



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

November 2011

**Final version
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This document summarizes the main events dealing with ALARA in EAN Member countries discussed at the occasion of the November 2011 Steering Group meeting.

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UK - HPA



1. The Environmental Permitting Regulations in 2011 (England and Wales) (Amendment) Regulations 2011 were implemented on 1st October 2011. These provide a new regulatory regime for exclusion and exemption of radioactive materials and waste. The new regime is based on the principles in the European BSS and it includes artificial sources and NORM. For the latter, a “positive list” of NORM industrial activities is included, plus exclusion levels of 0.5 Bq/g for the U-238 and Th-232 chains in equilibrium. Separate provisions are provided for exemption of NORM waste up to 5 Bq/g, subject to annual disposal limits, and up to 10 Bq/g subject to a suitable radiological impact assessment.

Guidance on the new regulations can be found at:

<http://www.environment-agency.gov.uk/business/sectors/133736.aspx> .

2. A UK-wide scheme for the recognition of Radioactive Waste Advisers (Qualified Experts) has been launched in the UK. More details can be found at:

http://www.sepa.org.uk/radioactive_substances/radioactive_waste_advisers/statement_and_guidance.aspx

3. The following HPA publications may be of interest:

[HPA-CRCE-028 - Radiation Risks from Medical X-ray Examinations as a Function of the Age and Sex of the Patient](#)

[HPA-CRCE-027: Review of Methodologies to Calculate \$A_1\$ and \$A_2\$ Values, and Exemption Values](#)

[HPA-CRCE-025: Review of the transfer of technetium to terrestrial crops and animal products](#)

[HPA-CRCE-021: Assessment of the Radiological Impact of the Recycling and Disposal of Light Bulbs Containing Tritium, Krypton-85 and Radioisotopes of Thorium](#)

The European Light Companies Federation commissioned this study by HPA.

[HPA-CRCE-019: An Analysis of Radon Remediation Methods](#)

Information on some 2,700 radon remediation projects has been analysed with the aim of identifying the factors that influence the performance of various remediation methods, including the specific remediation techniques applied, the physical characteristics of the home, the radon level before remediation and who carried out the work.



IRELAND - RPII



Radiological Protection Institute of Ireland
An Institiúid Éireannach um Chosaint Raideolaíoch

1. Requirements for the wearing of lead aprons in dental radiology.

The Radiological Protection Institute of Ireland and the Health Service Executive (HSE) have jointly issued a position statement setting out the requirements for the use of lead aprons in dental radiology by staff, patients and individuals assisting patients

The new advice states that there is no need for staff using X-ray equipment to wear lead aprons once they adhere to safe working practices and that there is no justification for aprons to be routinely worn by patients. Lead aprons should however be provided to anyone who holds or supports a patient during an X-ray and special consideration should be given to the shielding of the patient's thyroid. The publication of this statement should at last bring much needed clarity on this issue to dentists throughout Ireland

<http://www.rpii.ie/RPII/files/3c/3cac7398-f948-4f68-b30b-67b33c32fa01.pdf>

2. Requirements for personal dosimetry in dental radiology

The RPII has published new requirements on the need for personal dosimetry in dental radiology following an extensive review of this issue by the RPII's Regulatory Service. This review included an examination of the RPII's dosimetry records over the past ten years, current practices in other European countries as well as acknowledging the standard of dental X-ray units in Ireland today. Where previously a personal dosimetry programme was a mandatory licensing requirement, dentists are now required to undertake a risk assessment, in conjunction with their Radiation Protection Adviser (RPA), to determine whether such a programme is required. With the recent appointment of RPAs to all dental practices, dentists now have access to independent expert advice on radiation protection and decisions as to whether personal dosimetry is required can now be taken by the individual practice.

<http://www.rpii.ie/RPII/files/b1/b1ba9c9e-c6f2-4c49-8065-efd2264528fa.pdf>

3. Publication of Inspection Programme

This report marks a new development for the RPII as it 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 will provide 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 1737 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 2010 inspection programme and details of the programme for 2011.

<http://www.rpii.ie/RPII/files/8a/8a7ce31c-618f-40ec-91ec-0a28e0b5753d.pdf>



**GERMANY -
BFS**



Image-guided radiotherapy (IGRT)

In order to improve the precision of radiotherapeutical procedures, image-guided systems (IGRT) have been established. Before irradiation, the position of the patient is checked by imaging systems based on x-rays. The operation of such systems needs to be authorised.

The purpose of applying x-rays for positioning checks is to make sure that the target volume is correctly covered. Therefore the application of such systems falls under radiodiagnostic procedures and monitoring of radiation exposure of the patient is required. Currently, this is not always done, although the radiation exposure of the patient is not negligible.

See also the statement of the Radiation Protection Commission (SSK) in its recommendation on radiation hygiene requirements for IGRT („Strahlenhygienische Anforderungen an IGRT“): <http://www.ssk.de/de/werke/2010/volltext/ssk1005.pdf>.

Part-body dosimetry in nuclear medicine

Within the framework of the EU project ORAMED (<http://www.oramed-fp7.eu/>) extensive measurements of skin exposures were carried out of personnel working with Tc-99m and F-18 in nuclear medicine diagnostics and radionuclide therapy with Y-90 in 34 nuclear medicine departments. Measurements of the local skin dose were done according to a standardised protocol considering at least 11 measurement points at each hand of a person (see ORAMED Website, D4.3.pdf under Deliverables).

Results show that more than 20% of radiation exposed workers in this area receive more than 500 mSv (annual limit) skin dose per year assuming average numbers of patients in diagnostics and therapy. This is normally not discovered. Therefore, routine monitoring of skin dose and a well established way of wearing the finger ring dosimeter is recommended. Even then, the maximum skin dose is underestimated by a factor of 6. Therefore, the current procedure for dose estimation needs to be reviewed and modified to fit the requirements. This is done in a working group of BMU/BfS experts and representatives of the Länder radiation protection authorities.

Quality control of nuclear medicine equipment

Equipment used when applying radioactive substances in nuclear medicine is subject to internal quality assurance procedures. QA requirements are established by the German Radiation Protection Commission (SSK) in their recommendation on quality control of nuclear medicine equipment („Qualitätskontrolle von nuklearmedizinischen Geräten – Festlegung von Reaktionsschwellen und Toleranzgrenzen“). Experience shows that these recommendations are meaningful and appropriate, and should be required in the radiation protection ordinance. The European Commission will publish soon report RP 162, which describes reliability criteria for medical-radiological equipment containing acceptance and tolerance values.

Physical-technical quality assurance in radiotherapy – Implementation of a system for checking the entire treatment system

Modern radiotherapy systems consist of a number of components (imaging systems, irradiation planning system, treatment verification, dosimetry, etc.) and their interaction is currently not checked systematically. Especially the combination of different software systems implies a number of potential sources of errors.

SSK proposes in its recommendation physical-technical quality assurance in radiotherapy („Physikalisch-technische Qualitätssicherung in der Strahlentherapie – Vorschläge zur Prüfung des gesamten Behandlungssystems“). In addition to a number of individual recommendations, a strategy for checking the entire treatment system is requested.

In October 2011, the SSK working group quality assurance in medicine („Qualitätssicherung in der Medizin“) met and discussed the dosimetry checking of the entire treatment system in radiotherapy in general as well as gained an overview over those test specimens and test methods which do currently exist. In the next steps, some of the phantoms used will be further examined and requirements for checking procedures will be defined.

Revision of the Guideline „Competence of RPO in nuclear power plants and other nuclear installations“

The scope of the guideline should include installations for decommissioning (minimum level 50 kW(th)).

With regard to competence requirements of RPO (Radiation Protection Officer), minimum educational requirement is a bachelor degree in a technical, mathematical or natural science field, an appropriate training course and practical experience, which should be proved by completing a detailed training programme (OJT).

Outline of the radiation protection competence for decommissioning installations: In general, RPO competence during operation and during decommissioning phase should be the same. Because of the variety of the decommissioning procedures, it might not be sensible to establish graded procedures. If, at a later stage of the decommissioning phases, less competence requirements are appropriate for certain areas of work, this can be decided on a case-to-case basis.

For maintaining competence, the participation in suitable courses, technical meetings and conferences should be demonstrated (240 h in 3 years, in line with the requirements of the competence guideline for RPO with overall responsibility in NNP).

Mammography screening - mortality evaluation

The approval of the current German screening programme for early detection of breast cancer was given with the condition that the health benefit (decrease of breast cancer mortality) must be examined and followed-up. A scientific treatment of these questions will start in 2012 within the framework of a research project.

Early detection of lung cancer

The results of a study of the USA National Cancer Institute of the usefulness of radiological examinations for the early detection of lung cancer (National Lung Screening Trial -NLST) indicate that an annual low-dose CT of strong (asymptomatic) smokers reduces lung cancer mortality by 20 %. As consequence of these findings an increasing demand of smokers for early detection of lung cancer is expected which could lead to uncontrolled CT examinations („opportunistic screening“) without adequate quality control. However, several undesirable consequences may occur from early detection examinations. These, as well as the radiation risk, have to be thoroughly taken into account.

In Germany, radiological examinations for early detection of diseases are not covered by radiation protection regulations if they are not part of an approved screening programme. Because of the absence of symptoms which need clarification, these examinations are not considered as medical application. Therefore, it is necessary to discuss a framework for individual quality-assured early detection procedures to be integrated in the regulatory system in order to avoid uncontrolled “opportunistic screening” for smokers.

Particle therapy – justification and quality assurance

In recent years particle therapy, in particular with protons and heavy ions, is being discussed with regard to better risk/benefit considerations compared to photon therapy. Currently, there are several particle therapy centers operating in Germany (Berlin, Heidelberg, Munich). In the light of several more installations under construction, standardised criteria for operation and quality assurance measures are necessary.

Up-to-date scientific knowledge with regard to clinical safety and effectiveness of proton therapy is not yet sufficient to assess risk and benefit of this therapy modalities compared to recognised standard therapy methods. Professional associations for radiotherapy consider at present only two tumor types (melanomas of the eye and chordomas of the skull) as established indications for proton therapy.

The assessment (justification), if proton therapy should be considered in an individual case, has to be done by a physician with competence in radiation protection.

Operation of the High Activity Sealed Sources Register at BfS

Since 2006, the register is operating on a routine basis. About 23.000 high activity sealed sources are currently (October 2011) registered in the database and 111 representatives of 52 authorities as well as 629 license holders have access to the register.

The software has been constantly improved. Currently, the following improvements are projected:

- automatical operation of the system for routine notifications,
- additional storage capabilities for documents (i.e. source certificates or images of radioactive sources),
- implementation of a more secure electronic authentication method for the users of the register.

Operation of the Radiation Protection Register at BfS

In 2010, more than 341.000 occupationally exposed workers were monitored in Germany. From these 18 % were exposed (above detection limit) with a mean dose of 0.7 mSv and a collective dose of 40 person-Sievert. More than 21.230 persons were monitored for part-body exposure (extremities incl. skin), 29 % were actually exposed with an mean dose of 16.3 mSv. For 111 persons the exposure of the eye lens has been monitored resulting in an annual mean dose of 6.2 mSv and a maximum dose of 28 mSv. In 2009, around 37.000 air crew personnel were monitored with a mean annual dose of 2.4 mSv and a collective dose of 86 person-Sievert. New BfS reports on occupational radiation exposure and on radiation exposure of air crew personnel are available in German language

(see also <http://doris.bfs.de/jspui/handle/urn:nbn:de:0221-201105105835>).

BfS is involved in activities related to occupational radiation protection within Working Group 1 of HERCA as well as in other related activities of IAEA. BfS is chairing the expert group on occupational exposure (EGOE) of CRPPH. Some results of the work of EGOE were recently published by OECD/NEA as report on "Dose Constraints in Optimisation of Occupational Radiological Protection".



ITALY - ISS



Italy has long experience in the detection of radioactive sources in scrap metal or contaminated scrap metal¹. In 1995 the Italian Radiation Protection Act was promulgated, which implemented some Euratom directives on ionising radiation, and entrusted radioactive monitoring of scrap metal to metal scrap operators. The provisions concern industrial and trade operators and exclude carriers. As a consequence of the 2008 incident with stainless steel sheets in coils², in 2009 such obligations became applicable to importers of metallic semi-finished products as well. In June this year the articles of the Radiation Protection Act concerning radioactive monitoring of scrap metal were updated again to specify, among other things, the type of certificate to be released after monitoring and the persons authorised to do so.

This year's annual Conference of the *Italian Radiation Protection Association* (AIRP) was held from 12 to 14 October in Reggio Calabria. A lecture discussed the radioprotection problems connected with the so-called *non-medical-imaging-exposures* (NMIE), introduced by the draft of new Basic Safety Standards of EURATOM³. This definition replaces the expression *medico-legal exposures*, and includes several exposures which may not be considered as medical exposures nor are related with work activity with radiation. They range from body scanning in airports to the search of drugs within the body, from X-ray or CT of children (when abuse is suspected) to screening programs, etc.

This issue was presented at the Conference, aiming at involving the national radiation protection community in a discussion on the justification of these procedures and the optimisation of related exposures, in view of BSS implementation in Italy.

The Conference "Twenty-five years after the Chernobyl accident: studies, remarks and recent findings" was held in Udine (Italy) from 22 to 25 of June this year. Invited experts came not only from Italy, but also from Germany, Slovenia, Ukraine and the United Kingdom, and from the following international organizations: *Comprehensive Nuclear-Test-Ban-Treaty Organization* (Vienna, Austria), *Group of experts referred to in Article 31 of the Euratom Treaty*, *International Agency for Research on Cancer* (Lyon, France), and *International European Commission Joint Research Centre* (Ispra, Italy). Even though several presentations were made in Italian - with simultaneous translation - most of the slides were prepared in English and can be found at

<http://www.arpa.fvg.it/index.php?id=673>.

¹ See e.g. Risica, S., Nuccetelli, C. (2000). The Italian Experience and Policy on Radioactive Contamination of Metal Scrap. In: *Proceedings of the 10th International Conference of the International Radiation Protection Association. Harmonization of Radiation Human Life and the Ecosystem*. Centre Hiroshima. May 14-19, 2000 Hiroshima, Japan. (CDrom). T-8-3; P-4 b-242.

² See in the EAN website (www.eu-alara.net): Lessons learned from incidents, Case study n.25 Incident involving stainless steel sheets contaminated with Co-60 in Italy.

³ http://ec.europa.eu/energy/nuclear/radiation_protection/radiation_protection_en.htm.



NORWAY - NRPA



The revision of the basic regulation for radiation protection was finalized and the new regulations is effective from 2011. The former basic regulations have been split into two regulations: one for radiation protection regarding, practices, workers, etc and one for environmental protection. The environmental regulation is now established under the environmental pollution act contains a number of nuclide-specific tables, defining various exemption and clearance levels a.o. The revised radiation protection regulations, under the radiation protection act, are tightened on several points. Stricter requirements for medical screening programs are introduced, and the issue of self referral has been addressed. Also stricter requirements for radon concentrations in schools and kindergartens have been introduced following the WHO recommendations.

NRPA has continued to stimulate a national network between medical physicists working with ALARA and optimization in medical diagnostics in public and private hospitals.

5 clinical audits were carried out in 2011 in hospitals working with radiation therapy . Clinical audits is a good “ALARA instrument” in practice and is very much appreciated in the hospitals to address quality assurance issues.

In the industrial area inspections have been carried out in cooperation with other inspection authorities with focus on risk factors generally. From the NRPA side it was within industrial radiography where we participated in these “harmonized inspections”.

Otherwise a few cases with orphan sources have appeared in 2011 in metal recycling industries. Some of these sources have been traced back to the original owner and legal action have been enforced.

NRPA hosted the 13th. EAN ALARA workshop “ALARA and the medical sector” in June



SPAIN - CSN



Patient Safety

In relation with the development of the agreement between Health Authorities and CSN, we are continuing with the establishment of two projects with two Universities. 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 will be performed by the University of Malaga, starting in October 2011, until March 2013.

The second project is the study of dose from CT scanners in children and teenagers. This project is part of a European project with the participation of 11 European countries, EPI-CT (epidemiological study to quantify risks for paediatric and optimise doses). This project will be performed by CREAL (Environmental Epidemiology Research Centre) in Barcelona, through December 2015.

Also related to patient safety, another project is starting in the Radiological Protection FORUM in the Medical Field about dosimetric data in Nuclear Medicine procedures. This project will provide information to Dose DataMed II.

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 with representatives of seven Ibero-American countries, Spain and the IAEA) several actions, mostly focused on detailed technical matters will be presented to the Plenary of the FORUM for approval. The project that has dealt with application of Risk Matrix methodologies in Radiotherapy Services is finished (the final results have been published by the FORUM), though some follow-up activities have been set-up to develop a online tool for training an analysis. The FORUM is also considering a new project on Safety Culture in Radiation Protection, but it will be postponed until the celebration of IRPA 2012 in which this topic will be thoroughly discussed.

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.

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 Physic 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. The Medical Field FORUM has approved and issued this year a document about “Patient-Release criteria after a Radiopharmaceutical Therapy with I-131”.

A new working group has started debates and work on a new project that aims to address the issue of surveying and identifying the adequate technical and human resources that should be available at the Radiation Protection Services.

Finally, two new projects have been proposed to the FORUM by the CSN: 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.

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. The last one will be on 24-25 May 2011.

Participation in the last working group on Medical Applications of HERCA.

Courses

CSN has organized in July 2011 a summer course about “Radiological protection and Health” in the Menendez Pelayo University in Santander.

Information

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



GENERAL TOPICS

Protection against ionising radiation and the safety of CERN's facilities: the tripartite agreement between France, Switzerland and the CERN comes into force on 16th September 2011

On 28th August 2011 the Official Journal published the decree of the agreement, signed in Geneva on 15 November 2010 on the protection against ionising radiation and the safety of the facilities at CERN (European Organisation for Nuclear Research).

The agreement signed between France, Switzerland and the CERN entered into force on 16 September 2011. It is the result of intense consultation between the host States and the CERN on technical and legal matters. It is also the fruit of a strong will, shared by all the signatories, to achieve a common and rigorous approach on issues regarding the safety of nuclear installations at the CERN and protection against ionising radiation. This agreement allows the ASN and its Swiss counterpart, the Federal Office of Public Health (OFSP) to completely discharge their monitoring functions.

MEDICAL, INDUSTRIAL AND RESEARCH ACTIVITIES

1. Industrial accident at the Centraco facility:

The accident that occurred on Monday, September 12, 2011 in the melting furnace of the Centraco facility in Codolet (Gard) caused the death of an employee and injured four others, one of them severely. The three workers who were slightly injured were allowed to return home the day after the accident. The one who was severely injured is still hospitalized in the Paris region. None of them show signs of radioactive contamination.

After verification by the French Nuclear Safety Authority (ASN), it appears that at the time of the accident the melting furnace contained approximately 4 tonnes of metal with a radioactivity level of approximately 30 MBq, not 63 kBq as initially indicated by the operator. Although this value is still low, the ASN has nevertheless asked the operator to provide an explanation for this underestimation.

The room where the furnace is located was partially damaged. However, the building containing the furnace room was not damaged. The furnace room has been sealed off by the Attorney General for legal investigation and is currently not accessible.

All environmental radioactivity measurements performed by the operator and subsequently by specialized local fire department specialists and by the French Institute for Radiation Protection and Nuclear Safety (IRSN), the technical support of ASN have confirmed the absence of radiological consequences for local populations and the environment. No population protection measures were necessary.

Without prejudice to the measures that may be taken as part of the legal proceedings, ASN has decided that the restart of the facility's melting and incineration furnaces (shut down shortly after the accident) will be subject to prior authorization. The resolution was issued by the ASN's Commission on September 27, 2011.

Although the strictly radiological considerations associated with this event are minimal, ASN nevertheless considers it a severe industrial accident given the human consequences involved. According to INES criteria (International Nuclear Event Scale, ranging from 0 to 7 in increasing order of severity), the event is rated as Level 1 due to the low-level radiological activity of the melting furnace.

2. Radiography Incident classified at level 2 on the INES scale.

On September 22, 2011, an incident involving the use of radiography occurred within the company STIC in Rambervillers (88) during a welding control performed by the testing laboratory from Montereau (LEM). The manual intervention of an operator on the damaged equipment has led ASN to reclassify this event at 2 on the INES scale.

The ejection gain had been deformed by a falling piece of metal and had prevented the return of the radioactive source (Iridium 192 source of 500 GBq) in its safety position. The analysis of the incident showed the company LEM had tried to release the source through a manual intervention in the ejection gain on the supposed position of the source. Although the intervention was very short, this is against the rules of radiation protection. This analysis led ASN to reclassify the event at level 2 on the INES scale.

Due to the very short duration of the operation, the operator exposure was estimated at 1.5 mSv. Exposure of the hands has been the subject of further assessment at the request of the ASN technical support, the IRSN. Nevertheless it does not reveal a risk of developing irreversible effects to the operator.

3. ASN considers that increasing doses of ionizing radiation delivered by medical imaging (mainly CT and interventional radiology) is worrying and must be controlled.

The doses of ionizing radiation delivered to patients are increasing in France as in other developed countries because of the broad contribution of medical imaging in diagnosis, guidance of the therapeutic strategy, monitoring the effectiveness of treatment and to achieve accurate control in the imaging of therapeutic procedures (interventional radiology).

ASN has decided to act on radiation protection and control doses in medical imaging. It has published two deliberations of ASN College. The actions proposed by the ASN to improve radiation protection in medicine and master higher doses include:

- The development of alternative techniques, foremost among them the magnetic resonance imaging (MRI);
- A more rigorous implementation of the principles of radiation protection (justification and optimization);

- Increased training in radiation protection;
- Greater involvement of radiation physicists in the field of medical imaging,
- Increasing the availability of competent persons in radiation protection and the means allocated to them.

ASN has called health actors (professional and institutions) to mobilize on this.

4. Formalization of ASN and AFPPE cooperation in the field of medical physics

ASN and the French Association of Paramedical Staff in Electro-radiology (AFPPE), signed June 27, 2011 a framework agreement for collaboration between the two organizations in the field of medical imaging and radiotherapy. The signing of this agreement formalizes cooperation between the two institutions. It aims to facilitate the exercise of their missions and achieve common or complementary actions.

5. Quarterly report of ASN/SFRO level 1 radiotherapy events reported during second quarter 2011

Twenty-one events, classified as level 1 on the ASN-SFRO scale, were reported between 1 April and 30 June 2011. 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.

Fourteen of the events concerned patient positioning errors, 6 events concerned an error in patient identification and 3 events concerned dosage error.

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

6. ASN and AFSSAPS make recommendations for increase of requirements on radiotherapy medical devices

Two serious incidents in 2006 and 2007 led the French authorities to implement a series of measures to strengthen the security of the practice of external radiotherapy.

In line with these measures, ASN and AFSSAPS (French health products safety agency) have committed a specific reflection on the relationship between the radiation protection requirements of the Directive 97/43/Euratom and IAEA recommendations to the essential requirements of Directive 93/42/EEC applicable to devices including external radiotherapy linear accelerators of electrons.

This reflection was conducted in an ad hoc working group composed of experts in these matters, representatives of users, a representative of the French office of standardization in the Electrotechnical sector and representatives of the competent Belgian, Swiss and French. This group produced a report presenting an analysis of the European regulatory framework and international requirements for medical devices used in radiotherapy. In addition, this document contains recommendations for increase the measures to affix the CE marking on these facilities and to complete the project of Euratom Directive on aspects of risk analysis and reporting of significant events.

ASN and AFSSAPS submitted this work to the European Commission and wish defend these recommendations at European level.

7. 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>.

EPIDEMIOLOGY

Recommendations by an interdisciplinary working group to find out more about the risk factors involved in childhood leukaemia.

On 7 November 2011, the French Nuclear Safety Authority (ASN), the Directorate General for Health (DGS) and the Directorate General for Risk Prevention (DGPR) issued a report including an inventory of current knowledge of childhood leukaemia and recommendations for new studies and research required to drive progress in this area.

In particular, the report recommends continuing and stepping up ongoing epidemiological research into the possible risks of leukaemia induced by low-dose ionising radiation, coupled with studies of exposure to other potential carcinogenic substances and related genetic factors.

The report was prepared by the interdisciplinary working group set up in 2008 by the ASN, DGS and DGPR, and tasked with analysing available knowledge concerning the risk of leukaemia in children living near basic nuclear installations. The working group was set up after a German study, published in 2008, reported excess risks of leukaemia in children, aged zero to five years, living within a 5 km radius of German nuclear power plants.

In addition to the inventory of current knowledge of childhood leukaemia, the interdisciplinary working group's report includes several recommendations aimed at: a) supporting epidemiological studies and research into the effects of possible genetic and environmental factors, including low-dose ionising radiation and certain carcinogenic substances; b) specifying the conditions required to allow continued epidemiological investigations in the vicinity of nuclear sites and; c) keeping the public better informed through clear communication, whatever the scientific uncertainties.

The ASN, DGS and DGPR have decided to set up an interdisciplinary committee to track progress in these initiatives. The working group report can be consulted on the ASN, DGS and DGPR websites.

<http://www.french-nuclear-safety.fr/index.php/English-version/News-releases/2011/Recommendations-about-the-risk-factors-involved-in-childhood-leukaemia>



BELGIUM - SCK•CEN
MOL



1. Workshop on NORM

4th EAN_{NORM} Workshop on "Transportation of NORM, NORM Measurements and Strategies, Building Materials"

Organised by NuteC XIOS in Hasselt Belgium Nov. 29th - Dec. 1st 2011, contributions from Finland, Spain, Belgium, Italy, Germany, Poland, Norway, Croatia, Romania and The Netherlands.

Feedback from the workshop will be provided to the steering group and to the program committee of the next EAN workshop

Contributions:

- Janssens, A. (EC): *Current status of the revision of the BSS*
- Haridasan, P. P. (IAEA): *Implications of the revised international basic safety standards on natural sources*
- Schwela, U. (Tantalum-Niobium International Study Centre, Belgium): *Denial of transport of NORM'*
- Steffan E.-M. (EXXON MOBILE, Germany): *Classification, Labelling and Packaging of NORM Production Residuals from Crude Oil and Natural Gas Production*
- Fias, P.; Pepin, S. (Controlatom – FANC, Belgium): *NORM transportation in the port of Antwerp: overview and lessons*
- Welbergen, J. (COVRA, The Netherlands): *International transport of radioactive materials including NORM*
- Nilsen, M. (NRPA, Norway): *Transfrontier shipment of NORM waste*
- Weiss, D. (GRS, Germany): *Exposure of Workers from the Transport of NORM in Germany*
- Schulz, H. (IAF, Germany): *News and perspectives of EAN-NORM*

- Poffijn, A. (FANC, Belgium): Announcement of EU – NORM, Tallin
- García Tenorio, R. (University of Seville, Spain): Occupational and Public Exposure Assessment in a Spanish Titanium Dioxide industry: a case study
- Kunte, A. (LfU, Germany): Industrial uses of zircon and zirconia and the related exposure in Bavaria
- Natvig, H. (NRPA, Norway): Measurements of NORM in the Oil and Gas Industry
- Smith, B. (AF Decom, Norway): NORM Management in Decommissioning of Petroleum Installations
- Reichelt, A. (TÜV, Germany): Sampling and sample preparation of NORM residues
- Botezatu, E. (CNCAN, Romania): Radiological characterization of stocked phosphogypsum from former phosphate fertilizers factories (Romania)
- Casacuberta, N. (University of Barcelona, Spain): Study of a dicalcium phosphate industrial plant in the NORM context and within the regulatory Spanish framework
- Sidhu, R. (IFE, Norway): NORM services provided by Institute for Energy Technology
- Poffijn, A., Vanmarcke H., Wiegers, R. (FANC, SCK-CEN, Belgium, IBR, The Netherlands): The revision of the EU-BSS and its implications for the building industry and the EU-society
- Hoffmann B. (BfS, Germany): Radon Exhalation Measurement and Assessment of Building Materials: why and how?
- Pepin, S. (FANC, Belgium): Belgian acceptance criteria for NORM residues: theory and practice
- Hiller, P. (NNL,UK): NNL's Systematic Approach to the Characterisation, Treatment and Disposal of Radioactive Wastes and its Application to NORM.
- Prlic, I.; Vučić, Z.; Hajdinjak, M. (IMI, Croatia): A practical simple ambient dose rate mapping method to assess the area of pockets containing enhanced concentration activities of NORM at a large slag and ashes deposition site
- Gellermann, R. (FUGRO Consult, Germany): Control of masses, activities and doses during remediation measures at a radioactive contaminated site in Hannover
- Varskog, P., Schulz, H. (Norse Decom AS, Norway - IAF, Germany): Radon in an underground NORM Repository
- Michalik, B. (GIG, Poland): The fate and behaviour of NORM with respect to environmental protection
- Nuccetilli, C. (ISS, Italy): Natural radioactivity in building materials in the European Union: a database and an estimate of radiological significance
- Mora, J.C. (CIEMAT, Spain): Radiological impact of fly ashes from coal combustion

- Pontikes, Y. (KULeuven, Belgium): *Radioactive elements in Bayer's process bauxite residue and their impact in valorization options*
- Bolivar, J. P. (Universidad de Huelva, Spain): *Minimization and elimination of NORM waste from titanium dioxide industry through their valorisation in final commercial products*
- Stals, M. (NuTeC-XIOS, Belgium): *The use of portable equipment for the Activity Concentration Index determination of building materials: Methodology and first results*
- Quintana Arnés, B. (University of Salamanca, Spain): *Galea, an expert gamma analyzer for NORM at environmental level*
- Vuorinen, P. (CEN/TC 351/WG 3, Finland): *A method for the determination of the activity concentrations of the radionuclides ^{226}Ra , ^{232}Th and ^{40}K in construction products using semiconductor gamma-ray spectrometry*

2. Myrrha

Development of an accelerator driven reactor system based on heavy liquid cooling.

The selection of engineering companies will take place in the beginning of next year. Information will be given to the companies on the ALARA approach in the Myrrha-design in order to underline the importance of ALARA in the design phase.

3. Incidents Belgium

- a. Internal contamination of a person with Phosphor 32 used in veterinary medicine at the university of Liege (12 October 2011). Level 1 on the INES-scale.
- b. During the yearly inspection of fissile material (4 October 2011) a bottle with a small amount of plutonium fell to the floor. Three persons were contaminated (2 inspectors EURATOM, IAEA and 1 operator from Belgoprocess). The contaminated persons transferred to SCK•CEN for decontamination. The dose due to the external was small. The dose due to internal contamination was within the regulatory dose limits. The event was registered as level 2 on the INES-scale
- c. 15 september 2011: A company in France signals to the Belgian authorities that radioactive material is present in a shipment of the Belgian company Duferco La Louvière Produits Longs. The FANC together with AIB Vinçotte Controlatom investigates and finds although the company is equipped with detection system that the contamination is caused by a Cs-137 source that was melted in the oven. Actions were taken to check internal contamination of the Duferco workers, no internal contamination was found. Contamination was found in the technical installation of Duferco a plan to decontaminate the installation is prepared. Measurements in the environment in the vicinity of Duferco were performed and showed no contamination. The event was registered as level 1 on the INES-scale

- d. 20 September 2011: Wrong delivery of sources to a client of SCK•CEN. Instead of receiving 20 sources a client received 19 sources of Se-75. An error during the manipulation resulted in a not correct filling of the transport. The source in question is afterwards retrieved in the hot cell of SCK•CEN. This was scaled as level 1 on the INES-scale.
- e. 29 August 2011: A shipment of I-131 to a French institute was incorrect. The source received was not the one ordered by the institute. French authorities were contacted. The event is scaled as level 1 on the INES-scale.



SWITZERLAND - SFOPH



IRRS in the nuclear sector in Switzerland

The Swiss Federal Nuclear Safety Inspectorate ENSI is the supervisory authority for nuclear safety and security. ENSI will undergo an Integrated Regulatory Review Service (IRRS) from the IAEA in November 2011. The IAEA IRRS is designed to strengthen and enhance the effectiveness of the national regulatory infrastructure of States for nuclear, radiation, radioactive waste and transport safety and security of radioactive sources whilst recognizing the ultimate responsibility of each State to ensure safety in the above areas. This expressed purpose of the IRRS is to be accomplished through consideration of both regulatory technical and policy issues, with comparisons against IAEA safety standards and where appropriate, good practices elsewhere. The scope of the IRRS mission to Switzerland covers all facilities and activities that are supervised by ENSI, i.e.:

- Nuclear Power Plants
- Research Reactors
- Waste Facilities
- Decommissioning

The continued operation of the existing nuclear power plants and the management of radioactive waste are the major challenges of ENSI. Therefore, the IRRS mission planned for November 2011 focuses primarily on nuclear power plants and waste facilities. The IRRS Mission to Switzerland includes the 10 core modules based on the IAEA's document "Integrated Regulatory Review Service, Guidelines for the Preparation and the Conduct of IRRS Missions". In addition, the mission scope comprises the optional module regarding interfaces with nuclear security and thematic modules covering radiation protection issues, waste management and transports. Report of the IAEA with recommendation is expected for next year.

Revision of the Swiss radiation protection legislation

The Swiss legislation on radiation protection is in force since 1994. It is based on the recommendations of ICRP of 1990 (ICRP 60), which has been replaced in 2007 by ICRP 103.

The recommendations of ICRP 103 shall be implemented into Swiss legislation. Since also a harmonization to the radiation protection concepts of the EU is aimed for, the Euratom Basic Safety Standards Directive (Draft) serves as a guideline for the revision of the Swiss radiation protection legislation. Several working groups of experts were established in order to analyze the consequences of the concept of the new BSS on the Swiss legislation. The main consequences and changes focus on the following items:

- Training of radioprotection expert, difference and responsibility of RPO and RPE
- Clearance levels (many nuclides are not present in the BSS)
- A and B workers, flight personal
- Norm (radon, tenorm, norm)
- Clinical audit in medicine
- Existing exposure situation

These working groups should make some propositions for changes for articles in the radiation protection ordinance and in the affiliated technical ordinances. Two to three years of work from now on are planned in order to have a draft version of the new ordinances and to put it into force.

Childhood cancer in the vicinity of the Swiss nuclear power plants, Results of the CANUPIS study

During the last 20 years several studies have addressed the question whether people living in the vicinity of nuclear power plants are exposed to health risks. One focus of these investigations has been childhood cancer, since children are more susceptible to ionizing radiation than adults. Some studies have found an association with childhood cancer, which is difficult to explain because emissions from nuclear power plants during normal operation are low in comparison to the annual background exposure.

For the first time, a nationwide study was conducted in Switzerland by the Department of Social and Preventive Medicine of the University of Bern in collaboration with the Swiss Childhood Cancer Registry and the Swiss Paediatric Oncology Group to examine the question if residence close to a nuclear power plant is associated with an increased risk of childhood cancer (CANUPIS study: Childhood Cancer and Nuclear Power Plants in Switzerland). This large nationwide longitudinal study initiated by the Swiss Federal Office of Public Health found no evidence of an increased risk of cancer in children born near nuclear power plants in Switzerland. Further Information about this study can be found at the following Internet address:

<http://www.canupis.ch/index.php?id=2116>



Development of the registers used to supervision purposes

A new Dose Register will be taken into use in early 2012 and, at the same time, radiation safety licenses will be connected to the employer data. Also the definition work of the register for control of natural radiation is currently in progress and this register will be combined to the other registers.

Determination of exposure level to lens of the eyes

The study for determination of dose level to lens of the eyes will start 2012. The aim of the study is to gain knowledge of exposure level in different tasks in use of radiation as well as to specify the critical worker groups which should be monitored. This project is based on the change in a dose limit for lens of the eyes presented in BBS draft.

Disused radiation sources

In industrial use of radiation, disused radiation sources are sometime placed in the storages. Those sources have been collected systematically during a few years. The aim is to prevent the sources not to get lost or fall into the wrong hands. This work has been done during the inspections and also by the separate campaigns.

Reporting of radiological incidents

It is mandatory to report of radiological incidents to STUK. Previously the incidents in use of X-rays in health care, in particular, haven't been reported. During the last year there have been alteration in practices and more and more reports are made - even of the small events. STUK together with responsible parties are now trying to find out some appropriate guidelines for the types of incidents which must be reported.



THE NETHERLANDS - NRG



Unusual events at Dutch nuclear facilities in 2010

Last September the Dutch inspectorate for the nuclear sector issued the annual report on unusual events which were reported by the nuclear facilities in the Netherlands in 2010. Twenty events were reported, of which three were scaled at INES-level 1. The others were below INES (level 0).

Nine events were reported by the Borssele NPP. The number of events is not significant different from those reported in previous years. Since all events were below level 2 no reporting to the IAEA was done.

The events that were scaled at INES-level 1 are:

Failure to start-up of the emergency power supply during a regular test at the Borssele NPP.

The cause of this incident is a too slow opening of an air valve. After consultation of the supplier it was decided to replace the air valves of all three emergency power supplies and to raise the testing frequency. The event is internationally reported to the IAEA/NEA IRS system, so that other nuclear facilities can learn of this incident.

Water leakage in the basement of the HFR reactor hall followed by tritium contamination of the groundwater.

During the repair of the HFR a water hose struck loose unnoticed and an amount of 70 m³ was released in the basement. A ¹³⁷Cs concentration of 160 Bq/l was measured in the basement water. About 1 month after the incident a slight tritium contamination about twice the background activity was observed in the groundwater next to the reactor building which was ascribed to the incident. The incident was scaled at INES level 1 because of the unintended leaking of radioactive contaminated water to the environment.

Unauthorized handling of UF₆ transport packages at Urenco

During handling and opening a UF₆ transport container, for which no prior authorization was given by the RPO, an amount of about 1 kg UF₆ was released which led to internal contamination of a worker. The calculated committed dose was relatively low, only 2 µSv, and emission to environment was negligible, but the incident was given nevertheless a scaling of level 1 at the INES scale, because the worker so obviously neglected the safety precautions.

Revision of the Dutch Radiation Protection decree

The Dutch Radiation Protection decree which is into force since June 2001 is now being revised. Presently almost all applications of radiation, with only a few exceptions, need prior authorization by the authorities. In the new decree a larger number of applications, which pose a relatively low risk, will be subject to reporting instead of authorization. This applies for instance to dental and veterinary radiography with fixed equipment, X-ray diffraction and spectroscopy, density measurements with well shielded X-ray equipment, luggage controls at airports, ECD using Ni-63 sources and industrial applications of radiation sources. Since these applications are no longer ruled by the prescriptions in a license they are now subjected to a number of general rules and regulations which are part of the decree. It is envisaged that the new decree will come into force at 1 July 2012.



GREECE - GAEC



1. DDM2 Workshop on European Population Doses from Medical Exposure, 24-26 April 2012, Athens, Greece

Second Announcement - Call for Papers

The Greek Atomic Energy Commission, as a partner in the EC-funded project entitled "Study on European Population Doses from Medical Exposure" (Dose Datamed 2), organizes Workshop on European Population Doses from Medical Exposure (Athens, 24-26 April 2012).

The objectives of the Workshop will be:

- to disseminate the feedback achieved during the DDM2 project before its submission to the European Commission
- to provide an opportunity to present and exchange information and experiences on national systems, diagnostic reference levels and population dose estimations from radiodiagnostic procedures (X-ray and nuclear medicine)
- to provide a forum for discussions on the establishment of the European Guidance and to investigate the need for amendments
- to conclude on and address future issues concerning European Population Doses estimation from medical exposures.

The workshop is addressed to:

- all medical radiation practices professionals in Europe
- representatives of professional societies
- national organizations responsible for collecting health care statistical information
- competent radiation protection authorities

The workshop programme consists of oral and poster presentations of contributed papers. Keynote presentations will be given by experts in the project. An on-line abstract submission form with instructions for authors is available at <http://ddmed.eu/workshop>.

Abstracts should be submitted by January 15, 2012.

Conference topics

- Experiences in collection of frequencies (X-rays and nuclear medicine)
- National systems of coding for X-ray and nuclear medicine procedures
- National population doses and their trends for X-ray procedures
- National population doses and their trends for nuclear medicine procedures
- Establishing diagnostic reference levels for X-ray procedures
- Establishing diagnostic reference levels for nuclear medicine procedures
- Sex and age distributions of frequencies and patient doses

Key dates and deadlines

Deadline for submission of abstracts: January 15, 2012

Notification of acceptance to authors: February 2012

Deadline for registration: March 31, 2012

Workshop: 24-26 April 2012

The Dose Datamed 2 project

The Dose Datamed 2 project (DDM2) is an EC-funded project aiming at the collection of available data on patient doses from radiodiagnostic procedures (X-ray and nuclear medicine) in the European Union and at the facilitation of further implementation of the Radiation Protection 154 Report “European Guidance on Estimating Population Doses from Medical X-ray Procedures”.

The DDM2 project aims at:

- providing advice and collecting feedback from the application of the guidance RP 154;
- providing estimates of population doses in EU Member States and the population dose in European Union as a whole;
- providing a database for population dose information which will enable continuous collection and follow-up of European population doses.

The DDM2 project partners are: the Radiation and Nuclear Safety Authority (STUK, Finland), the Public Research Center Henri Tudor (CRP-HT, Luxembourg), the

Norwegian Radiation Protection Authority (NRPA, Norway), the National Centre of Radiobiology and Radiation Protection (NCRRP, Bulgaria) and the Greek Atomic Energy Commission (GAEC, Greece).

Detailed information about the project and the workshop is available at www.ddmed.eu.

2. IRRS mission in Greece

GAEC, as the national competent authority for radiation protection and nuclear safety, submitted two years ago to the International Atomic Energy Agency (IAEA) a request for an international peer review. The review, known as Integrated Regulatory Review Service (IRRS), will focus on the radiation protection and nuclear safety national regulatory framework and its implementation.

Aiming at the multiple benefits of such a process, like the identification of strengths and weaknesses, the improvement of the efficiency and effectiveness, the sharing of international experience and good practices, a ten-day mission of radiation protection and nuclear experts will be conducted in Greece in May 2012. Upon the completion of the review GAEC will make public the final report.

This initiative is in line with the requirements of the more recent European Directives on nuclear safety and waste management, since both directives include the international review as a tool for ensuring high safety standards.

3. Accreditation of GAEC according to IEC/ISO 17020

Aiming at the improvement of services provided by the Licensing & Inspections Department, a Quality Assurance Management System was adopted in compliance with IEC/ISO 17020 requirements. After the successful completion of the review process, GAEC is accredited as a notified body for performing inspections in ionizing radiation applications.

4. GAEC recognized as IAEA's Regional Training Center in Europe for Radiation, Transport and Waste Safety

After the successful completion of the Education and Training Appraisal (EduTA) mission to GAEC in 2008, GAEC was recognized as the IAEA's Regional Training Center in Europe for Radiation, Transport and Waste Safety. A Long Term Agreement between the Government of the Hellenic Republic and the IAEA, to support GAEC as a Regional Training Centre in Europe for Radiation, Transport and Waste Safety was signed on July 11, 2011. This agreement is now on the procedure of its ratification by the parliament of the Hellenic Republic.

Currently, GAEC runs the fourth Post Graduate Educational Course on “Radiation Protection and Safety of Radiation Sources”. The course begun on October 10, 2011 and will be completed on March 30, 2012. It is attended by 14 participants coming from 12 European countries. The course is co-organized by GAEC and the IAEA, and is supported by the National Research Center “Demokritos”, the University of Athens, the National Technical University of Athens and the University of Ioannina.