MEDICAL USES OF IONISING RADIATION

CHAPTER 9

For more than a century now, and for both diagnostic and therapeutic purposes, medicine has made use of a variety of sources of ionising radiation, 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 ionising radiation, 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 (see chapter 3). The installations themselves and their use are required to comply with specific technical and administrative rules, while the use of radioactive sources is subject to specific management rules contained in the Public Health Code (see chapter 3).

In recent years, the technical regulations have been considerably strengthened with the creation of a new set of regulations dedicated to patient radiation protection (see chapter 3). 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 dose limitation does not apply to patients, given the resulting health benefits for them and the fact that doses must reach a certain level to obtain an image of diagnostic quality or the desired therapeutic effect.

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, transfer and archival storage of the images obtained.

Radiodiagnosis, which is the oldest of the medical applications of radiation, is a discipline containing all the techniques for morphological examination 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 radiology, interventional radiology, computed tomography, angiography and mammography) and a wide variety of examinations (radiography of the thorax, the abdomen, and so on).

The request for a radiological examination by the physician must be part of a diagnostic strategy taking account of the relevance of the information sought, 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).

1|1|1 Medical radiodiagnosis

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 two main families:
– radiodiagnosis performed in fixed installations specifically built for the purpose;
– radiodiagnosis carried out using mobile devices, especially by the patient's bedside. This practice is however restricted to those patients who cannot be transported.

Digital subtraction angiography

This technique, which is used to explore the blood vessels, is based on the digitisation of images before and after injecting a contrast medium. Computer processing removes the structures around the vessels by subtracting the pre-contrast images from the later ones.

Mammography

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

Computed tomography

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

For some investigations, this technique is today facing a strong challenge from magnetic resonance imaging (MRI). However, the new generation of devices (multi-slice CT scanners) enables the scope of investigation of computed tomography to be expanded, with easier and faster investigation. however can be that more images can be taken, which runs contrary to the

Computed tomography scanner control station

optimisation principle, thus leading to a significant rise in the doses of radiation delivered to the patients.

Teleradiology

Teleradiology makes it possible to guide the performance of radiological examinations carried out in another location and to interpret the results, also from a distance. Data transmissions must be carried out in strict application of the regulations (relating to radiation protection and image production quality in particular) and professional ethics.

Essentially two practices are concerned:
– telediagnosis, which enables the doctor on the scene (e.g. an emergency doctor), who is not a radiologist, to send images to a radiologist for interpretation for diagnostic or therapeutic purposes. If necessary, the radiologist can guide the radiological technician during the examination and imaging process;
– tele-expertise, whereby a practitioner can ask a teleradiologist (a radiologist specialised in remote radiology) to give or confirm a diagnosis and determine a therapeutic orientation or guide a remote examination.

The data transmissions are protected bidirectionally to preserve medical secrecy and image quality.

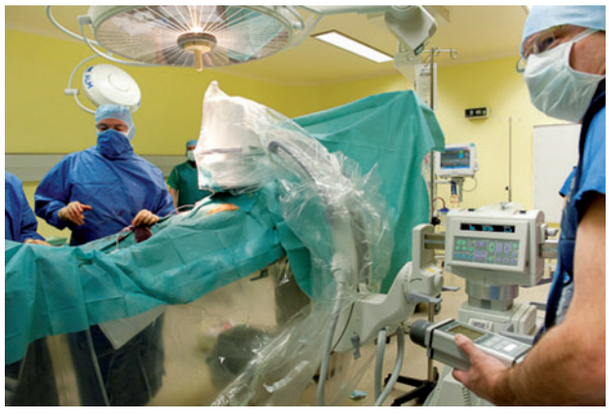
Teleradiology involves many responsibilities which must be specified in the agreement binding the practitioner performing the procedure (radiologist or not), to the teleradiologist.

1|1|2 Interventional radiology

This involves techniques that use fluoroscopy with an image intensifier and require special equipment, for example in surgical contexts or when using cardiovascular probes. These techniques are used during diagnostic interventions (examination of coronary arteries, etc.) or for therapeutic purposes (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 staff are usually working in the immediate vicinity of the patient and also exposed to higher levels than during other radiological practices. In these conditions, given the risk of external exposure for the operator and the patient, interventional radiology must be justified by a clearly determined medical need and its practice must be optimised in order to improve the radiation protection of both operators and patients.

Fixed interventional radiology installations are used in interventional neuro-radiology, interventional cardiology and, more generally, in vascular radiology. Mobile devices comprising a radioscopy mode are used in the operating theatre for a number of medical specialities, in particular digestive surgery, orthopaedic surgery and urology.

ASN does not know the exact number of installations in which interventional practices are performed. The ASN divisions initiated actions to compare the information held by the health insurance offices and the Regional Health Agencies (ARS) in order to obtain a more accurate picture of the health-care activities concerned.



Interventional radiology inspection by ASN at the university hospital (CHU) of Villefranche-de-Rouergue – December 2010

1|1|3 Dental radiodiagnosis

Intra-oral radiography

Intra-oral type radiography generators are 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.

Cone-beam computed tomography

In the dental radiology field, the development of devices using a cone-beam computed tomography mode (3D) is continuing

and the irradiation fields of view proposed by these devices are increasingly wide. ASN has defined practical means of guaranteeing operator protection, based on the conclusions of the IRSN assessment of the risks of external exposure linked to the use of this new equipment.

1|2 Technical rules for 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 procedures (NFC 15-161).

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 resulted in a reduction in the exposure limits for both the public and workers, these standards were revised at the end of 2010 (see box).

In addition to complying with the above-mentioned standards, the installations must be equipped with a generator less than 25 years old (medical devices used for medical care) and carrying the CE marking that has been mandatory since June 1998. This certifies that the device is in conformity with the main health and safety requirements mentioned in articles R. 5211-21 to 24 of the Public Health Code.

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 device can therefore only be installed in a room with a surface area of at least 20 m² 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.

The French radiological equipment pool comprised 905 computed tomography installations in 2009 (figure provided by the Revenue Court). This figure would rise to about 1150 if the devices used for radiotherapy simulation were included.

Inspection of the nuclear medicine unit of the North Saint-Denis Cardiology Centre by ASN – December 2010

UNDERSTAND

Revision of standards NFC15-160, NFC15-161, NFC15-162 and NFC15-163

The standards in the NFC15-160 series relative to installations for the production and utilisation of X-rays have been revised. These standards included general rules (NFC15-160) and specific rules for medical and veterinary radiodiagnosis installations (NFC15-161), for roentgen therapy installations[1] (NFC15-162) and for dental radiodiagnosis installations (NFC15-163). The new standard introduces a method of calculation for determining the thickness of the radiation shielding in all the medical installations in which X-ray generating devices and particle accelerators are used.

1. The roentgen therapy installations mentioned in this standard are radiotherapy installations

2 NUCLEAR MEDICINE

2|1 Presentation of nuclear medicine activities

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

This sector comprises a total of 236 operational nuclear medicine units, containing both *in vivo* and *in vitro* installations.

On the whole, the number of nuclear medicine units practicing in vivo diagnosis and therapy has been stable over the last three years. sixty percent of them are located in public or comparable structures and 40% are in private structures. There are about 70 positron emission tomographs (PET) in service.

Nuclear medicine involves about 500 specialist practitioners in this field, to which must be added 1,000 physicians working in the nuclear medicine units (housemen, cardiologists, endocrinologists, etc.).

2|1|1 *In vivo* diagnosis

This technique consists in examining the metabolism of an organ by administering a specific radioactive material – called a radiopharmaceutical – to a patient. The nature of the radiopharmaceutical, which has medication status, depends on the organ or function studied. The radionuclide can be used directly or fixed to a carrier (molecule, hormone, antibody, etc.). For example, table 1 presents some of the main radionuclides used in the various investigations.

The radioactive material administered, usually technetium-99m, 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 image acquisition and analysis system. This equipment is used to obtain images of how the investigated organs are functioning (scintigraphy). As these are digitised images, the physiological processes can be quantified, along with a three-dimensional reconstruction of the organs (single-photon emission computed tomography or SPECT), using the same principle as for the X-ray scanner.

Handling radioactive products during ASN's inspection of the nuclear medicine unit at the North Saint-Denis Cardiology Centre – December 2010

Table 1: some of the main radionuclides used in the various nuclear medicine examinations

Type of examination	Radionuclides used
Thyroid metabolism	Iodine-123, technetium-99m
Myocardial perfusion	Thallium-201, technetium-99m
Pulmonary perfusion	Technetium-99m
Pulmonary ventilation	Krypton-81m, technetium-99m
Osteo-articular process	Technetium-99m
Oncology – search for metastasis	Fluorine-18

Fluorine-18, a radionuclide that emits positrons, is today commonly used in the form of a sugar, fluorodeoxyglucose (FDG), for examinations in cancerology. It requires the use of a scintillation camera that can detect positron emitters (PET).

Nuclear medicine allows the production of 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. In order to make it easier to merge functional and morphological images, hybrid cameras have been developed: positron emission tomographs (PET) are now systematically coupled with a CT scanner (PET-CT) and more and more nuclear medicine units are acquiring gamma-cameras coupled with a CT scanner (SPECT-CT).

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 biological fluid samples taken from the patient: hormones, drugs, tumour markers, etc. This technique uses assay methods based on immunological reactions (antibody - antigen reactions labelled with iodine 125), hence the name RIA (radioimmunology assay). The activity levels present in the analysis kits designed for a series of assays do not exceed a few kBq. Radioimmunology is currently being strongly challenged by techniques which make no use of radioactivity, such as immuno-enzymology.

2|1|3 Targeted internal radiotherapy

Internal radiotherapy aims to administer a radiopharmaceutical emitting ionising radiation, which will deliver a high dose to a target organ for curative or remedial purposes.

Certain therapies require hospitalisation of the patients for several days in specially fitted out rooms in the nuclear medicine unit, until most of the radionuclide administered has been eliminated through the urinary tract. The radiological protection of these rooms must be appropriate for the type of radiation emitted by the radionuclides. This is in particular the case with treatment of certain thyroid cancers after surgery, involving the administration of about 4,000 MBq of iodine 131.

Other treatments can be on an out-patient basis. Examples include administering iodine-131 to treat hyperthyroidism, strontium 89 or samarium 153 for painful bone metastases, and phosphorus-32 for polyglobulia. Joints can also be treated using colloids labelled with yttrium-90 or rhenium-186. Finally, radioimmunotherapy can be used to treat certain lymphomas using yttrium 90-labelled antibodies. The treatment of hepatocellular carcinomas by spheres labelled with yttrium 90 is also currently being developed.

2|1|4 The new nuclear medicine tracers

In recent years, research has been underway in France and around the world to develop new radioactive tracers. This primarily concerns positron emission tomography and internal radiotherapy.

In 2009, clinical tests continued into the use of various fluorine 18 tracers in PET and antibodies labelled with yttrium 90 in internal radiotherapy. New tracers are available for research purposes, using alpha emitters in particular.

The use of new radiopharmaceuticals means that the radiation protection requirements associated with their use must be taken into account as early as possible in the process. Given the activity levels involved, the characteristics of the radionuclides and the known preparation and administration protocols, exposure of the operators, particularly their hands, could reach or even exceed the dose limits set by the regulations. ASN has reminded operators of the regulatory requirements and undertaken awareness-raising actions, notably by encouraging the development of automated preparation and/or injection systems for these radionuclides.

2|2 Nuclear medicine unit organisation and operating rules

Given the radiation protection constraints involved in the use of unsealed radioactive sources, nuclear medicine units are 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). Provisions are also made for the collection, storage and disposal of radioactive wastes and effluents produced in the installation, particularly the radionuclides contained in patients' urine.

From the radiological viewpoint, the workers are subjected to a risk of external exposure, in particular on the fingers, due to the handling of sometimes highly active solutions (as is the case with fluorine-18, iodine-131 or yttrium 90), and a risk of internal exposure through accidental intake of radioactive materials. In these conditions, the nuclear medicine units have to comply with specific layout rules, the main provisions of which are described below.

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 controlled areas, categorised in descending order of radioactive activity levels. They comprise at least:

- an entry and changing area for the staff, separating normal clothing from work clothing;
- examination and measurement rooms and waiting rooms for injected patients prior to examination;
- areas for storage and preparation of unsealed sources (radiopharmacy);
- an injection room adjoining the radiopharmacy;
- installations for reception of the radionuclides delivered and storage of radioactive waste and effluents.

Layout of premises

The walls are sized to ensure protection of the workers and the public in their vicinity. 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 entry area must be equipped with washbasins and a shower. 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 radiopharmacy must be fitted with one or more shielded cells for storing and handling radioactive sources, offering protection against the risks of external exposure and the dispersal of radioactive materials.

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 cells for storage and handling of radioactive materials in the radiopharmacy must be connected to independent extraction ducts fitted with filters.

In 2010, ASN began working on the updating of the design rules for nuclear medicine units (due for completion in 2011).

Collection and storage of radioactive solid waste and liquid effluents

The order of 28 July 2008 approving ASN decision 2008-DC-0095 of 29 January 2008 lays down the technical rules to be followed for the disposal of waste and effluents contaminated by radionuclides.

Generally speaking, nuclear medicine units have a room for interim storage of waste contaminated by radionuclides until disposal. Contaminated liquid effluents are channelled to a system of storage tanks to allow radioactive decay prior to discharge into the sewerage network.

3 EXTERNAL RADIOTHERAPY AND BRACHYTHERAPY

3|1 Presentation of the techniques

Alongside surgery and chemotherapy, radiotherapy is one of the key techniques employed to treat cancerous tumours. Some 200,000 patients are treated each year. Radiotherapy uses ionising radiation to destroy malignant cells. The ionising radiation necessary for treatment is either produced by an electric generator, or emitted by radionuclides in the form of a sealed source. A distinction must be made between external 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.

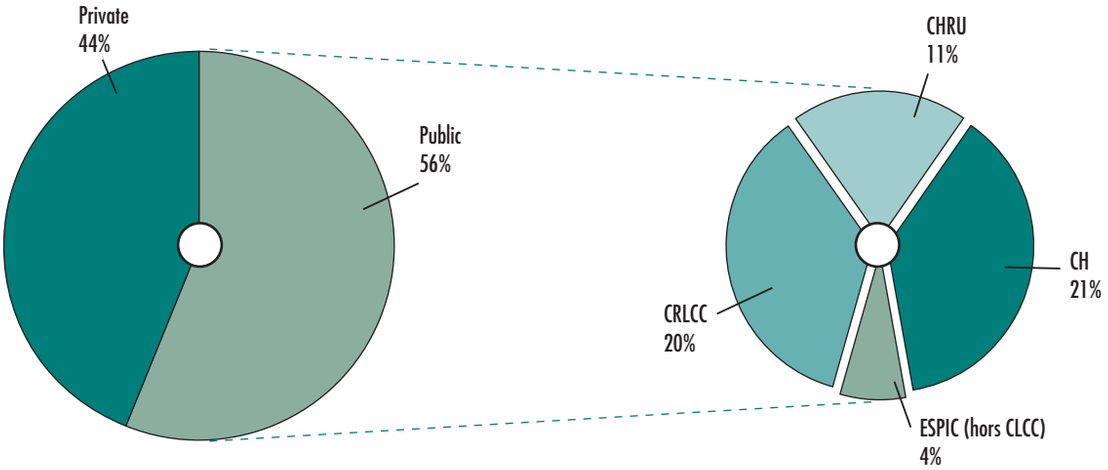
The French pool of external-beam radiotherapy facilities comprises a total of 429 treatment machines, namely 412 conventional linear accelerators, 1 telecobalt therapy unit and 16 "innovative" installations (see points 3|1|1 and 3|1|3). These facilities are installed in 178 radiotherapy centres, half with public status and half with private status. 544 radiation oncologists were identified, including 44% private practitioners and 56% salaried staff. 70 brachytherapy units are linked to these installations (Radiotherapy Observatory, September 2010).

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 irradiation beam setting 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 healthy tissues, requires close cooperation between the radiation oncologist and the medical physicist, but also the dosimetrists.

Irradiation is carried out using either linear accelerators producing beams of photons or electrons with an energy level of between 6 and 25 MeV and delivering dose rates of between 2 and 6 Gy/min, or telegammatherapy devices equipped with a source of cobalt 60 whose activity level is about 200 terabecquerels (TBq), although the number of these devices is declining in France. They are gradually being replaced by linear accelerators, whose superior performance offers a more complete range of treatments.

Diagram 1: Distribution of the number of linear accelerators in France according to type of establishment



CRLCC : Regional anti-cancer centre
CHRU : Regional university hospital centre
CH : Hospital centre
ESPIC : Private health establishment in the public interest

Stereotactic radiotherapy

Stereotactic radiotherapy is a treatment method which aims to offer millimetre-precise, high-dose irradiation, using small beams converging in the centre of the target, for intra-cranial pathology that is surgically inaccessible. Radio-surgery treatment is defined as being a single session of stereotactic radiotherapy. In stereotactic radiotherapy treatments, the total dose is delivered either in a single session or in a hypofractionated manner, depending on the type of pathology being treated. This technique requires considerable precision when defining the irradiation target volume and the treatment has to be as conformational as possible.

It was originally developed to treat non-cancerous pathologies in neurosurgery (artery or vein malformations, benign tumours) and uses specific localising techniques to ensure precise localisation of the damage. It is being increasingly used to treat cerebral metastases.

This therapeutic technique uses three types of equipment:
– dedicated systems such as Gamma Knife® which directs the emissions from more than 200 cobalt-60 sources towards a single focal spot (4 units are currently in service in three establishments), and CyberKnife® which consists of a miniaturised linear accelerator mounted on a robotised arm (see detail in point 3|1|3);
- dedicated linear accelerators offering dynamic mode irradiation (Novalis®, 4 units currently in service);
- "conventional" linear accelerators, providing dynamic mode irradiation and equipped with additional collimating systems (mini-collimators, localisers) to generate small beams.

In May 2010, 28 centres had equipment enabling them to perform stereotactic radiotherapy treatments.

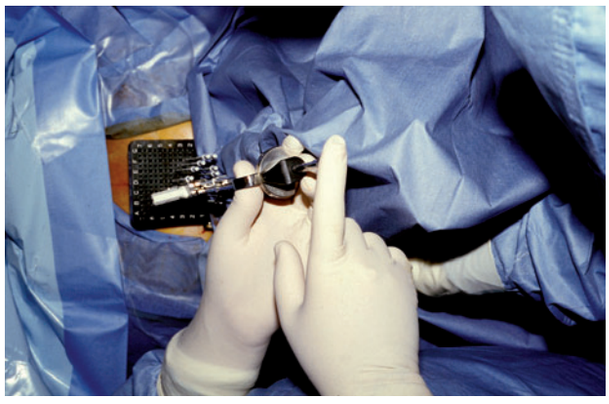
3|1|2 Brachytherapy

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 are caesium 137 and iridium 192, in the form of sealed sources. Brachytherapy techniques use three types of applications, low dose rate brachytherapy, pulsed medium dose rate brachytherapy and high dose rate brachytherapy.

With low dose rate brachytherapy, which requires the patient to be hospitalised for several days, dose rates of 0.4 to 2 Gy/h are delivered. The sources 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.

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



Injecting iodine 125 seeds in prostate brachytherapy

representing a total activity of 1,500 MBq, delivering a prescribed dose of 145 Gy to the prostate.

Pulsed medium dose rate 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 18.5 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 during the time he is hospitalised.

High dose rate brachytherapy uses a small dimension iridium 192 source (a few millimetres) with a maximum activity of 370 GBq delivering dose rates higher than 12 Gy/h. A source projector comparable to that used for pulsed brachytherapy is used. The treatments performed using this technique involve several sessions of a few minutes. These sessions are spread out over several weeks and conducted on an out-patient basis (no hospitalisation required). High dose rate brachytherapy is used mainly for gynaecological cancers but also for the oesophagus and bronchial passages. This technique is being developed for treatment of prostate cancers, usually in association with an external radiotherapy treatment.

3|1|3 The new radiotherapy techniques

New techniques, called "robotic" tomotherapy and radiotherapy are now supplementing conventional tumour irradiation methods and have been in use in France since the beginning of 2007.

Tomotherapy performs irradiation by combining the continuous rotation of an electron accelerator with the longitudinal displacement of the patient during irradiation. The technique employed is similar to the principle of helical image acquisitions obtained with computer tomography. A photon beam of 6 MV 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 damage which may be in anatomically independent regions. It is also possible to acquire images in treatment conditions and compare them with reference computer

tomography images, in order to improve the quality of patient positioning. Eight devices of this type have been installed in France since the end of 2006, including 2 in 2009, and have been used to treat patients since the first quarter of 2007.

Stereotactic radiotherapy with a robot arm consists in using a small particle accelerator producing 6 MV photons, placed on an industrial type robot arm with 6 degrees of freedom, marketed under the name CyberKnife®. 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-coplanar beams to irradiate small tumours that are difficult to access using conventional surgery and radiotherapy. This allows irradiation in stereotactic 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.

A new radiotherapy technique called volumetric modulated arc therapy (VMAT) has emerged and is progressively coming into use in France. Also known as RapidArc, after a manufacturer, VMAT is an intensity-modulated radiation therapy (IMRT) technique that consists in irradiating a target volume with continuous irradiation that rotates around the patient. Several parameters can vary during irradiation: the shape of the opening and the direction of the multi-leaf collimator, the dose rate, and the speed of rotation of the arm.

This type of treatment is performed using conventional linear accelerators that feature this technological option.

Five installations of this type are in service in France in 2010, in Nancy, Nice, Lille, Lyon and Tours.

3|2 Technical rules applicable to installations

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

3|2|1 Technical rules applicable to external radiotherapy installations

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

The protection of the premises, in particular the treatment room, must be determined in order to respect the annual exposure limits for the workers and/or the public around the premises. A specific study must be carried out for each installation by the machine supplier, together with the medical physicist and the person competent in radiation protection (PCR).

This study defines the thicknesses and nature of the various protections required, which are determined according to the conditions of use of the device, the characteristics of the radiation beam and the use of the adjacent rooms, including those vertically above and below. This study 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|2|2 Technical rules applicable to brachytherapy installations

Low dose rate brachytherapy

This technique requires the following premises:
– an application room, usually an operating theatre where the source carrier tubes (non-radioactive) are installed in the patient and their correct positioning is checked by X-rays or tomography imaging;
– hospitalisation rooms specially reinforced for radiation protection reasons, in which the radioactive sources are positioned and where the patient stays for the duration of the treatment;
– an area for radioactive source storage and preparation.

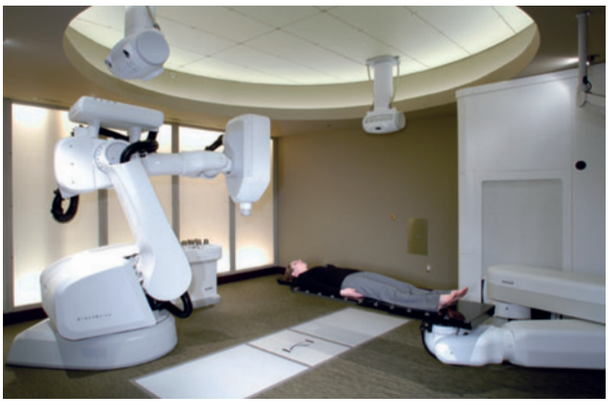
For certain applications (use of caesium 137 in gynaecology), a source applicator can be used to optimise staff protection.

Pulsed dose rate brachytherapy

This technique uses source applicators (generally 18.5 GBq of iridium 192). The treatment takes place in hospitalisation rooms with radiological protection appropriate to the maximum activity of the radioactive source used.

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.



The CyberKnife®

4 BLOOD PRODUCT IRRADIATORS

4|1 Description

Blood products are irradiated in order to eliminate certain cells that could lead to a fatal illness in patients requiring a blood transfusion. The blood bag is irradiated with an average dose of about 20 to 25 grays. This irradiation uses an device 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, irradiators are equipped either with radioactive sources (1, 2 or 3 sources of caesium 137 with a unit activity of about 60 TBq) or with electrical X-ray generators.

4|2 Blood product irradiator statistics

In 2009, the French pool of installations of this type totalled 30 irradiators in operation in blood transfusion centres, 16 with radioactive sources and 14 with electrical X-ray generators.

The trend is towards replacement of source irradiators with X-ray devices, in particular to eliminate the constraints involved in radioactive source management. This move has been under way for a number of years now, but intensified in 2009, with the scrapping of 9 irradiators using caesium 137 sources.

The rate of replacement of source irradiators by X-ray irradiators nevertheless slowed down in 2009 due to the lack of reliability of the X-ray irradiators. Frequent failures have meant that the continuity of service to patients cannot be guaranteed.

4|3 Technical rules applicable to installations

A blood product irradiator containing radioactive sources must be installed in a special room designed to provide physical protection (fire, flooding, break-in, etc.). Access to the device, which must have a lockable control console, must be limited to authorised persons only.

Blood product irradiator

5 THE STATE OF RADIATION PROTECTION IN THE MEDICAL SECTOR

Radiation protection in the medical sector concerns the patients receiving treatment or undergoing diagnostic examination, the health professionals (physicians, medical physicists, technologists, nurses, etc.) using or participating in the use of ionising radiation, and also the population, such as members of the public visiting family or friends in hospital, or population groups that could be exposed to waste or effluent from nuclear medicine units.

As of 2008, ASN began to prepare regional summaries based on the main lessons learned from its inspections. These summaries, which will be periodically updated, are now collated nationally and placed on-line on the ASN website. In 2009, two reports were published on the basis of the inspections carried out in 2008, one focusing on the state of radiation protection in nuclear medicine units, the other concerning safety in radiotherapy treatments. In 2010, two new reports to be published early 2011 were drawn up on the basis of the inspections performed in 2009: one concerns radiation protection in interventional radiology, while the other updates ASN's assessment of the radiation protection of radiotherapy patients.

As in 2009, ASN and the AFSSAPS jointly prepared a report of the radiation protection events notified by the radiotherapy centres. It is planned to publish this report, which concerns the years 2008-2009, early in 2011.

Over the last few years, alongside its inspection tasks, and associating where necessary the Advisory Committee for Medical Exposure (GPMED) or the IRSN, ASN has taken initiatives to request specific expert investigations or organise national or international events in what it considers to be priority domains given the stakes in terms of radiation protection.

Thanks to all these actions, ASN can assess the situation of radiation protection in the medical field.

5|1 Exposure situations in the medical field

5|1|1 Exposure of health professionals

The risks associated with medical applications using ionising radiation for medical staff are either external exposure risks, generated by the medical equipment (devices containing radioactive sources, or X-ray generators or particle accelerators), or internal contamination risks resulting from the use of non-sealed sources (radiopharmaceuticals in particular). The risks of health professionals being exposed to ionising radiation come under the provisions of the Labour Code relative to the radiation protection of workers.

5|1|2 Exposure of patients

Exposure of patients to ionising radiation differs from the exposure of other people (workers, population) because it is not subject to any limitations, with only the justification and optimisation principles being applicable. This is in fact the only situation in which ionising radiation is intentionally delivered to individuals, in this case, patients. The situation differs depending on 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 must be achieved by delivering the minimum dose required to obtain relevant diagnostic data, while in the second, the dose needed to destroy the tumour must be delivered, while maximising preservation of the surrounding healthy tissue.

Optimisation of the dose delivered to the patient depends on the quality of the equipment used along the entire preparation and treatment chain, from acquisition of the diagnostic image (X-ray generator, gamma-camera, image acquisition and processing system, etc.) to the actual treatment itself (linear accelerators, preparation and planning systems, etc.). All of these systems must be periodically inspected. The examination and treatment procedures and the equipment settings and programming also play an important role in implementing the optimisation principle.

Lastly, the progressive implementation of training of health professionals in the radiation protection of patients, which became compulsory in 2004, is of major importance to improve the radiation protection of patients in all domains.

5|1|3 Exposure of the population and impact on the environment

With the exception of incident situations, the potential impact of medical applications of ionising radiation potentially concerns:
- the professional categories liable to be exposed to effluents or waste produced by nuclear medicine units;
- members of the public, if the premises containing installations emitting ionising radiation are not fitted with the required protection;
- persons close to patients having received a treatment or a nuclear medicine examination that uses radionuclides such as iodine 131.

The available information concerning radiological monitoring of the environment carried out by IRSN, in particular measurement of ambient gamma radiation, on the whole reveals no significant exposure level above the variations background radiation. 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 (source: IRSN study, 2005). However, no trace of these radionuclides has ever been measured in water intended for human consumption.

The recommendations made by the physician after using radionuclides in nuclear medicine were the subject of the specific work by the French High Public Health Council, particularly

Positioning a patient for a computed tomography scan

Set-up for measuring wastewater radioactivity

with respect to examinations and treatment using iodine 131. The aim was to harmonise the advice on lifestyle already dispensed by each physician. The recommendations, which were published by ASN in 2007, concern the residual activity after hospitalisation (in the case of therapy using high activity levels) or the activity level administered if the patient receives iodine 131 without hospitalisation (exploration or treatment of hyperthyroidism).

5|2 Some general indicators

5|2|1 Authorisations and registrations

In 2010, ASN issued:
– 5,367 acknowledgements of receipt of declarations of medical and dental radiodiagnostic devices, of which nearly 71% concerned dental radiology devices;
– 614 authorisations (for entry into service, renewal or cancellation), of which 266 were in computed tomography, 169 in nuclear medicine, 133 in external-beam radiotherapy, 34 in brachytherapy and 12 for blood product irradiators.

5|2|2 The dosimetry of medical staff

According to the data collected by IRSN in 2009, 179,045 people working in sectors using ionising radiation for medical purposes, that is to say more than 56% of all exposed workers monitored, all activity sectors included, were subject to dosimetric surveillance. Medical radiology alone accounts for nearly 65% of the medical staff exposed.

In all, more than 98% of the health staff monitored in 2009 received an annual effective dose of less than 1 mSv, while 8 cases exceeding the annual effective dose limit of 20 mSv, and 3 exceeding the annual dose limit at the extremities (500 mSv) were recorded (in the radiology sector).

5|2|3 Assessment of significant radiation protection events

ASN was notified of 419 significant radiation protection events (ESR) in the medical domain in 2010, compared with 318 in 2009. This increase probably results from stricter application by the health professionals of the notification obligation, which was created in 2001, combined with ASN's publishing of a notification guide in 2007.

It is thus found that, depending on the domain of activity:
– 66% of significant events were notified in radiotherapy, of which 4% were in brachytherapy;
– 18% in nuclear medicine;
– 13% in diagnostic and dental radiology;
– 3% in interventional radiology.

According to the signification radiation protection event notification criteria defined by ASN (see ASN Guides 11 and 16):
– 63% of ESRs concerned exposure of a radiotherapy patient;
– 9% exposure of a radiodiagnosis patient (wrong patient, error in the administration of a radiopharmaceutical, appearance of a radio-induced effect);
– 8% exposure of the foetus in women unaware of their pregnancy at the time of a radiodiagnostic examination;
– 7% exposure of medical staff;

– 6% an event relating to the management of radioactive sources or waste and effluents (leak or overflow of radioactive effluent retention tanks, uncontrolled discharges, loss of sources);
– 5% any other event that can have radiation protection consequences (software malfunction, incorrect packaging, incorrect procedure, etc.);
– 2% exposure of the public.

Diagram 2: Distribution of the monitored populations and collective doses in the medical sector in 2009 (source: IRSN 2010)

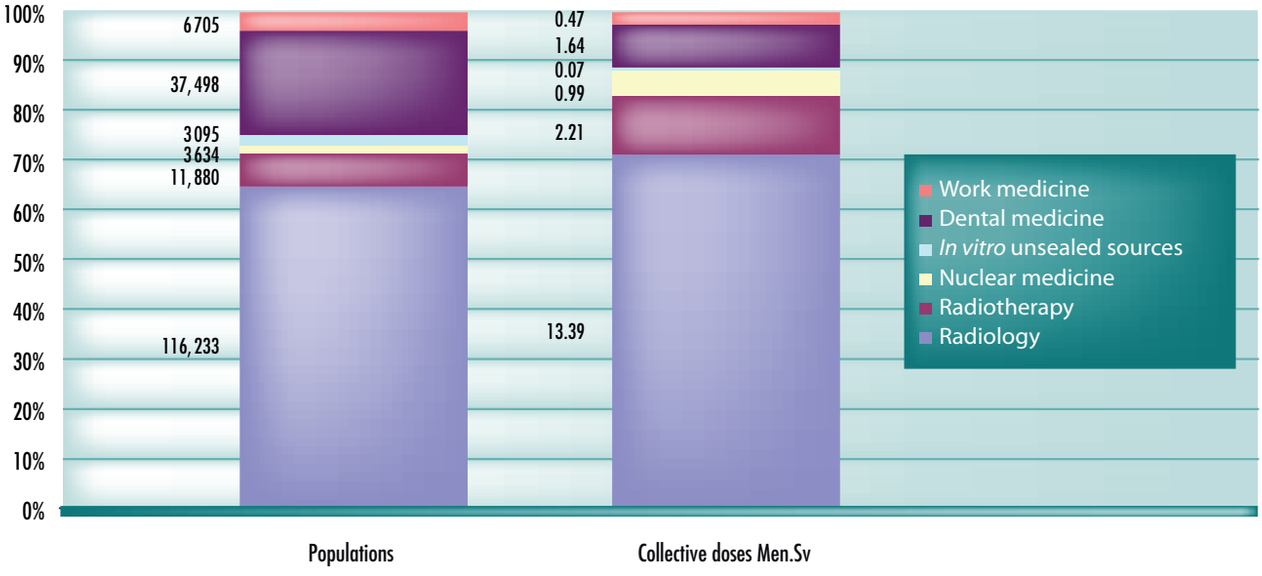


Diagram 3: Distribution of significant radiation protection events notified to ASN in 2010, per sector

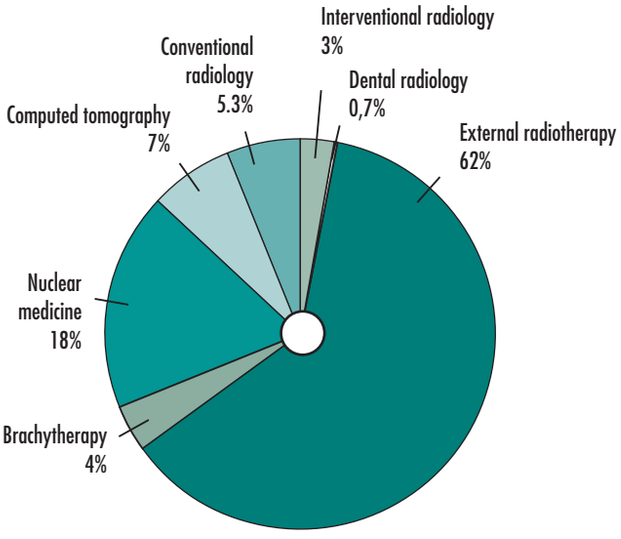
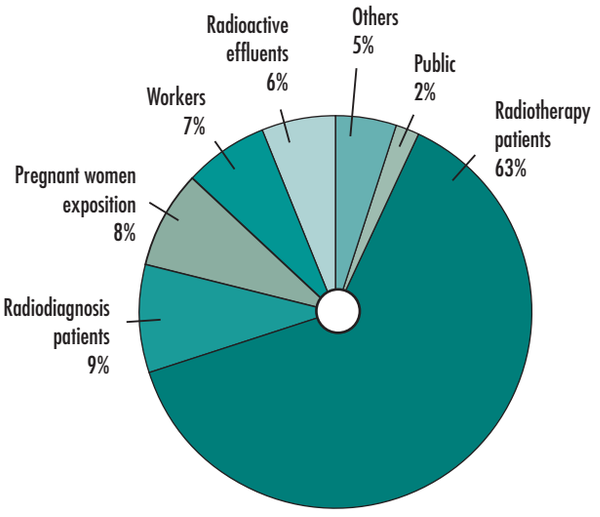


Diagram 4: Distribution of significant radiation protection events notified to ASN in 2010 per notification criterion



Events concerning medical staff: 31 events notified in 2010 compared with 9 in 2009

During 2010, ASN received 31 notifications of significant radiation protection events concerning persons working in medical facilities:
– 11 in nuclear medicine (exposure or contamination of staff when handling or preparing radiopharmaceuticals);
– 4 in radiotherapy (unexpected presence of staff in room during patient exposure);
– 5 in interventional radiology (significant exposure of operator's extremities with exceeding of the annual dose limit);
– 11 in radiology, of which 4 were in computed tomography (exposure of staff in room during the examination) and 2 in dental radiology (significant exposure of workers recorded by passive dosimetry).

It is noteworthy that 5 events were classified level 1 on the INES scale: they concern workers having exceeded one of the annual exposure limits in interventional radiology (2 cases of exceeding the annual exposure limits for the fingers), in diagnostic radiology (2 cases of exceeding the annual exposure limits due to failure to wear personal protective equipment, PPE, and inappropriate practices in dental radiology) and in nuclear medicine (a pharmacy dispenser exceeded the annual dose limit further to iodine 131 contamination after taking a sample of liquid iodine 131 solution for a therapeutic treatment).

Events concerning patients: 302 events reported in 2010 compared with 271 in 2009

In 2010, 302 significant events concerning patients exposed for diagnostic or therapeutic purposes were notified to ASN. The events were divided as follows: 254 in external-beam radiotherapy and 11 in brachytherapy, 19 in nuclear medicine and 18 in radiology.

Events concerning radiotherapy patients: 265 events notified in 2010 (of which 11 were in brachytherapy) compared with 244 in 2009

The notification of significant radiation protection events in radiotherapy has become predominant, representing nearly 66% of the notifications. The number of notifications received by ASN is slightly up on 2009. Furthermore, the number of centres having made at least one notification has increased to 80% of centres compared with 71% at the end of 2009. Seven external radiotherapy events were classified level 2 on the ASN-SFRO scale (versus 16 in 2009) and 171 events were classified level 1.

The second ASN/AFSSAPS report to be published in early 2011 presents a synthesis of the 519 significant radiation protection events in external radiotherapy notified to ASN, and of the 161 incidents or serious incident risks reported concerning radiotherapy devices declared to the AFSSAPS for 2008 and 2009 on account of medical device surveillance.

The trends observed during the experimental period (July 2007 to June 2008) have been confirmed, since the majority of events notified in 2008 and 2009 were linked to organizational and human failings (96%). ASN observes that the immediate causes (patient identification error, reference point error, omission of wedge filter, etc.) are usually identified by the notifying establishments, as are the first-level causes such as operator carelessness, communication error, failure to follow a protocol or to seek aid. This being said, the analysis made by the establishments still usually remains focused on the individuals involved in the event, and too rarely on the aspects relating to the context, work organisation, etc., which are nevertheless often predominant.

Consequently, the analysis of these events leads to corrective measures such as “reminder of operating instructions”, “training of the operator who made the error”, and sometimes the “addition of check points”, but the underlying root causes associated with the organisation of the units, the working environment or the institutional context are insufficiently examined. If the root causes are not addressed by suitable corrective measures, they could cause further events.

On the whole, ASN found that the analyses were performed without applying a set methodology (analysis methods inexistent or only partially deployed) resulting from a lack of skills, and above all a lack of time, on the part of the teams. This situation should change for the better with the obligations concerning the management of malfunctions and undesirable situations imposed by ASN decision 2008-DC-103 of 1 July 2008.

Moreover, since July 2008, the significant radiation protection events classified as level 1 on the ASN-SFRO scale - apart from serial events - are summarized in quarterly reports that do not indicate the names of the notifying establishments. These quarterly reports are published on the ASN website.

Events concerning nuclear medicine and radiology patients: 33 events notified in 2010 compared with 27 in 2009

These significant radiation protection events are often associated with a patient identification error (same name, lack of identification vigilance) or a radiopharmaceutical administration error (syringe labelling error, sample taken from wrong bottle).

Two events in interventional radiology were reported, one further to the observation of transient alopecia, the other due to the probability of occurrence of erythema.

Events concerning pregnant women: 39 events declared in 2010 compared with 12 in 2009

ASN was notified of 39 significant events concerning the public during 2010. They were essentially notifications of foetal exposure in women who were unaware of their pregnancy during a diagnostic radiological examination (14 in nuclear medicine and 25 in radiology).

Events concerning radioactive sources: 7 events notified in 2010, the same number as in 2009

In 2010, ASN was notified of five significant events involving losses of radioactive sources used in the medical field. These were sources used in nuclear medicine (technetium generator) and brachytherapy (iodine 125 seeds).

Two notifications reported a delivered source activity (iodine 131 capsule) that did not correspond to the activity that should have been administered.

Finally, ASN was notified of 16 events involving the dispersion of radionuclides, compared with five in 2009. These chiefly concerned leaks of radioactive effluents after the rupture or obstruction of pipes in the system carrying the radioactive effluents to the retention tanks (5 events) or the discharging of waste to an inappropriate treatment process (9 events).

To summarise:

Since 2008, the reporting of significant radiation protection events in the medical field has increased by more than 50%, reaching 419 annual notifications at the end of 2010 (i.e. an average of 35 declarations per month).

The reporting of significant radiation protection events is highest in radiotherapy, which accounts for nearly 66% of the notifications, and the numbers of centres that have never notified an event is dropping.

Although there are few significant radioprotection events concerning medical staff, the number is rising and their level on the INES scale shows that these events reflect either particularly exposing practices (long-duration interventional radiology procedures, radiopharmaceutical preparations), or professionals who are particularly and regularly exposed due to their expertise or their area of competence ("senior" consultants or radiopharmacists), whether in interventional radiology or nuclear medicine.

5|3 The radiation protection situation in radiotherapy

Radiotherapy

The safety of radiotherapy treatments has been a priority domain for ASN control since 2007, and each year all the radiotherapy centres are inspected. Furthermore, ASN actively participates in the work of the national committee for radiotherapy monitoring coordinated by INCa. In this context, the complementary actions to be incorporated in the radiotherapy roadmap, resulting from the conclusions of the international conference on the radiation protection of patients organised by ASN in Versailles in December 2009, were studied in 2010. The conclusions of this conference were jointly scrutinised by all the players concerned in order to identify the actions to supplement the national radiotherapy plan coordinated by INCa. This subject will be examined by the national plan monitoring committee in 2011.

Stereotactic radiotherapy

After the radiotherapy accident that occurred in the Rangueil hospital centre (Toulouse) between April 2006 and April 2007, and in addition to the notice issued in 2009 on the measurement of the absorbed dose in the very small photon beams used in stereotactic radiotherapy (see ASN decision 2009-DL-0009), GPMED issued a notice at the end of 2010 on the conditions of practising stereotactic radiotherapy and the associated medical physics. The opinion of GPMED, the report of the associated working group and the position of ASN on this subject will be made public in 2011.

5|3|1 Radiation protection of radiotherapy staff

The results of the inspections performed in 2009 and published in early 2011 revealed that in many centres there are large deviations from the provisions of the Labour Code relative to the procedures and safety instructions for the prevention of the irradiation risk after being accidentally shut in the treatment room.

TO BE NOTED IN 2010

Event notified by the GROP (Pau, June 2010)

In June 2010, the GROP (Pyrenees Radiotherapy and Medical Oncology Group) in Pau notified ASN of a significant radiation protection event affecting a patient. The event resulted from a problem in the transfer of irradiation parameters between the treatment planning system (TPS) and the record and verify (R&V) system. The result was that the patient, who was being treated for a head and neck cancer, received an overdose on the spinal cord. This significant event was provisionally classified at level 2 on the ASN-SFRO scale because the clinical consequences were not confirmed on the date of event classification.

The investigations conducted by ASN and AFSSAPS after AFSSAPS had sent a national alert to those centres that used a similar software combination, concluded that three centres had heard about the problem before the national alert was initiated, and that the majority of the centres did not use the configuration at risk used by the GROP. One centre found, through a retrospective analysis, that it had delivered fields with an incorrect jaw position to nine patients. For these nine patients however, the use of a multi-leaf collimator had limited the excess dose delivered, estimated by the centre at between 0.5% and 1%.

5|3|2 Radiation protection of radiotherapy patients

Status of human resources in medical physics

The inspections carried out by ASN in 2009 confirmed the increase in human resources dedicated to medical physics, which began in 2008. The third interim report of the national committee for radiotherapy monitoring (July 2010) states that the number of medical physicists working in radiotherapy at the beginning of 2010 attained 448 full-time equivalent (FTE), that is to say an increase of almost 50% since 2003.

Nevertheless, as in the previous year, ASN observed that at the end of 2009, the situation with regard to the organisation of medical physics remained fragile in several centres (about a dozen), notably those staffed with too few medical physicists. This situation has led ASN to declare the temporary closure of four centres. Furthermore, the measures taken in these centres to cope with absences of medical physicists of less than and more than 48 hours should be more clearly specified.

Assessment of treatment safety

The inspections also confirm a positive development in the implementation of management of the safety and quality of radiotherapy treatments. Inspection results show a true mobilisation of the health professionals under the national radiotherapy plan coordinated by INCa. ASN nevertheless notes considerable differences in progress and levels of involvement of departments, from one centre to another.

The situation regarding control of treatment preparation and delivery is considered satisfactory on the whole. With regard to risk management, however, the preliminary risk analyses are not widely implemented, firstly because they will not be obligatory for some time yet, and secondly owing to the lack of time and/or more specific skills in this field.

Making internal notifications of malfunctions and analysing them, on the other hand, are now common practice. This being said, further progress is required in the analysis of causes, in the medium- and long-term follow-up of treatment safety and quality management system improvements, and in the internal circulation of information on malfunctions and the improvements made.

5|3|3 Summary

To conclude, the progress made by radiotherapy centres in terms of organisation and control of patient care is considered encouraging. The effort must nevertheless be continued, when one considers that about half of the centres did not comply with certain regulatory obligations - that were not binding in 2009 - designed to ensure treatment safety (*in vivo* dosimetry, double calculation of monitor units, etc.).

ASN therefore considers highly positive the findings that demonstrate the awareness and responsiveness of the professionals regarding safety culture, the formalising of practices and the management of treatment-related risks. Mobilising the players in these areas must remain a priority in order to meet all the regulatory obligations that will be binding by the end of 2011.

5|4 The radiation protection situation in nuclear medicine

5|4|1 Radiation protection of nuclear medicine staff

The assessment of radiation protection in nuclear medicine in 2009 drawn up and published by ASN, and based on the inspections carried out in 2008 on approximately one third of the installations, underlined the shortcomings in worker radiation protection in many nuclear medicine units. The inspections carried out by ASN in 2009 on another third of the installations confirmed this result.

Thus, of the nuclear medicine units inspected, nearly half (34 units) still do not have supervised areas established on the basis of a risk assessment. This situation can be partly explained by the difficulties professionals have had in implementing the requirements of the order of 15 May 2006 relative to the delimiting and signalling of regulated areas in nuclear medicine services.

5|4|2 Radiation protection of nuclear medicine patients

The report published in 2009 on the inspections carried out by ASN in 2008 had also shown that on the whole the regulatory requirements for the radiation protection of patients were satisfied in the nuclear medicine units. It also indicated that the majority of the nuclear medicine units had a medical physicist. This observation must however be qualified, as the conditions of intervention of these physicists remain to be specified in most nuclear medicine units.

Lastly, the ASN inspections in 2008 had shown that few nuclear medicine units had been able to stay ahead of the regulatory deadlines for training staff in the radiation protection of patients, except as far as physicians were concerned. The inspections carried out in this area of activity in late 2009 show that a percentage of the medical staff concerned has still not received this compulsory training.

5|4|3 Protection of the population and the environment

Several significant radiation protection events notified in 2009 and 2010 chiefly concerned overflowing of contaminated liquid effluent storage tanks, leaks of pipes carrying contaminated liquid effluents, and triggering of radiation portal monitors. This led ASN to organise information actions to reiterate the prevention rules for nuclear medicine units.

The inspections conducted by ASN in 2009 show that nearly 80% of the nuclear medicine units inspected, i.e. some 60 units, have a waste and contaminated effluents management plan. Drawn up by the authorisation holder or the head of the establishment, this document specifies the provisions for disposing of contaminated waste and effluents. Although this aspect is globally satisfactory, progress must be made in numerous other areas to meet all the regulatory requirements introduced by ASN decision 2008-DC-0095, which sets the technical rules for the disposal of contaminated waste and effluents.

5|4|4 Summary

The main problems encountered in nuclear medicine concern non-compliance with the Labour Code requirements regarding risk and work station analyses, which often are not carried out, and application of the ASN technical decision on the disposal of (low-level) radioactive effluents in the public sewage networks.

While quite aware of the licensee's responsibility in these matters, ASN has decided to prepare recommendations (guidelines) to facilitate application of the regulations. They should be available in 2011.

Dosimeter rack in the nuclear medicine unit of the North Saint-Denis Cardiology Centre

5|5 The radiation protection situation in conventional radiology and computed tomography

5|5|1 Radiation protection of radiology staff

Targeted inspections in some one hundred radiology centres in 2008 and 2009 showed that the radiation protection regulations for staff were fairly well adhered to in the majority of cases, although some centres were to rapidly implement corrective measures to remedy the observed deviations. These inspections were not updated in 2009. The possibility of calling upon an external person with competence in radiation protection (PCR) (ASN decision 2009-DC-0147 of 16 July

UNDERSTAND

Experience feedback on the prevention of leaks in the effluent pipes coming from nuclear medicine units

The nuclear medicine units of the Val d'Aurelle - Paul Lamarque Regional Centre for Cancer Care (CRLC) in Montpellier, and the La Pitié Salpêtrière Hospital Group in Paris, in collaboration with the Marseille division of ASN, published a thematic poster (see below) at the Conference of the SFRP in June 2009.

This poster was inspired by the lessons drawn from leaks in pipes in these two establishments carrying contaminated liquid effluents from the hospitalisation rooms of patients treated with iodine 131.

The analysis of these events moreover revealed that certain regulatory obligations had not been fulfilled, and notably:

- *the obligation to identify visible pipes containing or transporting hazardous substances or preparations;*
- *the obligation to train the staff likely to work in monitored and controlled zones, by informing them of the general rules of prevention and radiation protection, the particular risks and procedures associated with the work station occupied, and the course of action to follow if an abnormal situation arises;*
- *the obligation to draw up a prevention plan describing the prevention measures for workers from outside companies performing or helping to perform operations in the establishment.*

2009) appears to provide an initial solution to the shortcomings, but this new measure must nevertheless be assessed.

5|5|2 Radiation protection of radiology patients

The increase in doses delivered to patients in medical imaging in France (average increase approaching 50% since 2002)- as in all other western countries - and especially in computed tomography, should lead ASN to adopt a position on this subject in early 2011, with the publication of the conclusions of the seminar it organised on 16 September 2010 with all the professionals and organisations concerned.

The upward trend in the exposure of patients in medical imaging can be attributed to several factors:
– the increase in the number of examinations performed because of their diagnostic value;
– the increase in the number of computed tomography scanners, which deliver higher doses than conventional devices;
– the increase in the number of new examinations delivering high doses (whole body tomography, virtual colonoscopy, heart scan, etc.).

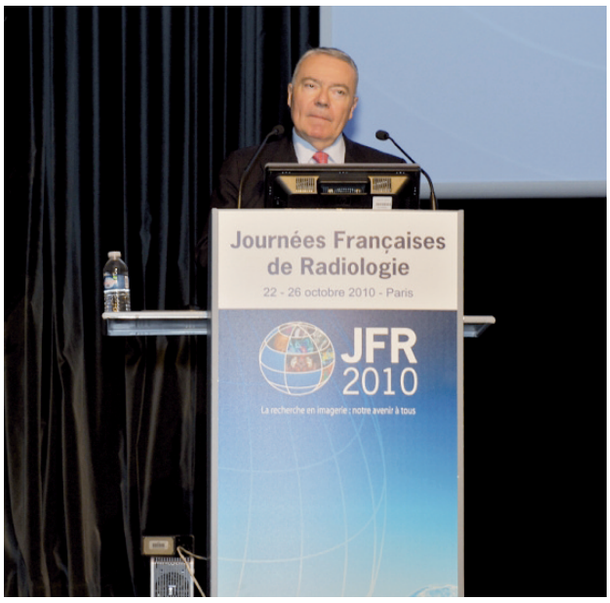
On the basis of the recommendations made at this seminar, ASN stresses the importance of the following two actions:
– the first aims at facilitating access to MRI by influencing the regional planning of high-investment equipment and promoting pricing policies that give more incentive to MRI;
– the second aims at continuing the training and recruitment of medical physicists: this began in 2008 to meet the urgent needs in radiotherapy, and must be continued for at least five years in succession to satisfy demand for medical imaging professionals.

5|5|3 Summary

Conventional radiology and computed tomography are not priority inspection areas for ASN, given the low risks of staff/worker exposure and the dose levels delivered to patients, which are much lower in medical imaging than in radiotherapy. This being said, the continuing increase in average doses for patients in France and internationally, due to the increase in computed tomography procedures and insufficient utilisation of the optimisation potential of the new equipment has led ASN to boost its actions in this area in 2011. At European level, ASN is participating in the initiative taken by HERCA (heads of the European radiological protection competent authorities) to encourage computed tomography scanner manufacturers to improve the optimisation tools on their equipment.

5|6 The radiation protection situation in interventional radiology

Since 2009, the regulation of radiation protection in interventional radiology has become the second subject of concern for ASN. Tasked with investigating this question, the GPMED (Advisory Committee for medical exposure) has submitted its conclusions to ASN, based on the report of the ad hoc working party. The results of this work will be published at the beginning of 2011, along with the position of the ASN, and the results of the inspections carried out in 2009.



André-Claude Lacoste, Chairman of ASN, giving a conference at the SFR Annual Convention – October 2010

5|6|1 Radiation protection of interventional radiology staff

The report on the inspections performed in 2009 (published in 2011) is drawn from the results of more than one hundred inspections of some 250 units practising interventional radiology. It shows that the radiation protection of workers, particularly where professional exposure is concerned, is better integrated in fixed radiology facilities than in operating theatres where mobile devices are used. Considered as a whole, the inspections reveal incomplete application of dose optimisation due to lack of training and/or inappropriate equipment, negligence in the wearing of personal protective equipment and dosimeters, the lack of medical monitoring of the practitioners, the lack of monitoring by dosimetry of extremities, and deficiencies in knowledge of the obligations to notify ASN of significant radiation protection events.

This report also highlights methodological and organisational difficulties encountered by PCRs in fulfilling their duties..

5|6|2 Radiation protection of interventional radiology patients

As with the medical staff, the radiation protection of patients appears to be better in fixed facilities than in operating theatres, particular with regard to the adaptation of the radiological equipment to the medical procedures performed. On the whole, the inspections reveal incomplete application of dose optimisation due to a lack of training and/or appropriate equipment, the lack of medical physicists to set up dose optimisation, the absence of radiation protocols for the majority of procedures performed in the operating theatre, and sub-optimal knowledge of the doses emitted during the procedures.

5|6|3 Summary

The expert investigations by the GPMED in 2010 and the results of the inspections performed in 2009 show that there is substantial room for improvement in the radiation protection of staff and patients in interventional radiology, and in particular in the operating theatres in which numerous image-guided surgical procedures are performed.

The question of human resources and the associated skills, particularly for the tasks assigned to PCRs and medical physicists, is determining for effective implementation of optimisation procedures, especially given that the new devices have considerable potential for dose reduction without compromising medical precision.

User awareness-raising and training also represent a major avenue for progress.

Dosimeter worn by medical personnel in the nuclear medicine unit of the North Saint-Denis Cardiology Centre

6 OUTLOOK

With a cure rate of about 80% of patients treated (i.e. some 50% of patients suffering from cancer), radiotherapy is a fully justified method of cancer treatment. However, given the organisational weaknesses detected by inspection in some radiotherapy centres, ASN - with the assistance of its regional divisions - will be maintaining its inspections in all radiotherapy centres at least until 2012. It will be particularly vigilant with regard to the effective increase in medical physics staffing levels, to compliance with the interim criteria published in July 2009 by the Minister for Health and to the gradual development of quality assurance, for which the first requirements have been binding since the beginning of 2010.

2011 is a reference year in that the activity authorisation criteria for radiotherapy care, defined by INCa become fully applicable, especially the criterion concerning the presence of the medical physicist during treatments. In this context, ASN shall be particularly attentive to the centres in which, due to staff shortages, it will be necessary to call upon external service providers or to set up inter-centre cooperation arrangements to meet the medical physics needs. Over and beyond the difficulty of strictly complying with the formal obligation to ensure the effective presence of the medical physicist during treatments, ASN shall endeavour to verify the robustness of the medical physics organisation, particularly in the GCS's (health care cooperation groups). In this respect, ASN would not be against clarifying the regulatory criterion concerning the presence of the medical physicist during treatments, by introducing the notion of a medical physics team comprising medical physicists and dosimetry technicians.

As far as staff radiation protection is concerned, compliance with the provisions of the Labour Code relative to prevention of the irradiation risk after being accidentally shut in a treatment room, and the associated safety rules, is a priority short-term objective. Radiation protection inspectors shall be instructed to apply coercive measures in cases where these divergences are not remedied in 2010.

Recourse to increasingly high-performance medical imaging, particularly in computed tomography, seems justified to improve diagnostic quality and better orient therapeutic strategies. With interventional practices, imaging can also be used to guide the intervention and ensure greater precision for the benefit of the patient.

Particular attention must nevertheless be paid to the increases in doses of ionising radiation delivered to patients. Consequently, ASN will closely monitor the national implementation of actions under the responsibility of the Minister for Health, particularly regarding the development of the number of non-irradiating imaging techniques (MRI in particular). It will also, in cooperation with the professionals, actively support the development of decision aids to support application of the principle of justification, and the continued increasing of staffing levels in medical physics, which guarantee true application of the principle of optimisation of doses delivered to patients.

As of the beginning of 2011, ASN should state its position on the necessary improvement of radiation protection of staff and patients in interventional radiology, especially in the operating theatres in which numerous image-guided interventions are performed. The question of human resources and the associated skills - particularly for the tasks ensured by PCRs and medical physicists - and the question of user training when new equipment is put into service will be at the core of ASN recommendations.