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"ALARA AND THE MEDICAL SECTOR"

SUMMARY AND RECOMMENDATIONS

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WORKSHOP BACKGROUND, OBJECTIVES AND PROGRAMME

The medical sector faces a number of radiation protection challenges: the rapid development of new technologies and procedures involving ionising radiation; significant increases in patient doses; associated increases in occupational exposures; and the occurrence of serious radiation incidents. With these in mind, the aims of the Workshop were:

- To consider how the ALARA principle can be better implemented in the medical sector, with regard to both patient and staff exposures from diagnostic and therapeutic uses of ionising radiation.
- To bring together relevant European medical professionals, networks and other stakeholders working with the ALARA principle, to exchange practical ideas and experiences, and to identify further improvements.

As with previous workshops, half the programme was devoted to presentations, and half to Working Group discussions and their findings. There were 69 participants from 20 different countries, and a total of 29 oral presentations and 2 posters arranged within the following sessions:

- Introduction and scene-setting – International organisations, European societies and networks
- Tools for ALARA implementation in the medical sector
- Practical ALARA implementation in the medical sector
- ALARA culture in the medical sector
- ALARA competence and skills in the medical sector

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

- Challenges for the optimisation of patient and staff radiation protection in the medical sector (2 working groups)
- Policies and tools for implementing ALARA in the medical sector

- Education, training and communication to improve ALARA in the medical sector
- Technical developments and quality control in the implementation of the ALARA principle

On the final day, the reports from the five working groups were presented and discussed, and form the workshop conclusions and recommendations described below. Individual presentations (papers and slides), and the working group reports, are available to download from the EAN website (http://www.eu-alara.net/).

At large amount of information was presented at the workshop, and it soon became clear that all the ALARA challenges facing the medical sector could not be addressed in a 3 day workshop. It was also noted that there was relatively little attention was paid to radiotherapy. However, some key themes and issues did emerge, and these are summarised below from an EAN perspective.

THEMES AND ISSUES ARISING

The international scene-setting presentations clearly highlighted the very substantial radiation exposures associated with the medical sector – in terms of individual and collective doses, for both patients and staff. These are increasing significantly: the average *per caput* doses in some European countries from medical exposures is now thought to exceed that from natural sources, which could be regarded as something of a milestone in the evolution of radiation protection.

Of course, the benefits produced through medical exposures – both individually and collectively – are generally huge, and, from a global perspective, are also increasing as medical technology and procedures become more sophisticated and widespread. An increase in doses, set against an increase in benefits, does not, of course, mean that ALARA is not being achieved. Instead, it is the potential for, and costs of, dose reduction measures that need to be considered. The presentations highlighted a range of dose reduction measures in areas such as nuclear medicine and (especially) CT, many of which can substantially reduce doses at little or even no cost. On this basis alone, it must be concluded that ALARA is far from being achieved.

The dominance of CT doses in national dose statistics (accounting for up to 80% of the collective dose in some countries) was noted in several presentations; these doses have increased by up to a factor of 3 in 20 years. However, it would seem from a number of presentations that there is the potential to reverse this trend, through a combination of:

- accurate referrals;
- optimised equipment set up and operation;
- optimising the image quality according to the clinical purpose or diagnostic needs of the examination (i.e. using an acceptable rather than the best achievable image quality); and
- improving the education and training of medical personnel.

The very large scope for dose reduction raises questions about which factors help drive ALARA implementation, and what obstacles exist. The most obvious factor is the legal requirement to optimise exposures, which is driven by Regulatory Authorities and by the medical sector itself. With regard to the latter, there were many excellent examples of ALARA measures being identified and implemented by radiographers, radiologists and medical physics personnel. However, not all staff involved in medical exposures are equally committed to ALARA, and a repeated theme from the workshop was the need for multidisciplinary teams involving all relevant medical stakeholders (e.g. referrers, physicians and practitioners, nurses, technologists and medical physicists, manufacturers and maintenance engineers of medical radiation devices, etc.), supported by appropriate radiation protection training.

Regarding stakeholder representation, it is often difficult for medical staff to attend radiation protection events: not surprisingly, at this workshop only 30% of the participants were directly employed within the medical sector (compared to 40% from regulatory authorities). However, the Workshop highlighted the role of the professional medical societies, which can provide a more effective means of stakeholder involvement, and who are increasingly working together and forging new links through networks such as the European Medical ALARA Network (EMAN - www.eman-network.eu).

One group of stakeholders repeatedly discussed were equipment manufacturers and suppliers (who were not represented at all at the Workshop). It is clear that manufacturers play a large role in optimising doses: through the design of equipment; the modes of operation provided; and the training of users. Efforts are being made to engage with manufacturers and to encourage them to accept that they have responsibilities to enable and support the implementation of ALARA. The hope is to foster a culture of engagement and co-operation between manufacturers, regulators and users. If successful, this could be a very significant step forward.

Other factors that encourage ALARA were identified during the workshop, including the costs of providing medical exposures, the duties of the medical profession, the rights of the patient, and (increasingly) the impact of bad publicity (after radiation accidents or overexposures). Obstacles to ALARA include a lack of resources (both in the medical sector and in regulatory authorities), and a lack of ALARA culture in the sector in general. The question of ALARA culture was raised several times, and interestingly it was suggested that training alone cannot always guarantee the correct attitude and behaviour.

Occupational doses in the medical sector were discussed in several presentations. There are long-standing concerns about staff exposures from interventional radiology, and increasingly there are issues with nuclear medicine especially hand/finger and lens of the eye doses, which have the potential to exceed dose limits unless the principles of time, distance and (especially) shielding are effectively employed.

It is also possible that staff doses may be higher than records suggest. In some cases, basic precautions such as ensuring the right dosemeter is worn in the right place still remain an issue. On a more positive note, there is increasing interest in the use of electronic personal

dosemeters. These can provide an insight into the causes of radiation exposure, and their value in ALARA implementation has already been demonstrated in other sectors. It seems unlikely that they will replace passive dosemeters in the medical sector, at least for the foreseeable future. However, they are already proving useful as a training tool, and for specific ALARA studies.

There were many other interesting presentations and discussions on subjects such as medical screening, individual health assessments, risk communication to patients, clinical audits, peer review and self assessment, which are not summarised here.

WORKSHOP CONCLUSIONS AND RECOMMENDATIONS

As mentioned above, the working group presentations, containing details of the discussions, conclusions and recommendations, are available at http://www.eu-alara.net/. A brief summary of these is given below.

Challenges in the optimisation of patient and staff radiation protection

- It is useful to consider a long-term "vision" for optimising medical exposures, for example:
    - Avoid all inappropriate medical exposures
    - No deterministic injuries to patients or staff
    - In every case adopt a patient-centred (i.e. individual) approach to optimisation

  NOTE: In addition to the above, the following aim was also suggested:

    - *"Every CT procedure to give an effective dose below 1 mSv"*

  This has caused much debate – at the Workshop, and subsequently in collating comments on these conclusions. It has had some support from equipment manufacturers, and is already achievable for some procedures. However, it overlooks the technical problems associated with measuring effective dose, and may not be reasonably achievable in all cases. In addition, it is unclear how this fits into an approach to optimisation based on DRLs. Nevertheless, it has prompted a debate on optimising CT procedures – something which is clearly needed. If only for this reason, it could be considered a useful (but very-long term) challenge.

- Equipment manufactures and suppliers should work with a multidisciplinary team at the hospital to determine optimum operating parameters, and to ensure that users are familiar with all the optimisation tools available.
- Intelligent software solutions should be developed:
    - To help avoid inappropriate referrals, through reference to referral guidelines, clinical indications and patient exposure history tracking.
    - To encourage and assist CT operators in delivering optimised dose procedures.

- Image quality is a key factor in the ALARA process: it is important to consider this as well as the doses received, and to understand the inter-relationship with DRLs. Image quality should also be optimised, i.e. of an acceptable quality, rather than the best quality achievable. There is also a link with the quality of the referral information – if this is good, a more informed decision on the required image quality can be made.
- It is important that the effectiveness of ALARA actions is assessed, i.e. through comparing the doses received before and after these actions. Information from research projects and organisations such as EURADOS and ORAMED should be disseminated to the medical sector through the professional societies.
- Access to integrated wide area RIS/PACS[1] solutions is encouraged. These can facilitate effective work flows, data sharing between medical professionals, and re-use of existing images, and can improve the quality and efficiency of care, including the optimisation of medical exposures.

Policies and tools for Implementing ALARA in the Medical Sector

- Clinical audits are considered a very important ALARA tool. They should address both justification and optimisation, and should be adopted across the EU. It is recommended that the European Commission consider a pilot project to undertake clinical audits in Member States that have not yet done so.
- The establishment of national referral criteria is a key element in implementing ALARA, and the European Commission should strongly encourage this in all Member States. Health Authorities should ensure that hospitals adopt these criteria via a multidisciplinary clinical approach to implementation.
- Diagnostic Reference Levels continue to be integral to the ALARA process, although it is important to remember that:
    - They are not limits, but an upper boundary to optimisation, ie optimisation should be applied <u>below</u> DRLs.
    - Doses exceeding DRLs are an indicator of poor practice.
    - National circumstances should be taken into account when establishing DRLs, which should be based on common (rather than specialist) working practices. They should include DRLs for paediatric imaging techniques.
    - DRLs must be periodically reviewed and updated to ensure they remain fit for purpose.
    - The use of lower local DRLs than those established at the national level should be promoted and encouraged.

Education, training and communication to improve ALARA in the medical sector

[1] Radiology Information System (RIS).
Picture Archiving and Communication System (PACS)

- Education and training in radiation protection are essential to ALARA. These should be an integral part of the healthcare organisation's health and safety programme, and be subject to performance indicators to assess effectiveness. The clinical audits referred to above should also consider whether suitable staff training is provided.
- Radiation protection training should be provided for all staff involved in patient exposure, but should be targeted and tailored to ensure it is effective. Long and detailed training courses are expensive and difficult to arrange in a clinical environment, and there is evidence that shorter, more focused training packages have a greater impact.
- The purchase of new equipment should include provision for the initial training of users by the suppliers, and this training should be repeated (or refreshed) at appropriate intervals. The content of this training should be discussed and agreed with the site RPE and MPE, who should be encouraged to also actively participate in this training.
- Equipment suppliers must ensure that their own staff are also suitably trained, ie to be able to provide the required training and information to users, especially on appropriate dose reduction techniques. Persons engaged in the maintenance or repair of equipment should also have received training in radiation protection and understand the importance of the ALARA principle.
- Regulatory authorities should ensure that inspectors have a good understanding of the application of radiation protection in the hospital environment, through the provision of specific training if required. Inspections should include an evaluation of the radiation protection training programme for medical staff, which should consider experience and competence, as well as education and training qualifications.
- Although operational dose quantities are essential for quality assurance and optimisation, they are not an appropriate tool for communicating radiation risks to the patient. Even effective dose (which is a risk-based quantity), is not intended to determine the risk to a specific individual. It is suggested that a simple system of dose (or risk) bands be considered – which could be used for communicating the radiation risks to patients, and also to staff.
- Although DRLs are a useful means of identifying and communicating poor practices, they do not do the same in respect of good practices. Some countries have recommended using the 1st quartile of patient dose distributions, as a representing a "desirable dose value". It is recommended that the possible use of this concept as an optimisation tool be explored further.

Technical developments and quality assurance in the implementation of the ALARA principle

- The European Commission should consider establishing a European "platform" on the evaluation of new medical technology and equipment using ionising radiation. The purpose of this platform should be to:

- Develop suitable test equipment, measurement protocols and QA procedures, in collaboration with standardisation organisations.
- Exchange technical parameters on image quality and dose, performance characteristics, and pathology-specific and patient-specific protocols.
- Consider the establishment of a European Network for those involved in equipment evaluation and type-testing.

- The European Commission and National Authorities should strengthen the role of Medical Physicists in Radiology, and should encourage an increase in their numbers.
- Imaging and data recording systems system should contain tools to provide information for Quality Assurance. Manufacturers should be asked to include these in RIS, HIS[2] and PACS.

The Workshop agreed that it was important to follow-up and monitor progress on the extensive list of recommendations above. Thus it was agreed to ask EMAN, as a network focusing on the implementation of ALARA in the medical sector, to undertake this.

NEXT EAN WORKSHOPS

The 14th EAN Workshop, on "ALARA in Existing Exposure Situations", is planned for 4-6 of September 2012, and the 15th EAN Workshop on "ALARA Culture" is planned for May 2014 in Croatia. Details of both workshops will be announced on the EAN website.

[2] Hospital Information System (HIS)

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