Protection of Patients in Medical Exposures

Madan Rehani*, Pedro Ortiz López

International Atomic Energy Agency, Vienna, Austria.

Abstract. Patient exposure, which has been the largest exposure to the human population from man-made radiation sources, has become still larger during the past decade, in contrast to occupational exposure which has remained relatively unchanged, as well as exposures from other radiation sources. One might expect that improved technology would have reduced absorbed doses from almost all medical procedures over the last several decades. This is true for most low-dose examinations (such as radiography), but not so for relatively high-dose procedures (such as CT scans), primarily due to changes in practice, covering larger body areas in CT examinations. This paper describes the IAEA's actions in the area of radiation protection of patients. These include launching of a new public website on radiation protection of patients (http://rpop.iaea.org), development of training material for specific target audiences, projects on patient dose management in radiography, interventional procedures, mammography and CT, guidance documents, actions in avoidance of accidental exposures in radiotherapy and programme impact assessment. These actions have been undertaken within the frame of an international action plan. The experience shows that significant dose reduction to patients is possible without compromising on clinical benefit of diagnostic and interventional procedure.

KEYWORDS: Radiation protection of patient, radiation risks, patient safety, radiation doses to patients.

There has been more than a century of experience with radiation protection of occupationally exposed workers and this experience has resulted in substantial reduction in individual exposure to occupational exposed workers. The approach of individual monitoring with life-time record of radiation doses and the provision of dose limits has been very successful. Unlike occupationally exposed worker protection, patients have been intentionally excluded from the application of dose limits. Further, there are generally no mandatory requirements on monitoring of patient doses in a large part of the world, with few exceptions in some countries. This requires innovative approaches where generic requirements of protection of patients exist in international standards [1] and national regulations, but tools of dose limits and mandatory records of patient doses in diagnostic and interventional procedures are practically non-existent with few exceptions. However, the system of diagnostic reference levels (DRLs) and educational actions are useful tools for patient protection and, when supported by mandatory actions of licensing of facilities, accreditation of individuals and mandatory reporting to regulatory authorities of accidental exposures, provides a good framework of protection. It has been well known that medical exposure to patients constitutes the largest source of radiation exposure to human population from man-made sources.

1. What is patient protection?

The overall facts and principles of radiation protection of patients are: a) Benefits outweighing the risks; b) Radiation exposure should be no more than necessary for getting the desired clinical information or the outcome of the procedure; and c) deterministic injuries in interventional procedures and accidental exposures in radiotherapy should be avoided. It also includes communication with the patient and assurance to the patient that the patient is getting radiation exposure no more than necessary and that at this level of radiation exposure, the risks are much smaller than the benefits.

* Presenting author, E-mail: M.Rehani@iaea.org

2. Scope

This presentation will deal with experience gained through the IAEA programme on radiation protection of patients. It shall cover:

1. Public website on radiation protection of patients;
2. Development of training material for a specific target audience;
3. Dissemination of training material and training action;
4. Projects on patient dose management in radiography, interventional procedures, mammography and CT;
5. Guidance documents;
6. Actions in avoidance of accidental exposures in radiotherapy;
7. International actions and cooperation with international organizations;
8. Programme impact assessment and conclusions.

The presentation will not deal with protection of the patient other than radiation protection, regulatory actions on authorizing, licensing and reporting and issues of communication with the patient.

2.1 Public website on radiation protection of patients

The IAEA has developed a dedicated website (http://rpop.iaea.org) for information on radiation protection of patients. This site has information for health professionals in the form of short and crisp answers to questions of interest to professionals in the areas of diagnostic and interventional radiology, radiotherapy, nuclear medicine, interventional cardiology and other medical specialists who use fluoroscopy. Further, the website has IAEA training material for free download as power point slides, free download of IAEA publications, and information for countries that are involved in Technical Cooperation (TC) projects with the IAEA. The website is frequently updated. Since many people have internet access, this is an excellent and very cost effective avenue for communication and knowledge dissemination.

2.2 Development of training material for specific target audience

In view of the fact that persons who work in diagnostic radiology, radiotherapy, nuclear medicine or cardiology invariably spend their entire working time in these fields, it was deemed appropriate to design audience specific training courses. Therefore training modules, CDs and training courses specific to the audience, have been designed. The slides for standardized training material of the IAEA can be downloaded freely from the website as:

Radiation Protection in Diagnostic and Interventional Radiology: The material has been developed in collaboration with WHO, PAHO, ILO, ISR, IOMP and ISRRT.

Radiation Protection in Radiotherapy: In collaboration with WHO, PAHO, ILO, ISR, IOMP and ISRRT.

Radiation Protection in Nuclear Medicine: In collaboration with WHO, PAHO, ILO, IOMP.

Prevention of Accidental Exposures in Radiotherapy: In collaboration with WHO.

Radiation Protection in Cardiology: In collaboration with WHO, IOMP.

Radiation Protection in PET/CT: In collaboration with IOMP, WHO, WFNMB.

The following training CDs are currently being finalized:

- Radiation protection in digital radiology
- Radiation protection for doctors using fluoroscopy (non-cardiologists, non-radiologists)
- Radiation protection in paediatric radiology

The training material has been found to be very useful by medical professionals as is evident from the download statistics and feedback in training courses and from meetings.

2.3 Dissemination of training material and training action

- A CD is sent to anyone who requests to patient.protection@iaea.org.
- Professional societies are given permission to make copies of CDs and distribute to members. Many thousands of professionals have received CDs through this mechanism.
- Conference organizers are also given permission to make copies and distribute to participants.

Almost 60 training courses (regional and national) have been organized during the last 6 years and more than 3000 participants in these courses have benefited from the training material. The programme for training of cardiologists in radiation protection is particularly worth mentioning. It was launched in 2004, and the IAEA now has a leading place in the world in this area. Cardiologists from over 50 countries have been trained. Another new programme for training of doctors involved in fluoroscopic procedures (urologists, orthopaedic surgeons, gastroenterologists, gynaecologists and other surgeons) was launched in September 2006. This, too, is an important activity which provides a leading edge to the IAEA. Four courses have been held during 2006-2008 for this group of medical specialists in Asia, Europe and Latin America.

2.4 Projects on patient dose management in radiography, interventional procedures, mammography and CT

There are currently about 80 countries enrolled in IAEA´s regional projects pertaining to radiation protection of patients.

A common approach was established for the regional projects with scope for individual customization by each country. The approach consisted of classifying the work into seven tasks. Radiation protection in diagnostic and interventional radiology made up five of the tasks, whereas nuclear medicine and radiotherapy were covered by one task each, as follows:

Task 1: Avoiding radiation injuries in interventional procedures;

Task 2: Surveys of image quality and patient doses;

Task 3: Adopting image intensifying screens for general radiography;

Task 4: Survey of mammography practice;

Task 5: Patient dose management in computed tomography;

Task 6: Providing guidelines on the release of patients after radionuclide therapy;

Task 7: Preventing accidental exposures in radiotherapy.

Further information about each task is available at the IAEA website:
http://rpop.iaea.org/RPoP/RPoP/Content/InformationFor/MemberStates/1_RegionalProjects/index.htm

Through regional coordination meetings, representatives from each country choose the tasks they wish to carry out, and country-specific action plans are developed. Preliminary results of these projects have become available and are in the process of being published [2, 3]. This puts patient dose assessment and dose management on the agenda of countries. Some countries are at the initial stage of gathering statistics on work practices, some are gathering baseline information on exposure factors and image quality, while others are fairly advanced in patient dose management.

The results of one of these projects published recently [2] have shown that patients in developing countries often need to have X ray examinations repeated so that doctors have the image quality they need for useful medical diagnosis. The findings come from a survey involving thousands of patients in 45 hospitals and 12 countries of Africa, Asia and Eastern Europe. The paper also reports that the quality of X ray images improved up to 16 percentage points in Africa, 13 % points in Asia and 22 % points in Eastern Europe. At the same time, patient dose reductions ranging from 1.4% to 85% were achieved overall.

Through a coordinated research project (CRP) conducted in 5 countries on avoidance of unnecessary dose to patients while transitioning from analogue to digital radiography, it was found that the retake rates in digital radiography were in the range of 1.5 % to 9% with errors in collimation and positioning contributing most to the reasons for retakes. Entrance surface air kerma (ESAK) values were within the diagnostic reference levels (DRLs). Use of automatic exposure control (AEC) on the X ray unit, wherever this was available, was found to have a potential for patient dose reduction. The transition from film to digital offers a special and important opportunity to optimize dose [4, 5].

Interventional procedures involve high radiation exposure to patients and a number of incidents of skin injuries among patients have been reported [6]. The IAEA has given due emphasis to this area. Through a number of projects on radiation protection in fluoroscopically guided interventional procedures, nearly 75 patients were found to have a peak skin dose (PSD) exceeding the threshold for skin erythema of about 2 Gy, while for 20 of them the PSD had exceeded 4 Gy [7-9]. Complexity of the procedure and multiple procedures on the same patient were important contributors to the accumulation of dose in a patient's skin. Monitoring the radiation dose to a patient's skin to manage near-term adverse effects is an important aspect of patient care. Fluoroscopy time is correlated with the dose to the patient, but is a poor predictor of the dose because it does not account for the effects of image acquisition modes and the various uses of different beam geometries and output modes of operation. The kerma area product (KAP) is more strongly correlated to skin dose than the fluoroscopy time, since KAP registers the actual radiation falling on the patient. With careful application and in certain circumstances, PSD may be estimated from KAP. However, this cannot be conducted under application of a conversion factor obtained from some external source. The ratio of PSD to KAP varies according to the procedure, the equipment, and the physician. The conversion ratio must be verified through independent testing on-site. Any rule to derive the PSD from the KAP must be done carefully with attention paid to consistency in performance for the on-site circumstances.

In another project, it has been shown that it is possible to establish guidance levels, provided that account is taken of the complexity of procedures by means of a correction factor (the 'complexity index') to the values of the guidance levels [10, 11]. In addition, investigation levels are also suggested for very low doses under which the image information might be insufficient and might result in a loss of confidence in the outcome of the procedure. The project has demonstrated its value in practice, by identifying hospitals with higher doses and achieving a substantial dose reduction from the optimization of protection performed in the project. The following direct impact of the project is documented: i) One hospital was routinely using cine at 25 frames per second, while the others ranged from 7 to 15 frames per second. The high total KAP in this hospital was reduced by reducing the cine rate, implying a reduction of about 50% in KAP of the cine part of the procedures (about 30% of the

total KAP; ii) a second hospital was not monitoring performance at all, with the result that it was exposing patients to an unnecessarily high degree, both in fluoroscopy and in the cine sequences. An initial control of the radiological equipment brought the exposure below the guidance levels (dose reduction of more than 30%).

In another CRP on dose reduction in CT while maintaining diagnostic confidence, it was shown that it is possible to reduce CT patient doses (by about 30%) for chest and abdominal examinations while maintaining image quality and hence diagnostic confidence. At constant tube current (mA) time product (mAs) levels, the noise decreases too strongly for small patients and may become excessive for obese patients. To maintain a balance between image noise and patient size, individual dose adaptation is therefore warranted. This study shows that it is possible to develop a relationship between image noise and patient mass that can be used to adapt the dose for a specific image quality. However, it is an oversimplification to suggest universally applicable mass-based monograms for optimized mAs, as scanners vary in output (on account of factors such as scanner geometry, detector efficiency and so on). Adopting an approach based on reducing abdominal dose requirements by a certain percentage (30% in this study) appears to work in practice [12, 13].

2.5 Guidance documents

In keeping with its mandate to apply safety standards, the IAEA has produced a safety guide and a series of safety reports in specific areas [14-20]. A safety report on release of patients after radionuclide therapy is under preparation.

2.6 Actions in avoidance of accidental exposures in radiotherapy

The IAEA has published a series of documents [21-26] and a summary of major accidents has been made available on the website as well as training material on prevention of accidental exposures in radiotherapy which is available. 15 training courses have been conducted during the last 6 years in different parts of the world on radiation protection in radiotherapy and on prevention of accidental exposures.

2.7 International actions and cooperation with international organizations

Much of the above results have been achieved through international cooperation and through International Action Plan. In 1999 – in resolution GC(43)/RES/12 – the General Conference (GC) of the IAEA requested the Secretariat "to organize as soon as feasible, in close collaboration with the World Health Organization ... an international meeting on the radiological protection of patients for the purpose of an exchange of information and the development of recommendations, as appropriate, regarding the radiological protection of patients". In response to the General Conference's request, the IAEA organized the *International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy*, which was held in March 2001 in Málaga, Spain. The Conference was hosted by the Government of Spain, cosponsored by the World Health Organization (WHO), the Pan American Health Organization (PAHO) and the European Commission, and organized with the co-operation of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP), the International Organization for Medical Physics (IOMP), the International Radiation Protection Association (IRPA), the International Society of Radiation Oncology (ISRO), the International Society of Radiographers and Radiological Technologists (ISRRT), the International Society of Radiology (ISR) and the World Federation of Nuclear Medicine and Biology (WFNMB). In September 2001, the Board requested the Secretariat to convene a group of experts to formulate - on the basis of the Conference's findings, conclusions and recommendations – an action plan for future international work relating to the radiological protection of patients, and to submit the action plan to it for approval - a request subsequently endorsed by the General Conference in resolution GC(45)/RES/10.A. The technical committee met and formulated the *International Action*

Plan for the Radiological Protection of Patients. The Action Plan was approved by the IAEA's governing bodies in 2002. In 2003, a Steering Panel was established to keep under review the implementation of the activities under the Action Plan with a view to providing guidance, on a continuing basis, on the overall approach to the implementation of the Action Plan, and to make proposals for adjustments as may appear necessary. The panel consists of all the organizations listed above and several others such as the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). The Steering Panel has had three meetings so far in 2004, 2006 and in 2008, in which the Panel reviewed progress and made additional prioritized concrete recommendations for actions.

2.8 Programme impact assessment and conclusions

There has been significant focus on assessment of impact of the IAEA's actions, in particular training actions. A good example is the impact of training cardiologists in radiation protection. Through the surveys conducted in 7 training courses using questionnaires, 85-100% of cardiologists mentioned that they have no training in radiation protection [27, 28]. Subsequently, the IAEA has information from cardiologists who have collected data on how they used to perform cardiac catheterization procedures before the IAEA training and how they do so now. This shows a change in practice and application of training in daily life for safety of patients and staff. A network of cardiologists in radiation protection has been created with the help of the IAEA and the network has started a Newsletter. These newsletters clearly depict the changes that have occurred in the practice of radiation safety. Cardiologists are among the major users of X ray fluoroscopy, wherein a very large number of deterministic injuries have been reported [6] and thus this impact has greater significance than any other area such as radiography. A summary of results of IAEA actions on reduction in patient doses while maintaining image quality is available in a recent publication [29].

As per the recently concluded meeting of UNSCEAR in July 2008 (report yet to be published), patient exposure, which has been the largest exposure to the human population from man-made sources, has become still larger during the past decade, in contrast to occupational exposure which has remained relatively unchanged, as well as exposures from other radiation sources. One might expect that improved technology would have reduced absorbed doses from almost all medical procedures over the last several decades. This is true for most low-dose examinations (such as radiography) but not so for relatively high-dose procedures (such as CT scans), primarily due to changes in practice of covering larger body areas in CT examinations. Despite efforts by professionals, national and international organizations, there continue to be unintended exposures and cases of radiation induced injuries to patients and significant risks to staff in some situations. One can, unfortunately, expect this to continue as the complexities in diagnostic and therapeutic procedures increase, and with less than optimal levels of training and infrastructure in many countries. On the other hand, it must be appreciated that vast experience gained in optimization of radiation protection has shown substantial improvement in radiation safety of the patient in radiography. The documentation of patient dose reduction protocols in CT and interventional procedures is also a significant step that needs to be propagated to large part of the world.

REFERENCES

[1] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

[2] MUHOGORA, W.E., et al., Patient doses in radiographic examinations in 12 countries in Asia, Africa, and Eastern Europe: Initial results from IAEA projects, Am. J. Roentgenol. **190** 6 (2008) 1453-1461.

[3] MUHOGORA, W.E. et al., CT Patient doses in Nineteen Countries: Initial results from

International Atomic Energy Agency projects. Med Phys (communicated).
[4] NG, K.H., REHANI, M.M. (Editorial), X ray imaging goes digital. Br. Med. J. 333 (7572), 765-766 (2006).
[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Avoidance of unnecessary dose to patients while transitioning from analogue to digital radiology. Report of a Coordinated Research Project, IAEA-TECDOC-Series (under publication).
[6] REHANI, M.M., ORTIZ LOPEZ, P. (Editorial), Radiation effects in fluoroscopically guided cardiac interventions - keeping them under control. Int. J. Cardiol. 109 **2** (2006) 147-151.
[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Quantitative evaluation and promotion of patient dose optimization in fluoroscopically guided interventional procedures. Final report of a coordinated research project, IAEA-TECDOC-Series (under publication).
[8] TSAPAKI, V., et al., Radiation exposure to patients during interventional procedures in 20 countries: Initial IAEA project results. AJR (communicated).
[9] Padovani, R., et al., Patient skin doses in interventional radiology and cardiology practice in 6 countries participating in an IAEA coordinated research project. World Congress on Medical Physics and Biomedical Engg., Seoul, South Korea (27 Aug-1 Sept 2006).
[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing Guidance Levels in X ray Guided Medical Interventional Procedures A Pilot Study, Safety Reports Series 59, IAEA, Vienna (2008) (under publication).
[11] FAULKNER K., ORTIZ LOPEZ, P., VANO, E., Patient dosimetry in diagnostic and interventional radiology: a practical approach using trigger levels, Radiation Protection Dosimetry **117** 1-3 (2005) 166-8.
[12] TSAPAKI, V., et al., Dose reduction in CT while maintaining diagnostic confidence: Diagnostic reference levels at routine head, chest and abdominal CT - IAEA coordinated research project, Radiology **240** 3 (2006) 828-834.
[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Dose reduction in CT while maintaining diagnostic confidence. A feasibility/demonstration study, IAEA-TECDOC-Series, Vienna (under publication).
[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiological Protection for Medical Exposure to Ionizing Radiation, Safety Guide, Safety Standards Series No. RS-G-1.5, IAEA, Vienna (2002).
[15] INTERNATIONAL ATOMIC ENERGY AGENCY, EUROPEAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY, INTERNATIONAL LABOUR OFFICE, INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Applying Radiation Safety Standards in Radiotherapy, Safety Reports Series No. 38, IAEA, Vienna (2006).
[16] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS, INTERNATIONAL SOCIETY OF RADIOLOGY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays, IAEA Safety Report Series No. 39, IAEA, Vienna (2006).
[17] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS, PAN AMERICAN HEALTH ORGANIZATION, WORLD FEDERATION OF NUCLEAR MEDICINE AND BIOLOGY, WORLD HEALTH ORGANIZATION, Applying Radiation Safety Standards in Nuclear Medicine, Safety Reports Series No. 40, IAEA, Vienna (2005).
[18] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection in newer medical imaging techniques, Vol. I: PET/CT, Safety Reports Series, IAEA, Vienna (under publication).
[19] INTERNATIONAL ATOMIC ENERGY AGENCY, WORLD HEALTH ORGANIZATION, INTERNATIONAL SOCIETY FOR RADIATION ONCOLOGY, Radiation protection in newer medical imaging techniques, Vol. II: Cardiac CT, Safety Reports Series, IAEA, Vienna

(under publication).
[20] INTERNATIONAL ATOMIC ENERGY AGENCY, WORLD HEALTH ORGANIZATION, INTERNATIONAL SOCIETY FOR RADIATION ONCOLOGY, Radiation protection in newer medical imaging techniques, Vol. III: CT Colonography, Safety Reports Series, IAEA, Vienna (under publication).
[21] INTERNATIONAL ATOMIC ENERGY AGENCY, Lessons Learned from Accidental Exposures in Radiotherapy, Safety Reports Series No. 17, IAEA, Vienna (2000).
[22] INTERNATIONAL ATOMIC ENERGY AGENCY, Investigation of an Accidental Exposure of Radiotherapy Patients in Panama, IAEA, Vienna (2001).
[23] INTERNATIONAL ATOMIC ENERGY AGENCY, Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica, IAEA, Vienna (1998).
[24] INTERNATIONAL ATOMIC ENERGY AGENCY, Accidental Overexposure of Radiotherapy Patients in Bialystok, IAEA, Vienna (2004).
[25] INTERNATIONAL ATOMIC ENERGY AGENCY, The Radiological Accident in Samut Prakarn, IAEA, Vienna (2002).
[26] INTERNATIONAL ATOMIC ENERGY AGENCY, The Radiological Accident in Goiânia, IAEA, Vienna (1988).
[27] REHANI, M.M., Training of interventional cardiologists in radiation protection - the IAEA's initiatives, Int. J. Cardiol. 114 (2007) 256-260.
[28] REHANI, M.M., The IAEA's activities on radiation protection in interventional cardiology, BIIJ (http://www.biij.org/2007/2/e31/e31.pdf).
[29] REHANI, M.M., IAEA activities on radiological protection in digital imaging. Rad Prot Dosimetry 2008; doi: 10.1093/rpd/ncn155.