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MEASURES TO STRENGTHEN INTERNATIONAL CO-OPERATION IN NUCLEAR, RADIATION, TRANSPORT AND WASTE SAFETY

INTERNATIONAL ACTION PLAN FOR THE RADIOLOGICAL PROTECTION OF PATIENTS

Report by the Director General

BACKGROUND

1. In October 1999 - in resolution GC(43)/RES/12 - the General Conference requested the Secretariat *"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"*.
2. In response to the General Conference's request, the Agency organized the *International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy*, which was held in March 2001 in Málaga, Spain. The Conference was hosted by the Government of Spain, co-sponsored by the World Health Organization (WHO), the Pan American Health Organization (PAHO) and the European Commission, and organized with the co-operation of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP), the International Organization for Medical Physics (IOMP), the International Radiation Protection Association, 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).¹

¹ The proceedings of the Conference were published by the Agency in 2001 under the symbol STI/PUB/1113.

3. In September 2001, the Board requested the Secretariat to convene a group of experts to formulate - on the basis of the Conference's findings, conclusions and recommendations - an action plan for future international work relating to the radiological protection of patients, and to submit the action plan to it for approval - a request subsequently endorsed by the General Conference in resolution GC(45)/RES/10.A.

FORMULATION OF THE ACTION PLAN

4. Pursuant to that request, the Secretariat convened a technical committee consisting of senior experts from a number of Member States² and representatives of WHO, PAHO, the European Commission, UNSCEAR, ICRP, the International Commission on Radiation Units and Measurements, the International Organization for Standardization, the International Electrotechnical Commission, IOMP, ISRO, ISRRT, ISR and WFNMB. The technical committee met from 28 January to 1 February 2002 under the chairmanship of Professor Fred Mettler, University of New Mexico, United States of America, and recommended the *International Action Plan for the Radiological Protection of Patients* that is contained in the Attachment to this document.³

RECOMMENDED BOARD ACTION

5. It is recommended that the Board approve the attached *International Action Plan for the Radiological Protection of Patients* in principle and request the Secretariat to implement it without prejudice to the Board's consideration of the draft programme and budget for 2004 and 2005.

² Bulgaria, Canada, Chile, China, Finland, France, Germany, India, Israel, Italy, Poland, the Russian Federation, Spain, Switzerland, the United Kingdom and the United States of America.

³ In 2002 and 2003, the Secretariat will endeavour to carry out the activities envisaged in the *International Action Plan* through a refocusing of general programme implementation. The *International Action Plan* will be taken into account by the Secretariat when preparing the draft programme and budget for 2004 and 2005.

INTERNATIONAL ACTION PLAN FOR THE RADIOLOGICAL PROTECTION OF PATIENTS

1. INTRODUCTION

1.1 Background

Ionizing radiation is used extensively in medicine; worldwide, about 2000 million diagnostic X ray examinations and 32 million nuclear medicine procedures are carried out annually, and of about 10 million cancer patients 40-50 % receive radiotherapy. Moreover, it is hoped that its use in medicine will increase, as the benefits for patients are enormous, far exceeding the risks.

In the 2000 report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), it was stated that medical applications of ionizing radiation represented by far the largest man-made source of ionizing radiation exposure. According to the International Commission on Radiological Protection (ICRP), however, there is considerable scope for dose reduction in diagnostic radiology and simple, low-cost measures are available for reducing doses without loss of diagnostic information. At the same time, while new diagnostic equipment and techniques are bringing new benefits, some of the procedures involve the delivery of relatively high radiation doses to patients. In addition, a number of radiation injuries in interventional radiology and accidental exposures in radiotherapy have been reported. These facts have focused attention on the need to improve the radiological protection of patients in diagnostic and interventional radiology, nuclear medicine and radiotherapy.

One of the statutory objectives of the Agency is to seek “to accelerate and enlarge the contribution of atomic energy to ... health... throughout the world”. The Agency pursues that objective through, in particular, the Human Health programme of its Major Programme 2, “Nuclear Techniques for Development and Environmental Protection”. This programme, with its predecessor Agency programmes, has made a significant contribution to the use of ionizing radiation in medicine by making the benefits accessible - through, inter alia, technology transfer - to large numbers of people, especially in developing Member States.

At the same time, the Agency is authorized by its Statute 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 ... to provide for the application of these standards ...”. The Agency performs that function through, in particular, the Radiation Safety programme of its Major Programme 3, “Nuclear Safety and Protection against Radiation”. Under that programme, and its predecessor Agency programmes, a corpus of safety standards for the protection of health has been created and a wide range of activities providing for the application of those standards has been initiated.

The safety standards that are applicable to this International Action Plan are the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS).¹ Also applicable will be a Safety Guide on

¹ The BSS are jointly sponsored by the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, the International Labour Organization, the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development, the Pan American Health Organization and the World Health Organization.

Radiological Protection for Medical Exposure to Ionizing Radiation which was published recently. The mechanisms for implementing the International Action Plan will be the same as those for providing for the application of Agency safety standards - namely, promoting education and training, providing assistance, rendering services, fostering information exchange and co-ordinating research.

1.2 Principles of the International Action Plan

Because medical uses of radiation represent a large source of exposure, special attention must be paid to minimizing the risks, which range from trivial to serious depending on the situation. Patients have a right to expect the radiation to be used in a safe and effective manner.

Health professionals involved in the processes of diagnosis and treatment are the critical link. Training them properly and ensuring intensive information exchange among them are, therefore, probably the most cost-effective ways of achieving patient safety.

Radiation protection programmes in medicine must allow the dose to be sufficient for obtaining adequate diagnostic information and for treatment. To this end, quality assurance (QA) systems are essential. Radiation safety regulations and guidance should not impair medical care; they should focus on performance and allow for flexibility in achieving the desired outcomes.

The objective of the International Action Plan is to make progress in patient safety as a whole. The involvement of international organizations and professional bodies is crucial to performing the actions and achieving the goals outlined in it.

Accordingly, the principles underlying the International Action Plan are that all components should:

- i. strengthen systems for the radiological protection of patients;
- ii. fit within existing sub-programmes, maximizing the use of current activities and existing documents; and
- iii. result in the identification of activities for implementing the recommendations of the Málaga Conference.

The International Action Plan consists of relevant current activities and of proposed new ones (including modifications of current activities). A summary of the relevant current activities is given in Attachment 2, while Attachment 3 contains summaries of relevant activities of other international organizations and a number of professional bodies.

1.3 Structure of the International Action Plan

The actions have been grouped according to the main uses of ionizing radiation in medicine. Some of them are applicable to all these uses and have therefore been placed under "Actions common to diagnostic and interventional radiology, nuclear medicine and radiotherapy"; others are more specific and also have been placed in their respective subject areas. As there are various Agency mechanisms for implementing the actions, a second level of classification has also been used, with the following sub-headings: education and training, information exchange, appraisals and other services, assistance, guidance and co-ordinated research.

2. THE INTERNATIONAL ACTION PLAN

2.1 Actions common to diagnostic and interventional radiology, nuclear medicine and radiotherapy

Education and training

The education and training of staff (together with QA) are essential for ensuring the best radiological protection of the patient while preserving the necessary diagnostic information or therapeutic treatment. To be effective, education and training and continuous professional development need financial and moral support at the local, national and regional levels. The relevant international organizations and professional bodies can contribute substantially through the development of appropriate training material.

Education and training programmes should be targeted at particular audiences, taking account of their specialties — medical practitioners (specialists, general practitioners, and also non-radiologists who use X ray equipment), technologists, nurses, medical physicists, radiopharmacists, equipment designers, equipment maintenance engineers, biomedical and clinical engineers, administrators, regulators, etc. That requires the development of a systematic approach to education and training, with the recipients' needs and the means of meeting those needs clearly identified and the training material made available in all official languages of the United Nations (Arabic, Chinese, English, French, Russian and Spanish). Translation of the training material into other languages should be encouraged.

Action: to complete the development of a standard syllabus and packages for training in the application of safety standards.

Action: to train the trainers involved in national training programmes using the above mentioned packages.

Specially qualified experts are necessary for ensuring compliance with the BSS by carrying out or supervising calibration, dosimetry and QA in radiotherapy and advising on imaging and QA in diagnostic radiology and nuclear medicine (BSS, Appendix II, sections 1 and 2). However, there are not many such experts at present, which constitutes a challenge for education and training.

Action: to arrange for a review of the syllabus for the Agency training courses in medical radiation physics by appropriate professional bodies and to publish the results.

In view of the large numbers of people requiring education and training in the radiological protection of patients, consideration should be given to making use of distance learning and the Internet. The relevant international organizations and professional bodies could contribute substantially through the development of appropriate material.

Action: to explore the potential uses of information technology and distance learning, identifying application areas and types of information technology.

Information exchange

There are many well described dose reduction and QA techniques that are not being applied owing to lack of resources and also to the fact that information about them has not been widely disseminated. Making such information available is a cost-effective way of achieving a major improvement in the area of patient protection.

Information exchange mechanisms such as the Internet could be used for disseminating a periodically updated list of publications of the organizations that co-sponsored the Málaga Conference and the professional bodies that co-operated in organizing it – and those other professional bodies that have co-operated in the development of the International Action Plan. The exchange could involve the Inter-Agency Committee on Radiation Safety and web links between the co-sponsoring organizations and co-operating professional bodies, and also an actual exchange of publications among the organizations and professional bodies. Consideration should be given to disseminating information about relevant congresses, symposia, courses, workshops, meetings, protocols, reports etc. and to providing physicians who refer patients for radiological procedures with information about associated risks.

Action: *to explore mechanisms for widely disseminating information related to the protection of the patient.*

Information about accidental exposures - mainly in interventional radiology, therapeutic uses of radiopharmaceuticals and radiotherapy - could, if properly collected and disseminated, help to prevent similar occurrences in the future. In addition, the collection of information about events that did not have, but could have had, clinical consequences and the dissemination of lessons learned from such events could be very useful. Collection and dissemination programmes are being developed by professional bodies, and the Agency should work together with those bodies.

Action: *to collect and disseminate, using the Agency's International Reporting System for Unusual Radiation Events (RADEV), information about accidental medical exposures, including, as far as possible, information about events that did not have clinical consequences but from which prevention-relevant lessons can be drawn.*

Assistance

The requirements of the BSS are comprehensive, and many developing countries do not at present have the resources or expertise necessary for fully meeting them. Substantial responsibilities are placed on the users of radiation in medicine, and it is recognized that meeting the requirement of the BSS must be a step-by-step process.

Action: *to support Member States in the gradual transition from the basic to advanced stages of implementation of the BSS.*

Remark: the stages of implementation will be defined in the course of activities carried out under “**Guidance**”.

Different types of professionals, particularly medical physicists and technologists, carry out QA and radiation protection in medicine. With regard to medical physicists, in many countries their availability and role are limited by lack of official recognition; currently, for example, medical physicists are not recognized by the International Labour Organization (ILO) as health professionals. With regard to technologists, who carry out day-to-day procedures with an impact on patient doses, they represent a largely untapped resource for the radiological protection of patients.

Action: *to promote the formal recognition of medical physicists responsible for the radiological protection of patients as health professionals.*

Action: *to promote - through the provision of advice about the functions, responsibilities and training of technologists - recognition of the impact of technologists involved in day-to-day procedures on the radiological protection of patients.*

Many Member States need Agency support with regard to the traceability of dose measurements in radiotherapy. The Agency should ensure, through continued verification, consistency among Member States, involving organizations such as WHO, the Bureau international des poids et mesures (International Bureau of Weights and Measures), the International Commission on Radiation Units and Measurements and the International Organization of Legal Metrology. Auditing for quality in dosimetry is also needed for radiotherapy facilities in Member States.

***Action:** to continue current activities in radiotherapy concerned with the traceability of dose measurements and with audit services, including the development of local expertise, and to extend these services to diagnostic radiology and nuclear medicine.*

Guidance

Risk-informed regulations can positively affect the benefit/risk ratio. However, it is not the role of radiation safety regulators to scrutinize an individual decision to use radiation in medicine; rather, it is their role to enforce good practice without unnecessary interference in the care of the patient. Regulatory requirements should be performance-oriented, and the technical detail should be provided in the form of guidance. The practice-specific documents under preparation should be finalized as guidance rather than regulations, and they should include input from professional bodies, from international organizations and from authorities with responsibility for radiation protection and medical care.

Guidance should include advice, provided in a non-prescriptive manner, about the radiation protection expertise necessary for various levels of sophistication of the medical applications. It should also include advice about the gradual transition from basic to advanced stages of implementation. The advice should be disseminated through education and training.

***Action:** to finalize the existing draft practice-specific guidance documents, seeking input from professional bodies, international organizations and national authorities responsible for the radiological protection and medical care of patients..*

There are important safety issues related to the transfer of second-hand equipment to developing countries - for example: the real needs of the recipient country; the provision of tools, accessories, spare parts and manuals; arrangements for acceptance testing, commissioning and maintenance; and training in the use of the equipment with its specific radiation protection features.

***Action:** to provide guidance to donors, recipients and NGOs on the safety issues related to the transfer of second-hand equipment.*

2.2 Actions in diagnostic and interventional radiology

Education and training

Substantial dose reductions can be achieved through - for example - the proper use of equipment, the selection of adequate tube voltages, the proper collimation of radiation beams (to avoid the exposure of tissues other than those of interest), filtration (to limit the exposure to low-energy radiation that has no diagnostic value), and the regular reviewing and updating of radiographic and fluoroscopic protocols in the light of the technique and the equipment type being used, with special emphasis on the number of images and fluoroscopy time.

With over 250 million paediatric diagnostic examinations conducted every year worldwide, special attention should be paid to neonates, infants and children, because the

risks of stochastic effects are higher than for adults and because of the wide range of weights, which complicates the standardization of procedures. It is estimated that doses to paediatric patients could be reduced by 35–75% without image quality being affected.

Improvements in the use of equipment could be achieved through the provision of training in conventional radiology for those involved in the daily use of X ray equipment, such as radiographers and radiologists.

Action: *to provide for the training of radiographers and radiologists in the optimum management of doses in conventional radiology.*

Because an image receptor with a dynamic range much broader than that of film is used in digital radiology, patient exposure is not restricted by the characteristics of the image receptor, with the consequence that doses higher than is necessary for obtaining the information needed for diagnosis may be used. In fact, such unnecessarily higher doses reduce quantum mottle, which may encourage their use.

Action: *to provide for training in the application of digital techniques for staff at facilities which are in transition from conventional to digital equipment, with a view to ensuring the proper management of patient exposure.*

Computed tomography (CT) offers considerable benefits but involves relatively high doses. With techniques such as multi-slice CT and CT fluoroscopy, the doses can be particularly high. Techniques appropriate to adults are often used in the case of children. It is important that the doses be kept to a minimum, through the careful design of protocols, strict patient referral criteria, the use of automatic exposure controls (when available) and the careful choice of scanning techniques, including the use of paediatric protocols.

Action: *increase - through training and information exchange - the awareness of users of CT techniques (including multi-slice CT and CT fluoroscopy) regarding radiation dose and image information and to promote the use of paediatric CT protocols.*

Appraisals and other services

Diagnostic radiology guidance (reference) levels should be established on the basis of the dose distributions observed and the image quality and equipment performance data obtained in a given region or country. The role of international organizations would be to encourage countries to develop their own guidance (reference) levels, providing them with a methodological approach.

Action: *to develop a methodology for establishing local guidance (reference) levels for diagnostic radiology, through simple surveys taking into account image quality, to disseminate the methodology, to promote programmes for assessing it and, during the assessments, to help countries with the conduct of quality control tests involving the use of phantoms and patient dose measurements.*

Action: *to develop a methodology for assessing the infrastructure for patient protection in diagnostic radiology, through peer reviews that cover training, equipment, procedures, image quality, patient doses and QA programmes.*

Guidance

Methods for reducing doses to patients while preserving diagnostic information have been documented in the literature, including ICRP publication 34. There is, however, only very limited information on the effectiveness and costs of the different methods, which makes

it difficult to prioritize actions and to devise strategies for implementation.

Replacing manual by automatic film processing can facilitate the management of patient exposures, but it involves a substantial investment and is advisable only where there is a substantial volume of film to be processed and where there is an appropriate infrastructure in terms of water, electricity and maintenance. Similarly, replacing direct fluoroscopy by image-intensified fluoroscopy, using radiography instead of fluoroscopy or using film-screen combinations of higher speed (rare-earth screens for example), would achieve substantial dose reductions, but it involves substantial investment and does not necessarily facilitate patient diagnosis. It is for Member States to assign the necessary priority to such replacements and to draw up the necessary plans, which should take medical and financial aspects into account.

***Action:** to carry out a study on the cost-effectiveness of the various approaches to protection optimization that reduce doses while preserving the diagnostic information and to provide guidance on priorities and strategies for implementation.*

Problems of connectivity among components of computerized systems and among different systems, for images used in diagnosis and therapy, may cause loss of images or of image information, leading to repeated radiation exposures of patients. There is a need for standardization, relating to connectivity, in picture archiving and communication systems (PACS) and radiological information systems (RIS). This standardization should cover the dose data to be incorporated into equipment design.

***Action:** to conduct consultations with manufacturers on achieving interconnectivity of computerized imaging equipment.*

***Action:** to conduct consultations with manufacturers and standards organizations on standardizing, displaying and recording data related to patient doses for CT, fluoroscopy and interventional techniques.*

Co-ordinated research

Guidance (reference) levels have proven to be useful for dose management in standard types of diagnostic examinations. However, their applicability in the case of complex procedures, including interventional procedures, is not so obvious, although the issue is very important given the high doses involved. Several groups are exploring the feasibility of establishing guidance levels for interventional procedures, and there is a need to co-ordinate their efforts.

***Action:** to co-ordinate research work on exploring the feasibility of establishing guidance (reference) levels for complex procedures in diagnostic and interventional radiology.*

2.3 Actions in nuclear medicine

Optimization in nuclear medicine requires the proper selection of radiopharmaceuticals and activities, taking into account the special needs in the case of children and providing for higher activities in the case of overweight patients. It also requires the use of methods for blocking uptake by organs not being studied and for accelerated excretion. In the use of imaging equipment, optimization depends on appropriate image acquisition and processing. All of this can be facilitated by existing standards, guidelines, protocols and QA procedures.

Action: *to promote in developing countries - through training and the dissemination of information - the use of existing standards, guidelines, protocols and QA procedures in both diagnostic and therapeutic applications, including radiopharmacy.*

New techniques, such as positron emission tomography (PET), which provide new diagnostic information are being increasingly used. The doses from such techniques are often, however, higher than those from more conventional techniques.

Action: *to complete the task of developing a technical document on the quality control of PET systems.*

2.4 Actions in radiotherapy

Information exchange

The Agency's Directory of Radiotherapy Centres (DIRAC), which includes information about – inter alia – sources and equipment used in teletherapy and brachytherapy, treatment planning computers, and QA equipment, is an important tool for the dissemination of information, especially in the cases of accidental exposure.

Action: *to maintain the Directory of Radiotherapy Centres (DIRAC)*

Assistance

The Málaga Conference concluded that QA is particularly important for ensuring effective and safe treatment in radiotherapy. Audits of quality are important, and the Agency - together with WHO - provides a service to radiotherapy facilities in Member States under the IAEA/WHO (IAEA/PAHO in Latin American and Caribbean countries) TLD postal dose quality programme. Follow-up on abnormal results improves reliability and helps to prevent accidental exposures.

Action: *to follow up on abnormal results of the postal dose quality checks and assist in the establishment of national and regional dosimetry programmes.*

Guidance

Harmonizing dosimetry methods worldwide through the development of international codes of practice continues to be an essential role of the Agency.

Action: *to continue to develop and disseminate codes of practice for dosimetry.*

A recent accident in Panama showed the need for guidance on the testing of treatment planning (TP) systems for radiotherapy. This need relates not only to TP systems but also to the other equipment and accessories involved in simulation and treatment.

Action: *to develop guidance on commissioning equipment and accessories involved in simulation and treatment, including TP systems, and on QA of the whole radiotherapy process.*

Co-ordinated research

The current techniques of biological dosimetry have proven valuable for assessing the dose in cases of whole-body or large partial-body exposure, but they have not been verified for radiation accidents occurring during radiotherapy, diagnostic examinations or nuclear medicine treatments. As knowledge of the dose absorbed during an accidental exposure is important for further patient care, research aimed at developing absorbed dose estimation

techniques would be useful. In addition, it would be useful to ascertain whether biological dosimetry could contribute to QA in radiotherapy.

***Action:** to facilitate the critical review of research on biological methods of assessing absorbed dose and to disseminate information about such research.*