ACTIVITIES REGULATED BY ASN

MEDICAL USES OF IONISING RADIATIONS

1	MEDICAL AND DENTAL RADIODIAGNOSIS INSTALLATIONS	273	
1 1	Presentation of the equipment inventory		
1 1 1	Medical radiodiagnosis		
1 1 2 1 1 3	Interventional radiology Dental radiodiagnosis		
1 2	Technical rules for radiology and tomography installations		
2	NUCLEAR MEDICINE	276	
2 1 2 1 1 2 1 2	Presentation of nuclear medicine activities In vivo diagnosis		
2 1 2 2 1 3 2 1 4	Internal radiotherapy The shortage of technetium-99m		
2 1 5	The new nuclear medicine tracers		
<mark>2</mark> 2	Nuclear medicine unit organisation and operating rules		
3	RADIOTHERAPY	281	
3 1 3 1 1 3 1 2	Presentation of radiotherapy techniques External radiotherapy Brachytherapy		
3 1 3	The new radiotherapy techniques		
3 2 3 2 1 3 2 2	Technical rules applicable to installations Technical rules applicable to external radiotherapy installations Technical rules applicable to brachytherapy installations		
4		285	
4 1	Description	205	
4 2	Blood product irradiator statistics		
4 3	Technical rules applicable to installations		
5	SOURCE SUPPLIERS	285	
6	THE STATE OF RADIATION PROTECTION IN THE MEDICAL SECTOR	286	
6 1	Radiation protection of medical workers		
6 6 2	General indicators Dosimetry	/	/
6 1 2	Significant radiation protection events liable to affect medical workers		
<mark>6</mark> 2	Radiation protection of patients		
6 2 1	Human resources (medical radiation physics, training)		
6 2 2 6 2 3	Patient exposure from medical imaging Radiotherapy treatment security		
6 2 4	Radiation protection of nuclear medicine patients		
<mark>6</mark> 2 5	Significant radiation protection events liable to affect patients	/	
6 3	The impact on the environment and the population		
6 3 2	Significant events		
7	OUTLOOK	294	

For more than a century now, and for both diagnostic and therapeutic purposes, medicine has made use of a variety of sources of ionising radiations, 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 radiations. Behind exposure to natural ionising radiations, 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 radiations 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 radiations, the principle of limitation of the dose delivered to the patient does not apply, owing to the health benefits derived by the patient, because a certain dose is required either to obtain a diagnostic quality image, or to obtain the desired therapeutic effect.

Since 2005, ASN has received a large number of radiotherapy event notifications. For some, no health consequences have as yet come to light, while others entail serious complications for the patients, even resulting in death in a few cases. In this context, ASN has since 2007 been inspecting all the radiotherapy centres, concentrating in particular on organisational and human factors. At the same time, in addition to publishing criteria for the notification of significant radiation protection events, ASN in conjunction with the French Society of Radiation Oncology (SFRO) developed a scale for rating the severity of events affecting patients undergoing a medical radiotherapy procedure.

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 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 or 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 to be looked for, the expected benefit for the patient, the anticipated exposure level and the possibility of using other non-irradiating investigative techniques (see medical imaging good practices guide, chapter 3).

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 three main families:

- radiodiagnosis performed in fixed installations specifically built for the purpose;
- radiodiagnosis carried out using mobile appliances, especially by the patient's bedside. This practice is however restricted to those patients who cannot be transported;
- radiodiagnosis in the operating theatre as a tool contributing to the satisfactory performance of interventional procedures. In this case mobile X-ray generators fitted with an image intensifier are used, outputting images on



Conventional radiology appliance



Computed tomography appliance

a screen (radioscopy) that can be used in real time to guide the surgeon's hand.

Digital angiography

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



Mammography appliance

Mammography

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

Computed tomography

Using a closely collimated X-ray beam, emitted by a generating tube rotating around the patient and a computercontrolled image acquisition system, tomography appliances give a three-dimensional picture of the organs with image quality higher than that of conventional equipment, providing a more detailed and threedimensional 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 appliances (multi-slice scanners) enables the scope of investigation of computed tomography to be expanded, with easier and faster investigation. The counterpart can be a greater number of images being taken, which runs contrary to the optimisation principle, thus leading to a significant rise in the doses of radiation delivered to the patients.

1 | 1 | 2 Interventional radiology

This covers techniques using radioscopy with image intensifier and requiring special equipment. 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



Intervention in an interventional radiology installation

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.

1 | 1 | 3 Dental radiodiagnosis

Intra-oral radiography

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

Panoramic dental radiography

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

Cranial tele-radiology

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



Panoramic dental radiology appliance

In the dental radiology field, the development of appliances using a cone-beam computed tomography mode (3D) is continuing and the irradiation fields of view proposed by these appliances 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 radiations 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 led in particular to a reduction in the exposure limits for both the public and workers, a revision of these standards was initiated by UTE. ASN and IRSN are taking part in this standards revision work. The draft standard was sent for public and professional consultation in April 2009. The comments made on the occasion of this consultation are currently being analysed.

In addition to complying with the above-mentioned standards, the installations must be equipped with a generator less than 25 years old (medical appliances used for medical care) and carrying the CE marking that has been mandatory since June 1998. This certifies that the appliance is in conformity with the main health and safety requirements mentioned in Articles R. 5-211-21 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 appliance cannot therefore be installed in a room with a surface area of less than 20 m^2 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 pool comprises 1,026 tomography installations (2008 figures). This figure includes appliances intended for radiotherapy simulation purposes.

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.

The number of nuclear medicine units practicing in vivo diagnosis and therapy has been on the whole stable over the last three years. 60% of them are located in public or comparable structures and 40% are in private structures. After a period during which the units acquired positron emission tomography (PET) appliances (2003-2006), the PET pool has stabilised (71 in service). In vitro diagnostic activity using radionuclides is continuing to fall and in certain cases entails closure or merging of laboratories, or these laboratories being absorbed into nuclear medicine units. Nuclear medicine involves about 500 specialist practitioners in this field, to which must be added 1,000 physicians working in the nuclear medicine units (residents, 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 is classified as a drug, depends on the organ being examined. 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 acquisition and analysis system. This equipment is used to obtain images of how the investigated organs are functioning (scintigraphy). As these images are digitalised, the physiological processes can be quantified, along with a three-dimensional reconstruction of the organs, using the same principle as for the X-ray scanner.

Fluorine-18, a radionuclide that emits positrons with a half-life of 110 minutes, is today commonly used in the form of a sugar, fluorodeoxyglucose (FDG), for examinations in cancer treatment. It requires the use of a scintillation camera able to detect positron emitters (PET).

Nuclear medicine is used to produce functional images and therefore complements the purely morphological pictures obtained with the other imaging techniques: conventional radiology, X-ray scanner, echography or magnetic resonance imaging. In order to make it easier to merge functional and morphological images, hybrid appliances have been developed: PET machines are now

T.L	a 1.	an a man	1			:	:		1:	1ha				l: .:	avaminations
lab	le I:	some or	ш	e mam	raa	IONUC	IU	es useu		me	various	nuclea	r mec	licine	examinations

Type of examination	Radionuclides used
Thyroid metabolism	lodine-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



Gamma camera used in scintigraphy



Handling of radioactive products in the Nantes university hospital nuclear medicine unit (Loire-Atlantique *département*) – September 2007

systematically coupled with a scanner (PET-CT) and more and more nuclear medicine units are acquiring gammacameras coupled with a 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 Internal radiotherapy

Internal radiotherapy aims to administer a radiopharmaceutical emitting ionising radiations, 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 to the type of radiations 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. They are for example designed to treat hyperthyroidism by administration of iodine-131, painful bone metastases by strontium 89 or samarium 153, and polyglobulia by phosphorus-32. Joints can also be treated using colloids labelled with yttrium-90 or rhenium-186. Finally, radioimmunotherapy, which has appeared more recently, can be used to treat certain lymphomas using antibodies labelled with yttrium 90.

2 | 1 | 4 The shortage of technetium-99m

Since September 2008, the activities of nuclear medicine units have been seriously disrupted by problems with the procurement of technetium-99m generators, owing to the simultaneous shutdown of several of the European nuclear reactors manufacturing molybdenum-99, which is the raw material for these generators.

Technetium-99m, which is the radionuclide used in about three-quarters of all nuclear medicine examinations (see table 1), is produced by the radioactive decay of molybdenum-99 in a generator, followed by elution with

ASN's position statement concerning the technetium-99m shortage

The reactors producing most of the world's output of radionuclides for medical uses are now more than 40 years old. ASN considers that shortages such as this are bound to happen again in the short and medium term. The simultaneous shutdown of several of these reactors is inevitable owing to scheduled maintenance or modification outages, failures due to ageing of equipment and structures and the absence of any replacement of the existing reactors for several more years. In the light of this situation, ASN organised a seminar on 7 and 8 January 2009 on the "safety-availability of radioisotope production installations". The conclusions of this seminar in particular include the need to set up an information exchange network between nuclear regulators to deal with these issues of reactor safety and availability and to harmonise the safety of plants, research reactors and production installations. The NEA also organised a seminar on 29 and 30 January 2009 concerning the supply of radiopharmaceutical drugs; one of the measures identified for improving the security of supply in the short term is to boost coordination of maintenance schedules among the reactor licensees.

In view of the risk of long-term shortages in supply of radioisotopes for medical use, ASN believes that the solution is not to extend the operation of these older reactors as this could jeopardise the safety of these facilities. For ASN, the solution lies in dialogue, cooperation and discussion at international level aiming at: the optimisation of the use of technetium-99m, research into alternative production methods (for example using an accelerator), the investigation of other methods of medical imaging, and the construction of a robust economic model for the production of these radioisotopes as the current model does not take account of the full cost of manufacturing the radioisotopes, in particular the cost of manufacturing molybdenum in state-owned research reactors.

physiological saline solution. The chemical form of this technetium99m, its short radioactive half-life (6 hours) and its low gamma radiation energy, make it one of the most widely used radionuclides in nuclear medicine and one that entails the least irradiation for the patient. The activity level administered to a patient for an examination is generally a few hundred megabecquerels (MBq).

In June 2009, the technetium-99m supplies market experienced a further period of severe shortages, which led the health authorities (the French Health Product Safety Agency AFSSAPS and DHOS, the Directorate for Hospitalisation and Health Care Organisation) to reactivate monitoring of the supplies to 220 nuclear medicine centres. This monitoring identified two critical thresholds for meeting health needs and the performance of priority examinations: receipt of a nominal activity of less than 2 GBq per week and/or less than 30% of the activity ordered.

In cases of difficulty of supply, the recommendations are:

- to focus on optimising the scheduling of examinations;
- to abide by the situations defined as high-priority for the use of the remaining quantities of technetium-99m;
- to envisage the alternative techniques identified and recommended for myocardial and bone scintigraphy.

Six situations were identified with the professionals as being high-priority:

- peroperative detection of sentinel nodes in the event of cancer metastasis;
- search for pulmonary embolism in pregnant women;
- patients with a contraindication to radiological contrast media;
- preoperative search for hyperfunctional glands in the event of hyperparathyroidism;
- paediatric nuclear medicine examinations as a whole;
- emergency nephrectomy (total or partial).

The recommended alternative imaging techniques to myocardial and bone scintigraphy are taken from the medical imaging examinations good practice guide (www.sfmn.org or www.sfr-radiologie.asso.fr).

2 | 1 | 5 The new nuclear medicine tracers

In recent years, research has been under way 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.

The use of new radiopharmaceuticals in nuclear medicine 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. In addition to issuing a reminder of regulatory requirements, ASN has also initiated awareness raising programmes, in particular by encouraging the development of automated systems for preparation and/or injection of these radioactive products.

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 must be designed and laid out so that they can



Arronax Cyclotron in Nantes (Loire-Atlantique département)

receive, store, prepare and then administer unsealed radioactive sources to patients or handle them in laboratories (radioimmunology for instance). Arrangements also need to be made for collection, interim storage and disposal of radioactive waste and effluents produced in the installation.

From the radiological viewpoint, the workers are subjected to a risk of external exposure, in particular on the fingers, owing to handling of sometimes highly active solutions (the case with fluorine-18, iodine-131 or yttrium 90 in radio-immunotherapy), along with a risk of internal exposure through accidental intake of radioactive materials. As the patients eliminate the administered radioactivity through their urine, special treatment of it is required in order to limit discharges into the public domain. In these conditions, the nuclear medicine 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 simple measurement areas and waiting areas for the patients prior to and after 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.

ASN has begun to look at revising the regulatory requirements resulting from the order of 30 October 1981, which specifies the conditions for use of artificial radionuclides in unsealed sources for medical purposes.

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 however sent to a system of storage tanks prior to discharge into the sewerage network.

3 RADIOTHERAPY

3 | 1 Presentation of radiotherapy techniques

With surgery and chemotherapy, radiotherapy is one of the key techniques employed to treat cancerous tumours. 200,000 patients are treated every year. Radiotherapy uses ionising radiations to destroy malignant cells. The ionising radiations necessary for treatment are 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 pool of external radiotherapy installations comprises 399 treatment appliances, including 3 telecobalt therapy devices and 382 conventional linear accelerators located in 178 radiotherapy centres, nearly half of which are public, with the other half being private. 537 radiotherapists were identified, including 46% private practitioners and 54% salaried staff. 70 brachytherapy units are linked to these installations (INCa figures for 2007; Radiotherapy Observatory, 2006-2007).

3 | 1 | 1 External radiotherapy

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

Irradiation is carried out using either particle accelerators producing beams of photons or electrons with an energy level of between 4 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 particle accelerators, whose superior performance offers a more complete range of treatments.

Stereotactic radiotherapy

Stereotactic radiotherapy is a treatment method which aims to offer millimetre-precise, high-dose irradiation, using mini-beams converging in the centre of the target, for intra-cranial damage that is surgically inaccessible. Radio-surgery treatment is defined as being a single session of stereotactic radiotherapy. For stereotactic radiotherapy treatments, the total dose is generally split up. 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,



Particle accelerator for radiotherapy



Use of a stereotactic frame for external radiotherapy

benign tumours) and uses specific localising techniques to ensure precise localisation of the damage. It is being increasingly used to treat cerebral metastasis.

This therapeutic technique has been in use in France since 1986, and employs three types of equipment:

- dedicated systems such as:
 - the Gamma Knife[®] using emissions from more than 200 Cobalt 60 sources focused on a single point. Three units are currently in service in two establishments;
 - the CyberKnife[®] consisting of a miniaturised linear accelerator mounted on a robot arm (see detailed information in 3 | 1 | 3);
- dedicated linear accelerators offering dynamic mode irradiation (Novalis[®], 3 units currently in service);
- "conventional" linear accelerators, providing dynamic mode irradiation and equipped with additional

collimating systems (mini-collimators, localisers) to generate mini-beams.

In 2008, 20 centres had equipment enabling them to perform stereotactic radiotherapy treatments.

It is worth noting that ongoing technical developments concerning new equipment such as tomotherapy, or "robotic" radiotherapy, as well as developments in "conventional" accelerators associated with irradiation techniques slaved with breathing (gating) or with organ movements (tracking), enable this type of stereotactic irradiation to be used for extra-cranial damage.

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.

Low dose rate brachytherapy, which requires patient hospitalisation for several days, delivers dose rates of from 0.4 to 2 Gy/h. The iridium 192 sources implanted inside the tissues generally come in the form of wires 0.3 to 0,5 mm in diameter, with a maximum length of 14 cm and whose linear activity is between 30 MBq/cm and 370 MBq/cm. Endocavity techniques (inside natural cavities) use either iridium 192 wires or caesium 137 sources.



Insertion of an iridium wire for brachytherapy

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 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 source of iridium 192 (a few millimetres) and with a maximum activity of 370 GBq, delivering dose rates higher than 12 Gy/h. A source applicator 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 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. Seven devices of this type have been installed in France since the end of 2006, including 3 in 2009, and have been used to treat patients since the first quarter of 2007.

Stereotactic radiotherapy with a robot arm, also called "robotic radiosurgery" 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.

Three installations of this type have been installed in France, i.e., in Nancy, Nice and Lille.

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.



Tomotherapy appliance



The Cyberknife

3 2 1 Technical rules applicable to external radiotherapy installations

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

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

This study defines the thicknesses and nature of the various protections required, which are determined according to the conditions of use of the appliance, the characteristics of the radiation beam and the use of the adjacent rooms, including those vertically above and below. This 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.

4 BLOOD PRODUCT IRRADIATORS

4 | 1 Description

Blood products are irradiated in order to eliminate certain cells liable to lead to a fatal illness in patients requiring a blood transfusion. The blood bag is irradiated with an average dose of about 20 to 25 grays. This irradiation uses an appliance with built-in lead radiological shielding, so that it can be installed in a room which does not require additional radiation protection. Depending on the version, 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 2008, 30 installations of this type were in service, in the blood transfusion centres:

- 19 irradiators with radioactive sources;
- 11 irradiators using 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.



Blood products irradiator

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 SOURCE SUPPLIERS

Further to the expansion of its licensing competence to include source suppliers in the medical sector, ASN will have an overview of the entire chain of health products containing radionuclides, from their manufacture up to their utilisation, an area that was already subject to ASN authorisation. The experience already acquired in industrial and research activities will be put to good use, taking account of the regulations which also apply to health products.

The health products supplier sector comprises 22 manufacturers and 26 distributors, with or without storage site. It should be noted that 20 manufacturing sites for health products containing radionuclides in France are establishments that primarily manufacture 18-FDG and that a number of others are on the drawing board. The proximity between the production units and the user units is a necessary constraint linked to the short half-life of these drugs. The rising number of sites parallels the development of the indications for this type of molecule.

6 THE STATE OF RADIATION PROTECTION IN THE MEDICAL SECTOR

The potential dosimetric impact of medical installations concerns the patients undergoing treatment or examination, the health professionals (physicians, medical radiation physicists, radiographers, nurses, etc.) using ionising radiations or involved in their use, but also the public, for example those living near installations, or population groups who could be exposed to waste or effluents originating in 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, will be collated nationally and placed on-line on the ASN website. In 2009, two national surveys were published, one concerning the state of radiation protection in nuclear medicine units and the other on the safety of radiotherapy treatment.

6 | 1 Radiation protection of medical workers

6 | 1 | 1 General indicatros

The state of radiation protection in nuclear medicine units

In 2008, the inspections carried out by ASN in the nuclear medicine units enabled it to produce a picture of the state of radiation protection in these units.

The survey published by ASN (October 2009) shows that the regulatory requirements concerning worker radiation protection, which is a key issue for nuclear medicine, were not adequately followed in the nuclear medicine units. For example, the workstation analyses and risk assessments are generally either not carried out or are incomplete; the worker dosimetric monitoring results are insufficiently analysed; the medical monitoring of certain workers such as physicians (nuclear physicians or cardiologists) or workers referred to as "occasional" (cleaners, technician interns, etc.) needs to be improved. However, these shortcomings must be put into perspective with regard to the risk. The results of the dosimetric monitoring transmitted to IRSN in recent years showed no overdoses in relation to the regulatory annual limit.

The state of radiation protection in the radiology units

In 2008 and 2009, the Nantes, Lyons, Bordeaux, Marseilles, Dijon, Douai and Chalons divisions carried out targeted inspections in about a hundred radiology practices. This campaign shows that the majority of practices on the whole comply with radiation protection regulations, but that certain practices will need to take corrective measures quickly in order to make up for the shortcomings observed. For example, equipment is not always notified to ASN and any notifications are rarely updated; the equipment annual technical checks are not always carried out, personnel training in patient radiation protection is behind schedule, the person with competence for radiation protection is not always actually appointed and the radiologists checked seem to be unaware of the fact that the radiation protection regulations also apply to them personally.

6 | 1 | 2 Dosimetry

According to the data collected by IRSN for 2008 (IRSN report entitled "Worker radiation protection, 2008 results", the exposure of nearly 184,000 people working in the sector using ionising radiations for medical purposes, or more than 59% of all the exposed workers monitored, all sectors included, was subject to dosimetric surveillance. Medical radiology covers about 60% of the medical personnel exposed. In total, more than 98% of the persons monitored in 2008 and working in medicine or dentistry received an annual effective dose of less than 1 mSv while an overdose exceeding the annual limit of 20 mSv was recorded on 8 occasions.

Each overdose must lead to a significant event notification to ASN by the licensee of the nuclear activity. This triggers an individual investigation, jointly with the occupational physician and possibly in collaboration with the conventional safety inspectorate (circular of 16 November 2007 concerning coordination of the work of the radiation protection inspectors and the conventional safety inspectors with regard to the prevention of risks linked to ionising radiations).

6 | 1 | 3 Significant radiation protection events liable to affect medical workers

During the course of 2009, 9 significant radiation protection event notifications were sent to ASN, concerning individuals working in medical installations.

These events concerned medical staff working in radiology on four occasions and in nuclear medicine on one occasion.

One of the events notified to ASN in 2009 concerned an operating theatre nurse whose passive dosimeter had integrated a dose of 21 mSv in one quarter, a dose which is higher than the annual limit of 20 mSv defined by the



Table of dosimeters used by the Nantes university hospital staff (Loire-Atlantique département) — September 2007

Labour Code. The event was detected by the hospital when the passive dosimeter readings were taken.

Another notified event was linked to an annual dose limit overdose received by the hands of a radiologist conducting digestive interventional radiology. This overdose was partly due to a malfunction of the automatic collimators on the radiology installation.

In the light of the overdoses recorded, ASN rated these two events level 1 on the INES scale.

A third event was notified following an abnormal dose value recorded on the passive dosimeter of an interventional radiographer. The dosimeter apparently fell from the radiographer's pocket into the sheets while the patient was being positioned on the table.

A fourth notified event was linked to internal contamination of a radiopharmacy preparation technician by iodine 131.

6 2 Radiation protection of patients

Patient exposure to ionising radiations is differentiated from the other types of exposure (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 radiations are intentionally delivered to individuals, in this case, patients. The situation is different whether the patient is being exposed for diagnostic reasons (radiology or diagnostic nuclear medicine) or is receiving external or internal radiotherapy treatment. In the first case, optimisation is necessary by delivering the minimum dose necessary to obtain relevant diagnostic data, while in the second, the dose needed to sterilise the tumour must be delivered, while maximising preservation of the surrounding healthy tissue. Optimisation of the dose 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.

6 | 2 | 1 Human resources (medidcal radiation physics, training)

Medical radiation physicists (PSRPM)

The optimisation process can be improved if a medical radiation physicist (PSRPM) is present in the unit to determine and guarantee the doses delivered. Overall, according to ASN sources, in 2007 only 64% of the units for which the indicators were recorded employed a PSRPM, all units included (radiotherapy, radiology, nuclear medicine). This overall figure indicates a shortage of staff with this qualification, in particular in radiology units.

The results of the inspections carried out in 2008 and published in 2009 in the radiotherapy centres show that there are still insufficient staff (radiation oncologists, medical radiation physicists and radiographers (MERM)) in many centres. The still acute shortage of PSRPM is the main reason for the instability of the physics staffing levels and is still a critical factor in the robustness of the organisations in about 20% of the centres. In January 2007, ASN identified about 300 full-time equivalent (FTE) PSRPM dedicated to radiotherapy. According to the National Cancer Institute (SFPM conference, Montauban, June 2009), the level was 410 FTE PSRPM in 2009, including 5 to 10% outside radiotherapy.

The admission conditions for the medical and radiological and physics qualifying diploma (DQPRM) were revised by the order of 18 March 2009. This enabled 77 students to be admitted in 2009 instead of 55 in 2008. Moreover, a commission tasked with issuing an opinion on the professional qualifications of the PSRPM holding a diploma issued outside France was set up following the decree of 19 June 2009. Its aim is to enable citizens of the European Union to obtain recognition of their training as an expert in medical physics and thus be able to work in France.

Faced with these staff shortages, ASN in 2009 temporarily suspended its authorisation to use accelerators in the radiotherapy centres of Blois, Gap and Roanne owing to the departure of the single PSRPM, who was not replaced.

Training of patient radiation protection professionals

The ASN inspections conducted in recent years are a means of checking gradual implementation of the patient radiation protection training for health professionals that has been mandatory since 2004. According to the order of 18 May 2004 concerning training programs to cover the radiation protection of patients exposed to ionising radiations, this training should have been carried out before 20 June 2009.

In the radiotherapy field, the centres devoted considerable efforts to patient radiation protection training in 2008. Despite this progress, some centres were unable to complete this training before the 20 June 2009 deadline. They are however committed to doing so before the end of 2009 or early 2010.

In nuclear medicine, the ASN inspections carried out in 2008 showed that few nuclear medicine units were able to anticipate the stipulated deadlines and the inspections conducted at the end of 2009 in this sector show that some of the professionals concerned have still not followed this mandatory training.



Publication by the EFOMP (European Federation of Organisations for Medical Physics)

6 2 2 Patient exposure from medical imaging

The available international data show a very significant rise in the average doses delivered in the field of medical imaging, particularly in tomography and interventional radiology (see chapter 1).

For radiology and tomography, the new IRSN and InVS estimates of the average doses in France during the most common examinations are keenly awaited. In the light of the rise in the number of tomography appliances in recent years, and their performance in terms of image quality, it is probable that the trend observed internationally will be confirmed.

In the case of radiology and nuclear medicine, setting up internal dose measurement or calculation procedures, for comparison with the diagnostic reference levels (DRL) defined in the regulations, should enable each radiology unit to better identify and thus better manage the doses delivered. The results of the IRSN evaluations of the doses of ionising radiations delivered to patients during radiology and nuclear medicine examinations shows clear progress in implementation of the regulations, as only 68% of nuclear medicine units, 23% of conventional radiology units and 50% of tomography units had transmitted DRL information during the course of 2008 (source: IRSN, 2010).

In nuclear medicine, the activity levels administered vary widely from one unit to another and from one country to another. Even if the doses are generally lower than in radiology, there are variations that cannot always be justified. For a pulmonary perfusion scintigraphy performed as part of the diagnosis of a pulmonary embolism, the activity level administered can vary from 100 MBq (Netherlands) to 300 MBq (France), or an estimated delivered dose variation of 1.25 mGy to 3.75 mGy.

In interventional radiology and more particularly in interventional neurology and cardiology, the doses delivered to the patients, albeit poorly documented, can reach dose levels liable to lead to deterministic effects (see box on the Hautepierre event).

6 2 3 Radiotherapy treatment security

The results of the inspections carried out on all the radiotherapy centres in 2008 were published in 2009. In relation to 2007, the situation in the radiotherapy centres differs more noticeably between the regions and even within the same region. This difference becomes more marked between those centres which as of 2007 had started to set up quality assurance measures and the other centres. The drafting of the procedures needed for performance of the treatment and for recording of the treatment validations was improved, reflecting the major efforts made by many units. However, about 30% of the centres have insufficient access to the quality assurance training necessary for correctly implementing these measures. ASN identified about fifty centres which would need assistance in 2009-2010 if they are to achieve the hoped for level of safety management and treatment quality. Apart from these cases, the significant progress made in terms of internal notification of malfunctions or abnormal situations allows for a real continuous improvement of safety and treatment quality management systems.

For most of the units inspected, significant progress will need to be made in implementing the lines of defence in the next few years. There is a need in particular for:

1. the performance of internal quality checks on the medical appliances, conforming in particular to the frequency of these checks set by the regulations;

2. more formal validation of treatment preparation by means of procedures, protocols and recordings associated with these practices;

3. giving preliminary risk analysis the importance it deserves in implementing the safety and treatment quality management system;

4. an analysis of malfunctions so that feedback can be shared and the organisation improved on an ongoing basis;

5. the implementation and monitoring of improvement measures resulting either from a preliminary risk analysis or from feedback; 6. the development of internal communication in order to maintain staff motivation.

The ability of the centres to achieve more rigorous organisation and traceability on a day to day basis will be a determining factor in the coming three years. This will not be possible without training the personnel in the centres in quality assurance and risk management and without the involvement of the establishment management.

6 | 2 | 4 Radiation protection of nuclear medicine patients

The results of the inspections published by ASN in 2009 show that the regulatory requirements concerning patient radiation protection are on the whole complied with in the nuclear medicine units.

6 | 2 | 5 Significant radiation protection events liable to affect patients

The consequences of significant radiation protection events on the health of patients vary widely:

 they usually affect a single isolated patient, but can also concern cohorts (Épinal hospital, Toulouse university hospital)



Medical imaging examination using a tomography installation



ASN guide for radiotherapy risk analysis

- they can lead to death (Épinal hospital, Lyon Sud university hospital) or to serious or severe complications (Tours hospital, Grenoble university hospital)
- generally they do not become immediately apparent, requiring medical surveillance;
- there may not actually be any consequences because the event can, in certain cases, be compensated for in the subsequent treatment.

Once notified by the heads of the establishments concerned, and through application of the radiation protection events notification guide (available at www.asn.fr), ASN:

- organises a reactive inspection, when necessary with the technical support of experts (IRSN, SFPM, SFRO, etc);
- disseminates operating experience feedback to the professionals;
- informs the health agencies (DGS, DHOS, Afssaps, InVS, INCa);
- informs the public after prior (mandatory) information of the patients by their radiotherapist, using the published severity scale updated in July 2008 (www.asn.fr).

In 2009, 131 significant events concerning patients exposed for therapeutic purposes, were notified to ASN. Most of these events (97%) occurred during an external radiotherapy medical process. 4 events occurred during bra-



Typology of failures leading to radiotherapy events (results concerning 117 events notified in 2008)

chytherapy treatment, owing to malfunctioning equipment or errors in calculation of the treatment time.

About two-thirds of the events are random in nature: the error occurred for a single patient during a single session and took place during the treatment session without there being an error in the patient's technical file. However, more than one third of the events were systematic in nature, in other words linked to the presence of erroneous data in the patient's file and reproduced during each session until the error was detected. Finally, and more rarely, the events were due to errors in dosimetric characterisation of the equipment (calibration error for instance).

For all the external radiotherapy events, the origin was usually ascribable to human and organisational factors: defective organisation (failure of check-points, poor communication between technicians, etc.).

The majority of the events notified in 2009 had no consequences for patient health. With regard to external radiotherapy, 120 of the 127 events notified were rated 1 or lower. Seven events were rated level 2 on the ASN-SFRO scale, as events causing or liable to cause a moderate alteration in an organ or function, and resulted in posting of an incident notification on ASN's website. Moreover, one of the 4 brachytherapy events was rated level 2 on the ASN-SFRO scale.

Significant events concerning patients exposed for diagnostic purposes

In 2009, 27 significant events concerning patients exposed for diagnostic purposes, were notified to ASN.

74% of the events notified concerned nuclear medicine procedures. One of them originated in an error in administration of iodine 131 in nuclear medicine: a patient admitted for a diagnostic examination was mistakenly given a therapeutic dose of iodine 131.

International conference on the radiation protection of radiotherapy patients

From 2 to 4 December 2009 in Versailles, and with the support of the World Health Organisation (WHO), the International Atomic Energy Agency (IAEA) and the European Commission, ASN organised the first international conference on the radiation protection of radiotherapy patients, with the participation of numerous professional organisations and associations and patient associations.

The main advances in the new techniques used for external radiotherapy and brachytherapy were presented, along with an inventory of the available scientific and medical data on the side-effects and possible complications linked to radiotherapy and on the individual radiosensitivity of the patients, plus the main lessons to be learned from accidents and preventive risk reduction measures. Round-tables were held to discuss risk acceptability and patient information, with the participation of and first-hand accounts from several patient associations.

The conference was attended by more than 330 participants from 34 different countries, with 50 talks from leading world specialists and more than 70 poster displays. It brought together all the professionals and organisations involved in radio-therapy safety, in particular health professionals, patient associations, representative authorities and equipment manufacturers. The following conclusions were reached:

- the crucial role of radiotherapy in the treatment and cure of cancers was restated;
- although technical developments in the field are beneficial, they also create new risks. Operator training therefore needs
 to be strengthened and the initial uses of these new techniques require independent assessment by professionals using
 procedures as yet to be internationally defined;
- local and international efforts need to be intensified with regard to recording and analysing treatment side-effects and complications. Significant event notification systems must be developed to ensure analysis and operating experience feedback;
- the safety culture in radiotherapy centres must continue to grow, through the implementation of quality assurance and risk analysis, using trained professionals in sufficient numbers;
- greater involvement by the authorities is necessary in order to promote actions in the fields of quality assurance, risk analysis, clinical good practices and clinical audits;
- coordination of research programs is essential if quick and simple radiosensitivity tests are eventually to be developed;
- the involvement of patients and their associations is desirable in assessing the quality and safety of treatment and risk management and communication.



Round-table on radiotherapy challenges, chaired by Mr Bourguignon, ASN commissioner — Versailles — December 2009

Five events concerned interventional radiology.

One of them was notified to ASN by the Strasbourg university hospitals (HUS) in March 2009 following the appearance of side-effects in four patients treated for cerebral vascular pathologies. The various investigations and appraisals carried out highlighted the fact that there was no technical failure of the appliance in question. The effects observed were caused partly by the choice of the

appliance operating modes by the practitioners, contributing to the delivery of a very high dose level for the pathology being treated, and partly by a failure to optimise the settings as a result of organisational shortcomings. The lessons learned from the analysis of this event enabled the HUS not only to improve the quality and safety of its interventional radiology procedures, but also to issue recommendations for improving practices in interventional neuro-radiology.



Summary of the radiation protection monitoring notifications received by AFFSAPS and ASN

Implementation of this wide-ranging and innovative action plan makes the HUS one of the French establishments adopting the most advanced patient radiation protection practices in the field of interventional radiology. Significant dosimetric reductions have been achieved (from -50 to -70%) and measures to monitor dosimetric data and implement in vivo dosimetry will make a national contribution to obtaining an increasingly precise picture of the doses received by patients.

In November 2009, ASN sent the heads of interventional vascular neuro-radiology units and the director generals of regional and university hospitals a circular recalling the regulatory obligations concerning in particular the optimisation principle, personnel training, drafting of radiological protocols and the need to call on the services of a medical radiation physicist to optimise the radiological procedures. Recommendations to facilitate implementation of the optimisation principle, drafted in conjunction with the French Society of Radiology (SFR) and the French Society of Medical Physics (SFPM), were also sent out.

Furthermore, 11 events involving exposure of pregnant women during diagnostic examinations, before they were aware of their pregnancies, were notified to ASN in 2009. In all the cases, this exposure had no consequences for the foetus.

At an international level, ASN focuses on disseminating the experience acquired:

- through meetings both bilateral (Germany, Belgium, Switzerland, Ireland and Spain) and multilateral (Euratom and IAEA committees, EAN network);
- by taking part in the working group set up by IAEA to prepare a scale for rating events concerning patients radiation protection.
- by taking part in WHO work initiated in 2008 on the radiation protection of patients ("Global Initiative on Radiation Safety in Health Care Settings");
- an international conference on radiotherapy treatment safety, organised by ASN, was held from 2 to 4 December 2009, with the participation of IAEA, the WHO and the European Commission (see box).

6 3 The impact on the environment and on the population

6 3 1 Dosimetric impact on the population

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

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

The available information concerning radiological 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 background radiation variations. However, radioactivity measurements in major rivers or wastewater treatment plants in the larger towns occasionally reveal the presence above the measurement thresholds of artificial radionuclides used in nuclear medicine (iodine 131, technetium-99m). The available data on the impact of these discharges indicate doses of a few microsieverts per year for the most exposed individuals, in particular the workers employed in the sewerage networks (source: IRSN study, 2005). However, no trace of these radionuclides has ever been measured in water intended for human consumption. The recommendations that should be made by the physician after radionuclides are used in nuclear medicine were the subject of the work done by the "nuclear medicine" working group of the French High Public Health Council, in particular with respect to examinations and treatment using iodine 131. The aim was to harmonise the advice and lifestyle hints already dispensed by each physician. The work done was based on European recommendations but also on simulations and measurements taken in real-life situations. The recommendations, which 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).

The inspections carried out by ASN in 2008 in the nuclear medicine units did not enable ASN to check the extent of effective implementation of the regulations introduced by the 23 July 2008 order on the removal of effluents and waste contaminated by radionuclides, or liable to have been so contaminated as a result of a nuclear activity, these regulations themselves implementing the requirements of Article R. 1333-12 of the Public Health Code. Improving the management of contaminated effluents and waste remains a challenge to be faced by nuclear medicine units in the coming years.

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

6 | **3** | **2** Significant events

In 2009, ASN was notified of seven significant events involving losses of radioactive sources used in the medical field. This concerned the loss of sources used in nuclear medicine and iridium wires used in brachytherapy.

ASN was also notified in 2009 of an event involving the discovery of sources. This concerned the discovery of two batches of radium 226 needles stored in a locked and lead shielded compartment, inaccessible to the public, in the former boiler-house of a radiology practice. The discovery was made during an inspection by an approved organisation, triggered by the results taken from an ambient dosimeter placed in a radiology room adjacent to the room concerned.

Finally, ASN was notified of five events involving the dispersion of radionuclides. Four of these cases concerned the dispersal of radioactive effluents from nuclear medicine units. The fifth concerned the breakage of a bottle containing a radionuclide used during surgery with a search for sentinel nodes.

7 OUTLOOK

With a cure rate of about 80% of patients treated, radiotherapy is a fully justified method for cancer treatment. However, in the light of the organisational weaknesses detected during inspection of some radiotherapy centres, ASN will – with the assistance of its regional divisions – be maintaining its inspections at least until 2012 in all radiotherapy centres: particular vigilance will be given to the actual increase in medical radiation physics staffing levels, to compliance with the interim criteria published in July 2009 by the Minister responsible for Health and to the gradual development of quality assurance, concerning which the first requirements will become binding as of the beginning of 2010.

At the beginning of 2010, at a meeting of the national committee in charge of monitoring the national radiotherapy action plan decided on by the Minister for Health, ASN will be presenting the conclusions of the international conference it organised in December 2009 on the radiation protection of radiotherapy patients. This will allow identification of any additional actions required. ASN will continue with its international consultations with IAEA, WHO and the European Commission, in order to identify new initiatives or areas of research to improve knowledge and increase the safety of radiotherapy care. In the field of interventional radiology, in particular for the practices involving the highest levels of irradiation, ASN intends to send recommendations to the Minister responsible for Health, based on the advice of the Advisory Committee for medical exposure, so that a national action plan can be defined to improve radiation protection of patients and professionals in this field.

In the field of tomography, and without waiting for the new IRSN and InVS dosimetry estimates of the average doses delivered to patients during radiological examinations, ASN will define the measures necessary to promote non-irradiating techniques (updating of the SFR medical imaging guide), steps to train technicians in optimisation, and implementation of procedures for evaluation of professional practices (clinical audit) in radiology. At a European level, as part of the work done by the Heads of European Radiation Control Authorities (HERCA), ASN will take part in the steps to be taken with the manufacturers of radiology and tomography appliances.

Finally, after publication of the radiotherapy inspection follow-up letters on www.asn.fr in July 2008 ASN will, as of the beginning of 2010, pursue its goal of publishing all the follow-up letters to the radiation protection inspections conducted in the medical sector.