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European ALARA Newsletter

Editorial

THE EUROPEAN ALARA NETWORK: RECENT EVOLUTION AND PROJECTS

Two new European countries have recently joined the Steering Group of the European ALARA Network: Iceland and Slovenia. Therefore, the representatives of **20 countries** now manage EAN. Most of the other EU countries, or applicant States, are members of the RECAN (Regional East European and Central Asian countries ALARA Network) network with whom EAN has a very close relationship. It is therefore possible to say that all European countries are participating in one way or another to an ALARA network.

This is even more the case, when looking at the setting up of new ALARA sub-networks or new networks with more and more different stakeholders and countries. 2006 has seen the setting up of a European regulatory bodies ALARA sub-network, ERPAN (European Radiation Protection Authority Network); January 2007 have seen the start of a non Destructive Testing ALARA Network with representatives of both EAN and the EFNDT (European Federation of Non Destructive Testing); February 2007 will give rise to a European NORM ALARA Network. The European Commission supports these last two networks and EAN will have very close institutional links with them. Moreover, four European organisations, ESR (radiologists), EFOMP (medical physicists), ECRRT (medical radiographers) and EAN are working together to propose to the European Commission the creation of another ALARA network in the medical area. Thus, EAN becomes more and more **a "cooperation facilitator" between existing networks and a driving force for the setting up of new ones**.

Most of the aforementioned European professional organisations, as well as ICRP, UNSCEAR, ILO, IAEA and OECD NEA have participated to the 10th EAN Workshop at Prague in September 2006 on "Experience and new developments in implementing ALARA in occupational, public and patient exposures". The workshop has shown that the ALARA principle is firmly embedded within radiation protection culture. However, a number of key issues related to the further evolution of ALARA have emerged in the last few years. These include the role of networking, how to increase stakeholder involvement, the importance of education and training in establishing an ALARA culture, and the integration of ALARA into a wider safety management philosophy ("the holistic approach"). All these topics were discussed and recommendations were provided that are presented in this issue of the Newsletter.

This issue also provide the results of an ERPAN survey performed on the setting up of Diagnostic Reference Levels (DRLs) in Europe, and the conclusions and recommendations from the last RECAN workshop, which was also devoted to medical exposures.

The 11th EAN workshop will take place at Athens (Greece) during spring 2008 and will be devoted to **"ALARA and Waste Management"**. The Workshop will take into account occupational and public exposure, political, technical and social aspects in all the different sectors (nuclear, medical, NORM…).

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EAN 10th Workshop "Experience and new Developments in Implementing ALARA in Occupational, Public and Patient Exposures" Summary and Recommendations

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WORKSHOP OBJECTIVES AND PROGRAMME

This was the 10-year anniversary of the European ALARA Network, and unlike the previous workshops that addressed a particular ALARA topic, the aim of this workshop was to consider the implementation of the optimisation principle in all domains of activities (nuclear and conventional industry, medical sector, NORM - Naturally Occurring Radioactive Materials - industry). This principle is fundamental to radiation protection, and the workshop drew together key stakeholders to discuss its past, present and future status. The workshop was asked to consider the practical implementation of ALARA, and how this might be improved in the next 10 years.

The objectives of the 10th EAN workshop were to:

- Review the past evolution of the ALARA concept, internationally, within the EU, and nationally, in terms of the practical impact on radiation protection;
- Examine the current status of the implementation of the ALARA principle; and
- Identify needs for future developments in the concept and implementation of optimisation.

As with previous workshops, half the programme time was devoted to invited presentations, and half to Working Group discussions and report backs, so that all participants could consider the objectives, contribute to discussions, and formulate the final recommendations of the workshop.

In total, there were 23 invited oral presentations, as well as a number of poster presentations, organised under the following titles:

- Introduction and setting the scene;
- Identifying needs for future development; and
- ALARA implementation in different sectors - problems to be solved.

Two afternoon sessions were set aside for Working Group discussions, based on the following four topic areas:

- How to encourage the involvement of different stakeholders in implementing ALARA;
- How to further develop ALARA culture (including education and training);
- How to assess ALARA implementation (including performance indicators); and
- How ALARA interfaces with the justification principle, and with other types of risk management.

The reports from the groups were presented and discussed on the final day, from which the key findings and recommendations from the workshop were derived.

Individual presentations (papers and slides) are available to download from the EAN website (http://www.eu-alara.net/). From these, and the discussions that followed, a number of significant themes and issues emerged, and these are described below.

THEMES AND ISSUES ARISING

The introductory and scene-setting session contained keynote presentations from ICRP (on the content of its draft Recommendations) IAEA, EC and EAN. Together with subsequent presentations from ILO, UNSCEAR, ESOREX, EFNDT (European Federation for Non-Destructive Testing), EFOMP (European Federation of Organisations of Medical Physics), ECRRT (European Committee of Radiographers and Radiological Technologists), these provided an excellent international overview of the evolution of the ALARA principle and of its implementation. EAN has always aimed to bring together a wide range of stakeholders, and the extended involvement of international organisations throughout the workshop was considered especially valuable.

The presentations in the following two sessions provided a multi-angle analysis of the implementation and application of ALARA in practice. This included assessments of ALARA successes and failures from different stakeholders (regulators, licensees, workers, etc.), and from the perspective of different work sectors (medical, NDT, NORM, etc.). Also considered was how ALARA fits into the wider protection philosophy, both radiological and non-radiological.

From the presentations and subsequent discussions a number of themes emerged. In terms of looking back over the last 10 years:

- The ALARA principle is firmly embedded within radiation protection culture, and in many sectors there is evidence of progress both in terms of dose restriction and the ways in which the principle is applied in practice. Having said this, there are still some sectors where evidence of progress is lacking, either because ALARA culture has not fully developed (e.g. NDT and NORM), or has not kept pace with developments in that sector (e.g. medical).
- A number of key issues related to the further evolution of ALARA have emerged in the last few years. These include the role of networking, how to increase stakeholder involvement, the importance of education and training in

establishing an ALARA culture, and the integration of ALARA into a wider safety management philosophy ("the holistic approach").

In terms of looking forward to the next 10 years, the following issues were identified:

- The concept and application of networking should continue to be developed. Forging new links with stakeholders, and encouraging the sharing of information on good practice remain key objectives. In particular, EAN should develop links with EFNDT, ESR (European Society of Radiology), EFOMP, ECRRT, EUTERP (European Training and Education in Radiation Protection Platform) as well as with other regional ALARA networks (i.e. RECAN – Regional East European and Central Asian countries ALARA Network – funded by IAEA). Specific networks, for Regulatory Inspectors, Research Reactors, NORM, NDT, and Medical are supported.
- In the draft ICRP recommendations, the application of ALARA to existing exposure situations has been further developed. Consequently, there is work to be done in terms of how ALARA should be implemented in practice in such situations. ICRP have also developed and expanded the concept of constraints/reference levels - these are intimately linked with ALARA, and the practical outcome of the ICRP recommendations needs further consideration.
- In the medical sector there have been rapid developments in terms of the emergence of new or improved diagnostic and therapeutic techniques involving ionising radiation. More than ever, there is a need for the radiation protection community to become actively engaged with the medical community to ensure that the ALARA principle remains a key consideration.

WORKSHOP RECOMMENDATIONS

Each working group produced conclusions and recommendations, and gave a report back on the final day of the workshop. The output of the Working Groups was collated by the EAN co-ordinators, to produce the formal recommendations of the workshop, as listed below.

RECOMMENDATION 1: Justification of practices

It is recommended that national authorities should periodically re-evaluate the justification of existing practices. This re-evaluation should consider alternative practices or procedures which could give rise to lower radiation risks. The old practice, or procedure, may be reclassified as no longer being justified, and then abandoned.

It is recommended that the EC consider including this in the next revision of the Basic Safety Standards Directive as a "shall" requirement instead of a "may" requirement (Article 6.2 of the Council Directive 96/29/EURATOM: "*Existing classes or types of practice may be reviewed as to justification whenever new and important evidence about their efficacy or consequences is acquired*").

RECOMMENDATION 2: Holistic approach

Radiation Protection Authorities and Occupational Health and Safety Authorities should work together in establishing an overall safety culture. This could be extended to environmental safety aspects. On an operational level, the consideration and implementation of all safety issues, whether radiological, chemical or conventional, should be recognised and addressed as being interdependent, in order to assure a holistic approach in establishing global safety goals.

RECOMMENDATION 3: ALARA Culture

Despite the wide acceptance of the need for an ALARA culture, there is no universally agreed definition of what this is. To further the understanding of this concept, it is recommended that EAN propose - and publish on its website - an expanded definition of "*ALARA culture*". This definition should focus on what the concept means in practice, in terms of the protection framework, and the state of mind and attitudes to be taken up and shared by all stakeholders involved in radiation safety management.

RECOMMENDATION 4: ALARA Training

There is a need to generally improve the integration of ALARA into the training of all stakeholders (nuclear and non-nuclear workers, safety inspectors, etc). At the national level, regulatory bodies should stimulate procedures for the establishment of a framework for ALARA in education and training. International Organisations (EC, IAEA, and ILO) should stimulate the development and co-organisation of syllabi for radiation protection, and foster and support ALARA programmes in specific areas such as medicine, NORM, industrial radiography, etc.

RECOMMENDATION 5: Training in the medical sector

All personnel involved in prescribing and delivering medical exposures should receive appropriate training, so as to understand the risks associated with such exposures, and the need to apply the principles of justification and optimisation of protection in each case. This is relevant both in terms of initial training and programmes for continued professional development.

At a national level, those stakeholders responsible for the provision of education and training in the medical sector should aim to increase the amount of effort devoted to radiation protection in general, and ALARA in particular. Such stakeholders should ensure that these topics are embedded in both initial and ongoing education and training programmes.

Appropriate education and training programmes should be targeted at all personnel involved in prescribing and delivering medical exposures, and should make each group aware of their individual responsibilities. The European Medical ALARA Network (EMAN) and the EUTERP Platform should work together to establish internationally agreed criteria for training and education programmes in this area.

RECOMMENDATION 6: ALARA focus through inspection and control

Regulatory Bodies have an important role to play in encouraging ALARA, and should do this through a combination of guidance and enforcement. They should ensure that assessing ALARA implementation is an integral part of regulatory inspections. To facilitate this, Regulatory Bodies should provide guidance to licensees/employers on what types of evidence of ALARA implementation inspectors might expect to see.

Their role is especially important in sectors where ALARA implementation may need further development, such as with NORM, radon, and emerging medical exposure technologies and techniques. Regulatory Bodies should give priority to such areas, and ensure that their resources are allocated appropriately.

RECOMMENDATION 7: Stakeholder involvement

EAN should take positive steps to address the issue of stakeholder involvement, especially workers, as identified in this and previous workshops. In particular, EAN should:

- Establish a working group to specifically consider workers involvement in occupational exposure management;
- Contribute to discussion on a *code of conduct* currently being prepared by British, French and Spanish RP societies (for IRPA); and
- Collect and disseminate examples of stakeholders' involvement in radiation protection.

Regulatory Bodies have an important role to play in facilitating stakeholder involvement, and are encouraged to establish mechanisms for communicating with relevant parties and encouraging their participation. This may, for example include, seminars, consultation exercises, public meetings, internet forums, etc.

The 2nd RECAN Workshop on "Implementation of ALARA in Medicine"

P. Deboodt (IAEA)

The second workshop of the Regional East European and Central Asian countries ALARA Network has been held in Cavtat, Croatia, 18-20 October 2006. Jointly organized by the IAEA and EKOTEH with the support of the Croatian Regulatory Authorities, the workshop was attended by more than 45 participants representing 24 countries (1).

Four sessions provided presentations on "Networking as a useful means to improve the Radiation Protection", on "Regulations and Medical Uses of Ionising Radiations", on "Radiation Protection Management in Medical Areas" and on "Commitment of the medical specialists and physicists". A fifth session was devoted to the discussions in four Working Groups. Each working group had to address one of the following questions:

1) What are the problems in implementing regulations for medical RP?
2) What is the role of the medical staff in RP?
3) What is the relation between QM and RP programme?
4) What are the problems with RP education and training in the medical field?

During the last session, the main findings and the recommendations from the workshop were finalized. The main findings can be summarized as follows:

- Usefulness of the workshop
  - Participants acknowledged the support of IAEA in the creation of networks such as RECAN and welcomed the possibility of making personal contacts with people having similar problems
  - Participants became aware of the availability of several training packages dedicated to specific medical professions but also stressed the lack of translated materials

- Other important issues raised in the presentations and during the discussions
  - Use of dose reference levels and the difference (if any) with the concept of dose constraints
  - Quality Management in relation to ALARA is a major issue in many presentations and case studies (QA; QC; QMS)
  - There is a need for increasing the awareness of radiation risks at each level of the operational and management line
  - Strong emphasis on the need for E&T in RP in medical professions

- Role and recognition of the Medical Physicist
- Role of the suppliers (manuals, maintenance of equipment)
- Basic elements of the optimization process in the medical field are:
  - QA/QC for equipment and procedures
  - Standardization of protocols for examinations
  - Adequately skilled and trained staff

Based on the discussions and as the main results of the working groups, six recommendations have been produced.

Rec. 1: It is recommended that the IAEA further assists Member States in achieving the objectives of the **T**hematic **S**afety **A**reas (in particular TSA-1,-2 ,-3 and -6) by supporting the countries with expert missions, providing equipment, developing guidance material and providing support to E&T activities.

Rec. 2: Regulatory bodies are recommended to stress the importance of RP issues in the medical field through binding regulations - on adequate staffing; organization of RP, equipment, human and financial resources; education and training requirements. This accounts both for the medical practices and for the regulatory bodies themselves.

Rec. 3: National regulatory bodies, in cooperation with appropriate professional organisations, should ensure that guidance material on **D**ose **R**eference **L**evels is available for users. Where necessary, the DRLs may be modified with respect to the prevailing conditions. Medical practitioners should use these DRLs in establishing their own protocols.

Rec. 4: It is recommended that regulatory bodies, in close cooperation with professional organizations, ensure the development and the implementation of comprehensive E&T programs for medical practitioners. Basic education in RP should be ensured in medical vocational education.

Rec. 5: QMS is an important tool for optimization in RP. It is recommended that regulatory bodies set requirements on development and implementation of QMS in the authorization process for medical practices. Inspectors should check compliance with these requirements in their inspection programs.

Rec. 6: It is recommended that RECAN, in collaboration with other networks compiles and disseminates examples of good and bad RP practices, in particular in the medical field.

The detailed information will be made available on the RECAN website as well as the presentations.

The quality of the organization of the workshop was unanimously recognized as well as the contribution of two members of the EAN by providing presentations, chairing some sessions and preparing, with the RECAN Steering Committee members the draft of the recommendations.

The 3rd RECAN workshop will be held in Brasov, Romania in October 2007 and will address some aspects of the "Problems in implementing practical optimization".

(1) *Albania, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Cyprus, Czech Republic, Estonia, France, Georgia, Kazakhstan, Latvia, Lithuania, Macedonia, Malta, Moldova, Romania, Serbia, Slovenia, Tajikistan, The Netherlands, Turkey, Ukraine, Uzbekistan*

Diagnostic Reference Levels (DRLs) in Europe: some examples from France, Germany, Greece, Italy, Netherlands, Sweden, Switzerland and UK

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INTRODUCTION

The concept of the Diagnostic Reference Level (DRL), as an investigation tool to identify situations where patient doses are unusually high and in most urgent need of reduction, was adopted by the International Commission on Radiological Protection in ICRP Publications 60 and 73 and by the European directive 97/43/Euratom.

Diagnostic Reference Levels are values which are usually easy to measure and have a direct link with patient doses. They are therefore established to aid efficient dose management and to optimize patient doses. If such doses are found to exceed the corresponding reference dose, possible causes should be investigated and corrective action taken accordingly, unless the unusually high doses could be clinically justified.

The ICRP publications recommended that values should be determined by professional medical bodies, reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in observed dose distributions and be specific to a country or region. The concept of Diagnostic Reference Level is beginning to be a well-defined tool in many countries and is used to reduce patient dose during medical interventions and examinations.

The aim of this article is to present the status of the different concepts of Diagnostic Reference Levels in

Europe in the following countries: France, Germany, Greece, Italy, Netherland, Sweden, Switzerland and the United Kingdom. The methods used to establish reference levels for medical examination and interventions and to enforce them in surgeries and hospitals as well as training developed for the medical staff are presented. This article also gives information on the periodicity and the methods used to update the DRLs as well as on the future outlook.

MEDICAL APPLICATIONS FOR WHICH DRLs ARE DEFINED

France

In France, Diagnostic Reference Levels are established for 21 x-ray examinations and for 10 nuclear medicine examinations. The levels apply to radiography examinations (fluoroscopy is excluded) of standard-sized adult patients. Examination for which DRLs have been proposed include:

- 9 types conventional x-ray including mamography on adult patients
- 2 types of conventionnal x-ray (thorax and pelvis) for children – 0 to 1 5 years old
- 7 types of conventionnal x-ray for children – 5 years old
- 4 types of CT examination on adult patients
- 10 nuclear medicine examinations including ^{18}F-PET

Germany

In Germany, Diagnostic Reference Levels are established for x-ray and nuclear medicine examinations. In particular DRLs are established for:

- 12 types of radiograph for adult patients
- 5 types of radiography/fluoroscopy examinations for adult patients
- 7 types of CT examination for adult patients
- 2 types of fluoroscopically-guided interventional procedure for adult patients
- 6 types of radiograph for paediatric patients (2-5 years old)
- 1 type of radiography/fluoroscopy examination for paediatric patients (4 years old)
- 17 types of diagnostic nuclear medicine procedures for adult patients and conversion factors for children

Greece

The requirement for the establishment and application of Diagnostic Reference Levels is imposed by the Greek Radiation Protection Regulations. The Greek Atomic Energy Commission (GAEC) as the national authority for radiation protection, is responsible for the establishment and enforcement of the national DRLs. DRL values for mammography and 12 types of nuclear medicine examinations have already been approved by GAEC's board. DRL values for 7 types of computed tomography examinations are in the process of approval, while DRLs for 10 conventional radiography and for fluoroscopy examinations are expected to be determined in the near future.

Italy

In Italy, Diagnostic Reference Levels are established and applied to:

- 7 types of conventional x-ray on adult patients
- 4 types pf conventional x-ray on infant patients (≤ 5 years old)
- 1 type of mammography examination
- 4 types of CT-examinations on adult patients
- 48 types of diagnostic nuclear medicine procedures on adult patients and, based on scaled values taking into account the body mass, on pediatric patients

Netherlands

The Decree on Radiation Protection of 2001 stipulates that the Minister of Health, Welfare and Sport shall promote the establishment and use of DRLs, but it has not lead to the implementation of DRLs in the Netherlands yet.

Sweden

In Sweden, Diagnostic Reference Levels are established for 12 x-ray examinations and for 19 nuclear medicine examinations. The levels apply to complete examinations of standard-sized adult patients. Examination for which DRLs have been established include:

- 6 types conventional x-ray on adult patients
- 4 types of CT examination on adult patients
- 2 types of mammography examination
- 19 nuclear medicine examinations

Switzerland

In Switzerland, Diagnostic Reference Levels are applied to conventional radiology, interventional radiological procedures, computer tomography and nuclear medicine, for adult, and in many cases also for infant, patients. DRLs are established for:

- 9 types of conventional x-ray on adult patients
- 1 type of mammography examination
- 8 types of interventional procedures in radiology on adult patients
- 4 types of interventional procedures in cardiology on adult patients
- 8 types of CT examination on adult patients
- 4 types of CT examination on infant patients
- 47 types of diagnostic nuclear medicine procedure on adult patients and infant patients

United Kingdom

A Department of Health DRL Working Party has been set up in the UK to formally adopt national DRLs in compliance with the requirements of the Ionising Radiation (Medical Exposure) Regulations 2000. The Working Party will consider proposals for DRLs from relevant professional groups and organisations (primarily NRPB/HPA and ARSAC) based on published patient dose data from UK national surveys. Medical applications for which DRLs had been proposed by 2005 include:

- 13 types of individual radiograph on adult patients
- 15 types of radiography/fluoroscopy examination on adult patients
- 12 types of CT examination on adult patients
- 5 types of fluoroscopically-guided interventional procedure on adult patients
- 3 types of radiography/fluoroscopy examination on paediatric patients (5 years old)
- 2 types of CT examination on paediatric patients (3 years old)
- 96 types of diagnostic nuclear medicine procedure on adult patients

METHODS AND MEANS USED TO DETERMINE THE DRLs

France
The first step consisted of making a list of the most common radiological procedures and in writing down the corresponding standardised protocols with the French Society of Radiology (SFR) , the Institute of Radiation protection and Nuclear Safety (IRSN) and ASN. On the basis of protocols and data sheets established with the French Society of Medical Physics (SFPM). TLD measurements (entrance dose) and examinations data (parameters or Dose length product) were measured, recorded or calculated. The data were collected in 24 volunteer centers and 8 examinations have been selected: 4 in conventional radiology and 4 in computed tomography. Mean dose values and third quartile values were determined for approximately 1300 patients in conventionnal radiology and 600 in CT. In conventionnal radiology, it was first concluded that the DRLs proposed by the European Commission can be applied in conventionnal radiology but for CT the European DRLs can be lowered. For nuclear medicine, the value of activity recommended in the marketing autorization for radiophamaceuticals was choosen as first value for the reference levels.

Germany
The initial values of the German DRLs in diagnostic radiology were proposed by an expert group of physicians and medical physicists chaired by the Federal Office for Radiation Protection (BfS), including representatives of the professional medical societies. For radiographs of adult patients, the European DRLs were adopted accordingly. For fluoroscopy examinations, a restricted survey of current practices in university hospitals, and for CT examinations, a national survey of CT practice performed in 1999 were used to derive the DRLs. For diagnostic nuclear medicine procedures, BfS had proposed national DRLs based on the results of a national survey on frequencies and administered activities in diagnostic nuclear medicine, on recommendations of national and international societies and on proposals for DRLs in other countries. The BfS proposal was finally discussed with members of the German Radiation Protection Commission (SSK). The quantities used to express the DRLs are:

- Dose-area-product (DAP) for conventional x-ray examinations (for radiographs, the entrance surface air Kerma (ESAK) and entrance surface dose (ESD) can be used alternatively)
- Computed tomography dose index ($CTDI_{Vol}$) and dose-length product (DLP) for computed tomography
- Entrance surface dose (ESD) for mammography
- Administered activity for nuclear medicine

Greece
The determination of DRLs is based on the data collected during the on-site inspections performed by GAEC in radiology and nuclear medicine laboratories. The on-site inspections are carried out as a part of the licensing procedure of the laboratories every 2 years for nuclear medicine and 5 years for radiology laboratories respectively. As it concerns the radiological examinations, adequate dosimetric measurements are performed for the different types of examinations performed, while for nuclear medicine examinations the administered activities for each diagnostic procedure are considered as the appropriate quantity. The DRL for each examination is determined as the rounded 3rd quartile value of the distribution of the corresponding dosimetric or activity values registered. More specifically, the quantities used to express DRLs are:

- Entrance surface dose (ESD) for conventional x-ray
- Computed tomography dose index (CTDI) for computed tomography
- Entrance surface dose (ESD) and Average glandular dose (AGD) for mammography, and
- Administered activity for nuclear medicine examinations

Italy
The values of the DRLs were established on the basis of a survey of data reported in the literature, with particular regard to Guidelines published by the EC. The quantities used for the DRLs are:

- Entrance skin dose for conventional x-ray examinations and mammography
- Dose length product (DLP) and weighted computed tomography dose index ($CTDI_w$) for computed tomography
- Administered activity for diagnostic nuclear medicine

For all examinations for which a DRL exists, hospitals have to determine the dose or administered activity for a standard sized patient, whose values are compared with the corresponding DRL. If the level is exceeded actions have to be taken in order to reduce the dose.

Sweden
The present DRLs were determined by studying the radiation dose levels in hospitals. A national survey of doses for x-ray examinations was carried out in 1999. For nuclear medicine examinations the dose situation was roughly known from the nominal administered activities that have been reported each year. The DRLs

have been established on the basis of the resulting dose distributions. The quantities used for the DRLs are:

- Dose-area-product for conventional x-ray examinations
- Dose-length-product and the volume computed tomography dose index for computed tomography
- Mean glandular dose for mammography and
- Administered activity for nuclear medicine

For all examinations for which a DRL exists hospitals have to determine the radiation dose or administered activity for a standard sized patient. This standard dose or administered activity is compared with the corresponding DRL - if the level is exceeded actions have to be taken in order to reduce the dose, if possible.

Switzerland

The method adopted to determine the Diagnostic Reference Levels (DRLs) varied according to the modality. In 2002, Switzerland took part in a Europe-wide survey on computed tomography (CT). In this case, data from Swiss hospitals were used to establish the DRLs in the CT area. In the following years – 2003 and 2004 – the Institute of Applied Radiophysics (IRA) was commissioned by the Swiss Federal Office of Public Health (SFOPH) to study high-dose applications in interventional radiology and cardiology. For nuclear medicine, Basel University Hospital was commissioned by the SFOPH in 2004 to conduct a nationwide survey of administered activities. For conventional radiography, the SFOPH adopted the values recommended by the European Commission. A programme currently under way is designed to provide a broader basis for the DRLs in interventional radiology and cardiology. While the DRLs in this area have previously only been based on data obtained from university hospitals, a representative selection of all the Swiss centres where such procedures are performed is now being taken into account. It will be interesting to note any difference that may emerge, e.g. how patients' exposure levels are influenced by factors such as investigation frequency or operators' experience.

United Kingdom

For x-ray imaging procedures, DRLs are based on national surveys of patient doses conducted by NRPB/HPA or the National Health Service Breast Screening Programme (for mammography). National reference doses are set at the rounded 3rd quartile values of the distribution of mean doses seen on representative samples of patients at each hospital in large national surveys. For diagnostic nuclear medicine procedures, national DRLs are based on DRLs recommended by the Department of Health's Administration of Radioactive Substances Advisory Committee (ARSAC).

The quantities used to express the DRLs are:

- Entrance surface dose (ESD) and dose-area-product (DAP) for conventional x-ray examinations
- Computed tomography dose index (CTDI) and dose-length product (DLP) for computed tomography
- Mean glandular dose for mammography
- Administered activity for nuclear medicine

WAYS AND MEANS USED TO ENFORCE THE DRLs IN SURGERIES AND HOSPITALS

France

The DRLs are set in the ministerial order of 12 February 2004 as a part of the tranposition into French regulation of the European directive 97/43/Euratom. According to this order, each radiologist or nuclear medicine practitionner must evaluate every year for 20 "standard" patients (or on an anthropomorphic phantom) and for 2 types of procedures defined in the order, the parameter choosen for quantifyng DRLs (Entrance skin bose, dose length product or activity). The procedures must be different every year and the data must be sent to IRSN, who is in charge of data collection and analysis and determine the possible need to change DRLs.

Germany

With the amendment of the Radiation Protection Ordinance (Strahlenschutzverordnung, StrlSchV) in 2001 and the X-Ray Ordinance (Röntgenverordnung, RöV) in 2002, the requirements of the European Directive 97/43/Euratom were adopted into German legislation. StrlSchV and RöV demand that DRLs, to be established and published by the BfS, have to be considered for X-ray and nuclear medicine examinations of humans. The so called "Ärztliche Stellen" (ÄS), Medical Authorities which are already involved in the process of quality control concerning image quality and compliance with the guidelines of the Federal Medical Board, must check compliance of the average patient exposure in the various radiological installations with the DRLs. The normal control period is about 2 years. If the ÄS find that the DRLs are exceeded without medical justification, they give advice for optimization and reduction of patient doses. In this case, the control period is shortened to about half a year. According to StrlSchV and RöV, the ÄS are obliged to report any consistent, unjustified exceeding of DRLs to the competent Authorities of the "Bundesländer" (German Federal States).

Greece

The Greek Radiation Protection Regulations require that the medical physicists employed as Radiation Protection Experts (RPE) in radiology and nuclear medicine departments are responsible for organising and running adequate programmes for the determination of local reference levels for each type of examination performed. These levels must be compared to the national DRL values and if required adequate measures must be taken for the further reduction of patient doses.

Italy

The DRLs were set in the Legislative Decree n. 187 of 26 May 2000, that implemented in the Italian law the

European Directive 97/43/Euratom. According to this Decree, each Radiological or Nuclear Medicine Department must set up a suitable quality control programme, aimed at the optimisation of the procedures. Moreover, the doses delivered to patients in each procedure must be evaluated every two years, checking their compliance with the DRL. All the personnel engaged in the use of ionising radiation for medical purposes must participate every five years to a refresher course on radiation protection, with special regard to the exposure of the patient.

Sweden
Diagnostic Reference Levels were implemented into the national regulations in 2002. The determination of standard doses and administered activities is mandatory according to these regulations and have to be determined for the first round within two years. The national authority can require the reporting of the determined standard doses at any time, and did so for the first round of measurements where detailed data on the level of the individual patient were asked for. Normally the determination of standard doses is also checked in connection with inspections.

Switzerland
The DRL system is also being taken into consideration in the current revision of radiological protection legislation. A special article is to be established, requiring users to review and optimize exposure levels in relation to the DRLs. The applicable DRLs are published in Directives of the Swiss Federal Office of Public Health.

United Kingdom
The Ionising Radiation (Medical Exposure) Regulations 2000 require all hospitals, surgeries, etc that carry out medical exposures to develop written procedures for the establishment, use of and adherence to DRLs. Further guidance on how to do this is provided by IPEM Report 88, 2004, – 'Guidance on the Establishment and Use of DRLs for Medical x-ray Examinations'. There is also a requirement in the Ionising Radiations Regulations, 1999, for every hospital, surgery, etc to provide a suitable quality assurance programme for all equipment used for medical exposures, which should include periodic assessments of representative doses to patients (patient dose audits). Guidance on how to comply with this requirement, including the DRL-related levels of patient dose above which remedial action should be taken, is given in IPEM Report 91, 2005, - 'Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems'. These two sets of regulations and guidance provide the main framework for the implementation and enforcement of DRLs in the UK. The IPEM guidance documents were prepared by joint working parties comprising representatives of the Institute of Physics and Engineering in Medicine, the National Radiological Protection Board (now the Radiation Protection Division of the HPA), the College of Radiographers, the Royal College of Radiologists and the British Institute of Radiology.

TRAINING, INFORMATION AND PUBLICATIONS ON DRLs DEVELOPED FOR MEDICAL STAFF

France
Training courses were organized along with the guidance on how to determine the standard doses and administered activity for the medical personal to facilitate the application of the regulation. Dose data recording forms were produced to help collect data.

Germany
The DRLs were first published in August 2003. In October 2004, guidelines for the use of DRLs, especially in diagnostic radiology, were issued to the ÄS of the "Bundesländer" for further distribution to the various radiological installations in their region. A paper "Establishment and application of Diagnostic Reference Levels for nuclear medicine procedures in Germany" has been published in the journal Nuklearmedizin (2004; 43: 79-84) to inform medical staff. A similar publication is being prepared for diagnostic radiology. According to legislation (StrlSchV and RöV) it is the responsibility of BfS to publish the DRLs.

Greece
GAEC, as the competent authority on radiation protection issues, organises special courses on the establishment and the implementation of DRLs for personnel in radiology and nuclear medicine departments. Moreover, the RPEs in large hospitals are responsible for providing the required training on the use of DRLs to the medical staff. Also, the importance of the use of DRLs as a radiation protection optimisation tool is also underlined during the on-site inspections of GAEC.

Italy
Medical physicists provide local training for radiologists, technicians and every physician (with particular regard to cardiologists and surgeons) engaged in the different uses of ionising radiation for medical purposes.

Sweden
The regulations are accompanied by guidance on how to determine the standard doses and administered activity. It also gives examples of good radiological practice for the various examinations. In the beginning the authority put a great deal of effort into informing personnel about the concept of DRLs at different national meetings and courses run for the diagnostic community. Personal communications also played an important role in the information process.

Switzerland
Implementation of the DRL concept is promoted by the Swiss Federal Office of Public Health in various ways:

users receive training on the concept directly during audits, and information is provided at conferences held by the relevant professional associations; at the same time, training DVDs are made available to users, giving a detailed account of radiological protection for patients and staff. In addition, awareness of the concept is to be raised by the publication of a booklet on this subject.

United Kingdom
Medical physicists in the UK provide local training for health service staff and IPEM and BIR have run a number of meetings on the use of DRLs. Training is primarily based on guidance on the establishment and use of DRLs for medical x-ray examinations' in IPEM Report 88, 2004. Presentations on the use of DRLs have been given at the UK Radiology Congress and NRPB has published related articles in the British Journal of Radiology and specialist journals and magazines aimed at radiographers. NRPB/HPA also publishes regular reviews of its national patient dose databases which include recommended national reference doses for a wide range of diagnostic and interventional x-ray procedures. The Department of Health's Administration of Radioactive Substances Advisory Committee (ARSAC) publishes notes for guidance on nuclear medicine procedures that include DRLs and are updated at regular intervals.

PERIODICITY AND METHOD USED TO UPDATE THE DRLs

France
So far, no update of DRLs has been planned but it is expected that progress will be made with the improvement of x-ray machines with respect to their ability to give information on the dose delivered during examinations, and with the improving awareness of practitioners.

Germany
There is no definite period for the update of the DRLs. But it is agreed that the DRLs should be updated within about 3 – 5 years by BfS. It is planned that the BfS will be informed anonymously by the ÄS about the relevant mean patient doses of all radiological installations. After a complete review of patient doses by the ÄS, updated DRLs can be established by the BfS based on the third quartile values of the distributions of the relevant mean patient doses in diagnostic radiology and on the mean activity values in nuclear medicine.

Greece
Although the procedure of DRLs establishment has not been completed yet, it is expected that they will be updated on a five year basis, if of course there is a need for that. Their updating will be based on the analysis of the data collected during GAEC's on-site inspections.

Italy
So far, the DRLs have not been updated. Concerning the DRLs in x-ray procedures, the Italian Association of Medical Physics (AIFM) has formed a few working groups, devoted respectively to conventional procedures and mammography (with special regard to a comparison between the doses in screen-film vs. digital imaging) and CT (with special regard to new MSCT equipment). These groups are collecting data from selected radiological departments, throughout the whole Italian territory.

Sweden
The DRLs have not been updated yet, but new updated values for nuclear medicine are on their way. Next year the authority is planning to analyze the standard doses reported for x-ray examinations and use this analysis as an input for the revision of the regulation – which will probably result in additional examinations included in the concept and in lower values of Diagnostic Reference Levels for the existing ones.

Switzerland
It is envisaged that the DRLs will be updated every 5 to 10 years. The Swiss Federal Office of Public Health also supports solutions involving modern information technologies and networks. At the Bern University Children's Hospital, an application of this kind has been implemented. Here, all the patient data and radiation doses are stored on a dedicated server and can thus subsequently be used to determine the DRLs. Efforts are also being made to enable a direct graphic comparison – dose administered vs reference level – to be displayed for CT and interventional procedures. Future RIS and PACS systems should fully exploit these possibilities.

United Kingdom
NRPB/HPA publishes five-yearly reviews of its National Patient Dose Database (NPDD) which includes recommended national reference doses for a wide range of diagnostic and interventional x-ray procedures apart from those using CT. A separate database (called PREDICT – Patient Radiation Exposure and Dose in CT) is held by NRPB/HPA for CT examinations and is based on national surveys of UK CT practice conducted in 1999 and 2003. The periodic reviews of these two databases (NPDD & PREDICT) comprise the major source of proposed national DRLS for x-ray imaging procedures in the UK. Reviews of NPDD have been published for the five-year periods ending in 1995 and 2000 and the latest review for the 5 years ending in 2005 will be published soon. It is anticipated that the PREDICT database will be updated and reviewed with a similar frequency. National DRLs for diagnostic nuclear medicine procedures are regularly updated by the Department of Health's Administration of Radioactive Substances Advisory Committee (ARSAC). They were last updated in 2006.

FUTURE OUTLOOK

France
ASN will support any initiative aiming at the international harmonisation of any radiation control practice, including the harmonisation of DRLs. However, this practice being rather new, efforts may be

placed in priority on the harmonisation of other radiation protection practices that are more generally applied than DRLs.

Germany
In the near future another expert meeting concerning DRLs is planned by BfS. Besides the update of the existing DRLs, the possible inclusion of dental x-ray examinations and paediatric CT examinations in the concept will be discussed.

Greece
It is of great importance to ensure that the established DRL values are applied properly in all medical laboratories. As it concerns the completion of a full set of DRLs, priority is given to the definition of DRLs for pediatric examinations and interventional procedures.

Italy
Concerning the DRLs in x-ray procedures, the Italian Association of Medical Physics (AIFM) has formed a few working groups, devoted respectively to conventional procedures and mammography (with special regard to a comparison between the doses in screen-film vs. digital imaging) and CT (with special regard to new MSCT equipment). These groups are collecting data from selected radiological departments, throughout the whole Italian territory.

Netherlands
In May 2006, the Ministry has organized a meeting with a number of medical professional organizations, in order to exchange information about knowledge and experience with DRLs and to discuss how to start the development and implementation in the Netherlands. It was concluded that the Radiology and Nuclear Medicine Platform of the National Committee on Radiation Dosimetry should play a role in this process. At this moment, the Ministry and the Platform are discussing a project plan for the implementation of DRLs. It is expected that this plan will be finalized early 2007. From that time onwards, the implementation activities will start.

Sweden
It is recognized that pediatric and interventional examinations should be included in the concept, although both have their difficulties due to varying body size and varying complexity, respectively.

Switzerland
In the near future, the DRLs should be routinely applied in Switzerland whenever ionizing radiation is used in medicine.

United Kingdom
Regarding the standardisation of DRLs internationally, in the past the UK has provided a substantial amount of the patient dose data that was used to establish European reference doses for diagnostic radiographic images for adult and paediatric patients and for CT. The UK will continue to participate in the European Study Group developing quality criteria and European DRLs in CT. However, the UK sees little benefit for the optimisation of patient protection in the UK to justify any future attempts to standardise DRLs at a European or even wider international level. To be effective in the UK, DRLs need to be based on current UK radiology practice. In the future it is hoped that our regular five-yearly reviews will be extended to cover other high-dose imaging procedures, particularly in CT and interventional radiology.

CONCLUSION

Many developments and concepts to collect and use DRLs have already been introduced in France, Germany, Greece, Italy, Sweden, Switzerland and the United Kingdom. In Netherlands it is expected that a plan for the implementation of DRLs will be finalized in 2007 and from that time onwards, the implementation activities will start. The methods used to implement the diagnostic reference levels, to inform and train the medical staff are quite different for each country. The future outlook and the ways DRLs will be developed in these countries are not clearly defined but several projects are well under way. Diagnostic Reference Levels give a direct link to patient doses and are an important tool to perform efficient dose management and to optimize patient doses. Countries should therefore try to develop concepts in order to implement and use diagnostic reference level to ensure patient doses are reduced as much as possible. The directions shown by these countries for the DRLs are quite promising. Regulatory bodies, medical staff as well as patient organizations should invest time in this constantly developing concept to optimize dose to patient in the different fields using ionizing radiation.

More Information
Further information about DRLs can be found on the following websites or requested from the following persons:

France	Web: www.asn.fr Email: marc.valero@asn.fr
Germany	Web: www.bfs.de Email: rveit@bfs.de
Greece	Web: www.eeae.gr Email: vkamenop@gaec.gr
Italy	Web: www.ieo.it Email: giampiero.tosi@ieo.it
Netherlands	Web: www.minvws.nl Email: mj.alphenaar@minvws.nl
Sweden	Web: www.ssi.se Email: anja.almen@ssi.se
Switzerland	Web: www.str-rad.ch Email: philipp.trueb@bag.admin.ch
United Kingdom	Web: www.hpa.org.uk Email: barry.wall@hpa.org.uk

Radiotherapy Incidents and Accidents in France

Since 2003, three severe radiotherapy accidents have occurred in France.

In 2003 in Grenoble a patient was overexposed due to a problem of data transmission between different software. The accident was discovered in 2004. In Lyon, in 2004, one patient was overexposed due to a wrong adjustment of the irradiation field. She died in 2006 but a direct link with the overexposure has not been established.

In Epinal, 23 patients treated by external beam therapy for prostate cancer between May 2004 and May 2005 received an exposure at a dose exceeding (by 7% to 34%) the radiation dose initially prescribed. The French Nuclear Safety Authority (ASN) was informed on July 6, 2006. Currently, 16 patients have already developed acute complications (rectal inflammation/burns), and at least one patient died as a result of the overexposure. This repetitive accident was caused by a lack of training of the operators on the use of the treatment planning software (TPS) and by design aspects - the software was not translated into French, and some acronyms used were unclear - that couldn't prevent a subsequent incorrect setting of the accelerator. The TPS simulation was performed with static wedges, but the accelerator was set with dynamic wedges thus leading to an excess of the exposure time.

The ASN notified this event to the French health products agency (AFSSAPS). The manufacturer has been contacted by the AFSSAPS to implement corrective actions at two other beam therapy centres still using the TPS in France. The ASN also asked its technical support organization IRSN to assess the radiological consequences precisely and to propose recommendations for undertaking curative therapeutical actions.

Following these accidents and some other incidents, the French Nuclear Safety Authority took some actions, which are described in the following ASN statement.

OFFICIAL ASN STATEMENT

Several radiotherapy incidents and accidents were recently declared to ASN. This challenges the global impression of progress that was recorded during these last years in the field of medical radiation protection.

Thus, in 2005 and 2006, serious radiotherapy accidents occurred in various hospitals in France. (Grenoble, Lyon, Epinal).

In addition, various types of incidents, so far, without health consequences have also been declared:

- *Two mismatches of patient identifications occurred on 21 August and 19 October 2006 at the radiotherapy department in Angers;*
- *The administration of radiation to the wrong patient on 28 June 2006, during a radiotherapy session at Saint-Etienne;*
- *A forgotten source of iridium-192 on a patient who was undergoing a brachytherapy treatment on 2 June 2006 at Amiens.*

If the increase in the number of incident reports from professionals is definitely a sign of increasing radiation safety culture in the medical field in France, the serious consequences, for several patients, of an overexposure during a radiotherapy treatment are of major concern for ASN.

The investigations systematically conducted by ASN following these events demonstrated that these incidents, to a large extend, originated from organisational and human failures. In April 2006, ASN did already send to radiotherapy professionals a circular letter, so as to increase their awareness of prevention means of radiotherapy accidents.

ASN feels it necessary to reinforce this initiative, therefore:

- *ASN has requested professionals and the national institute of cancer (InCA) to present their action plans for the full integration of human and organisational factors in the activities of radiotherapy departments;*
- *ASN realises in 2007, with its local delegations, an inquiry at radiotherapy departments so as to identify possible understaffing of medical physicists;*
- *ASN prepares a commission's decision to better regulate the system of incident reporting, in particular, the record keeping and analysis of events at each department likely to induce incidents;*
- *ASN will extend in 2007 its control of medical activities to the field of organisational and human factors with a systematic checking of their record keeping and analysis.*

The Revised German Guideline for Incorporation Monitoring

A. Dahleimer, K. Dettmann, K. König, D. Noßke (BfS, Germany)

TASK

With the revision of the German Radiation Protection Ordinance of July 20, 2001 [SSV 01] a number of guidelines, e.g. those relating to incorporation monitoring, have to be adapted, too. This includes within the context of occupational exposure

- The Guideline for Physical Radiation Protection Surveillance of 1994;
- The Guideline for Assessment of Exposures by Incorporated Radiation Emitters of 1997; and
- The Guideline for Requirements for Measuring Laboratories of 1996.

THE NEW GERMAN GUIDELINE

The revised German Guideline for Incorporation Monitoring [RIL 06] incorporates the changes required by the revised German Radiation Protection Ordinance of 2001 [SSV 01] with respect to incorporation monitoring of occupationally exposed staff. These changes are in particular made to reflect the lower dose limits for the effective dose and the new biokinetic and dosimetric models described in the ICRP Publication 68 [ICR 94]. A separate guide [BFS 06] regulates the monitoring of radiation exposures from activities according to part 3 of the Radiation Protection Ordinance.

The current draft combines the three above Guidelines. It is divided into the following sections:

- General principles;
- Design of monitoring measures;
- Implementation of monitoring measures;
- Requirements for measuring laboratories and for analysis and measuring procedures; and
- Procedures for the calculation of body doses.

The more technical specifications as well as the comprehensive data (retention and excretion data, dose coefficients etc.) are contained in seven annexes.

Particular attention should be paid to the following changes introduced in the revised German Guideline for Incorporation Monitoring compared with the existing three Guidelines:

- Incorporation monitoring measurements shall generally be conducted by officially authorised measuring laboratories, which shall also determine the body dose and report it to the German Radiation Protection Register run by the Federal Office for Radiation Protection (BfS). If the incorporation monitoring objectives can only be achieved through indoor air measurements, the facility shall conduct these monitoring measurements itself (permitted for a dose range of up to the investigation level of 6 mSv). The competent radiation protection supervisor or radiation protection officer shall ensure that these doses are determined and reported to the Radiation Protection Register (see table below).
- With the new dose limit of 20 mSv per calendar year for the effective dose, the decision level (in the case of open radioactive sources which are handled in the control area incorporation monitoring shall be compulsory if the potential annual effective dose exceeds the decision level) is defined as an effective dose of 1 mSv from internal and external exposure.
  In the event that both external and internal radiation sources contribute to the exposure, the competent authority may reduce the decision level to 0.5 mSv for both external and internal exposure.
- In the case of youths (persons aged 16 to 18) handling open radioactive sources, incorporation monitoring shall be compulsory if the potential annual effective dose exceeds the decision level of 0.5 mSv.
- If it can be shown that the individual effective doses do not exceed 1 mSv per calendar year, it shall not be compulsory to implement incorporation monitoring measures (see table).
  It can also be seen from the table that the new Guideline no longer defines activity thresholds (such as the previous limit value for the annual activity intake) but only dose thresholds (decision level, investigation level).
- The adoption of the current biokinetic models as described in the ICRP Publication 68 [ICR 94] as well as the new dose thresholds required a number of changes: Monitoring intervals had to be redefined (with consideration given to the "factor of 3 rule"), any retention and excretion data had to be recalculated and the requirements for measuring procedures had to be reformulated on the basis of the dosimetric specifications. These requirements include in particular the so-called dosimetric detection limits to be obtained, which have been calculated on the basis of an effective dose of 1 mSv per calendar year.
- As far as regular monitoring is concerned the standard assumptions for the reference procedure were updated (in particular the value of 5 μm for the AMAD).
- The body dose has generally to be calculated from every measured value above the detection limit (activity in the body, activity in the excretions, activity concentration in the indoor air).
  Effective doses which have to be reported and which are below 0.05 mSv shall be considered as zero in a similar fashion as it is required for values measured for the external individual dose

which are reported to the German Radiation Protection Register run by BfS [RIL 02].

- According to the regulations for personal dose measuring laboratories [RIL 02], officially authorised incorporation measuring laboratories shall establish a quality management system (QMS) and shall prove their technical and organisational competence by an accreditation.
- As part of the quality assurance measures applied to their monitoring procedures the officially authorised measuring laboratories shall participate in intercomparisons organised by the *Coordinating Office on Incorporation Monitoring of the BfS*.

The suggested regulations set out in the new German Guideline for Incorporation Monitoring do not consider the particular problem of incorporation monitoring of female workers of child-bearing age in relation to the dose limit of 1 mSv for the unborn child.

FURTHER ACTION

The Guideline will come into force on 1st of March 2007.

The "Incorporation Monitoring Working Group (AKI)" of the German-Swiss Radiation Protection Association (FS) in cooperation with the *Coordinating Office on Incorporation Monitoring of the BfS* plans to hold an introductory workshop concerning the new German Guideline in June this year in Dresden.

The Coordinating Office and the Working Group will then, after about a year, hold an expert discussion about the first experiences with the new Guideline.

LITERATURE

BFS 06 Überwachung von Strahlenexpositionen bei Arbeiten, Leitfaden für die Umsetzung der Regelung nach Teil 3 Kapitel 1 und 2 StrlSchV, Bericht BfS-SW-03/06, 2006

ICR 94 Dose Coefficients for Intakes of Radionuclides by Workers; ICRP Publication 68, Annals of the ICRP Vol. 24 No. 4, 1994

SSV 01 Verordnung über den Schutz vor Schäden durch ionisierende Strahlung (Strahlenschutzverordnung - StrlSchV) vom 20. Juli 2001, BGBl. I S. 1714, ber. 2002 I S. 1459

RIL 02 Richtlinie über Anforderungen an Personendosismessstellen nach Strahlenschutz- und Röntgenverordnung vom 10. Dezember 2001, GMBl. 53 Nr. 6, 2002

RIL 06 Richtlinie für die physikalische Strahlenschutzkontrolle zur Ermittlung der Körperdosis, Teil II: Ermittlung der Körperdosis bei innerer Strahlenexposition (Inkorporationsüberwachung), 13.01.2007.

Table: Limits defined for incorporation monitoring of staff working in the control area on the basis of the potential dose incorporated [RIL 06]

Potential effective dose by incorporation per calendar year	**Monitoring objective**	**Monitoring measures**	**Responsibility for the monitoring measures**
≥ 1 mSv [1]	Determine individual body dose values (§ 40, sentence 1, Radiation Protection Ordinance	Regular incorporation monitoring by in-vivo procedures / in-vitro procedures	Officially authorised measuring laboratory
		Regular incorporation monitoring by indoor air measurements [2]	Competent radiation protection supervisor or radiation protection officer
0.5 mSv to < 1 mSv	Supply evidence that values remain below 1 mSv (*decision level)*	Regular measurements of the threshold value with calibration instruments [3] in order to determine the: - activity in the body - activity in the excretions - activity in the indoor air	Competent radiation protection supervisor or radiation protection officer
< 0.5 mSv	No monitoring		

[1] If the exposure is mainly external, the competent authority may reduce this threshold to 0.5 mSv.

[2] This rule shall only be applied on the following conditions: Only if the potential dose incorporated is below 6 mSv (investigation level), with the exception of portable aerosol collectors; accompanying measurements with the help of in-vivo or in-vitro procedures shall be conducted by an officially designated measuring laboratory.

[3] The results can also be used to closely determine the moment of incorporation (near-term indicator measurements).

Implementation of the Council Directive 2003/122/EURATOM on the control of high-activity sealed radioactive sources and orphan sources (HASS-Directive) in Sweden

B. Ekström (SSI, Sweden)

The Council Directive 2003/122/Euratom on the control of high-activity sealed radioactive sources and orphan sources [1] (HASS-directive) was adopted on the 22nd December 2003 with the purpose to prevent exposure of workers and the public to ionising radiation arising from inadequate control of high activity sealed radioactive sources or orphan sources. The Directive also aims to harmonize controls in place in Member States by setting out specific requirements ensuring that each such source is kept under control. The Member States should have implemented the Directive before the 31st of December 2005.

Transposition in Sweden

Amendment to the Radiation Protection Act and Ordinance
The Swedish Radiation Protection Act [2] and Ordinance [3] have been amended. The amendments entered into force 1st July 2006.

Amendment to the Ordinance with Instruction for the Radiation Protection Authority
In the Ordinance with Instruction for the Radiation Protection Authority [4] SSI is designated as the Competent Authority from the 1st of July 2006.

Regulations and administrative provisions
SSI has the mandate to issue regulations and administrative provisions based on the Radiation Protection Act. The new regulations, SSI FS 2006:2 [5], issued by the Swedish Radiation Protection Authority entered into force 1st October 2006.

Many of the articles in the Directive are implemented through those new regulations. The regulations cover:

- Detailed requirements for authorisation (Art.3)
- Record keeping and reporting (Art.4-5)
- Detailed requirements for holders (tests, security measures, return of disused sources, notifications to the competent authority) (Art.6)
- Identification and marking (Art.7)
- Training of personnel (Art. 8)

Other issues
SSI has developed its record keeping system to include not only information on licensed holders and approved equipment but also details on each source covered by the Directive. The record keeping system was tested during autumn 2006 and was taken into use the 1st of January 2007.

Guidance material in the form of pamphlets and web based information to holders, personal at customs stations and metal recycling plants have been developed (could be found in Swedish at http://www.ssi.se/roentgen/Industri_verksamhet/Herrelosastral.pdf).

Preparation of emergency preparedness plans to include advice, assistance and response in case of orphan sources is under development. The Government has decided to dedicate 1 million Swedish crowns (about 110 000 €) per year to cover the cost of taking care of orphan sources.

One of the most crucial parts of the implementation of the Directive was article 3.2 b in relation to financial security. During spring 2007 the Government will promulgate an ordinance on producer's responsibility to finance the collecting and handling of disused sources. The main requirements in the ordinance follow the WEEE-directive (Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment). SSI will be mandated to issue closer regulations on the obligations in the ordinance. Since the ordinance yet not is promulgated SSI cannot formally issue regulations, so at the time being it is too early to make any comments on the assumed content of such regulations.

From the 1st of July 2006 the SSI has a mandate to either by general regulations, or on a case-by-case basis, set up conditions on financial security. This mandate is meant to be used in cases not covered by the ordinance mentioned above; principally in situations were the generator or holder of the waste will be responsible. Such circumstances could be when a producer according to the definitions in the ordinance on producer's responsibility not could be recognized, or in situations were NORM-waste is generated. Also in this case it is too early to draw any conclusion of the effectiveness of the mandate since SSI yet has limited experience from using the mandate.

[1] Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources. Official Journal L 346, 31/12/2003 P.0057-0064.

[2] Strålskyddslag (The Swedish Radiation Protection Act), SFS 1988:220.

[3] Strålskyddsförordning (The Swedish Radiation Protection Ordinance), SFS 1988:293.

[4] Förordning med instruktion för Statens strålskyddsinstitut (The Ordinance with Instruction for the Radiation Protection Authority), SFS 2006:524.

[5] Föreskrifter om kontroll av slutna radioaktiva strålkällor med hög aktivitet (The Swedish Radiation Protection Authority's Regulations on the Control of High-Activity Sealed Radioactive Sources), SSI FS 2006:2.

ALARA NEWS

❑ Creation of an independent administrative authority for the supervision of nuclear safety and radiation protection in France

The Law on "Transparency and Security in the Nuclear Field" of June 13, 2006 has been adopted by the Parliament.

The law transforms the former Nuclear Safety Authority into an "Independent Administrative Authority". The new authority is a Commission of 5: the Chairman (Mr André-Claude LACOSTE) and 2 (Mr Michel BOURGUIGNON and Mr Marc SANSON) appointed by the President of the Republic, 1 (Mrs Marie-Pierre COMETS) by the President of the National Assembly and 1 (Mr François BARTHELEMY) by the President of the Senate; they were nominated by a decree published on November 9th: the new ASN was thus created. The Commission first met on November 13th, thus starting effective operation; the staff was then placed under the authority of the Chairman.

The new law sets up a renewed, comprehensive and solid legislative basis for nuclear installations supervision (the former legislative basis for safety and radiation control in France dated back to 1961). It also includes a number of provisions related to transparency in the nuclear field.

❑ NORM V: 5th International Symposium on Naturally Occurring Material – Seville, Spain

The University of Seville, in co-operation with the IAEA, the Spanish Nuclear Security Council (CSN) and the University of Huelva, is organising the NORM V International Conference, to be held in Seville (Spain) in March 19th – 22nd, 2007. Its main objective is the dissemination of new information and knowledge on exposures to radionuclides of natural origin in mining and other industrial operation involving NORM, including impacts associated with NORM residues and discharges. Special attention will be devoted in the conference to the following NORM topics:

- Processing and use of zircon and zirconia;
- Industrial uses of thorium;
- Production of titanium dioxide;
- Recycling of contaminated metals;
- Extraction and processing of rare earths;
- Extraction, processing and use of phosphate minerals.

More information can be found on the following web site: http://www.congreso.us.es/normv

❑ International Conference on Environmental Radioactivity: from Measurements and Assessments to Regulation

This International Conference, organised by IAEA in co-operation with the UNSCEAR, the South Pacific Environmental Radioactivity Association (SPERA), the National Food Investigation Institute of Hungary (NFII) and the Belgian Nuclear Research Centre (SCK • CEN), will be held in Vienna (Austria) from 23 to 27 April 2007.

Developing and implementing a regulatory regime requires that information be collected and interpreted. This can involve a complex set of actions such as collection of samples, measurements carried out in the field and laboratory, data evaluation, and environmental modelling. It is important that both the information collected be appropriate for the needs of regulators, and that regulators understand the uses and limitations of the data they obtain.

Technical developments in recent years have expanded the options for information collection for environmental radioactivity studies, raising a number of questions for regulators and information providers. Which methods provide fit-for-purpose data at the most reasonable price? How can the users of the data assess its quality and its fitness for the required purpose? Which parts of the data collection process are the greatest contributors to the total uncertainty? Can we compare data collected using different methodologies, or do we need to recommend more standardized methods to improve comparability? If we wish to recommend a standardized method, on what basis do we decide on the method?

The conference is intended to bring together professionals in the field to discuss these issues. The objective is to foster information exchange between professionals working in the broad range of disciplines associated with environmental radioactivity from sampling design to regulation. The conference will provide a forum to review current methodologies, and to discuss future trends and developments, and evaluate their practical implications for compliance.

Detailed information is available on the conference web site:
http://www-pub.iaea.org/MTCD/Meetings/Announcements.asp?ConfID=145

❑ EAN and stakeholder engagement in radiological protection

A recommendation from the 10th EAN Workshop is that EAN should take positive steps to address the issue of stakeholder involvement, especially workers, as identified in this and previous workshops. In particular, EAN should: contribute to discussion on a code of conduct currently being prepared by British, French and Spanish RP societies (for IRPA). That proposal has been forwarded to the second international workshop on "processes and tools for stakeholders engagement in radiological protection " (Montbéliard, France, November 2006), where such a code has been discussed. Therefore it has been agreed that in the near future the draft code of conduct, will be send to EAN and distributed for comments and amendments in all EAN participating countries, through all EAN contacts.

❑ ALARA Training Courses (in French)

These courses will be held in Saclay, from 20th to 22nd March 2007, at the Commissariat à l'Energie Atomique (Centre de Saclay – INSTN / UGL / BCSE – F-91191 Gif-sur-Yvette Cedex) and will be organised by the "Institut National des Sciences et Techniques Nucléaires" (INSTN).

The subject will deal with the Implementation of the ALARA principle and how to manage occupational exposure. It will comprise lectures and case studies as well as work in small groups.

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The EAN Steering Group meeting, December 2006

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