed sources, are caesium 137 and iridium 192, which have definitively replaced the radium 226 needles or tubes used in the first half of the 20th century. Brachytherapy techniques involve three types of applications.

- **low dose rate brachytherapy**, which requires hospitalisation of the patient for several days, delivers dose rates of from 0.4 to 2 Gy/h. The iridium 192 sources positioned inside the tissues generally come in the form of wires 0.3 to 0.5 mm in diameter, with a maximum length of 14 cm and whose linear activity is between 30 MBq/cm and 370 MBq/cm. Endocavity techniques (inside natural cavities) use either iridium 192 wires or caesium 137 sources. In both cases, the sources remain in place in the patient for the duration of hospitalisation.



Iridium 192 sources used in low dose rate brachytherapy



In recent years, low dose rate brachytherapy techniques have been supplemented by the use of sealed sources of iodine 125 (half-life of 60 days) to treat prostate cancers. The iodine 125 sources, just a few millimetres long are permanently installed in the patient's prostate. Their unit activity is between 10 and 30 MBq and treatment requires about one hundred grains representing a total activity of 1500 MBq, delivering a prescribed dose of 145 Gy to the prostate.



Iodine 125 sources used for prostate brachytherapy

- **medium dose rate pulsed brachytherapy** uses dose rates of 2 to 12 Gy/h delivered by a small-dimension iridium 192 source (a few millimetres), with maximum activity limited to 185 GBq. This source is applied with a specific source applicator. This technique delivers doses identical to those of low dose rate brachytherapy, and over the same period, but given the higher dose rates, irradiation is split up into several sequences (pulses). The patient does not therefore carry the sources permanently, which is more comfortable and enables him to receive visitors. This technique, which is likely to be increasingly used, significantly improves the radiation protection of the personnel, who can now work with the patient without being exposed, once the source has been returned to the applicator's storage container.

- **high dose rate brachytherapy** uses a small-dimension iridium 192 source (a few millimetres) and a maximum activity of 370 GBq, delivering dose rates higher than 12 Gy/h. A source applicator comparable to that used in pulsed brachytherapy is used. The treatment times are very short (no more than a few minutes), unlike the previous techniques. High dose rate brachytherapy is primarily used to treat cancers of the oesophagus and bronchus.

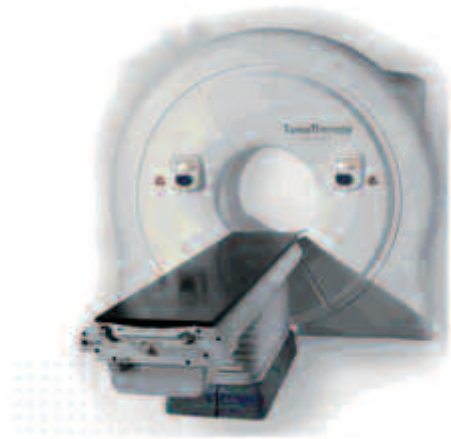


High dose rate brachytherapy appliance

## The new radiotherapy techniques

In addition to conventional methods of tumour irradiation, new techniques called tomotherapy and radiosurgery should shortly start being used in France.

Tomotherapy performs irradiation by combining the continuous rotation of an electron accelerator with the longitudinal displacement of the patient. The technique employed is similar to the principle of helical acquisitions obtained with computer tomography. A photon beam of 6 MeV at 8 Gy/min formed by a multi-leaf collimator enabling the intensity of the radiation to be modulated will allow irradiation of large volumes of complex shape as well as extremely localised lesions which may be in anatomically independent regions. It is also possible to acquire images of the zone being irradiated and compare them with reference tomography images in order to improve patient positioning quality. This technique is currently employed in about fifty centres in the United States and Europe. Three devices of this type should be installed in France as of the end of 2006 and enable the first patients to receive treatment in the first quarter of 2007.



Tomotherapy installation

Robotic arm radiosurgery consists in using a small 6 MeV particle accelerator, placed on the arm of an industrial type robot with 6 degrees of freedom. By combining the robot's ability to move around the treatment table and the degrees of freedom of its arm, it is thus possible to use multiple, non-planar beams to irradiate small tumours that are difficult to access using conventional surgery and radiotherapy. This allows irradiation in stereotaxic conditions that can also be slaved to the patient's breathing.

Given the movement capabilities of the robot and its arm, the radiation protection of the treatment room does not correspond to the usual standards and will therefore require a specific study.

This technique is at present employed in three centres in Europe (Germany, Belgium, Italy). Two installations of this type entered into service at the end of 2006 and a third installation is planned for the first quarter of 2007.



Radio-surgery installation

### 3 | 2

#### Key figures: rising numbers of accelerators

##### External radiotherapy installations

The radiotherapy installations inventory is rising and currently comprises 359 accelerators (2005 figures). These installations, along with the brachytherapy units mentioned below, are used by about 600 radiotherapists (350 in the public sector and 250 in the private) who work in 179 radiotherapy centres (source: SFRO).

##### Brachytherapy units

This inventory comprises 102 brachytherapy units, with 52 in the public sector and 50 in the private (2005 figures).

### 3 | 3

#### Installations subject to licensing and designed to guarantee staff radiation protection

The rules for radioactive source management in radiotherapy are comparable to those defined for all sealed sources, regardless of their use.

### 3 | 3 | 1

#### Technical rules applicable to external radiotherapy installations

These machines must be installed in rooms specially designed to guarantee radiation protection of the personnel, turning them into true bunkers (the thickness of the ordinary concrete walls can vary from 1 m to 2.5 m). A radiotherapy installation comprises a treatment room including a technical area containing the appliance, a control station outside the room and, in the case of some accelerators, auxiliary technical premises.

The protection of the premises, in particular the treatment room, must be determined in order to respect the annual exposure limits for the workers and/or the public around the premises. A safety case must be produced for each installation by the supplier of the machine, together with the PSRPM and the person with competence for radiation protection (or the department with competence for radiation protection) of the establishment in which it is to be installed.

This safety case defines the thicknesses and nature of the various protections required, which are determined according to the conditions of use of the appliance, the characteristics of the radiation beam and the use of the adjacent rooms, including those vertically above and below. This safety case should be included in the file presented to support the application for a licence to use a radiotherapy installation, examined by ASN.

In addition, safety systems must indicate the machine status (operating or not) or must switch off the beam in an emergency or if the door to the irradiation room is opened.

### 3 | 3 | 2

## Technical rules applicable to brachytherapy installations

### Low dose rate brachytherapy

This technique requires the following premises:

- an application room, where the source carrier tubes (non-radioactive) are positioned on the patient and their correct positioning is checked by radiological imaging;
- hospitalisation rooms specially reinforced for radiation protection reasons (on the basis of 8,100 MBq of caesium 137 or 5,550 MBq of iridium 192), where the radioactive sources are put in place and where the patient remains for the duration of the treatment;
- an area for radioactive source storage and preparation.

For certain applications (use of caesium 137 in gynaecology), a source applicator can be used to optimise staff protection.

### Pulsed dose rate brachytherapy

This technique can only be used in units which already employ low dose rate brachytherapy. The rooms set aside for hospitalisation of patients receiving this treatment must have radiological protection appropriate to the maximum activity of the radioactive source used (generally 18.5 GBq of iridium 192).

### High dose rate brachytherapy

The maximum activity used is 370 GBq of iridium 192, so irradiation may only take place in a room with a configuration comparable to that of an external radiotherapy room and fitted with the same safety systems.

### 3 | 3 | 3

## Radiotherapy licensing

Use of radiotherapy installations requires prior licensing from ASN. The renewable 5-year license is issued to the practitioners, who are then responsible for it.

The license application dossiers are based on a form that can be downloaded from the ASN website ([www.asn.fr](http://www.asn.fr)). These dossiers, accompanied by the required backup items, are to be returned to ASN (locally competent division) for examination.

In 2006, ASN issued 70 decisions concerning radiotherapy installations and 45 decisions concerning brachytherapy activities (commissioning or renewal licenses, license revocation notices).

## 4 BLOOD PRODUCT IRRADIATORS

### 4 | 1

#### Description

Blood products are irradiated in order to eliminate certain cells liable to lead to a fatal illness in patients requiring a blood transfusion. After this treatment, these products can be administered to the patients. This irradiation uses an appliance with built-in lead radiological shielding, so that it can be installed in a room which does not require additional radiation protection. Depending on the version, the irradiators may be equipped with one, two or three caesium 137 sources with a unit activity level of about 60 TBq. The blood bag is irradiated with an average dose of about 20 to 25 grays. Regional blood transfusion centres are equipped with this type of appliance.



Blood product irradiator

### 4 | 2

#### Blood product irradiator statistics

In 2006, the inventory of installations of this type, most of which were in operation in blood transfusion centres, remained stable at 29 units. There are however clear signs of a new trend in which the irradiators are being replaced by X-ray devices with fewer operational constraints and with which there are no further problems of radioactive source management.

### 4 | 3

#### Technical and administrative rules

The room in which the labile blood products irradiator is installed must be specifically dedicated to this appliance and be as isolated as possible, protected from all risk of flooding, short-circuit, explosion or traffic accident. It must be designed to prevent any possibility of break-in or any spread of fire.

Access must be via a solid door equipped with an effective system automatically closing the door after it has been opened and only allowing access by authorised persons. If in a regulated area, the outside of the door must carry the appropriate radiation hazard sign for the type of regulated area.

The irradiator control console must be fitted with a control key which is to be removed from the device and stored in a safe place under the responsibility of an individually designated person.

These installations are subject to licensing, in the same way as for nuclear medicine and radiotherapy. Source management rules also apply. In 2006, ASN issued 4 decisions concerning blood product irradiators.

## 5 IMPACT OF MEDICAL INSTALLATIONS ON THE EXPOSURE OF PERSONNEL AND PUBLIC

The potential dosimetric impact from medical installations concerns patients receiving treatment or undergoing examination, the health professionals (doctors, radiophysicians, electroradiology operators, nurses, etc.) using ionising radiation or participating in their use, but also the population, for example people living near the installations or population groups who could be exposed to waste or effluent from nuclear medicine departments.

### 5 | 1

#### Medical exposure of patients

Patient exposure to ionising radiation is differentiated from the other types of exposure (workers, population) because it is not subject to any limitations. This is also the only case in which exposure is delivered for the direct benefit of the exposed persons, i.e. the patients. The situation is different whether the patient is being exposed for diagnostic reasons (radiology or diagnostic nuclear medicine) or is receiving external or internal radiotherapy treatment. In the first case, optimisation is necessary by delivering the minimum dose necessary to obtain relevant diagnostic data, while in the second, the dose needed to sterilise the tumour must be delivered, while maximising preservation of the surrounding healthy tissue.

Optimisation of the dose received by the patient depends on the quality of the equipment used, which for example fully justifies retiring obsolete equipment and developing a quality control system for the medical appliances used. This concerns not only the irradiating equipment, but also that used for this exposure (if a radiological film viewer is defective, this could lead to an increase in doses delivered in order to produce the films). On the whole, inspections have shown that 60% of the units exercised quality control of their appliances, while 15% have undertaken to set up a process of this type. The dose also depends on the nature of the procedures and the emission of radiation (X-ray tube, particle accelerator, unsealed source of radionuclides, etc.).

At present it is hard to gain a precise picture of overall exposure of medical origin, because the number of examinations carried out (per type) is still inadequately known and the doses delivered for the same examination may vary widely, depending not only on the performance conditions but also on the morphology of the patients (see point 1|3|4).

Table 3 below presents the breakdown of the number of procedures and associated doses for conventional radiography, computed tomography, nuclear medicine and interventional radiology.



Guide of good practice for medical imaging published by the French Radiology Society



Type of procedure	Approximate percentage of number of procedures	Contribution to individual mean dose
Conventional radiology	90%	36%
Interconventional radiology	1%	17%
Tomography	8%	40%
Nuclear medicine	1%	7%

**Table 3: contribution to the individual dose from radiological and nuclear medicine procedures**

The studies conducted so far generally show a wide variability in the doses delivered for a given examination. The range of doses delivered by medical exposure is fairly wide. For example, in radiology, measurements taken in the same conditions for a given examination performed in three hospitals (report by the Bonnin/Lacronique, OPRI and SFR mission, March 2001) revealed doses (doses at the entry surface on a phantom) varying by a factor of 1 to 3 for a lumbar examination (profile) or a factor of 1 to 10 for a cervical examination (profile).

In nuclear medicine, the activities administered vary widely from one department to another, from one Member State to another. Even if the doses are generally lower than in radiology, there are variations that cannot always be justified. For a pulmonary perfusion scintigraphy performed as part of the diagnosis of a pulmonary embolism, the activity administered can vary from 100 MBq (Netherlands) to 300 MBq (France), or an estimated delivered dose variation of 1.2 mGy to 3.75 mGy.

The optimisation process can be improved if a person specialising in medical radiophysics (PSRPM) is present in the department to determine and guarantee the doses delivered. Overall, according to ASN sources, only 60% of departments for which data are available currently have a PSRPM. This figure highlights the lack of staff with this qualification in the departments concerned, but does not reflect the situation in the radiotherapy departments alone. In these departments, the presence of the PSRPM, who has a role in treatment safety and whose presence is mandatory during treatment, is certainly higher than for the other disciplines (nuclear medicine and radiology) for which the regulations only stipulate periodic interventions: an ASN inquiry is currently in progress to identify the PSRPM requirements in radiotherapy departments.

The preparation of a medical radiophysics plan, required by the regulations since 2004, should enable the head of the establishment and the physicians to identify the resources needed to develop medical radiophysics. Progress is needed in this field because to date only 14% of establishments have such a plan, while 30% are in the process of preparing one.

With regard to radiology and nuclear medicine, diagnostic reference levels (NRD) give a clearer picture of the doses delivered and thus allow better management of them. However, according to ASN sources, only 30% of users currently follow them while 12% are in the process of doing so. These figures can be compared with those presented by IRSN (JFR, 16 October 2006 - Annual Convention of the French Society of Radiology): about 50% of nuclear medicine departments, 2% of conventional radiology departments and 5% of tomography departments have submitted NRD information.

In its inspections, ASN will aim to have these new regulations applied, particularly with regard to the medical radiophysics plans and the reference diagnostic levels, which both contribute to optimising the doses delivered to the patients.

## Patient exposure incidents

A number of serious radiation protection accidents occurred in radiotherapy departments in France in recent months, leading to serious pathologies among the patients exposed, with two of them dying. As soon as they were notified by the heads of the establishments concerned, in accordance with WHO recommendations for notification of serious incidents, ASN intervened, in coordination with the French Health Products Safety Agency (AFSSAPS), to identify the causes and inform the entire radiotherapist community so that the factors leading to the event, usually human or organisational, could be identified and managed in all the installations.

The measures taken by ASN:

- increased hospital inspections to check the steps taken to ensure radiation protection of the patients (check on traceability of steps taken to justify and optimise procedures, organisation in the field of medical radiophysics and dosimetry);
- verification of the steps taken by hospitals to train the health care personnel;
- distribution to professionals of a draft guide containing the procedures for recording and notifying events and incidents.

After the radiotherapy accident in Épinal, the Minister for Health and Solidarity entrusted the General Inspectorate for Social Affairs (IGAS) and the Nuclear Safety Authority with an assignment which was, in particular, to “begin a nationwide examination of technical, organisational and human failures, in order to prevent other accidents in this type of therapeutic care and, as applicable, to draw up proposals for recommendations and regulations”. Together with the Ministry for Health and Solidarity and the health safety agencies, a number of working subjects have already been identified (qualification requirements for radiotherapy software, improvements in quality assurance, operator training, etc.). The conclusions of this assignment will be made public.

## Radiotherapy accidents at the Lyon-Sud Hospital

On 21 February 2006, ASN received notification of an accident at the Lyon-Sud Hospital. In November 2004, during radiotherapy treatment of a serious but non-cancerous pathology, a patient had been the victim of an operator error. The unexpected appearance of abnormal clinical signs, in May 2005, raised suspicions of radiation hypersensitivity. As a result of successive complications, the patient died on 11 March 2006.

During this radiotherapy treatment, incorrect adjustment of the irradiation field resulted in exposure of a larger zone than that specified for the treatment. The error was detected during the single treatment session.

The investigations carried out by ASN, in particular by its Lyons regional division, with the support of IRSN, brought to light an error in the unit of measurement (cm instead of mm) used to define the irradiation field, as this unit had not been specified in the exchange between two operators.

ASN considers that transmission errors must be considered within the broader scope of organisational and human failures. These were the cause of most fatal radiotherapy accidents worldwide in recent years.

Consequently, ASN has asked that the radiotherapy professionals undertake an in-depth analysis of organisational and human failures: jointly with the profession, the aim is to define tools for preventing incidents/accidents in radiotherapy departments, in order to improve the safety of medical treatment.



To do this,

- ASN sent out a circular dated 19 April 2006 to all French radiotherapy departments, to ensure that they are aware of the means of preventing radiotherapy accidents;
- ASN asked the working group it was coordinating on the subject of optimisation of radiotherapy procedures to include organisational and human failures in its scope of work.

## 5 | 2 | 2

### Radiotherapy accidents at the Épinal Hospital

23 prostate cancer patients treated between May 2004 and May 2005, were exposed to a dose of radiation significantly higher than that initially planned for their treatment in the Jean Monnet hospital in Épinal.

To date, of these 23 patients, one died on 25 June 2006, ostensibly for reasons directly linked to over-exposure, and three other patients died without it being possible to establish a direct link with the accident. Another thirteen patients experienced complications such as proctitis (inflammation of the rectum) and six showed no symptoms.

The first cases of complications appeared in the summer of 2005, as the delay before biological manifestation of the first signs in these cases of over-exposure was generally lengthy, at about a year.

The Directorate for Hospitalisation and the Health Care Organisation (DHOS) was informed on 4 July 2006 and immediately notified ASN. An inspection supervised by ASN was carried out in-situ



Presentation by Professor Bourguignon on the France 5 TV magazine on 17 October 2006 concerning the use of radiotherapy treatment planning software

on 19 July 2006, in association with the regional hospitalisation agency (Lorraine ARH), the departmental Directorate for Health and Social Affairs (Vosges DDASS) and with the support of IRSN.

In September, the inspection concluded that:

- these over-exposures were the result of an error in data entry into the dosimetry software used to prepare the treatments;
- the personnel were inadequately trained in the use of this software, which was itself not particularly user-friendly;
- information to the victims was inadequate.

In the light of these evident malfunctions, Xavier Bertrand, the Minister for Health and Solidarity, asked the General Inspectorate for Social Affairs (IGAS) and ASN to shed all light on this matter, precisely establish where the responsibility lay and draw all necessary conclusions, both locally and nationally, with regard to the safety conditions surrounding radiotherapy, in terms of its technical, organisational, human and administrative supervision aspects.

The final conclusions should be available by the end of February 2007.

## 5 | 2 | 3

### Brachytherapy incident at the Amiens University Hospital (CHU)

On 2 June 2006, ASN was informed by the Amiens CHU that an iridium 192 source had been left inside a patient who had been treated by low dose rate brachytherapy in the radiotherapy unit.

ASN information note concerning the brachytherapy incident at Amiens university hospital

This throat cancer patient had in a single session received the dose for the two treatment sequences prescribed. About twenty members of CHU staff and the family members who had been in the vicinity of the patient were also exposed.

On 5 June 2006, ASN inspected the radiotherapy department concerned in order to identify the precise circumstances of this incident. The ASN investigations brought to light an anomaly in the management of radioactive sources and incorrect use or failure to use the radioactivity monitoring devices at the end of the patient's hospitalisation period.

ASN informed the SFRO (French Oncological Radiotherapy Society) and the SFPM (French Medical Physics Society) of the circumstances of this incident, to ensure distribution of feedback to the profession. At the same time, ASN referred the matter to IRSN, for an assessment of the doses of radiation received by the various parties exposed.



ASN information note concerning the brachytherapy incident at Amiens university hospital

Reminder of four serious radiotherapy accidents around the world in the past twenty years

DATE	PLACE	DESCRIPTION	RESULT
1990	Saragossa clinic – Spain	Malfunction following repair of a particle accelerator and communication error	27 patients over-exposed, of whom at least 15 died
1996	San Juan de Dios hospital – Costa Rica	Beam calibration error in a tele-cobalt therapy unit	115 patients over-exposed. At least 17 patients died two years after the accident
2000	Justo Arosema hospital – Panama	Modification of a computer system data entry procedure for planning radiotherapy treatments	28 patients over-exposed. At least 5 deaths one year after the accident
2001	Byalistok regional oncology centre – Poland	Malfunction of a particle accelerator following a power cut	5 patients over-exposed

5 | 2 | 4

**Three radiotherapy patient identification errors, at present with no consequences**

On 4 July 2006, ASN was informed of a patient identification error resulting in unjustified irradiation on 28 June, in the radiotherapy unit at the Loire Cancerology Institute (ICL) in Saint-Étienne.

Confusion between patients with the same name led to one person receiving irradiation during radiotherapy treatment not intended for him. The treatment was given by a team of electroradiology operators who did not know the patient. The error was detected when the patient was returned to his room.

On 4 July 2006, the ASN and the DDASS medical inspectors of the *Loire département*<sup>1</sup>, carried out an inspection visit to identify the precise circumstances of this incident.

The ICL modified its patient identification procedure and reinforced the procedures for reconciling the data in the radiotherapy treatment file and the patient hospitalisation files.

On 12 October 2006, ASN carried out an inspection to check that the corrective action it deemed necessary had actually been taken. It considers that the quality efforts made at the ICL need to be pursued. It will in particular ensure that the protocols describing the patient handling procedures are finalised and that the patient's photo is included in each file.

Finally, two other identification errors, currently with no consequences for the patients, took place in August and October 2006 at the Centre Paul Papin in Angers. These repeated events are nonetheless symptomatic of organisational and human shortcomings and show the need for a combination of several independent lines of defence to be set up (wrist-band or barcode, photo, asking the patient for his/her identity, etc.) in order to prevent this type of incident from happening again.

1. *département*: administrative region.

## 5 | 3

### Radiation protection of medical personnel

#### 5 | 3 | 1

##### Dosimetry

According to the data collected by IRSN in 2005 (IRSN report on worker radiation protection, 2004 summary), about 135,000 people working with medical uses of ionising radiation - or 54% of the total number of monitored exposed workers, covering all activity sectors - were subject to dosimetric exposure monitoring. Medical radiology covers about 67% of the medical personnel exposed. In total, nearly 98% of the persons monitored in 2005 and working in medicine or dentistry received an annual effective dose of less than 1 mSv while 28 overshoots of the annual limit of 20 mSv were recorded (34 in 2004). These overshoots can be broken down as follows: 24 in medical radiology and 4 in occupational medicine. Inquiries are systematically carried out by the occupational medicine services in order to identify the origin of these individual cases.



Thermoluminescent ring for staff radiation protection (dose measurement at the extremities)

#### 5 | 3 | 2

##### Organisation of radiation protection

Apart from dosimetric surveillance, ASN defined 5 other indicators for assessing how personnel radiation protection is organised.

The presence of a person with competence for radiation protection (PCR) or a department with competence for radiation protection (SCR) is therefore essential to the radiation protection organisation within the establishment. This indicator has now reached highly satisfactory levels as 79% of the establishments assessed have a PCR and 11% of them an SCR.

However, the results concerning the workstation studies, which are the starting point for any examination of how work is organised and for optimisation of exposure, are not quite as convincing: 24% of the establishments carry them out and 40% intend to do so.

Similarly, continuous training in radiation protection must continue to be given, as the results show that 36% of establishments train their personnel and that 39% intend to implement training programmes.

In addition, 68% of establishments have periodic checks carried out by approved organisations and 15% are in the process of setting up such a system.

## 5 | 4

### The impact on the environment and the population

Barring special circumstances, there is no particular surveillance of the impact of medical applications on the environment and the population owing to its extremely diffuse nature. Except in the case of incidents, the potential impact could concern:

- specific professional categories liable to be exposed to effluent or waste produced by nuclear medicine departments;
- members of the public, if the premises containing installations emitting ionising radiation are not fitted with the requisite protection;
- the entourage of patients who have received nuclear medicine treatment or examination involving radionuclides such as iodine 131.

The available information concerning radiological surveillance of the environment carried out by IRSN, in particular measurement of ambient gamma radiation, on the whole reveals no significant exposure level above the background radiation variations. However, radioactivity measurements in major rivers or wastewater treatment plants in the larger towns occasionally reveal the presence above the measurement thresholds of artificial radionuclides used in nuclear medicine (iodine 131, technetium 99m). The available data on the impact of these discharges indicate doses of a few microsieverts per year for the most exposed individuals, in particular the workers employed in the sewerage networks (IRSN 2005 study). No trace of these radionuclides has ever been measured in water intended for human consumption.

The indicator defined by ASN concerning the existence in the establishments of a radioactive waste and effluent management plan shows that the professionals in the medical sector are not yet sufficiently committed to improvement in this area, as only 47% of the establishments questioned have a radioactive waste and effluent management plan, while 13% have begun to examine the question.

The recommendations that should be made by the physician after radionuclides are used in nuclear medicine were the subject of the work done by the “nuclear medicine” working group of the French High Public Health Council, in particular with respect to examinations and treatment using iodine 131. The aim was to harmonise the advice and lifestyle hints already dispensed by each physician. The work done was based on European recommendations but also on simulations and measurements taken in real-life situations. The recommendations, which should be published by ASN in 2007, concern the residual activity after hospitalisation (in the case of therapy using high activity levels) or the activity administered if the patient receives iodine 131 without hospitalisation (exploration or treatment of hyperthyroidism).



For the members of the public, the recommendations will be relatively undemanding, with the exception of particular situations (flights lasting longer than 7 hours, close working contact in particular with pregnant women or children). For family members, the recommendations made concern the partner and children under 10 years of age. The harmonised advice for everyday life, established according to the activity levels administered, will concern the length of time off work, the length of restrictions on contact between spouses and with children.

## 6 OUTLOOK

In 2006, with the hindsight of several years of supervision of medical installations, ASN observed considerable heterogeneity of radiation protection practices in the medical field. As in 2005, it underlines the wide range of situations encountered between purely administrative radiation protection, the purpose of which is to declare the use of a radiology installation or obtain a license, and a true radiation protection culture integral to a structured organisation designed to boost the awareness and accountability of all players concerned in use of sources. The entire radiologist community therefore has to be mobilised concerning assessment of the doses delivered to patients, so that the existing radiology installations can be equipped with the appliances needed for estimating the dose delivered to the patients, particularly children, and that the new regulations concerning patient radiation protection can be effectively implemented.

In 2006, the situation is still not good enough, despite increasing involvement on the part of learned societies and professional labour organisations with respect to training and awareness, with a view to setting up good practices compatible with the principles of justification and optimisation.

This context of gradual improvement in medical radiation protection was however deeply affected in 2006 by ASN declaration of several serious radiotherapy accidents, involving a number of deaths or requiring extensive interventional intervention.

The creation of a system of serious event declarations is among the actions implemented by ASN since 2002 in the field of patient radiation protection which led to a new body of legislative and regulatory texts, to development of inspection with greater resources, and - jointly with the learned societies - to the distribution of guides of good practice and the provision of training. The declarations recorded in 2005 and 2006 were immediately followed by reactive inspections, assessment of the causes with the support of IRSN, distribution of recommendations to the entire community of radiotherapists and information to the public through press releases.

Against a backdrop of a rising treatment workload and equipment modernisation programmes, marked by extremely rapid development of new technologies, ASN aims to extend the scope of its inspections in 2007 to cover human and organisational factors, in order to check compliance with the safety requirements applicable to radiotherapy installations.

In addition to its own supervisory duties and the powers of inspection recently granted to it, ASN hopes to establish effective cooperation with the organisations in charge of supervising health care establishments, to examine the practicalities of increasing the material resources allocated to radiation protection when necessary, and of course to alert them if patient safety were to be threatened. To ensure improved patient radiation protection, ASN has also set itself the goal of developing close ties with all health safety stakeholders, whether in charge of resource planning (regional hospitalisation agencies, National Cancer Institute), of assessing medical practices (High Health Authority) or of specific supervisory actions (AFSSAPS).

The ASN report on improving the safety of radiotherapy treatment, requested by the Minister for Health and Solidarity, will be particularly keenly awaited in 2007.