

1	MEDICAL AND DENTAL RADIODIAGNOSIS INSTALLATIONS	253
1 1	Presentation of the equipment inventory	
1 1 1	Medical radiodiagnosis	
1 1 2	Interventional radiology	
1 1 3	Dental radiodiagnosis	
1 2	Technical rules for radiology and tomography installations	
2	NUCLEAR MEDICINE	258
2 1	Presentation of nuclear medicine activities	
2 1 1	<i>In vivo</i> diagnosis	
2 1 2	<i>In vitro</i> diagnosis	
2 1 3	Targeted internal radiotherapy	
2 1 4	The new nuclear medicine tracers	
2 2	Nuclear medicine unit organisation and operating rules	
3	EXTERNAL-BEAM RADIOTHERAPY AND BRACHYTHERAPY	261
3 1	Description of the techniques	
3 1 1	External-beam radiotherapy	
3 1 2	Brachytherapy	
3 1 3	The new radiotherapy techniques	
3 2	Technical rules applicable to installations	
3 2 1	Technical rules applicable to external-beam radiotherapy installations	
3 2 2	Technical rules applicable to brachytherapy installations	
4	BLOOD PRODUCT IRRADIATORS	265
4 1	Description	
4 2	Blood product irradiator statistics	
4 3	Technical rules applicable to installations	
5	THE STATE OF RADIATION PROTECTION IN THE MEDICAL FIELD	265
5 1	Exposure situations in the medical field	
5 1 1	Exposure of health professionals	
5 1 2	Exposure of patients	
5 1 3	Exposure of the general public and environmental impact	
5 2	Some general indicators	
5 2 1	Authorisations and declarations	
5 2 2	Dosimetry of medical staff	
5 2 3	Report on significant radiation protection events	
5 3	The radiation protection situation in radiotherapy	
5 3 1	Radiation protection of radiotherapy staff	
5 3 2	Radiation protection of radiotherapy patients	
5 3 3	Summary	

5 4	The radiation protection situation in nuclear medicine	
5 4 1	Radiation protection of nuclear medicine staff	
5 4 2	Radiation protection of nuclear medicine patients	
5 4 3	Protection of the general public and the environment	
5 4 4	Summary	
5 5	The radiation protection situation of patients in conventional radiology and computed tomography	
5 6	The radiation protection situation in interventional radiology	
5 6 1	Radiation protection of interventional radiology staff	
5 6 2	Radiation protection of interventional radiology patients	
5 6 3	Summary	
6	OUTLOOK	275

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 general public to ionising radiation. Behind exposure to natural ionising radiation, they represent the second source of exposure for the general public 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, to obtain an image of diagnostic quality or the desired therapeutic effect, the doses must reach a certain level.

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 the French 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



Mammography examination

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, which can however mean that more images are taken, which runs contrary to the 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 radiologists can exchange opinions by asking a remote expert radiologist (“teleradiologist”) to refine and/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

Interventional radiology concerns “all invasive diagnostic and/or therapeutic medical procedures, as well as surgical procedures using ionising radiation for per-procedural guidance, including monitoring¹”.

This involves techniques that use fluoroscopy with an image intensifier or flat panel detector 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.) as well as during surgical procedures using ionising radiation to guide or monitor the surgeon’s actions. They might require long-term exposure of the patients, who then receive high doses which can sometimes lead to radiation-related deterministic effects (cutaneous lesions, etc.). The staff are usually working in the immediate vicinity of the patient and are also exposed to higher dose 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



ASN “interventional radiology” inspection at the Villefranche-de-Rouergue university hospital – December 2010

1. Definition from the Advisory Committee for medical exposure (reporting to 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.

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 the practical aspects of ensuring operator protection.

1.2 Technical rules for radiology and computed tomography installations

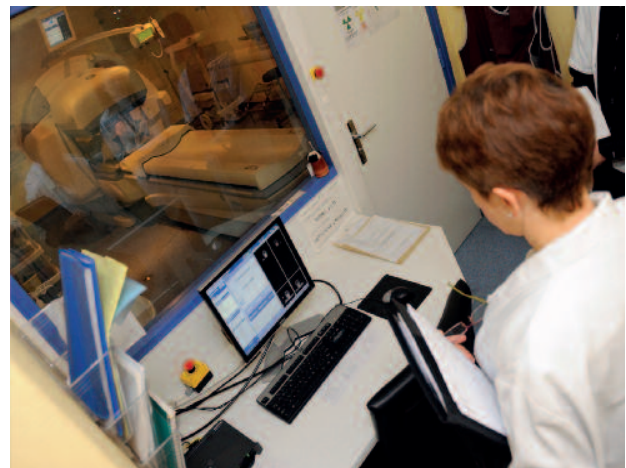
Radiology installations

A conventional radiological installation comprises a generator (high-voltage unit, X-ray tube and control unit), associated with a support 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 devices must bear the CE marking, which has been mandatory since June 1998. This certifies that the device is in conformity with the essential requirements of health and safety mentioned in articles R. 5211-21 to 24 of the Public Health Code. It should be noted that the 25-year limit on the lifetime of the generators was abrogated by the order of 1st December 2011, amending the order of 14 May 2004 concerning the general licensing and registration regime defined in chapter V-I "ionising radiation" of the Public Health Code. This duration had been set before the periodic quality controls on medical devices stipulated by a decision of the Director General of the AFSSAPS became mandatory. These ensure that the long-term performance of the medical devices



ASN inspection on the CT installation in the nuclear medicine unit of the Oscar Lambret centre in Lille – November 2011

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 therapy² installations (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.

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

is maintained. The regulations concerning medical devices also enable bans to be issued, as applicable, for any equipment that proves to be obsolescent.

Computed tomography installations

Computed 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 computed tomography device can therefore only be installed in a room with a surface area of at least

20m² and in which no linear dimension is smaller 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 1.5mm of lead, depending on the purposes for which the adjoining rooms are used. The French radiological equipment pool comprised 905 computed tomography installations in 2009 (figure provided by France's Court of Audit). This figure would rise to about 1,150 if the devices used for radiotherapy simulation were included. The 25-year limit on the lifetime of the generators was abrogated by the above-mentioned order of 1 December 2011, amending the order of 14 May 2004.

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 90 positron emission tomographs (PET) in service at the end of 2011. Forty nuclear medicine units are equipped with targeted internal radiotherapy rooms.

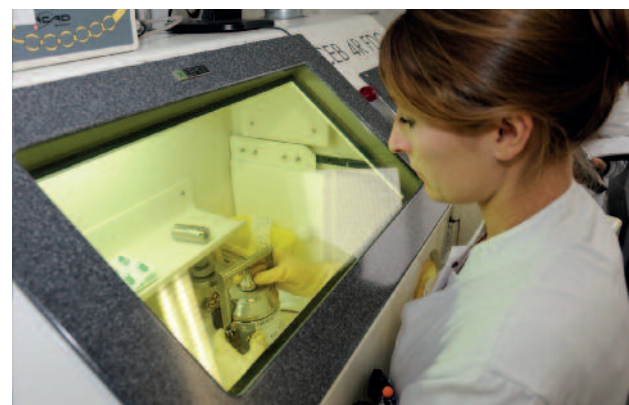
Nuclear medicine comprises about 500 specialist practitioners, to whom should be added 1,000 physicians working jointly with the nuclear medicine units (internists, cardiologists, endocrinologists, etc.).

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 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.

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



Handling of radioactive products during the inspection of the nuclear medicine unit of the Oscar Lambret centre in Lille – November 2011

The radioactive material administered, usually technetium-99m, is located in the organism by a specific detector – called a scintillation camera or gamma-camera – which consists of a sodium iodide scintillation crystal (in most cameras) 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.

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 (*radioimmunity assay*). The activity levels present in the analysis kits designed for a series of assays do not exceed a few kBq. Radioimmunity 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 targeted internal radiotherapy.

In 2009, clinical tests continued into the use of various fluorine-18 tracers in PET and antibodies labelled with yttrium-90 in targeted 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 design 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 (radioimmunity for instance). Provision is 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;



ASN inspection on the outfitting work in the nuclear medicine unit's premises in the Oscar Lambret centre in Lille – November 2011

- 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 updating the design rules for nuclear medicine units (see box).

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.

In 2010, ASN began work on updating the design rules for the premises in which nuclear medicine is carried out. A report defining the orientations and requirements was drawn up jointly with representatives of the profession. It will be presented to the Advisory Committee for medical exposure (GPMED) in early 2012 and an ASN technical decision will then be published.

TO BE NOTED

3 EXTERNAL-BEAM RADIOTHERAPY AND BRACHYTHERAPY

3|1 Description 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 beam 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.

At the end of 2010, the external beam radiotherapy installations comprised 439 treatment devices, including 419 isocentric linear accelerators (see points 3|1|1 and 3|1|3). These facilities are installed in 176 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, INCa).

3|1|1 External-beam 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, as well as the duration of each treatment session. Preparation of this plan, which aims to set conditions for



ASN inspection of the Dentellières clinic in Valenciennes on the subject of commissioning a radiotherapy installation – October 2011

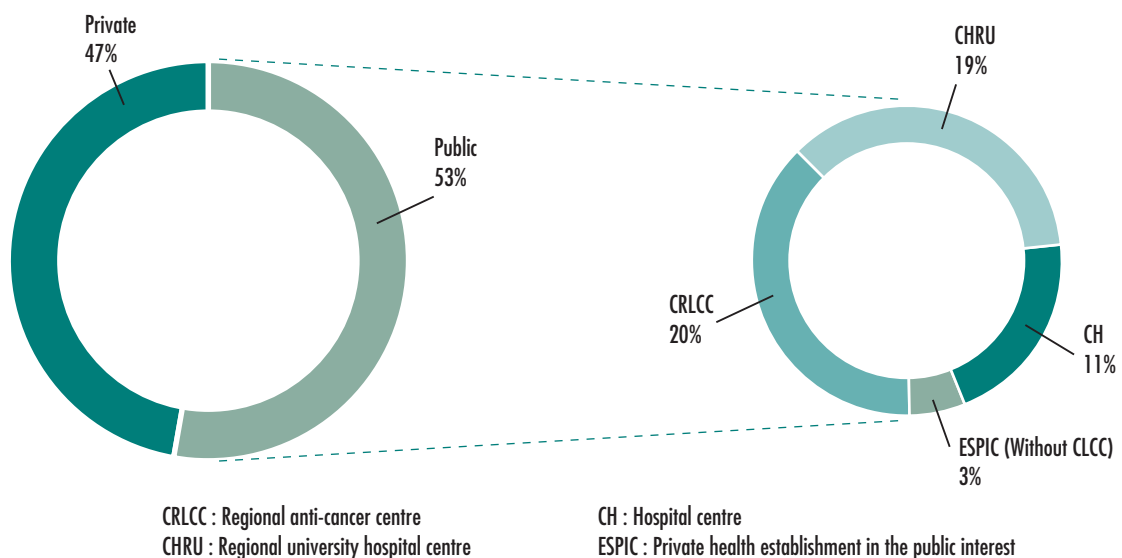
achieving a high dose in the target volume while protecting healthy tissues, requires close cooperation between the radiation oncologist and the medical physicist, but also the dosimetrists.

For the vast majority of treatments, irradiation uses linear particle accelerators with an isocentric arm, producing beams of photons or electrons with an energy ranging between 6 and 25 MeV and delivering dose rates of between 2 and 6 Gy/min.

For certain specific therapeutic indications (see point 3|1|3), a number of centres propose treatments that are made possible through the use of:

- a specific linear particle accelerator;
- a gammatherapy device equipped with more than 200 sources of cobalt 60 focused on a single point;
- a cyclotron producing proton beams.

Diagram 1: breakdown of the number of linear accelerators in France according to the status of the establishments



It must be remembered that in France, telegammatherapy devices are no longer used for patient treatment.

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 techniques to ensure precise localisation of the lesion. It is also more and more frequently used to treat cerebral metastases, but also for extracranial tumours.

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 (four units are currently in service in three facilities), and CyberKnife® which consists of a miniaturised linear accelerator mounted on a robotic arm (see detail in point 3.1.3);
- dedicated linear accelerators offering dynamic irradiation mode (Novalis®, five units currently in service);
- “conventional” linear accelerators, providing dynamic irradiation mode 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 H&N field, as well as of the skin, the breast or the genitals.

This technique consists in implanting radionuclides, exclusively in the form of sealed sources (iridium-192 wires, considered to

be unsealed sources, are a special case), either in contact with or inside the solid tumours to be treated.

The main radionuclides employed in brachytherapy are caesium-137 (¹³⁷Cs, half-life 30 years), iridium-192 (¹⁹²Ir, half-life-74 days) and iodine-125 (¹²⁵I, half-life 60 days).

Brachytherapy techniques involve three types of applications:

- **Low Dose-Rate (LDR) brachytherapy:**
 - delivers dose rates between 0.4 and 2 Gy/h;
 - using ¹⁹²Ir sources in the form of divisible wires, ¹³⁷Cs sources implemented using a specific source applicator. These sources are put into place for a limited duration;
 - using ¹²⁵I sources, in the form of seeds, installed permanently.

The iridium-192 sources, positioned inside tissues, take the form of wires 0.3 or 0.5 mm in diameter, with a maximum length of 14 cm at delivery and with an activity per unit length ranging from 30 MBq/cm and 370 MBq/cm.

The caesium-137 sources take the form of sealed sources 3 mm in diameter and 2 to 8 cm long. The brachytherapy ward must have a “library” of the various sources, corresponding to the types of applications the user wishes to employ. The sources are placed in a storage unit and transferred to the applicator system at the time of treatment.

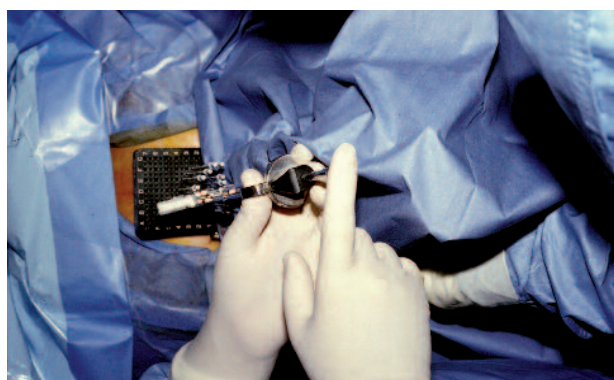
Low dose rate brachytherapy requires patient hospitalisation for several days in a room with radiological protection appropriate to the maximum activity of the radioactive sources emplaced (rooms with radiological protection) where the patient stays for the duration of his or her treatment (except for brachytherapy of the prostate with seeds of iodine-125 and ophthalmic brachytherapy).

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.

For the treatment of prostate cancers, iodine-125 sources are used. These sources, 4.5 mm long and 0.8 mm in diameter, are positioned permanently inside the patient's prostate gland. Their unit activity is between 10 and 30 MBq and treatment requires about a hundred seeds representing a total activity of 1 to 2 GBq.



Treatment of a brain tumour by multi-beam stereotactic radiotherapy



Brachytherapy of the prostate

Low dose rate brachytherapy requires that the following premises be available:

- 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;
- an area for radioactive source storage and preparation.

Low dose rate brachytherapy using sources of ^{192}Ir and sources of ^{137}Cs is in the process of being phased out. The technique using sources of ^{125}I (prostate and ophthalmic brachytherapy) is rapidly growing.

- **Pulsed Dose-Rate (PDR) brachytherapy:**
 - delivers dose rates of between 2 and 12 Gy/h;
 - using ^{192}Ir sources in the form of a source 3.5 mm long, 1 mm in diameter and maximum activity of 18.5 GBq, implemented with a specific remote-controlled afterloader.

This technique requires patient hospitalisation for several days in a room with radiological protection appropriate to the maximum activity of the radioactive source used.

This technique is based on the use of a single radioactive source, which delivers several pulses: the source moves step-wise along each application vector and stops in predetermined positions for predetermined times (the various parameters being set during planning of the treatment).

The doses delivered are identical to those of low dose rate brachytherapy, but are delivered in sequences of 5 to 20 minutes, or sometimes even 50 minutes, every hour for the duration of the planned treatment, hence the name pulsed dose-rate brachytherapy.

Pulsed dose-rate brachytherapy offers a number of radiation protection advantages:

- no handling of sources;
- no continuous irradiation, thus enabling the patient to receive medical care without irradiating the staff or having to interrupt the treatment.

However, it is necessary to make provision for accident situations related to the operation of the afterloader and to the high dose rate delivered by the sources used.

- **High Dose-Rate (HDR) brachytherapy:**
 - delivers dose rates in excess of 12 Gy/h;
 - uses ^{192}Ir sources in the form of a source 3.5 mm long, 1 mm in diameter and maximum activity of 370 GBq, implemented with a specific remote-controlled afterloader.

This technique requires no patient hospitalisation in a room with radiological protection and is performed on an out-patient basis, in a room with a configuration comparable to that of an external beam radiotherapy room. The treatment is performed with an afterloader containing a ^{192}Ir source and involves one or more sessions of a few minutes, spread over a period of several weeks.

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 beam radiotherapy treatment.

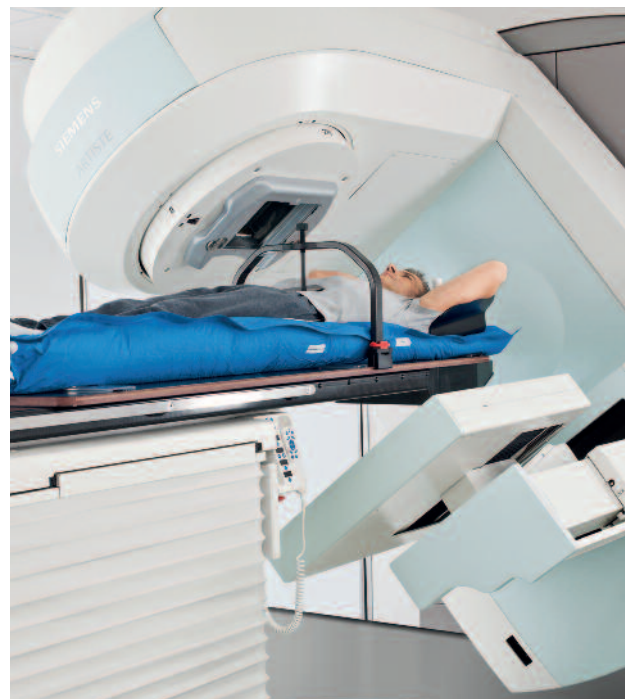
3|1|3 The new radiotherapy techniques

New techniques, called tomotherapy and “robotic” 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 computed 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 lesion which may be in anatomically independent regions. It is also possible to acquire images in treatment conditions and compare them with reference computed tomography images, in order to improve the quality of patient positioning. Eleven devices of this type have been installed in France since the end of 2006, and have been used to treat patients since the first quarter of 2007.

Stereotactic radiotherapy with a robotic arm consists in using a small particle accelerator producing 6 MV photons, placed on an industrial type robotic 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 synchronised with the patient’s breathing.

Given the movement capabilities of the robot and its arm, the radiation protection of the treatment room does not



Linear accelerator for IMRT and specialised treatments

correspond to the usual standards and will therefore require a specific study. Six installations of this type are in service in France in 2011, in Nancy, Nice, Lille, Lyon, Tours and Caen.

Following on from intensity modulated radiation therapy³ (IMRT), a new radiotherapy technique was recently developed and is being gradually introduced into France: volumetric modulated arc therapy. This technique, referred to differently (VMAT, RapidArc) depending on the manufacturer concerned, consists in irradiating a target volume by continuous irradiation rotating around the patient. Several parameters can vary during the irradiation: the shape of the multi-leaf collimator aperture, the dose rate, and the rotation speed of the arm.

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

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-beam radiotherapy installations

The devices must be installed in rooms specially designed to guarantee radiation protection of the staff, turning them into veritable 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 low dose rate 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 beam radiotherapy room.

3. For the duration of the session, the collimator leaves move while the beam is being emitted, thus modulating it in a complex manner.

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 a 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 2011, the French installations of this type totalled 31 irradiators in operation in blood transfusion centres, 9 with

radioactive sources and 22 with electrical generators and X-ray tubes.

The policy to replace source irradiators with X-ray irradiators, implemented in 2009, was slowed down by the lack of reliability of the X-ray generators, in particular with regard to electrical instability and problems with X-ray tube cooling. From now on, the companies installing these irradiators are proposing appropriate systems for avoiding recurring failures and guaranteeing the continuity of service to the patients.

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.

5 THE STATE OF RADIATION PROTECTION IN THE MEDICAL FIELD

Radiation protection in the medical field 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 moving around a health facility, or population groups that could be exposed to waste or effluents from nuclear medicine units.

As of 2008, ASN began to prepare regional reports 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. The following were published:

- the ASN reports of the radiation protection situation in the nuclear medicine units (published in 2009 for the 2008 inspections) and in interventional radiology (published in 2011 for the 2009 and 2010 inspections);
- the ASN reports of the safety of radiotherapy care (published in 2009 and 2011 for the 2008, 2009 and 2010 inspections).

As in 2009, ASN and the AFSSAPS jointly prepared a report of the radiation protection events notified by the radiotherapy centres. This report, concerning the years 2008-2009, was published 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.

These actions as a whole enabled ASN to draft a report of the state of radiation protection in the medical field (*Contrôle* magazine no. 192) which was presented to the press in July 2011.

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, general public) because it is not subject to any limitations, with only the justification and optimisation principles being applicable. This is in fact

Table 2: different exposure levels from medical examinations using ionising radiation

	Type of examination	Adult exposure value (effective dose in mSv)
Conventional radiology	Thorax (front)	0.02
	Pelvis (front)	0.7
	Mammography	0.6
Computed tomography	Head	1.3
	Thorax	9
	Abdomen – Pelvis	10
	Heart (CT angiography)	8 to 30
Scintigraphy (diagnostic nuclear medicine)	Skeleton	4
	Thyroid (99mTc)	0.5
	Lungs (ventilation and perfusion)	0.6 +1.1 or 1.7
	Cerebral (HMPAO)	3.6
	Myocardium with molecules marked with 99mTc	8
	Myocardium with 201Tl	23
	PET-Scan	10 to 20
Source IRSN, SFR, SFMN		



Check on medical staff dosimetry in the Oscar Lambret centre in Lille

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, treatment planning systems, etc.). Periodic quality controls must be performed on all of these systems. The examination and treatment procedures and the equipment settings also play an important role in implementing the optimisation principle.

Finally, the gradual implementation of patient radiation protection training for the health professionals, which has



Radiotherapy session at the Pitié Salpêtrière Hospital in Paris – May 2011

been mandatory since 2004, is a key factor in progressing towards improving the radiation protection of patients in all fields.

5|1|3 Exposure of the general public and environmental impact

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 in the 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 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 declarations

In 2011, ASN issued:

- 5,977 acknowledgements of receipt of declarations of medical and dental radiodiagnostic devices, of which nearly 70% concerned dental radiology devices;
- 661 authorisations (for entry into service, renewal or cancellation), of which 352 were in computed tomography, 155 in nuclear medicine, 125 in external-beam radiotherapy, 25 in brachytherapy and 4 for blood product irradiators.

5|2|2 Dosimetry of medical staff

According to the data collected by IRSN in 2010, 188,073 people working in sectors using ionising radiation for medical purposes, that is to say more than 57% of all exposed workers monitored, all activity sectors included, were subject to dosimetric surveillance. Medical radiology alone accounts for nearly 59% of the medical staff exposed.

In all, more than 98% of the health staff monitored in 2010 received an annual effective dose of less than 1 mSv, while 4 cases exceeding the annual effective dose limit of 20 mSv, and 4 exceeding the annual dose limit at the extremities (500 mSv) were recorded (in the interventional radiology field).

5|2|3 Report on significant radiation protection events

ASN was notified of 470 significant radiation protection events in the medical field in 2011, compared with 419 in 2010. On the whole, there is a significant rise in notifications in the nuclear medicine and computed tomography sector and a stable number of notifications in radiotherapy.

It is thus found that, depending on the domain of activity:

- 55% of significant events were notified in radiotherapy, of which 2% were in brachytherapy;
- 22% in nuclear medicine;
- 20% in diagnostic and dental radiology;
- 2% in interventional radiology;
- 1% in fields involving a mixed activity (radiotherapy and radiology or radiology and nuclear medicine).

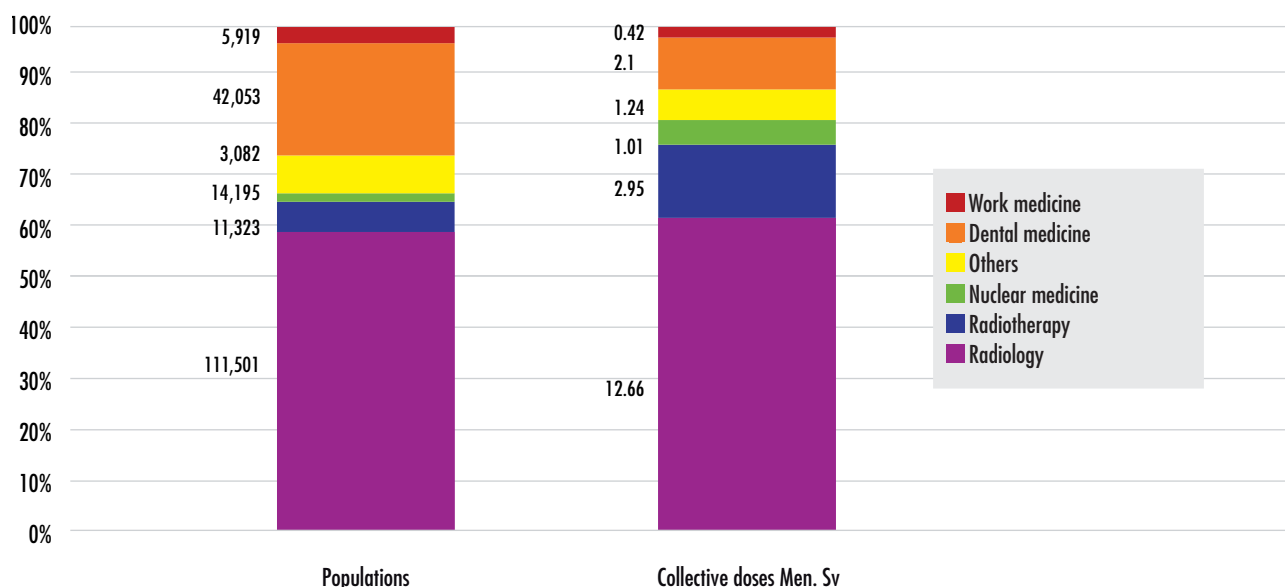
According to the signification radiation protection event notification criteria defined by ASN (see ASN Guides 11 and 16):

- 53% of events concerned exposure of a radiotherapy patient;
- 16% concerned exposure of a radiodiagnosis patient (wrong patient, error in the administration of a radiopharmaceutical, appearance of a radio-induced effect);
- 16% concerned exposure of the foetus in women unaware of their pregnancy



ASN-AFSSAPS report

Diagram 2: breakdown of population monitored and collective doses in the medical field in 2010 (source IRSN 2011)



- at the time of a radiodiagnostic examination;
- 7% concerned staff exposure primarily in nuclear medicine and computed tomography;
- 4% concerned 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);
- 4% concerned any other event liable to have radiation protection consequences (operating anomaly, worker exposure below regulation limits, packaging fault, procedural error, etc.).

Events concerning staff (criterion no. 1 of ASN notification guide no. 11): 27 events recorded in 2011 as opposed to 31 in 2010.

During 2011, ASN received 27 notifications of significant radiation protection events concerning persons working in medical facilities. They primarily concern nuclear medicine and medical imaging and, to a lesser extent, radiotherapy and interventional radiology.

- nuclear medicine: staff exposure or contamination when handling or preparing radiopharmaceuticals, contamination by splashing when using injection equipment;
- radiology including computed tomography: staff exposure in the room during the examination, or dosimetry result showing significant exposure but without exceeding the regulation dose limits;
- external beam radiotherapy and brachytherapy: worker locked in during operation of the accelerator, exposure from unconfined sealed sources;
- interventional radiology: significant exposure of the extremities of the operator – surgeon or radiologist in interventional CT.

Events concerning patients (criteria no. 2.1 and 2.2 of ASN guide no. 11): 314 events notified in 2011 as opposed to 302 in 2010.

In 2011, 314 significant events concerning patients exposed for diagnostic or therapeutic purposes were notified to ASN.

They can be broken down as follows:

- 78% in radiotherapy (external beam radiotherapy, brachytherapy and targeted internal radiotherapy);
- 16% in nuclear medicine;
- 4% in computed tomography;
- 2% in radiology (including interventional radiology).

Events concerning patients in radiotherapy (criteria no. 2.1 of ASN guide no. 11): 243 events notified in 2011.

Most of the events were due to a patient positioning anomaly or an error in patient identification, with no consequences for the health of the patient. They are rated level 0 or 1 on the ASN-SFRO scale. 139 ESR, notified in 2011, were rated level 1 on the ASN-SFRO scale. Quarterly reports of these level 1 ESR are produced and published on the ASN website.

Three external beam radiotherapy events, notified in 2011, were rated level 2 on the ASN-SFRO scale (7 in 2010). The incident notifications are published on the ASN website.

The radiotherapy event notification approach is the most significant and accounts for about 77% of the patient event notifications. The proportion of radiotherapy units which have declared at least one event to ASN since the notification system was set up in 2007, is significant (86%). Over the past three years, about half of the units have declared at least one event per year.

Since July 2011, a web address has given access to a site to help with drafting a radiation protection significant event notification (www.vigie-radiotherapie.fr). This site, designed in partnership with the AFSSAPS, with and for the radiotherapy professionals, helps them meet their notification obligations with regard to radiation protection and medical device surveillance. Since the site opened, most event notifications have been drafted with the help of this notification portal.

It has been possible to build on experience feedback owing to the rising number of notifications collected (more than 1,000 since 2007) and the analyses carried out by the centres.

The second ASN/AFSSAPS report, published in 2011, presents a summary of the 519 significant radiation protection events in external beam radiotherapy notified to ASN, and 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.

A radiotherapy patient safety bulletin was designed by the radiotherapy professionals and ASN. Two issues appeared in 2011, one on patient identification and the other on the first treatment session for a radiotherapy.

Events concerning nuclear medicine and radiology patients (criterion 2.2 of ASN guide no. 11): 71 events recorded in 2011 as opposed to 33 in 2010.

ASN observes a gradual rise in the number of events notified by the nuclear medicine units, indicating that the notification culture is being assimilated.

These events are mainly linked to an error in administration of the radiopharmaceutical (syringe labelling error, wrong flask collected), or a patient identification error (similar name, lack of vigilance in patient identification).

Two interventional radiology events were notified, one following observation of temporary alopecia and the other because of the appearance of deterministic effects in a patient who underwent two particularly lengthy and delicate interventional radiology procedures. The procedure took place on a device unable to offer optimised protocol conditions and not comprising any dose indication device.

Events concerning pregnant women (criterion no. 3 of ASN guide no. 11): 74 events notified in 2011 as opposed to 39 in 2010.

ASN was notified of 74 significant events concerning the public during 2011. This only concerns notification of exposure of the fetus in women who were unaware that they were pregnant at the time of the examination (13% in nuclear medicine and 87% in radiology). The doses received as a result of these diagnostic procedures have no consequences for the fetus or the child once it is born⁴.

Events concerning sources (criteria no. 4.0, 4.1, 4.6 of ASN guide no. 11): 9 events notified in 2011 as opposed to 7 in 2010.

In 2011, ASN was notified of 9 significant events involving losses of radioactive sources used in the medical field. This concerns the loss of calibration or localisation sources used in nuclear medicine. Two notifications concerned a source leak in its container and the loss of a mobile X-ray generator, respectively.

One of the events concerning a source loss was rated level 1 on the INES scale and was the subject of an incident notification.

Events linked to the dispersion of radionuclides (criteria no. 4.3, 4.4 and 4.5 of ASN guide no. 11): 8 events were notified to ASN in 2011, as opposed to 16 in 2010.

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, or the discharging of waste to an inappropriate treatment process.

One event was rated level 0 on the INES scale and was the subject of an incident notification owing to discharge of effluents into the sewerage network.

Events considered to be significant by ASN or the notifying party (criteria 6.1 and 6.2 of ASN guide no. 11): 38 notifications in 2011 (27 in 2010).

38 notifications refer to events considered to be significant by the notifying party or ASN. These events do not meet the definition of notification criteria no.1 to 5 in ASN guide no. 11, but are notified owing to their interest in terms of experience feedback, either at the initiative of the notifying party, or at the request of ASN. However, most of them are notified as a result of insufficient knowledge of the notification criteria, in particular for those events involving radiotherapy patients.

These extremely diverse events can concern equipment anomalies (injection equipment, faulty medical device, etc.), installation malfunctions (flooding, effluent retention tanks filling anomaly, etc.), minor exposure or contamination of the staff. These notifications are interesting, because they constitute early-warning signs of an event liable to have greater consequences.

It should be noted that some of the events notified are covered by several notification criteria: this concerns patient exposure associated with a loss of traceability of the treatment source, or exposure or contamination of a worker associated with the dispersion of radionuclides.

An event relative to the loss of traceability of a source and exposure of the patient was the subject of an incident notification rated level 1 on the INES scale and provisionally level 2 on the ASN-SFRO scale (see box).

4. ICRP 103

To summarise:

Since 2008, the reporting of significant radiation protection events in the medical field has risen, reaching 470 annual notifications at the end of 2011 (i.e. an average of 39 declarations per month).

The event notification approach in radiotherapy is the most significant and accounts for more than half of all notifications. The number of centres which have never issued a notification is down and the number of notifications has been stationary since 2010.

Event notifications are clearly up in the field of nuclear medicine and those concerning identity surveillance have doubled in two years.

The number of fetus exposure notifications is rising and has doubled in the field of CT radiology.

There are very few significant radiation protection events concerning interventional radiology, despite these procedures involving particularly high doses for the patient and the operator.

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 into 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 presented in 2011. ASN in particular hopes that research will lead to the definition of a patient radiosensitivity test (see chapter 1) – this request was also brought before the European Commission – and that a risk/benefit assessment of new radiotherapy practices will be carried out, with the participation of the users.

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 opinion 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 an opinion in June 2010 on the conditions for practising stereotactic radiotherapy and the associated medical physics.

On the basis of this opinion, and following the deliberations of the Commission (see ASN decision no. 2011 DL-0025 concerning the improvement of radiation protection during stereotactic radiotherapy procedures), ASN informed the units and agencies linked to the Ministry for health, and the professionals, of the actions it considered to be necessary in order to improve the radiation protection of patients during stereotactic radiotherapy procedures.

Event notified by the Claudius Regaud Institute (Toulouse, September 2011)

In September 2011, ASN was informed of the discovery of a fragment of iridium 192 wire in medical waste, after a detection portal was triggered at the entrance to a waste treatment centre.

Analysis of the event revealed that organisational and human factors led to the loss of traceability of the fragment of an iridium wire, which had remained for several months in a patient, after removal of the wires used for interstitial brachytherapy treatment.

After a patient consultation in a clinic in the region, the fragment of wire was removed by a surgeon, unaware of the fact that it was radioactive. The waste was taken to an infectious risk medical waste disposal facility.

The patient received a significant dose in excess of that prescribed, leading to the event being provisionally rated 2 on the ASN-SFRO scale. The breakdown in source traceability also means that the event was rated level 1 on the INES scale.

ASN carried out an inspection following this event and asked the Claudius Regaud Institute to have all iridium wires removed in the presence of a radiation oncologist, to comply with procedures checking the number and length of the wires used during treatment and to use a measuring instrument to check that no radioactive sources remain in the patient, before he or she is released from the care unit.

ASN and the regional health agency are investigating the failure to transmit patient information to the surgeon carrying out the biopsy.

IRSN was asked to carry out an appraisal of the evaluation of the dose received by the patient and the expected consequences. The results will either confirm or entail changes to this rating criterion.

Generally speaking, ASN considers that the treatment of intra- or extracranial lesions by stereotactic ionising radiation, should be subject to the authorisation and quality assurance rules and approval criteria applicable to external beam radiotherapy. It however specifies that these rules and criteria should be adapted when this type of treatment is carried out with a single dose of ionising radiation, especially in neurosurgery.

Over and above the regulatory issues, ASN considers that among the steps to be taken to improve patient radiation protection, there is a particular need to extend the initial training of the professionals involved, with additional theory and practical training in stereotactic radiotherapy, to establish a guide of good practices, to develop quality assurance with the assistance of the medical physicist, and to define specific quality control procedures for equipment and devices, including the various associated imaging techniques, such as magnetic resonance imaging.

5|3|1 Radiation protection of radiotherapy staff

The inspections carried out checked that the deviations from the provisions of the Labour Code observed in 2009, regarding prevention of the risk of irradiation after being accidentally locked in the treatment room, had been corrected.

5|3|2 Radiation protection of radiotherapy patients

Status of human resources in medical physics

The ASN inspections carried out in 2010 confirm the positive trend begun in 2008 and continued in 2009, with regard to the increased human resources deployed in the medical radiation physics field. The results of these inspections show that a significant number of medical physicists were hired, following the increase in the number of training places decided on in the national radiotherapy plan and, to a lesser extent, that radiation therapy technicians were assigned to dosimetrist positions.

The situation with regard to the organisation of medical physics, especially in terms of the number of centres with too few medical physicists (12 centres at the end of 2009), improved, although it is not yet fully satisfactory, because six of them had still to meet their additional staffing requirement as at the end of 2010. At the end of 2011, four centres still only had a single medical physicist. However, the permanent presence of a medical physicist for the duration of treatment is guaranteed.

Assessment of treatment safety

Even if ASN has also observed progress in the implementation and widespread adoption of safety and quality management with regard to the care given to the patients, it considers that the involvement of the senior staff of the



Quality control of a linear accelerator by a medical physicist at the Pitié Salpêtrière Hospital in Paris

establishments in overseeing this management of safety and quality of care is still insufficient. Some centres need to further reinforce their culture of safety and quality of care, in particular by formally drafting patient care practices and training the staff in risk analysis methods.

In general, the effort to draft formal practices and competences must be continued for many centres, with regard to the delegation⁵ procedures within the teams and validation of the control images for patient repositioning during the course of treatment.

Although internal notification of malfunctions is now widely used, analysis of the causes and medium and long term monitoring of improvement measures still needs to be improved.

5|3|3 Summary

To conclude, ASN is on the whole satisfied with the progress made by the centres and feels that its observations at the end of 2010 are encouraging. There has been a very real rise in awareness and reactivity within the profession, with regard to radiation protection culture, formal drafting of practices and risk management with regard to external beam radiotherapy patient treatment. Moreover, the steps taken as part of the 2009-2013 cancer plan and the continuation in 2011 of the numerous measures initiated by the centres in 2010 to meet both the quality criteria set by INCa and ASN decision no. 2008-DC-0103 of 1st July 2008 should enable this situation to be improved still further.

5|4 The radiation protection situation in nuclear medicine

In 2010, ASN carried out 73 inspections in the field of nuclear medicine, or about 35% of the nuclear medicine units within ASN's geographical area of competence (metropolitan France and overseas France).

5. The transfer of medical procedures to other health professions is regulated by the steps taken pursuant to Act 2009-879 of 21st July 2009 on hospital reform, relating to patients, health and territories (HPST) in particular its article 51 requiring the establishment of protocols.

5|4|1 Radiation protection of nuclear medicine staff

The inspections carried out by ASN in 2010 show that there is still inadequate compliance in the nuclear medicine units with the regulatory requirements concerning worker radiation protection, which is a key issue for nuclear medicine: the workstation analyses and risk assessments are generally either not carried out or are incomplete; insufficient use is made of the worker dosimetry results, medical monitoring of “occasional” workers is rare, etc.

For example, 30% of the units inspected in 2010 use a “historical” zoning of the premises which is not based on any risk assessment, and 16% of the units which produced an assessment of their risks did not adopt any zoning for all the premises concerned.

The 2011 update of the INRS⁶ radiation protection sheets for nuclear medicine, work that was carried out in collaboration with the professionals concerned, IRSN and ASN, should make it easier to implement the regulations concerning risk assessment, zoning and workstation evaluations.

These inadequacies must however be put into perspective in terms of the corresponding risk. The results of the dosimetric monitoring transmitted to IRSN in 2009 for this field showed no overdoses in relation to the regulatory annual limit.

The ASN inspections of nuclear medicine units will be continued in 2012. A report on radiation protection in nuclear medicine units, based on the inspections carried out in 2009, 2010 and 2011, will be published in 2012.



Discussions between the ASN inspectors and the staff of the nuclear medicine unit of the Oscar Lambret centre in Lille – November 2011

5|4|2 Radiation protection of nuclear medicine patients

Most of the regulatory requirements concerning radiation protection of patients are generally well-known and adhered to by the nuclear medicine units inspected in 2010 (e.g.: transmission of dosimetric readings for comparison with the diagnostic reference levels, inclusion of dosimetric data in the patient report, training of workers in radiation protection of patients, etc.).

Although the findings are on the whole satisfactory, the ASN inspections showed that certain points needed to be taken further or improved, such as drafting of the medical physics organisation plans⁷ or quality controls on the nuclear medicine installations used for diagnostic purposes.

5|4|3 Protection of the general public and the environment

In 2009, about 80% of the licensees or heads of nuclear medicine units inspected had drawn up a contaminated waste and effluent management plan. The inspections carried out in 2010 showed that nearly all the units inspected (97%) today have a contaminated waste and effluent management plan.

However, it must be said that these documents do not always comply with the requirements of the order of 23rd July 2008⁸. Only half of the existing plans are in fact in conformity with the current regulations. The publication of the guide to disposal of effluents and waste contaminated by radionuclides, in order to clarify the procedures for implementation of the order, should make it easier to apply these regulations (publication in March 2012).

5|4|4 Summary

In addition to the inspections carried out in 2011 in the nuclear medicine units, ASN initiated or continued work to improve radiation protection in this field of activity. For example:

- the creation of a working group involving members of the profession (SFMN, AFTMN, AFPPE, SoFra⁹, etc.) to define minimum design, operating and maintenance rules for nuclear medicine installations (in progress);
- the publication in early 2012 of the guide designed to help with application of ASN decision no. 2008-DC-0095 of 29 January 2008, approved by the order of 23 July 2008, concerning the disposal of effluents and waste contaminated by radionuclides produced in facilities licensed under the Public Health Code;
- drafting of the first report on significant radiation protection events notified to ASN in the field of nuclear medicine and

6. <http://en.inrs.fr/>

7. NB: the organisation of medical physics within a nuclear medicine unit, to be defined by the head of the establishment, must be described in a medical physics organisation plan in accordance with the order of 19th November 2004 concerning the training, duties and working conditions of the medical physicists.

8. Order of 23rd July 2008 approving ASN decision n°2008-DC-0095 of 29th January 2008, setting the technical rules applicable to the disposal of effluents and waste contaminated by radionuclides, or liable to be so contaminated owing to a nuclear activity, implementing the provisions of article R. 1333-12 of the Public Health Code.

9. SFMN (French Society of Nuclear Medicine), AFTMN (French association of nuclear medicine technicians), AFPPE (French association of radiographers), SoFra (French association of radiopharmacists).

consultation of representatives of the profession. This report was distributed on the occasion of the 31st study and training seminar organised by the French association of nuclear medicine technicians (AFTMN), in May 2011, in Toulouse.

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

In 2011, ASN continued the work started in 2010 on the question of the increased doses delivered to patients undergoing medical imaging (an average increase of nearly 50% since 2002), especially in computed tomography (CT). The deliberations of the ASN Commission on 14 June 2011 concerning the increase in the doses delivered to patients during CT and conventional radiology examinations, based on the conclusions of the seminar held by ASN on 16 September 2010 with all the professionals and organisations concerned, presented proposals to achieve satisfactory management of the doses delivered to the patients.

ASN thus considers that the rise in doses in imaging is of increasing concern and that urgent measures must be taken to control the doses delivered to the patients during medical imaging examinations, in particular CT examinations.

ASN considers that the principle of justification of radiological examinations needs to be more effectively applied, so that each examination performed is actually useful, and that the doses delivered during the examinations need to be optimised, through greater quality assurance at all stages. ASN draws the attention of the health authorities to the lack in France of MRI, a non-irradiating imaging technique, and the need to promote access to this system to avoid having to use CT examinations when they are not justified.

ASN also underlines the need to continue the medical physicist training and recruitment effort for at least five consecutive years, so that there are sufficient numbers of them to be able to staff the medical imaging field.



Commissioning inspection of a radiotherapy installation in the Dentellières clinic in Valenciennes – October 2011

The various stakeholders (health authorities, health professionals) were notified of the measures identified by ASN.

At the same time as the recommended measures for achieving better dose management, ASN in 2011 decided to devote a part of its inspection programme to the radiation protection of CT patients.

Finally, at the European level, ASN is taking part in the HERCA¹⁰ initiative aimed at ensuring that CT manufacturers improve the optimisation tools on their medical devices.

5|6 The radiation protection situation in interventional radiology

Since 2009, the monitoring and regulation of radiation protection in interventional radiology has become a national priority 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. This work, published in 2011, along with the report of the inspections carried out in 2009, led ASN to issue a position statement following its deliberations of 14 June 2011 concerning the improvements to radiation protection in interventional radiology.

5|6|1 Radiation protection of interventional radiology staff

The report on the inspections carried out in 2010 is based on the results of inspections of 260 units carrying out fluoroscopy-guided interventional procedures (168 fixed installations and 92 operating theatres). This 2010 report is characterised by a rise in the number of establishments inspected (+17%) by comparison with 2009.

The report on the inspections carried out in 2010 confirms the 2009 observations. It shows that the radiation protection of workers is better integrated in fixed radiology facilities than in operating theatres where mobile devices are used.

Overall, the inspections revealed inadequacies in the risk assessments, workstation studies and in identification and delimitation of regulated areas. Incomplete use of active dosimetry and a lack of appropriate dosimetric monitoring, in particular of the extremities in the case of certain fluoroscopy-guided procedures, as well as an absence of medical monitoring of the practitioners, are also significant shortcomings.

For the PCRs (person competent in radiation protection), there are still methodological and organisational difficulties and they do not always have the means or the powers enabling them to perform their duties in full.

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

10. <http://www.herca.org/>

equipment to the medical procedures performed. Overall, the inspections revealed incomplete application of the principle of dose optimisation, mainly owing to inadequate operator training, both in patient radiation protection and in the use of the radiology devices, as well as a shortage of medical physicists but also of appropriate equipment. The lack of radiological protocols for most of the procedures performed in the operating theatre and an imperfect understanding of the doses emitted during the procedures contributed to a failure to apply the optimisation principle, creating potential risk situations.

5|6|3 Summary

ASN considers that urgent steps must be taken to improve the radiation protection of patients and workers in interventional radiology, particularly for fluoroscopy-guided interventional procedures in operating theatres. Even if in certain aspects (medical physicist numbers, user training, quality assurance, audit of professional practices), the proposals are similar to those for medical imaging, measures specific to interventional practices are required.

The availability of PCRs and the means given to them must be increased, in order to make up for the inadequacies observed, in particular in terms of risk assessment, workstation analysis and wearing of individual protective equipment and dosimeters, especially for monitoring the dose at the extremities or the lens of the eye of the operator.

ASN also considers that an initiative must also be taken with regard to the managers of public and private health

establishments, in particular the directors of CHU (university hospitals) and CHR (regional hospitals), underlining the specific risks of interventional procedures for both patients and professionals, and recalling their statutory obligations as employers. This initiative should be accompanied by recommendations for improved radiation protection in this field, in particular entailing strong incentives to equip existing facilities with devices able to estimate the radiation dose emitted during radiological procedures, if not already so equipped. Together with the departments concerned at the Ministry for Labour, Employment and Health, ASN thus sent out a letter to the regional health agency Director Generals in November 2011, describing the current radiation protection situation in the medical field. This letter highlights the necessary improvements concerning the radiation protection of patients and health staff, especially in terms of human resources.

ASN also asked the learned societies and professional organisations representing the radiologists and non-radiologist practitioners (interventional cardiologists, vascular surgeons, neurosurgeons, orthopaedists, etc.) who perform interventional radiology procedures, to step up their efforts with regard to training and the drafting of guides of good practice.

The measures identified by ASN were transmitted to the various stakeholders (health authorities, health professionals).

Owing to the inadequacies observed in radiation protection in the interventional radiology field, ASN is maintaining the national priority status it accords to the control of interventional radiology in its 2012 inspection programme.



Press conference on the occasion of publication of number 192 of *Contrôle* magazine devoted to medical imaging

6 OUTLOOK

The gradual improvement in the safety of radiotherapy procedures, year after year since 2007, observed by ASN through its inspections, must be continued in order to achieve complete control of procedures and thus guarantee the radiation protection of the patients. In this new quality management culture, ASN will remain particularly attentive in its inspections to the identification and internal analysis of deviations, which is the only way to ensure permanent improvement and progress. The centres which are still understaffed with medical physicists will continue to be the subject of particularly close attention.

In the medical imaging field, following the publication of two decisions in July 2011, jointly with the health administrations and the health professionals, ASN will be organising detailed monitoring of the steps taken to achieve true control of the doses delivered to the patients in conventional radiology and in computed tomography and to improve radiation protection in the field of interventional practices. ASN will in particular remain highly attentive to the question of human resources and

the corresponding skills, on the one hand to ensure compliance with the provisions of the Labour Code in operating theatres where radiology equipment is used and, on the other, to enable medical physicists to intervene in all fields of medical imaging, computed tomography and interventional radiology.

In the field of medical physics, the efforts made since 2007 to boost the numbers of medical physicists, must be continued in order to meet the medical imaging needs. In 2012, ASN will prepare recommendations for the health authorities, so that the organisation and implementation of the regulations applicable to medical physicists are consolidated, with regard to the involvement of professionals, other than medical physicists, in the performance of medical physics tasks.

Finally, ASN will play an active part in the work overseen by the French national authority for health, concerning the assessment of clinical practices exposing individuals to ionising radiation for medical purposes. This work began in November 2011.