Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy

Proceedings of an international conference held in Málaga, Spain, 26–30 March 2001, organized by the International Atomic Energy Agency and co-sponsored by the European Commission, the Pan American Health Organization and the World Health Organization

RADIOLOGICAL PROTECTION OF PATIENTS IN DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY, NUCLEAR MEDICINE AND RADIOTHERAPY

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THE INTERNATIONAL ATOMIC ENERGY AGENCY
AND CO-SPONSORED BY THE EUROPEAN COMMISSION,
THE PAN AMERICAN HEALTH ORGANIZATION
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FOREWORD

Medical applications of ionizing radiation (or 'radiation' for short) are accepted worldwide as essential tools for protecting and improving human health. However, they also represent by far the largest human-made source of radiation exposure. The United Nations Scientific Committee on the Effects of Atomic Radiation estimates that diagnostic medical applications of radiation account for about 95% of the exposure to radiation from human-made sources and about 12% of total exposure. Furthermore, there is certain to be a continuing increase in the prevalence of medical applications of radiation, including high dose procedures, as in the following cases:

— Radiological interventional procedures, which are increasingly being used to replace surgery, can lead to very high radiation doses, both to patients and to medical staff, in some cases exceeding thresholds for deterministic effects.
— The use of helical computed tomography (CT) has improved the diagnostic quality of CT examinations, and the procedures are faster and more flexible than with non-helical equipment. However, the increased number of procedures and the increased number of scans per procedure may lead to a significant increase in radiation exposure to patients.

In diagnosis, the radiological protection objective is to keep doses as low as reasonably achievable while obtaining the necessary diagnostic information. According to the International Commission on Radiological Protection, doses from similar radiological investigations can differ by as much as two orders of magnitude. There is therefore considerable scope for dose reduction in diagnostic and interventional radiology and also in nuclear medicine. In therapy, the objective is to ensure that the target tissue is given the prescribed dose while minimizing the dose to surrounding healthy tissue. If the dose, dose distribution or dose fractionation is significantly different from that prescribed, serious consequences can arise, as in recent incidents involving the accidental exposure of radiotherapy patients. The application of well designed quality assurance programmes is necessary in order to ensure the protection of patients.

In October 1999 the IAEA General Conference issued resolution GC(43)/RES/12 requesting the Secretariat of the IAEA "to organize as soon as feasible, in close collaboration with the World Health Organization and within the Agency's current budgetary resources, 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 that request, the IAEA organized the International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy, which was co-sponsored by the European

Commission, the Pan American Health Organization and the World Health Organization, and which was hosted by the Government of Spain. The conference took take place in Torremolinos (Málaga), Spain, from 26 to 30 March 200l.

Other international organizations and professional societies co-operated in the conference, namely the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP), the International Organization of 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).

The conference was the first of its kind specifically focused on the radiological protection of patients. Apart from the opening and closing sessions, the conference programme comprised background sessions with papers by representatives of the co-sponsoring organizations and the professional societies, a briefing session with five papers to introduce the subject of the conference, 13 topical sessions and six round tables.

The proceedings contain all the presentations and the summaries of all discussions, and also include the opening addresses and the conclusions and recommendations. The contributed papers are provided on a CD-ROM which accompanies these proceedings.

The IAEA gratefully acknowledges the support and generous hospitality extended to the conference participants by the Spanish authorities.

EDITORIAL NOTE

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EXECUTIVE SUMMARY

The International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy took place in Torremolinos, Málaga, Spain, from 26 to 30 March 200l. It was hosted by the Government of Spain. Nearly 800 senior officers and scientists from 88 Member States, four co-sponsoring organizations, two co-operating organizations and six international professional bodies participated in the conference. The conference was co-sponsored by the European Commission, the Pan American Health Organization and the World Health Organization. The following international organizations and professional bodies co-operated in the organization of the conference: the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP), the International Organization of 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).

The officers of the conference were as follows:

President: Celia Villalobos Talero, Minister of Health and Consumer Affairs, Spain.

Vice-Presidents: Juan M. Kindelán Gómez de Bonilla, President of the Nuclear Safety Council, Spain; Francisco Vallejo Serrano, Health Counsellor of the Regional Government of Andalucía; and Antonio Díez de los Ríos Delgado, Rector of the University of Málaga, Spain.

Chairperson of the Progamme Committee: F. Mettler, School of Medicine of the University of New Mexico, United States of America.

Chairperson of the Organizing Committee: R. Ruiz Cruces, University of Málaga, Spain.

Chairperson of the Spanish Scientific Committee: J. Hernández Armas, University of La Laguna, Canary Islands, Spain.

Membership of the Programme Committee: C.E. de Almeida, Universidad do Estado de Rio de Janeiro, Brazil; J. Cosset, Institut Curie, France; M. Magnusson, Icelandic Radiation Protection Institute, Iceland; Y. Sasaki, National Institute of

Radiological Sciences, Japan; E. Vañó (Vice-Chairperson), Universidad Complutense de Madrid, Spain; L. Wagner, University of Texas Medical School, United States of America; P. Ortiz López, International Atomic Energy Agency; A.J. González, International Atomic Energy Agency; S. Groth, International Atomic Energy Agency; A. Meghzifene, International Atomic Energy Agency; H. Ostensen, World Health Organization (WHO); C. Borrás, Pan American Health Organization (PAHO); K. Schnuer, European Commission.

Chairpersons of Technical Sessions and Round Tables: C.G. Standertskjöld-Nordenstam, Helsinki University Hospital, Finland; G. Klempfner, St. Frances Cabrini Hospital, Australia; V. Sinitsyn, Cardiology Research Center, Moscow Medical Academy, Russian Federation; J. Konishi, Kyoto University School of Medicine and Hospital, Japan; E. Vañó, Universidad Complutense de Madrid, Spain; W. Leitz, Swedish Radiation Protection Institute, Sweden; P. Corr, Faculty of Medicine, University of Natal, South Africa; C. Pérez, Washington University School of Medicine, United States of America; H. Amaral, Medicina Nuclear, Clínica Alemana, Chile; C. Lavoie, Radiation Protection Bureau, Canada; S. Nazarenko, Tallin Central Hospital, Estonia; G. Drexler, Universidad do Estado do Rio de Janeiro, Brazil; F. Vargas Marcos, Ministerio de Sanidad y Consumo, Spain; B. Balaban, United States of America; J. Hendry, Christie Hospital NHS Trust, United Kingdom; J.P. Oliva González, Instituto Nacional de Oncología y Radiobiología, Cuba; M. Verdejo Silva, Dirección General de Salud Ambiental, Mexico; Commissioner N.J. Díaz, US Nuclear Regulatory Commission, United States of America; A. Hefner, Austrian Research Centre, Austria, and the Holy See.

The topics covered in the conference were:

Briefing sessions

- Current uses of radiation in medicine
- Current levels of radiation dose to patients
- History of the use of radiation in medicine and lessons learned from past experience
- Benefits and radiological risks from medical exposure
- International regulatory climate

Topical sessions

- Radiological protection of patients in general diagnostic radiology
- Radiological protection issues in specific uses of diagnostic radiology, such as mammography and computed tomography (with special consideration of the

impact of digital techniques)
- Radiological protection in interventional radiology, including fluoroscopy not carried out by radiologists (this topic covered the radiological protection both of patients and of staff carrying out interventional radiology)
- Radiological protection of patients in nuclear medicine
- Developing and using guidance (reference) levels in radiology and nuclear medicine examinations
- Radiological protection of the embryo and foetus in pregnant patients
- Radiological protection of paediatric patients
- Radiological protection of patients in radiotherapy (including the prevention of exposures differing from prescription)
- Radiological protection of patients in biomedical research
- Influence of standardization in the design and development of medical radiological equipment on the radiological protection of patients
- Education, training and continuous professional development in the radiological protection of patients
- Topics for research and development in the radiological protection of patients
- Implementation of regulations on the radiological protection of patients

Round tables

- Expectations of patients' advocates
- What should be done about radiation sensitive groups?
- Establishing priorities for the radiological protection of patients
- Risks and benefits: Can they be assessed? How?
- Regulations: Too much or not enough?
- What is the acceptable (non-occupational) exposure for caregivers?

FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

General

1. Medical practice involving the use of ionizing radiation (hereinafter referred to as radiation) is by far the largest contributor to human exposure from human-made sources of radiation; it accounts worldwide for about 95% of the total dose from such sources. Worldwide, about 2 billion diagnostic X ray examinations, 32 million nuclear medicine procedures and 5.5 million radiation therapy treatments are currently being carried out annually, and the trend is upwards.
2. There are enormous health benefits to be derived from medical uses of radiation, and there is no doubt about the need to increase the availability of radiological equipment and services in many countries. The radiological risks associated with diagnostic procedures are typically low (there are some notable exceptions which are discussed below), but it is important to manage the exposure of patients so that it is no higher than is needed to obtain the required diagnostic information. The consequences of accidental exposures in radiotherapy[1], however, can be very serious and therefore exposures must be managed in such a way that they are sufficiently high to produce the desired therapeutic results in the target area, but are as low as reasonably achievable to other organs and tissues.
3. The conference confirmed that there is scope for reducing the radiological risks involved in both diagnostic and therapeutic uses of radiation without reducing the medical benefits. It recognized that everyone in the health care community has a role to play in this. Education and training of staff and appropriate quality assurance arrangements were regarded as essential for this purpose and were underlying themes throughout the conference, and therefore will be reiterated in the detailed findings of the topical sessions discussed below only when particular emphasis needs to be given to them.

[1] Accidental exposure is referred to in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources as including "any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute or secondary effects."

Findings of the topical sessions

Radiological protection of patients in general diagnostic radiology

4. The conference identified a number of important means of reducing doses to patients. These include ensuring that:

- appropriate quality control is exercised over the processing of films;
- radiation beams are appropriately collimated, to avoid the exposure of other tissues than those of interest, and filtered, to limit the exposure to low energy radiation which has no diagnostic value;
- fluoroscopy is not used without image intensifiers;
- the X ray tube potential (kVp) used is appropriate for the particular examination being performed; and
- fluoroscopy protocols are regularly reviewed and updated in the light of the technique and the equipment type being used, with special emphasis on fluoroscopy time.

It was noted that the replacement of fluoroscopy units which do not currently use image intensifiers entails a significant investment and requires planning.

Radiological protection issues in specific uses of diagnostic radiology, such as mammography and computed tomography (with special consideration of the impact of digital techniques)

5. The conference noted that mammography is the procedure in diagnostic radiology for which most specific guidance and regulations have been developed, particularly in industrialized countries. Training and quality assurance are important, especially for screening mammography, where large numbers of asymptomatic women are exposed. Quality assurance needs to be required by regulations, but the protocols need to be allowed to evolve readily with changing technology.
6. Special attention also needs to be given to digital mammography. The fact that digital images are relatively easy to obtain and delete may encourage less care to be taken over the positioning of patients, which may, in turn, lead to an increased potential for repeating the exposures. In addition, because digital mammography uses an image receptor with a much broader dynamic range than film, the exposure to the patient is not restricted by the characteristics of the receptor, with the consequence that a higher dose than is necessary to obtain the information needed for diagnosis may be used. It is possible to record a digital mammographic image with much higher doses than would be used in

screen-film mammography, e.g. 2 to 4 times higher or more. In fact, these higher doses result in even better image quality, as the appearance of quantum mottle, or noise, is reduced (this is true for all digital radiological images, but may be especially critical for mammography).

7. Computed tomography (CT) has considerable benefits in the diagnosis of disease, but, unlike most general diagnostic radiology, involves relatively high doses. Newer techniques such as multislice CT and CT fluoroscopy can result in even higher doses. It is important that these potentially very high doses be kept to a minimum through careful assessment of protocols, strict referral criteria for patients, use of automatic exposure controls and choice of scan techniques.

Radiological protection in interventional radiology, including fluoroscopy not carried out by radiologists (this topic covered the radiological protection both of patients and of staff carrying out interventional radiology)

8. Interventional radiology (IR) is a technique with significant benefits for patient care, and its use is increasing rapidly. It involves, however, relatively high doses and, in a number of cases, deterministic effects are reported to have been produced in patients as a result of radiation exposure. In addition to the protection of patients, the protection of staff is an important issue requiring a comprehensive approach and standardized methods of exposure monitoring. Areas of the body of particular concern in this respect are the skin (of patients), and the lens of the eye and hands (of the interventionists). There is also concern about non-radiologists (cardiologists, surgeons, urologists, etc.) conducting the interventions, who may cause higher doses to patients and to themselves. Thus, education and training programmes should also address these professionals.
9. To improve the radiological protection of patients, there is a need:

- to develop standardized methods for determining the doses, especially to the patient's skin, during IR;
- to explore the possibility of establishing guidance (reference) levels[2];
- to develop image quality criteria;

[2] The expression 'diagnostic reference levels' is used in European Union directives and ICRP documents and has the same meaning as the expression 'guidance levels for medical exposure', which is used in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS). The definition in the BSS is "a level of a specified quantity above which actions should be considered. In some circumstances, actions may need to be considered when the specified quantity is substantially below the guidance level."

- to develop guidance on beam projection and dynamic features of IR such as the frame frequency;
- to develop material for education and training in radiation protection for radiologists and the other specialists involved in IR;
- to establish quality assurance programmes that include simple constancy tests;
- to ensure closer collaboration between radiologists, radiographers and medical physicists and non-radiologists performing IR; and
- to ensure that IR is performed with specialized equipment and not with general-purpose equipment.

10. The conference noted that the uses to which IR is put are evolving very rapidly, and the approaches to radiation safety and the training of personnel will need to keep pace with developments.

Radiological protection of patients in nuclear medicine

11. Nuclear medicine, which involves the administration of radioactive materials to patients, is a widely used technique for obtaining diagnostic information as well as for therapeutic purposes using radiopharmaceuticals. New techniques, such as positron emission tomography (PET), which provides new diagnostic information, are being increasingly used. The doses from such techniques are often, however, higher than those from more conventional techniques using, for example, technetium-99m. The conference concluded that:

- as a tool in the optimization of protection, diagnostic guidance (reference) levels of administered activity for nuclear medicine should be developed on a national or local basis, but used in a way that takes account of the size of the patient, with particular allowance being made for children, on the one hand, and overweight patients, on the other;
- before nuclear medicine techniques are used, particular care should be taken to find out whether female patients are pregnant or breastfeeding and adapt the technique or advise the patient accordingly;
- following the administration of radiopharmaceuticals, women should be advised to delay pregnancy so as to limit the dose to the foetus;
- consideration should be given to the appropriate ways of informing patients regarding the two previous points;
- in the event of accidental exposure, especially of therapeutic doses, measures should be taken to increase excretion; and
- because of the increased exposure from PET studies, specific consideration should be given to the optimization of protection.

Developing and using guidance (reference) levels for medical exposures in radiology and nuclear medicine examinations

12. The objective of guidance (reference) levels is to assist in the management of the exposure of patients in such a way that the radiation doses resulting from the conduct of a medical imaging task are commensurate with the clinical purpose. They are advisory and should be used flexibly. In essence, they should act as investigation levels and, as such, should be a part of any quality assurance arrangements. Exceeding them should stimulate questions regarding the equipment or the procedures used[3]. The view was expressed that they can be applied in a number of ways: (a) in a triage of patient dose distributions for general clinical tasks in order to reduce the number of unjustified high or low values in the distribution; (b) in promoting good practice for a specific clinical application; and (c) in promoting the optimum use of medical radiation exposure for a specific clinical protocol, with more precisely defined clinical and technical conditions.
13. The conference agreed that the guidance (reference) levels should be developed through co-operation between health and radiation protection authorities and the appropriate professional groups and should be derived from the distributions of doses observed in practice in the relevant region or country. The focus so far has been on establishing upper levels, but the conference felt that lower levels also need to be specified so as to indicate when the relevant diagnostic information would not be obtained.
14. In complex procedures such as interventional radiology, guidance (reference) levels could assist in the management of the stochastic effects, but, with regard to the deterministic effects of radiation exposure, doses should be monitored continuously to determine whether the threshold doses are being approached.

Radiological protection of the embryo and foetus in pregnant patients

15. The conference discussed the specific issues surrounding the protection of the embryo and foetus. The discussion covered the effects of radiation exposure, the doses received from medical practice, the administrative measures necessary to avoid unintended exposures, the management of medical examinations involving pregnant patients and the possible need for counselling after radiation exposure. It was noted that the risk factors for stochastic effects, such as carcinogenesis, are assumed to be similar to those in early childhood. Additional

[3] The BSS also require that "corrective actions be taken if doses or activities fall substantially below the guidance level and the exposures do not provide useful diagnostic information…".

health effects, however, are associated with prenatal exposure — for example, malformation and growth retardation — although these are largely restricted to a particular period of prenatal development and only occur above a threshold of 100 mGy or more. In cases of genetic predisposition, which are rare, malformations can also be induced in the pre-implantation phase.

16. Doses to the embryo and foetus from diagnostic examinations do not normally exceed the threshold dose of about 100 mGy. However, there might be some exceptions to this, for example in some extended CT examinations of the abdomen.

Radiological protection of paediatric patients

17. Special attention should be given to infants and children: first, because the risks of stochastic effects are higher than for adults; second, because of the wide range of their weight, which makes standardization of procedure more complicated; and third, because of the number of paediatric diagnostic procedures conducted annually — currently above 250 million throughout the world. There are issues relating to both justification of a procedure and optimization of the protection associated with the procedure. Particular problems that were noted include poor beam collimation, inadequate devices for immobilization, lack of adequate quality control and the need for age-specific exposure factors based on appropriate anatomical parameters, especially with CT examinations. It was estimated that, with appropriate care, doses to paediatric patients could be reduced by 35–75% without affecting image quality.
18. To achieve better patient care in this area, the conference recommended that:

- protocols with referral (justification) criteria based on clear clinical indications should be developed for paediatric patients;
- techniques and procedures should be specifically tailored for paediatric patients, necessitating improvement in both equipment and staff training; and
- patient preparation guidelines, exposure factors, diagnostic guidance (reference) levels and image quality criteria should be developed.

Radiological protection of patients in radiotherapy (including the prevention of exposures differing from prescription)

19. Radiotherapy is an extremely important tool in the treatment of cancer. However, it is essential to limit the exposures of tissues other than the target and the risk of accidental exposure. Quality assurance is essential for patient protection to ensure safe and effective treatment, including the prevention of accidental medical exposure. New techniques, such as intensity modulation,

dynamic therapy, computer controlled accelerator therapy and tomotherapy, are being introduced and these require their own well developed quality assurance, which in turn requires an adequate commitment of resources. Also, endovascular brachytherapy poses new radiation protection problems. The session on this subject also highlighted the need to pay attention to the protection of staff and the public.

Radiological protection of patients in biomedical research

20. Biomedical research involving the radiation exposure of persons, not as part of any diagnosis or treatment, carries with it important ethical considerations and should only be undertaken in accordance with the relevant standards established by the World Medical Assembly, the ICRP, WHO, the IAEA and the European Commission. The basic principles are:

- voluntary participation;
- justification of the exposure;
- optimization of protection; and
- prior approval by an ethics committee.

21. It was noted, however, that these basic principles are not always fully met. The following are particularly important:

- the informed consent of the person concerned;
- the approval by an ethics committee which includes members appropriately qualified in radiation protection and capable of arriving at an informed judgement;
- monitoring by the ethics committee to ensure observance of the conditions of approval; and
- the avoidance of financial incentives for volunteers, which can create an ethically unclear situation.

Influence of standardization in the design and development of medical radiological equipment on the radiological protection of patients

22. Equipment standards relate to the manufacture, maintenance and quality control of equipment, whereas the use of equipment in obtaining images of the quality required for diagnosis is the responsibility of the medical practitioner. The standards for medical radiological equipment should reflect the state of the art and should be reviewed from time to time in the light of changes in technology and practices. Standardization should not, however, be allowed to

impede the development of medical radiological equipment. There is a particular need to improve the standardization of digital radiological systems for connectivity among components of a system and among different systems and imaging modalities, i.e. standardization in relation to connectivity in picture archiving and communication systems (PACS) and radiological information systems (RIS). This standardization should include dose data to be incorporated into equipment design. The conference also noted that standardization related to radiation safety and effectiveness of the equipment is not a matter for developed countries alone, but should be applicable and verifiable in all countries.

Education, training and continuous professional development in the radiological protection of patients

23. Education, training and continuous professional development were seen as key to the effective radiological protection of patients and should be incorporated into the overall quality management system in radiology, nuclear medicine and radiation oncology. Programmes should be comprehensive and specifically targeted at their particular audiences, taking account of their specialities — medical practitioners (including general practitioners), technologists, nurses, medical physicists, equipment designers, equipment maintenance engineers, administrators and regulators. This requires the development of a systematic approach to education and training in which the needs of the recipients and the means of meeting those needs are clearly identified, with the overall objective of discriminating against bad practice. An individual's training should be documented, but particularly in the case of continuous professional development it was felt that care should be taken to ensure that the programmes are effective and that documentation does not become an end in itself. Education and training programmes should also encourage the adoption of a balanced approach to the benefits and risks of medical radiology. Furthermore, the potential for using information technology and distance learning should be thoroughly examined.
24. Education, training and continuous professional development should be reinforced by legislative and administrative requirements and receive the necessary financial and moral support at the local, regional and national level.
25. It was strongly recommended that the organizers of the conference should work towards the establishment of a harmonized approach to education, training and continuous professional development in the radiological protection of patients. On an associated topic, it was also recommended that relevant information concerning radiological protection should be developed and provided to patients in order to facilitate obtaining their informed consent before the use of any particular procedure involving radiation exposure.

Topics for research and development in the radiological protection of patients

26. It was noted that the use of radiation in medicine is growing rapidly and that research has failed to keep pace with the technological developments. Further research was therefore regarded as essential, the following areas being identified:

- quantification of the risks and benefits of medical exposure;
- the applicability of current methods of assessment of radiological risk in medicine;
- the dosimetric infrastructure and biological dosimetry methods;
- the interrelationship between the various dose quantities used;
- the development of criteria for image quality;
- the development of dosimetric techniques for the purposes of optimization of protection;
- the evaluation of dose reduction techniques, such as the use of increased tube filtration, pulsed flouroscopy, beam profile filters, road mapping and other digital image processing;
- the development of guidance (reference) levels to include complex procedures;
- the assessment of methods of evaluating equipment performance, particularly in relation to new technologies in digital radiology, with emphasis on research on the trade-off between patient dose and image quality (noise);
- recording and retrieval of data related to patient doses to be incorporated into equipment design;
- standardization in relation to connectivity in picture archiving and communication systems (PACS) and radiological information systems (RIS);
- research to address radiation protection issues posed by intravascular brachytherapy;
- recommendations to address difficulties in evaluating equipment performance in countries with various levels of development.

Implementation of regulations on the radiological protection of patients

27. Justification and optimization are the fundamental principles underlying radiation protection regulations, and they need to be reflected in regulatory requirements. However, in order to implement these requirements effectively, close liaison between regulators and medical and paramedical professionals needs to be fostered and a safety culture should be encouraged as part of the implementation of radiation protection regulations. Regulations should require quality assurance programmes to be established, but the programmes and protocols

should not be part of the regulatory text, in order to allow for developments in technology.

Findings from the round tables

Expectations of patients' advocates

28. Patients expect, before giving their consent to a procedure involving radiation exposure, to be adequately informed about the nature of the proposed procedure, about the benefits and risks, about the alternatives and about the duties of the medical staff. Many patients dislike being transferred from one physician to another and being isolated from the medical staff during diagnostic and therapeutic procedures. Patients should be partners in treatment decisions and be represented on committees and other groups dealing with health policy issues.

What should be done about radiation sensitive groups?

29. Some 0.1–1% of people are highly radiation sensitive. The main problems due to high radiosensitivity occur in radiotherapy, and will possibly emerge in high dose diagnostic radiology procedures involving prolonged fluoroscopy. The currently available laboratory techniques for screening for such sensitivity are not sufficiently accurate and specific to provide a reliable predictive test. However, radiotherapy patients who are observed after treatment to be radiosensitive should be examined frequently (once a week at least) in order that any serious complications due to the radiation exposure can be mitigated. Cancer patients with certain types of tumour and a family history of cancer may be genetically predisposed to both cancer and radiosensitivity. Genetic counselling and testing for radiosensitivity are particularly important for these patients, with consideration being given to alternative treatments or modified radiotherapy, if necessary.

Establishing priorities for the radiological protection of patients

30. There should be one system of radiation protection for all countries, even if different levels of implementation exist. Regulations should emphasize the need for and specify the elements of quality assurance programmes. Familiarity with diagnostic guidance (reference) levels and how they are used is important. Radiation protection should not be compromised by market pressures.

Risks and benefits: Can they be assessed? How?

31. The benefits and risks associated with medical uses of radiation vary substantially from one individual to another and each use should be judged on its own merits. The benefits and risks for a particular individual are difficult to quantify, and justification decisions must therefore be taken on the basis of the physician's training and experience and of knowledge regarding the individual patient's medical history.

Regulations: Too much or not enough?

32. Regulations should be such as to result in a benefit. Risk-informed regulations can positively affect the benefit/risk ratio. However, it is not the regulators' role to scrutinize the benefits of medical uses of radiation; rather, it is their role to enforce good practice. It was felt that there was a possible danger associated with too much regulation in this area. The motto in such circumstances should be "fewer but better regulations", the particular point being that regulations are necessary but not sufficient alone to achieve the necessary safety standard. The development and implementation of regulations was seen as a corporate exercise involving all the key stakeholders — regulators, physicians, physicists, paramedical staff and representatives of professional associations.

What is the acceptable (non-occupational) exposure for caregivers?

33. The risk to 'comforters' (caregivers) is mainly from gamma emitters used in brachytherapy and nuclear medicine, especially radiopharmaceuticals used in therapy. The exposure of comforters should be voluntary and risk-informed.

Recommendations relating to international co-operation

34. The relevant international organizations should promote the distribution and appropriate use of basic radiographic equipment. Consideration should be given to promoting the use of high kVp rather than low kVp techniques for chest radiography. Fluoroscopy units without image intensifiers should be replaced and the use of photofluorography for screening should be reduced.
35. Education and training should be promoted, with programmes specifically addressing the management of medical radiation exposures. Future training, possibly provided through CD-ROM-based courses, should include training in the use of information available on the Internet. Preference should be given to the use of existing material, rather than to the development of new material.

36. Quality assurance programmes should be promoted, with a strong emphasis on image quality, as dose assessment needs to be associated with evaluation of the diagnostic information provided by the images.
37. The relevant international organizations should tailor their programmes, recommendations and standards to each country's resources and priorities, in order to avoid resource misallocation. A coherent philosophy should be developed regarding flexibility in the application of regulations, for example in the use of guidance (reference) levels.
38. Guidelines should be developed regarding intercountry transfers of second-hand equipment.
39. The relevant international organizations should encourage countries to develop their own guidance (reference) levels.

Overall recommendation of the Málaga Conference

40. The relevant international organizations should convene a group of experts, including experts from professional societies and regulatory bodies, to formulate an action plan based on the findings of the conference for future work relating to the radiological protection of patients.

OPENING SESSION

OPENING ADDRESS

C. Villalobos Talero
Ministra de Sanidad y Consumo,
Madrid, Spain

I would like to welcome the Health Adviser of the Andalusian Regional Government and the Rector of the University of Málaga, and representatives of the IAEA, the World Health Organization, the Pan American Health Organization and the European Union.

First of all let me extend a very warm welcome to you all and express my most sincere appreciation of your participation in this conference. It is a pleasure for me to be with you here today at this important meeting, which, without doubt, will help increase our knowledge of the radiological protection of patients.

I would like to congratulate the IAEA on its excellent organization of this first International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy. At the same time, I should like to express my gratitude to the co-sponsors — the European Commission, the Pan American Health Organization and the World Health Organization. Allow me also to mention the contribution made by the authorities of the Andalusian Regional Government, and the generous participation of the University of Málaga and the Radiological Protection Research Group of the University of Málaga.

I cannot but mention the co-operation provided by the following scientific and technical organizations: the International Commission on Radiological Protection, the United Nations Scientific Committee on the Effects of Atomic Radiation, the International Organization for Medical Physics, the International Radiation Protection Association, the World Federation of Nuclear Medicine and Biology, the International Society of Radiology, the International Society for Radiation Oncology, and the International Society of Radiographers and Radiological Technologists. It is an honour for me, as the Minister of Health and Consumer Affairs, to host this conference in a city with which I have strong personal ties.

The radiological protection of patients is a priority activity for the Ministry of Health and Consumer Affairs as part of the work carried out by the General Directorate for Public Health and Consumer Affairs pursuant to our General Health Act.

One of the things that we have done in recent years is to develop legislation on the radiological protection of patients subjected to medical exposures. As you know, the public want safe and quick high quality services that enable disorders to be diagnosed and treated without any health risk. It is our obligation to provide health care

services that guarantee the fair and effective use of ionizing radiation. More than 30 years have passed since the radiologist Richard H. Chamberlain highlighted the fact that two thirds of the human race do not have access to the most basic radiological techniques; the situation is similar for radiotherapy and, of course, nuclear medicine.

I hope that the holding of this conference will help us make significant progress towards reducing the disparities that exist in the access of people throughout the world to radiological treatment and diagnostic services, irrespective of where they live. The use of new information technologies should facilitate the acquisition, analysis and transmission of images from anywhere on the planet.

In the European arena, the 1984 patient protection directive recognized that, apart from exposure to natural sources of radiation, which is to a large extent inevitable, medical exposure is the most significant source of exposure to ionizing radiation for citizens of the European Union.

This directive established basic measures to improve the radiological protection of patients, without jeopardizing the benefits to be obtained from radiation as regards early detection, diagnosis and treatment. These measures seek to prevent inadequate or excessive exposure to radiation, and to improve the quality and effectiveness of medical radiological procedures.

In 1990 the European Community legislation was incorporated into the Spanish legal system by means of a Royal Decree establishing basic measures for the radiological protection of persons undergoing medical examinations and treatments.

One of the basic principles inspiring this directive was the need to avoid the unnecessary proliferation of radiological installations. With this in mind, the Ministry of Health and Consumer Affairs, in close co-ordination with the autonomous communities, has compiled a national inventory of installations that provide radiodiagnosis, radiotherapy and nuclear medicine services.

With a view to implementing this standard, the Ministry of Health and Consumer Affairs has published four Royal Decrees, three of which deal with quality criteria in radiodiagnosis, including interventional radiology, radiotherapy and nuclear medicine, respectively. These Royal Decrees contain provisions on quality assurance programmes, the protection of persons exposed voluntarily in the course of medical research, the evaluation of doses to patients, etc. A fourth Royal Decree regulates the granting of the official titles of specialists in hospital radiophysics.

We believe that the inclusion of hospital radiophysics as one of the specialization fields in the health sector was an important step. These specialists are trained for three years in the hospital system. To date, four groups have been trained and a fifth will finish in May of this year.

The work that is being done to provide training in radiological protection for those responsible for using ionizing radiation equipment in medicine is also important. The medical specialization fields directly related to the use of ionizing radiation, such as radiodiagnosis, radiotherapeutic oncology and nuclear medicine, have now

incorporated radiological protection into their teaching programmes, and it is planned to include the subject in the teaching programmes of other specialist fields, such as cardiology, traumatology and orthopaedic surgery, that also employ diagnosis and therapy techniques based on the use of ionizing radiation.

Furthermore, the study programmes for specialized technicians in the diagnostic and radiotherapeutic imaging field already cover radiological protection.

A Royal Decree will be published very shortly on justification of the use of ionizing radiation in medicine, as provided for in the European Community standard. The draft covers the need for medical specialists, dentists and chiropodists, and referring physicians, to justify radiological practices. The possibility of including radiological protection in the training programme of faculties of medicine and dentistry and in university schools of chiropody is also addressed.

Despite the problems and difficulties that the implementation of all these regulations might entail, it is worth making the necessary effort to set up quality assurance programmes in radiological installations with a view to optimizing the radiological protection of patients.

We should not forget the special precautions for the treatment of children, pregnant or breastfeeding women, and practices involving high exposure levels and health screening programmes.

The health authorities and the professionals involved in medical radiological procedures should all be involved in this effort.

I hope that this meeting, where experts from 100 countries have gathered together, will be an excellent forum for exchanging experience and opinions, helping further to improve the radiological protection of patients.

The conclusions of this conference will clearly benefit all authorities, radiological protection experts, medical specialists and referring physicians, and other health professionals, and all representatives of international organizations and societies in the radiological protection field.

Finally, I should like to thank all the members of the Programme Committee, the Conference Secretariat, the Spanish Organizing Committee and the Spanish Scientific Committee for their superb work.

I wish you a pleasant stay in the wonderful city of Málaga.

OPENING ADDRESS

J.Á. Azuara
Consejo de Seguridad Nuclear,
Madrid, Spain

As the representative of the Nuclear Safety Council (NSC) at this meeting I wish, first of all, to pass on to you the greetings of its President, who cannot be here today as he had wished owing to unavoidable commitments. I should also like to express our appreciation to the organizers and sponsors of this conference for their invitation to take part in this opening ceremony. In particular, the NSC would like to express its gratitude to the IAEA for having accepted the invitation from the Government of Spain to hold this event in this country.

I will take this opportunity to share with you some general thoughts on the system for regulating radiological protection, with particular reference, of course, to the medical related aspects and, especially, protection of the patient.

First of all, I should like to emphasize that regulation of radiological protection is based not only on the scientific knowledge of harmful effects, but also on ethical values and principles. These ethical values should be in keeping with the values prevailing in other areas of social and political life if these principles are to be universally accepted.

The evolution of radiological protection during the twentieth century can be explained with reference to ethical and scientific arguments, and three stages can be distinguished. Until the 1950s, when the scientific community discovered the possible carcinogenic and hereditary effects of radiation, the basic protection principle was to protect individuals from the appearance of lesions of a deterministic nature, keeping exposures below specific thresholds. No social considerations were taken into account, as low doses of radiation were considered to be beneficial.

From the 1950s, and in particular at the end of the 1970s, when non-deterministic effects began to be taken into account, the protection system started to work on the principle that if society was adequately protected so was the individual, bringing into play the principles of justification and optimization. In maximizing the benefit for the community an eminently social ethical principle was being applied. These principles, though they do apply to patient protection, were implemented in a more discretionary manner in the field of medical practice.

The current recommendations of the International Commission on Radiological Protection (ICRP) apply restrictions to optimization in order to prevent excessive disparities in the exposure of individuals. Since the beginning of the 1990s there has been an increasing interest in the protection of individuals and of their rights, which

is reflected both in the legal sphere and science (e.g. the genetic susceptibility of individuals). The ICRP is now considering revising these recommendations, taking into account the ethical dimensions of radiological protection in the present day social context, and establishing a new regulatory framework based on the principle of equality in which all individuals have the right to a certain level of protection. Patient protection would seem to fit in better in this new framework.

I should now like to highlight one of the characteristics of and, in turn, one of the real values of, regulation in this field, namely the high level of harmonization internationally both with regard to the basic principles and the specifics of the various fields of applications.

Advances in our understanding of the effects of ionizing radiation are the objective of many studies carried out at research centres all over the world; the results of those studies have traditionally been compiled and systematized by a number of national and international organizations, including the United Nations Scientific Committee on the Effects of Atomic Radiation [1] and the Committee on the Biological Effects of Ionizing Radiation [2] of the United States Academy of Sciences. The work carried out by these bodies forms the basis on which the ICRP develops its recommendations, which usually serve as the effective point of departure for a revision of the standards.

Although there is no consensus on what model depicts accurately the relationship between exposure to ionizing radiation and its effects at low doses, the majority of scientific and regulatory bodies accept that a linear, non-threshold relationship is the most prudent hypothesis to take when establishing the basis for the regulation of radiological protection. We may recall the conclusions of the International Conference on Low Doses of Ionizing Radiation, held in Sevilla in 1997 [3], which was sponsored by the IAEA and the World Health Organization and co-ordinated by the Nuclear Safety Council, and which reaffirmed that this scenario was adequate for regulatory purposes.

The established procedure in the international community for elaborating regulations in this field is a great help in preventing a disparate and contradictory approach. As I have mentioned already, the ICRP recommendations played a crucial role in the establishment of universal benchmarks for the development of these regulations. Their acceptance by the IAEA and Euratom at the end of the 1950s helped consolidate appropriate mechanisms for the promotion of an international consensus on these efforts.

In Spain, as in the other States of the European Union, radiological protection standards are developed and updated by incorporating European Community directives into our legal system. Thus Directive 84/466/Euratom, which has now been replaced by Directive 97/43/Euratom, lays down the basic measures for the radiological protection of patients and facilitates improvements of the quality and effectiveness of medical radiological procedures, avoiding unnecessary or excessive exposures

without hampering the use of ionizing radiation for the early detection, diagnosis or treatment of disease.

The incorporation into national law of the second of these directives on protection against the health risks of ionizing radiation exposure in medicine has given rise to three Royal Decrees establishing quality criteria for radiodiagnosis, nuclear medicine and radiotherapy, and to the Royal Decree on justification of the use of ionizing radiation in medicine, which is in the final stages of approval.

With the making of these Royal Decrees, Spain is in a similar position in this field to other countries. However, we should not forget that radiological protection, and, in particular, the optimization of protection as regards both medical exposures and other types of exposure, requires more than regulation and quality assurance programmes for equipment. To a large extent it is a matter of attitude, goodwill and commitment of the professionals involved.

Finally, I am confident that this conference will promote discussion and sharing of experience, both being so necessary to improve even further the harmonization of regulations based on ethical principles and in-depth scientific knowledge; it should also help disseminate state of the art knowledge and good practice in this field throughout the world. This will not only meet effectively the objectives of the regulations, it will also be a great help in transmitting a message of confidence to society.

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[1] UNITED NATIONS, Sources, Effects and Risk of Ionizing Radiation (Report to the General Assembly), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (1988).

[2] NATIONAL RESEARCH COUNCIL COMMITEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATION, Health Effects of Exposure to Low Levels of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC (1990).

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OPENING ADDRESS

A. Díez de los Ríos Delgado
Rector of the University of Málaga, Spain

I welcome you not only in my capacity of Rector of the University of Málaga but also as a research worker who is concerned with questions of radiological protection and who is a member of a research group that participated in the organization of this conference.

I hope that this conference will be productive, helping to ensure that radiological protection becomes more and more effective in the face of the fresh challenges constantly being posed by medical practice.

I wish to express my gratitude to the IAEA, and especially Mr. Abel González, for having chosen the University of Málaga as one of its partners in organizing this conference, following a very successful course on the radiological protection of patients that we held three or four years ago. They say that one has to sow a lot in order to harvest a little, but I am sure that that will not be so in the case of this conference.

In thanking the other participants and organizers, I should like to say how pleased I am that Her Excellency the Minister of Health found time in her very busy schedule to be with us here today.

OPENING ADDRESS

R. Ruiz Cruces
President of the Organizing Committee,
PRUMA, University of Málaga,
Torremolinos, Spain

Welcome to the International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy. Welcome to Málaga. We are all very happy to see our city serve as a meeting point for scientists from all over the world. For one week we will have the opportunity to exchange experience, discuss, work and pool criteria in order to verify and optimize protection, and to reduce excessive or unnecessary radiation doses; in short, we are here for the benefit of patients, who are our raison d'être as professionals in the field of ionizing radiation.

As organizers we wish to express our gratitude to all those bodies, both public and private, that have contributed to making this meeting possible. As scientists we are expecting a great deal from this week's work. We are in no doubt as to the high standards of the working sessions, and the excellence of the physical and human environment in which they are going to be held.

Welcome to this conference. Welcome to Málaga, the place that is to be your home for the next few days.

OPENING ADDRESS

F.A. Mettler
University of New Mexico Health Sciences Center,
Albuquerque, New Mexico, United States of America

Medical radiation exposure is rapidly increasing around the globe, and currently benefits hundreds of millions of people each year. However, as with any medical treatment, there is a social, moral and ethical responsibility to manage exposure appropriately.

We have ambitious goals for this week, and we are going to be concentrating particularly on protecting patients without unduly compromising the benefits to those patients. There are two purposes of this conference: first, to foster information exchange in the area of patient protection; second, to formulate recommendations and findings regarding further international co-operation in this area.

The input will come from the 197 accepted papers, the Round Tables, the Topical Sessions and, more importantly, you, the audience from 80 different countries. There will be chances for audience participation during each Round Table and Topical Session.

I should like to thank the conference organizers, the IAEA, and the co-sponsoring organizations, the World Health Organization, the Pan American Health Organization and the European Commission. Finally, I thank the Government of Spain and the authorities of Andalucía and Málaga for the hospitality accorded to us, and the organizing committee for all its hard work.

OPENING ADDRESS

A.J. González
Director of the Division of Radiation and Waste Safety,
International Atomic Energy Agency,
Vienna

I wish to convey to you all a warm welcome from the Director General of the IAEA, Dr. Mohamed ElBaradei, who, owing to unexpected commitments, cannot be with us today.

We welcome you to this friendly Spanish city of Torremolinos, in the Andalusian Province of Málaga, and to this first international gathering aimed at fostering information exchange on the pressing issue of protecting patients against exposure to ionizing radiation incurred as a result of diagnostic or therapeutic medical procedures.

My initial remark is to express my gratitude, which I am sure is shared by the intergovernmental organizations co-sponsoring this conference together with the IAEA — namely the European Commission (EC), the World Health Organization (WHO) and its regional office for the Americas, the Pan American Health Organization (PAHO) — our gratitude to you all for making this magnificent event possible.

With the discovery of X rays by Roentgen a century ago, ionizing radiation began to be used in revealing the parts of the human body that previously could not be seen, thereby improving the diagnostic techniques available to the medical profession. Not much later ionizing radiation began to be used also in the treatment of various ailments, and today it is an essential tool in procedures for treating and curing cancer.

However, the properties that make radiation so effective for diagnostic and therapeutic purposes, namely its ability to penetrate tissue and to kill and transform tissue cells, can also make it hazardous to health. Employing radiation in medicine, therefore, presents a dilemma: on one hand the use of radiation should be encouraged in order to enhance human health and welfare, on the other hand the overall radiation exposure of people in medical practices should be kept as low as reasonably achievable, in order to minimize its deleterious effects. According to the United Nations, radiation exposure in medical practices accounts for most of the exposure of people to human-made sources of radiation.

This dilemma, namely using radiation in medicine as much as feasible while keeping exposures as low as possible, is the fundamental reason for the discipline termed the radiological protection of patients. The dilemma permeates the radiation

related activities of international organizations such as the IAEA and of the other organizations co-sponsoring this conference.

The IAEA, for instance, has a statutory responsibility to establish standards for the protection of people against exposure to ionizing radiation and to provide for the worldwide application of those standards; this responsibility is unique within the United Nations system, and it is the reason why the IAEA's Division of Radiation and Waste Safety, which is under my supervision, was entrusted with the task of organizing this conference.

The IAEA's Statute also requires, however, the IAEA to seek to accelerate and expand the contribution of ionizing radiation to health. So, like the WHO the IAEA has a health mandate, a mandate to promote nuclear applications for health in nuclear medicine, for radiodiagnostic, radiotherapeutic and other procedures. This programme is executed by, inter alia, transferring relevant technologies to its Member States, while at the same time fostering a culture of quality assurance (QA). These QA activities include a thermoluminescent dosimetry audit service, which the IAEA has been running jointly with the WHO and the PAHO since 1969. QA and the radiological protection of patients are two disciplines that are inherently integrated. That is why my colleague, Dr. Steffen Groth, Director of the IAEA's Division of Human Health, which has this particular responsibility within the IAEA, is also present at this conference.

The conflict between promoting and restricting radiation exposure has continued throughout the history of radiology. Its resolution has been so elusive that the radiological protection of patients remained for years a pragmatic discipline based on the case by case consideration of individual situations. It should not be surprising, therefore, that for many years there was an absence of universally accepted criteria and generic approaches, and no internationally accepted standards for the radiological protection of patients were established. As astonishing as it might seem, apart from a certain amount of general national guidance, the radiological protection of patients was effectively excluded from international standards until as recently 1996, when the IAEA, together with the other relevant organizations of the United Nations system, including the WHO and the PAHO, established the current international radiation safety standards, the so-called Basic Safety Standards [1], which contain several requirements relating to the protection of patients. Thus the need for general standards became evident and many international organizations are following up with detailed guidance, notably the EC, which has issued specific directives, and Committee 3 of the International Commission on Radiological Protection (ICRP), which, under the chairmanship of Professor Fred Mettler, has sped up the issuing of detailed recommendations for the medical community.

The establishment of standards, however important and even essential it is, represents only one element of ensuring the protection of patients. The second element is the application of such standards in practice. As I mentioned before, the IAEA has

a statutory responsibility to provide for the application of such standards and employs a variety of mechanisms for this purpose. One important mechanism is the fostering of information exchange. This conference is a good example of how we employ this mechanism in discharging that statutory responsibility.

The IAEA has organized this conference in the manner in which it usually organizes its major meetings on radiation safety. Following a decision of the IAEA General Conference calling for this conference, we sought a host government and the co-operation and collaboration of relevant international organizations. As to the former, we once again gratefully received an offer of hospitality from the Government of Spain. As to the latter, the EC, WHO and PAHO immediately took on the challenge of co-sponsoring this conference with us. We subsequently convened a programme committee of high level experts from all over the world, chaired by Professor Fred Mettler, to decide on the main issues to be covered by this conference. These issues are:

— The radiological protection of patients in diagnostic radiology, including such specific procedures as mammography and computed tomography, in interventional radiology, including fluoroscopy not carried out by radiologists, and in nuclear medicine;
— The use of guidance or reference levels in radiology and nuclear medicine examinations;
— The radiological protection of the embryo and foetus in pregnant patients;
— The radiological protection of paediatric patients, including those undergoing radiotherapy;
— The radiological protection of patients in biomedical research;
— The influence that standardizing medical radiological equipment has on radiological protection;
— Education and training, research and development, and the implementation of regulations.

Contributed papers were requested on all these issues. They have been reproduced in a substantial book, which you should have received when registering for this conference. We have also arranged for the preparation of papers by keynote speakers and on overviews by the Rapporteurs introducing the issues, which will also cover the subsequent discussions among you.

In addition, six Round Tables have been organized. They will provide an opportunity to discuss a number of controversial questions not included among the main issues before this conference. They include such questions as:

— What are the expectations of patients from the use of ionizing radiation?
— How does one deal with patients belonging to radiation sensitive groups?

— What should the priorities be in the radiological protection of patients? This is one of the dilemmas faced by developing countries.
— How should a medical doctor quantify risks and benefits in order to justify prescribing radiological procedures and in order to optimize patient protection?
— Are there too many regulations or not enough? (Radiologists and radiotherapists seem to regard regulatory standards as an obstacle; conversely, regulators seem to feel that the regulation of radiodiagnosis and radiotherapy is inadequate.)
— How should caregivers be protected? Is it acceptable that so many caregivers, for example family members and those who dedicate their lives to caring voluntarily for the sick, should receive high exposures?

Let me share with you the IAEA's ambitious expectations for this conference.

Firstly, we would like you to engage in a candid discussion on all the issues and questions that I have mentioned, with the aim of finding solutions to the problems presented. Following each session and Round Table the Chairpersons, with the support of the Rapporteurs and the Secretariat, will, we hope, summarize the findings. The President of the Conference, with the help of the President of the Programme Committee, will try to amalgamate all the findings into a short, simple document, aimed mainly at political decision makers. If that objective is achieved, the Secretariat of the IAEA will, as is customary after IAEA radiation safety conferences, submit the findings to the policy making organs of the IAEA with the view to their approving an international action plan to strengthen the radiological protection of patients. The IAEA will then implement the action plan in co-operation with other relevant international organizations. These are our expectations, and I urge you to help in ensuring that they are realized.

The keynote papers to be presented during this week, and an edited English version of the discussions, will form the proceedings of this conference, which will be issued by the IAEA in its usual matter. The contributed papers, which you have received in draft form, will be made available on compact disk in addition to the proceedings.

Let me now take a few minutes of your time in order to speak about the magnificent organization of this event. It is obvious that convening such an enormous gathering as this, with so many reputed scientists from a wide range of disciplines, requires tremendous efforts on the part of many people. We are indebted to all those who have made this event possible. It would take me the remainder of the morning to pay tribute to each one of them, so I apologize to all those silent workers for not fulfilling what should perhaps be my main obligation in this opening speech.

I will try, however, to express our gratitude to so many by speaking briefly about just a few. Firstly, we are extremely grateful for the generous hospitality extended once again by the Governments of Spain and Andalucía. Andalucía, this

land of hospitality, has hosted three major IAEA conferences in the past few years. Sevilla, Córdoba and now Málaga have become part of the history of radiation safety by hosting important events that foster the exchange of information among experts in this discipline.

Spain is represented here today by its Ministry of Health and Consumer Affairs, headed by Her Excellency Dr. Celia Villalobos Talero, who is also the President of the Conference. Through her I would like to convey to the Government of Spain the IAEA's recognition of its unremitting support for the IAEA's activities. His Excellency Dr. José Ángel Azuara represents Spain's Nuclear Safety Council, which is the regulatory authority in Spain with responsibility for radiation protection (and I apologize to Dr. Azuara for an unforgivable printing error: the Nuclear Safety Council is not mentioned in the programme leaflet that has been distributed; a corrigendum has, however, been issued). Andalucía is represented here by His Excellency Dr. José Luis Marcos of the Andalusian Ministry of Health, whom I would ask to convey to the authorities of Andalucía our thanks for the hospitality that has been extended to so many gatherings organized by the IAEA in this beautiful part of Spain. Our host city is represented by its highest authority, His Excellency the Mayor of Torremolinos, Mr. Pedro Fernández Montes, to whom I should like to say, on behalf, I am sure, of the thousand or more people in this room, how greatly we appreciate the superb facilities, including this magnificent Palace of Congresses, made available for our conference, and the kindness and hospitality of the people of Torremolinos.

This event would certainly not have been possible without the enthusiasm and professionalism of the University of Málaga and its research group PRUMA, represented here by His Excellency Dr. Antonio Díez de los Ríos Delgado, to whom I offer my heartfelt thanks, with a request that he convey our gratitude to the university staff and undergraduates who worked so hard in preparing for this event.

I also wish to express the gratitude of the IAEA to the sister organizations co-sponsoring this conference, namely the EC, PAHO and WHO, and to the ICRP, the United Nations Scientific Committee on the Effects of Atomic Radiation and the many professional societies that have co-operated in the organization of this event: the International Organization of Medical Physicists, the International Radiation Protection Association, the International Society of Radiology, the International Society of Radiation Oncology, the International Society of Radiographers and Radiological Technologists, the World Federation of Nuclear Medicine and Biology and the United States Conference on Radiation Control Program Directors.

However, the major organizational task fell on the shoulders of the three main committees of this conference: firstly, the Programme Committee, chaired by Professor Fred Mettler from the United States of America (thank you Fred for your unremitting efforts on behalf of this conference, and kindly convey our thanks to all the other members of the committee); secondly, the Spanish Scientific Committee, chaired by Dr. J. Hernández Armas of the University of La Laguna, Canary Islands

(thank you Pepe, and my thanks also to your colleagues); and, thirdly, above all, the Spanish Organizing Committee, chaired by Dr. Rafael Ruiz Cruces, Vice Dean of the Faculty of Medicine of the University of Málaga (Rafael, you have been the real guiding spirit during the preparations for this conference, and we are greatly indebted to you).

In addition to the Spanish Nuclear Safety Council, many other regulatory organizations are represented here. I will mention just one of them, the Nuclear Regulatory Commission of the United States, which is represented here by its Commissioner Nils Díaz.

The IAEA wishes all of you who have travelled from afar an enjoyable stay in Torremolinos, in this most hospitable part of Spain, Andalucía. The IAEA is very grateful to you all, to the institutions to which you belong and to the Member States from which you come for the unstinting support accorded to our activities in the field of the radiological protection of patients.

The success of this conference lies in your expert hands.

REFERENCE

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OPENING ADDRESS

K. Schnuer
European Commission,
Luxembourg

I am delighted to have the opportunity to welcome you to this important International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy here in Torremolinos. It would be negligent of me if I did not first express my thanks to the Government of Spain and the University of Málaga for inviting us to the Costa del Sol and its beautiful capital, Málaga. I should also like to thank the IAEA for its initiative, and the World Health Organization and the Pan American Health Organization for their support.

This conference provides a timely opportunity to initiate a new debate on the future direction of radiological protection in the medical sector. It will help to focus attention on the role that national regulators, medical services, doctors and medical staff will play in implementing the most recent international and national provisions on the radiological protection of persons undergoing medical investigations involving ionizing radiation.

The European Commission has defined the responsibilities for radiation protection within the European Union and therefore has a keen interest in the proceedings of this conference. As you know, the European Union places heavy emphasis on nuclear safety and radiological protection. In particular, the most recent multiannual work programme of the European Commission recognizes the importance of the use of radiation in relation to medical diagnosis and treatment, as well as the necessary protection requirements.

The European Commission has actively sought to strengthen international health and safety regulations to enhance radiation protection in general and in the medical sector in particular.

The importance of appropriate and effective radiation protection policies cannot be overemphasized. Exposure to ionizing radiation can lead to detrimental health effects in humans, and there is an obligation on each government to ensure that the highest standards of safety and radiological protection are employed.

The subjects that will be discussed over the course of the next few days concerning the exposure of patients to ionizing radiation are the result of a number of years of careful and detailed deliberations by scientists and medical and radiation protection experts. The provisions of the most recent international and European recommendations and regulations will profoundly influence radiological protection world-

wide for a considerable time and will represent a significant step forward in the radiological protection of patients.

All of you here this morning will be aware of the major contribution that the European Commission has made to advance discussions in this field, including those that will take place at this conference. I am pleased to see that the IAEA, in initiating this conference, is committed to continuing its support to the international medical community as it prepares to implement and to transpose the most recent scientific information into operational practice.

The additional radiation protection requirements for the protection of patients will undoubtedly have financial consequences. A critical concern will be to ensure the optimum benefit and welfare of the patients and the minimum adverse impact on financially stressed national health care budgets.

It is a major task for politicians to create the legal basis and the conditions required for the protection of persons in general against all sorts of dangers affecting their health and welfare. As recent epidemics and disasters have shown, there is a need for such political efforts based on sound and comprehensive scientific information.

The protection of patients against the dangers arising from ionizing radiation is not an isolated subject in health politics. It should be part of a package of regulatory measures and actions taken in the social and health policy sector.

The European Commission is aware of the fact that an unequal administrative or financial burden on national health services may create an unwanted economic misbalance. However, assurance should be provided that it is not used to justify incisive social change.

The subject of radiation protection in medical practice is a multidisciplinary initiative involving different interest groups and specialized services. It is a subject that will continue to be of importance in the twentyfirst century.

I invite the responsible representatives in this field to contribute to a constructive exchange of information and experience and to put all their efforts into the development of practical solutions that are acceptable to all involved in the medical health sector.

I firmly believe that, through a process of negotiation and discussion, such as that provided at this conference, we will gain a deeper insight and a better appreciation of the many issues involved in the operational implementation of international and national medical radiation protection requirements and the more efficient use of diagnostic and nuclear medicine techniques.

The European Commission will do its best to make this conference a successful step forward to achieve this goal.

To conclude, I would like to wish all participants every success in their deliberations. Regardless of the weather conditions, I hope that you all will have an opportunity to sample some of the splendours and hospitality of Málaga and Torremolinos

over the next few days. To those visiting from abroad, I hope you will have a pleasant stay and return again soon.

OPENING ADDRESS

C. Borrás
Pan American Health Organization,
Washington, D.C.

On behalf of the Director of the Pan American Health Organization (PAHO), Dr. Sir George Alleyne, welcome. It is a great pleasure for the PAHO to co-sponsor a conference on a subject, that of patient care, that we consider to be entirely related to public health.

As many of you are aware, next year PAHO will complete 100 years of uninterrupted work in the field of public health. Its history is interesting; perhaps we can review it a little.

Public health co-operation in the Americas began at the end of the nineteenth century. In 1890 the First International Conference of American States took place, at which the International Union of American Republics, now the Organization of American States (OAS), was set up. In 1901 the Second International Conference of American States recommended that regular regional conferences of health representatives should be held to draw up health agreements and regulations. The union proposed that a permanent executive body should be set up in the form of the International Sanitary Bureau. Its mandate was finalized in 1902, in Washington, DC, during the First International Sanitary Convention of the American Republics. This gave rise to what we now know as the Pan American Health Organization and had seven members and a budget of US $5000.

Between 1902 and 1920 there were six international conferences on health in the Americas, at which the International Sanitary Bureau was responsible for gathering and disseminating sanitary information. In 1924 the Pan American Sanitary Code was signed, and is still in force today.

After the Second World War in 1945 the need arose to establish the United Nations and the specialized agencies that have a global reach. In 1946 the World Health Organization (WHO) was founded, and it began its activities in 1948. Several months after the WHO signed its constitution the body now known as the Pan American Sanitary Organization (PASO) ratified its own constitution and, in 1949, both organizations signed an agreement through which the latter agreed to operate as the WHO Regional Office for the Americas. In 1950 the PASO formalized its relations with the Organization of American States, which continues to recognize it as a specialized agency of the inter-American system. In 1958 PASO became the Pan American Health Organization.

PAHO currently has 38 Member States and one associate member, Puerto Rico. The United Kingdom, France and the Netherlands, which have territories in the western hemisphere, are Member States. Spain and Portugal, which do not have territories there, are observers.

Concern for patients subjected to radiodiagnostic procedures, radiotherapy or nuclear medicine dates back to the 1950s, when PAHO began to promote radiological protection as an essential public health function and provided grants for training in the use of radiation in medical practice. In 1960 a regional radioprotection unit was set up, the aim of which was to encourage the sanitary authorities to develop radiological safety procedures and regulations.

In April 1968 in Caracas, Venezuela, the PAHO, WHO and IAEA sponsored a symposium on dosimetry needs in radiotherapy centres. This event produced recommendations of great importance, including the establishment of the network of secondary standard dosimetry laboratories — Argentina and Mexico were among the first countries to have such laboratories. The main aim of these laboratories was to verify the calibration of cobalt therapy units with FLi thermoluminescent dosimeters, an activity that is still being carried out today with the current Dosimetry and Medical Radiation Physics Section of the IAEA's Division of Human Health.

In 1991 we began collaborating with the Division of Radiation and Waste Safety, when the PAHO became part of the Inter-Agency Committee on Radiation Safety, comprising the Food and Agriculture Organization, the IAEA, the International Labour Organization, the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development, the WHO, the PAHO, the European Commission and the United Nations Scientific Committee on the Effects of Atomic Radiation. The primary objective of this committee was to draw up the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources [1], or the BSS as they are affectionately known in English. The PAHO played an important role in the part on medical exposure. Following their adoption by our governing bodies, the PAHO has contributed to additional publications, the majority with the IAEA and the WHO's headquarters, and to introducing them through training courses, especially in the countries that are members of the PAHO but not of the IAEA.

We consider that this conference will be a landmark in the control of medical exposure. We are grateful to the organizers for the opportunity they have given us to put forward our point of view. Within the overall public sector reform in the countries of Latin America and the Caribbean, the role of the PAHO is to strengthen the leadership of the sanitary authorities in the health sector. Irrespective of whether the provision of health services is public or private and of whether a ministry of health acts as the radioprotection regulatory authority, it is the responsibility of the sanitary authorities to control medical exposure by establishing standards and guidelines so that medical procedures involving the use of ionizing radiation are safe, effective and

of a high quality. We await with interest the conclusions of this conference so that we are able to specify the function and responsibilities of each of the public and private organizations involved in dealing with medical exposures.

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[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 the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

OPENING ADDRESS

H. Ostensen
World Health Organization,
Geneva

On behalf of the World Health Organization (WHO) I would like to welcome all participants to this very important International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy.

The safe and appropriate use of ionizing radiation in hospitals and medical practices is of major concern to the WHO, and the seriousness of the matter is underlined by an alarming number of reports from all over the world of injuries caused by the incorrect use of radiation for diagnostic or therapeutic purposes. Rapid development and the introduction of new equipment and procedures may be responsible for some of these problems. However, education and training on how to apply international and national laws practically and regulations on radiation protection are of high importance both in highly developed and in less developed countries.

Laws and regulations are important and necessary, but they are of little use when not followed properly at all levels. National authorities should be encouraged to implement and strengthen regulations and controls on the use of ionizing radiation for medical purposes. Equally important, however, is to ensure that the necessary and adequate knowledge is conveyed properly to the medical staff involved, be they in a small, remote clinic with limited resources, or in a highly specialized hospital with most types of equipment and staff. As an increasing number of diagnostic and therapeutic procedures involving ionizing radiation are performed by staff not primarily trained in radiation protection issues, it is of great importance to include such groups when discussing radiation safety or planning educational programmes.

At the WHO we see the necessity for an extended dialogue between international organizations and national authorities on one side and end-users on the other, and see it to be of major importance for practically improving radiation safety both for the patients and medical staff involved. This conference is one important step in that direction, and we believe that the scientific programme planned will contribute significantly to a better understanding of the necessity of not only developing regulations and recommendations but also implementing them in practical daily work.

As the WHO is a co-sponsor of this conference, I should like to wish you all some scientifically successful days here in Torremolinos, and I believe that the outcome of the conference will contribute significantly to our common goal, which is health for all.

GLOBAL VIEW ON THE RADIOLOGICAL PROTECTION OF PATIENTS

(Background Session)

Chairpersons

F. METTLER
United States of America

J. HERNÁNDEZ ARMAS
Spain

ROLE OF THE IAEA IN THE RADIOLOGICAL PROTECTION OF PATIENTS

P. ORTIZ LÓPEZ, A.D. WRIXON
Division of Radiation and Waste Safety

A. MEGHZIFENE, J. IZEWSKA
Division of Human Health

International Atomic Energy Agency,
Vienna
E-mail: P.Ortiz-Lopez@iaea.org

Abstract

The paper discusses the role of the IAEA in relation to the radiological protection of patients. Within the IAEA there are two major programmes which have an impact on the protection of the patient. Firstly, patient protection is part of the programme on radiation safety; secondly, the human health programme contains a number of activities related to quality assurance (QA), and these also contribute to the protection of patients. A function of the IAEA, as stipulated in its Statute, is "to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property…and to provide for the application of these standards …". There are three different levels of the IAEA Safety Standards: Safety Fundamentals, Safety Requirements and Safety Guides. The Standards are supported by other documents such as Safety Reports. There are five means used by the IAEA in providing for the application of the Standards: co-ordinating research, promoting education and training, providing assistance, fostering information exchange and rendering services to its Member States. All these means are used in the programme on radiological protection of patients as described in the paper. The IAEA is assisting its Member Sates in the development and implementation of QA programmes. These activities help disseminate not only the technical knowledge but also the basic ingredients of the QA culture. The IAEA assistance is directed at: (1) national regulatory bodies for the establishment of a regulatory framework which complies with the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources; (2) standards laboratories for metrological traceability; and (3) end users at medical institutions for the development and implementation of QA programmes. Traceability of radiation measurements for radiotherapy, radiodiagnostic and radiation protection level dosimetry, and quality audit services, such as the IAEA/World Health Organization postal service for the verification of the clinical beam calibration using thermoluminescent dosimeters, are also offered to Member States. Other QA related activities are the development and dissemination of dosimetry techniques and Codes of Practice, and the training of medical radiation physicists

in QA. Close co-operation with international organizations and professional bodies is maintained by the IAEA to co-ordinate these activities on QA.

1. BACKGROUND

Over the last decade or more there has been a growing awareness throughout the world of the need to give greater emphasis to the protection of patients undergoing radiation exposure for medical purposes. This has been driven by the realization that medical exposure is responsible for by far the largest component of exposure from human activities, that there is scope for reduction of exposures in particular examinations, and that serious accidents can result from inadequate control, particularly in radiotherapy. It was this growing awareness that in 1999 led the General Conference of the IAEA to request the Secretariat to organize "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". The present international conference, which is co-sponsored by the European Commission, the Pan America Health Organization (PAHO) and the World Health Organization (WHO), was organized in response to this request.

While the protection of patients undergoing radiation exposure for medical purposes requires special consideration involving the full application of the principles of radiation protection, it must be recognized that activities associated with the development of medical uses necessarily include the promotion of quality assurance (QA) to ensure the most effective diagnosis or treatment (mainly through traceability of dose measurements and documented quality control (QC) procedures). To provide an independent quality audit of the dose delivered by radiotherapy treatment machines, the IAEA in 1969 launched a programme in collaboration with WHO.

2. ESTABLISHING AND PROVIDING FOR THE APPLICATION OF STANDARDS

The IAEA's safety functions consist essentially of two elements: establishing standards of safety and providing for their application. These are considered separately in the following sections.

2.1. Establishing standards of safety

The statutory function regarding the establishment of standards of safety and providing for their application has been given strong emphasis by the IAEA since its inception. The Board of Governors first approved radiation protection and safety measures in March 1960 and the first 'basic safety standards' in June 1962. Revisions of these standards were published in 1967, 1982 and, most recently, in 1996 [1]. Such standards provide the basic requirements that must be satisfied to ensure safety for particular activities or application areas.

There is now a well developed structure related to the IAEA's Safety Standards publications, namely:

(1) *Safety Fundamentals.* These present basic objectives, concepts and principles of safety and protection in the development and application of nuclear energy for peaceful purposes.
(2) *Safety Requirements.* These establish the requirements that must be met to ensure safety. These requirements, which are expressed as 'shall' statements, are governed by the objectives and principles presented in the Safety Fundamentals.
(3) *Safety Guides.* These recommend actions, conditions or procedures for meeting safety requirements. Recommendations in Safety Guides are expressed as 'should' statements, with the implication that it is necessary to take the measures recommended or equivalent alternative measures to comply with the requirements.

These Safety Standards publications are supported by various technical documents and reports.

The IAEA's Safety Standards have a clearly defined pedigree. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), a body set up by the United Nations in 1955, compiles, assesses and disseminates information on the health effects of radiation and on levels of radiation exposure due to different sources. This information is taken into account in developing the standards. In addition, account is taken of the recommendations of the International Commission on Radiological Protection (ICRP), which also take account of the scientific information provided by UNSCEAR. At the time that the IAEA's Board of Governors first approved radiation protection and safety measures in March 1960, it was stated that 'the Agency's basic safety standards…will be based, to the extent possible, on the recommendations of the International Commission on Radiological Protection (ICRP)".

The current version, the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS), issued

in 1996 [1], is co-sponsored by the Food and Agriculture Organization of the United Nations, the International Labour Organization, the OECD Nuclear Energy Agency, WHO and PAHO. The BSS contain the principal requirements covering all practices, including uses of radiation in medicine, agriculture, industry, research and teaching, and intervention in the event of an accident and in chronic exposure situations such as those due to residues from past activities. Detailed requirements are given in six Appendices, one of which addresses medical exposure. The Appendix on medical exposure covers the responsibilities of those involved; the justification of medical exposures; the optimization of protection, including design and operational considerations, calibration, clinical dosimetry and QA; the establishment of guidance levels; the maximum activity for patients in therapy on discharge from hospital; the investigation of accidental medical exposures; and records.

Recommendations on how to comply with the requirements of the BSS relating to medical exposures will be provided in the Safety Guide on Radiation Protection and Safety in Medical Exposure, now in the process of publication. This Safety Guide is jointly co-sponsored with PAHO and WHO. It describes strategies to involve organizations outside the regulatory framework, such as professional bodies, whose co-operation is essential to ensure compliance with the BSS requirements for medical exposures. Examples of cases where this is necessary include the establishment of guidance levels for diagnostic medical exposures, acceptance testing processes for radiation equipment, calibration of radiotherapy units and reporting of accidental medical exposure.

2.2. Providing for the application of the Safety Standards

There are five means used by the IAEA to provide for the application of the Safety Standards: co-ordinating research, promoting education and training, providing assistance, fostering information exchange and rendering services to its Member States. All these means are used in the programme on radiological protection of patients described below.

Initial steps in IAEA co-ordinated research in developing countries were taken in recent years by pilot studies on radiation doses in diagnostic radiology focused on radiographic procedures, the results of which were published in a technical document [2]. This research was followed by a second programme involving fluoroscopy and computed tomography (CT) procedures. The results will be published in 2001. A third programme on radiation dose and image quality in mammography is expected to be completed by the end of 2001 and the results will be published in 2002.

The most comprehensive programme of assistance is the Model Project on Upgrading Radiation Protection Infrastructure, which was started in 1996 to assist those Member States which have inadequate infrastructures and are already receiving IAEA technical assistance so that they can comply with the BSS. Initially 52 countries were involved. A number of documents and some software have been developed that provide

support in building the infrastructure. The elements of the infrastructure are expressed in terms of five milestones: (1) regulatory framework, (2) occupational exposure, (3) medical exposure, (4) public exposure, and (5) emergency preparedness and response.

In 2000, the implementation of the Model Project was assessed and as a result two groups of countries were identified: those that had achieved milestones (1) and (2), and those that had not. The project was then divided to accommodate the two groups of countries. A number of additional countries decided to join the project, and a total of more than 70 are currently involved in this endeavour.

The IAEA is in the process of developing a comprehensive approach to promote national sustainable education and training programmes, by training 'trainers' and providing them with standard training materials in order to enable them to train the different groups of professionals with responsibilities for radiological protection in the main medical practices using radiation, i.e. diagnostic and interventional radiology, nuclear medicine and radiotherapy.

Information exchange has been provided through international symposia, seminars and conferences. So far, the most important event of information exchange on the radiological protection of patients is this conference, which will undoubtedly provide a new impetus to the IAEA's programme in this area. Information exchange has also been fostered through other means, such as the publication of lessons learned from accidental medical exposure [3].

3. PROMOTING QUALITY ASSURANCE IN THE MEDICAL USE OF RADIATION

Any medical use of radiation necessitates the establishment of an appropriate QA and QC culture to ensure that the technology is used in a reliable fashion. This is reflected in BSS requirements for "a comprehensive quality assurance programme for medical exposures with the participation of appropriate qualified experts in the relevant fields…".

The IAEA assists Member States to establish and implement national QA programmes through its programmatic activities and Technical Co-operation projects. IAEA assistance is aimed at establishing an infrastructure that enables end users to comply with BSS requirements on QA, at providing metrological traceability through standards laboratories, and at promoting the development and implementation of QA programmes by end users at medical institutions.

3.1. Traceability and quality audit services to Member States

In the framework of the international measurement system, the IAEA in collaboration with other international organizations, including the Bureau

International des Poids et Mesures (BIPM), provides the metrological link for the traceable calibrations needed in radiotherapy, through the IAEA/WHO network of Secondary Standard Dosimetry Laboratories (SSDLs) [4]. The IAEA's support is accomplished through the provision of calibration factors for national measurement standards linked to the international measurement system, mainly to those countries who are not members of the Metre Convention and do not have access to a primary standard. As a second step, dose quality audits and follow-up programmes are implemented to help Member States ensure that the measurement standards provided to national calibration laboratories and hospitals are kept within the levels required by the international measurement system. These programmes include intercomparisons using ionization chambers and dose quality audits using mailed thermoluminescent dosimeters (TLDs). Both programmes are essential for ensuring high accuracy in clinical dosimetry. The TLD programme for hospitals aims at ensuring proper calibration of radiotherapy beams. It checks approximately 400 clinical beams per year and has checked a total of approximately 4000 radiotherapy beams in more than 1100 centres. Follow-up actions on poor results have helped the radiotherapy centres to resolve the discrepancies, thus preventing further errors in treatment of patients. The TLD programme is implemented through a close collaboration between the IAEA and WHO (PAHO, in Latin America). The programme receives the support of the BIPM, Primary Standard Dosimetry Laboratories (PSDLs) and some advanced radiotherapy centres. These institutes provide reference irradiations of the TLDs, acting as an external QC of the service. The results of the TLD programme for radiotherapy hospitals are given elsewhere [5].

3.2. Developing and disseminating Codes of Practice

The IAEA has maintained an interest in standardization and development of Codes of Practice for radiotherapy dosimetry going as far back as the 1970s, with several publications in the field. The IAEA published the first Code of Practice in 1970 [6], followed by Absorbed Dose Determination in Photon and Electron Beams, Technical Reports Series No. 277, first published in 1987 and updated in 1997 [7]. Following the world trend in radiation dosimetry, the IAEA developed a new Code of Practice based on absorbed dose to water standards. This Code has been endorsed by WHO, PAHO, and the European Society of Therapeutic Radiology and Oncology (ESTRO) and has recently been published by the IAEA as Technical Reports Series No. 398 [8]. The Codes of Practice developed by the IAEA on absorbed dose determination in radiotherapy beams are presently used by many physicists involved with dosimetry in radiation therapy and have been adopted by several countries as their national dosimetry protocol.

Until recently, most of the effort of the IAEA was concerned with the development of Codes of Practice for external beam therapy. To address the different aspects

of QA in brachytherapy, guidelines on standardized procedures for the calibration of brachytherapy sources at SSDLs and hospitals have also been developed [9]. Currently, a Code of Practice is being developed to aid in the standardization of various dosimetry techniques in X ray diagnostic radiology.

3.3. Fostering exchange of information on QA in radiotherapy

An important part of the programme of the IAEA to foster exchange of information includes providing assistance to Member States to improve QA and safety in the use of ionizing radiation. Experience gained from different centres can be of use to others using similar equipment. Also, lessons learned from problems and incidents in one centre can be of benefit to other users having the same or similar equipment. In this context, it was decided to make available an updated and complete directory of radiotherapy centres around the world and their therapy sources. Since 1959, the IAEA has maintained a register of radiotherapy hospitals and clinical institutions having radionuclide and high energy teletherapy machines. The electronic version of the Directory of Radiotherapy Centres (DIRAC) is continuously updated on the basis of information provided by Member States. It includes data on teletherapy machines, sources and devices used in brachytherapy, and equipment for dosimetry, patient dose calculation and QA. Data on staff strength at the installations (numbers of radiation oncologists, medical physicists, technicians, etc.) are also included.

4. IAEA ACTIVITIES ON THE RADIOLOGICAL PROTECTION OF PATIENTS IN 2002–2003

The development of the IAEA programme on the radiological protection of patients is currently under way, and the final programme will be influenced by the conclusions of this conference. Most of the activities described below are intended to be carried out in co-ordination with the international organizations with an interest in patient protection.

4.1. Guidance

The requirements of the BSS are to be fulfilled by the users of sources of radiation but they may need guidance on how certain regulatory requirements are to be fulfilled in particular practices. A set of examples or model regulations for the three main medical practices using radiation — diagnostic and interventional radiology, nuclear medicine and radiotherapy — will therefore be provided. Professional societies will be invited to take part.

An essential component of any programme to improve radiological protection is the promotion of education and training. The programme to promote national sustainable training, mentioned above, will also cover the radiological protection of patients in diagnostic and interventional radiology, nuclear medicine and radiotherapy.

4.2. Assessment of specific problems in the radiological protection of patients

The UNSCEAR report published in 2000 [10] highlights an important increase in collective doses caused mainly by CT and interventional radiology. Deterministic effects from interventional radiology are also an issue of concern. In addition, new protection problems arise, for example, through the use of radiation sources in endovascular brachytherapy.

The UNSCEAR report has been used as the basis for elaborating the following list of research activities, the results of which will be incorporated into IAEA guidance and training:

— Quantitative assessment of dose reduction techniques (pulsed fluoroscopy, filters, road mapping, image processing) in complex procedures such as interventional radiology;
— Optimization of protection in CT, including new technologies such as beam intensity modulation, multiple slices and CT fluoroscopy;
— Trade-off of radiation dose and image quality in digital radiology;
— Radiation protection problems and possible emergency situations in intravascular brachytherapy.

4.3. Worldwide surveys of patient doses in radiology

Doses differing by as much as two orders of magnitude for similar radiological investigations have been reported [11]. There is therefore considerable scope for dose reduction in diagnostic radiology and also in nuclear medicine. For this reason, and in order to provide guidance on what is achievable with current good practice, the BSS require that “guidance levels for medical exposure be determined as specified in the Standards, revised as technology improves and used as guidance by medical practitioners” and that “the guidance levels be derived from the data from wide scale quality surveys”.

These surveys need to be done in each country, and consideration needs to be given to local variability, for example with respect to existing equipment and the level of training and experience of a large population of medical and paramedical staff. Not only the doses but also the associated image quality need to be surveyed, in order to

ensure that images meet the clinical objectives and that changes made in technical factors do not lead to a loss of needed information.

Surveys are resource consuming, involving governmental authorities, professional associations, and medical and paramedical staff. A methodology to plan and carry out these surveys will therefore be developed to assist Member States in undertaking them as efficiently and effectively as possible. Workshops will be organized to promote the use of the methodology.

The use of guidance levels as part of a programme of optimization of protection is already widely accepted for simple examinations, but their use is less obvious for complex examinations, such as interventional radiology. Co-ordinated research programmes (CRPs) will be set up to explore how guidance levels for interventional radiology might be developed.

4.4. Promotion of self-assessment and peer reviews

Self-assessment is necessary initially and during the implementation of a programme on radiation protection. Peer reviews, or external audits, are also desirable both at the national level, to assess the effectiveness of national strategies (as described in the Safety Guide mentioned in Section 2.1), and at the hospital level, to assess specific programmes. In order that these assessments and reviews are undertaken systematically, a methodology will be developed and promoted. The IAEA is establishing a service to provide peer reviews, upon request by Member States, based on this methodology. The aim of the peer reviews will be to assess how requirements of the BSS are addressed and whether internationally harmonized protocols for QA are adopted to meet those requirements. They will also address activities which require national strategies, such as the development of guidance levels for diagnostic radiology, and nuclear medicine and education, as well as sustainable education and training programmes related to the radiological protection of patients.

4.5. Feedback from experience

Within the context of self-assessment, an area needing feedback from experience into the practice is the therapeutic use of radiation, in which the potential consequences of errors and equipment faults can be detrimental. The IAEA has compiled and published lessons from more than 90 events, some of them involving severe accidental exposure and even fatalities. In addition, it has set up an international reporting system of unusual radiation events (RADEV) [12], which includes incidents involving exposure of patients. Retrospective review and feedback of this experience into the formulation of guidance are essential. Prospective methods such as probabilistic safety assessment [12], at present being evaluated

under a CRP, will be applied for the protection of patients in the therapeutic use of sources.

4.6. Promoting traceability and standardization of measurements to ensure consistency in radiation dosimetry

In the coming years, the IAEA will continue to strengthen its support services to Member States, including provision of traceability and quality audit services to SSDLs and end users in hospitals. The IAEA will further promote international standardization in dosimetry and consolidate its traceability links to the international measurement system in the framework of the Mutual Recognition Arrangement (MRA) [13]. The MRA aims at enhancing the worldwide mutual recognition of national measurement standards and of calibration and measurement certificates.

A new CRP will support the development of techniques at the SSDLs for the dissemination of the new standards based on absorbed dose to water for radiotherapy dosimetry. This will make possible the implementation in Member States of the new radiotherapy Code of Practice based on absorbed dose to water [8].

The IAEA dosimetry laboratory has expanded its measurement capabilities to include conventional diagnostic radiology and mammography beam qualities to support calibration services to its Member States.

For brachytherapy, the service is, at present, limited to calibrations at ^{137}Cs radiation quality for low dose rate. The development of calibration procedures at SSDLs for ^{192}Ir high dose rate will be considered. The IAEA will develop procedures and guidelines for standardization of measurements and traceability in nuclear medicine. The long term plan is also to develop measurement standards for radioisotopes and to assist Member States in the establishment of traceability of measurements in nuclear medicine.

4.7. Developing and promoting the use of internationally accepted Codes of Practice in radiotherapy and diagnostic radiology

Continued emphasis is also being given to international harmonization of radiation dosimetry through the development and dissemination of standards of radiation measurements and Codes of Practice for dosimetry techniques among Member States.

Standardized procedures for dosimetry in diagnostic radiology will continue to be developed within the framework of a CRP.

The new Code of Practice for radiotherapy dosimetry based on the standards of absorbed dose to water is being tested by SSDLs and end users at hospitals in the framework of a CRP. The goal is to assist SSDLs and users in hospitals in developing

the systematization needed to implement the new Code of Practice, which is very different from the previous air kerma standards.

4.8. Quality assurance and dose audits

A key element in QA is the quality audit of radiation dose delivered to patients. The IAEA will continue to provide an independent verification of beam calibration in radiotherapy centres using TLDs and to assist end users in achieving the required levels of accuracy in radiotherapy.

Support to the establishment of national QA programmes in Member States to provide external and independent peer review of practices in radiotherapy, such as the External Audit Groups (EAGs), established in the framework of a CRP, will continue. The EAGs aim to establish a TLD audit to check the beam calibration (i.e. reference conditions) in a first phase and to extend their scope of work to include checks in non-reference conditions (per cent depth doses, output factors, etc.) in a second phase.

4.9. IAEA Co-operative Centres for Quality Assurance in Radiotherapy and Nuclear Medicine

A new activity planned by the IAEA will be the assignment of IAEA Co-operative Centres for Quality Assurance (IAEA-CCQA). Each centre will agree with the IAEA to develop and verify QA and QC procedures pertaining to a specific technology. Collectively the information thus created will effectively further contribute to the establishment of a close-knit worldwide culture of QA and QC. These centres will also be used to promote good practice, as recommended in the BSS.

5. CONCLUSIONS

This paper has described the two programmes of the IAEA which have an impact on the radiological protection of patients, that within the overall programme of radiation safety and that which is an integral part of the programme of human health. These programmes are complementary and emphasize the importance of appropriate co-ordination between medical practitioners, qualified experts in medical physics (radiotherapy, diagnostic imaging) and radiation protection experts. The IAEA will continue strengthening its two programmes and it regards this conference as seminal in that it believes that the results of the conference will have a major influence on its work in the years to come.

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EU LAWS AND GUIDANCE REINFORCE THE RADIOLOGICAL PROTECTION OF PATIENTS

M. SARRÓ VAQUERO
European Commission,
Directorate-General Environment,
Luxembourg
E-mail: Mercedes.Sarro-vaquero@cec.eu.int

D. TEUNEN
European Commission,
Directorate-General Research,
Brussels
E-mail: Diederik.Teunen@cec.eu.int

Abstract

European legislation developed under the Euratom Treaty has set uniform safety standards to protect the health of the public and workers from the dangers of ionizing radiation. Council Directive 97/43/Euratom, supplementing Council Directive 96/29/Euratom, covers patients and individuals in relation to medical exposures. It sets requirements for radiological protection in diagnosis and treatment, stressing training for staff, clinical audits, quality assurance programmes, patient dose assessments and the protection of pregnant women and children. The directives had to be transposed into national legislation by 13 May 2000. The Radiation Protection Unit of the Directorate-General Environment of the European Commission monitors and controls the implementation of European Community radiation protection legislation by Member States. The European Commission's Communication on the Sixth Environment Action Programme includes the environment and health as priority areas. Research performed under European Research Framework Programmes in the medical area aims to obtain suitable tools to optimize radiological diagnostic procedures. It focuses on exposures associated with high individual risks and/or high individual doses. The main outcomes have been guidelines on quality criteria for radiological procedures, including paediatric exposures, computed tomography, interventional radiology and digital mamography. Dosimetry aspects and quality of imaging are also addressed. The Sixth European Research Programme will emphasize the development of the European Research Area.

1. INTRODUCTION

Medical diagnosis and treatment is the largest human-made source of radiation exposure in Europe. The medical use of ionizing radiation continues to expand and, more importantly, tends towards more complex examinations entailing higher

exposures. However, at the same time, the use of ionizing radiation has allowed for great progress to be made in diagnostic and therapeutic medical procedures.

Council Directive 97/43/Euratom [1] on the health protection of individuals against the dangers of ionizing radiation in relation to medical exposures recognizes these facts and, therefore, requires careful justification and optimization of radiological procedures. The latter means that the requested diagnostic information is obtained at the lowest possible dose. Practical implementation of this principle is only possible when suitable tools, such as diagnostic reference levels for radiological diagnostic examinations, are available.

This conference, organized by the IAEA and cosponsored by the Pan America Health Organization (PAHO), the World Health Organization (WHO) and the European Commission, aims to promote the exchange of information and the development of recommendations in relation to the radiological protection of patients. There is evidence of the value of debate and co-operation between stakeholders to get better outcomes and ensure public trust and political support. Hence, we are sure that this conference will be a success and will benefit patients and citizens.

2. EUROPEAN UNION ROLE IN SETTING STANDARDS

European legislation for radiation protection, developed under the Euratom Treaty signed in 1957, applies to the control of exposure to ionizing radiation from human-made sources and, in some cases, from natural sources. It now covers the control of exposure in the medical use of ionizing radiation.

The Euratom Treaty stipulates that the European Community shall establish uniform safety standards to protect the health of workers and the general public, and ensure that they are applied (Article 2.b and Chapter III, Health and Safety). Article 30 defines the concept of ‘basic standards’: (a) maximum permissible doses compatible with adequate safety, (b) maximum permissible levels of exposure and contamination and (c) the fundamental principles governing the health surveillance of workers.

Under the legal framework provided by Chapter III of the Euratom Treaty, European Community initiatives and actions in the field of radiation protection have ensured high standards of protection and added value at the European level, while achieving a fair degree of harmonization throughout the European Union (EU).

3. WORK OF THE EUROPEAN COMMISSION

Further to its work, the European Commission pursues three constant objectives: to identify the European interest, to consult as widely as necessary and to

respect the principle of subsidiarity. Its functions include the legislative initiative, the control and monitoring of the correct application of EU legislation by Member States, and executive and negotiation responsibilities.

Subsequent to a recent restructuring of European Commission services, the Radiation Protection Unit in charge of the implementation, anticipation and follow-up of European Community legislation for radiation protection has been placed within the Directorate of Environment and Health in the Directorate-General Environment. Hence coherence with general environment and health policy has become essential.

However, the European Commission does not set out to undertake all actions itself within the field of radiological protection, but instead works with the national authorities to achieve this aim.

4. LEGAL INSTRUMENTS AND PROCEDURES FOR SETTING SAFETY STANDARDS

Article 161 of the Euratom Treaty defines the different legal instruments available to the European Community to accomplish its mission. The main instruments are European Council directives, regulations and decisions. European Council directives are binding on Member States within the framework of national legislation. Regulations are binding in their entirety and directly applicable. Decisions are binding on these to whom they are addressed.

The procedure for setting standards is also laid down in the Euratom Treaty. Firstly, the European Commission receives guidance from a group of experts set up under Article 31 of the Treaty, which then gives rise to a European Commission proposal.

This proposal is submitted to the Economic and Social Committee. Then, after incorporation of all or part of its observations, it is published in the Official Journal and forwarded to the Council and the European Parliament. The European Parliament then proposes amendments to the European Commission proposal, which are examined by the European Commission and taken up as a whole or in part in a revised European Commission proposal, which is again submitted to the European Council.

Finally, under the terms of the Euratom Treaty, it is the European Council that decides and eventually adopts the directive by a qualified majority.

5. REVISED BASIC SAFETY STANDARDS DIRECTIVE (COUNCIL DIRECTIVE 96/29/EURATOM)

The most important European legal instrument in the field of radiation protection is the Basic Safety Standards (BSS) Directive. It was last revised in 1996 by

Council Directive 96/29/Euratom of 13 May 1996 [2], which lays down basic safety standards for the health protection of the public and workers against the dangers of ionizing radiation. It had to be transposed into national legislation by 13 May 2000.

It confirms the general principles underlying radiation protection: justification of practices, optimization of protection and dose limitation. It covers practices, interventions and work activities, and strengthens the regulatory requirements.

In addition, it sets more stringent dose limits for the public and workers, including the staff of medical radiological installations. The dose limit for workers is now 50 mSv effective dose per year with an average of 100 mSv over a period of five years or, in practice, 20 mSv/year (Member States may decide on an annual amount). For the public the dose limit has been reduced to 1 mSv (exceptionally, more than 1 mSv may occur as long as the average over five years remains less than 1 mSv).

6. REVISED MEDICAL EXPOSURES DIRECTIVE (COUNCIL DIRECTIVE 97/43/EURATOM)

Council Directive 97/43/Euratom [1] of 30 June 1997 on the health protection of individuals against the dangers of ionizing radiation in relation to medical exposures, the Medical Exposures Directive (MED), supplements the BSS Directive. The MED ensures a high level of radiation protection in diagnosis and treatment. Members States had, again, until 13 May 2000 to transpose it into national legislation.

The MED lays down provisions to achieve a high level of health radiological protection in diagnosis and therapy. It expands and strengthens the previous directive on a number of important issues.

Firstly, it applies to the exposure of patients, as part of their diagnosis or treatment, and the exposure of individuals, such as those volunteers participating in medical or biomedical research, those exposed as part of occupational health surveillance, health screening programmes and medicolegal procedures, and those exposed helping persons undergoing diagnosis or treatment with radiation.

The MED requires the application of the justification and optimization principles to all medical exposures. The principle of dose limitation does not apply to medical exposure.

According to the MED, all new and existing radiological medical practices must be justified and each medical exposure has to show a sufficient net benefit against the individual detriment that it might cause. What is more, all unnecessary exposures must be avoided. To facilitate the application of the justification principle, the MED defines the procedures and system for the justification of practices and individual exposures, requiring that both the prescriber and the practitioner are involved in the justification process.

In addition, the MED details the provisions for the optimization process in relation to medical exposures, distinguishing between radiodiagnostic and radiotherapeutic procedures. In diagnosis the optimization goal is to keep doses as low as reasonable achievable while obtaining the necessary diagnostic information; in therapy the goal is to ensure that the target tissue is given the prescribed dose while minimizing the dose to non-target volumes and tissues.

It also introduces new requirements and strengthens the existing ones on a number of important issues, such as the protection of pregnant women and children

In addition, it defines the roles, responsibilities and training for the staff of medical facilities, both for radiological practices and for radiation protection. It also lays down provisions on procedural requirements, such as the availability of referral criteria for medical exposures, the use of diagnostic reference levels as a tool for optimization and the performance of clinical audit and quality assurance programmes. Moreover, it sets provisions relating to equipment, including acceptance testing, performance testing and quality control measures. It deals with the prevention of potential exposures and accidents, particularly in radiotherapy, and it requires the assessment and evaluation of patient dose or administered activities.

To conclude, the MED constitutes a major step forward and offers an excellent opportunity to reinforce radiation protection applied to medical radiological practices for the benefit of all European citizens.

7. GUIDANCE

In order to facilitate the correct application of the directives, the European Commission has sponsored a few workshops on the implementation of the MED and has organized seminars on relevant topics, such as:

— Genetic susceptibility and new evolutions on genetic risk,
— Thyroid diseases and exposure to ionizing radiation,
— Low dose ionizing radiation and cancer risk.

In addition, it has published several technical guidelines, developed with the assistance of the group of scientific experts under Article 31 of the Euratom Treaty. These include:

— Referral guidelines for imaging,
— Guidelines on education and training in radiation protection for medical exposures,
— Guidance on diagnostic reference levels for medical exposures,

— Guidance for the protection of unborn children and infants irradiated owing to parental medical exposures,
— Guidance on medical exposures in medical and biomedical research,
— Radiation protection following ^{131}I therapy (exposures owing to out-patients or discharged in-patients),
— Criteria for the acceptability of radiological (including radiotherapy) and nuclear medicine installations.

Technical guides are drawn up to facilitate implementation of the MED. However, they are not binding on Member States. The above documents can be downloaded from the European Commission web site at http://www.europa.eu.int/comm/environment/radprot

8. ENVIRONMENT AND HEALTH — FUTURE DEVELOPMENTS

On 24 January 2001 the European Commission adopted a communication to the European Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the Sixth Environmental Action Programme of the European Community, 'Environment 2010: Our Future, Our Choice'. In addition, it presented a proposal for a Decision of the European Parliament and of the European Council, laying down the Community Environment Action Programme 2001–2010, as the legal basis of a European Commission treaty.

The Sixth Environmental Action Programme (6EAP) is an strategic document that emphasizes the need for a new approach to policy making based on wide participation and dialogue with stakeholders in different issues. It deals with environmental problems and objectives, identifies the driving forces behind those problems and indicates four priority areas where integration action is required. The priority areas are: climate change, nature and biodiversity, environment and health, and natural resources and waste.

Environment and health is a topic of interest and concern for European citizens, as regularly shown in the Eurobarometer surveys.

The 6EAP basic approach is that society must aim at decoupling prosperity from environmental impacts. Eco-efficiency and technological development can help institutions and companies achieve a better environmental performance, while improving efficiency and competitiveness.

The 6EAP will cover a ten year period, during which most applicant countries are expected to join the EU. Thus the strategic approach and the priority themes chosen will apply to an enlarged EU. Applicant countries' full compliance with European Community law at the time that they join the EU will entail large benefits not only to

the environment and health of their populations, but also to neighbour Member States and Europe as a whole.

9. EUROPEAN COMMISSION'S RESEARCH PROGRAMME ON THE MEDICAL USES OF IONIZING RADIATION

The work in this area under the 4th Framework Programme (FP4) (1994–1998) was complementary to previous work on quality criteria under the European Research Programme, which was in fact to a great extent at the basis of a number of important principles present in the European Council directive. It contains optimization strategies based on the evaluation of the correlation between patient dose, radiological and technical procedures and diagnostic information requested by practitioners.

FP4 contracts mainly focus on diagnostic examinations associated with a relatively high individual risk, such as the exposure of children in paediatric radiological procedures and examinations associated with relatively high individual doses per examination, such as computed tomography (CT). However, the work also envisages improving the scientific basis for the evaluation of diagnostic image quality criteria and their practical implementation.

Interesting achievements are the development and publication of European guidelines on quality criteria for CT for six frequently performed examinations, including the setting of diagnostic reference levels using the weighted CT dose index and the dose–length product, the development of two draft guidelines on the optimization of paediatric imaging techniques for a number of frequent examinations, including fluoroscopic examinations and CT examinations, and establishing a list of quality criteria and dose criteria. An improvement and refinement of the existing European Commission quality criteria guidelines for adult chest and lumbar spine radiographs was also developed together with an analysis of dose audit techniques.

Under the 5th Framework Programme (FP5) (1998–2002) emphasis is put on interventional radiology, which is a rapidly developing branch of minimally invasive medicine that has a potential for the optimization of procedures to avoid adverse effects. Quality criteria will be adapted to further digital imaging procedures, in particular for digital mammography, and for interventional radiology. Constancy testing programmes will be established for different digital systems. Good methods for patient dosimetry will be developed for both digital and interventional equipment, including the setting of dose reference values. Furthermore, clinical evaluation projects in interventional radiology and cardiology are scheduled, which aim to develop image criteria and to set 'complexity indices' for both therapeutic and diagnostic procedures.

Another project aims at establishing methodologies for assessing objectively the quality of clinical radiographic images, including the detailed characterization and representation of both normal and abnormal anatomical structures. This would result in the development of a programme of physical measurements that can be performed on clinical images produced by direct digital X ray image capture systems. Also the role and function of the human observer in the diagnostic process and his or her impact on the clinical outcome will be studied. Through modelling procedures the whole process should lead to modelled image quality descriptors that ultimately can help to optimize the design of radiographic imaging systems. Practically applicable physical parameter and measurement protocols for direct digital radiographic imaging systems should enable practitioners to assess their performance.

Finally, a European survey on the clinical applications of CT with a focus on the evaluation of CT protocols and the assessment of patient dose should lead to an update of the quality criteria guidelines for CT, including new emerging modalities such as fluoroscopic CT and multislice CT, and further the development of dose reference levels through better methods for dose assessment.

As regards the future of the European Research Programme, emphasis will be put on the development of the European Research Area. The programme will focus on areas where European Community action provides the greatest added value compared with national actions; it will promote networking between the main stakeholders in Europe and will enhance efficiency by channelling resources to projects of greater magnitude and longer duration.

Although the medical use of ionizing radiation is recognized by the European Community as an important area where, through better justification and optimization of procedures significant dose saving can be achieved without jeopardizing the patient's benefit, it is yet too premature to say what the effects of this radical change in policy will be on the programme in this particular area.

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GLOBAL VIEW ON THE RADIOLOGICAL PROTECTION OF PATIENTS: PAHO POSITION PAPER

C. BORRÁS
Program of Essential Drugs and Technology,
Division of Health Systems and Services Development,
Pan American Health Organization,
Regional Office for the Americas,
World Health Organization,
Washington, D.C.
E-mail: borrasca@paho.org

Abstract

The Pan American Health Organization/World Health Organization (PAHO/WHO), founded in 1902, initiated a radiological health programme in the 1950s. Within this programme, there are currently three lines of work: (a) radiology services; (b) radiation safety; and (c) radiological emergencies. Radiology services deals with health services for diagnostic and interventional imaging, and for radiation therapy. Radiation safety studies the three types of exposures to both ionizing and non-ionizing radiation: occupational; medical; and public. Radiological emergencies involve radioactive waste management programmes and emergency plans. The radiological protection of patients is addressed in each of these areas: (a) when analysing the infrastructure of radiology services; and (b) when determining medical exposures; and (c) when investigating overexposures in interventional or therapeutic procedures or under-doses in radiation therapy.

1. TECHNICAL CO-OPERATION STRATEGIES

At the Pan American Health Organization/World Health Organization (PAHO/WHO), patient radiological protection is part of the 'Program of Essential Drugs and Technology' within the Division of Health Systems and Services Development (HSE/RAD). This programme provides consultation upon request involving a wide range of subjects. Among the most common are: planning radiological services, including shielding design; specification, selection, acceptance testing, maintenance and repair of radiological equipment; review of diagnostic and therapeutic radiological procedures; calibration of radiation beams for diagnosis and treatment; physical and clinical dosimetry; radioactive waste management in medical facilities; development and implementation of quality control and quality assurance

(QA) programmes; and prevention, preparedness and response in case of a nuclear accident or a radiological emergency.

HSE/RAD provides technical co-operation in collaboration with the responsible national authorities (e.g. ministries of health, radiation regulatory authorities and standards laboratories); international organizations (the International Atomic Energy Agency (IAEA), the International Labor Organization); PAHO/WHO Collaborating Centers (Center for Diagnostic Imaging in Mammary Pathology (CIM)), Argentina, Institute of Radioprotection and Dosimetry (IRD), Brazil, the US FDA's National Center for Devices and Radiological Health (CDRH), USA, Radiation Emergency Assistance Center/Training Site, USA); national organizations (American Association of Physicists in Medicine (AAPM), American College of Radiology (ACR), US National Council on Radiation Protection and Measurements (NCRP), UK National Radiological Protection Board (NRPB), Health Physics Society (HPS)); regional organizations (Asociación Latino-Americana de Físicos en Medicina (ALFIM), Colegio Inter-Americano de Radiología (CIR), Círculo de Radioterapeutas Ibero-Latino-Americanos (CRILA), Grupo Latino-Americano de Curieterapia–Radioterapia Oncológica (GLAC–RO)); global bodies (International Commission on Radiological Protection (ICRP), International Organization for Medical Physics (IOMP), International Society of Radiology, International Society of Radiographers and Radiological Technologists); scientific, professional and technical societies and co-operative groups (Acuerdos Regionales Cooperativos para la Promoción de la Ciencia y Tecnología Nucleares en América Latina (ARCAL).

2. TECHNICAL CO-OPERATION ACTIVITIES

2.1. Data collection and situation analysis

HSE/RAD staff visits countries mainly for the purpose of assessing national policies and resources and advising on the role to be played by the health authorities, especially in view of their steering role within the area of health sector reform. The number and quality of diagnostic and therapeutic radiology services differ widely in the Americas, depending on demographic and socioeconomic factors. The number of diagnostic X ray units and megavoltage high energy radiotherapy machines for cancer treatment and associated staff in Latin American and Caribbean countries, as well as information on QA programmes, are compiled periodically by HSE/RAD and sent to PAHO's Health in the Americas [1] and to the United Nations Scientific Committee on the Effects of Atomic Radiation [2] for publication.

Information on radiation protection legislation and regulations is also collected. Of the 38 PAHO Member States, only 19 had radiation regulatory authorities, and in only two of them was the responsibility located in the ministry of health. The others

were in atomic energy commissions, or the regulatory responsibilities were divided between two (or more) governmental agencies. This situation led PAHO to join the international efforts to prepare the 'International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources' (BSS) [3].

2.2. Development of standards and guidelines

In 1994, the Pan American Sanitary Conference, PAHO's highest governing body that meets every four years, endorsed the BSS, the final version of which were published by the IAEA in 1996 in English and in 1997 in Spanish. Standards on radiology services were presented in 'Organization, Development, Quality Assurance and Radiation Protection in Radiology Services: Imaging and Radiation Therapy' [4]. This publication describes the organizational and technical aspects of radiology services, analysed within the context of PAHO's strategic and programmatic orientations. It is aimed at politicians, administrators, planners and health professionals, as well as the ministries of health, to help them allocate resources and determine technological configurations for the provision of radiology services. It seeks to strike a balance between basic principles of decentralized health services and the requirements that emerge as advances in medical knowledge are incorporated and applied in various areas of the health services. As a complement to the concepts developed in the text, the appendices in the book present examples of equipment specifications and legislation on practices and specialties, and provide information on technical aspects of QA and radiation protection. The English and Spanish editions were published by PAHO/WHO in December 1997 and are now being updated.

Other areas in which standards are currently being developed by HSE/RAD involve health technology assessment, especially regarding digital radiology and conformal radiotherapy; QA; education and training and teleradiology.

2.3. Preparation, review and distribution of technical documents and publications

In addition to preparing and distributing its own publications, HSE/RAD cosponsors as many relevant publications as possible, especially with the IAEA, with whom recently it elaborated a Safety Guide on radiation protection in medical exposures.

HSE/RAD purchases and distributes to its Member States some of the publications produced by international and national scientific organizations (for example from AAPM, ACR, ICRP, NCRP and NRPB). It also plays a significant role in reviewing technical documents prepared by national authorities, other international organizations and the scientific community at large. After the publication of the BSS, practically all Latin American and Caribbean radiation protection and health author-

ities have revised their legislation/regulations. Significant examples of the regulations of health authorities that were reviewed by PAHO were those from Brazil, Costa Rica, Mexico and ARCAL projects.

2.4. Educational activities

HSE/RAD has been very active in organizing, co-sponsoring and supporting educational activities, such as courses, seminars, workshops, congresses and conferences at the national, regional and global levels, aimed at physicians, physicists, engineers and technologists. In the last 13 years, it is estimated that more than 1700 people have been trained. Most of the courses have been aimed at PAHO Member States that are not IAEA members, and have dealt with the implementation of the BSS in the medical practice. For the latter, a training manual consisting of 1200 slides, developed by HSE/RAD for IAEA and PAHO/WHO training courses, has been used.

This manual is divided into four sections, with the first covering general aspects of radiation protection. It is the only area with a review of basic principles, both in radiation detection and measurements, as well as in biological effects of radiation. The second, third and fourth modules address the applications of radiation protection in diagnostic radiology, nuclear medicine and radiation therapy, respectively. Each one starts with background material on the corresponding radiological application, followed by: the biological effects specific to that practice; the radiation protection aspects for the staff and the public; and medical exposures. It ends with investigation of accidents. Particular emphasis has been placed in the protection of the patient. The medical exposure section includes a justification of each practice and optimization of the protection. The optimization starts with design considerations followed by operational aspects, and ends up with calibration, clinical dosimetry and QA requirements.

2.5. Upgrading of diagnostic radiology services

PAHO/WHO plays a significant role in advising ministries of health on the development, organization and improvement of radiology services according to levels of health care. It tries to reconcile the goal of universal health care coverage (WHO's "Health for All") with QA and radiation protection requirements. The fundamental issues are: the identification of health problems; their frequency, magnitude and severity; their geographic and demographic distribution; their evolution and trends; and the resources available. Physical infrastructure needs, equipment and supplies, human resources, preventive and corrective maintenance and quality control (QC) and QA programmes are addressed.

Within the framework of health sector reform, and given the deteriorating condition of radiology services, the health authorities of Latin America and the Caribbean are questioning their role in the provision of these services. Should they upgrade the

existing public installations, purchase services from private facilities or enter into some kind of partnership with them? If the services are offered privately, how is the ministry of health going to monitor their quality? Most health authorities do not have mandatory standards for QA programmes. Who has the responsibility to establish them? The answers are not simple; they have to be tailored to the specific needs of the country and resources, taking into account technological, radiation safety and financial aspects. Radiological equipment is among the most expensive in medicine, and radiology services require multidisciplinary teams to run the services effectively and safely. What technologies are to be accepted? Do they really improve the long term care of the patients?

Access to diagnostic radiology and other imaging equipment in most developing countries is far from being equitable; only approximately two-thirds of the world's population has access to such services. Most of the rural and urban poor populations have no access at all. The majority of the diagnostic and imaging services can be found in the larger cities, where the quality and care received may be questionable. Furthermore, estimates indicate that 30–60% of the imaging equipment that does exist may not be in working order. To remedy the situation, in the 1970s WHO introduced the Basic Radiological System (WHO–BRS) as a "safe, inexpensive diagnostic imaging system for developing countries". This system includes a battery powered generator to overcome problems with undependable electricity supply and a C-arm type support stand, which permits general-purpose radiography, including chest X rays. Training manuals for radiographic and darkroom techniques and for radiographic interpretation were published in several UN languages. In the 1990s, WHO changed the specifications to incorporate computerized X ray controls and diagnostic software to the same X ray tube. This upgraded version is called the World Health Imaging System for Radiography (WHIS-RAD) [4].

PAHO purchased 11 of these units and installed them in Haiti in the mid-1990s. Figure 1 shows a map with their geographical location and photos of the X ray unit and a typical radiology facility. In spite of the inherent reliability of the equipment, the services have serious problems because of lack of maintenance, poor X ray technician training and inadequate radiation protection measures. Efforts continue at the regional level to seek funds for Haiti to: provide basic training to X ray technicians in the radiology services; create a university based maintenance training programme; set up a maintenance contract with the X ray manufacturers; and establish a radiation protection programme at the national level. It is felt that only under these circumstances will any X ray technology function adequately [5].

The greatest problem in radiology services in Latin America and the Caribbean is film processing. Will the new digital systems be the answer? From a purely economic viewpoint, the cost of the digital processor and phosphor plates will equal in a few years that of the film developer, the processing chemicals and the supplies of films, screen and grids. But what about maintenance support and training issues? Can

FIG. 1. Location of radiology services with WHIS-RAD equipment, Haiti.

they be secured? For how long? How will the practice impact on patient protection? Because phosphor plates can be reused, will the repetition rate be greater than with conventional radiology using film? Because of the large dynamic range of the digital system, will the exposures be larger? PAHO is currently working on requests from ministries of health to advise them on upgrading diagnostic radiology services in Belize, Haiti, St. Kitts and Nevis and Trinidad and Tobago.

2.6. Promotion and development of QA programmes in diagnostic radiology

A regional diagnostic radiology programme aimed at evaluating the quality of mammography services in Latin America and the Caribbean, which — according to some current national surveys — is not satisfactory, is being developed at present by HSE/RAD in collaboration with the Inter-American College of Radiology (CIR), a non-governmental organization with official relations with PAHO. The purpose of the study is to document the situation with regard to mammography services in the region and to develop a comprehensive QA programme tailored to the situation. Initially, data will be obtained in a representative number of mammography services concerning equipment and supplies, mammographic techniques and the education and training of personnel, along with measurements using breast simulating phantoms and

thermoluminescent dosimeters (TLDs). The results will be interpreted following the imaging criteria of the ACR — an adviser to the project — and the guidance dose levels published in the BSS. The work is being conducted with the co-operation of three PAHO/WHO Collaborating Centers: the Institute of Radiation Protection and Dosimetry, in Brazil; the Center for Diagnostic Imaging of Mammary Pathology, in Argentina; and the Center for Devices and Radiological Health of the Food and Drug Administration in the USA. It is expected that the resulting comprehensive QA programme — to be co-ordinated by HSE/RAD — will be made available to all mammographic services in Latin America and the Caribbean, thereby improving their quality.

2.7. Review and participation in research programmes

HSE/RAD has been stimulating and supporting applied research activities in diagnostic radiology services mostly in Cuba and Argentina. Some of the results have been published in the scientific literature. In 1999, HSE/RAD won the research competition convened by PAHO's Director with the theme: "Quality Assessment of Radiology Services" and prepared the terms of reference for the submission of projects. Seven countries applied and five — Argentina, Bolivia, Colombia, Cuba and Mexico — were awarded a research contract, which involves medical physicists and radiologists in these countries. While maintaining their own research interests, the five participants have agreed to perform a common multi-centric study. Its purpose is to correlate quality indicators of radiology services with the accuracy of the radiological interpretation as determined by a panel of experts. The project, co-ordinated by HSE/RAD, is achieving two very important goals. First, it is bringing together investigators from countries at different stages of development who will benefit from the exchange of information and experience. Perhaps, most importantly, it is promoting the collaboration between diagnostic physicists and radiologists in each country. This should ultimately improve radiology services in Latin America. A summary of the results to date have been presented at this Conference.

2.8. Upgrading of radiation therapy services

After cardiovascular diseases, cancer is currently considered to be the most serious health problem in the industrialized countries. According to WHO [6]. Cancer affects nine million people and causes five million deaths annually. In developed countries it is the second most common cause of death, and epidemiological evidence points to the emergence of a similar trend in developing countries. Radiation therapy, together with surgery and chemotherapy, is one of the pillars of cancer treatment. It is estimated that radiation therapy is used in the management of approximately 40–80% of all cancer patients, either as the sole method of treatment or in conjunction with

surgery, chemotherapy and/or hyperthermia. Yet, in many countries appropriate technology and the human resources needed to provide accurate dose calculations, treatment planning and good patient care are lacking. This is the case in many Latin American and Caribbean countries, where the most prevalent cancers are of the cervix (25 000–30 000 Latin American women die each year due to cervical cancer), breast, and head and neck, all radiosensitive, and hence, potentially curable with radiation therapy.

Recognizing the problems associated with the existing teletherapy equipment, PAHO's HSE/RAD, in collaboration with WHO Headquarters, the IAEA, and the United Nations Industrial Development Organization, convened an Advisory Group meeting in Washington in 1993 to assess the current situation and make recommendations for the development of megavoltage X ray machines that would be simpler to operate and maintain than the linear accelerators in use at the time [7]. To date, no new accelerator has emerged. In fact, the situation has worsened, since most features in today's linear accelerators are computerized. Recent uses of computers are conformal treatments and three dimensional dose distribution computation and displays. In external beam therapy, conformal treatments are achieved through dynamic wedges and/or intensity modulated radiation beams, which may change the dose rate, gantry angle, couch angle and collimator settings during treatment. Treatment verification may be done through radiographic or electronic portal imaging. The latter can now be used for dose computation.

Brachytherapy innovations include low, medium and high dose rate remote-afterloading devices. Treatment planning systems involve the capability of 'inverse planning', i.e. once the desired dose distribution is decided, the field size, gantry, collimator and couch angles, etc., are automatically selected. The computer can also delineate tumour volumes. Recognizing how labour intensive and prone to human error is the transfer of parameters from one device to another, many manufacturers offer an electronic 'linkage'. Diagnostic images acquired for tumour localization are fed to the simulator — if these two processes are not obtained in the same machine — from there to the treatment planning system and finally to the accelerator (or vice versa if inverse planning is not performed). The claim is that this automatic process yields a more accurate precision radiotherapy. Does it? PAHO's perception is that this may be so only if appropriate standards, including clinical protocols and radiation safety standards, are developed and implemented. A point of concern deals with imaging standards for radiotherapy, which seem to be lacking. There are no criteria, for example, for tumour volume delineation by CT or magnetic resonance imaging (MRI); how well are the tumour borders visualized? What are the minimum contrast and resolution needed? When tumour volume definition is done by the computer, is it more accurate than when done by the doctor, especially a relatively untrained one?

Are those the types of accelerators that will replace cobalt units? They will allow for increased patient throughput, but they require continuous testing by a

qualified radiation therapy physicist. Where are they to be trained? As for brachytherapy units, are high dose rate afterloaders the best? Again, the patient throughput is higher, but so are the costs of the radiation shielding required. Also, if the teletherapy ^{60}Co sources — with a five year half-life — are not being replaced on time (see Fig. 2), how can we ensure that ^{192}Ir sources — which need to be replaced every three months because of their three month half-life — will be? In general, HSE/RAD has leaned towards advising low dose rate remote afterloading units. The ministries of health are looking to PAHO for guidance in these areas.

Recent examples of technical co-operation in this area include the upgrading of radiotherapy services in Colombia, where a country wide evaluation is being conducted; Honduras, where remote control low dose rate brachytherapy was introduced; Trinidad and Tobago, where new teletherapy machines and a computerized treatment planning system are being installed, and Panama, which is considering a comprehensive cancer therapy centre.

2.9. Promotion and development of QA programmes in radiation therapy services

The implementation of standards at the institutional level is best monitored by QA programmes. At the regional level, the oldest programme HSE/RAD co-ordinates is the IAEA/WHO (IAEA/PAHO in Latin America and the Caribbean) Postal

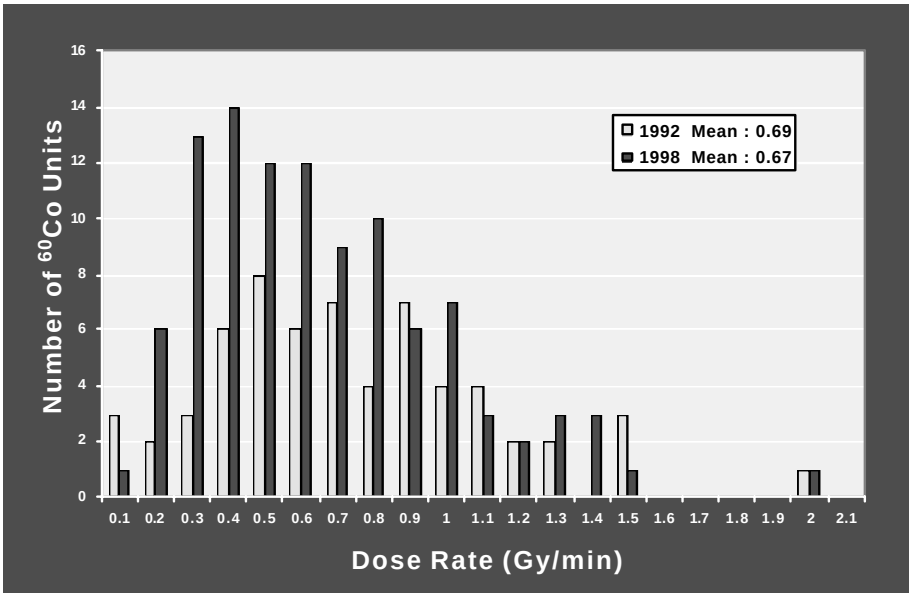

FIG. 2. Absorbed dose rate at 5 cm depth for Latin American and Caribbean ^{60}Co units.

Dosimetry Service, dating from the 1960s. The programme verifies the accuracy of the calibration of high energy radiotherapy units used for cancer treatment by checking the radiation dose delivered to TLDs that are placed by the user in the radiation beam simulating a tumour under treatment. More than 100 units are evaluated yearly in Latin American and Caribbean public and private radiotherapy facilities. The programme runs efficiently thanks to the co-ordination of HSE/RAD with PAHO's country offices in the distribution of the dosimeters to the radiotherapy facilities. The results of the last 30 years were recently published by the IAEA and are reproduced, with permission, as Figs 3 and 4 [8]. They show not only that PAHO's participation in the programme is the largest among the WHO's region, but that the accuracy has been significantly improved in the last ten years.

Had the results of the programme in the San Juan de Dios Hospital in San José, Costa Rica — showing a continued significant deviation — been taken into account by the Costa Rican physicians, it would have prevented the serious radiation overexposure that affected 115 patients, half of whom died, while others exhibited significant conditions such as paralysis.

3. NEED FOR CO-ORDINATION OF STANDARDS

To ensure patient protection, all standards affecting diagnostic and/or therapeutic medical procedures involving ionizing radiation need to be co-ordinated. This means that the ministries of health, responsible for health care standards, and the radi-

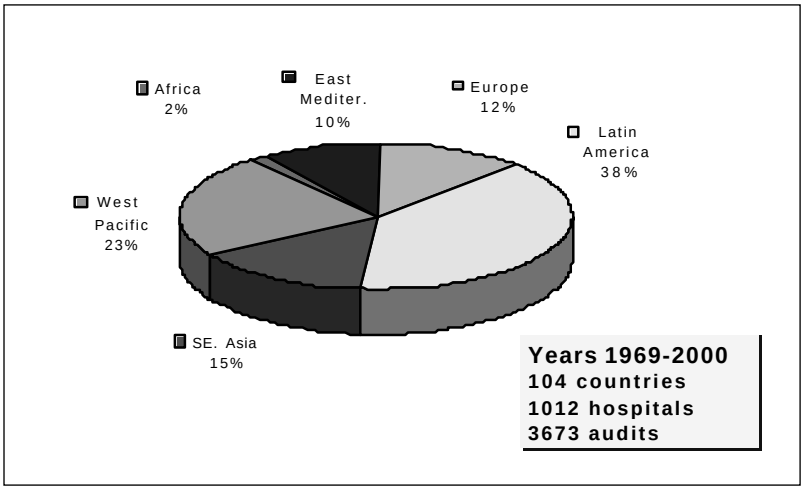

FIG. 3. IAEA/WHO TLD Postal Dose Quality Audit — regional participation.

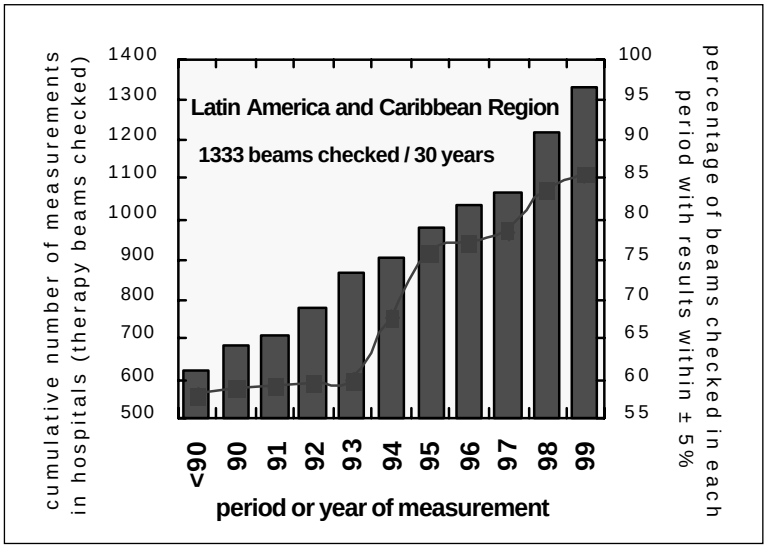

FIG. 4. IAEA/WHO TLD Postal Dose Quality Audit — PAHO participation.

ation safety regulatory authorities, responsible for radiation safety standards, need to collaborate effectively. Furthermore, regulators are not to implement QA programmes in the facilities they inspect. Quality assurance must be performed by the medical facility staff. They are to develop QA procedures to improve the clinical outcome and ensure safe fulfillment of the medical management. Regarding radiation safety, the BSS state that the calibration, QA and clinical dosimetry requirements are to be met by, or be under the supervision or with the advice (in the case of diagnostic radiology) of an expert qualified in the relevant discipline, who is in fact is a medical physicist. The regulator has to ensure that this is done properly and with the periodicity required by the regulations. Only in this manner will the radiological protection of the patients be assured.

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GLOBAL VIEW ON THE RADIOLOGICAL PROTECTION OF PATIENTS: THE WORLD HEALTH ORGANIZATION POSITION

H. OSTENSEN
World Health Organization,
Geneva
E-mail: ostensenh@who.ch

Abstract

Following a major restructuring of the World Health Organization (WHO) the work planned and carried out in the area of radiation medicine as applicable to medical practices now focuses on diagnostic imaging, including not only radiography but also ultrasonography and other imaging modalities as appropriate, and with radiation safety issues incorporated as a natural part of that. The increased focusing on diagnostic imaging has become necessary because a majority of the world's population still has no access to the most basic diagnostic imaging services, and, where it is available, both quality and safety, including radiation protection measurements, are often to be questioned. Consequently, the most important challenge for the WHO Team of Diagnostic Imaging and Laboratory Technology in the area of radiation safety is to advocate for and to assist countries in implementing and following existing laws and regulations, and to educate and train the staff involved in how to do so.

During the past three years and following a major restructuring of the World Health Organization (WHO) the work planned and carried out in the area of radiation medicine as applicable to medical practice has been revitalized and significantly upgraded. However, priorities are now given to the needs of Member States with limited resources. Also, and in addition to the area of radiotherapy, special focus is given to all aspects of diagnostic imaging, including not only radiography but also ultrasonography and other imaging modalities as appropriate; radiation safety issues are incorporated as a natural part of this. Therefore, the former WHO unit of Radiation Medicine has changed its name, and is today part of the Team of Diagnostic Imaging and Laboratory Technology.

The increased focus on diagnostic imaging has become necessary through the simple facts that, firstly, at least one third of all patients requiring medical treatment also need diagnostic imaging before a correct diagnosis can be established and eventual treatment given and, secondly, that a majority of the world's population has no access to the most basic diagnostic imaging services, and, where available, both safety and quality are often to be questioned. Therefore our priority is to try to help improve such services. It would certainly be inappropriate to focus mainly on

sophisticated radiotherapy in areas where no proper medical diagnosis can be established. Similarly, it would be of very little use to allocate major resources primarily to the area of radiation protection in countries and regions where little, if any, diagnostic imaging or therapy equipment is functioning or even installed.

That said, however, we are well aware of our obligations not only towards countries and regions with limited resources but also towards the rest of the world, thereby focusing on how ionizing radiation is being used both for diagnostic and therapeutic purposes.

The rapid development of both equipment and techniques, as well as the increased use of such equipment and techniques by persons other than those specially trained for the purpose, are of major concern to all of us. Reports of injuries to both patients and medical staff using ionizing radiation, especially in interventional and therapeutic procedures, come from all over the world, and it may be reasonable to assume that the published reports represent only the most serious incidents and that there is significant underreporting.

Everybody is aware of the existence of international and national laws, regulations and recommendations on how to ensure the safe and proper medical use of ionizing radiation. To be effective, however, such laws and regulations have to be understood, implemented and followed not only by national authorities but also by each individual involved, be they medical physicist, radiologist, other physician, radiographer and technician, nurse or hospital administrator.

Consequently, the most important challenge for the WHO Team of Diagnostic Imaging and Laboratory Technology in the area of radiation safety is to advocate for and to assist in implementing and following existing laws and regulations, and to educate and train the staff involved in how to do so. The majority of adverse effects or serious accidents caused by the medical use of ionizing radiation can be traced back to human error, be it equipment malfunctioning owing to insufficient maintenance or improper handling, or be it the neglect or lack of knowledge of the staff involved. Thus educational programmes and training materials now being developed and implemented encompass the managerial, medical and technical aspects of diagnostic imaging, including practical radiation safety measurements adapted to local needs, in both small, remote hospitals with very basic equipment and a lack of properly trained staff and larger medical institutions with most types of high technology equipment and well educated staff.

Regardless of location and infrastructure, no education, laws or regulations can prevent accidents and injuries if not every person involved, at all levels from the ministries of health to the least knowledgeable assistant in a specific hospital, understands and sufficiently acknowledges the potential hazards involved in the use of ionizing radiation. Someone has said “radiation does not smell”, and therefore its potential dangers are often not taken seriously enough. Although a physician carrying out a percutaneous transluminal coronary angioplasty may be insufficiently trained in

radiation protection measurements, she or he would most probably know that it could be dangerous. She or he may also be aware of the existence of laws and regulations instituted to prevent injuries and adverse events. The seriousness of not following such laws and regulations, however, needs to be explained over and over again, and not only to national authorities. Thus an increased awareness of everybody involved of the necessity for radiation safety measurements, both in planning and in the practical, medical use of ionizing radiation, is a major obligation for the WHO Team of Diagnostic Imaging and Laboratory Technology. The work performed is aimed at bridging the possible gap between existing laws and regulations on one side and their practical applications on the other.

In our view, this conference represents a unique opportunity for building further on this bridge between laws and regulations and their practical applications. Both aspects are important and necessary, but an eventual success, or improvement of the situation, should be expected only when national and regulatory authorities extend and improve their communication with the target groups in a clear and understandable language. Not everybody working in this area has the knowledge of a medical physicist. 'Gray', 'sievert' and 'effective dose' are important, and mathematical formulas for calculating potential risks may also be beneficial; however, the less scientific aspects of radiation protection, such as a damaged or missing door between an X ray examination room and a waiting area, may well be of some importance. Another example could be to promote research for developing safe, practical, cheap and really usable sterile gloves for the radiological protection of staff performing interventional procedures. Such activities, together with the necessary education and training, are aspects of major concern for the WHO Team of Diagnostic Imaging and Laboratory Technology.

In addition to promoting such rather practical aspects of radiation safety, the WHO Team of Diagnostic Imaging and Laboratory Technology also has a major obligation to ensure that the necessary and updated international and national information, recommendations and guidelines are prepared and in place. In this context we acknowledge the very important necessity of a close collaboration between the various actors in the field, such as other United Nations organizations, the European Community, governmental and non-governmental organizations, and various scientific societies. The development of the Basic Safety Standards [1] was one such task. The ongoing and nearly accomplished project of publishing a new edition of the Manual on Radiation Protection in Hospitals and General Practice [2] is another. Further examples are the IAEA/WHO project on the quality control of radiotherapy installations and, certainly of major importance, this very conference.

When everybody is doing what they are best at, and the closest possible collaboration is achieved, it is our sincere belief that our common goal, namely to improve health for everybody regardless of who they are and where they live, may be accomplished not only more successfully but also without unnecessary delay.

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THE ROLE OF THE UNITED NATIONS SCIENTIFIC COMMITTEE ON THE EFFECTS OF ATOMIC RADIATION IN RELATION TO MEDICAL RADIATION EXPOSURES

P.C. SHRIMPTON
National Radiological Protection Board,
Chilton, Didcot, United Kingdom
E-mail: paul.shrimpton@nrpb.org.uk

1. INTRODUCTION

In 1955, growing global concerns about ionizing radiation led the General Assembly of the United Nations to establish the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). The mandate of this committee, which presently includes 21 Member States, is to assess and report on the levels and effects of exposure to ionizing radiation. Accordingly, UNSCEAR applies scientific judgement in undertaking comprehensive reviews and evaluations concerning radiation and maintains an independent and neutral position in drawing its conclusions. These are published in authoritative reports to the UN General Assembly, with there having been 14 such substantive reports, with technical annexes, since 1958 [1]. The information provided by UNSCEAR assists the General Assembly in making recommendations in relation, for example, to international collaboration in the field of health. Governments and organizations all over the world rely on the committee's evaluations as the scientific basis for estimating radiation risk, establishing radiation protection and safety standards, and regulating radiation sources.

2. UNSCEAR 2000 REPORT

The most recent analysis of the sources and effects of ionizing radiation is published in the UNSCEAR 2000 Report [1]. This comprises two volumes, the first reviewing the sources of ionizing radiation and the second the effects, each being supported by five technical annexes, as listed in Table I. The review addresses all sources of exposure for populations: natural sources, human-made sources such as nuclear weapons and nuclear power production, the occupational exposure of workers and, in particular in Annex D of Volume I, exposures due to the extensive use of radiation in medicine. This comprehensive approach provides a unique balanced analysis of global exposure to ionizing radiation.

TABLE I. SCIENTIFIC ANNEXES TO THE UNSCEAR 2000 REPORT [1]

Volume	Annex	Topic
I — Sources	A	Dose assessment methodologies
	B	Exposures from natural radiation sources
	C	Exposures to the public from human-made sources of radiation
	D	Medical radiation exposures
	E	Occupational radiation exposures
II — Effects	F	DNA repair and mutagenesis
	G	Biological effects at low radiation doses
	H	Combined effects of radiation and other agents
	I	Epidemiological evaluation of radiation induced cancer
	J	Exposures and effects of the Chernobyl accident

3. WORLDWIDE EXPOSURES FROM MEDICAL RADIATIONS

The assessment of medical radiation exposures focuses primarily on exposures received by patients from the use of radiation generators or radionuclides as part of their diagnosis or treatment. Information is given on the frequencies and common

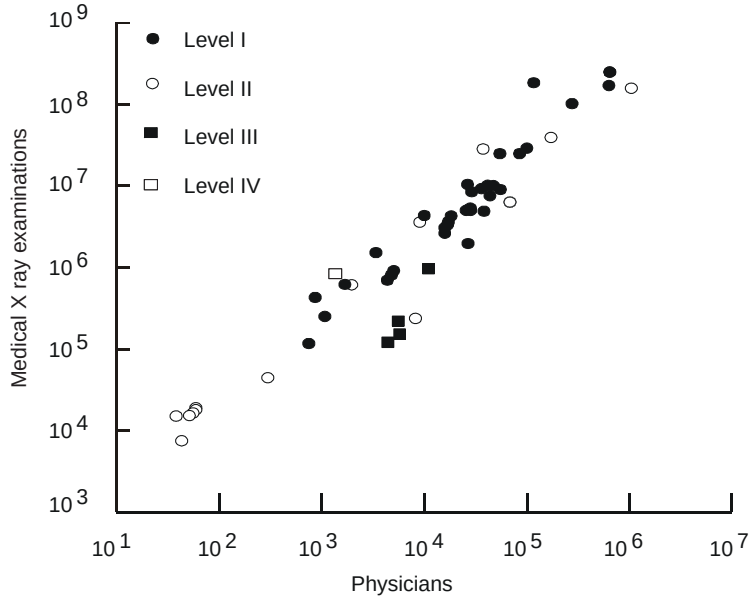

Fig. 1. Broad correlation between annual number of medical X ray examinations and number of physicians in different countries as the basis for their classification into four health care levels.

TABLE II. UNSCEAR POPULATION MODEL FOR THE GLOBAL ASSESSMENT OF MEDICAL EXPOSURES [1]

	Physicians per million population	Population	
		Millions	Per cent of total
Health care level I	>1000	1530	26
Health care level II	>300–1000	3070	53
Health care level III	100–300	640	11
Health care level IV	<100	565	10
World (1996)	—	5800	100

patient dose quantities for different radiological procedures, with diagnostic exposures being summarized in terms of effective doses to individuals and populations. There is also an analysis concerning the exposure of volunteers participating in medical research and a short discussion of radiation incidents in medicine. In all, Annex D of the UNSCEAR 2000 Report [1] includes a substantial amount of data on current medical exposures, both in relation to national and worldwide practices, presented in some 79 tables.

In compiling data for this review, the committee has relied primarily on systematic information provided by 60 countries in response to a questionnaire on national resources and practices in medical radiology for the period of 1991 to 1996. This information was supplemented by a review of the published literature, identifying over 1100 scientific references, so that data were finally included in relation to aspects of practice in 118 separate countries. Inevitably, this process still provides an incomplete picture of the world. For example, information on numbers of radiological procedures was available for about one half of the world population in the case of X ray examinations and only about one fifth for particular types of radiotherapy treatment. It was therefore necessary to scale the available data in order to derive global estimates of practice, and this extrapolation has been carried out by using a global population model previously devised by UNSCEAR for this particular purpose.

The basis for this model is the broad correlation, illustrated in Fig. 1, between the number of X ray examinations in a country and the number of physicians, which is a more commonly known statistic. Accordingly, all countries of the world can be categorized into four health care levels so that the available data within each level can be averaged to provide representative frequencies or exposures which then allow extrapolation to total populations. Clearly, this is a very simplistic approach; nevertheless, the model provides a sufficiently robust assessment of global practice in medical radiology for the purposes of comparison with previous data and the assessment of trends. Details of the population model are given in Table II. Health care level I

TABLE III. WORLDWIDE DOSES FROM IONIZING RADIATION IN 2000 [1]

Source	Worldwide annual per caput effective dose (mSv)
Natural background	2.4
Diagnostic medical examinations	0.4
Atmospheric testing	0.005
Chernobyl accident	0.002
Nuclear power production	0.0002

includes countries with more than 1000 physicians per million population, whereas level IV largely includes the least developed countries, where the ratio is less than 100 physicians per million. Out of the total world population of 5.8 billion in 1996, about one quarter are associated with health care level I, about one half with level II, and about 10% with either levels III or IV. It should be emphasized that this classification is solely for the purposes of modelling global practice and does not imply any judgement on the quality of health care in the countries in question.

Estimates from the UNSCEAR 2000 Report for the worldwide doses from ionizing radiation are summarized in Table III. Overall, the worldwide use of radiation for medical diagnosis gives rise to an annual effective dose of about 0.4 mSv, averaged over the entire population of the world, most of this being due to widespread practice with X rays. In comparison, natural radiation is responsible for a per caput effective dose of about 2.4 mSv per year. Diagnostic medical exposures therefore account for about 14% of the overall average worldwide exposure to ionizing radiation, while representing over 90% of that from all human-made sources. Such broad analyses clearly establish medical radiology as an important topic for radiation protection.

Notwithstanding this general picture, the data collated by UNSCEAR also show that there are significant differences in national practices with medical radiations and a very uneven distribution of doses amongst the world population. For example, over 80% of all the collective dose from diagnostic medical exposures arises from the countries with the highest provisions for health (classified in health care level I), which represent just one quarter of the world population and where the annual effective dose per caput is 1.3 mSv (Table IV). The corresponding per caput dose for health care level IV is lower by a factor of about 60, at only 0.02 mSv per year.

The periodic analyses by UNSCEAR also help identify changes in patterns of practice with time. For example, estimates of the global frequency of medical X ray examinations per 1000 world population have increased steadily between successive reports published in 1988 [2] (280 per 1000), 1993 [3] (300 per 1000) and 2000 [1] (330 per 1000). Similar increases in practice are apparent for health care level I: 810

TABLE IV. GLOBAL VARIATIONS IN PRACTICE WITH DIAGNOSTIC MEDICAL EXPOSURES[a] [1]

	Annual per caput effective dose (mSv)
Health care level I	1.3
Health care level II	0.15
Health care level III	0.03
Health care level IV	0.02
World	0.4

[a]Diagnostic examinations with X rays and radiopharmaceuticals.

medical X ray examinations per 1000 in 1988, 890 per 1000 in 1993 and 920 per 1000 in 2000.

4. CONCLUSIONS

UNSCEAR provides unique and wide ranging data on medical radiation exposures as part of broad periodic reviews of the sources and effects of ionizing radiation. The most recent authoritative analysis of this kind is presented in the UNSCEAR 2000 Report, which includes, in the Annex D of Volume I, qualitative and quantitative information on the frequencies and doses for diagnostic and therapeutic procedures, assessments of global practices, and evaluations of temporal and regional trends. This analysis establishes radiation in medicine as a significant and increasing source of exposure for the world population; yet large variations remain in national and regional usage. There is a continuing need for new national survey data, particularly from the developing world, as the basis for further reviews by UNSCEAR so as to monitor the rapidly evolving and important practices in medical radiology. UNSCEAR also undertakes critical reviews of the effects of exposure to ionizing radiation, with the most recent analysis presented in Volume II of the UNSCEAR 2000 Report. These UNSCEAR reviews are not intended as means to optimize radiological procedures or as guidelines for radiation protection, but nevertheless provide the essential background for such work. In particular, information presented in the latest report will help inform this important international meeting on patient protection.

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INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

F.A. METTLER
University of New Mexico Health Sciences Center,
Albuquerque, New Mexico, United States of America
E-mail: fmettler@salud.unm.edu

The International Commission on Radiological Protection (ICRP) has been involved with protection of patients in medicine since the commission was formed in 1928. The past and current work of the commission emphasizes the importance of patient protection.

Committee 3 is concerned with the protection of persons and unborn children when ionizing radiation is used for medical diagnosis, therapy of for biomedical research as well as with the assessment of the medical consequences of accidental exposures. The current committee membership includes eleven practicing physicians and four physicists from ten different countries.

Recent publications in the medical field include:

— Protection of the Patient in Diagnostic Radiology and Protection of the Patient in Nuclear Medicine (Summary of current ICRP principles) (1993) ;
— Radiological Protection in Biomedical Research, ICRP Publication 62 (1993);
— Radiological Protection and Safety in Medicine, ICRP Publication 73 (1996);
— Genetic Susceptibility to Cancer, ICRP Publication 79 (1999);
— Radiation Dose to Patients from Radiopharmaceuticals, ICRP Publication 80 (1999).

The current work of the committee has centred on producing short, readable, user friendly documents related to important and current issues. In this regard the committee and task groups have just published a document on Pregnancy and Medical Radiation. A document on Avoidance of Radiation Injuries from Medical Interventional Procedures is in press, and two documents, Prevention of Accidents to Patients undergoing Radiation Therapy, and Management of Patient Dose in Computed Tomography are being finalized for publication. Some of these documents have been put on the Internet for comment, and many useful comments have been received before manuscript completion.

The future work of Committee 3 will centre on whether new ICRP recommendations are needed and, if so, how they will apply to medicine. Work in progress includes appropriate use of reference values, education of medical students and general practitioners, doses from new radiopharmaceuticals and release of patients after

radionuclide therapy. Topic areas under review include paediatric issues, genetic susceptibility, medical low level waste disposal and high dose rate brachytherapy.

The ICRP and, in particular, Committee 3 are very interested in the comments by participants of this meeting. Statements on what areas the ICRP should address in the future are highly welcome.

ROLE AND RESPONSIBILITIES OF MEDICAL PHYSICISTS IN RADIOLOGICAL PROTECTION OF PATIENTS

A. NIROOMAND-RAD
International Organization for Medical Physics
San Antonio, Texas
E-mail: nirooma@gunet.georgetown.edu

Abstract

The paper provides a brief history of the International Organization for Medical Physics (IOMP), followed by some general comments on the radiological protection of patients. The importance of establishing scientific guidelines and professional standards is emphasized, as is the need to ensure the protection of patients undergoing radiation therapy. The responsibility of qualified medical physicists in the protection of patients in nuclear medicine and in diagnostic and interventional radiology is also discussed.

1. ABOUT IOMP

The International Organization for Medical Physics (IOMP) was founded in 1963 as an umbrella organization for national medical physics associations worldwide. Today IOMP has 72 national organizations representing about 16 000 medical physicists working in both clinical and research environments. IOMP has several corporate members and four international regional organizations:

(1) EFOMP: European Federation of Organizations for Medical Physics with 32 nations,
(2) ALFIM: Latin American Medical Physics Association with seven nations,
(3) SEAFOMP: South East Asia Federation for Medical Physics with four nations,
(4) NAFOMP: North American Federation for Medical Physics.

The objectives of the IOMP are:

(i) To organize international co-operation in medical physics and to promote communication between the various branches of medical physics and allied sciences.
(ii) To contribute to the advancement of medical physics in all its aspects.
(iii) To advise on the formation of national organizations of medical physics in countries lacking such organizations.

To achieve these goals, over the years IOMP has formed various committees: the Education and Training Committee, Science Committee, Publication Committee, Awards and Honors Committee and Professional Relations Committee. Most recently, the IOMP has formed the International Advisory Council with representatives from all regional chapters as well as international organizations with similar interests (e.g. the International Atomic Energy Agency (IAEA), World Health Organization (WHO), Pan American Health Organization (PAHO) and United Nations (UN)).

To promote improvements in medical physics and biomedical engineering, the IOMP and the International Federation for Medical and Biological Engineering (IFMBE) formed a union in 1981 called the International Union for Physical and Engineering Sciences in Medicine (IUPESM). The union became a full member of the International Council for Science (ICSU), formerly known as the International Council for Scientific Unions, in 1999.

At present the availability of medical physicists and medical physics educational programmes is unevenly distributed in the world. To change this we must share resources, ideas, discoveries, and clinical protocols/standards via international conferences. Furthermore, it is costly, both financially and in terms of staff, to assess new diagnostic and therapeutic devices and to demonstrate the importance of various clinical protocols in the management of cancer patients on a local scale. Therefore, we must share our expertise and resources. Finally, the IOMP is dedicated to protecting patients worldwide from unnecessary radiation exposure while providing optimal diagnostic and therapeutic dose in the management of diseases, especially cancer.

2. GENERAL COMMENTS ABOUT THE RADIOLOGICAL PROTECTION OF PATIENTS

The benefits of ionizing radiation in the diagnosis and treatment of cancer, as well as other conditions such as cardiac ablation, are well established. However, it is clear from this international meeting and other similar scientific meetings that the determination, monitoring and evaluation of patient doses are not easy. Furthermore, radiation doses for individual patients may vary greatly from one radiological procedure to another.

Attention is needed to reduce unnecessary radiation exposure to patients from all types of radiation producing machines and equipment. The patient risk from radiation injury — stochastic and/or deterministic — must be weighed against the benefits of a proper medical examination or treatment as well as the risk of depriving the patient of necessary medical care. The arbitrary reduction of radiological patient doses without regard to the *final outcome* is detrimental to proper medical

care provided to the patient. Sacrificing image quality in order to reduce patient dose is potentially harmful to the patient as well. We believe most individuals prefer to bear the risk of radiation if it means finding a life-threatening lesion, instead of missing it.

Furthermore, the role of radiation exposure incurred from screening procedures such as mammography needs to be properly considered and differentiated from medically indicated procedures. A known radiation induced risk needs to be balanced against the diagnostic efficacy of a screening procedure. In these cases, regulations on standards and guidelines for determination, monitoring, and evaluation of patient doses may be appropriate. Trends in mammography quality before and after the implementation of the US 'Mammography Quality Standards Act (MQSA)' of 1992 have recently been evaluated and published by Suleiman et al. [1]. In this report, the technical data collected in the USA have been compared with the corresponding data in Canada. However, even here it has been recognized that we cannot assume that one dose limit fits all. It is advisable to consider individual patient specifics if it means the difference between detection and missing something.

3. SCIENTIFIC GUIDELINES AND PROFESSIONAL STANDARDS

Universal standards and guidelines for determining, monitoring, and evaluating the medical exposure of patients have long been the objectives of many scientific and professional organizations, international regulatory bodies and government agencies. Efforts directed at attaining these objectives have occupied the time and effort of medical physicists worldwide. The evaluation of this apparent conflict between the two sides of the radiation sword — benefit and harm — is the joint responsibility of qualified medical physicists and authorized physicians. A *qualified* medical physicist has been defined by several organizations [2, 3] as an individual who is competent to practice independently and legally authorized to practice in one or more of the subfields in medical physics. Similarly, an authorized physician has been defined by a number of professional organizations [3–5] as a licensed physician with documented training in and understanding of physics in one or more of the subfields of radiation physics. Certification/licensing/national registry by a professional organization[1] [6] in the appropriate subfields(s), as well as continuing education in handling radiation-producing equipment is essential. A qualified medical physicist and an authorized physician have the expertise necessary to determine, monitor and evaluate this

[1] American Board of Radiology, Tucson, AZ, USA, http://theabr.org; American Board of Medical Physics, Galesburg, IL, USA, http://www.acmp.org/abmp/l; Canadian College Of Physicists in Medicine, Edmonton, Alberta, Canada, http://www.medphys.ca/index.cfm.

tradeoff between patient dose reduction and the patient's final outcome. They have the expertise to establish protocols for radiation procedures and evaluate radiation outcomes. Moreover, medical physicists are charged with educating hospital staff (such as nurses and radiation technologists) in the proper handling of radiation producing equipment and radioactive materials to avoid harmful practices. Experience shows that a substantial dose reduction (nearly 40%) in radiological procedures is possible by training of the physicians and staff [7, 8].

Standards for the performance of radiation procedures in radiotherapy, nuclear medicine, radiology as well as interventional radiology have been developed by scientific and professional organizations[2] [2, 4]. The objective of these standards, which are reviewed and revised on a periodic basis, is to improve the quality of radiation services for patients using increasingly complex technology. These scientific standards are not *rules* to be regulated but a *code of practice* to ensure high quality radiological care of patients. An existing standard may be modified for an individual patient and according to the available resources. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgement regarding the propriety of any specific procedure or course of conduct is the responsibility of an authorized physician in consultation with a qualified medical physicist in light of all the circumstances presented for the individual patient and/or situation.

To protect patients from unnecessary radiation, we need to understand the complexities of as well as the limitations in the assumptions that are made in determining, monitoring and evaluating the patient doses in therapeutic and diagnostic procedures. The role and responsibilities of medical physicists in the containment of radiation dose to the patients are described briefly below.

4. PROTECTION OF PATIENTS IN RADIATION THERAPY

In radiation therapy the first responsibility of a medical physicist and a radiation oncology physician is to the patient: they have to assure the best possible radiation treatment given the state of the current technology, the skills of the staff, and the resources available in the radiation oncology department. A radiation therapy physicist brings a unique perspective — that of a scientist trained in physics, including radiological and clinical physics — to the clinical team in a radiation oncology programme to ensure accurate delivery of all aspects of a treatment prescription. In radiation therapy the radiation protection of the patient is achieved by delivering an accurately prescribed dose (within ± 5%) to the organ/tissue of interest while minimizing the dose to the surrounding uninvolved organs/tissues. Because of potential serious

[2] International Society of Radiology, Bethesda, MD, USA, http://209.67.209.116.

patient injury in radiation therapy, the radiation treatment beams have to be planned by qualified medical physicists who give consideration to individual patient specifics. In addition, due to the ever-increasing complexity in treatment planning computer systems as well as treatment delivery equipment, the skills and training of qualified medical physicists need to be updated on an ongoing basis. With proper education and training of the physicists, the accidental overexposure of a large number of patients, such as what occurred in Costa Rica in 1996, could have been avoided.

Radiation therapy physicists are involved in measuring and calibrating radiation doses from radiation producing equipment such as cobalt machines, linear accelerators, simulators, and computer tomography (CT) simulations, as well as brachytherapy sources and equipment such as low, medium, and high dose rate (LDR, MDR and HDR) and intravascular devices. Following the guidelines and protocols provided by scientific organizations, medical physicists measure head and collimator leakage, the multi-leaf collimator (MLC) leakage/interleaf leakage for this increasingly complex equipment to ensure patient protection from unnecessary radiation. Physicists also perform characterization of radiation treatment beams by measuring and determining various treatment parameters such as beam quality/energy, depth dose characteristics of radiation beams, field size/shape dependence of radiation beams, characteristics of beam modifiers (such as physical, universal and dynamic wedges), and intensity modulation of radiation beams in intensity modulated radiation therapy (IMRT).

In radiation therapy medical physicists are also involved in providing radiation oncology physicians with optimal treatment plans using treatment planning computers with complex calculation algorithms that have inherent limitations in estimating patient doses under all possible conditions or configurations. The limitations in the existing dose calculation algorithms need to be understood and tested. Ensuring the accuracy of treatment parameters (so-called ‘quality assurance’) in radiotherapy, including correct transfer of parameters between the simulator, treatment plan and the treatment machine, and periodic reviews of each patient’s chart are the responsibility of medical physicists. As part of quality assurance (QA), medical physicists often have the output of the radiation treatment beam(s) checked independently either by another qualified medical physicist or by utilizing thermoluminescent dosimetry mailing services [3].

Medical physicists are also involved in the in vivo dose measurements of radiation patients using devices such as films, diodes, and thermoluminescent dosimeters (TLDs). The use of these devices requires special knowledge and expertise. Acceptance testing, commissioning of any radiation producing equipment and the use of any measuring devices in radiation therapy also requires careful application and the

[3] Radiological Physics Center, University of Texas at M.D. Anderson Cancer Center, Houston, TX, USA, http://rpc.mdanderson.org/rpc/index.htm; IAEA, Vienna, Austria, http://www.iaea.org.

attention of medical physicists. The role and responsibilities of medical physicists in radiation therapy have been described in detail by scientific organizations in many publications [9, 10].

5. PROTECTION OF PATIENTS IN NUCLEAR MEDICINE

In nuclear medicine qualified medical physicists are involved in testing, upon installation, all imaging equipment used in nuclear medicine. They also monitor the performance of the equipment on a periodic basis to ensure that everything is functioning within the manufacturer's stated specifications and acceptable performance standards. In diagnostic nuclear medicine — intended for planar as well as tomographic imaging — the goal is to produce the diagnostic images of the highest possible quality consistent with the clinical use of the equipment and to obtain the intended information from the examination. In general, the level of the radiation dose to the patients undergoing nuclear medicine examinations is very low. Therefore, the level of patient protection required in diagnostic nuclear medicine should be on a par with the level of radiation doses.

Furthermore, in nuclear medicine procedures with therapeutic intent, the medical physicist is responsible for preparing a table of organ doses for all the procedures that involve administration of radiopharmaceuticals to patients. The table is specific to the dosage schedule used at the facility. Models — Monte Carlo or otherwise — used for organ calculations assume standard weight, height, size, shape for a standard man, woman and child. Thus, separate tables for patient size and gender are needed. Due to the complexities involved in calculating patient/organ doses in therapeutic nuclear medicine, the radiation protection of patients should be the responsibility of a qualified medical physicist.

6. PROTECTION OF PATIENTS IN DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY

In diagnostic and interventional radiology qualified medical physicists are involved in the process of optimizing the radiation used for imaging. This involves several specific actions. The first is to ensure that the quality of images is adequate for the specific clinical objective. This is achieved through consultation on the selection of appropriate imaging equipment, evaluation of equipment performance in the context of QA programmes, and the education of medical and technical staff on the appropriate imaging procedures and protocols. The primary objective is to ensure that an examination produces the necessary diagnostic information without the application of unnecessary radiation to the patient. A physicist determines the amount of

radiation used for the different types of examinations. These data are used to ensure that sufficient exposure levels are used to produce the required diagnostic information and that appropriate patient dose limiting techniques are being applied. A related function of medical physicists in diagnostic and interventional radiology is to ensure that medical and technical personnel are utilizing appropriate practices to control the levels of radiation to which they are exposed. The medical physicist is a major source of information and a consultation resource to the clinical staff on the reduction of the risk associated with inadequate image quality and incorrect diagnoses. Through this process the medical physicist guides the use of radiation so that it is optimized to produce the necessary diagnostic information without unnecessary human exposure. The role and responsibilities of the clinical medical physicist in diagnostic radiology have been described in detail in many publications [11, 12].

In diagnostic radiology physicists are responsible for monitoring and evaluating the patient exposures and comparing them with the published surveys for similar examinations and calculation of specific organ doses for diagnostic procedures and/or for specific patients. The entrance skin dose (ESD) is still by far the simplest indicator of a patient's injury. The ESD can be measured directly with a TLD or ionization chamber. It can also be estimated from the dose area product (DAP). These quantities are used to determine the radiation risk. The ESD and DAP can be used for comparison purposes with published values such as reference values (RV) (American Association of Physicists in Medicine Task Group Report, in progress). The USA adopted RVs that are similar to the diagnostic reference levels (DRLs) recommended by the European Commission's Medical Exposure Directive [97/43/EURATOM (MED), 1997]. The RVs and DRLs are not and should not be regarded as regulatory limits. They provide upper level guidelines of patient exposure that should initiate facility investigation when the exposure is exceeded. The RVs and DRLs are established based on the judgement of medical physicists and imaging physicians for standard imaging protocols. These protocols are based on some standard conditions (such as phantom size and group of patients) with consideration given to adequate image quality. However, we must realize that RVs and DRLs will vary depending on the available technology, and may not exist for all procedures that are currently performed in radiology. Moreover, we must recognize that the ESD is strongly dependent on the patient's thickness and beam quality. Thus, any arbitrary reduction in the ESD can result in an increased 'noise' (or loss in contrast) and therefore loss in image quality. There are times, however, that patient dose can be reduced without a substantial loss in image quality. The medical physicist is the best suited individual to monitor patient doses and to reduce them (if possible) without substantially compromising the efficacy of diagnostic procedures. Medical physicists are also in charge of patient safety — including radiation, mechanical and electrical safety. They assist physicians in the evaluation of quantitative studies, such as the measurement of cardiac ejection fraction. In addition they are responsible for initial and continuing edu-

cation of the physician and imaging staff to ensure efficient and proper use of radiation producing equipment.

In interventional radiology, an increasing number of invasive procedures, mostly with therapeutic intent, involve the use of medical devices under fluoroscopic guidance. These procedures, typically involving extended fluoroscopic time, are performed by a variety of medical specialists who may not have proper training in the use of radiation. As the number of interventional procedures has increased in the recent past, medical physicists have become concerned about patients' radiation exposure in these procedures. Fluoroscopic devices can deliver radiation at a very high rate of 5 cGy/min. Physicians need to be aware of the potentially serious radiation induced skin injury caused by long periods of fluoroscopy employed in these procedures. Also, in recent years with the increased use of mobile CT in surgical procedures, the doses to the patients have increased considerably. Patients are often unaware that they are exposed to radiation and thus are uninformed of the ill effects of radiation in their procedures.

Examples of interventional procedures that typically require extended fluoro exposure time include, but are not limited to, angioplasty (coronary and other vessels), cardiac ablation, vascular embolization, stent placement, endoscopic cholangiopancreatography, biliary drainage and urinary or biliary stone removal. Although, angioplasty often takes about 45 minutes, on some occasions the procedure may last several hours. The types of injuries to the skin and adjacent tissues which may result from long exposure to fluoro have been reported in the literature [13, 14].

The absorbed dose rate in the skin from a direct beam of a fluoro is typically between 2 and 5 cGy/min, but may be as high as 50 cGy/min, depending on the size of the patient and the mode in which the fluoro is operated. In addition, many fluoro guided procedures involve image recording (fluorography) using films or digital means to record images permanently. The recording modes usually involve much higher dose rates than those used in fluoroscopy. Contributions from fluorography must also be included in assessing the total absorbed dose to the skin.

Radiation injuries, with the onset of months or years after the interventional procedures, cannot be diagnosed easily. When symptoms of injury occur, most interventional physicians may not be in direct contact with the patients. Therefore, many of them are unaware of the potential radiation injuries to their patients. In addition to skin injuries, there is an increased risk of late effects, such as radiation induced cancers in other tissues and organs. The potential for such late effects should be considered in the risk/benefit analysis, especially in paediatric and young adult patients, or in procedures involving exposure to radiosensitive tissues such as the breast. For these reasons, in 1994, the US Food and Drug Administration (FDA),[4] [15] issued a public health advisory warning to physicians about the potential risks of fluoro irradiation.

[4] Food and Drug Administration, Rockville, MD, USA, http://www.fda.gov/cdrh/.

The FDA recommended that institutions:

(1) Adopt standard procedures and protocols for each fluoroscopic procedure,
(2) Determine radiation dose for each fluoroscope,
(3) Evaluate treatment plans to gauge the risk of radiation injury,
(4) Change treatment plans to reduce that risk,
(5) Record in each patient's file the information needed to calculate the absorbed dose of radiation to the skin and other organs.

However, it should be noted that the FDA has no authority to force physicians or institutions to follow these recommendations. It is also worth noting that the interventional procedures could result in an increased occupational exposure to physicians and staff, which is of concern to medical physicists.

7. SUMMARY

A major concern of medical physicists in any of the subfields of radiation medicine — radiology, interventional radiology, nuclear medicine and radiotherapy — is to protect patients from unwarranted radiation. To achieve this, the IOMP concurs with the European Commission's Medical Exposure Directive requiring the services of qualified medical physicist at all radiation facilities. Furthermore, the IOMP recommends adoption of such a policy by regulators and government agencies. The IOMP also recommends establishment of a comprehensive standard operating procedures manuals for each specific radiation procedure in any radiation facility. The procedures should be consistent with the scientific and professional standards, which are established by national and international organizations. The manuals should address all aspects of the radiation procedures including, but not limited to, patient selection, normal conduct of the procedure, action levels in response to the complications, calibration procedures for all radiation producing equipment and radioactive sources, quality assurance checks of the equipment and dose measuring devices, dose calculation protocol, in vivo dose measurement, monitoring, evaluation, and documentation of patient dose(s), safety programmes, emergency procedures, patient education, and staff continuing education. We recognize that each radiation facility is unique. Therefore, the manual must be individualized based on the resources and goals of the programme. However, the basic principles of monitoring and evaluation of the patient doses as well as of the outcomes must be addressed on an ongoing, formalized, systematic, and comprehensive basis. It should also include sample quality assessment and improvement plans that lend themselves to a multi-disciplinary, problem solving approach that is consistent with the continuing quality improvement philosophy at a radiation facility.

In conclusion, the IOMP endorses any effort that promotes the safe use of radiation while minimizing unnecessary dose to the patients and staff. The IOMP does not favour the arbitrary imposition of radiation limits by regulators that would limit the ability of physicians and medical physicists to provide optimal therapeutic or diagnostic radiation to the patient.

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THE ACTIVITIES OF THE INTERNATIONAL RADIATION PROTECTION ASSOCIATION IN RELATION TO THE RADIOLOGICAL PROTECTION OF PATIENTS

G.A.M. WEBB
President,
International Radiation Protection Association

The International Radiation Protection Association (IRPA) was created in 1965 following an initiative from the United States Health Physics Society. The IRPA is an international organization with membership of individual professionals who are members of an affiliated national or regional radiation protection society. The association initially included 11 societies representing 16 countries. IRPA membership is now approaching 20 000 individuals from 42 societies covering more than 50 countries.

The primary objective of the IRPA is to provide a medium whereby international contacts and co-operation may be promoted among those engaged in radiation protection work, which includes relevant aspects of such branches of knowledge as science, medicine, engineering, technology and law, in the effort to provide for the protection of humans and their environment from the hazards caused by ionizing and non-ionizing radiation and thereby to facilitate the exploitation of radiation and nuclear energy for the benefit of humanity.

To accomplish this primary objective, the constitution lists a number of activities that are regarded as appropriate. In broad terms, they are:

— Establishment of radiation protection societies,
— Support for international meetings,
— Encouragement of international publications,
— Encouragement of research and education,
— Establishment and review of standards.

In the context of this conference, the IRPA can be seen as a representative of the professionals in ‘radiation protection’ or ‘health physics’. The IRPA membership includes most of the professionals working in all radiation protection areas and disciplines, including those concerned with protection in medicine, in essentially all developed and many developing countries.

It is also important to recognize what the IRPA is not. It is not a reviewer of basic science such as the United Nations Scientific Committee on the Effects of Atomic Radiation, not an issuer of recommendations such as the International

Commission on Radiological Protection (ICRP) or the International Commission on Radiation Units and Measurements and not a large United Nations organization such as the IAEA or the World Health Organization. The officers and members of the executive council who are elected at the general assembly held every four years are all part time and unpaid. The annual IRPA budget is only just over US $50 000 in total. Thus, although the IRPA has considerable resources in terms of expertise of its membership in its associate societies, it has only minimal resources in terms of central effort and funds.

It is not possible in this brief paper to elaborate on all the activities of the IRPA. A major focus of the IRPA effort is concerned with the control of occupational exposure which, although very relevant to radiation protection in medicine, is not the topic of this conference. However, an example that is relevant relates to the establishment and implementation of radiation protection standards. The current process of setting standards in ionizing radiation protection, which includes standards for the protection of patients, relies heavily on the ICRP to make recommendations. These are then translated into more or less binding form internationally (e.g. IAEA Basic Safety Standards), regionally (e.g. Euratom directives) and nationally. This second phase relies primarily on governmental nominees. This matter was discussed in depth at the Associate Societies Forum during the IRPA-10 Congress in Hiroshima in May 2000. A clear consensus existed among societies present that the IRPA must play a larger role in the standard setting process. Procedures are now being developed with some success. For example, the IRPA invited its member societies to comment on Professor Roger Clarke's proposals for revisions to the basic recommendations of the ICRP. Many societies formed working groups, or undertook member consultation exercises, in order to develop a view on the proposals. Following discussions in Hiroshima, the IRPA produced a report entitled IRPA Member Societies Contributions to the Development of New ICRP Recommendations and transmitted this to the ICRP. It is clear from the subsequent presentations by Professor Clarke that the results of this wide consultation were helpful to the ICRP in refining and developing the proposals. The IRPA intends to continue to use this mechanism for major proposals for standards, including in due course the revision of the Interagency Basic Safety Standards.

Dissemination of information on such consultation processes and other aspects of IRPA work including helpful information on 'hot topics' now takes place exclusively through the IRPA website, which was completely rebuilt during the second part of the year 2000. The site can be found at www.irpa.net.

The individual members of the IRPA have a substantial responsibility for implementing new standards, normally after they have been translated into national regulations. Another IRPA activity that is relevant here is to encourage the establishment of radiation protection societies throughout the world as a means of achieving international co-operation among those engaged in radiation protection. This may be seen as an activity aimed at improving professional levels and enhancing the global

'safety culture'. As the major use of radiation in a large number of countries throughout the world is in medicine, this emphasis on improvement of professional standards should have a direct impact on the protection of patients which relies to a substantial extent on a safety culture rather than on the rigid application of limits. Over the next few years particular attention will be paid to the promotion of new societies in Africa. The IRPA hopes to enlist the support of the societies in South Africa, the United Kingdom and France in this initiative. A complementary IRPA activity which also contributes to the overall safety culture is to encourage and provide for education, training and continuous professional development in radiation protection.

At the Hiroshima Congress, the IRPA Executive Council was asked to increase the interaction between the IRPA and other professional societies, especially those in the medical area. This conference will provide a useful and timely opportunity to do so, and the IRPA is very pleased to have been invited to co-operate in the conference.

INTERNATIONAL SOCIETY OF RADIOLOGY AND RADIATION PROTECTION

C.G. STANDERTSKJÖLD-NORDENSTAM
President,
International Society of Radiology

The purpose of the International Society of Radiology (ISR), as being the global organization of radiologists, is to promote and help co-ordinate the progress of radiology throughout the world. In this capacity and as a co-operating organization of the IAEA, the ISR has a specific responsibility in the global radiological protection of patients. In fulfilling this task, the ISR works together with other international organizations, the World Health Organization and its regional subsidiaries, the International Commission on Radiological Protection and the International Commission on Radiation Units and Measurements, the International Society of Radiographers and Radiological Technologists and now the IAEA and so many other bodies and societies.

Globally, there are many users of medical radiation, and radiology may be practised in the most awkward circumstances. The individuals performing X ray studies as well as those interpreting them may be well trained, as in industrialized parts of the world, but also less knowledgeable, as in developing areas. The problems of radiological protection, both of patients and of radiation workers, still exist, and radiation equipment is largely diffused throughout the world. That is why a conference like this is today as important as ever.

Radiation protection is achieved through education, on the one hand, and legislation, on the other. Legislation and regulation are the instruments of national authorities. The means of the ISR are education and information. Good radiological practice is something that can be taught. The ISR is doing this mainly through the biannual International Congress of Radiology (ICR), now arranged in an area of radiological need; the three previous ICRs were in China, in India and in South America; the next one is going to be in Mexico in 2002. The goal of the ICR is mainly to be an instructive and educational event, especially designed for the needs of its surrounding region.

The ISR is aiming at producing educational material. The International Commission on Radiological Education (ICRE), as part of the ISR, is launching the production of a series of educational booklets, which also include radiation protection. The ICRE is actively involved in shaping and organizing the educational and scientific programme of the ICRs.

The ISR is also active in distributing informative material. Criteria for the appropriate use of medical radiation, including the proper replacement of radiation

methods by non-radiation imaging modalities, have been worked out by the American College of Radiology (ACR Appropriateness Criteria 2000). The ISR is active in distributing this book to all the national societies of radiology for their perusal. The ISR will also be involved in distributing other important information on radiation protection, such as the ICRP Report 84 on Radiation and Pregnancy.

In industrialized countries, medical radiation forms approximately one quarter of the population exposure to ionizing radiation. Emerging modalities such as computed tomography change the scene of radiation exposure continuously. We need to participate actively in surveying this development and in informing the public and the authorities on radiological problems arising. The ISR will be part of this activity and in this context greets this IAEA meeting as a much needed one.

GLOBAL VIEW ON THE RADIOLOGICAL PROTECTION OF PATIENTS: POSITION PAPER BY THE INTERNATIONAL SOCIETY FOR RADIATION ONCOLOGY

H. SVENSSON
Representative of the International Society for Radiation Oncology
E-mail: hans.svensson@radfys.umu.se

I am very happy to be the representative of the International Society for Radiation Oncology (ISRO). This society is a federation of regional and national societies. These societies include about 80 000 radiation oncologists, physicists and related specialists.

I should like to point out that today there are about ten million new cancer cases per year in the world. The numbers of cases for developed countries are very high at higher ages, and there are also many cases at somewhat lower ages in developing countries. This is the present situation which will, however, change substantially. Indeed, in 15 years time we expect instead, ten million new cancer cases per year in developing countries, while in developed countries the situation will be much the same as today. It is obvious that we shall need a lot of resources for the developing countries in the future.

The incidence of cancer per year in developing countries is about 0.08 to about 0.2% of the population. In some developed countries, up to 0.5% of the population will be diagnosed with cancer each year — this is a very high figure. You must also look at prevalence: that is, how many of those that have had the diagnosis 'cancer' are still alive. In some developed countries, up to 3% of the population have had the diagnosis 'cancer' at some stage in their life. The projected number of new cases in the year 2000 is five million for developing and five million for developed countries. On the basis of practices exercised today in many advanced developed countries, it is estimated that 50% of these would need radiotherapy. In some countries, up to 60% of cancer cases receive at least one course of radiation treatment.

Of course, good quality assurance is a matter of life and death for the patient, and radiation protection and quality assurance are in many situations much the same thing. What can the international societies do in this context? We can try to inform and teach our friends in less developed countries. For this reason, many educational meetings have been organized by the ISRO. The society tries to hold these meetings outside developed areas such as Europe and north America, and to convene them in developing regions of the world, instead. By including experienced teachers from more developed areas, the society seeks to help those who do not yet have all the knowledge they need.

Finally, I want to corroborate the comment by the President of the Society, who noted that international meetings help to point out the differences in problems in various parts of the world, so that both developing and developed countries benefit from participation in these meetings. I think this is a very important comment. We all play a role in promoting safe and effective practice.

INTERNATIONAL SOCIETY OF RADIOGRAPHERS AND RADIOLOGICAL TECHNOLOGISTS AND RADIATION PROTECTION

A. YULE
President,
International Society of Radiographers and Radiological Technologists
E-mail: sandy.yule@uhw-tr.wales.nhs.uk

The International Society of Radiographers and Radiological Technologists (ISRRT) is delighted to have been asked to co-operate in this seminar, and I appreciate the opportunity to speak before this audience.

I would like to give you a very brief history and description of the organization and show how it works to promote radiation protection for both patients and workers.

The ISRRT was formed in 1962 with 15 national societies and by the year 2000 has grown to comprise more than 70 member societies. The main objects of the organization are to:

— Improve the education of radiographers,
— Support the development of medical radiation technology worldwide,
— Promote a better understanding and implementation of radiation protection standards.

The ISRRT has been a non-governmental organization in official relations with the World Health Organization (WHO) since 1967. It is the only international radiographic organization that represents radiation medicine technology and has more than 200 000 members within its 70 member countries.

Representatives of the ISRRT have addressed a number of assemblies of WHO regional committees on matters relating to radiation protection and radiation medicine technology. In this way, the expertise of radiographers worldwide contributes to the establishment of international standards in vital areas such as

— Quality control,
— Legislation for radiation protection,
— Good practice in radiographic procedures,
— Basic radiological services.

The ISRRT believes that good and consistent standards of practice throughout the world are essential.

To promote these efforts, individual members of the ISRRT act as advisers or consultants in specific WHO programmes related to radiation protection and in the production of related educational material.

In 1971, the ISRRT participated in a seminar in Tehran organized jointly by the WHO and the IAEA. The subject matter of this seminar was the training of radiographers and other technical personnel in the use of ionizing radiation and radionuclides. Since that time the ISRRT has been working hard with societies and organizations all over the world to promote the principles of the Tehran document.

The ISRRT is committed to the goals of the WHO and has established its own working committee to advance these objectives in the speciality of medical radiation technology. Within Europe, the society actively monitors all directives concerning radiation protection, and an expert group has been set up in order to provide a rapid and considered response. These directives are important to the practice of our profession but, unfortunately, many of them tend to arrive without notice and with little time left before deadlines for comments. It is obviously important that such documents arrive in good time if the valuable comments from this working party are to be considered.

— The international society considers that the radiographer or the radiological technologist is the most important individual within the radiation medicine team for the implementation of safe radiation protection practice.

It is estimated that more than 90% of ionizing radiation in medicine is applied by radiographers or radiological technologists. By their expertise, skill and care, they will determine, within agreed limits, the amount of radiation administered to patients.

The technologists' prime expertise and responsibility is to undertake the whole range of techniques in diagnostic imaging and radiation therapy and to subsequently assess the quality and outcome of the work done.

To ensure that correct examination or treatment is performed effectively and safely, the technologist must be

— Appropriately qualified,
— Able to communicate with patient and staff,
— Able to correctly position the patient,
— Set the parameters for the source of the radiation and image recording device,
— Use complex equipment safely and correctly,
— Assess the quality of the final image,
— Ensure that the image is delivered quickly to those responsible for the care of the patient.

As we all know, the use and application of radiation medicine technology differ greatly all over the world. The ISRRT recognizes these differences, and one of its

fundamental aims is to support developing countries by assisting national societies to formulate and maintain training programmes and continuing educational activities. Professional organizations that are members of the ISRRT can therefore call on the full range of education experience and practical expertise of the world's leading radiographic societies.

Different countries have different problems. In the majority of cases these problems can only be solved by those who have the responsibility for the delivery of medical imaging and radiation therapeutic services in each individual country. However, the requirement for education, training and continuing education of those involved in the application of ionizing radiation to people should have high priority on the agenda of all countries.

To promote these agenda the ISRRT is currently collaborating with the WHO in the production of training manuals, to be used primarily as education tools for the training of radiological technologists in developing countries. The first manual which deals with the important subject of quality assurance should be available for free distribution by the WHO, by the end of July.

To encourage the exchange of information, the ISRRT organizes international conferences, seminars and workshops in all regions of the world. In particular, improvement in education is promoted through international teacher seminars being held in various countries, specifically to further the understanding of the requirements for radiation protection.

An important area of expertise available from the ISRRT is its close co-operation with smaller developing countries. As an example, several workshops have been held for technologists in the African region. These workshops are extremely well attended, and radiation protection of both patients and staff is given a prominent position in these workshops. It is hoped that with the co-operation between the ISRRT and governments, the number of workshops provided could be increased.

I would like to end by emphasizing that the ISRRT has both the expertise and the ability to contribute to the improvement of safe radiation practices all over the world by:

— Promoting awareness of the fact that the largest amount of ionizing radiation received by individuals for medical purposes is administered by radiographers or radiological technologists;
— Insisting that all those who apply ionizing radiation to humans should be appropriately trained and educated;
— Improving communication between all professionals involved in the delivery of imaging and therapeutic services worldwide;
— Co-operating fully with the WHO and other international organizations;
— Assisting in the establishment of professional radiographic societies to promote the development of education and, in particular, radiation protection;

— Promoting and encouraging research in practical areas;
— Developing and co-operating in the production of specialized publications;
— Organizing conferences, seminars and workshops in radiation protection;
— Being prepared to give advice and assistance whenever requested.

GLOBAL VIEW ON THE RADIOLOGICAL PROTECTION OF PATIENTS: POSITION PAPER BY THE WORLD FEDERATION OF NUCLEAR MEDICINE AND BIOLOGY

H. AMARAL
President,
World Federation of Nuclear Medicine and Biology
E-mail: hamaral@alemana.cl

It is a great honour and a source of satisfaction for me to represent the World Federation of Nuclear Medicine and Biology (WFNMB), which is an organization with 60 member countries that are represented by their national nuclear medicine societies and whose main aim is to promote the correct use of this form of medical specialization.

I would like to congratulate the organizers of this conference for bringing to the discussion table a topic of such importance, which unites the main international organizations and experts in a field that is currently highly sensitive. The radiological protection of patients has rarely been the focus of such attention as it is on this occasion.

In particular, I would like to thank the IAEA, the World Health Organization and the Pan American Health Organization, as well as the Spanish authorities and the European Union, for organizing this extraordinary event.

The world is undoubtedly changing at an unprecedented rate. We can now see how human activities are pushing our physical and biological environment to the limits of what appears to be tolerable. In the nineteenth century, the great hope for progress was based on a generalized optimism that science would bring about a gradual improvement in living conditions, and bring us even closer to a kind of paradise on earth where technological advances would solve all our ills; in the second half of the twentieth century, this same faith placed more emphasis on politics as the source of progress for humanity. At the beginning of the new millennium, economic factors will probably emerge as the dominant force in human development.

Now, at the dawn of the twentyfirst century, we are concerned to see that science is losing ground in global decision making processes relating to progress. This is particularly obvious as regards ionizing radiation. To a large extent, this is due to a certain degree of public mistrust in technology, possibly owing to irresponsible management of this precious resource.

We are now living in a world where extreme positions and opposing visions regarding progress flourish. On the one hand, we find ‘technophile’ movements, which are based on the belief that humanity can find all it needs for its complete realization and well-being in scientific and technological development. In opposition to these groups, so-called ‘technophobe’ movements flourish apace that fanatically

believe that technology and, by extension, science are the root of all the evil in the world. These groups attract, in particular, young people and some progressive intellectuals. Everyone is acquainted with these groups. They structure and organize themselves as international movements. They can now count on a warm welcome on the part of many communications media and put their opinions forward with great fluency in the assemblies of many world organizations. Often, science has no place or is simply not heeded in these fora. Nowadays, we often find important decisions regarding an activity or a region being taken on the basis of somewhat emotional or even pseudoscientific reactions. In many cases, propaganda, a pamphlet or a protest demonstration carry more weight than a serious discussion of ideas.

Unfortunately, we must recognize that, as with all human advances, science offers the hope of well-being and life for many, but it also has many aspects that can be criticized.

Undoubtedly, science and technology have made great mistakes throughout history. In the case of nuclear energy, for reasons I will not go into here, we see that all aspects of the development of this technology are especially vulnerable to public criticism. One only needs to say the word ‘atomic’ or ‘nuclear’ for a significant number of people to show an immediate negative emotional reaction.

Nuclear energy has benefited humanity tremendously and, provided it is kept safe, will bring even more benefits in the future, considering its many peaceful uses. The recent advances in our knowledge of the effects of radiation on biological systems should substantially enhance the public perception of nuclear energy. The failure to understand that ionizing radiation is an inherent part of nature gives rise to feelings of anxiety and insecurity. Although ionizing radiation is a known carcinogenic agent for humans, we now know that it is safe and effective if it is used responsibly. Over the past fifty years, numerous epidemiological studies have been carried out of adult human populations exposed to radiation through medicine, their occupation or in the military, and the lowest radiation dose that has been found to constitute a statistically significant risk is 100 mSv (10 rem).

Another aspect worthy of note at this conference is the emphasis that has been given to the relationship between radiation and biomedical research. Scientific progress is not divorced from the negative phenomena referred to above. Moreover, since this branch of science is closest to humanity it is probably the one that generates the largest number of ethical conflicts. Happily, we are now seeing increased awareness in the design of medical research. It is inconceivable nowadays for a scientific institution not to have an independent ethics committee that approves any research project involving or affecting human beings at all stages of their development. To take one example from the nuclear field: cases such as those that occurred just a few decades ago, where disabled people, orphans, convicts and old people were used as research subjects for nutritional studies and studies to evaluate the risk of exposure to ionizing radiation, would be unthinkable today.

These factors frequently go beyond the regulations, and we must bear in mind that the ultimate responsibility for the protection of patients against ionizing radiation lies with the doctor treating them. The training of professionals is therefore a critical element in any plan aiming to reduce radiation levels in medical practices.

Medical research must now comply with strict bioethics criteria that are applied almost universally. Factors such as social value, scientific validity, the risk/benefit ratio and respect for people participating in research are now indispensable in the design of any scientific project.

One of the great advances in medicine and medical research has been the acceptance that obtaining the informed consent of people participating in the research is an essential requirement. This also means that we have to make sure that the individuals understand the aim of the study and are aware of its risks and potential benefits as well as the existence of possible alternatives. We are thus obliged to respect their freedom of choice to participate in, or subject themselves to, a study on an entirely voluntary basis, and their complete freedom to leave a study if they so desire.

I would like to take up one final point that relates to the rational use of resources. Until quite recently, it was thought that any lawfully available technological resource could be used, a view that was especially true in relation to medicine. Nowadays, however, there is a strong trend towards the view that the use of both diagnostic and therapeutic techniques must be based on scientific evidence of their usefulness. The empirical use of available resources, without some evidence justifying this use and without a favourable cost–benefit ratio, is no longer accepted as good practice.

Conferences such as this one are undoubtedly the most serious manner in which we can tackle these problems, and the conclusions and recommendations we reach must be widely disseminated in the community. The medical applications of radiation have the greatest potential for reversing the negative reputation of nuclear energy, and our institutions and organizations should make every effort to conduct a worldwide campaign to publicize the ‘good atom’ — a highly beneficial force for humanity when it is used rationally and safely.

BRIEFING SESSION

Chairperson

H.M. OLERUD
Iceland

THE CURRENT USES OF RADIATION IN MEDICINE

P.C. SHRIMPTON
National Radiological Protection Board,
Chilton, Didcot, United Kingdom
E-mail: paul.shrimpton@nrpb.org.uk

Abstract

Ionizing radiation is firmly established as an essential tool for diagnosis and therapy in medicine, although patterns of use vary widely around the world. Diagnostic examinations are conducted mainly with X rays (diagnostic radiology) and less commonly by administering radiopharmaceuticals to patients (nuclear medicine). Radiotherapy is mostly carried out using external beams of radiation (teletherapy), although some patients receive direct applications of sealed radionuclide sources (brachytherapy) or therapeutic administrations of radiopharmaceuticals. Global data from the United Nations Scientific Committee on the Effects of Atomic Radiation indicate an annual total of about 2500 million diagnostic radiological examinations in 1996: 78% involving medical X rays (at a mean rate of 330 per 1000 world population), 21% involving dental X rays (mean rate 90 per 1000) and only 1% involving nuclear medicine (mean rate 5.6 per 1000). Over 90% of the estimated annual total of about 5.5 million complete courses of radiation treatment are conducted by teletherapy or brachytherapy, with mean rates of 0.8 and 0.07 per 1000 world population, respectively; radiopharmaceuticals are used in only 7% of all treatments (mean rate 0.065 per 1000). Over three quarters of all diagnostic procedures and over half of all treatments occur in developed countries, which collectively represent only one quarter of the world population. The general global trend is for increasing numbers of procedures. The paper discusses the current uses of radiation in medicine, including diagnostic radiology, diagnostic nuclear medicine and radiotherapy.

1. INTRODUCTION

Ionizing radiation was first used in medicine at the turn of the 19th century, following the discovery of X rays. Over the last 100 years, radiology has found increasing application in medicine and is today firmly established as an essential tool for diagnosis and therapy. The overwhelming benefits to patients from properly conducted procedures have fostered the widespread use of medical radiology, although patterns of use vary significantly around the world.

Medical radiology can broadly be categorized into three general areas of application. The most widespread use of radiation remains diagnostic radiology, which involves imaging with X rays. Diagnostic procedures are also conducted by the administration to patients of radiopharmaceuticals as biological tracers in the practice

of nuclear medicine. Finally, radiation is used in a quite different manner in radiotherapy, where the clinical intention is to deliver cytotoxic levels of dose to well defined target volumes of the patient to effect treatment.

Global reviews of the use of radiation in medicine have been conducted periodically by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), most recently for the period 1991–1996 in the UNSCEAR 2000 report [1]. Practice worldwide has been assessed by extrapolation from the limited national

TABLE I. PATTERNS OF PRACTICE WITH X RAYS

	1996 [1]				1990 [2]
Examination	HCL I[a]	HCL II[b]	HCL III[c] and IV[d]	World[e]	World
	Per cent contribution to annual total number of medical X ray examinations				
Chest	36	58	19	41	57
Skeleton	32	21	41	29	21
Head	6	4	14	6	4
Abdomen	4	8	7	5	4
GI tract	6	3	10	5	6
CT	6	1	0.4	5	3
Mammography	3	0.4	<0.1	2	1
Angiography and interventional	1	0.2	<0.2	1	0.6
All medical X rays	Absolute annual number of examinations (millions)				
	1410	470	24	1910	1600
	Annual frequency of examinations per 1000 population				
	920	150	20	330	300
All dental X rays	Absolute annual number of examinations (millions)				
	475	42	0.1	520	—
	Annual frequency of examinations per 1000 population				
	310	14	0.2	90	—

[a]Health care level I: >1000 physicians per million population (26% of world population).
[b]Health care level II: >300–1000 physicians per million population (53% of world population).
[c]Health care level III: 100–300 physicians per million population (11% of world population).
[d]Health care level IV: <100 physicians per million population (10% of world population).
[e]World population in 1996: 5800 million.

data available on the basis of a global population model in which countries are stratified into four levels of health care determined by the number of physicians per million population, as defined in Table I. Results from this analysis by UNSCEAR of global practice in medical radiology are presented below. These should not, however, be overinterpreted beyond the significant uncertainties in the reliability and representativeness of the data presented [1].

2. DIAGNOSTIC RADIOLOGY

Imaging with X rays utilizes a range of techniques. The most well established and common technique is conventional radiography, in which a static image of the X ray beam is captured, after transmission through the patient, using a film sandwiched between intensifying screens in a cassette. Real time imaging is provided by fluoroscopy, where generally an electronic image intensifier is used to detect the X ray beam and images are displayed on a TV monitor. This is used, for example, in studies of the gastrointestinal (GI) tract commonly known as barium meals and barium enemas, where barium is introduced into the stomach or colon to enhance image contrast.

In the 1970s, diagnostic radiology was literally revolutionized with the development of computed tomography (CT). This utilizes a rotating fan beam of X rays, a bank of detectors and a computer to reconstruct high quality cross-sectional images of the patient. Continuing technological developments, such as spiral (or helical) scanning, multislice scanners and CT fluoroscopy, have improved both the speed and the quality with which images are obtained and have fuelled a steady growth in CT. CT represents one of the earliest forms of digital X ray imaging, in which images are captured and stored in a digital format. More general developments in digital radiology include digital fluorography based on the image intensifier, computed radiography (CR) utilizing a special storage phosphor plate and, most recently, active matrix detectors of amorphous selenium or silicon. Such digital imaging provides key advantages in the manipulation, storage and transmission of images. For example, images taken before and after an intravenous injection of iodine can be subtracted so as to provide a clear image of the blood vessels, known as a digital subtraction angiogram.

The advances in imaging and in catheter technology have facilitated the development of interventional radiological techniques, in which imaging is used to help guide therapeutic procedures. For example, angioplasty involves placing and expanding a balloon catheter inside a blood vessel so as to dilate the vessel and improve blood flow. Interventional radiology continues to evolve, and other commonly used techniques include embolization, in which blood vessels are occluded, and the placement of catheters to drain abscesses, take biopsy samples and deliver drugs.

Diagnostic radiology is in general conducted by doctors and technicians with specialist training, such as radiologists and radiographers, although circumstances may vary between different countries, particularly in the developing world. Some examinations may also be performed by other groups, such as the use of fluoroscopy in operating theatres by orthopaedic surgeons or interventional procedures conducted, for example, by cardiologists.

Global practice with X rays is summarized in Table I, together with data concerning regional and temporal trends. The annual number of all types of medical X ray examination in the world was about 1900 million in 1996, corresponding to an annual frequency of 330 examinations per 1000 world population. This frequency is about 10% higher than the previous estimate by UNSCEAR of 300 per 1000 for the period 1985–1990 [2], so that practice is clearly continuing to expand. It is also evident that there is a very uneven distribution of examinations between countries, with much of the world having insufficient access to X ray services. Three quarters of all examinations occur in the countries of health care level I, which account for only one quarter of the world population. Only 1% arises from the lower health care levels III and IV, which include one fifth of the world population. The average frequencies for the levels vary by a factor of 50, being 920 per 1000 in health care level I and only 20 per 1000 in levels III and IV.

Table I also includes data concerning the relative importance of broad types of examination. Chest X rays remain the most common procedure, representing about 40% of the total on a global scale. Examinations of the skeleton account for about a further 30%, while the more complex procedures involving the GI tract and CT each provide about 5%. There are also contributions of 2% from mammography and about 1% from angiography and interventional procedures.

As well as significant differences in the overall use of X rays between the different health care levels of the global model, the UNSCEAR analysis also reveals variations in patterns of practice. Table I indicates clear differences in the relative importance of each type of examination between the levels. In particular, complex examinations, such as CT, and angiography and interventional procedures, are much more important in health care level I. This is also the case for mammography, which in many developed countries is used for population screening for breast cancer.

Moreover, the analyses by UNSCEAR reveal changing patterns of practice with time. Global practice for 1990 [2] is also summarized in Table I. Apart from an increase of 10% in the overall worldwide frequency of examinations between 1990 and 1996, particular increases in importance on a global scale are also apparent for CT, mammography, and angiography and interventional radiology.

In addition to the above medical X ray examinations, X rays are also commonly used in relation to dental care. Such dental X rays are often conducted by dentists, working away from hospitals or medical clinics. On a global scale, there are about 500 million dental X ray examinations per year, which corresponds to a frequency of

90 per 1000 world population (Table I). This is just over a quarter of the rate of medical X rays and once again there is a very uneven distribution between countries. Over 90% of all practice arises from the countries in health care level I, where the average frequency is 310 per 1000 population. At the lowest levels (III and IV), the rate is lower by a factor of 1500.

3. DIAGNOSTIC NUCLEAR MEDICINE

The second important use of radiation for imaging and diagnosis is in nuclear medicine. This involves the administration of radionuclides to patients, by injection, inhalation or ingestion, broadly as a biological tracer technique to study organ or tissue function. Diagnostic nuclear medicine is more about physiology and pathology than anatomy. The techniques hinge on incorporating a suitable radionuclide into a pharmaceutical appropriate to the nature of the investigation. In practice a wide range of pharmaceuticals are used, incorporating more than 20 radionuclides that meet the necessary requirements for effective and efficient imaging, although ^{99m}Tc forms the basis for over 80% of all radiopharmaceuticals. Iodine-131 is also still widely used in many countries, particularly in the developing world.

Uptake of the radiopharmaceutical in particular organs, such as the thyroid, can be measured with a simple radiation detector, whereas imaging is carried out using a rectilinear scanner or, more commonly, a large field of view gamma camera. In addition to conventional planar imaging, techniques have also been developed to allow emission tomography which, rather like X ray CT, provides cross-sectional information. These techniques include single photon emission computed tomography (SPECT) or the specialized technique of positron emission tomography (PET), which uses short lived biologically active radionuclides, such as ^{15}O, ^{11}C, ^{18}F and ^{13}N.

Global practice in diagnostic nuclear medicine is summarized in Table II, together with data concerning regional and temporal trends. Such procedures are much less common than X ray examinations, by about a factor of 60. The annual global total in 1996 was about 32 million procedures, corresponding to a frequency of 5.6 per 1000 world population. This estimate is about 25% higher than the frequency for 1990 and indicates quite a considerable expansion in practice. Once again, procedures are very much concentrated in the developed world, with nearly 90% of all practice occurring in health care level I, at a rate of 19 per 1000 population. The mean frequency for the lowest levels (III and IV) is some 100 times lower.

Diagnostic nuclear medicine has applications across a wide range of medical disciplines, with bone scans for metastases being the most common procedure on a global scale, followed by thyroid scans and cardiovascular scans (Table II). Patterns of practice also vary between different countries with, for example, uptake studies and scans of the thyroid dominating in the lower health care levels. In terms of trends with

TABLE II. PATTERNS OF PRACTICE IN DIAGNOSTIC NUCLEAR MEDICINE[a]

Procedure	1996 [1]				1990 [2]
	HCL I	HCL II	HCL III and IV	World	World
	Per cent contribution to annual total number of diagnostic nuclear medicine procedures				
Bone	24	21	18	24	29
Thyroid scan	22	27	57	22	11
Cardiovascular	14	15	6	14	15
Liver/spleen	11	8	2	11	8
Lung perfusion	10	2	2	9	12
Brain	7	4	4	7	2
Renal	5	14	7	6	9
Thyroid uptake	5	3	2	5	5
Lung ventilation	2	1	0.1	2	7
All procedures	Absolute annual number of procedures (millions)				
	29	3	0.2	32	24
	Annual frequency of procedures per 1000 population				
	19	1.1	0.2	5.6	4.5

[a]See footnotes to Table I for definitions of the UNSCEAR global population model.

time, bone scans, renal scans, and lung perfusion and ventilation studies have all decreased in relative importance since the previous analysis by UNSCEAR for 1990 [2], whereas there have been relative increases for thyroid, liver/spleen and brain scans.

4. RADIOTHERAPY

The third general application of radiation in medicine is in radiotherapy, which is particularly important in the treatment of malignant disease. The clinical intention may be either to eradicate cancer (curative treatment) or to alleviate symptoms (palliative treatment). Three different treatment modalities are employed.

The principal mode of treatment is teletherapy, in which external beams of radiation are focused onto a target treatment volume. Superficial treatments utilize lower

energy X ray beams or electrons, whereas deep seated tumours are treated with high energy photon beams from conventional X ray units, linear accelerators (LINACs), or large sealed radionuclide sources, principally ^{60}Co. Treatments are carefully planned and delivered, and typically include multiple fields and series of exposures over a period of time. On a global scale, over a fifth of all teletherapy treatments involve the breast (21% of the total number), with the next most important broad categories being lung (17%), followed by head and brain (13%), gynaecological tumours (11%), prostate (7%), lymphoma (5%) and rectum (4%). Treatments of leukaemia and benign disease each account for about 3% of the total practice.

The second important treatment modality is brachytherapy, in which an encapsulated source, or group of such sources, is positioned on or in the patient by surface, intracavitary or interstitial application. Sources may be implanted temporarily into superficial and easily accessible tumours in the form of wires, pellets or needles of ^{137}Cs, ^{60}Co or ^{192}Ir. These may be positioned manually or loaded remotely following implantation of an applicator. Permanent implants are sometimes used for deep seated tumours, as grains or sutures incorporating, for example, ^{198}Au, ^{125}I or ^{103}Pd. One of the most recent developments is endovascular brachytherapy to inhibit restenosis of blood vessels after angioplasty. Brachytherapy is overwhelmingly used for gynaecological tumours (75% of all such treatments worldwide), often in combination with

TABLE III. PATTERNS OF PRACTICE IN RADIOTHERAPY[a] AND RADIONUCLIDE THERAPY

	1996 [1]				1990 [2]
	HCL I	HCL II	HCL III and IV	World	World
	Annual number of complete courses of treatment (millions)				
Teletherapy	2.3	2.1	0.3	4.7	4.9[b]
Brachytherapy	0.3	0.05	0.02[c]	0.4	—
Radiopharmaceuticals	0.3	0.1	0.01	0.4	0.2
	Annual frequency of treatments per 1000 population				
Teletherapy	1.5	0.7	0.3	0.8	0.9[b]
Brachytherapy	0.2	0.02	0.02	0.07	—
Radiopharmaceuticals	0.2	0.04	0.01	0.065	0.04

[a]See footnotes to Table I for definitions of the UNSCEAR global population model.
[b]Includes teletherapy and brachytherapy.
[c]Assumed value in the absence of full data.

TABLE IV. DISTRIBUTION BY AGE OF PATIENTS UNDERGOING MEDICAL RADIOLOGICAL PROCEDURES [1]

	Age distribution (%)		
	0–15 years	16–40 years	>40 years
Medical X rays	11	29	60
Dental X rays	8	47	45
Diagnostic nuclear medicine	5	12	83
Teletherapy	1	11	88
Brachytherapy	0	9	91
Radiopharmaceutical therapy	3	38	59

external beam therapy. In some areas of the world, these treatments are still conducted for economic reasons using ^{226}Ra sources, with which the technique was first developed. Brachytherapy is also used to provide a boost in dose in the treatment of breast cancer (9% of all brachytherapy practice worldwide).

Radionuclide therapy is conducted by the direct administration to patients of radiopharmaceuticals, generally incorporating medium energy beta emitters, to provide biological targeting of dose. Such radionuclide therapy is an important treatment modality for both malignant and benign disease, particularly in relation to the thyroid and the use of ^{131}I. Treatments of hyperthyroidism account for nearly two thirds of all practice, with thyroid malignancy providing about a further quarter. Other diseases treated include bone metastases (4%), synovitis (3%) and polycythaemia vera (1%).

Global practice in radiotherapy and radionuclide therapy is summarized in Table III. Overall, about 85% of all complete courses of radiotherapy treatment are by teletherapy, with an annual total of 4.7 million treatments and a corresponding frequency of 0.8 per 1000 world population. Brachytherapy and therapy with radiopharamaceuticals each provide about 0.4 million treatments per year. In each case, the majority of practice arises from countries in health care level I. The combined frequency of teletherapy and brachytherapy, 0.9 per 1000 world population, is about the same as the estimate for 1990, whereas the figure of 0.07 per 1000 for radiopharmaceutical treatments represents an apparent rise of about 60%.

5. PATIENT POPULATIONS

Medical radiological examinations and treatments are distributed unevenly amongst the population. Representative data for the age distributions of patients undergoing different applications of radiation in health care level I are summarized in

Table IV [1]. The populations of patients are in general skewed towards older ages, particularly for radiotherapy. The percentage of patients aged over 40 years is greater for radiotherapy (teletherapy and brachytherapy) than for either diagnostic nuclear medicine or X rays, although significant numbers of children do undergo radiological procedures, particularly with X rays.

6. RADIOLOGICAL EQUIPMENT

Such widespread practice of medical radiology is underpinned by large amounts of equipment for imaging and therapy. Worldwide estimates for the numbers of principal types of equipment are summarized in Table V [1]. These amount broadly to 1.5 million X ray units, 34 000 CT scanners, 12 000 gamma cameras and 9000 high energy teletherapy machines, although these numbers are very much concentrated in the more developed world (countries of health care level I).

7. CONCLUSIONS

Ionizing radiation is widely used in medicine, principally for diagnosis, with an annual global total of about 2400 million X ray examinations and about 32 million diagnostic nuclear medicine procedures. Therapeutic uses are also important, but less common, with a further annual total of about 5.5 million complete courses of radiotherapy treatment worldwide. There are significant variations in practice between

TABLE V. WORLDWIDE INVENTORY OF RADIOLOGICAL EQUIPMENT IN 1996 [1]

	Unit	Thousands	Per cent in HCL I[a]
X rays	Medical X ray	650	69
	Dental X ray	850	79
	Mammography	38	95
	CT	34	79
Diagnostic nuclear medicine	Gamma camera	12	92
	Rectilinear scanner	2	62
Teletherapy	Radionuclide	4	59
	LINAC	5	85

[a]Health care level I: countries with >1000 physicians per million population (includes 26% of world population).

countries, with much of the world still having insufficient access to imaging and therapy services. Over three quarters of all diagnostic procedures and over half of all treatments occur in developed countries (classified in level I of the UNSCEAR global population model), which collectively represent only one quarter of the world population. The overall trends are for increasing numbers of diagnostic and therapeutic procedures, furthered by continuing developments in technology and evolution in clinical practices. For X rays, there will be particular growth in importance for complex X ray procedures such as CT. New pharmaceuticals will continue to expand the role of nuclear medicine, and ageing populations and improved delivery of dose will lead to increased use of radiotherapy.

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RADIOLOGICAL RISKS ASSOCIATED WITH THE VARIOUS USES OF RADIATION IN MEDICINE WITHIN THE CONTEXT OF THEIR ASSOCIATED BENEFITS

F.A. METTLER
University of New Mexico Health Sciences Center,
Albuquerque, New Mexico, United States of America
E-mail: fmettler@salud.unm.edu

Abstract

Medical procedures represent the largest source of human-made radiation exposure. Most radiation sources expose populations to a risk and these persons may receive no benefit or only an indirect benefit. There are some specific features of medical exposure that make the benefit/risk assessment different from that for other sources of radiation exposure. In medical exposure the exposed person is the direct recipient of an intended benefit that can be compared with the potential risk to that same individual, and the exposure is voluntary. Most radiation exposures should be limited to doses that are as low as reasonably achievable, but in medicine the doses must be at least high enough to obtain an image of diagnostic quality or to eradicate a tumour. The use of very high doses in radiation therapy makes it impossible to make comparisons using effective dose. The paper addresses the radiation risks from diagnostic radiology, nuclear medicine and radiotherapy; discusses the determinants of radiation risk, the measures of benefit and the factors affecting the balance between benefit and risk; and reviews the application of the radiation protection philosophy to medical exposure.

1. INTRODUCTION

Medical procedures represent the largest source of human-made radiation exposure. UNSCEAR 2000 [1] has estimated that the worldwide annual per caput effective dose from diagnostic medical examinations is 0.4 mSv, and the dose from natural background is 2.4 mSv. These values can be compared with 0.005 mSv from atmospheric nuclear testing, 0.002 mSv from the Chernobyl accident and 0.0002 mSv from nuclear power production.

It has always been difficult to treat medical exposure in a manner similar to exposure from other radiation sources, for several reasons. Most radiation sources expose populations to a risk, and these persons may receive no benefit or only an indirect benefit. In medical exposure the exposed person is the direct recipient of an intended benefit that can be compared with the potential risk to that same individual, and the exposure is voluntary. Medical exposure is also limited to specific body parts or is very inhomogeneous in distribution. Most radiation exposures should be limited to doses that are as low as reasonably achievable, but in medicine the doses must be

high enough to obtain an image of diagnostic quality or to eradicate a tumour. The use of very high doses in radiation therapy makes it impossible to make comparisons using effective dose.

2. BENEFIT AND RISK

There are a wide variety of terms used to estimate the value of a particular action. A commonly used method is assessment of the benefit versus the risk. To begin the process one must determine who the recipients of the benefit actually are. Is it society as a whole, a group of persons or an individual? The definitions of benefit and risk are also sometimes difficult to agree upon. Benefit is defined as an advantage or useful aid. In medical situations it may apply to a wide variety of factors such as making an accurate diagnosis, improving life span, improving psychological well being or improving quality of life.

Definition of risk is also not simple. Risk usually means a possibility of danger or the potential for an undesirable event. The probability of such events often can be measured and quantified by scientific studies [2, 3]. Risk is not the only issue that should be considered in such analyses. Monetary cost is an example of another factor to be considered.

3. WHAT ARE THE RADIATION RISKS?

Adverse radiation effects are usually divided into two categories: stochastic and deterministic effects. Stochastic effects most commonly refer to the radiation induction of neoplasms or hereditary effects. These effects are due to unrepaired or misrepaired DNA damage. The probability of incurring these effects is a direct function of dose and there is no known threshold below which these effects do not occur. However, at low doses the probability of the effects may be so small as to be impossible to find using epidemiological or population studies. The severity of stochastic effects is dose independent. Epidemiological studies have shown that the mean latent period, the time from exposure to clinical appearance, is 7–10 years for leukaemia and about 20 years for solid tumours [1, 4].

Deterministic effects are mostly due to cell killing. If only a few cells in a given tissue are killed, no effect will be apparent. If enough cells are killed, there will be an obvious clinical effect. An example of a deterministic effect is skin necrosis. Thus for deterministic effects there is a threshold below which the clinical effect will not be apparent, and the severity of a deterministic effect is a direct function of dose.

The title of this paper broadly refers to radiation risks associated with the practice of medicine. Obviously there are potential risks to the patient, medical staff,

families and possibly the public. In the context of this conference, this paper deals with the risks to the patient only.

4. WHAT ARE THE RADIATION RISKS FROM VARIOUS PRACTICES?

4.1. Diagnostic radiology

Diagnostic radiology includes plain film radiography and mammography, which have organ doses in the range 1–20 mGy. It also includes computed tomography, which gives organ doses in the range 10–100 mGy. In all these cases the risks are relatively small and are predominantly from tumour induction.

Diagnostic radiology also includes the use of fluoroscopic machines. These machines produce dose rates of 0.02 Gy/min in normal mode but can produce 0.2 Gy/min in high dose rate mode. Use of these machines in high dose rate mode for 30–100 min can result in deterministic injuries to the skin (including ulceration). It should be pointed out here that one typically thinks of diagnostic radiology as being performed only by radiologists. However, fluoroscopic machines are often used by cardiologists, pulmonologists, gasteroenterologists and orthopaedic surgeons, who have little or no knowledge regarding radiation risks and effects.

4.2. Nuclear medicine

Risks as a result of diagnostic nuclear medicine examinations are related to potential late induction of tumours. Risks from the use of unsealed radionuclides as a therapeutic modality are specific to deterministic effects in the tissues where the radiopharmaceuticals accumulate. Examples are bone marrow depression from treatment of diffuse metastases with ^{89}Sr or radiation parotitis as a result of ^{131}I therapy for thyroid cancer.

4.3. External radiotherapy and brachytherapy

Radiotherapy has been predominantly used to treat malignancies but it also is occasionally used to treat benign diseases. Adverse effects from radiotherapy can occur both early and late as a result of deterministic effects. As a result of extensive clinical experience, radiotherapists have constructed tables of the tolerance dose of different tissues. They also have experience regarding what dose is required for disease control. Combining these two parameters results in a prescribed dose and treatment schedule. The prescribed dose is usually in a fairly narrow range since normal tissue tolerance and cancer radiosensitivity are not very different. Doses less than the correct prescribed dose will result in few complications but also few cures.

Higher doses will result in an unacceptably high rate of severe complications. In addition to adverse deterministic effects, if the patients survive more than several years, there is an increased risk of radiogenic tumours in and around the treatment area.

5. WHAT ARE THE DETERMINANTS OF RADIATION RISK?

The most obvious factor affecting risk of radiation effects is absorbed dose. The higher the dose, the higher will be the probability of stochastic effects and the more severe will be the deterministic effects. Dose rate also plays a role. As the absorbed dose is spread out in time, the tissues have more chance to repair themselves and the effect will be less. Dose rates in diagnostic radiology are relatively high and there is little opportunity to reduce risk by reducing dose rate. In radiotherapy, doses are usually protracted or fractionated, allowing the use of higher doses.

Radiation risks are significantly affected by patient age. Risks usually are higher the younger the age at exposure. For reasons that are incompletely understood, for a given absorbed dose, infants and children are at about a 2–4 fold higher risk for radiation induced tumours than are adults. This has been well documented for both breast and thyroid cancer. The latent period also plays a role relative to risk varying with age. Obviously, if solid tumours have a mean latent period of 20 years between irradiation and clinical presentation, radiation induced neoplasms are not likely to be expressed in persons who are 60–80 years of age at exposure.

The body part irradiated plays a major role in radiation risk for both stochastic and deterministic effects. There is only a risk to that tissue which is irradiated. A CT scan of the head or pelvis will pose no risk in terms of radiation induced lung cancer or breast cancer. Deterministic effects also occur only in those tissues directly irradiated. The clinical impact will be completely different if radiosensitive tissues such as lung and spinal cord are in the field than in the case where the same dose is applied to a body part that is relatively radioresistant (such as an extremity).

There is a possibility of increased risk from medical exposure to persons who are genetically susceptible to cancer as a result of a variety of conditions. Overall, this issue does not appear to be a problem in most diagnostic radiology or nuclear medicine. It can be a problem in those patients receiving radiotherapy or who have experienced high exposures from prolonged fluoroscopy [5].

While this discussion is focused on radiation risks, one should not lose sight of the fact that there are non-radiation risks or costs associated with medical tests and therapy. There are monetary, logistical and psychological problems associated with false positive and false negative results of medical tests [6, 7]. There are also well documented reactions to intravenous contrast used for certain procedures. Finally,

there may be significant negative ramifications associated with not having a certain diagnostic test or refusing a certain therapy.

6. WHAT ARE THE MEASURES OF BENEFIT?

In order to balance benefit and risk from medical radiation we must also define benefit and review the contributing factors. It will soon become clear that assessment of benefit is much more difficult than determining radiation risk.

For diagnostic radiology and nuclear medicine one can examine the broad category of 'efficacy'. A number of authors have attempted to grapple with this problem with various degrees of success [8]. A first level of efficacy is related to technical factors and image quality. This would include such parameters as resolution or image sharpness. A second level of efficacy is related to the sensitivity, specificity and accuracy of an examination test or procedure. Evaluation of data accumulated relative to a specific test is a complex process since it depends on the population that was examined, the prevalence of disease, the type of disease and a number of other factors.

A third level of efficacy relates to whether the test actually was helpful in making the diagnosis or changed the diagnosis. As one might suspect, simply having made a diagnosis with a certain test does not help the patient much if there was no change in planned therapy or if the therapy was ineffective [9, 10]. Some measures of benefit in outcome may be reduced morbidity and mortality or improved quality of life [11, 12]. Some authors use an additional term of societal efficacy, which relates to cost effectiveness as judged from a societal viewpoint.

7. WHAT AFFECTS THE BENEFIT/RISK BALANCE?

There are a number of factors that affect the benefit/risk balance. Some of these are general and some are specific to an individual patient.

7.1. General factors

Change in the natural history of the disease (prevalence/incidence) can affect the benefit/risk balance. Certain screening and clinical practices are based upon how likely the disease is to be present in the population. Obviously there is little need to perform screening for tuberculosis in countries where it is extremely uncommon. An outbreak of tuberculosis, however, might justify the reinstitution of screening procedures. In a similar fashion, screening may reflect the fact that certain diseases occur more frequently in specific populations; for example, screening for gastric cancer is practised in Japan but not in the USA.

7.1.1. Resources

Lack of resources in terms of equipment, supplies and trained staff all will limit the potential benefit available to a population. On a simplistic basis one might suppose that the more resources available the better the benefit/risk ratio would be.

7.1.2. Education

Education of the patient, physicians and technical staff should always improve the benefit/risk ratio. Examples include knowing which study is appropriate, what advanced techniques will improve cures in radiotherapy, or technicians simply knowing enough to collimate the radiation beam and select appropriate technical factors. Lack of education in radiation effects has recently surfaced as a major issue in the occurrence of radiation injury from interventional procedures.

7.1.3. Regulations

It may not be intuitively obvious how regulations can play a role in changing the benefit/risk ratio, but the experience regarding use of mammography in the USA can be illustrative. United States federal regulations require evaluation of dosimetry, image quality, physician experience and even continuing medical education. Recent programmes have shown that as a result of the regulations, image quality has significantly improved and dose has been reduced.

7.1.4. Technology

Even though there are clear relationships between the availability of equipment and potential benefit, even with a specific level of resources there can be differences in equipment that provide better images or less radiation exposure. Examples of this may be the availability of fast screens and film. One should not surmise that newer technology always improves the benefit/risk ratio. Use of digital imaging techniques often results in a higher absorbed dose to the patient without a clear improvement in disease outcome. There are also simple technologies (such as shielding) that can sometimes be used to reduce the risk without interfering with diagnostic quality.

7.2. Patient specific factors

7.2.1. Patient age

As we have seen, risk changes with age at exposure. The benefit also changes with patient age but in a much more complex way depending upon the disease. In

mammography screening the radiation risk decreases with age but the disease incidence increases with age, and the breast parenchyma becomes less dense, making lesions more conspicuous [13–15]. All these factors tilt the balance greatly towards the benefit side with increasing age. With other diseases the balance may shift in the other direction, particularly for diseases that predominantly occur in children or adolescents.

7.2.2. Risk factors

Clearly any patient with a known set of risk factors should receive more benefit from an appropriate test. For example, a person with hypertension and hypercholesterolaemia and who is a smoker is likely to obtain more benefit from a nuclear medicine myocardial perfusion scan than a person without such risk factors.

7.2.3. Stage of the disease in an individual

A chest radiograph may be valuable in the initial assessment of a patient with lung cancer but in a terminal patient there is usually little value in monitoring the growth of a tumour or metastases. There are also similar differences in the use of radiotherapy relative to the stage of the disease. Curative treatment of cervical cancer in possible with localized disease but with widespread disease the treatment would be only palliative or perhaps not even indicated.

8. RADIATION PROTECTION PHILOSOPHY APPLIED TO MEDICAL PRACTICE

Most practising physicians have minimal knowledge of either radiation effects or radiation safety and often have little interest in these subjects. It is important to provide radiation protection and safety without unduly burdening physicians or restricting the benefits of medical radiation exposure. Any radiation protection philosophy that does not take into account the real world of clinical practice is doomed to failure [16].

The current philosophy of the International Commission on Radiological Protection (ICRP) relative to medical practice is that any use of radiation should be justified [17]. A simple example of this would be the question, “Does mammography find more tumours than it causes?” [18]. Even if scientific studies show this to be true for a given population, it still does not mean the test is right for everybody. There needs to be individual justification. This is normal procedure for physicians. They do not routinely order mammograms for young women but rather for older women or for high risk women who are more likely to benefit from the procedure. Individual

justification takes into account many of the patient specific factors mentioned in Section 7.2.

After there has been justification, it is important to optimize the procedure. In radiography this means using as low a dose as reasonable to obtain an image of diagnostic quality. In nuclear medicine it may mean adjusting administered activity in nuclear medicine to body size, and in radiotherapy it may mean using conformal techniques.

Recently there has been discussion about the concept of controllable dose and whether a radiation protection philosophy can be developed on this basis. Whether such a philosophy could be practically applied to medical exposure remains to be seen.

9. SUMMARY

In some instances it is clear that a certain test or therapy is ineffective or unnecessary. Unfortunately, even though there are tens of thousands of articles published in the medical literature each year and there is a push for evidence based medicine, there is very little literature to provide the physician with concrete information or data that can be applied to the individual patient situations encountered each day [19, 20]. A number of organizations [21, 22] have provided appropriateness guidelines based on a review of the literature and using a Delphi method for obtaining consensus by a panel of experts. It is not clear that such efforts have had a significant impact on medical practice, much less on patient outcome. Ever changing technology and the market place rather than a true analysis of the benefit/risk ratio predominantly drive the uses of radiation in medicine. The practice of medicine remains largely an art and less an evidence based science.

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CURRENT LEVEL OF RADIATION DOSE TO PATIENTS

A. SERVOMAA
STUK — Radiation and Nuclear Safety Authority,
Helsinki, Finland
E-mail: antti.servomaa@stuk.fi

Abstract

Assessment and optimization of the radiation dose received by patients in diagnostic and interventional radiological procedures are important tasks in radiological protection. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) collects global data on all significant sources of ionizing radiation. The published reports of UNSCEAR also contain views and trends concerning both the use of ionizing radiation in medical radiology and radiation doses to patients. The IAEA, jointly with other international organizations, has issued general requirements and specific guidance levels pertaining to dose and dose rate for radiological examinations. The European Medical Exposure Directive (97/43/Euratom) sets requirements for regular follow-up of radiation doses to patients and for comparisons with national reference dose levels. The European Commission has issued guidelines and quality criteria with reference dose recommendations for various types of X ray examinations for adult and paediatric patients. The review paper deals with the current level of radiation doses to patients in X ray examinations.

1. INTRODUCTION

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) has collected and published data on the medical use of radiation since its foundation in 1955. The latest report was issued in 2000 [1], the previous one in 1993 [2]. The UNSCEAR Survey of Medical Radiation Usage and Exposures (1991–1996), supplemented by an extensive literature review, has improved the estimates as to worldwide medical use of radiation and patient doses. Among the world's population, medical exposures constitute the greatest share of human-made radiation exposures per capita. The collective effective dose from diagnostic X ray examinations is estimated to account for more than 90% of the dose from all diagnostic medical examinations.

Together with the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organisation (ILO), the OECD Nuclear Energy Agency (NEA/OECD), the Pan American Health Organization (PAHO) and the World Health Organization (WHO), in 1996 the IAEA issued the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources [3]. This set of safety standards includes radiological protection

requirements for the medical use of radiation and guidance levels concerning dose and dose rate for various X ray examinations.

The Council of the European Union has adopted the Medical Exposure Directive (97/43/Euratom of 30 June 1997) concerning the medical use of radiation [4]. The Member States of the European Union were obligated to implement the directive in their respective national regulations by 13 May 2000. The directive introduces the concept of diagnostic reference levels (DRLs) as a tool for optimization and quality assurance, requiring regular assessment of patient doses and comparison with the reference dose levels. Special attention is focused on paediatric diagnostic examinations, health screening programmes and high dose procedures.

The European Commission has financed several radiological projects in the framework research programmes, has established and financed working groups for setting up European guidelines on quality criteria for various X ray examinations [5–7], and has organized European meetings for patient dose estimation [8–10]. Reference dose values have been incorporated into the European guidelines on quality criteria for diagnostic radiographic images of adult [5] and paediatric [6] patients and for computed tomography (CT) [7], and are being developed for paediatric fluoroscopy and CT [11]. In Europe, national and regional surveys on patient doses originating from X ray examinations have shown wide variations in doses between hospitals, and have demonstrated the need for quantitative guidance on patient exposure [12–14].

Generally recommended measurable dose quantities are the entrance surface dose (ESD) for individual radiographic projections and the dose–area product (DAP) for complete X ray examinations. The ESD can be directly measured with thermoluminescence dosimeters (TLDs), or it can be estimated on the basis of measured radiation output values for the X ray tube. The total DAP from a complete examination, even when it involves both fluoroscopy and radiography, can be measured with a DAP meter and then compared directly against an appropriate reference level. Since dose is critically dependent on patient size, it is recommended that measurements should be made for a representative sample of standard sized patients. The average dose of such a sample for each particular type of radiograph or examination would provide a good indication of the typical clinical practice in each room of an X ray department. The average doses should also be compared against national reference doses, in order to assess local performance.

The ESD and the DAP are directly measurable quantities. They can be used for comparison against reference levels and for other quality assurance purposes, but they are not directly risk related quantities. Effective doses are needed in order to assess the population's collective effective dose arising from the medical use of radiation. Organ doses and/or the effective dose cannot be measured but can be estimated on the basis of measured ESD or DAP values. Tables of coefficients and computer programs are available for such calculations for adult and paediatric patients [15–17].

2. WORLDWIDE TRENDS IN RADIATION DOSES TO PATIENTS IN X RAY EXAMINATIONS

In the UNSCEAR 2000 report [1], the global model developed in the earlier reports [2] was applied to extrapolate the information on national practices received from a sample of countries in order to obtain worldwide assessments of global practices, even though the calculated results may involve significant uncertainties. The mean annual effective dose per capita varies significantly between the four health care levels defined in the global model, reflecting large differences in examination frequencies between the four levels. In the first-level countries, the mean annual effective dose per capita is 1.2 mSv from medical X ray examinations and 0.08 mSv from nuclear medicine procedures. In the second-level countries, the dose per capita is 0.14 mSv from X ray examinations and 0.008 mSv from nuclear medicine.

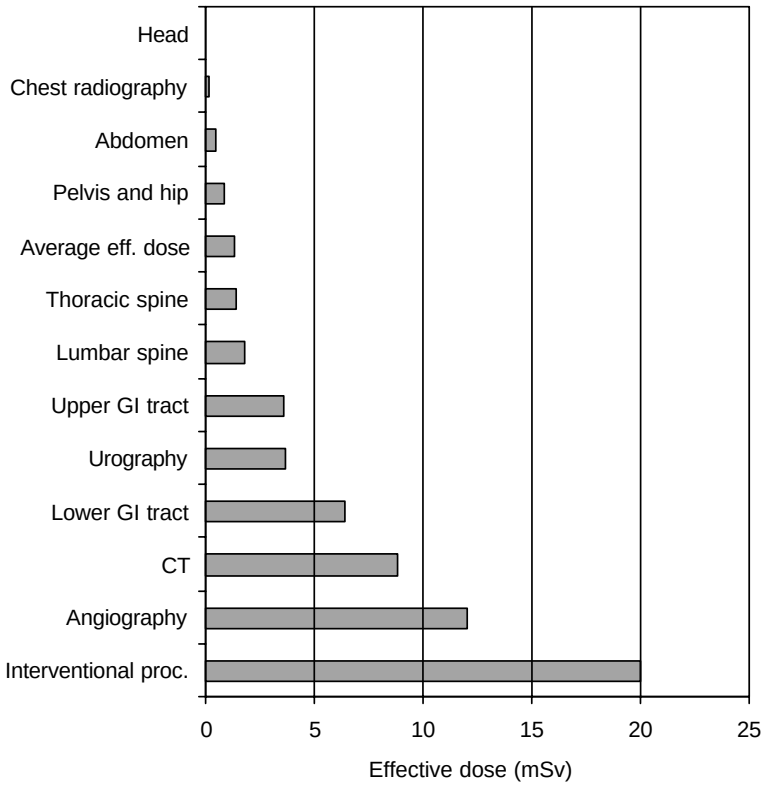

FIG. 1. Effective doses from diagnostic X ray examinations and interventional procedures in health care level I (1991–1996) ([1], from Table 30).

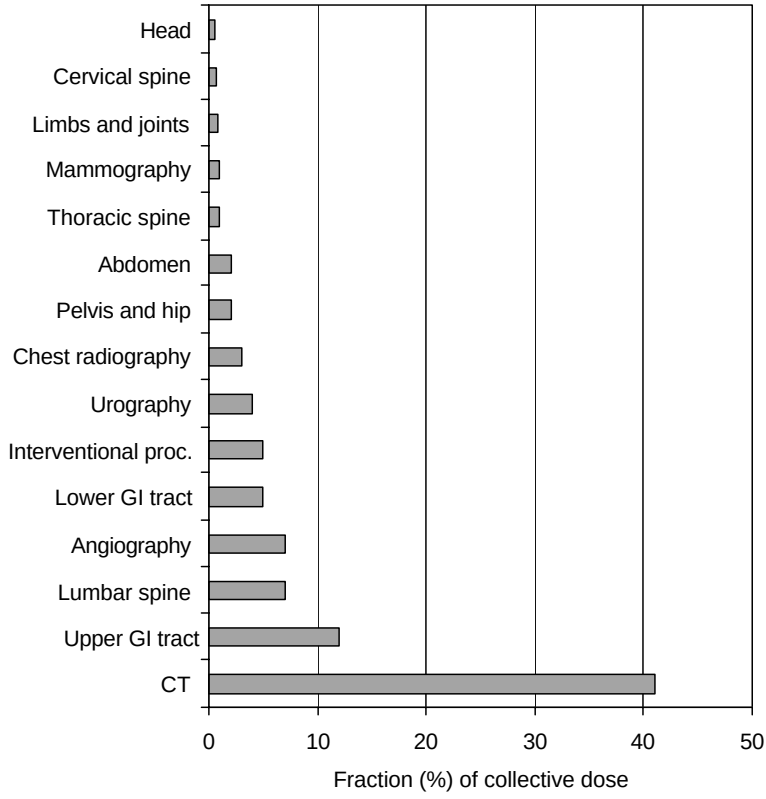

FIG. 2. Contribution to collective dose from various types of diagnostic X ray examinations in health care level I (1991–1996) ([1], from Table 31).

Figure 1 shows the mean effective doses for some examination types, and Fig. 2 the relative contributions to the total collective dose derived from all diagnostic X ray examinations, as reported in the UNSCEAR 2000 report [1] for the first health care level in 1991–1996. The effective doses are the highest in the interventional procedures, angiography and CT. The differences between Figs 1 and 2 result from the different examination frequencies employed. For example, CT accounts for about 6% of the total frequency of all X ray examinations and for about 40% of the collective effective dose. In interventional procedures and angiography, the average effective doses per examination are higher than in CT but, owing to their low frequencies, the percentage contributions to the collective dose are only about 5–7%. As an example of a low effective dose, chest radiography accounts for about 30% of the total frequency but for only about 3% of the collective effective dose from all X ray examinations.

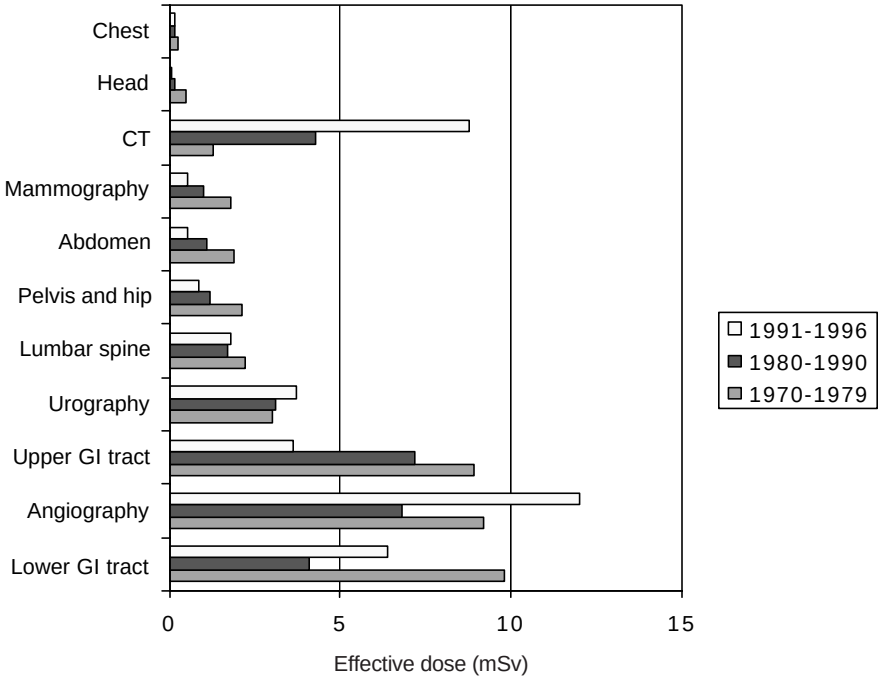

FIG. 3. Trends in average effective doses from diagnostic X ray examinations in health care level I (1991–1996) ([1], from Table 35).

Figure 3 shows some temporal trends in the mean effective doses from diagnostic X ray examinations. In most examinations, the doses decreased from the 1970s to the 1980s. From the 1980s to the 1990s, the doses decreased for some examinations but increased clearly for some others, especially CT examinations.

3. RADIATION DOSES TO PATIENTS FROM X RAY EXAMINATIONS IN VARIOUS COUNTRIES

In the UNSCEAR Survey of Medical Radiation Usage and Exposures, the mean patient doses vary, on relatively wide scales, between countries. Table I presents the mean ESDs and DAPs for radiographic examinations in countries of the first health care level. The mean DAPs for fluoroscopic examinations are given in Table II.

Table III shows the average effective doses to patients undergoing some common types of diagnostic X ray procedures in various countries. These mean values (per examination) are independent of examination frequencies, and thus reflect the

examination methods and techniques. The mean values per capita, as well as the collective doses, are also proportional to the frequencies. Table IV shows, for all diagnostic X ray examinations combined, the mean effective dose per examination and the mean annual effective dose per capita in countries of the first health care level. In the various countries the effective dose per examination ranges from 0.5 to 1.5 mSv, and the annual effective dose per capita from 0.45 to 1.9 mSv. In countries of other health care levels the annual effective dose per capita is much lower.

The DAPs of five X ray examination types were measured in a regional Nordic study conducted at several hospitals in each of the Nordic countries [12, 13]. Table V

TABLE I. PATIENT DOSES FROM DIAGNOSTIC RADIOGRAPHIC EXAMINATIONS (PROJECTIONS) IN VARIOUS COUNTRIES
(data from UNSCEAR Survey of Medical Radiation Usage and Exposures in Health Care Level I ([1], from Table 16))

TABLE I(a). ESD (mGy)

	Skull		Chest		TH spine		LS spine		Abdomen	Pelvis
	AP/PA	LAT	PA	LAT	AP	LAT	AP	LAT	AP	AP
Australia	1.9	1.2	0.12	0.63			6.1	15.1	4.2	3.9
Canada		0.68	0.11		1.82		3.34		2.35	
Finland	3.4	1.9	0.24	0.73	4.9	11.6	8.8	18.2	7.1	6.2
Greece	3.5	2.7	0.69	2.9	8.3	10.9	18.9	44.9	11.2	12.5
Lithuania	2.1	2.7	0.81	1.4			22.8	35.5	20.4	21.4
New Zealand	3.0	1.56	0.22	1.24	4.32	13.3	5.47	18.9	4.57	3.98
Poland			0.20	0.88	5.1	8.3	7.5	12.0	4.7	2.5
UK	3.0	1.5	0.16	0.57	4.7	13.0	6.1	16.0	5.6	4.4

TABLE I(b). DAP ($Gy \cdot cm^2$)

	Skull		Chest		TH spine		LS spine		Abdomen	Pelvis
	AP/PA	LAT	PA	LAT	AP	LAT	AP	LAT	AP	AP
Finland	1.6		0.44		4.1		8.3		6.9	3.8
Germany	1.07		1.37		3.51		9.32		3.62	3.62
New Zealand	0.96	0.57	0.17	0.62	1.54	3.53	1.88	3.92	2.67	2.37
Norway			0.64						7.6	3.5

Notes: AP: antero-posterior; LAT: lateral; LS spine: lumbo-sacral spine; PA: posterio-anterior; TH spine: thoracic spine.

TABLE II. MEAN DAP (Gy•cm^2) IN DIAGNOSTIC FLUOROSCOPIC EXAMINATIONS IN VARIOUS COUNTRIES
(data from UNSCEAR Survey of Medical Radiation Usage and Exposures in Health Care Level I ([1], from Table 16))

	Upper GI tract		Lower GI tract	Urography	ERCP
	Swallow	Meal	Enema		
Germany	13.1	35.9	61.5	20.3	33.7
Iceland			43.6–7.4		
Norway	7.41	24.8	49.1	18.1	31.8
Switzerland	13.5	68.5			37.1
UK	9.3	13.0	25.8	13.4	

Note: ERCP: endoscopic retrograde cholangiopancreatography.

shows the mean DAP values, ranges, medians, third quartiles and Nordic Guidance Levels for the DAP for complete examinations. The results show that the examination techniques are rather similar in the five countries. There are large variations between hospitals, but the differences in the national mean DAP values between the Nordic countries are much smaller than the variations within each country.

In the United Kingdom, the National Radiological Protection Board (NRPB) and the X ray departments have performed very extensive measurements of doses to patients [14, 15]. The 1995 review included the results of 21 000 ESD evaluations and 31 000 DAP measurements from 25% of all UK hospitals. Tables VI(a) and VI(b) show the summaries of the mean ESD per room for radiographic projections, and of the mean DAP per room for complete examinations for adult patients in 1988–1995. Typically, 30–40% reductions from the earlier survey were reported in the mean doses for common types of radiographic examinations. Less than 10% of the hospitals exceeded the national reference doses for common X ray procedures, compared with 25% in 1983–1985.

4. PAEDIATRIC RADIOLOGY

The European Commission has organized several working groups for studying radiation doses to paediatric patients. Table VII shows the summary of ESD measurements from surveys of paediatric radiography in Europe [1]. Cook et al. reported reduced doses in paediatric radiography when attention was paid to good techniques [18]. The doses were remarkably lower than the measured doses shown in Table VII. This indicates that patient doses in paediatric X ray examinations can be reduced

TABLE III. AVERAGE EFFECTIVE DOSE PER PROCEDURE (mSv) TO PATIENTS UNDERGOING SOME COMMON TYPES OF DIAGNOSTIC MEDICAL X RAY PROCEDURES (1991–1996)
(data from UNSCEAR Survey of Medical Radiation Usage and Exposures in Health Care Level I ([1], from Table 15))

	AU	FIN	GER	JPN	NL	N	P	SE	SUI	UK	Av.
Chest radiography	0.02	0.1	0.3	0.057	0.06	0.13	0.11	0.15	0.1	0.02	0.14
Chest fluorography				0.053		0.23	0.82		0.5		0.65
Limbs and joints			0.06				0.02	0.1	0.05		0.06
Lumbar spine	2	2.3	2	1.45	2	1.1	4.33	3	1.5	1.3	1.8
Thoracic spine		1	0.7	0.65	1	0.5	3.03	1	0.8	0.7	1.4
Cervical spine		0.2	0.2	0.26	1	0.2		0.2	0.2		0.27
Pelvis and hips	0.6	1.3	0.8	0.58	1	0.5	0.61	1.5	1	0.7	0.83
Head		0.1	0.03	0.09	0.1	0.2	0.1	0.1	0.1	0.04	0.07
Abdomen	1	2.2	1.2	0.24	1	1	2.2	2.5	0.5	0.7	0.53
GI tract (upper)		9	8.3	3.33	6.4	4	14	3	5	2.6	3.6
GI tract (lower)		9.7	17.7	2.68	4.7	8	22.7	8	5	7.2	6.4
Cholecystography			7.1	0.88				6	8		2.3
Urography		4.5	4.9	2.47	4	2	3.1	5	4	2.4	3.7
Mammography, screening		0.1			0.1			0.1		0.06	0.07
Mammography, clinical		0.2			0.1	0.12		0.2			0.21
CT, head	2.6	1.3	2.6		1.7	2		2	2	2	2.3
CT, body	10.6	7.9	15.4		10.2	10		10	5	9	13.3
Angiography, cerebral								1	2		2.0
Angiography, cardiac		14.8		5.56	5			12	10		7.3
PTCA			23		5		7	22	10		22

Notes: AU: Australia; FIN: Finland; GER: Germany; JPN: Japan; NL: Netherlands; N: Norway; P: Poland; SE: Sweden; SUI: Switzerland; UK: United Kingdom; Av.: average of health care level I; PTCA: percutaneous transluminal coronary angioplasty.

considerably. The potential reduction in the doses to infants is about 75%. The difference is smaller in the groups of five-year-olds and ten-year-olds.

The optimization of paediatric fluoroscopic examination techniques was studied in four hospitals in Finland, in one hospital in Germany and in one hospital in the UK [19] by measuring the detectability of iodine contrast material details in fluoroscopic images of phantoms of various sizes. It was found that, without impairing image quality, the doses could be reduced, on average, by 35%. The image quality and

TABLE IV. MEAN EFFECTIVE DOSES (mSv) FROM ALL DIAGNOSTIC X RAY EXAMINATIONS COMBINED
([1], from Table 29)

	Effective dose per examination	Annual effective dose per capita
Australia	1.3	0.8
Canada	1.05	0.94
Denmark	0.7	0.36
Finland	0.63	0.45
France		1.0
Germany	1.5	1.9
Netherlands	1.0	0.6
Poland	1.2	0.8
Sweden	1.2	0.68
USA	0.5	0.5

radiation dose levels at the Finnish hospitals were much higher than at the reference hospitals. Reduction of the dose was attempted at two Finnish hospitals, and the image quality remained sufficiently good for examination purposes, even though the dose rates were decreased by 30–80%, depending on the hospital and the patient size.

Dosimetry in paediatric radiology is difficult owing to the large variations in the size of paediatric patients. Radiation doses are sometimes given for standard phantom ages of 0, 1, 5, 10 or 15 years and sometimes for specified age groups, such as <1, 1–4, 5–9 and 10–15 years. Owing to the large variations in patient size, comparison of the doses may be difficult. Patient size may vary much within a single age group,

TABLE V. RESULTS FROM MEASUREMENTS OF DAP (Gy•cm^2) OF FIVE X RAY EXAMINATION TYPES IN THE NORDIC COUNTRIES
(DAP values are given for complete examinations)

	Chest	Pelvis	Lumbar spine	Urography	Barium enema
Mean DAP	0.54	3.3	9.0	22.4	43.5
Range DAP	0.10–3.0	0.73–12.4	0.39–35.7	6.8–65.7	5.5–165.6
Median DAP	0.47	2.6	7.9	19.2	34.7
75% DAP	0.65	3.9	10.9	28.9	53.1
NGL[a] DAP	1.0	4.0	10	20	50

[a] NGL: Nordic Guidance Level.

TABLE VI(a). SUMMARY OF DATA ON MEAN ESD (mGy) PER ROOM FOR ADULT PATIENTS IN THE UK (1988–1995)
([15], from Table 10)

	Mean	Range	Third quartile
Lumbar spine AP	6.4	1.0–42.0	7.4
Lumbar spine LAT	15.0	2.2–75	19.0
Chest PA	0.17	0.01–1.9	0.2
Chest LAT	0.73	0.04–3.6	0.77
Abdomen AP	5.8	0.8–28.0	7.2
Pelvis AP	4.7	0.9–25.0	5.4
Skull AP/PA	2.8	0.1–10.0	3.7
Skull LAT	1.5	0.1–6.0	1.9
Thoracic spine AP	4.2	0.2–27.0	5.0
Thoracic spine LAT	12.0	0.5–5.0	14.0

Notes: AP: antero-posterior; LAT: lateral; PA: posterio-anterior.

TABLE VI(b). COMPLETE EXAMINATIONS: SUMMARY OF DATA ON DAP (Gy•cm^2) PER ROOM FOR ADULT PATIENTS IN THE UK (1988–1995)
([15], from Table 14)

	Mean	Range	Third quartile
Barium enema	27.0	6.9–79	33
Barium follow-through	12.0	4.2–40.8	16.0
Barium meal	13.0	2.8–54.0	16.0
Barium swallow	9.8	2.4–39.0	12.0
IVU	16.0	4.5–39.0	24.0
Venogram	3.0	1.7–5.9	3.8

causing large uncertainties in the mean ESD. Methods for comparison of doses as a function of patient size have been developed for paediatric patients [20].

5. ANGIOGRAPHY AND INTERVENTIONAL RADIOLOGY

Patient doses in fluoroscopic examinations are measured mostly with a DAP meter for the complete examination. Calculation of the effective dose is difficult because it is not possible in practice to record all of the changes in the techniques during the examination. One way to estimate the magnitude of the effective dose is to use

TABLE VII. SUMMARY OF ESD (μGy) MEASUREMENTS FROM SURVEYS OF PAEDIATRIC X RAY EXAMINATIONS IN EUROPE
([1], from Table 27)

	Infant (10 months)	Five-year-old	Ten-year-old
Chest AP (1 kg)	45		
Chest PA/AP	75	67	71
Chest AP mobile	90	68	91
Chest LAT		140	153
Skull PA/AP	930	967	1036
Skull LAT		703	577
Pelvis AP		485	812
Thoracic spine AP			887
Thoracic spine LAT			1629
Lumbo-sacral spine AP			1146
Lumbo-sacral spine LAT			2427
Abdomen AP/PA	440	588	729

Notes: AP: antero-posterior; LAT: lateral; PA: posterio-anterior.

proper conversion factors from DAP to effective dose. Table VIII shows the ranges of the average DAP and effective dose per procedure from angiographic examinations as presented in the literature [1]. For all examinations and studies, the average DAP ranges from 5 to177 Gy•cm^2 and the average effective dose from 1 to 24 mSv.

In interventional radiology, it is possible on some occasions that the ESD is so high that deterministic effects may appear on the skin. Table IX shows the ranges of average DAP and effective dose per interventional procedure [1]. The average DAP varies between 20 and 520 Gy•cm^2 and the average effective dose between 2 and 84 mSv.

6. COMPUTED TOMOGRAPHY

The effective dose from CT examinations accounts for about 40% of the collective dose from diagnostic X ray examinations. Table X shows the mean effective doses per procedure from CT in some European countries. The mean effective doses are relatively high and vary from one country to another by a factor of 2 to 4. The newest EC guidelines on quality criteria for CT [7] recommend the weighted CT dose index ($CTDI_w$) and the dose–length product (DLP) as measurable patient dose quantities. Table XI shows the estimated values of $CTDI_w$ and DLP on the basis of UK survey data [21].

TABLE VIII. RANGES OF AVERAGE DAP AND OF AVERAGE EFFECTIVE DOSE PER PROCEDURE FROM ANGIOGRAPHIC EXAMINATIONS IN VARIOUS STUDIES PRESENTED IN THE LITERATURE
([1], from Table 18)

	Range of average DAP ($Gy•cm^2$)	Range of average effective dose (mSv)
Coronary	13.3–58.7	3.1–10.6
Cerebral	27.4–98	1.6–10.6
Abdominal	39.8–177	6–23
Peripheral	4.9–78	0.9–14

TABLE IX. PATIENT DOSE PER PROCEDURE DURING INTERVENTIONAL RADIOLOGY IN VARIOUS STUDIES
([1], from Table 18)

	Range of average DAP ($Gy•cm^2$)	Range of average effective dose (mSv)
PTCA	28.5–143	6.9–28.9
PTA	43.5–140	10–12.5
TIPS	77–525	8–83.9
Radiofrequency ablation	43.6–116	17–25
Embolization	79–391	1.67–68
Biliary	20.1–150	6.9–38.2
Stent (superior vena cava)	42	5.8

Notes: PTCA: percutaneous transluminal coronary angioplasty; PTA: percutaneous transluminal angioplasty; TIPS: transjugular intrahepatic porto shunt.

7. CONCLUSIONS

(1) Comparison of the UNSCEAR 1993 and 2000 reports [1, 2] reveals that the overall mean effective dose per examination has risen by about 20% and the annual collective effective dose by nearly 50%. The overall trends in radiation exposures originating from diagnostic examinations involving X rays stem from changes in the type and frequency of procedures carried out, and from changes in the dose levels to individual patients for given procedures.

(2) Doses are affected by quality assurance, patient protection and the continuing advances in techniques for the production, detection and control of radiation, including the development of alternative modalities for diagnosis. Development

TABLE X. MEAN EFFECTIVE DOSE PER PROCEDURE (mSv) TO ADULT PATIENTS FROM CT IN VARIOUS COUNTRIES
([1], from Table 18)

	Head	Cervical spine	Chest	Abdomen	Liver	Kidneys	Pelvis	Lumbar spine
Australia	2.6	5.2	10.4	16.7	12.7		11.0	5.2
Finland	1.3		5.1	11.6				5.0
Germany	2.6	9	20.5	27.4				9.0
Norway	2.0		11.5	12.8	11.9	9.9	9.8	4.5
Sweden	2.1	6	10	10	10	10	10	6
UK	1.6	11.5	9.7	12.0	10.3	9.1	9.8	3.3

TABLE XI. ESTIMATED VALUES OF $CTDI_w$ AND DLP FROM UK SURVEY DATA [21]

	$CTDI_w$ (mGy)	DLP (mGy•cm)
Head	50.0	882
Chest	20.3	517
Abdomen	25.6	597
Pelvis	26.4	443

of imaging technology, particularly technology involving non-ionizing radiation, will have a significant effect on the practice of radiology and on the medical exposure of the population. Digital radiological techniques also offer the potential of improved image quality, although in general this comes at the expense of higher patient doses.

(3) The requirements laid down by the Medical Exposure Directive (97/43/Euratom) [4], stipulating that hospitals start regular patient dose measurements and that the authorities establish national reference dose levels, have advanced the radiation protection of patients. Many Member States of the European Union have started both patient dose measurements and the establishment of the dose reference levels. An extensive task for the near future is the implementation of the current European radiation protection requirements in countries that do not as yet belong to the EU. Education and training courses on radiation protection in medical radiology will be needed for a long time to come.

(4) Large variations occur in the effective doses both between various countries and between hospitals. The national average doses in many countries are much lower than the European recommendations. This indicates that national reference levels are needed.

(5) National radiation dose measurements show that radiation doses in paediatric radiographic and fluoroscopic examinations can be reduced, as indicated by the doses measured when good techniques were used [1, 18, 19].

(6) In CT, the doses per examination are relatively high. Since the number of examinations is increasing, CT examinations result in a high and growing collective dose.

(7) In some cases, the patient skin doses in interventional radiology may be so high that acute skin effects appear. More research work is needed in order to develop dosimetry and reference dose levels for interventional radiology. One problem in establishing these reference dose levels is the complexity of the procedures involved.

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LESSONS LEARNED IN RADIOLOGY

D.J. GOODENOUGH
George Washington University Medical Center,
Washington, D.C.,
United States of America

Abstract

The paper reviews aspects of the history of radiology with the goal of identifying lessons learned, particularly in the area of radiological protection of the patient in diagnostic and interventional radiology, nuclear medicine and radiotherapy. It is pointed out that since the days of Röntgen there has been a need not only to control and quantify the amount of radiation reaching the patient but also to optimize the imaging process to offer the greatest diagnostic benefit within allowable levels of patient dose. To this end, in diagnostic radiology, one finds the development of better films, X rays tubes, grids, screens and processing techniques, while in fluoroscopy, one sees the increased luminance of calcium tungstate. In interventional radiology, one finds an improvement in catheterization techniques and contrast agents. In nuclear medicine, the development of tracer techniques into modern cameras and isotopes such as technetium can be followed. In radiotherapy, one sees the early superficial X rays and radium sources gradually replaced with radon seeds, supervoltage, ^{60}Co and today's linear accelerators. Along with the incredible advances in imaging and therapeutic technologies comes the growing realization of the potential danger of radiation and the need to protect the patient (as well as physicians, ancillary personnel and the general population) from unnecessary radiation. The important lesson learned is that we must walk a tightrope, balancing the benefits and risks of any technology utilizing radiation to produce the greatest benefits at the lowest acceptable risk. The alternative techniques using non-ionizing radiation will have to be considered as part of the general armamentarium for medical imaging whenever radiation consequences are unacceptable.

1. INTRODUCTION

The end of the 19th century was indeed a remarkable time. The medical significance of Wilhelm Röntgen's discovery of X rays in 1895 is linked to their ability to cause light scintillation in phosphor screens as well as their direct and indirect (via light) property of producing a latent image in film. In fact, Röntgen's discovery of X rays was more an 'observation' of these image producing properties. Certainly, it is our ability to transduce or extract energy from the X ray beam that produces the great imaging tools X rays offer today. Unfortunately, the biological effects of the accompanying cellular deposition of radiation energy present a simultaneous

challenge to the safe and efficacious use of X ray and gamma ray radiation in medical imaging.

2. RADIOLOGY

This section examines some of the history and lessons learned over time, from the first publication announcing the discovery of X rays to the comprehensive guidance document of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [1].

As has been noted many times, the rate of introduction of the practical and commercial applications of the discovery of X rays by Röntgen was amazing. Rarely has such a discovery propagated into the heart and fabric of society as did these rays that showed bone and other parts of the body. By the time Röntgen died in 1923, at the age of 78, of carcinoma of the intestines, "X rays were out of the tube" and medical imaging science never looked back.

In 1896, the Dean of the Medical School of Vanderbilt University was persuaded to undergo a skull examination to try to image his brain. Unfortunately, not only was his brain not seen, but within three weeks his hair fell out [2]. Even more alarming among other early subjects of irradiation was the rapid observation of dermatitis, burns and ulcers of the flesh. The first acknowledged fatality from excess radiation appeared to be the case of Clarence Dally in 1904 [3]. Dally was an assistant of Edison who routinely used his hand in the field to adjust and calibrate X ray equipment. Many other cases of injury or death were subsequently associated with the early use of radiation.

The unfortunate lesson learned was that great discoveries may bring great benefit but may also sometimes be accompanied by negative sequelae such as cancer induction. Radiation must be used cautiously to achieve the desired medical images, and unnecessary exposure to patients and medical personnel must be avoided.

In 1898, William Herbert Rollins, a New England dentist and brother-in-law of Francis H. Williams (who was known as the 'first American radiologist') suffered X ray burns to his own hands while experimenting [3]. He subsequently urged the use of the smallest exposure to accomplish the purpose.

In addition, he suggested several precautions in using X rays:

— Shield (lead paint) the tube box;
— Shutter the X rays during warm-up;
— Use dual intensifying screens;
— Use rectangular collimators (not introduced into general practice until the 1950s);

— Use remote controlled collimator and centring devices;
— Use selective filtration of the X ray beam;
— In fluoroscopy, irradiate only the necessary area — cover the rest with opaque (lead) material;
— Use pulsed fluoroscopy because of the integration time of the eye.

Why was Rollins generally ignored? Part of the problem was poor public relations. Another problem was that Rollins had a poor writing style and was poorly published.

The lessons learned are to publish or (have your ideas) perish! How many radiation injuries may have been prevented if Rollins' suggestions had been followed in the early years?

Although people learned to respect the dangers that could be associated with X rays, the desire for improvement in image quality continued. Thus, increased system speed (shorter patient exposure and patient motion), decreased X ray statistical noise, improved contrast and latitude characteristics, and decreased scatter inevitably lead to improved intensifying screens, scatter rejection grids, H&D film characteristics, and improvements in X ray generation design for improved X ray spectra and maximum milliampere high output tubes. Along with hardware developments, such as cones, diaphragms and filters, came improvements in radiographic technique and positioning. Still, these improvements were slow in becoming generally available and the consequences were profound. For example, in 1980, Smith and Doll published data showing that British radiologists who entered the profession before 1921 showed a death rate from cancer some 75% higher than that of other medical practitioners [4].

A good example of the sometimes competing desire for improved image quality even at the expense of increased dose to the patient was the need for grids. In 1903, Otto Pasche developed slit apertures, and by 1913 Gustav Bucky practised with honeycomb grids. From 1913 to 1917, Bucky, Eugene Caldwell and Hollis E. Potter further improved grids by moving parallel slits [3]. Scatter was decreased and image quality improved, but patient dose increased.

Grids were also important because with less scatter, image receptors could become larger than glass plates, and one finds the conversion to film.

2.1. Interventional radiology

The very important area of interventional radiology came from the introduction of contrast agents and angiographic techniques along with improved catheters.

In 1964, Charles Dotter and Melvin Judkins made the important but incidental observation of recanalization of totally occluded right common iliac artery during a conventional angio study. Many remarkable developments soon followed [5].

During the 1960s and 1970s, many developments in catheters were witnessed, ranging from catheters with two side holes to the double lumen balloon catheter. The techniques performed were: intravenous thrombolisis, emblotherapy and transvenous interruption of vena cava. In 1970, the first commercially safe device was brought to the market with the Mobin Uddin umbrella filter. Likewise, precuteous aspiration biopsy and abscess drainage were developed in 1960 by S. Franzen and others using a thin needle technique. This technique would prove important for modern CT and ultrasound guidance applications.

2.2. Image quality and dose

At this point in time, it is important to understand the often competing demands of increased image quality and decreased patient exposure. The ultimate limit for detectability is the statistical fluctuation in the number of detected X rays (the quantum sink). Unfortunately, improved image quality by reduced noise places a quadratic demand on patient dose. Then too, improvements in the spatial resolution of many image receptors usually require thinner image receptors with lower detective quantum efficiency (or stopping power) and often place a linear demand on patient dose. Scatter rejecting devices such as grids place their own demands (probably at least linear) on patient dose, depending on the degree of scatter rejection. Thus, increased image quality by simultaneously decreasing noise, increasing resolution and decreasing scatter could easily place a cubic or quartic demand on patient dose! The key question then emerges as to how much image quality is enough.

This question is rhetorical because one would first need to identify what anomaly or signal one is trying to detect or rule out. Although clearly the radiologist should be able to use the radiation dose necessary to perform the imaging task required, he/she should be well aware of the risks, such as those shown in Tables I and II.

It is also important for the physician to be aware of the data shown above and to justify the procedure or consider non-ionizing alternatives which may exist to

TABLE I. RISK COEFFICIENTS (%·Sv^{-1}) FOR CANCERS IN BOTH SEXES AT LOW DOSES AND DOSE RATES AND AT HIGH DOSES AND DOSE RATES [6]

	Fatal cancer	Total cancer
Whole population	5.0 (10)	6.1 (12.2)
Working population	4.0 (8)	4.9 (9.8)
Individuals up to age 15 years, exposed in utero	3.0 (6)	6.0 (12.0)

Note: Values in parentheses are for high doses and high dose rates.

TABLE II. FATAL CANCER RISK COEFFICIENT BY AGE AT EXPOSURE [6]

Age at exposure (years)	0–20	21–40	41–60	61–80	>80	Workers 18–65
Lifetime probability of fatal cancer (%·Sv^{-1})	11.5	5.5	2.5	1.2	0.2	4.0

acquire similar diagnostic results. In particular, ultrasound and magnetic resonance imaging offer non-ionizing alternatives for many imaging tasks.

What we do know is that the physician should be the final arbiter of the required levels of image quality. However, it is the duty of the physicist, engineer and radiographer to attempt to optimize equipment and techniques that minimize unnecessary patient dose. An important example can be seen from a recent study on scoliosis [3] which illustrates the resulting dose to the breast (Table III).

This retrospective cohort study conducted in 5573 female patients with scoliosis who were treated at any of the 14 orthopaedic treatment centres in the USA from 1912 through 1965. Patients underwent an average of 25 radiographs, and the total mean estimated radiation dose to the breast was 10.8 cGy. A key lesson learned is that for these women a statistically significant 70% excess risk of dying of breast cancer was observed compared with the general population. Patterns were consistent with radiation as a causative factor, in that risk increased with increasing number of diagnostic radiographic examinations and cumulative radiation dose to the breast.

TABLE III. ESTIMATED RADIATION DOSE TO BREAST (cGy) FROM A FULL SPINE RADIOGRAPHIC EXAMINATION, BY AGE AT EXAMINATION AND FOR VARIOUS TIME PERIODS [7]

Age (years) and view	1940–1959	1960–1975	1976–1989
>13			
Anteroposterior	0.588	0.350	0.090
Posteroanterior	0.005	0.005	0.005
Lateral	0.300	0.225	[a]
<13			
Anteroposterior	0.780	0.470	0.125
Posteroanterior	0.003	0.003	0.003
Lateral	0.300	0.225	[a]

[a] Parameters were not available for this view in this time period.

Potential confounding between radiation dose and severity of disease may explain some of the excess risk observed.

Most of the examinations in this study were made before 1976, when the doses to patients were considerably higher than with current techniques. For example, the adult (>13 years) breast dose from a full spine anteroposterior view in 1940–1959 was approximately six times higher than the dose in 1976–1989, as shown in Table III. A lesson learned is that using a posteroanterior rather than an anteroposterior view reduces the breast dose significantly. With more recent techniques, a full spine posteroanterior view provides a breast dose approximately 20 times lower than the anteroposterior view.

Likewise, in fluoroscopy, clearly the interventionist should take as much time as necessary to perform the intervention required. However, he/she should be well advised of the data presented in Table IV.

In addition, a lesson learned is that there are methods of reducing entrance dose during high dose rate fluoroscopy (see Table V).

Knowledge of data shown in Table IV and V should help the interventionist reduce unnecessary doses not only to the patient, but also to the doctor and ancillary personnel.

TABLE IV. RISK OF FATAL CANCER ATTRIBUTABLE TO RADIATION FROM FLUOROSCOPY[a] [6]

Age (years)	Sex	Risk of fatal cancer[b] attributable to fluoroscopy time of:			
		1 hour	2 hours	3 hours	4 hours
1–14	Male	1:460 (1.0%)	1:230 (1.9%)	1:155 (2.9%)	1:115 (3.9%)
	Female	1:380 (1.2%)	1:190 (2.3%)	1:130 (3.5%)	1:95 (4.6%)
15–34	Male	1:640 (0.7%)	1:320 (1.4%)	1:120 (2.1%)	1:160 (2.8%)
	Female	1:500 (0.9%)	1:250 (1.5%)	1.165 (2.7%)	1:125 (3.6%)
35–54	Male	1:980 (0.4%)	1:490 (0.9%)	1.325 (1.4%)	1:250 (1.8%)
	Female	1:1087 (0.4%)	1:540 (0.8%)	1:360 (1.2%)	1:270 (1.6%)
55–74	Male	1:1220 (0.4%)	1:610 (0.7%)	1:410 (1.1%)	1:305 (1.4%)
	Female	1:1520 (0.3%)	1:760 (0.6%)	1:510 (0.9%)	1:380 (1.32%)
All	Male	1:760 (0.6%)	1:380 (1.2%)	1:250 (1.8%)	1:190 (2.3%)
	Female	1:730 (0.6%)	1:360 (1.2%)	1:240 (1.8%)	1:180 (2.4%)

[a] Reproduced, with minor editorial changes, from Ref. [8] with permission from Excerpta Medica, Inc.

[b] The chance of developing a fatal cancer induced by radiation is also expressed (in parentheses) as a percentage of the spontaneous fatal malignancy rate for each group and sex.

TABLE V. TECHNICAL FACTORS FOR REDUCING ENTRANCE DOSE IN FLUOROSCOPY [6]

Methods of reducing entrance dose	Relative entrance dose (%)
Collimation	60
Removal of grid	50
Increased applied potential	60–90
Additional filtration	40–80
Pulsed fluoroscopy	10–80

3. RADIATION THERAPY

In radiation therapy, there has been a progression from the early radium and soft X ray systems to orthovoltage approaches to modern cobalt and supervoltage machines, leading to today's linear accelerators and intensity modulated radiotherapy (IMRT), as well as the evolving fields of modern brachytherapy and high dose rate techniques (HDRT), as well as current monoclonal antibody approaches.

An important lesson learned in the process of development is the importance of accurate measurement of dosimetry, and the need for calibration and quality control of radiation output for the adequate treatment of the patient and protection of the patient and operating personnel.

Intensity modulated radiotherapy is a modification of external beam radiation therapy where the photon fluence delivered to the patient is varied over space and/or time to optimize dose (conformably) to the target region and minimize dose to normal tissue. In a strict sense, this new concept builds on the 30-year-old technique developed by Henry Kaplan and others to utilize partial thickness blocks overlaying parts of the complex treatment field to deliver different daily doses to help reduce dose to normal tissue. In IMRT, the concept is extended to subdivide the treatment beam intensity with a number of 'leafs' of various transmission intensity. In some respects, IMRT represents a type of inverse of CT involving back-projection of intensity readings, whereas in IMRT, forward projection of modulated intensities achieves a localization of intensity to a given region. As finer leafs appear in multiple-leaf collimators, one can achieve even finer treatment (spatial) resolution and even better conformal dose distributions.

Of course, brachytherapy utilizing relatively low range beta or photon radiation is also employed to even further try to optimize dose delivery to the target lesion while minimizing dose to normal tissue. With monoclonal antibody approaches, the search continues for the 'golden bullet' which will provide dose delivery only to the cancerous cells with little or no effect on normal cells.

Along these lines, the need for dose optimization in radiotherapy to deliver the dose necessary to kill the cancer cells while minimizing damage to non-cancerous cells is important for the protection of the patient. Radiation to normal tissue has a number of possible negative sequelae including the possible induction of secondary cancers. For example, the study by Biti et al. [9] showed an increased secondary tumour risk observed in treatment of Hodgkin's disease, especially when the initial treatment was with chemotherapy. Other non-cancer complications are encountered, such as urinary and rectal complications in cervical and prostate treatment. Several studies have shown that morbidity (sometimes fatal) is significantly related to the volume of irradiated normal tissue (such as the rectum) as well as the actual dose delivered to the normal tissue.

4. NUCLEAR MEDICINE

Nuclear medicine followed the concept of radiotracers developed by George Hevesy in the 1920s. One sees a progression from radium C tracer studies by Blumgart et al. in 1926 [10], measuring blood transit times, to the concept of artificially produced radionuclides (originally used for therapy), to widespread use of ^{131}I for diagnosis and treatment of thyroid disease [3]. However, it was the work of Benedict Cassen on the rectilinear scanner in the 1940s, and Hal Anger's large field of view gamma camera in the late 1950s, that led to useful image devices. Similar contributions were made by Kuhl and Edwards in SPECT in the 1960s and 1970s. Michel Ter-Pogossian, Michael Phelps and others made similar contributions for PET in the 1970s [3].

In particular, the utilization of ^{99}Tc^{m} by Paul Harper in 1961 led to the widespread use of this tracer for numerous human studies. This generator-produced isotope had excellent image properties and could be safely produced by 'hot labs' at local hospitals. Technetium based agents are widely used and result in reasonable radiation dose levels to the patient and staff.

4.1. Patient precautions in nuclear studies

Good axioms for the protection of the patient and staff, as well as efficacy of procedures, include: checks must be in place so that the correct patient receives the correct amount of radioactivity for the indicated study; all studies must have correct requisitions; patient identity must be clearly established (for example by checking wristband or asking for date of birth). In terms of radiopharmaceuticals, kits should be colour coded so that, for example, a bone agent is not confused with a thyroid agent; the radionuclide must be assayed and compared with the recommended

activity; the syringe must be properly labelled; the correct route of administration must be used; in addition, caution must be used to prevent administration of a useless radiation dose to the patient, such as extravasation.

In the USA, the Nuclear Regulatory Commission requires that for ^{131}I or ^{125}I procedures greater than 30 mCi, or for any other unsealed source therapy procedures such as ^{32}P or ^{89}Sr, a written directive must be completed by the authorized user (i.e. the nuclear medicine physician authorized for unsealed source therapy procedures). The written directive must identify the patient, the procedure, the radiopharmaceutical form, and the route of administration. The directive must be signed and dated, and before administration the patient must be identified in two ways. Prior to administration by the authorized user, the material must be assayed and documentation provided that the radioactivity is within 10% of the prescribed amount. It must also be documented that the administration is in accordance with the written directive, for example by having the authorized user who administers the procedure sign the dose slip. Written documentation must be kept on file. In the USA, such policies and precautions should be contained in the institution's written quality management programme [11].

4.2. Technical developments

In terms of imaging developments, improvements are found in the number and quantity of photomultiplier tubes, crystal size and thickness (intrinsic resolution), and collimator design (extrinsic resolution), leading to improvements in image quality in such areas as resolution and uniformity. In addition, the development of multihead cameras led to increased sensitivity and the practical acquisition of SPECT studies. One can note, however, that the fundamental limitations imposed by finite patient dose and emitted gamma ray fluence, along with the limited solid angle of capture, losses in efficiency due to collimation and the need to reduce scatter, make gamma ray imaging particularly sensitive to noise resulting from the finite number of detected gamma rays making up the final image. Thus nuclear medicine studies are forced to work with spatial resolution levels an order of magnitude worse than most diagnostic studies (X ray and CT), and several orders of magnitude lower count density per unit area. For example, nuclear medicine spatial resolution is of the order of several millimetres compared with fractions of a millimetre for CT and image intensifiers, and for radiography of the order of 100 mm or better.

An important lesson learned is that we can work with much lower spatial resolution and much more noise when the target signal is relatively large and when the target somewhat self-isolates from a relatively unstructured background, as provided, for example, by CT. An important lesson learned is that tomographic approaches that extract signals from complex backgrounds have very high diagnostic yields.

5. SUMMARY

As can be seen, the history of radiology offers many examples of lessons learned. In the quest for better diagnosis in X ray and nuclear studies, better intervention in cardiology and angiography, and better radiation therapy treatment, it is important to understand ways to improve efficacy and provide protection for patients and staff. We must walk a tightrope, balancing the benefits and risks of any technology utilizing radiation to produce the greatest benefits at the lowest acceptable risk. The alternative techniques using non-ionizing radiation will have to be considered as part of the general armamentarium for medical imaging whenever radiation consequences are unacceptable.

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THE INTERNATIONAL REGULATORY CLIMATE

J.-F. LACRONIQUE
Ministry of Health,
Office de Protection contre les Rayonnements Ionisants,
Le Vésinet, France
E-mail: jflacronique@opri.fr

Abstract

The paper describes how it has been possible to change the situation in regard to the radiation protection of patients from one of almost total professional freedom to worldwide organized control, thanks to a 'climate' that has stimulated changes across national boundaries, cultures and traditions.

1. INTRODUCTION

The scene is the Earth. Forces of different origins are evident, crossing all boundaries, sometimes changing direction. These forces carry energy that has unexpected consequences, leading here to major changes that reshape the landscape, there to mere amendment, and elsewhere to nothing. Patterns can be described showing countries that share the same way of responding to these forces. This paper deals with 'climate' at a time when global changes are under discussion. However, the term climate is here applied to something different from temperature, humidity, wind and rain. Instead, a climate is described that pertains to regulations in the field of the medical use of radiation on an international level.

The beginning of the 21st century coincides with the application, in many European countries, of a new directive that aims at protecting individuals against the dangers of ionizing radiation in relation to medical exposures. The Directive should have been implemented simultaneously in 15 countries, beginning in May 2000, after being signed by all the Ministers of the Member States in June 1997. A Directive is one of the regulatory measures that the European Commission can issue. In the case of radiation exposure, all the regulatory texts have to be placed under the Euratom Treaty, signed in 1957. Article 2(b) of the Euratom Treaty states that "the Community shall establish uniform safety standards to protect the health of workers and of the general public against the dangers arising from ionising radiation and ensure that they are applied."

The same Treaty defines the hierarchy of the different provisions in its article 161:

— A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States.
— A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of forms and methods.
— A decision shall be binding in its entirety upon those to whom it is addressed.
— Recommendations and opinions shall have no binding force.

To give illustrations of these different provisions, the Basic Safety Standards (BSS) [1] are linked to a directive, such as the directive on external workers, the one on medical exposures or the one on shipment of radioactive waste.

Regulations were issued on imports of foodstuffs in 1986, after the Chernobyl accident, after several recommendations.

A directive imposes on all Member States the requirement to integrate into their national regulations the entire substance of a text that has been prepared at a supranational level. The effort towards protecting the public against the risks attached to medical exposures is not unique to Europe. Many other countries are heading in the same direction, but with various degrees of acceptance and application. One objective of this conference is to compare the level of maturity in this process. In some instances, these new requirements will be considered as futile and unnecessary precautionary principles. But for the majority, the new regulations constitute a historical landmark in the general idea of protecting the public from the possible harmful effects of radiology and nuclear medicine.

2. THE NATURE OF THE FORCES

The forces that were mobilized were numerous. The most important is represented by the professionals in the field, and we will show that nothing would have been possible without the strong involvement of the professional bodies. However, we must first analyse why and how the professionals have been proponents and not opponents of this change. Radiologists are not known to be prone to any kind of regulation. The large majority of them do not like constraints on what they consider as the most important feature in the practice of medicine, which is freedom. A large number of them are working as independent private practitioners. They have made large financial investments in their equipment, and they hope to enjoy returns on this investment. Others work in public institutions, and they have quite different motivations, but they share the same appetite for freedom as the vast majority of MDs, and they do not like administration. Except for this simplistic sociological analysis of the profession, we would be facing a rather complicated international

TABLE I. ITEMS OF EQUIPMENT IN DIFFERENT COUNTRIES IN 1999

	Number of machines			Number per million inhabitants		
	MRI	CAT	PET	MRI	CAT	PET
USA	7 452	7 453	170	28	28	0.64
Japan	3 825	10 250	37	30	81	0.29
Germany	1 148	1 654	75	14	20	0.91
Italy	444	1 154	10	8	20	0.17
Spain	340	457	9	9	12	0.23
UK	313	296	13	5	5	0.22
France	182	595	5	3	10	0.08
Turkey	115	192	1	2	3	0.01
Belgium	55	236	17	5	23	1.67

scene, with a strongly contrasting picture of the practice of radiology among countries.

On the European scene alone, the ratio of items of equipment to population (Table I) shows considerable differences. These differences determine differences in access of the population to care, differences in health investment and expenditures, and differences in the health care production function. The question of the similarity of ‘needs’ in terms of quality assessment and control is certainly a good one, but I doubt that this has been seriously studied. The term ‘need’ is one of those which generates allergies and rejection among makers of health policy.

How do these diverse types of practitioners react to the new regulation principles? The expectation is that there should be very different professional attitudes among various groups and among various countries and cultures. However, even while that is partially true, I would say that these variations are not perceptible for the time being, and that there is little evidence that rejection has been observed so far. But we are still far away from a widely implemented policy.

The reason for this apparent current consensus is that radiologists cannot escape from social pressure. They know that the patients, in all countries, are paying much greater attention to radiation, and that they could be vulnerable if they do not display a sensitivity to the risk of patient exposure.

Another important source of evolution in the minds of the professionals lies in the coherence between the different regulatory approaches in the different uses of radiation. If expectations for the safety of the public have to be respected, then how is it possible to make acceptable, without concern, doses that sometimes exceed several hundred times the annual basic safety standards?

Patient irradiation started to be a real concern in the 1970s, when it was widely published that the level of radiation in the medical field represented 99% of all human-made exposure to the public. Until then, the undesirable side effects of the medical applications of radiation were limited to the practitioners, who paid quite a large price in terms of harmful effects. But no incident or accident was ever reported in the normal use of radiology for the patient, even in the most exposed groups of patients. However, visible effects of radiation can still be noticed on patients after exposures during interventional radiology procedures, in the form of rashes, with doses that cannot be considered as low.

But schematically, the need for special attention came with the epidemiological and the biological advances that showed that there could be a long term effect of radiation at relatively low doses. The issue of the 'no threshold linear hypothesis' by the International Commission on Radiological Protection (ICRP) opened a new door in the evaluation of risks attached to radiation exposure: a simple calculation could be made, implying that X rays used in normal practice could generate thousand of deaths per year by cancer. The fear of legal action then followed, and the professional bodies made the strategic decision to accept the challenge, and to take a position that would be interpreted as intended to protect the patient.

3. RECOMMENDATIONS PRECEDE REGULATION

These changes are reflected in the evolution of the ICRP: in 1957, a series of recommendations specifically devoted to the methods of evaluation of the exposure of humans arising from medical procedures was issued. Committee 3 of the ICRP was created in 1962, devoted to radiological protection in medicine. However, most of the published work of the ICRP during the two subsequent decades was focused on the study of the impact on health of the radionuclides which were the main concern during the emerging civil use of nuclear power. The first specific text from the ICRP on the protection of patients was published in 1970 [2], followed by an update in 1982 [3].

The role of the ICRP is very unusual on the international scene, since it gives to a non-governmental organization the power to initiate a 'flow of information' that can lead to regulations. I do not know of any other health protection fields where national regulatory powers have been that much influenced by the 'climate' generated by an organization that is self-administered and self-appointed. The nature of radiation and its capacity to have unknown delayed effects might explain the need for an independent scientific body that has an international status. This very original role preceded the work of all other international organizations, such as the International Atomic Energy Agency, the World Health Organization and the European Commission, and the ICRP became naturally not only a source of scientific data, but

the inspiration for all regulatory actions undertaken by all other international and national bodies.

In the European countries, the EC directives are directly based on the ICRP recommendations (this is specifically mentioned in the preamble of the first 84/4666 EC directive), setting the basic safety measures relating to the protection of persons undergoing a medical examination or treatment. The first EC directive had a great deal of influence, with or without implementation at the national regulatory level. As a matter of fact, this first directive was followed by very different attitudes in the then 12 European Member States. However, from the point of view of practical implementation, the comparative situation in the behaviour of the professionals in the field does not show the contrast that could be expected from this diversified scene. An example is provided by the attitude towards direct fluoroscopy, which has been considered as potentially highly harmful, but which in many countries has not been banished from the list of authorized equipment. It is to be hoped that this outmoded equipment is not being used in practice, but the trend for its withdrawal has not been stimulated by regulations but rather by other 'natural forces'.

4. THE SPIRIT OF LAWS

Montesquieu said in 1735, "Laws, in their most extended meaning, must reflect the forces that derive from the natural order of things." There cannot be a better citation for the understanding of when and why it became necessary to regulate the field of patient irradiation in medical practices.

The forces that Montesquieu referred to are concentrated, in our area of interest, mostly in the professional bodies. These bodies have many personal international ties, and most of the decision makers in this field exploit the international scene to keep their countries in the mainstream of practice. There are journals, congresses and visits that continuously animate the exchanges. These 'natural' international forces are stimulated by the manufacturers of equipment, particularly in radiology, where there exists a tendency towards concentration and internationalization. The advances in technology, which have been continuous in the past 50 years, have been the principal source of the evolution that has most often preceded any kind of regulation.

5. WORKING TOGETHER

It follows from this analysis (and from Montesquieu) that the legislation, even if it comes from national regulatory bodies, has only a small chance of being applied if it fails to involve organizations outside the regulatory framework. The full endorsement of professional representatives is necessary to ensure compliance with the

standards adopted at an international level. This wide consultation must include the national professional bodies, who have the responsibility for the prescription (on the demand side), and those who have to fill the prescription (on the offer side). That includes:

— The professional unions, particularly the general practitioners, at the individual level. The practising physicians do not remember the basics of physics that they learned in the first years of medical school, and they have little concern about the doses that patients receive during a radiological procedure. Most often, they do not want to learn about previous radiological examinations, and they do not hesitate to make a new prescription. There is almost nowhere (except in Austria, to my knowledge), a mention of the total doses encountered by a patient, and regulations are far from implementing this requirement in the near future.
— The medical societies in radiology. These are often subdivided into many chapters (geographical and/or thematic: paediatrics, neurology, cardiovascular). In contrast to what was said about general practitioners, these bodies have had very positive reactions to the new regulations, and have organized working groups that have issued recommendations and guidelines.

The reason for these bodies to accept regulation, after decades of relative freedom, is the perception of a new challenge issuing from the demand for safety in health care, after numerous worldwide controversies such as the contamination of blood with HIV, bovine encephalopathy, the rise of thyroid cancer after Chernobyl and so on. In medical diagnosis, the profession is now volunteering control of irradiation that would protect them from potential future claims by patients.

Thus, a second set of ‘natural forces’ can now be seen, where the administration would like to anticipate a ‘public expectation’ that is, for the time being, relatively discrete and limited in its expression to a very small number of militant anti-nuclear organizations. So far, these organizations have made little criticism of radiology, which maintains a rather positive image in the public mind. Radiology enjoys a deserved reputation of being far more useful than harmful, but nobody can predict how long this privilege can be kept untouched: in nuclear medicine, for example, criticisms are much closer to being accepted.

What has been said so far means that there is no hurry. Since there is still no sense of emergency, the process of regulation can involve a series of actors that can play a role in the implementation of the regulations, and in that sense, the subject is a model in public health issues, since it involves a lot of potential ‘partners’:

— Another set of bodies that have to be included in the consultation process are the agencies that are in charge of the licensing, safety and quality assurance of medical devices. In the United States of America, the model would be the Food

and Drug Administration, and this model has been copied in many countries. In France, for instance, the former 'Drug Agency' was transformed in 1998 into a new national agency for the safety of health products (AFSSAPS), with a strong regulatory power that applies to all kinds of consumer goods that relate to health care. This agency issues the authorization to sell drugs or devices to the public. It deals only with efficacy and safety and does not set prices. It also has the power to withdraw a product that would not meet the quality requirements. To give an example, the agency was asked to cancel the authorization for operating various mammography devices that were not judged satisfactory by experts in 1999.

— In some countries there now exist distinct agencies that are responsible for the evaluation and/or the accreditation of health facilities. In the USA, this role is played by the Agency for Health Care Research and Quality, which sets up clinical practice guidelines. However, this agency shares this responsibility with the previously mentioned medical societies, and offers only a methodological framework. In the United Kingdom, this role is given to the National Health Services Executive, the practical work being done by the Royal College of Radiologists. The same scheme is followed in France with the National Agency for Evaluation and Accreditation in Health Care (ANAES) and the French Society for Radiology (SFR). In addition, these agencies also have the role of determining cost/benefit ratios, particularly in comparison with other diagnostic procedures (other imaging techniques, endoscopies, biology), with the help of health economics experts.

— The bodies that validate the price of medical procedures are another set of administrators that have a major role in the regulation of medical examinations. Such administrators sometimes set ratios of equipment per population, when this equipment can lead to heavy public expenditures. Setting ratios, reimbursement prices or coverage prices can lead to complex reactions in the market. One key element is the prices given to different techniques that can be considered as complementary or additive. For example, CAT scan and MRI are not identical in terms of clinical performance, but there exist a large number of situations where substitution can be discussed. In countries where a scarcity of this equipment exists, the demand is high, and the real price (and not the official price), which includes the waiting lines and sometimes a black market price, can be very high. There appears a new dimension that cannot be underestimated, which is the inequality of access, which is obviously encouraged by situations of shortage. I have to recognize that in that field, the French situation is not a model. In France, radiology is clearly viewed by the public health insurance system as one of the most important sources of diagnostic costs, and its proportion in total health expenditures is increasing with time. For that reason, there will inevitably be a conflict between the 'pure' objectives of public health,

when the issue of radiation control is brought about for safety reasons, and the 'impure' objectives of justification of radiological procedures. The question of whether the ethics of health economics (i.e. an optimal use of public resources) can exploit the ethics of safety is an important one, and one that has already had dramatic echoes in the press.

— The associations that are interested in radiation control, environmental protection or patient advocacy can also be included in the planning process. In some areas, such as the prevention of breast cancer, they have a major role, illustrating the real behaviour of the patient facing technocratic programmes, and for this they are a key element in view of their practical features.

— Last but not least, the radiation protection authorities are a good candidate for the co-ordination of the whole system. They can translate the regulatory texts into practice, and they can explain the scientific principles of the whole construction of the system and show the logic in it.

Economics is also the science of the distribution of resources, and we have already mentioned the international market. In other countries, the fear of 'supply generating demand' has led to control of equipment that is sometimes interpreted as a rationing policy. Numerous experimental regulatory mechanisms have been implemented in many industrialized countries, sometimes showing their limits: the Certificate of Need or the Professional Standard Review Organizations that were tried in the USA in the early 1980s are interesting examples of vanished regulations. Other planning mechanisms have been applied, creating a complex situation without any model or unity in the definition and responsibilities of the regulatory authorities. Moreover, inspectors or experts in this particular field are scarce, and there is currently no internationally accepted protocol for their intervention. The IAEA, the European Commission, the World Health Organization and the Pan American Health Organization would certainly be welcome in stimulating a co-ordinated effort in that direction.

At the other end of the spectrum of the distribution of wealth among nations, this body of inspectors could perform the task of stimulating the supply of equipment, because in the vast majority of developing countries, the worry is not the over-consumption of X ray examinations, but the insufficient use of them. In these countries, radiological machines are lacking, and radiological procedures are too expensive for the majority of the population. The UNSCEAR Report distinguishes two sets of countries where the annual frequency of X ray examinations is in the range of 10 per 1000 inhabitants, one hundred times less than the ratio in developed countries (of the order of one per inhabitant). It is obvious that the safety regulations in these countries do not have the same order of priority as in the most developed ones. UNSCEAR indicates that two thirds of the world's population is still lacking adequate diagnostic imaging and radiation therapy services, and the priority here is to

stimulate utilization rather than to control it. However, the dramatic need for equipment in these countries should not be interpreted as a lower need for safety and quality insurance.

In conclusion, the 'climate' for regulation in the area of medical exposure of the patient is like the weather on the globe: it is changing; it is different among countries and continents; it causes very different problems to the northern and the southern populations. It also needs a concerted effort to reach a common goal, the protection of the population against the potential harm of radiation. But one has to bear in mind that radiology and radiotherapy have brought immense and indisputable benefits to the human race, and that the risks attached to their possible over-utilization, in comparison, are low in magnitude.

Would a 'global climate' be sufficient to change the behaviour of the many professionals involved, of the patients or the general public? Certainly not. Regulations have to make things respected. National laws are necessary to organize and unify a change, and recommendations that comes from international bodies can be ignored. But laws without enforcement measures have similar weaknesses, and good regulatory principles must include all application measures, such as evaluation and inspection, marketing and teaching programmes, and even penalties for violators.

The objective is that a culture of radioprotection should prevail, meaning that any practice using ionizing radiation be justified and optimized, and that basic safety standards be adopted the in same way all over the world. It is to be hoped that, in contrast to the conference on the world climate last November in The Hague, there can be hope of an achievement in the international negotiations towards this common goal.

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