



**ALARA NEWS AND ALARA INFORMATION
IN EAN MEMBER COUNTRIES**

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This document summarizes the main events dealing with ALARA in EAN Member countries discussed at the occasion of the May 2012 Steering Group meeting.

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UK - HPA



1. In anticipation of a lower dose limit for the lens of the eye, HPA Personal Dosimetry Service is developing a new eye dosimeter which is worn on a headband and assesses dose in terms of $H_p(3)$. The type-testing of this dosimeter (using a new phantom designed according to the ORAMED specifications) is almost complete.

2. The following HPA publications may be of interest:

- [HPA-CRCE-032 - The Measurement of X-Ray Beam Size from Dental Panoramic Radiography Equipment](#)

This report describes a quick and accurate automated method using digitised images for the measurement of the dimensions of panoramic X-ray beams.

- [HPA-CRCE-031 - Human Biokinetics of Nasal Clearance by Particle Transport](#)

This report provides a comprehensive compilation of the data on extra-thoracic (ET) retention and ET clearance from a human volunteer study of nasal clearance conducted at HPA.

- [HPA-CRCE-030 - An Investigation of Monitoring by Nose Blow Sampling](#)

The potential for developing nose blow sampling into a robust screening method for exposure to radionuclides

- [HPA-CRCE-029 - Intercomparison of the 'R91' Gaussian Plume Model and the UK Met Office's Lagrangian Particle NAME III Model in the Context of a Short-duration Release](#)

This report compares the predictions of HPA's application of the 'R91' model with those of the UK Met Office's NAME III model. The study considers a simplified application of NAME and R91 to enable a fair model comparison.



IRELAND - RPII



Radiological Protection Institute of Ireland
An Institiúid Éireannach um Chosaint Raideolaíoch

1. Report on impact of the Fukushima accident in Japan on Ireland.

The RPII has published a report on the impact of the Fukushima nuclear accident in Japan on Ireland which concludes that radiation levels detected were miniscule and had no public health consequences.

The total estimated radiation dose to an adult in Ireland from the additional radioactivity resulting from the Fukushima accident was 0.26 microsievert. By comparison, the typical annual average dose in Ireland from all sources of radioactivity including naturally occurring radiation and medical exposures is 3950 microsievert. The doses in Ireland from exposure to radioactivity from Fukushima were therefore of no significance from a public health or food safety point of view.

<http://www.rpii.ie/RPII/files/47/47f5db75-dc90-4451-8d49-707bf618b36c.pdf>

2. Development of a graded approach to Authorisation

Since September 2011 the RPII has been working on the development of a new model for a graded approach to authorisation for Ireland. To date all practices, ranging from low risk cabinet X-ray or dental radiography all the way to higher risk activities such as radiotherapy or NDT, have required a licence. The new model will provide for other authorisation types, such as notification and registration, in addition to the current licensing system. The RPII is now commencing a series of stakeholder consultations with its licensees, professional associations, radiation protection experts and other interested parties. Feedback received from these consultations will be taken into account in the finalisation of the model. In addition, an international review panel will be set up to review the proposed model.

3. Publication of Inspection Programme

In March the RPII published a report on its inspection programmes which provides a detailed overview of the functions and practices of its Regulation and Information Management Division in line with a commitment to enhancing the transparency of its regulatory processes as provided for in the current Strategic Plan. The publication of this report provides a better understanding of the processes and priorities associated with licensing and inspection which may impact on licensees and other interested parties.

The report explains how the 1743 current licensees are categorised, with specific details provided for each category. The operation of the RPII's inspection programme under the scope of its ISO 17020 quality management system is described, together with details of how the annual inspection priorities and programme are developed. Finally,

the report includes a review of the 2011 inspection programme and details of the programme for 2012.

<http://www.rpii.ie/RPII/files/47/47f5db75-dc90-4451-8d49-707bf618b36c.pdf>

4. Re-approval of Radiation Protection Advisers (Qualified Experts)

In 2005 the RPII established a register of approved Radiation Protection Advisers (RPA) who could advise licensees on all aspects of radiation protection and on complying with Irish licensing requirements and legislation. To date 54 RPAs have been approved by the RPII Assessment Committees. The role played by RPAs in advising licensees is extremely important and has contributed significantly to ensuring that high standards of radiation protection are maintained across all sectors in Ireland.

The first of these approvals expired earlier this year and the RPII is currently re-assessing applications from these individuals who have applied for their approval to be extended by a further five years. Guidelines for approval were prepared by the RPII and these are available on its website:

<http://www.rpii.ie/RPII/files/9e/9e244595-9f5f-40d2-850e-aa8531934ba6.pdf>



GERMANY - BFS



CONSEQUENCES OF THE FUKUSHIMA EVENT

A: Activities of the BMU

Since the reactor accident in Fukushima, numerous insights and experiences were gained and analyses were made to improve emergency procedures. BMU has established a working group of the German Radiation Protection Commission to draw conclusions of lessons learned for the improvement of emergency management requirements.

The work programme is structured in several parts:

- Organisation and planning of work packages, documentation of working materials and results
- How can insights and lessons learned with regard to Fukushima Dai-ichi be included in objectives and conditions of emergency management regulatory requirements in Germany?
- Interface between internal and external emergency management of installations
- External emergency management including precautionary emergency management measures for the protection of the public and medical aspects of emergency management.

- Aspects of the radiological situation: estimation of the source term, performance of decision-making systems, radiological measurement and sampling programmes and situation reporting.
- Communication and information in emergencies, national and international communication technics.
- Cooperation (national, international): improvement of information exchange.

B: European requirements with regard to contamination of foodstuffs with radioactive substances

After the events in Fukushima, the import of foodstuffs from Japan was regulated on the basis of the Implementing Regulation (EU) Nr. 297/2011 of 25 March 2011 to protect the users in Europe. This regulation has been modified after each 3 months by new and updated requirements. BMU/BfB has the opinion that unified and consistent regulatory requirements are necessary for elaborating reference values of foodstuffs according to the Euratom Treaty and keep their application flexible, depending on type and severity of the accident.

PREPARATION OF THE INTERNATIONAL CONFERENCE RADIATION PROTECTION IN MEDICINE OF THE IAEA

The International Conference Radiation Protection in Medicine of the IAEA takes place 3-7 December 2012 in Bonn and is hosted by the German government, represented by BMU. Location will be the former German Parliament building in Bonn which is now the World Conference Center Bonn (WCCB). Further information can be found at homepages of BMU and IAEA: <http://www.bmu.de/veranstaltungen/doc/47848.php>, <http://www-pub.iaea.org/MTCD/Meetings/Announcements.asp?ConfID=41578>.

Experience has shown that communication with patients and patient organisations on issues of medical radiation protection is gaining importance. Equally important is the open and transparent exchange of knowledge and experience on incidents and accidents with medical radiation sources, for example by appropriate reporting systems. In view of these topics and of future trends and developments, it is the objective of this conference in December in Bonn, to combine efforts and to improve future international work in medical radiation protection.

The conference includes all aspects of radiation protection in the application of ionising radiation and radioactive substances in medicine. In particular,

- Identification of gaps in the present radiation protection concepts in medicine
- Identification of instruments to improve radiation protection in medicine
- Overview on progress, challenges and possibilities in the area of radiation protection in medicine

Evaluation of the consequences of the international action plan on the radiation protection of patients with the objective to prepare new international recommendations, considering

UPDATING THE DIAGNOSTIC REFERENCE VALUES IN NUCLEAR MEDICINE

BfS has published, for the first time in August 2003, diagnostic reference values (DRV) for radiological and nuclear medicine examinations. For radiological examinations, these DRV were updated in June 2010. Now also DRV for nuclear medicine examinations are to be updated. BfS is proposing new values on the basis of the results of a study project where in 2 years about 370.000 nuclear medicine examinations were evaluated including type of radiopharmaceutical and applied activities. The selected examination methods include 95% of all nuclear medicine examinations. The proposed values are oriented on median values. For paediatric examinations, the activities to be applied are calculated on basis of the values for a 70 kg adult. If there are no minimum values for adults, the examination should not be carried out for children.

ESTIMATION AND DOCUMENTATION OF THE BODY DOSE OF PATIENTS DURING RADIOIODINE THERAPY

German radiation protection regulation requires for treatment with radioactive substances, that the body dose is estimated and documented. In radioiodine therapy, radioactive iodine is accumulated mainly in the thyroid over a longer period of time. In addition, there are minor measurable radiation exposures of the gastrointestinal tract, lacrimal and salivary glands, urine bladder and gonads. The estimation of organ doses due to these exposures, and consequently the body dose, is very complex and there are no established procedures how to estimate the body dose. Therefore, in order to comply with the requirements, the BMU proposes for radioiodine therapy to only document the thyroid dose during treatments.

NEW RADIOPHARMACEUTICAL: ALPHARADIN (RA-223-CHLORIDE)

Alpharadin (radium-223 chloride) is in the late phase of clinical development at Bayer. It is used for the treatment of cancer which has already developed metastasis in the bone. The pharmaceutical is emitting alpha radiation. Radium-based alpha-pharmaceuticals, such as Alpharadin behave very similar in the body as natural calcium in the bone. It is deposited in regions with increased bone metabolism, i.e. around bone metastasis and irradiate these with alpha radiation. In a phase-III study, a prolongation of survival could be shown at patients with prostate carcinoma and symptomatic bone metastasis. US FDA (Food and Drug Administration) has approved a so-called fast-track licensing procedure for Alpharadin. Bayer is planning to apply for authorisation of Alpharadin in USA and Europe by mid 2012.

INTRAMACULAR BRACHYTHERAPY WITH THE VIDION SYSTEM

The VIDION® Anti-Neovascular (ANV™) Brachytherapy system is used for treatment of age related macular degeneration. The use of the system has already been licensed in several German Länder. A checklist has been elaborated as part of the license procedure which contains a number of issues to be monitored and documented by the MPE, in particular:

- Leakage tests should be carried out every 6 months by an expert appointed by the competent authority.

- In order to estimate the part body dose, it is recommended to wear two beta sensitive finger ring dosimeter (one each hand). This is foreseen for operators, radiotherapists, MPE and for all individuals handling the equipment directly (incl. Sterilisation and cleaning). After 12 months, the competent authority will check if the results justify a single finger ring dosimeter. The correct wearing position of the dosimeter is determined by the MPE.
- The MPE has to be present during the irradiation.

JUSTIFICATION OF WHOLE BODY FAT MEASUREMENTS BY MEANS OF DEXA (DXA)

In practice, the DEXA-Method (dual energy x-ray absorptiometry) is used more and more frequently for determining the content of body fat, mass of muscles and bones. Manufacturers of this equipment are promoting actually the use of this method for body fat determination. Within this method, the body is scanned with an x-ray source, which produces two discrete energy peaks. The calculation of body composition is done on the basis of the different attenuation of the radiation by the tissue to be analysed. This procedure is relatively complex. For the determination of body fat more simple methods not based on x-rays are available. Therefore, competent authorities and endocrinologists consider this method as not justified.

MAMMOGRAPHY-SCREENING-PROGRAMME - STATUS MORTALITY EVALUATION

The licence for the screening programme for early detection of breast cancer has been issued under the condition that the usefulness for health, i.e. decrease of breast cancer mortality is monitored and demonstrated (mortality evaluation). A science-based study of this issue is under preparation at BMU. The scientific and administrative steering of this project is done at BfS. A feasibility study is foreseen for the elaboration of a concept for the mortality evaluation in the next two years. The availability of the data required for the mortality evaluation is not yet assured due to data protection reasons, but measures are under way to solve this problem.

X-RAY EXAMINATION FOR THE EARLY DETECTION OF DISEASES

a) Lung cancer – low dose CT

In Germany, the application of x-rays to patients for the early detection of diseases is not covered by the X-ray Ordinance, since there are no symptoms of a disease at the time of the examination. The draft Euratom Basic Safety Standards contain a proposal for the determination of prerequisites for the application of x-rays for the individual early detection of diseases. The proposal assumes that justification should be based on guidance provided by medical professional societies. BMU is currently discussing how to formulate the requirements of the X-ray Ordinance so that x-rays can be applied for individual early detection of diseases within a defined framework. BfS is initiating a study to define quality requirements and criteria for carrying out early detection examinations within the framework of medical research, on the basis of the criteria for early detection of lung cancer. Due to the publications on possibilities of lung cancer

early detection by CT, an increase of demand for early detection examinations is expected, and consequently an increase of “gray lung screening” should be avoided.

b) Osteoporosis – DXA

Osteoporosis is a disease of the skeleton, which results in an increased susceptibility to bone fracture due to decomposition of bone substance and structure. The risk of developing osteoporosis increases with age. For diagnosis, bone density measurements are made. The dual-spectra-x-ray-absorptiometry (DXA) is considered the standard procedure for the determination of bone density with appropriate precision. Radiation exposure of a DXA-examination is typically 0,01 mSv. According to the German Osteological Society, DXA-examinations are indicated for women from age 70 on and for men from age of 80 on. For early detection examinations of women from age 54 on, a single examination is foreseen to identify women with an increased risk for osteoporosis-based fractures. The establishment of a general screening programme for the early detection of osteoporosis is considered to be not justified.

REVISION OF THE GUIDELINE RADIATION PROTECTION IN VETERINARY MEDICINE

a) CT in veterinary medicine

The revision of the Guideline in Veterinary Medicine is still in progress. However, due to the experience of the veterinary universities the radiation protection competence of veterinarians is of alarmingly low level. Therefore, BMU and German Länder competent authorities proposed a duration of the work experience between 30 days and maximum 12 months and a minimum of 50 CT-examinations and a special radiation protection course of 16 hours to acquire the necessary competence in radiation protection.

b) Further issues for the revision

- Examinations, in particular of horses with mobile x-ray units (for example by foreign non-veterinarians) within the process of purchase examinations etc.
- Determination and keeping of records of the body dose of animal [accompanying](#) persons
- Waste management, in particular after Jod-131 thyroid therapy of cats.
- Newer developments.

CONFIDENTIAL - RADIATION INCIDENT IN THE MEDICAL SECTOR

An incident occurred in a German hospital during an intervention within a clinical study according to the medical product law (September 2012)

Within the framework of a large clinical study, using new not yet established methods in cardiology, a patient was overexposed by x-rays during a minimal invasive intervention with the objective to treat a mitral valve insufficiency. The predicted radiation exposure was within the range of other catheter-based interventions. Therefore, no special authorisation was asked for. However, during the intervention, due to unforeseen complications, a much higher sequence of x-ray images had to be

taken to complete the intervention (altogether 833 sequences with 50 images in average) which caused a skin dose of 75 Gy (erythema dose is about 3-5 Gy, from 50 Gy on necrosis is expected).

It is too early to evaluate the radiation injuries of the patient, however, permanent damage is most probable. The exposure of the staff involved in the intervention was well below dose limits.

The competent authority asked for an expert opinion.



SWITZERLAND - SFOPH



Switzerland wants to introduce future clinical audits in RADIOLOGY

In 2011 Switzerland started a project to introduce future clinical audits in RADIOLOGY, i.e. in diagnostic radiology, in nuclear medicine as well as in radiotherapy. The goal of the project is to guarantee the optimal use of ionizing radiations for patients in RADIOLOGY. An analysis of the Swiss system with the participation of the main stakeholders showed that patients would benefit from the introduction of an audit organization.

This project requires the modification of the Swiss law, what is in progress. The next steps comprise the elaboration of the different guidelines for the good clinical praxis, the definition of the audit programs, the criteria that auditors will have to fulfill as well as their training.

The first official clinical audits are expected for 2017.

Radon

In order to take account of the new epidemiological findings and the related international directives (WHO Radon-Handbook 2009, ICRP-115 2010), the Federal Office of Public Health prepared a new “National radon action plan 2012-2020”, which was approved by the Swiss Federal council on 25th of May 2011.

The actual radiological protection ordinance (ORaP) sets the limit value for a mandatory remediation in dwellings at 1000 Bq/m³, and the guideline value for new buildings and radon mitigations at 400 Bq/m³.

As the international organizations agree on a reference level of 300 Bq/m³ and the application of the optimization principle, Switzerland needs to examine its legal values during the revision of the ORaP, which has already started. The Federal Office of Public Health plans to focus on building regulations for new houses. In addition, the authority plans to apply a graded approach that takes in account economical and social criteria and to implement cost-effective solutions for the mitigation of existing buildings over 300 Bq/m³, for example parallel to renovation works.



SPAIN - CSN



Radioactive Materials and Facilities Security

New regulation has been issued by the Parliament regarding security of nuclear and radioactive materials and facilities (Real Decreto 1308/2011 de Protección Física de Fuentes Radiactivas de categorías 1, 2 y 3 ¹). The main objective is to prevent theft of radioactive materials and sabotage of facilities.

According to the new regulation, facilities with radiation sources in categories 1, 2 and 3 shall implement a security plan, and the licensee is direct responsible for security. The CSN and the corresponding ministry will determine which facilities must have a dedicated security department. The remaining facilities shall implement the security requirements contracting third party companies. Requirements include physical resources, organizational and human resources and procedures. Further regulatory development will be provided by Instructions issued by the CSN.

Participation in MELODI

As a result of the works of the High Level and Expert Group (HLEG) on European Low Dose Risk Research, the European Commission supported the creation of the MELODI research platform, which in turn resulted in a new Network of Excellence, called DoReMi, set up in January 2010 between 12 partners with a duration of six years. The CSN has promoted the Spanish participation in Platform MELODI. It has considered that is of great interest as much for the own CSN as for the Spanish organizations who work in these subjects. The Spanish representation in platform MELODI has become through the UAM (Centre of Molecular Biology, CBM) and the University Rovira i Virgili (Laboratory of Toxicology and Environmental Health, LTSM). These two institutions signed the letter of adhesion to MELODI in 2010. CSN signed an agreement with the UAM to support participation in MELODI, and the next I+D Strategic Plan of the CSN in its section of Radiobiology and Dosimetry, will adopt the objectives outlined in the Strategic Research Agenda of MELODI. Steps are being taken for the creation of a national platform in Spain that will be coordinated by the Spanish participants in MELODI with the support of the CSN.

Participation in UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation.)

By Resolution 66/70 of the General Assembly of United Nations of 9 of December of 2011, Spain became member of the UNSCEAR. Since 2007, Spain had been invited to this Committee as an observer.

¹ http://www.csn.es/images/stories/acerca_csn/normativa_nacional/realdecreto1308_2011.pdf

Patient Safety

Two projects included in the framework of the agreement between Health Authorities and CSN described in previous ALARA NEWS are now functional: The first project, known as DOPOES, consists on a survey of the procedures used for medical radiation diagnosis in Spain, their frequency and the doses imparted to patients and population. This project is being carried out by the Universidad de Málaga with the collaboration of the Scientific Societies and Health Authorities. The second project is the study of dose from CT scanners in children and teenagers which is part of the European project with the participation of 11 European countries, EPI-CT (epidemiological study to quantify risks for paediatric and optimise doses). This project is performed by CREAL (Environmental Epidemiology Research Centre) in Barcelona, through December 2015.

Ibero-American Regulatory FORUM

Following the celebration of a workshop about the licensing of cyclotrons to obtain Positrons Emission Tomography (PET) elements (held in Madrid on 2-6 May 2011 at CSN), a technical meeting was held last March in Chile with representatives of seven Ibero-American countries, Spain and the IAEA with the aim of developing a Licensing Guide for Cyclotrons that can be applied by countries without previous expertise in this area. Experts

Radiological Protection FORUM

Work on the radiological protection FORUM continues concerning to the Medical field, the Industrial field and the Radiological Protection Units (UTPR), between CSN, Medical Physics and Radiological Protection Associations. Their aim is to encourage dialogue in order to improve Safety and Radiological Protection in the different practices and to favour the communication between regulators and stakeholders.

Two new projects have started in this area: One seeks the application of risk analysis methodologies (in particular Risk Matrix) to Radiotherapy services, following the information provided by the project developed by the Iberoamerican FORUM in this matter. The second one is aimed at the record and analysis of dosimetric data of Nuclear Medicine patients. CSN and the Professional Associations have set up working groups for both projects; the latter has already begun actual work development.

Participation in the WG on Medical Applications of HERCA

As a result of the participation in HERCA, the I-131 patients card model has been introduced in the protocol, and a letter will be issued by CSN to all related parties and facilities to promote its prompt and widespread adoption.

“Radiation And Radiological Protection”. Guidelines for Primary and Secondary Schools

The CSN has established an agreement with the Education and Science Ministry (MEC), competent organ in Spain in education, related to the population education concerning the field of ionizing radiation. In the framework of that agreement, updating a document published by the Directorate General XI (environment, Nuclear safety and radiation protection) of the European Commission, entitled "radiation and radiation protection: course for primary and secondary schools", was carried out.

Due to the time elapsed since the edition of the above-mentioned document and, to update it to the current educational system in Spain, it was necessary to develop two new documents. A teaching guide for primary schools was issued (aimed at students between 6 and 12 years old) and a teaching guide for secondary schools (high school and vocational training), for students aged 12 to 18 years old.

A general objective for the teaching guide for primary schools is to stimulate student's interest in the physical phenomena that reveal the existence of radiation in daily life, as well as to introduce the different types of radiation (ionizing and non ionizing) from both natural and man-made sources. These issues are explained in a very intuitive and general way, due to the fact that pupils of this age have not yet studied the internal composition of matter.

The teaching guide for secondary schools is more ambitious, its general objectives are wider, and try to explain the origin and types of radiations, their characteristics, devices for detecting and measuring them, biological effects of radiation on the human body, measures for radiation protection, and its implementation in medicine, industry, research, security, etc.

These guides were presented at the recent IRPA-13 meeting and there are available on CSN website at the following addresses:

http://www.csn.es/images/stories/publicaciones/otras_publicaciones/guia_radia_w eb.pdf

http://www.csn.es/images/stories/publicaciones/otras_publicaciones/guia_didactic a_primaria.pdf

INES Scale

- Participation in the INES Advisory Committee of IAEA, whose role is to establish and provide clarification in the policy regarding the application of the INES Scale to nuclear, radiation and transport events, as well as to review the rating of the annual events notified to the Agency.
- Participation in the IAEA meeting to study to introduce the medical events in relationship with patient in the scale

Other participations

CSN takes part in the “Permanent Group of Experts” of France Authority (ASN), group of medicine. This group holds meetings every two months in Paris.

Information

CSN provides an English version of all the Regulation and CSN Instructions at the website: www.csn.es



MEDICAL, INDUSTRIAL AND RESEARCH ACTIVITIES

1. ASN facilitates the process of applying for authorization for medical and industrial uses of ionizing radiation sources

To facilitate the process of applying for authorization of medical and industrial uses of ionizing radiation sources, ASN has simplified the use of online forms. This revision meets the demands expressed by applicants, including authorizations that involve multiple devices.

The new forms take into account the ASN decision No. 2010-DC-0192 of 22 July 2010, amending the documents to be attached to such authorization requests.

Among the main evolutions there is the possibility for industrial activities, to grant authorization to a corporation (moral person) and the strengthening, for medical activities, of the information to be provided relating to radiation protection of workers or the shared use of equipment.

2. Quarterly report of ASN/SFRO level 1 radiotherapy events reported during first quarter 2012

Thirty events, classified as level 1 on the ASN-SFRO scale, were reported between 1 January and 31 Mars 2012. Although these events are not expected to have any impact on patients' health, they are analysed to see if any lessons can be learnt from them (particularly as regards organisation) and to avoid any recurrence.

Twenty-nine events have concerned one single patient. One event has concerned 2 patients due to a consecutive error. Most of the events (19) have caused an unattended exposure in one area of the patient not expected to be irradiated. Six events have concerned an error in patient identification, 3 events concerned dosage error and 2 events due to an error in beam positioning.

ASN investigates level 1 events during specific inspections or during its regular inspections of radiotherapy centres.

3. ASN and AFSSAPS launch a website for reporting significant events in radiation safety and equipment monitoring aimed at radiotherapy centers.

The site www.vigie-radiotherapie.fr was launch on 7 July 2011 from a joint initiative between ASN and AFSSAPS. It allows radiotherapy professionals to fulfil all reporting obligations of significant events for patients or equipment. Regulatory obligations in this field are compiled in <http://www.vigie-radiotherapie.fr/?action=reglementations>.

4. ASN publishes the results of inspections conducted in 2010 in radiotherapy centers: the safety of care progressing steadily since 2008.

The assessment of inspections performed in 2010 by ASN in 127 radiotherapy centers confirms the increase of human resources devoted to medical radiation physics which began in 2008 and continued in 2009. This increase is particularly due to significant number of recruitments of specialists in medical radiation physics (PSRPM), following the strengthening of human resources in radiotherapy centers in the framework of the "Cancer Plan 2009-2013".

ASN noted that progress was also achieved in the general implementation and execution of safety management and quality of patient care. However, ASN believes that the involvement of institutional directions in safety management and quality of care remains inadequate. Some centers still need to strengthen their safety culture and quality of care including formalizing the practices of care for patients and training teams to the methods of risk analysis. In many centers, efforts to formalize practices and skills should be continued with respect to the terms of delegations¹ teams for image validation controls to reposition the patient during treatment.

Although declarations of internal malfunctions have generalized, cause analysis and follow-up medium and long term improvement actions need to progress further. The mobilization of professionals, supported by measures adopted under the Cancer Plan, must be maintained to meet all regulatory obligations that are enforceable by the end of the year 2011.

Inspection of radiotherapy centers remains a priority for ASN. Centers whose situation remains fragile because of either the small numbers in medical radiation physics or the weakness in steering the implementation of a system of safety management and quality of care, have received in 2011, a special awareness by ASN.

5. ASN regulates the removal of smoke detectors ionic

Two ASN decisions complete one order dated November 18th, 2011 governing the withdrawal, scheduled over ten years of 7,000,000 ionic smoke detectors installed in 300,000 sites in France.

In France, the use of ionic smoke detectors in private housing has been banned since 1966.

The process, launched several years ago by the ASN, in consultation with the fire safety professionals and the concerned ministries, helped lead to the withdrawal plan, based on some important points. Thus, the order dated November 18, 2011 provides:

- the renewal of the exemption from authorization under the public health code for institutions holders of lines of fire detection which have ISD installed. These institutions remain responsible for the management and recovery of the detectors they hold and are required to establish now, with the person in charge of maintenance of detectors, a census form to be forwarded to the IRSN no later than December 31, 2014;
- the establishment of a timeframe of 10 years for the withdrawal of the detectors, taking into account the importance of the installed park to ensure both the sustainability of industrial recovery sectors and the elimination of ionization detectors under satisfactory radiation protection conditions.

6. Presence of radionuclides in lamps: no health risk to ASN

Some lamps currently on the market contain a small amount of radioactive substances (krypton-85, thorium-232): its marketing has generally been committed before 2002. These bulbs are mainly for professional use, except those fitted to some cars headlights (xenon lamps). However, it was considered preferable to consider them in their entirety as consumer goods.

Since 2002, the French Public Health Code prohibits the intentional addition of natural or artificial radionuclides in consumer goods and the use for manufacture, materials or waste contaminated or likely to be. Derogations can however be granted if these additions are justified by their benefits in terms of health risks they may pose. Several European countries have exempted these additions from authorization based on their low impact in terms of radiation protection.

ASN having recalled the prohibition of the Public Health code to manufacturers of light bulbs concerned, these, federated within the European Lamp Manufacturing Companies Federation (ELC) have presented to the French Ministry of Labour, Employment and Health requests for waivers to allow them to continue manufacturing and distributing these products. The processing of applications, currently underway, has been entrusted to ASN.

The first elements resulting from the assessment of the risks conducted by the ASN with the support of its technical expert, IRSN, show indeed that the doses received by the public, in normal circumstances and incidental, are very low.

This assessment, based on international standards of safety and radiation protection considers several scenarios used to determine maximum values of incurred doses. Based on the results of these initial appraisals, ASN does not identify a health risk that would lead it to ask, preventively, the end of commercialization of these lamps and the withdrawal of lamps already in use.

OCCUPATIONAL RADIATION PROTECTION

1. ASN and the DGT support the HERCA initiative to harmonise monitoring procedures for workers exposed to ionising radiation

ASN and the DGT, France's Directorate-General for Labour, support the HERCA initiative to promote implementation of an EC-wide system for monitoring exposure to ionising radiation given the context of the free movement of workers across Europe.

ASN and the DGT made some comments on implementing the system proposed under HERCA in France, mainly regarding the "hardcopy" format of the proposed radiological monitoring document (not suited to the need to constantly update information), the scope of application (it should be extended to all workers exposed to ionising radiation), its content, which should focus on operational monitoring, and the need to examine the compatibility of this document with national regulations regarding the confidentiality of certain individual dosimetric data.

ASN and the DGT therefore propose two interrelated initiatives:

- the first, at European level, consisting in encouraging HERCA to pursue discussions on the feasibility of using an electronic data exchange system to which the centralised systems of each Member State can be connected;
- and the second, at national level, aimed at thinking about the changes in regulatory provisions governing dose monitoring procedures. To this end, a working group is being established, whose work will be defined in line with that of the COCT, the Working Conditions Committee. This work will be integrated in upcoming debates on transposing the future Euratom directive into national law.

The position statement taken by ASN and the DGT can be seen as continuing the vast consultation process undertaken in France by ASN as part of the HERCA initiative.

In the context of its studies relative to radiological protection for outside workers, HERCA has adopted a draft document on radiological monitoring (the "radiation passbook") which will improve operational protection of workers exposed to a risk of ionising radiation when working in controlled areas. This document will satisfy the requirements of Directive 90/641 EURATOM.

On the basis of this draft document, the radiological protection competent authorities have decided to launch, at national level, a consultation of the stakeholders involved. In France, in addition to asking the IRSN for its technical opinion as the administrator of SISERI, the information system for monitoring exposure to ionising radiation, and coordination with the public administration (DGT), ASN has undertaken a consultation, since September 2010, with:

- ASN Advisory Committees for radiation protection
- labour/management partners that sit on the COCT, particularly the representatives of trade unions

NATURAL RADIATION

1. **ASN publishes the 2011-2015 national action plan for the management of radon risk**

The Nuclear Safety Authority (ASN) has published the 2011-2015 national action plan for the management of radon risk. This document is the result of a collaboration between ASN, the ministries of health, housing and labor organizations and partners (Institute for Radiation Protection and Nuclear Safety-IRSN, National Institute of Health Surveillance, InVS, Centre Scientific and Technical Building-CSTB, the Limousin Regional Council). This second action plan follows the 2005-2008 plan whose assessment report was published by ASN in 2009 and available on its website.

The 2011-2015 national action plan focuses on reducing exposure in existing housing and new rules of construction in new buildings to help you find the lowest possible level of exposure persons.

This action plan includes 30 actions grouped around five main areas:

- Management of radon risk in existing buildings for residential use,
- The establishment of regulations for new buildings for residential use, particularly with regard to building regulations,
- Follow-up of regulations concerning public places and regulations applicable to workers,
- Development of new management tools; the establishment of an operational diagnosis in buildings and construction work by professionals,
- Coordination of policy studies and research, including the feasibility study of a fast measurement for assessing the potential entry of radon in homes

The success of this national action plan based on the active collaboration of various national and territorial actors on this topic. Also, several actions will be supported by regional and local initiatives, particularly taken in the context of regional "environmental health" plans. This will strengthen the capacity of local actors involved helping new actors emergence and encouraging the sharing of these skills