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European ALARA Network

Newsletter

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How to improve radiation protection for patients and workers during interventional procedures

Experience feedback from notified events

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Abstract

Among events occurring during interventional procedures notified to ASN, 16 of them involved patients, including in one case a group of patients, and some of them led to severe radiation injuries. The dose received were in some cases up to 60 Gy to the skin or 15 Gy to the brain. Sixteen events concerned operators, in five of them doses exceeded the annual dose limits, either for effective dose (up to 27 mSv/year) or for equivalent dose to extremities (up to 875 mSv/year to one hand).
Lessons learned from these events reveal several failures: a misunderstanding in the use of the X-ray equipment and incomplete application of the optimisation procedure and inconsistency between the devices used and the acts performed, an inadequate management of equipment settings with insufficient comprehension of manufacturer maintenance and adjustements, a poor knowledge of the dose delivered and the possibility of induced radiation deterministic effects leading to a lack in patient follow-up. In term of operators, there is evidence of wrong practices from a radioprotection point of view and poor use of personal or collective protective equipments.
The roles of the qualified experts and medical physicists are essential to improve the radiation protection of staff and patients in interventional radiology, particularly for professionals who are particularly and regularly exposed due to their expertise and for long-duration interventional radiology procedures. Users training, dose monitoring for patients and workers, particularly for the extremities also represent a major avenue for progress.

Introduction

The requirments for those in charge of a radiological activity are subject to notify incidents or accidents in the field of radiation protection to the administrative authority, are set out in the French Public Health Code. According to the provisions of Article L. 1333-3 of this code "the individual responsible for one of the activities referred to in article L.1333-1 must immediately notify to the nuclear regulatory body and to the State representative in the department[1] any incident or accident likely to affect the health of individuals through exposure to ionising radiations". This obligation includes health professionals who are involved in the treatment or follow-up of patients exposed to ionising radiations for medical purposes, and who have knowledge of an incident or accident associated with this exposure.

The objective of this paper is to present an assessment of events that had been notified to ASN since 2007 and the lessons learned in order to improve radioprotection for patients and workers during interventional procedures.

After presenting the number of notified events, we will describe the main notified events, the failure that occurred and the main causes. Afterwards, we will discuss actions and recommandations that could be given in order to improve radiation protection of patients and workers.

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Method

To formally structure the notification system, the ASN implemented on a trial basis from July 2007, a system for notifying significant radiation protection events based on certain criteria. Guide No. 11 by the ASN sets out the criteria and notification arrangements. It includes a template form for notifying and reporting significant radiation protection events. Among these criteria, criterion 2 relates specifically to events affecting one or more patients undergoing diagnostic or therapeutic exposure and criteria 1 to events affecting occupational exposure of operators.

After presenting the number of notified events, we will describe the main notified events, the failures that occurred and the main causes. Afterwards, we will discuss about actions and recommendations that could be given in order to improve radioprotection of patients and workers.

Results

Number of notified events

The number of events notified each year is shown in the Table n°1. Table n°2 shows the distribution of events according to the consequences (patient, workers, public or environmental). A serious patient event, notified at the beginning of 2012, is also included.

Events dealing with patients

Among the 16 patient-related events, five of them had consequences for the patient's health. Radiation-induced skin damage is a well-known complication of interventional radiology [1]. On rare occasions, severe injuries can be unavoidable life-saving necessity (Events n°2 in Table 3).

The procedures involved in the notified events are cardiology (fitting of cardiac defibrillator, Chronic Total Obstruction procedure), interventional neurology (embolisation for intracerebral arteriovenous malformations), vascular radiology (embolisation of the coeliac trunk), and uterine embolisation. Except for the fitting of cardiac defibrillators, skin damages appeared after several fluoroscopically guided interventional procedures.

The high doses delivered led to deterministic effects (erythema, dry or moist desquamation, temporary alopecia, necrosis), which prompted the notification. The dosimetric evaluations carried out by IRSN (see table 3) show that these procedures contribute to the delivery of very high dose level, particularly, to the skin or the brain.

Concerning event n°2, for which a group of patients was involved, a report on the experience feedback was published on the ASN website in March 2010 [2]. In this event, the follow-up did not reveal any neurological, meningeal or subcutaneaous abnormalities, and the cases of alopecia observed have fully regressed. ASN reiterated the regulatory requirements, in a memorandum dated December 11, 2009 and sent a number of recommendations to the heads of interventional vascular neurology departments together with the general managers of hospitals.

The main root causes of these events are:

- Inadequate operator training, both in patient radiation protection and in the use of the radiological devices. Concerning event n°1, the physician confused between the footswitch for radiography with the one for fluoroscopy.
- Imperfect understanding of the doses delivred during the procedures and a lack of detection and follow-up of patients liable to present radiation-induced deterministic effects; dosimetric data are very often not available and not detailed enough to produce a reliable estimate of doses.
- Almost non-existent application if the optimisation procedure and evaluation procedure for dosimetry.
- Use of inappropriate devices for long and complex procedures (device unable to offer optimised protocol conditions and no dose indicator device available).
- Inadequate management and follow-up of maintenance and

Year	2007	2008	2009	2010	2011
Number of events	1	3	9	10	13

Table 1 – Number of events notified each year

Criteria	Patient	Worker	Public or environmental
Number of events	16	16	4

Table 2 – Number of events according to the criteria

Event		**Skin dose (Gray)**	**Lung dose (Gray)**	**Brain Dose (Gray)**	**Heart dose (Gray)**
N°1	Fitting of defibrillator	16,2	8		
N°2	Uterine embolisation	15			
N°3	Intracerebral arteriovenous malformations	17		[11-15]	
N°4	Embolisation of the coeliac trunck	[17-13]			
N°5	Angioplasty (Total chronic obstruction)	[35-60]	[1-3]		2

Table 3 – Dosimetric reconstruction of events notified to ASN

adjustments performed by the manufacturer
- Failures in the management of the medical referral and its traceability.

The feedback reveals that incomplete application of dose optimisation is due to a lack of medical physicist input.

Events dealing with workers

Among events concerning medical staff, in five of them workers exceeded one of the annual dose limits (effective dose or dose to extremities). Table n°4 summarizes the maximal dose received by the operators.
The procedures involved in these events are digestive procedures (Biliary drainage, chemoembolisation, embolisation of digestive arteries) and orthopaedic procedures (vertebroplasty, kyphoplasty, infiltration). In these procedures, the physicians are working in the immediate vicinity of the patient and are exposed to higher levels of dose than during other radiological practices.

The main root causes of these events are:

- Inadequate operator training, both in occupational radiation protection and in the use of the radiological devices.
- Failure to wear individual protective equipment.
- Inadequate optimisation of procedures.

The feedback reveals that there is a lack of a radiation protection officer in operating theatres. The availability of the RP officers and the resource allotted to them must be increased to improve the radiation protection of workers. There is also a misunderstanding of doses likely to be received by the operators and a lack of radiation protection culture.

Conclusions

Since 2009, the monitoring and regulation of radiation protection in interventional radiology has become a national priority for ASN. ASN considers that urgent steps must be taken to improve the radiation protection of patients and workers in interventional radiology, particularly for fluoroscopy-guided interventional procedures in operating theatres. ASN issued a position statement on 14 June 2011 concerning the improvements to radiation protection in interventional radiology.

Together with the departments concerned at the Ministry for Labour, Employment and Health, ASN sent out a letter to the regional health agency Director Generals in November 2011, describing the current radiation protection situation in the medical field. This letter highlights the necessary improvements concerning the radiation protection of patients and healthcare staff, especially in terms of human resources.

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

Finally, ASN is anxious to underline the major role of the medical physicist and the radiation protection officer in the radiation protection of the patients and workers.

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

	Event	**Effective dose (mSv)**	**Doses to extremities (mSv)**
N°1	Nurse of operating theatre	21 / a quarter	
N°2	Digestive radiologist		523 / year
N°3	Orthopaedic surgeon	27 / year	
N°4	Digestive radiologist	3.5 / year	571 right hand / year 875 left hand / year
N°5	Radiologist (intra-articular injections)		525/ four months 677 /four months

Table 4 – Doses received by operators

References

1. Stephen Balter et al. *Fluoroscopically guided interventional procedure, a review of radiation effects on patients' skin and hair*. RSNA, 2010.
2. Experience feedback from the report of an interventional radiology event at the Strasbourg Academic Hospitals.

Radiation outside Workers; the current situation in Greece

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Introduction

The involvement of outside workers in activities carried out in controlled areas has been under consideration by many international scientific and professional organizations. The issue was initially addressed in order to ensure the safety of technical personnel involved in activities with ionizing radiation which were performed mainly in nuclear power plant facilities in the same or different countries. Several issues have been raised since then with respect to outside workers involving: a) the monitoring of their doses and who is responsible for summing the doses received at different facilities and checking if the annual dose limits have been exceeded b) their education and training on radiation protection and c) the localization of any possible overexposure.

Due to the importance of these issues, the European Community issued the Directive 90/641/Euratom "on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas"[1]. 'Outside worker' is defined as any worker of category A (according to Article 23 of Directive 80/836/Euratom [2]), performing activities of any sort in a controlled area, whether employed temporarily or permanently by an outside undertaking, including trainees, apprentices and students, or whether he provides services as a self-employed worker. 'Outside undertaking' is considered any natural or legal person, other than the operator, including member of his staff, performing an activity of any sort in a controlled area.

Regarding the safety of the outside workers Directive 90/641/Euratom presents specific requirements [1]. Outside undertakings must ensure the radiological protection of their workers in accordance with the relevant provisions of Directive 80/836/Euratom [2]. Moreover, the operators (i.e. any natural or legal person who under national law, is responsible for the controlled area in which the activity will be carried out) shall be responsible, either directly or through contractual agreements, for the operational aspects of the workers' radiological protection which are directly related to the nature of the controlled area and of the activities.

As far as the national competent authorities are concerned, they must establish specific mechanisms for the reporting or authorization of the outside undertakings. Additionally, they shall ensure that the radiological monitoring system affords outside workers equivalent protection to that for workers employed on a permanent basis by any operator

Current situation in Greece

In Greece there are no nuclear facility facilities and the issue concerns outside workers providing services mainly to public and private medical facilities using ionizing radiation, i.e.:

- Technicians performing the installation, maintenance and servicing of radiology, nuclear medicine and radiotherapy systems;
- People providing assistance during interventional procedures (pacemaker and stent positioning, orthopedics, etc);
- Persons undertaking the installation/replacement of radioactive sources.

Directive 90/641/Euratom was transposed in the national legislation as a Ministerial Order in 1996 [3]. Under this piece of legislation, the outside undertakings must be licensed to allow their employees to provide services in controlled areas. For a license to be granted the undertakings must submit to the Greek Atomic Energy Commission (GAEC) the following:

1. Application with the necessary information regarding the undertaking;
2. Legal documents describing the activities in controlled areas;
3. Assignment of responsibilities (undertaking representative, RPO);
4. List of the names of the personnel involved in activities within controlled areas including relevant skills as well as education and training in radiation protection;
5. Dose monitoring documentation. The worker must be equipped with an official dosimeter, an electronic dosimeter, as well as a radiation passbook;
6. A written commitment of the undertaking to report any amendment regarding the above.

After the evaluation of the submitted documentation GAEC performs on-site inspection at the installations of the outside undertakings in order to verify compliance with the existing requirements. The inspection includes: a) the compliance with the general radiation protection principles b) the provision of appropriate information and training on radiation protection and c) the existence of procedures for the assessment of exposures and for medical surveillance, etc. If compliance is verified, GAEC issues a license which is valid for 5 years.

It has to be pointed out that the competence of the outside workers is also evaluated by GAEC during the on-site inspections performed at the controlled areas where their activities take place. At this stage, GAEC also verifies the compliance of the operator with the respective legislative requirements. Before the initiation of any activity inside a controlled area, the operator must ensure that the worker is a) medically fit for the activity assigned to him b) has received specific training with respect to the characteristics of both the controlled area and the activities undertaken and c) has been provided with the necessary personal protective equipment. Additionally, the operator must ensure that after every job, the radiological data of individual exposure monitoring of the worker is recorded in the radiation passport.

The findings of the on-site inspections show that:

- Some outside workers:
  - do not use their electronic dosimeter
  - own a radiation passport without having an electronic dosimeter
  - use their personal electronic dosimeter as survey meters
- There is a lack of appropriate training on radiation protection as well as ALARA/Safety culture

among the outside workers.
- The parties involved (undertakings, workers, operators) are not fully aware of their role and responsibilities.

Furthermore, it was found that some outside undertakings and operators were not aware of their role and responsibilities in relation to the existing legislative framework.

Taking into account that most of the above findings were related to the lack of appropriate education and training, GAEC organized special seminars on radiation protection for outside workers which were performed in Athens (2) and in Thessaloniki (1).

These eight-hour seminars covered a wide range of topics, including:

1. The physics of ionizing radiations;
2. The biological effects of ionizing radiations;
3. The current legislative framework regarding outside workers;
4. Licensing procedure for outside undertakings;
5. Ionizing radiation detection systems;
6. Dose monitoring;
7. Practical aspects of radiation protection for outside workers in radiology, nuclear medicine and radiotherapy.

60 outside workers out of the 239 registered in the National Radiation Protection Data Base attended the three seminars already performed. Therefore, it is necessary for similar seminars to be organized in the near future. Additionally, appropriate actions (i.e. dissemination of informative material, continuous communication with related professional bodies, etc) should be taken in order to increase awareness of outside undertakings and operators and to support the development of ALARA/Safety culture among all the involved parties (undertakings, workers and operators).

References

1. European Commission Council Directive 90/641/Euratom, on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas. Official Journal of the European Community.
2. European Commission Council Directive 80/836/Euratom, amending the Directives laying down the basic safety standards for the health protection of the general public and the workers against the dangers of ionizing radiation Official Journal of the European Communities.
3. Government Gazette, Ministerial Decision No. 9087(FOR) 1004, Second Issue, Folio No. 849, November 13, 1996, "Protection in practice of outside workers exposed to ionizing radiation during their activities in controlled areas".
4. Government Gazette, Joint Ministerial Decision No. 1014 (FOR) 94, Second Issue, Folio No. 216, March 6, 2001, "Approval of Radiation Protection Regulations".

Incident in a brewery due to the installation of a new X-ray tube in a fill level gauge

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Description of the incident

The Slovenian Radiation Protection Administration was notified an incident in a brewery, during maintenance of an X-ray gauging system for verification of can fill level. One of the maintenance workers installed a new X-ray tube, which was already mounted on an electronic circuit. This simply required the circuit board to be inserted in the right slot inside the housing.

The worker then tested the system after installation, and realised that the current and voltage settings were too high (precisely 60 kV instead of 35 kV) so he adjusted them, switching the unit on and off a few times in the process. After adjustments he realised that the unit detector measured almost no signal, although the X-ray indicator was on.

Using a dose rate meter he could measure almost no reading at the detector position, but there was a significant dose rate at the position he was occupying. He switched the unit off immediately and contacted radiation protection experts. Further investigations showed that the tube had been mounted incorrectly (by the suppliers) on the circuit board, such that the tube window was facing a wrong direction (towards the worker instead of towards the line).

The worker was not wearing a personal dosemeter as brewery workers were not expected to enter any radiation fields (the company rules did not cover maintenance of the unit). A dose reconstruction was attempted, but the tube stopped working shortly after the incident occurred. Information was requested from the suppliers (in another country), but none was provided.

Dose consequences

A dose reconstruction was performed using output data for a similar X-ray tube. The effective dose was estimated to about 5 mSv, and the maximum equivalent dose (to an individual organ) was estimated to be 10 mSv

Lessons learned and actions taken

Maintenance and repair of equipment that emits ionising radiation requires special consideration to ensure that the standard of radiation safety is not compromised. It is essential that a suitable radiation safety survey is carried out immediately after any such work to ensure that there is sufficient protection from radiation, and that any safety and warning systems are operating correctly. In terms of this particular incident:

- A programme of workplace monitoring was introduced after the incident and personal dosimeters for maintenance staff

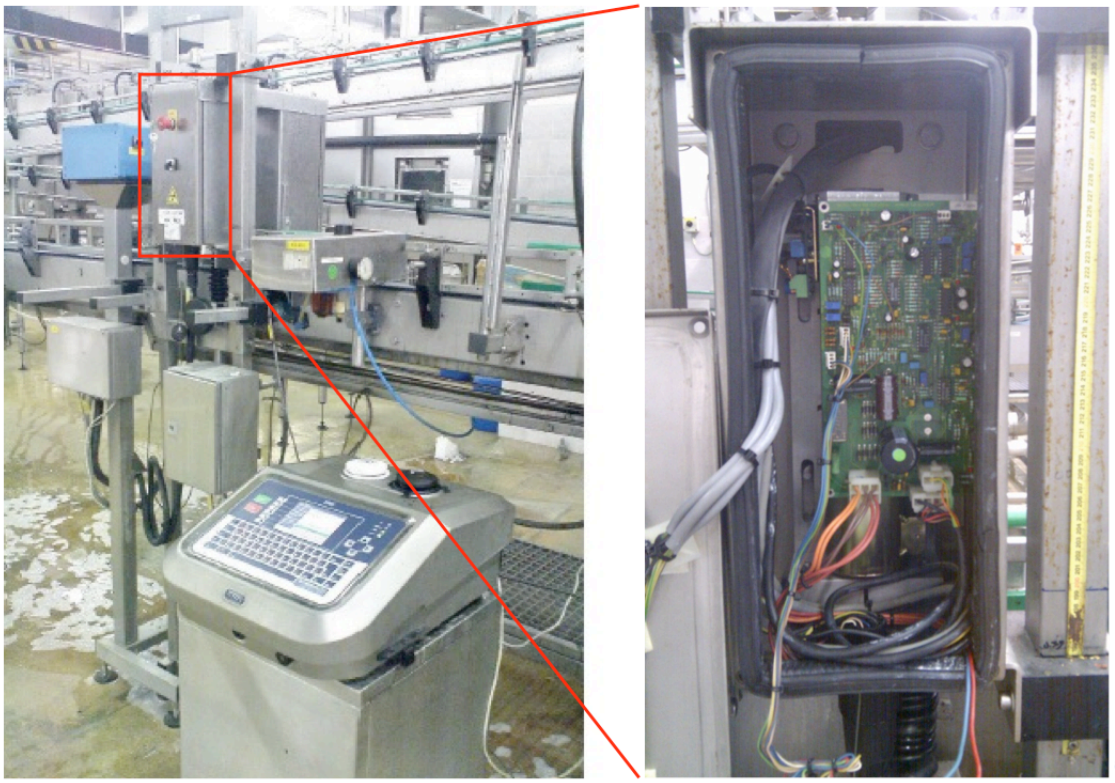

Figure 1 – The original gauging system on the can filling line (left), and inside the gauge cabinet (right): the X-ray tube is mounted on the rear of the circuit board.

are under consideration.

- Due to an old age and unavailability of spare parts the level gauge was replaced by a new one.
- Basic radiation protection training for all workers working in vicinity of sources of ionising radiation was organised after the incident.
- Additional measures were taken by the brewery to prevent such incidents in the future, as it was considered that the company should not rely on suppliers to provide properly constructed and functioning parts.

One of the problems identified was the difficulty of obtaining data from companies in other countries. In this case the absence of information from the tube supplier prevented a reliable dose reconstruction.

This incident was reported in the OTHEA database: http://www.othea.net/index.php/en.html

Norway is phasing out gamma based blood irradiators

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Norvegian Radiation Protection Authority

Norway has decided to substitute or phase out gamma based blood irradiators with almost mower risk blood irradiators based on X-ray technology. Changing to X-ray technology is considered to be feasible and is also required by the national regulations. Acquisition of new gamma based blood irradiators is considered not to be justified.

Background

Blood irradiators containing radioactive sources are according to the IAEA categorization system considered as category 1 sources. Due to security concerns, the Norwegian Radiation Protection Authority (NRPA) has evaluated the feasibility of substituning or phasing out these type of blood irradiator located in hospital environments with almost risk-free blood irradiators based on X-ray technology.

Legal basis

The two principles of substitution and justification are well implemented in the Norwegian Radiation Protection Regulation. Substitution from gamma sources to X-ray sources is required if the substitution is practically possible. Existing areas of use and methods shall be reconsidered when new information emerges relating to their justification.

The subject of substitution and justification was discussed with other Nordic countries in the forum of the Nordic Working Group on the Use of Sealed Sources (NORGIR), and we initiated an ERPAN survey to learn about other European countries experiences with blood irradiators

The ERPAN survey

Experience with X-ray based blood irradiators in other European countries were valuable input to our evaluation. We had three short questions for the ERPAN network:

Questions

- Do you have both types of blood irradiators in use?
- Can you indicate the number of X-ray based irradiators compared to gamma based irradiators in your country (any information is welcome)?
- What are the experiences with the X-ray technology, pros and cons (reliability, costs, maintenance etc.)?

Answers

The nine countries that answered were Spain, Slovenia, Sweden, France, Czech Republic, Belgium, Switzerland, Germany (Bavaria) and Luxemburg.

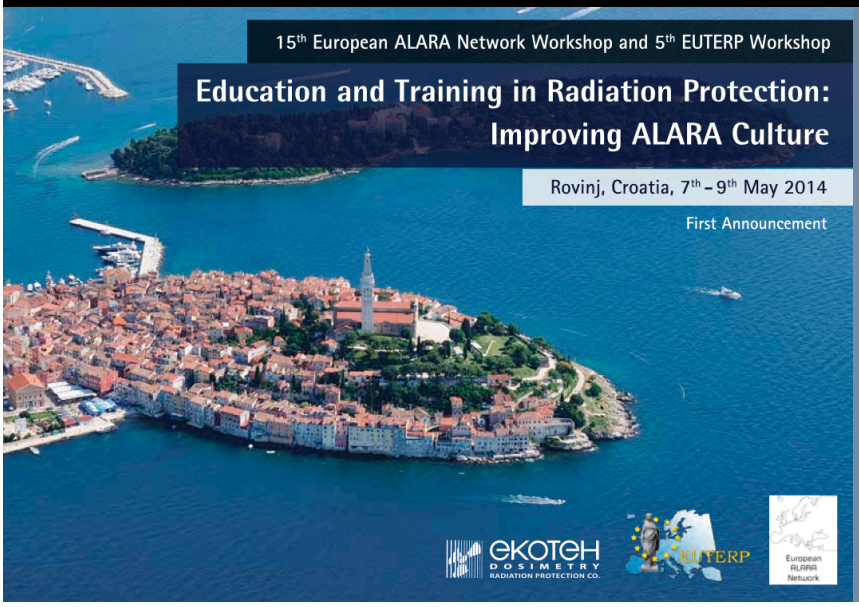
All the responding countries, except one, had gamma based blood irradiators and three countries had in addition X-ray based irradiators. One country indicated that they had started to substitute gamma based irradiators with X-ray a few years ago and that all gamma based irradiators will be replaced.

The total number of blood irradiators in the responding countries/states is estimated to be at least 104 gamma based and 19 X-ray based.

The impression from the feedback was that X-ray based irradiators work well, but there are some disadvantages. There are more breakdowns when installed in warm areas or rooms, the equipment needs maintenance which is expensive, and the system needs a continuous power supply which makes it essential to make sure the power supply and fuses can cope with the fluctuations that occur. It was also mentioned that X-ray based irradiators required longer time for irradiation.

National experience

Norway has 12 gamma based and two X-ray based blood irradiators. One of the hospitals has on their own initiative substituted a 189 TBq blood irradiator with an X-ray based irradiator. The hospital says that it was some technical issues after installation, but is well functioning now. They are in general satisfied with the machine and would have done the same substitution again.



The next European ALARA Network will be a joint EAN and EUTERP Workshop dealing with education and training in the field of radiation protection.

The workshop will take place at *Hotel Lone*, Rovinj, Croatia, from 7 to 9 may 2014.

Leaflet and registration form are available online :

http://ean-euterp.ekoteh.hr/

15TH EAN/5TH EUTERP Workshop on Education and Training in Radiation Protection: improving ALARA Culture

Aims and Objectives

Previous EAN and EUTERP workshops have noted the importance of delivering effective radiation protection education and training to workers and other stakeholders. Consequently, this joint EAN-EUTERP workshop considers how education and training programmes can be delivered effectively, to improve radiation protection in practice and disseminate ALARA culture.The workshop will consist of presentations (oral and posters) intended to highlight the main issues, and a significant part of the programme will be devoted to discussions within working groups. Participants will be expected to produce recommendations on education and training issues, to be addressed to relevant local, national and international stakeholders

Scope of the Workshop

The workshop programme covers education and training for various types of stakeholders and is expected to consider the following subjects:

- The new European BSS;
- European qualification and accreditation schemes (ECVET, EQF, etc.);
- The effectiveness and efficiency of education and training;
- Practical ALARA training;
- New learning tools;
- Elements contributing to ALARA culture;
- Incorporating ethical aspects into education and training;
- Education and training at all organizational levels.

Working Group Topics

- Tools to **improve the effectiveness** of training: new methods of delivery, blended learning and post-training interaction.
- How to measure the effectiveness of training: post-training assessment, ALARA evaluation, etc.
- The role of qualification and recognition schemes (ECVET, EQE, RPE) and their value in the workplace.
- Incorporating ALARA culture in training requirements for radiation workers and managers as well as regulators and inspectors.
- How to improve risk awareness and the radiation protection and ALARA knowledge for different stakeholders according to the exposure situations.

Target Audience

The workshop will be of interest to a variety of stakeholders including training providers, employers and employees' representatives, regulatory bodies, RP networks, research and other organisations involved in radiation protection.

Venue, Registration and Fees

The workshop will take place in Hotel Lone, in Rovinj, Croatia, starting on the 7th of May, 2014 and finishing on the 9th of May, 2014.

A welcome reception will be held on the evening of the 6th of May, 2014.

The registration fee will be 400 € and will include: welcome reception, workshop dinner, three lunches, two coffee breaks per day, transport to and from the workshop dinner, the excursion to Brijuni (Pula), and the usual workshop materials.

Participants should register before 15th of April, 2014 via the http://ean-euterp.ekoteh.hr/

Hotel booking, at a special rate, is possible via the workshop website, for Hotel Lone and Hotel Eden.

Call for Abstracts

Authors wishing to provide oral or poster presentation are invited to send an abstract, by the 29th of November, 2013.

ALARA NEWS

European ALARA Network is an ICRP Special Liaison Organization.

Following a correspondence between EAN and the International Commission on Radiation Protection (ICRP) began in February 2013, EAN has been granted the status of "ICRP Special Liaison Organisation". EAN will notably participate to ICRP Symposium in October 2013 (Abu Dhabi).
ICRP Special Liaison Organisations are listed on ICRP website: http://www.icrp.org/icrp_group.asp?id=80

OPERRA launching meeting

On June 18th 2013, IRSN (french Institut de Radioprotection et de Sûreté Nucléaire) organized the launching meeting of the project OPERRA (Open Project for European Radiation Research Area). This project (4 years) aims at setting up a structure of coordination and integration of the European research in radioprotection. Concretely speaking, the European Commission will delegate to this structure the organization of the future calls for projects of research in radioprotection. Benefiting from the acquired experience by the association MELODI (Multidisciplinary European Low-Dose Initiative), OPERRA will also appeal to the other competent associations in radioprotection, among which: NERIS for the management of emergency situations or EURADOS for the dosimetry.

Finally, the OPERRA consortium will launch at the end of the year on 2013 a call for projects on the risks related to low-doses and another one covering all the domains of research in radioprotection at the end of 2014.

General information regarding the project can be found by following this link:
http://www.melodi-online.eu/doc/PP_OPERRA.pdf

FAQ ALARA

On the ORPNET webpage, IAEA proposes a list of frequently asked questions (FAQs) which intends to provide information to radiation protection specialists so that they can answer quickly and correctly the most frequently asked questions. The ALARA Newsletter proposes in each issue a selection of these FAQs.

What is the difference between implementing good practices and an ALARA approach?

Extensive knowledge of the company's radiation protection culture helps in implementing certain common practices, which can be termed "good practices" (*e.g.* systematic deployment of radiation protection measures at hot spots). It may nonetheless be useful to carry out analysis from time to time in order to verify that these good practices are optimised. The results of that study should then be very clearly explained to all involved stakeholders.

Options for which the benefits in terms of limiting *both* doses and costs are immediately obvious will also be considered as good practices to be integrated as part of the optimized solution.

Reference:
http://www-ns.iaea.org/tech-areas/communication-networks/norp/faq.asp?fq=54

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