

IAEA SAFETY STANDARDS SERIES

Radiological Protection for Medical Exposure to Ionizing Radiation

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SAFETY GUIDE

No. RS-G-1.5



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RADIOLOGICAL PROTECTION
FOR MEDICAL EXPOSURE
TO IONIZING RADIATION

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SAFETY GUIDE

JOINTLY SPONSORED BY
THE INTERNATIONAL ATOMIC ENERGY AGENCY,
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FOREWORD

by Mohamed ElBaradei
Director General

One of the statutory functions of the IAEA is to establish or adopt standards of safety for the protection of health, life and property in the development and application of nuclear energy for peaceful purposes, and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under any bilateral or multilateral arrangement, or, at the request of a State, to any of that State's activities in the field of nuclear energy.

The following bodies oversee the development of safety standards: the Commission for Safety Standards (CSS); the Nuclear Safety Standards Committee (NUSSC); the Radiation Safety Standards Committee (RASSC); the Transport Safety Standards Committee (TRANSSC); and the Waste Safety Standards Committee (WASSC). Member States are widely represented on these committees.

In order to ensure the broadest international consensus, safety standards are also submitted to all Member States for comment before approval by the IAEA Board of Governors (for Safety Fundamentals and Safety Requirements) or, on behalf of the Director General, by the Publications Committee (for Safety Guides).

The IAEA's safety standards are not legally binding on Member States but may be adopted by them, at their own discretion, for use in national regulations in respect of their own activities. The standards are binding on the IAEA in relation to its own operations and on States in relation to operations assisted by the IAEA. Any State wishing to enter into an agreement with the IAEA for its assistance in connection with the siting, design, construction, commissioning, operation or decommissioning of a nuclear facility or any other activities will be required to follow those parts of the safety standards that pertain to the activities to be covered by the agreement. However, it should be recalled that the final decisions and legal responsibilities in any licensing procedures rest with the States.

Although the safety standards establish an essential basis for safety, the incorporation of more detailed requirements, in accordance with national practice, may also be necessary. Moreover, there will generally be special aspects that need to be assessed on a case by case basis.

The physical protection of fissile and radioactive materials and of nuclear power plants as a whole is mentioned where appropriate but is not treated in detail; obligations of States in this respect should be addressed on the basis of the relevant instruments and publications developed under the auspices of the IAEA. Non-radiological aspects of industrial safety and environmental protection are also not

explicitly considered; it is recognized that States should fulfil their international undertakings and obligations in relation to these.

The requirements and recommendations set forth in the IAEA safety standards might not be fully satisfied by some facilities built to earlier standards. Decisions on the way in which the safety standards are applied to such facilities will be taken by individual States.

The attention of States is drawn to the fact that the safety standards of the IAEA, while not legally binding, are developed with the aim of ensuring that the peaceful uses of nuclear energy and of radioactive materials are undertaken in a manner that enables States to meet their obligations under generally accepted principles of international law and rules such as those relating to environmental protection. According to one such general principle, the territory of a State must not be used in such a way as to cause damage in another State. States thus have an obligation of diligence and standard of care.

Civil nuclear activities conducted within the jurisdiction of States are, as any other activities, subject to obligations to which States may subscribe under international conventions, in addition to generally accepted principles of international law. States are expected to adopt within their national legal systems such legislation (including regulations) and other standards and measures as may be necessary to fulfil all of their international obligations effectively.

PREFACE

This Safety Guide provides recommendations on the practical implementation of Appendix II (Medical Exposure) of the International Basic Safety Standards (BSS) for Protection against Ionizing Radiation and for the Safety of Radiation Sources, jointly sponsored by the Food and Agriculture Organization of the United Nations (FAO), the IAEA, the International Labour Organisation (ILO), the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO).

This Safety Guide is jointly sponsored by the IAEA, PAHO and WHO. It recommends strategies to involve organizations, such as professional bodies, whose co-operation is essential to ensuring compliance with the BSS requirements in respect of medical exposures. Areas in which such co-operation is necessary include the establishment of guidance levels for diagnostic medical exposures, acceptance testing processes for radiation equipment, the calibration of radiotherapy units and the reporting of accidental medical exposures.

EDITORIAL NOTE

An appendix, when included, is considered to form an integral part of the standard and to have the same status as the main text. Annexes, footnotes and bibliographies, if included, are used to provide additional information or practical examples that might be helpful to the user.

The safety standards use the form 'shall' in making statements about requirements, responsibilities and obligations. Use of the form 'should' denotes recommendations of a desired option.

The English version of the text is the authoritative version.

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1. INTRODUCTION

BACKGROUND

1.1. When ionizing radiation (see Glossary) was discovered more than 100 years ago its beneficial uses were quickly discovered by the medical profession. Over the years new diagnostic and therapeutic techniques have been developed and the general level of health care¹ has improved. This has resulted in medical radiation exposures becoming a significant component of the total radiation exposure of populations.

1.2. Current estimates put the worldwide annual number of diagnostic exposures at 2500 million and therapeutic exposures at 5.5 million. Some 78% of diagnostic exposures are due to medical X rays, 21% due to dental X rays and the remaining 1% due to nuclear medicine techniques. The annual collective dose from all diagnostic exposures is about 2500 million man Sv, corresponding to a worldwide average of 0.4 mSv per person per year. There are, however, wide differences in radiological practices throughout the world, the average annual per caput values for States of the upper and lower health care levels being 1.3 mSv and 0.02 mSv, respectively [1].

1.3. It should, however, be noted that doses from therapeutic uses of radiation are not included in these averages, as they involve very high doses (in the region of 20–60 Gy) precisely delivered to target volumes in order to eradicate disease or to alleviate symptoms. Over 90% of total radiation treatments are conducted by teletherapy or brachytherapy, with radiopharmaceuticals being used in only 7% of treatments [1].

1.4. Increases in the uses of medical radiation and the resultant doses can be expected following changes in patterns of health care resulting from advances in technology and economic development. For example, increases are likely in the utilization of computed tomography (CT), digital imaging and, with the attendant potential for deterministic effects, interventional procedures; practice in nuclear medicine will be driven by the use of new and more specific radiopharmaceuticals for diagnosis and therapy, and there will be an increased demand for radiotherapy owing to an ageing population. In addition, further growth in medical radiology can be expected in developing States, where at present facilities and services are often lacking. The risks

¹ Health care level is used in United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) reports [1] and is defined by the World Health Organization (WHO) as the number of physicians available to serve the inhabitants of a State. They range from one physician per 1000 population at the highest level (level I) to one physician for more than 10 000 population in level IV.

associated with these expected increases in medical exposures should be outweighed by the benefits.

1.5. For the purposes of radiation protection, ionizing radiation exposures are divided into three types:

- Medical exposure, which is mainly the exposure of patients as part of their diagnosis or treatment (see below);
- Occupational exposure, which is the exposure of workers incurred in the course of their work, with some specific exclusions; and
- Public exposure, which comprises all other exposures of members of the public that are susceptible to human control.

1.6. Medical exposure is defined in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS, the Standards) [2] as:

“Exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.”

1.7. This Safety Guide covers all of the medical exposures defined above, with emphasis on the radiological protection of patients, but does not cover exposures of workers or the public derived from the application of medical radiation sources. Guidance relating to these exposures can be found in the Safety Guide on Occupational Radiation Protection [3].

1.8. In addition to the IAEA, several intergovernmental and international organizations, among them the European Commission, the International Commission on Radiological Protection (ICRP), the Pan American Health Organization (PAHO) and the World Health Organization (WHO), have already published numerous recommendations, guides and codes of practice relevant to this subject area. National authorities should therefore consult the relevant publications of these organizations, as appropriate.

OBJECTIVE

1.9. The objective of this Safety Guide is to give practical guidance on how to accomplish and ensure compliance with the BSS in respect of medical exposures. This Safety Guide will be of use to the Regulatory Authorities and authorized users

(registrants and licensees) who are responsible for facilities where medical exposures take place, employers, specialist advisers and health care professionals.

SCOPE

1.10. This publication provides practical guidance on how the BSS requirements may be fulfilled in relation to the protection of persons (patients, comforters, carers and research volunteers) from exposures resulting from the use of ionizing radiation in medical practice. It includes specific guidance for protection in all areas of medical exposure and, in particular, the radiological protection of patients, including equipment and operational factors.

STRUCTURE

1.11. This Safety Guide follows a structure similar to Appendix II of the BSS. Where appropriate in the text, reference is made to the requirements of the BSS appendix using its paragraph numbers in brackets (BSS, para. II.*). This convention is used to achieve consistency between this Safety Guide and the BSS.

1.12. This Safety Guide also refers to guidance from other publications, mainly IAEA-TECDOC-1067, Organization and Implementation of a National Regulatory Infrastructure Governing Protection against Ionizing Radiation and the Safety of Radiation Sources — Interim Report for Comment, as well as other publications of the IAEA, PAHO and WHO, as listed in the Bibliography. Section 2 describes a regulatory framework for medical exposure. Sections 3, 4 and 5 discuss specific aspects of radiological protection for medical exposure in diagnostic radiology (Section 3), nuclear medicine (Section 4) and radiotherapy (Section 5).

1.13. This Safety Guide should be read in conjunction with the BSS, specifically the Principal Requirements, Appendix II, Schedule II, para. II-9 and Schedule III (these parts of the BSS are attached to this document as Annexes I–IV), because they contain many specific requirements that are referred to but not repeated in this Safety Guide.

2. REGULATORY PROGRAMME FOR RADIOLOGICAL PROTECTION FOR MEDICAL EXPOSURE

INTRODUCTION

2.1. The primary aim of radiation protection is to provide an appropriate standard of protection for humankind against the harmful effects of ionizing radiation, without unduly limiting the beneficial practices of such exposures. In most situations arising from the medical uses of radiation, radiation sources are used to expose persons deliberately. Such situations are called ‘practices’.

2.2. The basic principles of protection for medical exposures can be summarized as follows:

- “Medical exposures should be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure” (BSS, para. II.4) (Justification of medical exposures).
- The doses from medical exposures should be the minimum necessary to achieve the required diagnostic objective or the minimum to the normal tissue for the required therapeutic objective (BSS, paras II.16 (a) (ii), II.17 (a) (i) and II.18 (a)) (Optimization of protection for medical exposures).

2.3. Medical exposures are usually intended to provide a direct benefit to the exposed individual. If the practice is justified and the protection optimized, doses to patients will be as low as is compatible with the medical purposes. Any further reduction in exposure might be to the patients’ detriment [4]. Consequently, dose limits should not be applied to medical exposures, although comforters, carers and research volunteers should be subject to dose constraints.

2.4. The protection of patients should be paid particular attention, as many people are exposed to ionizing radiation from medical practices and individual doses may be higher than from any other artificial sources of radiation. The elimination of unnecessary exposures, those not justified or that result in doses that are inappropriate for the achievement of the clinical objective, has become an important task in medical practice.

GENERAL ASPECTS

2.5. The Regulatory Authority should establish a system of regulations that ensures that medical exposures are carried out in compliance with the requirements of the

BSS. A fundamental concept that should be made clear in the regulations is that the prime responsibility for radiation protection and the safety of sources resides with registrants and licensees and with employers of occupationally exposed workers. Medical practitioners, qualified experts (e.g. medical physicists) and manufacturers have subsidiary responsibilities.

2.6. This process should include input from other government agencies, medical and health professional organizations, other professional associations, registrants, licensees, patient advocacy groups and the general public. Input from these groups may be obtained through various methods, including solicitation of written comments, public meetings (throughout the process), workshops and the adoption of previously established professional guidelines or protocols.

2.7. The regulations should be flexible enough to permit easy adaptation to evolving technology or changing conditions in medical procedures and practice. The regulations should not hinder the delivery of medical care.

2.8. The regulations should be consistent with international or national medical guidelines. Any questions or concerns in this respect by the Regulatory Authority should be referred to the national health ministry or an appropriate medical advisory body for review.

2.9. Radiation protection and, more generally, the achievement of a high standard of safety depends on the performance of individuals. For their part, institutional arrangements can greatly influence performance. These arrangements differ widely between States and between different types of installations within States. In relation to the medical exposure of individuals, the following parties have roles and responsibilities:

- The Regulatory Authority;
- The legal person (licensee/registrant);
- Employers;
- Medical practitioners;
- Qualified experts (e.g. medical physicists, radiation protection officers);
- Manufacturers or suppliers, and other parties with specific responsibilities.

GENERAL RESPONSIBILITIES

2.10. All parties have responsibilities with regard to the factors that affect the overall optimization of protection during medical exposures. Each party should ensure that all their staff engaged in duties associated with medical exposures are appropriately

and adequately trained for the tasks that they are required to perform. Each party should promote the concept of a safety culture, where any and every action is undertaken with radiation protection and safety as an essential objective. Radiation protection is an integral part of delivering medical exposure. Delegations of function and of the associated authority should be clearly and understandably defined, with a clear line of accountability to the most senior person in the organization concerned. Organizations and individuals involved in the delivery of medical exposures should disseminate information on the performance of equipment or any aspect of operational procedures that might lead, or has led, to inappropriate levels of exposure to patients, whether from underexposure or overexposure. Organizations and individuals should take actions within their area of responsibility, or inform those that can do so, to prevent unnecessary exposures to patients. Where such exposures have occurred, organizations and individuals, when appropriate, should promptly investigate the cause or causes of these events.

2.11. All public health and medical care organizations involved in medical exposures should co-ordinate their activities to achieve the required standards of radiation protection and safety.

REGULATORY CONTROL

Authorization of practices

2.12. Only those practices involving medical exposures that have been generically justified (BSS, paras II.4–II.8) should be authorized by the Regulatory Authority.

2.13. The Regulatory Authority should ensure that the regulatory requirements are consistent with existing national health care regulations.

2.14. Regulatory requirements for the use of sources or devices in diagnostic or therapeutic medical exposure will depend on the level of risk or complexity associated with the medical use, as determined by the Regulatory Authority. Guidance regarding education, training and experience are addressed below in this section.

2.15. Safety guides may be developed by the Regulatory Authority for each practice to identify the details that should be submitted in an application for authorization and to assist registrants and licensees in meeting the regulations. By reducing the communications necessary between the Regulatory Authority and the applicant, the efficiency of the authorization process is improved. Such safety guides should also provide examples of at least one way to meet the requirements of the regulations for

a specific practice and examples of procedures to accomplish specific tasks appropriate to the practice, for example the calibration of survey instruments, leak testing of sealed sources, the cleanup of spills and record keeping. The safety guides should be flexible and should be periodically revised without the need to go through an elaborate and time consuming formal regulatory process.

2.16. Guidance should also be developed for use by the Regulatory Authority when considering applications. The safety guides should identify the items that should be evaluated for each medical practice and for sources within practices, providing guidance on what is acceptable and what is unacceptable. These safety guides enable less skilled staff to conduct reviews and to focus on radiation protection and safety issues. Ultimately they will improve efficiency and consistency. Some guidance in this regard is provided in IAEA-TECDOC-1113, Safety Assessment Plans for Authorization and Inspection of Radiation Sources.

Inspection and compliance monitoring

2.17. Compliance monitoring should be conducted by the Regulatory Authority to determine whether sources are being used in accordance with the requirements of the relevant regulations and any conditions of authorization. Key elements of compliance monitoring include on-site inspections, radiological safety appraisals, incident notifications and periodic feedback from users about key operational safety parameters.

2.18. Compliance monitoring provides either the assurance that radiation protection and safety requirements are being met or the opportunity to require corrective action if they are not. It can take the form of on-site inspections or regulatory mechanisms that require the user to notify the Regulatory Authority in specified situations, for example of equipment malfunctions, accidents or errors with the potential for causing patients exposures significantly different from those intended. The most positive component of compliance monitoring is on-site inspection, and this is often the principal means for direct personal contact between the users and the staff of the Regulatory Authority.

2.19. For most medical practices an adequate inspection programme can be implemented by using personnel with basic training in radiation protection and safety and with a general knowledge of medical practices using ionizing radiation. An inspection manual should be developed to ensure efficiency and consistency. The manual should identify the items to be reviewed in the inspection of each medical practice in a simple checklist that provides the inspector with guidance on acceptable performance. For those cases requiring an inspection in greater depth, such as an accidental medical

exposure, the use of outside experts can supplement and enhance the skill level available to the Regulatory Authority.

2.20. The priority and frequency of inspection should depend upon the risk and complexity associated with the medical practice. In general, inspections of therapy practices, such as teletherapy or high dose remote afterloading brachytherapy, should occur more frequently than for nuclear medicine and diagnostic X rays. The factor that will weigh most heavily on inspection priority and frequency, however, will be the potential for unintended medical exposure and the severity of its consequences.

2.21. The Regulatory Authority should establish and publish an enforcement policy, both to encourage compliance and to correct non-compliance. Such a policy should be part of the general regulatory infrastructure established to meet the principle requirements of the BSS. This policy should include specific examples related to non-compliance in relation to medical exposures and the resulting enforcement action by the Regulatory Authority.

Dissemination of information

2.22. The Regulatory Authority should develop mechanisms for the periodic dissemination of information to relevant users, manufacturers, suppliers and other appropriate persons about radiation protection, safety, incidents and related findings, and licensing and inspection experience. This flow of information should keep those who might be affected by these incidents alert to problems they may encounter and to their consequences if these problems are not properly addressed. Information should be exchanged through the publication of newsletters and the periodic mailing of notices, by presentations at scientific and professional association meetings, by establishing a web site, or by co-sponsoring educational seminars and workshops with universities, technical schools, and professional and scientific associations. More rapid actions should be considered in response to real or potential problems that may result in significant consequences. In this case it is recommended that the Regulatory Authority promptly disseminates the information to and requests a relevant action from those registrants and licensees with a similar practice.

SPECIFIC RESPONSIBILITIES OF REGISTRANTS AND LICENSEES

General aspects

2.23. In hospitals, and sometimes in private medical premises, there may be a dual management system, with:

- The medical staff carrying the professional responsibility for their patients, and
- The administrative management carrying responsibility for the general running and financing of the institution.

2.24. Since responsibility can be exercised only by those who have the authority to act, it is essential to establish clear-cut lines of responsibility for those introducing procedures giving rise to medical exposures. Clear responsibilities should be assigned to the:

- Referring physicians who request radiological or nuclear medicine procedures,
- Physicians who undertake procedures involving medical exposure,
- Administrative managers who provide the resources [5].

2.25. Registrants and licensees shall ensure that medical exposures are prescribed and supervised by medical practitioners, whose primary task and obligation is providing the most effective health care for patients, including ensuring the protection of patients from unnecessary radiation exposure (BSS, para. II.1 (a) and (b)). Although Regulatory Authorities are responsible for enforcing requirements and professional bodies for providing advice, this does not diminish the responsibilities of the registrants and licensees. In all organizations, the delegation of function and the associated responsibilities should be clearly and understandably defined, and there should also be a clear line of retrospective accountability running right to the top of each organization.

2.26. Responsibilities should be clearly delineated for the identification of radiation protection and safety problems under abnormal operating conditions, the recommendation, initiation or implementation of corrective actions and verification that corrective actions have been implemented.

2.27. The registrant or licensee has the responsibility to ensure that radiation doses to comforters and other individuals helping in the care of patients are as low as reasonably achievable and constrained to 5 mSv during the period of the diagnostic examination or treatment procedure. This responsibility includes the need to ensure that doses to children visiting patients to whom radioactive materials have been administered are constrained to less than 1 mSv. (See Annex III of this Safety Guide.)

Calibration, clinical dosimetry and quality assurance

2.28. All registrants and licensees should establish a comprehensive programme for calibration, clinical dosimetry and quality assurance (QA) (see below in this section).

Record keeping

2.29. All records prescribed in the BSS (BSS, paras II.31 and II.32) in relation to medical exposures of patients and research volunteers should be made and kept for a period specified by the Regulatory Authority. In particular, registrants and licensees should keep and make available the results of calibrations, clinical dosimetry and periodic checks of the relevant physical and clinical parameters used during diagnostic examinations and treatments (BSS, paras II.19 and II.20). Also, registrants and licensees are required to keep written records of the relevant procedures and results of the QA programme (BSS, para. II.23).

Incidents and accidents

2.30. It is the responsibility of registrants and licensees to take all reasonable measures to prevent equipment failure and human errors. This can be achieved by establishing programmes for adequate QA, calibration, maintenance and training.

2.31. Emergency plans should be prepared for dealing with potential incidents and accidents and, when appropriate, emergency interventions. In particular, emergency planning is critical for therapeutic applications where high dose rates are involved. Such plans should be exercised at intervals specified by the Regulatory Authority.

2.32. The registrant or licensee is required promptly to investigate any occurrence that has caused, or has the potential to cause:

- (a) “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 secondary effects” (BSS, para. II.29 (a));
- (b) “any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance [reference] levels” (BSS, para. II.29 (b)); and
- (c) “any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended” (BSS, para. II.29 (c)).

2.33. When exposures are significantly different from those intended, the doses should be calculated and corrective measures taken (see Sections 3–5 for specific guidance). If relevant, the results should be reported to the Regulatory Authority as

soon as possible, and the patient and the patient's doctor should be informed of the incident (BSS, para. II.30). Examples of significantly different exposures from those intended are given in Ref. [6].

Medical exposures of research volunteers

2.34. Regulatory Authorities should require that registrants and licensees expose volunteers for medical research purposes only if the research is carried out in accordance with the provisions of the Helsinki Declaration [7] and the guidelines for its application given by the Council for International Organizations of Medical Sciences (CIOMS) [8] and the WHO [9]. Such research is also subject to the requirements of the BSS (BSS, para. II.8) and national regulations and is subject to advice from an Ethical Review Committee or other institutional body recognized by the Regulatory Authority. These committees (or bodies) should consider the effective doses and the applicable organ doses and the risks of health effects, balancing the net benefit to society or a potential net benefit to the research subject. Healthy children should not be involved in biomedical or medical research programmes. In therapeutic procedures there should be a direct health benefit to the exposed person. Specific dose constraints are required to be applied on a case by case basis, if such medical exposure does not produce direct benefit to the exposed individual (BSS, para. II.26), as advised by international bodies [8–10] and determined by national authorities. The final authorization should only be granted if the applicant complies with the recommendations given in this Safety Guide (e.g. on calibration, clinical dosimetry, QA) and is supervised by a certified medical physicist.

2.35. In some States such committees are associated with large teaching university hospitals, where individuals with the varied medical and dosimetric expertise are available. In such cases these committees should be used to review and approve radiation research projects that involve human subjects.

2.36. All proposals for research on volunteers shall include the requirement to obtain prior informed consent from the subjects.

SPECIFIC RESPONSIBILITIES OF MEDICAL PRACTITIONERS, QUALIFIED EXPERTS AND OTHER PARTIES

2.37. Medical practitioners shall be assigned the primary task and obligation of ensuring overall patients' protection and safety in the prescription of, and during the delivery of, medical exposure (BSS, para. II.1 (b)). Qualified experts, other health professionals

(e.g. medical physicists, technologists and paramedical staff), radiation protection officers and others have roles and responsibilities for the application of the relevant radiation protection regulations and rules in their particular fields of activity (see Sections 3–5). Ethical Review Committees are described in para. 2.34 and in Annex II.

SPECIFIC RESPONSIBILITIES OF MANUFACTURERS AND SUPPLIERS

2.38. Radiation protection criteria should be applied to the design, selection and maintenance of equipment. Information on the safe and correct use of the equipment should also be provided.

2.39. Consequently, the suppliers of equipment or sources, as well as companies that provide maintenance services, have specific responsibilities for the application of the radiation protection principles and national regulations. In order to meet these responsibilities, organizations:

- (a) Should apply for an authorization from the Regulatory Authority to perform the function of a supplier for the sources, equipment and instrumentation involved in medical exposures;
- (b) Should ensure the availability of spare parts and the provision of technical assistance for a reasonable period after supplying the equipment;
- (c) Should offer assistance when abnormal or unplanned events are identified in the operation of the supplied equipment, even if there is no immediate danger to health;
- (d) Should offer assistance for the proper handling and management of spent teletherapy sources;
- (e) Should offer specific training in the use of accelerators and for high dose rate brachytherapy;
- (f) Should ensure that the design, construction and safety of equipment conform with the relevant standards of the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO) or nationally recognized equivalent standards;
- (g) Should ensure that equipment used in medical exposure is so designed that “failure of a single component of the system be promptly detectable so that any unplanned medical exposure of patients is minimized” (BSS, para. II.11 (a)) and that “the incidence of human error in the delivery of unplanned medical exposure be minimized” (BSS, para. II.11 (b)).

2.40. The application for authorization to the Regulatory Authority should contain detailed information on:

- The design, construction and safety of the equipment (see (f) and (g) above);
- The procedures and results of prototype tests to demonstrate that the equipment will maintain integrity under circumstances likely to be encountered in normal use or in accidental medical exposures;
- The installation and acceptance test procedures, developed in co-operation with the registrant or licensee;
- The quality control procedures to ensure that the equipment meets the standards of the design and prototype tests and is authorized for importation;
- Specifications for operating and maintenance instructions in a language understandable to the users, as determined by the Regulatory Authority.

2.41. If the staff of the Regulatory Authority do not have at their disposal the entire range of skills necessary to evaluate the safety of the equipment used for the delivery of medical exposures, they should seek expert assistance in the design and construction of such equipment. In such cases the co-operation of manufacturers or suppliers with the Regulatory Authority can facilitate the development of generic safety assessments of specific components or complete equipment systems². Highly skilled experts or independent accreditation laboratories in the State concerned, or in other States or international organizations, can be used for a single, premarketing generic safety assessment. The accreditation laboratory would supply a certificate of compliance with the international industry standards (IEC, ISO) to the Regulatory Authority. Not only would this option be more cost effective, it would achieve a much better standard of safety than the alternative approach of conducting less expert evaluations whenever a potential user applies for an authorization. The generic assessment would be documented together with a summary of the conditions of use of the device and any appropriate limitations on its use. If properly catalogued, the assessment would be readily available whenever an application for authorization were considered and could also be of benefit to inspection staff conducting subsequent appraisals in the workplace. Such listings of approved equipment are available in several industrialized States. The user should ensure, before placing an order, that the equipment he or she orders is 'type approved', or carries a certificate of compliance, in accordance with the IEC or nationally recognized equivalent standards in the State of use.

² The co-operation of manufacturers and suppliers with the Regulatory Authority is particularly relevant in cases in which radiotherapy sources are imported by the licensee of the radiotherapy department concerned. In cases in which the equipment is imported by a supplier or is manufactured in the same State, it should be noted that the activities of manufacturing, importing and selling these sources are regulated practices that in many States are subject to a separate authorization, as specified in the BSS (para. 2.7).

2.42. Additional guidance for specific types of equipment is to be found in the following sections of this Safety Guide.

JUSTIFICATION

2.43. The process of justification is a balance between the risk of radiation health effects and the clinical benefits of the medical exposure to individuals: it includes the consideration of the risks and benefits of alternative diagnostic and therapeutic techniques. Relevant guidelines for justification have been established by a number of international bodies [5, 11–15] and established as requirements in the BSS (BSS, paras II.4 and II.8). In formulating a justification of medical exposure, the continuing involvement of medical professional societies [16, 17] should be ensured, as matters of effective medical practice will be central to these judgements (see also Sections 3–5 of this Safety Guide). The decision to perform or to reject a diagnostic or therapeutic procedure with ionizing radiation that has been required by a referring physician is incumbent on the relevant nuclear medicine physician, radiologist or radiation oncologist.

OPTIMIZATION OF PROTECTION FOR MEDICAL EXPOSURE

2.44. The basic aim of the optimization of patient protection in diagnostic and therapeutic procedures is to maximize the margin of benefit over harm, while taking into account social and economic circumstances. Since patients are deliberately exposed to radiation sources, the optimization of protection can be complex and does not necessarily mean the reduction of doses to patients, as priority has to be given to the acquisition of reliable diagnostic information and the achievement of the therapeutic effect, respectively.

Calibration of sources

2.45. “Registrants and licensees shall ensure that the calibration of sources used for medical exposure be traceable to a Standards dosimetry laboratory” (BSS, para. II.19 (a)). To meet this requirement the Regulatory Authority should support the development of a national strategy that enables medical facilities to calibrate medical sources. If a State has a Primary or Secondary Standards Dosimetry Laboratory (PSDL/SSDL) it should be feasible to have all instruments calibrated at the intervals established by the Regulatory Authority. If there is no standards dosimetry laboratory (SDL) in the State concerned, instruments should be sent to the SDL of another State. The shipment of the dosimetry instrumentation system should be carefully planned in order to prevent delays that could result in critical or dangerous situations, particularly for radiation therapy facilities, if dosimetry equipment is unavailable or not calibrated or

has not been recalibrated in accordance with national regulations. Factors to take into consideration include provisions for appropriate packaging, the means of transport and customs or export and import formalities.

2.46. The Regulatory Authority should support the development of a formal national strategy that includes institutional arrangements to facilitate quick import and export, using the offices of international organizations (e.g. the United Nations Development Programme, PAHO and WHO) and additional arrangements with SDLs (or an organized network among several States for calibration, for example the IAEA SSDL network), and that provides for safe packaging.

2.47. With regard to the circumstances and intervals of calibration, the BSS require that registrants and licensees ensure that:

“the calibrations be carried out at the time of commissioning a unit, after any maintenance procedure that may have an effect on the dosimetry and at intervals approved by the Regulatory Authority” (BSS, para. II.19 (e)).

2.48. Again, the complexity of the facility concerned, the stability of the equipment and the potential for accidents will determine the intervals between measurements.

2.49. Additional guidance specific to sources used for medical exposure, for example in diagnostic radiology, nuclear medicine or radiation therapy, can be found in Sections 3–5 of this Safety Guide.

Clinical dosimetry

2.50. In diagnostic medical exposures representative absorbed doses are required to be determined for adult patients of a typical size (see Sections 3–5). Similarly in therapeutic exposures, individual absorbed dose values are required to be determined for each patient, by calculation or direct measurement, at least at an adequate number of points that are representative for the target volume and the relevant organs of the patient (BSS, paras II.20 and 21) (see Section 5).

Quality assurance for medical exposure

2.51. Registrants and licensees are required to establish a comprehensive QA programme (BSS, paras II.22 and II.23) for medical exposures, which shall include among others:

- “measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter” (BSS, para. II.23 (a));
- “verification of the appropriate physical and clinical factors used in patient diagnosis or treatment” (BSS, para. II.23 (b));
- written records and operational procedures;
- procedures to establish the patient’s identity prior to any administration of radiation;
- procedures to ensure that medical exposures are in accordance with those prescribed by a medical practitioner;
- regular and independent quality audit reviews of the quality assurance programme that has been established.

Quality assurance programme for radiation sources

2.52. The QA programme for radiation sources (including equipment and other related systems):

- Should require that sealed and unsealed sources or devices used for medical exposure be purchased only from manufacturers or distributors approved by the Regulatory Authority.
- Should require that a detailed description of maintenance and service arrangements be provided with all equipment. This is especially important, since a proven safe design alone is not sufficient to ensure safety throughout the useful life of the equipment. The vendor (or the manufacturer) should be authorized to import (or install) equipment only if it guarantees that spare parts and maintenance will be provided for a reasonable period of time.
- Should require that, for donated equipment, the recipient ensure that quality control tests have been carried out on the equipment before agreeing to accept it. The report of the quality control tests should be included with the application for the import or reinstallation of the unit. The Regulatory Authority should require that further quality control tests be made on the equipment after installation but before first clinical use.
- Should require that, for refurbished equipment, the supplier demonstrate compliance with the Standards by carrying out appropriate tests. The report of the tests should be included with the application for authorization for importation.
- Should require the identification and measurement of the activity of all radioactive drugs prior to their administration to each patient or human research subject.
- Should require the establishment of QA procedures for all sources, equipment, systems and accessories that are:
 - Used in delivering medical exposure;

- Involved in obtaining diagnostic images (i.e. gamma cameras, film processors and image intensifiers); and
 - Used for treatment planning in radiotherapy.
- Should require the testing of sealed sources for leakage at regular intervals, as required by the Regulatory Authority.
 - Should require regular physical inventories of all radiation sources, at intervals determined by the Regulatory Authority.

Quality assurance of instrumentation for calibration and clinical dosimetry

2.53. The Regulatory Authority should require that QA of instrumentation used for the purposes of calibration and clinical dosimetry be undertaken by the licensee or registrant. The QA programme should provide for the regular calibration of each instrument in accordance with international standards or applicable national requirements.

2.54. The QA of each instrument should have as its starting point the selection and acquisition of the instrument itself, since instruments may differ widely in their performance. The choice of an appropriate laboratory for the calibration of the instrument should likewise be considered within the scope of QA.

2.55. A recommended procedure is:

- (a) Once received, an instrument should be subjected to a series of acceptance tests designed to establish whether its initial performance conforms with the manufacturer's specifications. At the same time, reference tests should be carried out to provide data against which its subsequent performance can be assessed by routine testing at regular intervals.
- (b) Operational checks should be performed on each day the instrument is used. Careful records of all the tests should be kept and, if these reveal unsatisfactory performance, appropriate action should be taken. Such QA does not obviate the need for preventive maintenance procedures, which should be carried out on a regular basis.

DOSE CONSTRAINTS

2.56. Dose constraints do not apply to patients, but the BSS (BSS, paras II.26 and II.27) specify the requirements for dose constraints for comforters, carers and research volunteers, who receive no direct benefit from the exposure. Specific guidance on dose constraints in diagnostic radiology and in nuclear medicine is given in this Safety Guide in Sections 3 and 4, respectively.

GUIDANCE LEVELS FOR MEDICAL EXPOSURE

2.57. The BSS require that guidance levels for medical exposures be established for use by medical practitioners (BSS, para. 2.27).

2.58. Guidance levels are intended to be a reasonable indication of doses for average sized patients. They are also meant to provide guidance on what is achievable with current good practice and therefore should be revised as technology and techniques improve.

2.59. The guidance levels should be specific to a State or region, taking into account local medical practices and the performance of the available equipment. Regulatory Authorities should therefore encourage and support professional bodies, such as radiology, nuclear medicine and medical physics organizations, to perform regional or national surveys in order to document typical doses and activities. The guidance levels are intended to be established by the relevant professional bodies in consultation with the Regulatory Authority following the requirements given in the BSS (BSS, paras 2.27, II.24 and II.25).

2.60. In the absence of wide scale national surveys, the guidance levels specified in Schedule III of the BSS should be used as the basis of comparison to assess the performance of diagnostic radiography and fluoroscopy equipment and of nuclear medicine equipment, taking into account the conditions under which they were measured and noting that they are appropriate only for typical adult patients. When applying these values in practice, account should be taken of body size and age.

2.61. If doses or activities fall substantially below guidance levels then corrective actions should be considered and reviews may be necessary if the levels are exceeded.

2.62. Since guidance levels are intended “to be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgement” (BSS, para. 2.27 (d)), doses to individual patients in excess of the guidance levels may not necessarily constitute a contravention of the requirements. However, guidance levels being repeatedly and substantially exceeded may indicate a fundamental problem and may be due to an accidental medical exposure, in which case an investigation will be required (see Sections 3–5).

EDUCATION, TRAINING AND EXPERIENCE

2.63. The BSS require that registrants and licensees ensure that:

- “medical and paramedical personnel be available as needed, and either be health professionals or have appropriate training” (BSS, para. II.1 (c)). Such training of staff should cover physics, engineering, biology and radiation protection to a level of knowledge sufficient to enable them to carry out their assigned duties competently and to be effective in an emergency response. Such personnel should also have suitable qualifications and experience for their involvement in operations [18].
- “training criteria be specified or be subject to approval, as appropriate, by the Regulatory Authority in consultation with relevant professional bodies” (BSS, para. II.1 (f)).

General

2.64. Depending on a facility’s complexity, the following staff should be trained in radiation protection and safety: radiation protection officers, appropriate senior administrators, members of the radiation safety committee, radiographers, radiologists, radiation oncologists, nuclear medicine physicians, technologists, medical physicists, maintenance personnel, radiation chemists, radionuclide pharmacists, clinical and/or research laboratory personnel and ancillary personnel, as appropriate. Nursing staff attending to patients undergoing medical exposures should be given adequate training. The level of this training will depend on the specialization of the individuals, their academic background and previous experience. Examples of training recommendations in radiation protection and safety are given in Refs [19, 20]. Requirements for training criteria are given in the BSS (BSS, para. II.1 (f)).

2.65. Registrants and licensees should be able to demonstrate proof of such training to the Regulatory Authority, particularly when applying for an authorization for a facility. Some Regulatory Authorities may choose to issue personal authorizations to individual medical practitioners or other health professionals as a way of formally acknowledging adequate training in radiation protection and safety.

2.66. If registrants and licensees cannot demonstrate that their staff are adequately trained, the Regulatory Authority may consider requesting applicants to take an examination or to attend a supplementary training course provided by an appropriate educational institution or professional body. However, the implications of time off work and financial costs should be taken into consideration, especially when several persons at one facility are involved in administering medical exposures.

2.67. Further guidance on training can be found in the sections on radiology, nuclear medicine and radiotherapy (see Sections 3–5).

Qualified experts

2.68. The BSS require that “for therapeutic uses of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and quality assurance requirements of the Standards be conducted by or under the supervision of a qualified expert in radiotherapy physics” (BSS, para. II.1 (d)); while “...for diagnostic uses of radiation the imaging and quality assurance requirements of the Standards [should] be fulfilled with the advice of a qualified expert in either radiodiagnostic physics or nuclear medicine physics, as appropriate” (BSS, para. II.2).

2.69. The qualifications required by such experts in what ideally should be subspecializations of medical physics may be difficult to assess by the Regulatory Authority. If the State concerned has a medical physics society, the Regulatory Authority may engage its collaboration in obtaining proper criteria for qualifications. If the State concerned does not have such a society, the Regulatory Authority may wish to establish an advisory body that can review the qualifications of such individuals when they are applying for a licence or named in an institutional authorization. In any case, the functions of these experts should not be confused with those of the radiation protection officer, even though in small institutions both functions may be fulfilled by the same individual. The extent to which a radiation physicist may fulfil both functions depends on the education and training of such a professional in each State and hence cannot be generalized. What the Regulatory Authority should bear in mind is that the functions are different, and not that different persons are required to fulfil them.

Continuing professional development

2.70. Changes that occur in equipment, instrumentation, practice, monitoring methods, recommendations and regulations make it essential that all the individuals involved in the use of ionizing radiation sources receive not just initial but also continuing education and training. Such training can range from informal interdepartmental meetings to structured and accredited continuing education programmes. Periodical practice drills for incidents and accidents conducted by registrants and licensees can be part of a training programme. The content, lectures, participants and results of a continuing education and training programme should be recorded. An application for authorization should describe the proposed mechanisms to achieve these training goals.

Transitional training arrangements

2.71. For those staff who do not meet the minimum required levels of training but are already involved in the delivery of medical exposures, the Regulatory Authority

should provide for a transition period (normally not greater than three years) to meet the training requirements. The Regulatory Authority should indicate to registrants and licensees that strong enforcement actions, such as a suspension or revocation of their authorization, will be taken if the training requirements are not met in a timely manner. Authorization by the Regulatory Authority to deliver medical exposures, which is based on radiation protection and safety proficiency, should not be construed as an authorization to practice in the appropriate medical specialty in the absence of appropriate professional qualifications in that specialty.

3. SPECIFIC ASPECTS OF RADIOLOGICAL PROTECTION FOR MEDICAL EXPOSURE IN DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY

INTRODUCTION

3.1. In this Safety Guide diagnostic radiology is the practice in which external radiation beams (usually X ray beams) are used to produce an image for the purpose of either diagnosing, excluding or evaluating the course of a disease or pathological condition. Interventional radiology is the practice in which X ray images are used as a tool in the conduct of therapeutic procedures.

JUSTIFICATION

3.2. Justification in diagnostic radiology should follow the BSS (see paras II.4 and II.9 of Annex II to this Safety Guide) and the recommendations of the ICRP [3, 4]. The Regulatory Authority should require that registrants and licensees have procedures to ensure that no patient is exposed to radiation for diagnostic purposes unless the procedure is prescribed by a medical practitioner who fulfils the national requirements on training and experience for prescribing procedures involving medical exposure. The prescriber should consider the efficacy, benefits and risks of alternative technology, for example ultrasound, magnetic resonance imaging and endoscopy. Ideally, the prescriber, often called the referring physician, should consult the radiologist on the necessity and appropriateness of the procedure to be performed. Additional consideration may be necessary where doses may be high (e.g. for CT, complex diagnostic procedures and interventional radiology procedures) or in situations in which risk may be high (e.g. in paediatric radiology and examinations during pregnancy).

3.3. Mass screening of population groups involved in medical exposure should be justified according to the BSS (BSS, para. II.7). Exposure of humans for biomedical and clinical research should be specifically justified, as established in the BSS (BSS, para. II.8). The use of diagnostic radiology in occupational health surveillance is not justified unless it provides information that is of benefit to the exposed individual. According to the BSS, any radiological examination for insurance purposes or for medico-legal purposes is deemed to be not justified unless it provides useful information on the health of the individual (BSS, para. II.6). In requesting diagnostic radiology procedures, relevant safety guides and other documents should be taken into account [16, 17, 21–23].

OPTIMIZATION OF PROTECTION FOR MEDICAL EXPOSURE

3.4. The objective of the diagnostic radiology process as a whole is to obtain the requested diagnostic information with the minimum patient exposure within prevailing resource limitations. In diagnostic radiology an expert in medical imaging physics should be involved, as appropriate, for consultation on the optimization of protection, including patient dosimetry and QA [2, 23]. The current global shortage of qualified experts in medical imaging physics may preclude the legal person from naming such an expert on each application for authorization. However, the Regulatory Authority should require that registrants and licensees seek advice, when appropriate and practical. Training of specialists of this kind should be promoted.

Equipment

3.5. To authorize the use of diagnostic radiology equipment, the Regulatory Authority should follow the requirements set forth in the BSS (BSS, paras II.11 and II.12) relative to equipment failures and human errors and (BSS, paras II.13 and II.14) relating to performance specifications. Particular attention should be given to conforming with the relevant IEC and ISO or nationally recognized equivalent standards in the State of use. Some radiological procedures, such as interventional radiology, dental radiology and mammography, should be performed with specifically designed X ray systems.

3.6. Whenever practicable, automatic exposure control systems should be used in radiographic units and automatic brightness control (or dose rate control), pulsed X ray systems and last image hold functions should be used in fluoroscopic units. These devices will facilitate the optimization of patient doses if appropriate maintenance and QA are available.

3.7. For the equipment in use, specific criteria of acceptability should be defined in order to indicate when remedial action should be taken, including, if appropriate, taking the equipment out of service. Examples of remedial and suspension criteria are given in Ref. [24]. A strategy or transition period for replacement based on social and economic factors is therefore required.

3.8. In States in which direct fluoroscopy units are still being used, a strategy for their replacement with units with image intensifiers should be encouraged.

Operational aspects

3.9. One of the aims of this Safety Guide is to provide guidance so that Regulatory Authorities, registrants and licensees can ensure that the radiation exposure of patients is the minimum necessary to achieve the required diagnostic or interventional objective. To reach this goal, the Regulatory Authority should require that protocols are available that specify the operational parameters to be used for common diagnostic radiology procedures; that is, which equipment and techniques are to be used for examinations on the chest, abdomen, thoracic and lumbar spine areas, pelvis and skull. This should include the parameters for the radiation generators (e.g. the ranges of tube voltage, kilovoltage, tube loading and milliamperes-seconds), the focal spot size, as well as the type of film–screen combination and film processing conditions (e.g. the chemicals used, developer time and temperature). For CT, doses may be particularly high, and hence specific protocols for CT and other complex digital radiology procedures should be available.

3.10. The purpose of requiring such documentation is not to assess the adequacy of the choices but to ensure that a facility develops protocols for every type of standard radiological procedure and for all equipment used. Examples of protocols are provided in Refs [25–31].

3.11. The Regulatory Authority should require that registrants and licensees have procedures to ensure that medical practitioners who prescribe or conduct radiological examinations do so in compliance with all the requirements of the BSS.

3.12. Compliance with these requirements may be difficult for some facilities that have never engaged in QA procedures. In States or regions where this is the case, the Regulatory Authority may ask the professional societies (of radiologists, technologists, physicists and engineers) to develop a subset of the above standards that may be more appropriate to the local situation. In subsequent inspections, the Regulatory Authority should seek to ensure that the optimization of protection is consistent with the production of adequate images and is being actively implemented on an ongoing basis.

3.13. Since in radiology the concept of the optimization of protection may be unfamiliar to the parties responsible for the exposures, the Regulatory Authority should promote educational activities in co-sponsorship with universities and technical schools. Likewise, the Regulatory Authority should interact with scientific and professional associations, especially medical and/or technical radiological societies and medical physics organizations, where these exist, by such means as publishing leaflets, participating in congresses and encouraging research.

3.14. Regardless of the mechanism by which the standards on optimization have been derived, the individuals who are using them (radiologists and technologists especially) should be given the opportunity to comment on their incorporation into the corresponding regulations. The process of consultation should help secure the support and endorsement by the medical professions of the regulations.

3.15. Because the optimization of protection is normally a gradual process that involves social and economic factors, Regulatory Authorities should bear in mind that compliance with the standards in diagnostic radiology facilities needs transition times commensurate with their complexity.

3.16. To improve compliance, institutions may benefit from sending appropriately qualified staff for training to other facilities that comply with the BSS requirements or the standards on optimization or to attend regional, national or international courses on this topic. Employers should therefore encourage their staff to undertake continuing education and training.

Calibration of sources and dosimetry systems

3.17. The BSS require that a traceable calibration of sources used for medical exposure be carried out (BSS, para II.19 (a)). In order to do so, the dosimetry instrumentation (e.g. electrometers and ionization chambers) should ideally be calibrated using X ray spectra and dose rates within the diagnostic radiology range.

3.18. Usually, dosimeter calibration is performed in an SDL to which registrants and licensees should have access. Dosimetry calibration should ideally be traceable to the national SDL in the State concerned, to which registrants and licensees should have access either directly or through a duly accredited secondary calibration laboratory. At present only some of the secondary SDLs of the IAEA/WHO network provide calibration services using diagnostic radiology spectra. However, since dosimetry accuracy is not critical in diagnostic radiology exposures, calibrations with beams of comparable half-value layers should be sufficient. Alternatively, the Regulatory Authority may accept instrument manufacturers' calibrations as spelled out in the

certificate of calibration issued by the instrument manufacturer, provided that the manufacturer operates a calibration facility officially registered by a recognized accreditation body. This certificate should state the overall uncertainty of the calibration factors. To ensure consistency among instruments, the Regulatory Authority may require users to participate in periodic intercomparisons of dosimetry equipment (for example in a local hospital or in the SDL).

3.19. In diagnostic radiology source calibration is to be interpreted as the measurement of the absorbed dose (or dose rate in fluoroscopy) in the centre of the field (on the X ray beam axis) at a specified distance from the source under standard conditions. In fluoroscopy the conditions will include typical values of tube voltage (in kilovolts) and tube current multiplied by time (in milliamperere-seconds); in radiography it will include typical values of tube voltage (in kilovolts) and current–time product (in milliamperere-seconds). In both, the ranges covered should be those used in clinical practice. It should be stated whether the doses (i.e. the exposure for calibration or air kerma) are measured free in air or at the surface of a phantom representing a patient, in which case backscatter will be included.

Clinical dosimetry

3.20. The BSS require that registrants and licensees ensure that “in radiological examinations, representative values for typical sized adult patients of entrance surface doses, dose–area products, dose rates and exposure times, or organ doses” be determined and documented (BSS, para. II.20 (a)).

3.21. For CT examinations appropriate dose quantities related to patient dose should be used (e.g. the multiple scan average dose [2], computed tomography dose index, dose–length product, etc.) [25, 31].

3.22. In interventional radiology the relevant quantities are the total fluoroscopy time, total number of images, fluoroscopy dose rate and dose per image at the entrance point of a patient, as well as the dose–area product.

3.23. The Regulatory Authority should authorize only registrants and licensees who state how patient doses will be determined and by which methods. Calculations of patient entrance surface doses may be considered acceptable from estimated or measured dose rates for typical techniques (in kilovolts and milliamperere-seconds) or from direct patient dosimetry on various ‘typical’ patients using thermoluminescent dosimeters or others types of dosimeters [24]. Typical doses for common diagnostic procedures should be available from registrants and licensees and should be periodically updated for every X ray machine.

Quality assurance

3.24. The Regulatory Authority should require that a comprehensive QA programme for diagnostic radiology facilities be established, with the participation of appropriate qualified experts in this field as required in the BSS (BSS, paras II.22 and II.23), and with account taken of the principles established by the PAHO [18] and WHO [19, 32].

3.25. This programme is required to include:

- Image quality assessments;
- Film reject analyses;
- Patient dose evaluations;
- Measurements of the physical parameters of the radiation generators (e.g. the kilovoltage, milliamperere-seconds, waveform ripple and focal spot size) and checks of imaging devices (e.g. film processors) at the time of commissioning and periodically thereafter;
- Verification of the appropriate physical and clinical factors used in patient diagnosis;
- Written records of relevant procedures and results;
- Verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment;
- Procedures for remedial actions, follow-ups and result evaluations.

3.26. The Regulatory Authority should require that registrants and licensees establish a QA programme as a precondition for authorization. The QA programme can range from an analysis of rejected films in dental facilities to a complete imaging quality assessment, patient dosimetry and full quality control in facilities that perform interventional radiology. Specific guidance may be found in Refs [16, 18, 19, 24, 30, 32, 33].

GUIDANCE LEVELS

3.27. The process of deriving guidance levels may be initiated by institutions ‘estimating’ the typical doses received by patients on the basis of the technical parameters used (e.g. the kilovoltage, milliamperere-seconds, focus film distance). Guidance levels should be expressed in terms of quantities that can be easily measured or estimated, such as the entrance surface dose or dose–area product. In complex procedures and in the absence of direct patient dose related quantities (e.g. dose–area products), other quantities, such as the total fluoroscopy time and total number of images, can be used to express guidance levels. An assessment of patient

doses may be implemented gradually and should always be undertaken in parallel with image quality assessments.

3.28. The Regulatory Authority should encourage professional associations and registrants and licensees to perform surveys of entrance surface doses or dose–area products, as appropriate, for typical adult patients for common diagnostic procedures. The results of these surveys will allow guidance levels to be determined and reviewed as technology improves (BSS, para. II.24). In the absence of wide scale surveys, the guidance levels specified in Schedule III of the BSS, Tables III-I to III-V (see Annex IV of this Safety Guide), can be adopted. They are appropriate only for typical adult patients. In applying the values in practice, account should be taken of body size and age. The values should not be applied for individual patients.

DOSE CONSTRAINTS FOR PERSONS HOLDING PATIENTS DURING PROCEDURES (COMFORTERS)

3.29. The Regulatory Authority should require that registrants and licensees have written procedures for the optimization of protection measures for individuals who hold patients (such as the very elderly, the very ill or infants) during radiology examinations. The protocol should include the following: methods to avoid the need for holding patients, for example the administration of sedatives (especially for long procedures such as CT examinations) and the use of infant restraints; criteria specifying which persons are allowed to hold patients, for example friends and relatives, provided that they are not pregnant, but not employees such as porters and nurses; methods for positioning and protecting the comforter so that his or her exposure is as low as reasonably achievable, for example by ensuring that the comforter is not in the direct beam of the radiation device and that appropriate personal protective clothing is used, for example a lead apron or ancillary shields of a specified lead equivalence. Steps should be taken by the radiologist and/or radiographer to avoid a repetition of exposures.

3.30. Registrants and licensees should be able to demonstrate that the effective dose to the holding person, by applying this protocol, is unlikely to exceed the dose constraint specified in the BSS (BSS, Schedule II, para. II-9).

TRAINING

3.31. Training is required for all persons involved in the use of X rays on humans for diagnostic purposes. The degree of training depends on the type of work and degree of responsibility, and should be provided for the following persons:

- The physicians who are responsible for individual justification and conducting the exposures;
- Physicians in training who perform procedures under the supervision and responsibility of such physicians;
- Radiation technologists or equivalent staff.

The Regulatory Authority should encourage health authorities, universities and professional associations to design and implement education and training programmes in radiation protection and safety for professional staff involved in diagnostic and interventional radiology.

3.32. The extent of medical knowledge required of persons involved in X ray procedures varies and may include the whole field of X ray diagnosis (e.g. radiologists) or a subspecialization (e.g. orthopaedic surgeons, traumatologists and cardiologists). The training of health professionals in relation to diagnostic radiology should include specific medical and radiation protection topics.

3.33. Specific training in radiation protection should be planned for specialists performing special procedures such as fluoroscopy, paediatric radiology or interventional radiology [18, 23].

INVESTIGATION OF ACCIDENTAL MEDICAL EXPOSURES

3.34. The Regulatory Authority should require registrants and licensees to carry out investigations in the event of the following:

- “any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels” (BSS, para. II.29 (b)).
- “any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended” (BSS, para. II.29 (c)).
- deterministic effects produced as a result of interventional radiology procedures.

3.35. Registrants and licensees are required, with respect to any such investigation, to estimate patient doses, analyse the possible causes and take measures to avoid further incidents. A written report should be provided to the Regulatory Authority and the patient, and his or her doctor should be informed about the incident. (BSS, para. II.30.)

4. SPECIFIC ASPECTS OF RADIOLOGICAL PROTECTION FOR MEDICAL EXPOSURE IN NUCLEAR MEDICINE

INTRODUCTION

4.1. In this Safety Guide nuclear medicine refers to the practice in which unsealed radioactive substances are administered to patients for diagnosis, treatment or research. The radiation exposure stems from the radioactive substance administered to the patient. Nuclear medicine is practised by nuclear medicine physicians and radiation oncologists, with the collaboration of nuclear medicine technologists, radiopharmacists, radiation physicists and nurses.

JUSTIFICATION

4.2. Justification in nuclear medicine should comply with the BSS (BSS, paras II.4–II.9) and the recommendations of the ICRP [6]. The Regulatory Authority should require that no patient be administered a radioactive substance for diagnostic purposes unless the procedure is prescribed by a medical practitioner who fulfils the national requirements on training and experience for prescribing procedures involving medical exposure. The prescriber should consider the efficacy, benefits and risks of alternative technology, for example ultrasound, magnetic resonance imaging and endoscopy. Ideally, the prescriber, often called the referring physician, should consult the nuclear medicine specialist for the appropriate procedure to be performed.

OPTIMIZATION OF PROTECTION FOR MEDICAL EXPOSURES

4.3. Acceptable image quality with the minimum patient dose should be the objective of the nuclear medicine diagnostic process as a whole. According to the BSS “Registrants and licensees should ensure that for diagnostic uses of radiation the imaging and quality assurance requirements of the Standards be fulfilled with the advice of a qualified expert in either radiodiagnostic physics or nuclear medicine physics, as appropriate” (BSS, para. II.2). Conformity could be achieved when a qualified expert in medical physics with expertise in nuclear medicine is available for that purpose. The operational aspects of diagnostic and therapeutic nuclear medicine require the particular training, knowledge and experience of the nuclear medicine specialist and the other medical or technical staff involved in a procedure. According to the BSS (BSS, para. II.17 (a)–(e)), the nuclear medicine specialist should select the appropriate test likely to give the expected result on the grounds of accepted current

medical knowledge, taking into account the patient's dose, whether the patient is pregnant, lactating or a child, and local resources.

Equipment

4.4. Unlike diagnostic radiology and radiotherapy, nuclear medicine technology, with the exception of positron emission tomography, does not use equipment that generates ionizing radiation. The Regulatory Authority should require compliance with IEC standards or nationally recognized equivalent standards in the State of use for gamma cameras and other nuclear medicine equipment.

4.5. For positron emission tomography installations that operate a cyclotron for radionuclide production, the Regulatory Authority should require that the registrant or licensee complies with the guidelines for the preparation and control of radiopharmaceuticals in hospitals. As cyclotrons are not directly involved in the exposure of patients, they are not subject to the standards for radiation generators and irradiation installations used for medical diagnosis and treatment. However, the Regulatory Authority should require that the registrant or licensee follow safety standards for cyclotrons similar to those applied in the industrial production of radionuclides.

4.6. The Regulatory Authority should require that activity meters used to measure the activity of a radiopharmaceutical to be administered to patients, both for diagnostic tests and for therapeutic purposes, be designed in such a way that they exhibit the performance required for that purpose, and that the effect of background radiation on the instruments is minimized. The Regulatory Authority should require assurance from the registrant or licensee that the performance of such equipment meets the IEC standards or nationally recognized equivalent standards in the State of use.

Operational aspects

4.7. Current medical practice is laid down in the form of manuals of procedures or protocols. These have been produced by a number of professional scientific organizations, both national and international (see the Bibliography). The Regulatory Authority should require the registrant or licensee to draw up a written manual of all procedures carried out by a department, which should be available at all times to all staff members involved in conducting the procedures.

4.8. Each protocol should follow the requirements of the BSS (BSS, para. II.17 (a)–(e)). Deviations from such protocols may be necessary owing to the special needs

of a particular patient or because of the local unavailability of components for a test. In these cases the nuclear medicine specialist should record a valid reason for his or her decision. The Regulatory Authority should require that radionuclide therapy involving high activity should be carried out in dedicated areas.

4.9. The operating procedures should specify that these aspects are periodically reviewed by registrants and licensees.

Calibration of sources and measurements of prescribed activity

4.10. According to the BSS (BSS, para. II.19 (d)), registrants and licensees shall ensure that for each patient the activity of the radiopharmaceutical to be administered is determined and recorded at the time of administration. To comply with this requirement the registrant or licensee should ensure that radionuclides are checked for radioactive impurities when these are liable to be present. This applies particularly to short lived radionuclides, as longer lived impurities may be present and could deliver a significant fraction of the absorbed dose.

4.11. Registrants and licensees should ensure that an activity meter is available for measuring activity in syringes or vials in a nuclear medicine unit. The validity of measurements should be ensured by regular quality control of the instrument, including periodic reassessments of its calibration, traceable to secondary standards.

Clinical dosimetry

Diagnostic exposure

4.12. The Regulatory Authority should require that registrants and licensees make available a list of representative values for absorbed dose or effective dose to typical patients for each type of diagnostic investigation carried out within a department. Registrants and licensees should obtain these values by calculation or extraction from tables using internationally accepted methods or compilations of standard data [12, 34, 35]. The Regulatory Authority should require that these dose values be included by registrants and licensees in their manual of procedures. In special cases, for example doses to an embryo or foetus, it may be necessary to calculate individual dose values (BSS, para. II.20 (d)).

Therapeutic exposure

4.13. The Regulatory Authority should require that registrants and licensees have access to the expert knowledge required to perform individual dose calculations for

therapeutic procedures, where appropriate. Each therapeutic dose should be calculated and recorded (BSS, para. II.20 (e)).

Quality assurance

4.14. The Regulatory Authority should require that the nuclear medicine registrant or licensee establish a comprehensive QA programme, which ideally includes the following steps [20]:

- Procedure (i.e. patient history and signs, diagnostic particulars, appropriateness of investigations and contraindications);
- Planning of procedure (i.e. reliable administrative procedures, patient information and patient preparation);
- Clinical procedure (i.e. approved suppliers and materials, storage, radiopharmaceutical preparation, clinical environment, patient handling and preparation, equipment performance, acquisition protocol and waste disposal);
- Training and experience of nuclear medicine specialists, physicists and technologists and others involved;
- Data analysis (i.e. processing protocol, equipment performance, data accuracy and integrity);
- Report (i.e. data, image review, results and further advice);
- General outcomes (i.e. clinical outcome, radiation dose, patient satisfaction and referring physician satisfaction);
- Audit.

4.15. A few of these steps should receive special attention from the Regulatory Authority. It should be ensured that any such actions do not contradict or overlap other aspects of the quality system as a whole. There should be co-operation between the Regulatory Authority and the registrant or licensee and harmonization between the requirements of the quality system based on medical grounds and the requirements for radiation protection.

4.16. The Regulatory Authority should require that the specific aspects of radiation protection and safety be included in the QA programme of registrants and licensees and that special attention be paid to the preparation and handling of radiopharmaceuticals, the performance of equipment and instrumentation, and dealing with accidents. Safety aspects for transportation, the storage of radioactive material and waste disposal are covered in Ref. [36].

Radiopharmaceuticals

4.17. The Regulatory Authority should require registrants and licensees to ensure that radiopharmaceuticals intended for administration to patients are prepared in a manner that meets clinical needs and satisfies both radiation safety and pharmaceutical quality requirements [18, 21, 35].

Equipment and instruments

4.18. The Regulatory Authority should require registrants and licensees to ensure that quality control of equipment and measurement instrumentation be undertaken as an integral part of the work and that the general principles outlined in Refs [20, 37] and in IAEA-TECDOC-602, Quality Control of Nuclear Medicine Instruments, be applied.

GUIDANCE LEVELS

4.19. The Regulatory Authority should encourage professional associations and registrants and licensees to perform surveys of administered activity for typical adult patients in common diagnostic procedures. An assessment of administered activity may be implemented gradually and should always be undertaken in parallel with image quality assessments.

4.20. The results of these surveys will allow guidance levels to be determined and reviewed as technology improves (BSS, para. II.24). In the absence of wide scale surveys, the guidance levels specified in Schedule III of the BSS, Table III-V (see Annex IV of this Safety Guide), should be used to assess the performance of nuclear medicine equipment. These values are appropriate only for typical adult patients. In applying them in practice, account should be taken of body size and age. These values should not be applied to individual patients. Positron emitting radiopharmaceuticals, such as ^{18}F -FdG fluorodeoxyglucose, have been developed since the preparation of these tables.

4.21. Deviations from the normally used amounts may be necessary under a variety of physical and pathological conditions. These cases should be given special consideration by the physician performing the procedure.

MAXIMUM ACTIVITY AT THE TIME OF DISCHARGE FROM HOSPITAL IN PATIENTS UNDERGOING TREATMENT WITH UNSEALED SOURCES

4.22. Patients who are receiving radionuclide therapy may be discharged only after the remaining activity subsides to an acceptable level. The Regulatory Authority should set the level according to international standards (BSS, Schedule III, Table III-VI), taking into account local conditions and the potential exposure of other members of the patients' households. Registrants and licensees should have a system to measure or to estimate the level of activity in patients prior to discharge. The results should be recorded. Before leaving the hospital, patients should be given written and verbal instructions concerning any precautions they may need to take to protect their families and other persons with whom they may come into contact. In some cases, such as for the elderly or children, it may be necessary to discuss the precautions to be taken with other family members. The instructions should indicate the length of time for which patients should observe the precautions.

DOSE CONSTRAINTS FOR COMFORTERS AND VISITORS

4.23. Registrants and licensees should ensure that comforters, visitors and members of the household of patients who are having a course of treatment with radionuclides (e.g. ^{131}I for hyperthyroidism and thyroid carcinoma, ^{89}Sr , ^{186}Re for pain palliation) receive adequate written instructions on the relevant radiation protection precautions (e.g. time in contact and proximity to the patient) so that they do not exceed the dose constraint as given in the BSS (BSS, para. II-9) (see Annex III of this Safety Guide).

TRAINING

4.24. The Regulatory Authority should encourage health authorities, universities and professional organizations to design and implement continuing education and training programmes in radiation protection and safety for nuclear medicine specialists, physicists, technologists and other professional staff involved in the practice of nuclear medicine. Such programmes for nuclear medicine should include radiopharmaceutical biokinetics and dosimetry, elution of generators, contamination control, waste management, waste prevention and the management of incidents and accidents.

INVESTIGATION OF ACCIDENTAL MEDICAL EXPOSURES

4.25. The Regulatory Authority should require that registrants and licensees promptly carry out an investigation following any of the incidents described in

para. II.29 of the BSS. Following any such incident, registrants and licensees shall estimate patient doses, analyse the possible causes and take measures to avoid further incidents.

5. SPECIFIC ASPECTS OF RADIOLOGICAL PROTECTION FOR MEDICAL EXPOSURE IN RADIATION THERAPY

INTRODUCTION

5.1. In this Safety Guide radiation therapy refers to the practice in which external beam sources (teletherapy, mainly photon and electron beams) and sealed radioactive sources (brachytherapy) are used for the treatment of patients.

5.2. Radiation therapy is practised by radiation oncologists, with the collaboration of qualified experts in radiotherapy physics (medical physicists) and radiotherapy technologists.

JUSTIFICATION

5.3. Justification in radiation therapy should follow the principles outlined in the BSS (BSS, paras II.4 and II.8). The Regulatory Authority should require that therapeutic medical exposures be administered to patients only if they have been prescribed by a medical practitioner who fulfils the national requirements on training and experience for prescribing procedures involving radiation therapy. The prescriber should consider the efficacy, benefits and risks of alternative procedures, for example surgery and chemotherapy, either alone or in combination with radiation therapy.

5.4. The objective of radiation therapy is to deliver a radiation dose to a selected target volume of an organ or tissue for the purpose of killing cells. Such therapy results in absorbed doses that are orders of magnitude greater than those encountered in diagnostic studies. The dose is usually delivered in more than one treatment fraction. The potential for complications with normal tissue is significant. Such effects will often be an unavoidable part of a properly justified procedure. Therefore, the justification for each procedure should be carefully considered.

OPTIMIZATION OF PROTECTION FOR MEDICAL EXPOSURES

5.5. The BSS requirement for optimization in radiation therapy is that doses to “normal tissue during radiotherapy be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume” (BSS, para. II.18 (a)). Since the aim of radiation therapy is to deliver a high dose, side effects to tissue surrounding the target volume are inevitable. The degree of such effects is a matter for radiation oncologists (or other authorized medical practitioners) to evaluate. However, if the effects differ significantly from the expectations of the clinician, this will be a matter of concern to the Regulatory Authority. Furthermore, in the case of accidental overdoses there will be no opportunity to correct the mistake. The Regulatory Authority should require registrants and licensees to report any unplanned or unexpected outcomes resulting from doses either higher or lower than intended.

5.6. According to para. II.1 (d) of the BSS, registrants and licensees shall fulfil the calibration, dosimetry and QA requirements in accordance with the BSS by or under the supervision of a qualified expert in radiotherapy physics. The operational aspects of radiation therapy require particular training, knowledge and experience on the part of the radiation oncologist, the medical radiation physicist and the other staff involved in the treatments. The BSS require that registrants and licensees select the appropriate treatment considering complications with normal tissue and the possible detriment to any embryo or foetus that might be present when the patient is a woman who is or is likely to be pregnant (II.18 (a), (b), (d) and (e)). The patient shall be informed of possible risks.

Equipment

5.7. To authorize the use of radiation therapy equipment, the Regulatory Authority should require that registrants and licensees follow the requirements given in the BSS (BSS, paras II.11–II.13 and II.15). Particular attention should be given to conforming with IEC and ISO standards or nationally recognized equivalent standards in the State of use.

5.8. A national strategy should be formulated when existing equipment does not meet the applicable IEC standard (BSS, para. II.13 (a)). Regulators should recognize that resources may not readily be available to replace equipment, especially when the IEC standard is new or recent, and more harm than good could be done if this equipment were not allowed to be used to treat patients. In this case an optimized solution should be found; it could consist of a transition period with provisions to ensure an acceptable level of safety. The provisions should be drawn up as a result of a safety assessment comparing the features of the existing equipment against the IEC requirements; for example, in connection with the requirement for two timers for terminating irradiation

in a ^{60}Co teletherapy unit, the temporary use of a chronometer together with a formal procedure to be strictly followed and documented may serve to improve safety until a second timer can be installed. Multiple safeguards for all critical components should be used, with the aim of preventing a single failure leading to serious consequences [5].

5.9. Especially critical for safety in radiation therapy is the understanding of equipment displays and the accompanying operational and maintenance documents. If the texts displayed and the accompanying operational and maintenance documents are in a foreign language, their written translation into the local language and terminology should be prepared and should be accessible at any time to the operational staff.

Operational aspects

5.10. The Regulatory Authority should require that all applicants requesting an authorization draw up written procedures for the delivery of therapeutic radiation consistent with the requirements of the BSS (BSS, para. II.18). The purpose of requiring such documentation is not to assess the adequacy of the treatment but to ensure that the applicant has adopted protocols for treatments. Particular attention should be given to the availability of ancillary equipment devices and treatment accessories.

5.11. The Regulatory Authority should encourage the timely replacement of sealed sources so that treatment times are kept reasonably short to ensure that the potential for movement of the patient is low. Isolation rooms for radionuclide therapy patients should be established.

Calibration of sources

5.12. The BSS require that the calibration of radiotherapy sources, which include both external radiotherapy beams and sources used in brachytherapy, be traceable to an SDL (BSS, para. II.19). The Regulatory Authority should require that registrants and licensees have their dosimetry instrumentation calibrated by an SSDL. The Regulatory Authority should require that registrants and licensees make arrangements to calibrate their dosimetry instrumentation at appropriate intervals. A period of two years is recommended. It may be necessary for instruments to be sent to another State if there is not a national standards laboratory in the State of use.

5.13. The calibration of sources should be made by or under the supervision of a qualified expert on radiotherapy physics (usually a medical physicist), following a nationally accepted code of practice [38, 39], at frequent intervals. Such calibrations should be undertaken at commissioning, after source change and after major repairs

or modifications that may affect dosimetry (BSS, para. II.19 (e)). The intervals for these calibrations may differ, depending on the type of source and unit.

5.14. The miscalibration of a radiation therapy source can result in inappropriate treatment involving many patients and can lead to serious consequences. The Regulatory Authority should encourage registrants and licensees to apply the principle of ‘defence in depth’, that is by means of redundancy and diversity to prevent miscalibration.

5.15. Particular attention should be paid to the calibration of sources used for special radiotherapy procedures (e.g. radiosurgery, intraoperative radiation therapy, intravascular radiation therapy, stereotactic radiotherapy, total body irradiation).

Clinical dosimetry and treatment planning

5.16. The Regulatory Authority should require that registrants and licensees meet the requirements of the BSS (BSS, paras II.20 (b), (c), (e) and II.21). To meet these requirements the Regulatory Authority should require that the prescription, planning, dose delivery and documentation follow internationally accepted terms and concepts:

- For all external beam patients, a prescription, dated and signed by the radiation oncologist, shall be obtained prior to treatment. It should contain the following information: the location of the treatment site, total dose, dose per fraction, fractionation and overall treatment period. In addition, the maximum doses to organs at risk in the irradiated volume should be stated. Specification of various volumes (e.g. gross tumour volume, clinical target volume, treatment planning volume) should follow the recommendations of the ICRU [40, 41].
- For all brachytherapy patients, a prescription, dated and signed by the radiation oncologist, shall be obtained prior to treatment. It should contain the following information: the total dose to a reference point and to organs at risk, the size of the reference dose volume, the number of sources and their dose distribution, the radionuclide and the source strength at a reference date. The specification of volumes and doses should follow the recommendations of the ICRU [40].

5.17. The Regulatory Authority should recommend registrants and licensees to perform phantom and in vivo measurements as part of clinical dosimetry [42].

5.18. Treatment planning systems are an essential component of treatment delivery, and therefore registrants and licensees should ensure that there is full documentation of the commissioning and validation processes for these systems. Such actions should be part of the registrant’s or licensee’s QA programme (see below).

Quality assurance

5.19. The BSS require that registrants and licensees establish a comprehensive QA programme with the participation of appropriate qualified experts in the relevant fields (BSS, paras II.22 and II.23). The Regulatory Authority should require that such a QA programme be established in radiotherapy institutions and that it be regularly reviewed and updated. The Regulatory Authority may encourage registrants and licensees to work with professional associations in the development of such programmes and protocols.

5.20. As the development of a national protocol may not be feasible in many States, a well established and proven international or national programme may be followed [43, 44]. A QA protocol should embrace the entire process of radiotherapy [45], including tumour localization, patient immobilization, treatment planning and dose delivery. It should include quality control of equipment, instrumentation and treatment planning systems (for both hardware and software). Particular attention should be given to the role of external quality audits (BSS, para. II.23 (e)).

5.21. One of the simplest mechanisms for independent verification of external beam calibration or physical dosimetry is participation in the IAEA/WHO thermoluminescence dosimetry postal dose quality audit. The Regulatory Authority should encourage registrants and licensees to participate in this or similar programmes.

5.22. The actions to be taken in cases of significant deviations should be part of the QA programme — under no circumstances should the results of these verifications be taken as an alternative to the performance of a full calibration.

TRAINING

5.23. The Regulatory Authority should encourage health authorities, universities and professional organizations to design and implement training programmes on radiation safety aspects for radiation oncologists, qualified experts in radiotherapy physics, radiotherapy technologists, dosimetrists and maintenance personnel. Training curricula can be found in Refs [46–48]. Hospital administrators who allocate resources should be trained on the implications of their decisions on protection and safety in medical exposure.

5.24. To meet the provisions of para. II.1 (f) of the BSS, training criteria should be specified or approved by the Regulatory Authority in consultation with professional bodies, for example the professional bodies for radiation oncology and medical

physics. Radiation safety aspects should cover radiation modalities, facility design, the characteristics of the safety features of sources and source related equipment, dosimetry, instrument calibration, treatment planning, radioactive waste disposal, accident prevention and emergency (including medical) procedures to deal with general and medical emergencies. The training should include lessons learned from past accidental medical exposures.

5.25. Basic education should be followed by continuing education, particularly when a new treatment modality or a different type of equipment is considered.

INVESTIGATION OF ACCIDENTAL MEDICAL EXPOSURES

5.26. Pursuant to the BSS, the Regulatory Authority should require that registrants and licensees carry out investigations of accidental exposures, as required in the BSS, paras II.29 and II.30. It should be taken into account that, in radiotherapy, accidental exposures may consist of either underexposures or overexposures (BSS, para. II.29 (a)). The Regulatory Authority should encourage the long term follow-up of any patients concerned by registrants and licensees, since the detrimental consequences may have a long latency period.

5.27. The Regulatory Authority may establish a national policy and formal procedures for an investigation, notification and feedback mechanism. The mechanism should include the collection and dissemination of information among manufacturers, suppliers, maintenance companies and users.

5.28. As the experience that can be accumulated in a single State may be limited, States should benefit from sharing information at the international level.

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Annex I

1. GENERAL REQUIREMENTS*

DEFINITIONS

1.1. Terms shall be interpreted as defined in the Glossary.

PURPOSE

1.2. These Standards specify the basic requirements for protection of people against exposure to ionizing radiation and for the safety of radiation sources, hereinafter termed protection and safety.

SCOPE

1.3. The Standards apply to practices, including any sources within the practices, and interventions which are:

- (a) carried out in a State that chooses to adopt the Standards or requests any of the Sponsoring Organizations to provide for the application of the Standards;
- (b) undertaken by States with the assistance of the FAO, the IAEA, the ILO, the PAHO, or the WHO, in the light of relevant national rules and regulations;
- (c) carried out by the IAEA or involve the use of materials, services, equipment, facilities and non-published information made available by the IAEA or at its request or under its control or supervision; or
- (d) carried out under any bilateral or multilateral arrangement whereby the parties request the IAEA to provide for the application of the Standards.

EXCLUSIONS

1.4. Any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of the Standards is deemed to be excluded from the Standards².

* Reproduced verbatim from the BSS (Principal Requirements, Section 1, pp. 13–16).

² Examples are exposure from ⁴⁰K in the body, from cosmic radiation at the surface of the earth and from unmodified concentrations of radionuclides in most raw materials.

RESPONSIBLE PARTIES

1.5. The Regulatory Authority and, in the case of intervention, the Intervening Organizations shall be responsible for the enforcement of the Standards.

1.6. The principal parties having the main responsibilities for the application of the Standards shall be:

- (a) registrants and licensees; and
- (b) employers.

1.7. Other parties shall have subsidiary responsibilities for the application of the Standards. These parties may include, as appropriate:

- (a) suppliers;
- (b) workers;
- (c) radiation protection officers;
- (d) medical practitioners;
- (e) health professionals;
- (f) qualified experts;
- (g) Ethical Review Committees; and
- (h) any other party to whom a principal party has delegated specific responsibilities.

1.8. The parties shall have the general and specific responsibilities set out in the Standards.

1.9. The general responsibilities of principal parties, within the requirements specified by the Regulatory Authority, are:

- (a) to establish protection and safety objectives in conformity with the relevant requirements of the Standards; and
- (b) to develop, implement and document a protection and safety programme commensurate with the nature and extent of the risks associated with the practices and interventions under their responsibility and sufficient to ensure compliance with the requirements of the Standards, and, within this programme:
 - (i) to determine the measures and resources needed to achieve the protection and safety objectives and to ensure that the resources are provided and the measures properly implemented;
 - (ii) to keep such measures and resources continually under review, and regularly to verify that the protection and safety objectives are being achieved;

- (iii) to identify any failures and shortcomings in the protection and safety measures and resources, and to take steps to correct them and prevent their recurrence;
- (iv) to establish arrangements, through representatives if appropriate, for facilitating consultation and co-operation between all relevant parties with respect to protection and safety; and
- (v) to keep appropriate records regarding the discharge of their responsibilities.

INSPECTIONS

1.10. The principal parties shall permit duly authorized representatives of the Regulatory Authority, and of the relevant Sponsoring Organizations when applicable, to inspect their protection and safety records and to carry out appropriate inspections of their authorized activities.

NON-COMPLIANCE

1.11. In the event of a breach of any applicable requirement of the Standards, principal parties shall, as appropriate:

- (a) investigate the breach and its causes, circumstances and consequences;
- (b) take appropriate action to remedy the circumstances that led to the breach and to prevent a recurrence of similar breaches;
- (c) communicate to the Regulatory Authority, and to the relevant Sponsoring Organizations when applicable, on the causes of the breach and on the corrective or preventive actions taken or to be taken; and
- (d) take whatever other actions are necessary as required by the Standards.

1.12. The communication of a breach of the Standards shall be prompt and it shall be immediate whenever an emergency exposure situation has developed or is developing.

1.13. Failure to take corrective or preventive actions within a reasonable time in accordance with national regulations shall be grounds for modifying, suspending or withdrawing any authorization that had been granted by the Regulatory Authority or, when applicable, by the relevant Sponsoring Organization.

1.14. Wilful breach of, attempted breach of or conspiracy to breach any requirement of the Standards is subject to the provisions for such infractions by the appropriate

national legislation of the State, or by the Regulatory Authority or, when applicable, by the relevant Sponsoring Organization.

ENTRY INTO FORCE

1.15. The Standards shall come into force one year after the date of their adoption or acknowledgement, as appropriate, by the relevant Sponsoring Organization.

1.16. Should a State choose to adopt the Standards, the Standards shall come into force at the time indicated in the formal adoption by that State.

1.17. If a modification to an existing practice or source is required by the Regulatory Authority or, where applicable, by the relevant Sponsoring Organization, in order to comply with some requirement of the Standards, such a requirement should take effect within an approved period if such a period is required for the modification.

RESOLUTION OF CONFLICTS

1.18. The requirements of the Standards are in addition to and not in place of other applicable requirements, such as those of relevant binding conventions and national regulations.

1.19. In cases of conflict between the requirements of the Standards and other applicable requirements, the Regulatory Authority shall determine which requirement is to be enforced.

1.20. Nothing in the Standards shall be construed as restricting any actions that may otherwise be necessary for protection and safety.

INTERPRETATION

1.21. Except as specifically authorized by the statutory Governing Body of a relevant Sponsoring Organization, no interpretation of the Standards by any officer or employee of the Sponsoring Organization other than a written interpretation by the Director General of the Sponsoring Organization will be binding on the Sponsoring Organization.

COMMUNICATIONS

1.22. The appropriate responsible party, as established by the Standards, shall report on compliance with the requirements of the Standards.

1.23. Reports on compliance and other communications on official interpretation of the Standards shall be addressed to the Regulatory Authority or the relevant Sponsoring Organizations, as appropriate.

Annex II

Appendix II. MEDICAL EXPOSURE*

RESPONSIBILITIES

II.1. Registrants and licensees shall ensure that:

- (a) no patient be administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner;
- (b) medical practitioners be assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;
- (c) medical and paramedical personnel be available as needed, and either be health professionals or have appropriate training adequately to discharge assigned tasks in the conduct of the diagnostic or therapeutic procedure that the medical practitioner prescribes;
- (d) for therapeutic uses of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and quality assurance requirements of the Standards be conducted by or under the supervision of a qualified expert in radiotherapy physics;
- (e) the exposure of individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment be constrained as specified in Schedule II; and
- (f) training criteria be specified or be subject to approval, as appropriate, by the Regulatory Authority in consultation with relevant professional bodies.

II.2. Registrants and licensees should ensure that for diagnostic uses of radiation the imaging and quality assurance requirements of the Standards be fulfilled with the advice of a qualified expert in either radiodiagnostic physics or nuclear medicine physics, as appropriate.

II.3. Medical practitioners shall promptly inform the registrant or licensee of any deficiencies or needs regarding compliance with the Standards with respect to protection and safety of patients and shall take such actions as may be appropriate to ensure the protection and safety of patients.

* Reproduced verbatim from the BSS (Appendix II, pp. 45–56).

JUSTIFICATION OF MEDICAL EXPOSURES

II.4. Medical exposures should be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

II.5. In justifying each type of diagnostic examination by radiography, fluoroscopy or nuclear medicine, relevant guidelines will be taken into account, such as those established by the WHO^{13–15}.

II.6. Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is deemed to be not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.

II.7. Mass screening of population groups involving medical exposure is deemed to be not justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment. Account should be taken in justification of the potential of the screening procedure for detecting disease, the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease.

II.8. The exposure of humans for medical research is deemed to be not justified unless it is:

- (a) in accordance with the provisions of the Helsinki Declaration¹⁶ and follows the guidelines for its application prepared by Council for International Organizations of Medical Sciences (CIOMS)¹⁷ and WHO¹⁸; and
- (b) subject to the advice of an Ethical Review Committee (or any other institutional body assigned similar functions by national authorities) and to applicable national and local regulations.

¹³ WORLD HEALTH ORGANIZATION, A Rational Approach to Radiodiagnostic Investigations, Technical Reports Series No. 689, WHO, Geneva (1983).

¹⁴ WORLD HEALTH ORGANIZATION, Rational Use of Diagnostic Imaging in Pediatrics, Technical Reports Series No. 757, WHO, Geneva (1987).

¹⁵ WORLD HEALTH ORGANIZATION, Effective Choices for Diagnostic Imaging in Clinical Practices, Technical Reports Series No. 795, WHO, Geneva (1990).

II.9. Radiological examinations for theft detection purposes are deemed to be not justified; should they nonetheless be conducted, they shall not be considered medical exposure but shall be subject to the requirements for occupational and public exposure of the Standards.

OPTIMIZATION OF PROTECTION FOR MEDICAL EXPOSURES

II.10. The requirements in this subsection shall be considered to be in addition to any relevant requirements for optimization of protection specified in other parts of the Standards.

Design considerations

General

II.11. The requirements for the safety of sources specified in other parts of the Standards shall also apply to sources used in medical exposure, where relevant, and, in particular, equipment used in medical exposure shall be so designed that:

- (a) failure of a single component of the system be promptly detectable so that any unplanned medical exposure of patients is minimized; and
- (b) the incidence of human error in the delivery of unplanned medical exposure be minimized.

II.12. Registrants and licensees shall:

- (a) taking into account information provided by suppliers, identify possible equipment failures and human errors that could result in unplanned medical exposures;

¹⁶ Adopted by the 18th World Medical Assembly, Helsinki, 1964, and as amended by the 29th World Medical Assembly, Tokyo, 1975, the 35th World Medical Assembly, Venice, 1983, and the 41st World Medical Assembly, Hong Kong, 1989; available from the World Medical Association, F-01210 Ferney-Voltaire, France.

¹⁷ COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES in collaboration with WORLD HEALTH ORGANIZATION, International Ethical Guidelines for Biomedical Research Involving Human Subjects, CIOMS, Geneva (1993).

¹⁸ WORLD HEALTH ORGANIZATION, Use of Ionizing Radiation and Radionuclides on Human Beings for Medical Research, Training and Non-Medical Purposes, Technical Report Series No. 611, WHO, Geneva (1977).

- (b) take all reasonable measures to prevent failures and errors, including the selection of suitably qualified personnel, the establishment of adequate procedures for the calibration, quality assurance and operation of diagnostic and therapeutic equipment, and the provision to personnel of appropriate training and periodic retraining in the procedures, including protection and safety aspects;
- (c) take all reasonable measures to minimize the consequences of failures and errors that may occur; and
- (d) develop appropriate contingency plans for responding to events that may occur, display plans prominently, and periodically conduct practice drills.

II.13. Registrants and licensees, in specific co-operation with suppliers, shall ensure that, with regard to equipment consisting of radiation generators and that containing sealed sources used for medical exposures:

- (a) whether imported into or manufactured in the country where it is used, the equipment conform to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or to equivalent national standards;
- (b) performance specifications and operating and maintenance instructions, including protection and safety instructions, be provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to 'accompanying documents', and that this information be translated into local languages when appropriate;
- (c) where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in a major world language acceptable to the user;
- (d) radiation beam control mechanisms be provided, including devices that indicate clearly and in a fail-safe manner whether the beam is 'on' or 'off';
- (e) as nearly as practicable, the exposure be limited to the area being examined or treated by using collimating devices aligned with the radiation beam;
- (f) the radiation field within the examination or treatment area without any radiation beam modifiers (such as wedges) be as uniform as practicable and the non-uniformity be stated by the supplier; and
- (g) exposure rates outside the examination or treatment area due to radiation leakage or scattering be kept as low as reasonably achievable.

Requirements for radiation generators and equipment using sealed sources for diagnostic radiology

II.14. Registrants and licensees, in specific co-operation with suppliers, shall ensure that:

- (a) radiation generators and their accessories be designed and manufactured so as to facilitate the keeping of medical exposures as low as reasonably achievable consistent with obtaining adequate diagnostic information;
- (b) operational parameters for radiation generators, such as generating tube potential, filtration, focal spot size, source–image receptor distance, field size indication and either tube current and time or their product be clearly and accurately indicated;
- (c) radiographic equipment be provided with devices that automatically terminate the irradiation after a preset time, tube current–time product or dose; and
- (d) fluoroscopic equipment be provided with a device that energizes the X ray tube only when continuously depressed (such as a ‘dead man’s switch’) and equipped with indicators of the elapsed time and/or entrance surface dose monitors.

Requirements for radiation generators and irradiation installations for radiotherapy

II.15. Registrants and licensees, in specific co-operation with suppliers, shall ensure that:

- (a) radiation generators and irradiation installations include provisions for selection, reliable indication and confirmation (when appropriate and to the extent feasible) of operational parameters such as type of radiation, indication of energy, beam modifiers (such as filters), treatment distance, field size, beam orientation and either treatment time or preset dose;
- (b) irradiation installations using radioactive sources be fail-safe in the sense that the source will be automatically shielded in the event of an interruption of power and will remain shielded until the beam control mechanism is reactivated from the control panel;
- (c) high energy radiotherapy equipment:
 - (i) have at least two independent ‘fail to safety’ systems for terminating the irradiation; and
 - (ii) be provided with safety interlocks or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel;
- (d) the design of safety interlocks be such that operation of the installation during maintenance procedures, if interlocks are bypassed, could be performed only under direct control of the maintenance personnel using appropriate devices, codes or keys;
- (e) radioactive sources for either teletherapy or brachytherapy be so constructed that they conform to the definition of a sealed source; and

- (f) when appropriate, monitoring equipment be installed or be available to give warning of an unusual situation in the use of radiation generators and radio-nuclide therapy equipment.

Operational considerations

Diagnostic exposure

II.16. Registrants and licensees shall ensure for diagnostic radiology that:

- (a) the medical practitioners who prescribe or conduct radiological diagnostic examinations:
 - (i) ensure that the appropriate equipment be used;
 - (ii) ensure that the exposure of patients be the minimum necessary to achieve the required diagnostic objective, taking into account norms of acceptable image quality established by appropriate professional bodies and relevant guidance levels for medical exposure; and
 - (iii) take into account relevant information from previous examinations in order to avoid unnecessary additional examinations;
- (b) the medical practitioner, the technologist or other imaging staff select the following parameters, as relevant, such that their combination produce the minimum patient exposure consistent with acceptable image quality and the clinical purpose of the examination, paying particular attention to this selection for paediatric radiology and interventional radiology:
 - (i) the area to be examined, the number and size of views per examination (e.g. number of films or computed tomography slices) or the time per examination (e.g. fluoroscopic time);
 - (ii) the type of image receptor (e.g. high versus low speed screens);
 - (iii) the use of antiscatter grids;
 - (iv) proper collimation of the primary X ray beam to minimize the volume of patient tissue being irradiated and to improve image quality;
 - (v) appropriate values of operational parameters (e.g. tube generating potential, current and time or their product);
 - (vi) appropriate image storage techniques in dynamic imaging (e.g. number of images per second); and
 - (vii) adequate image processing factors (e.g. developer temperature and image reconstruction algorithms);
- (c) portable and mobile radiological equipment be used only for examinations where it is impractical or not medically acceptable to transfer patients to a stationary radiological installation and only after proper attention has been given to the radiation protection measures required in its use;

- (d) radiological examinations causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant be avoided unless there are strong clinical reasons for such examinations;
- (e) any diagnostic examination of the abdomen or pelvis of women of reproductive capacity be planned to deliver the minimum dose to any embryo or foetus that might be present; and
- (f) whenever feasible, shielding of radiosensitive organs such as the gonads, lens of the eye, breast and thyroid be provided as appropriate.

II.17. Registrants and licensees shall ensure for nuclear medicine that:

- (a) the medical practitioners who prescribe or conduct diagnostic applications of radionuclides:
 - (i) ensure that the exposure of patients be the minimum required to achieve the intended diagnostic objective;
 - (ii) take into account relevant information from previous examinations in order to avoid unnecessary additional examinations; and
 - (iii) take into account the relevant guidance levels for medical exposure;
- (b) the medical practitioner, the technologist or other imaging staff, as appropriate, endeavour to achieve the minimum patient exposure consistent with acceptable image quality by:
 - (i) appropriate selection of the best available radiopharmaceutical and its activity, noting the special requirements for children and for patients with impairment of organ function;
 - (ii) use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable;
 - (iii) appropriate image acquisition and processing;
- (c) administration of radionuclides for diagnostic or radiotherapeutic procedures to women pregnant or likely to be pregnant be avoided unless there are strong clinical indications;
- (d) for mothers in lactation, discontinuation of nursing be recommended until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable effective dose to the nursling¹⁹; and
- (e) administration of radionuclides to children for diagnostic procedures be carried out only if there is a strong clinical indication, and the amount of activity administered be reduced according to body weight, body surface area or other appropriate criteria.

¹⁹ Examples of good practice are at least 3 weeks for ⁶⁷Ga, ¹¹¹In, ¹³¹I and ²⁰¹Tl, at least 2 days for ¹²³I and at least 12 hours for ⁹⁹Tc^m.

Therapeutic exposure

II.18. Registrants and licensees shall ensure that:

- (a) exposure of normal tissue during radiotherapy be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume, and organ shielding be used when feasible and appropriate;
- (b) radiotherapeutic procedures causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant be avoided unless there are strong clinical indications;
- (c) administration of radionuclides for therapeutic procedures to women who are pregnant or likely to be pregnant or who are nursing be avoided unless there are strong clinical indications;
- (d) any therapeutic procedure for pregnant women be planned to deliver the minimum dose to any embryo or foetus; and
- (e) the patient be informed of possible risks.

Calibration

II.19. Registrants and licensees shall ensure that:

- (a) the calibration of sources used for medical exposure be traceable to a Standards dosimetry laboratory;
- (b) radiotherapy equipment be calibrated in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions, e.g. following the recommendations given in IAEA Technical Reports Series No. 277²⁰;
- (c) sealed sources used for brachytherapy be calibrated in terms of activity, reference air kerma rate in air or absorbed dose rate in a specified medium, at a specified distance, for a specified reference date;
- (d) unsealed sources for nuclear medicine procedures be calibrated in terms of activity of the radiopharmaceutical to be administered, the activity being determined and recorded at the time of administration; and
- (e) the calibrations be carried out at the time of commissioning a unit, after any maintenance procedure that may have an effect on the dosimetry and at intervals approved by the Regulatory Authority.

²⁰ INTERNATIONAL ATOMIC ENERGY AGENCY, Absorbed Dose Determination for Photon and Electron Beams, Technical Reports Series No. 277, IAEA, Vienna (1987).

Clinical dosimetry

II.20. Registrants and licensees shall ensure that the following items be determined and documented:

- (a) in radiological examinations, representative values for typical sized adult patients of entrance surface doses, dose–area products, dose rates and exposure times, or organ doses;
- (b) for each patient treated with external beam radiotherapy equipment, the maximum and minimum absorbed doses to the planning target volume together with the absorbed dose to a relevant point such as the centre of the planning target volume, plus the dose to other relevant points selected by the medical practitioner prescribing the treatment;
- (c) in brachytherapeutic treatments performed with sealed sources, the absorbed doses at selected relevant points in each patient;
- (d) in diagnosis or treatment with unsealed sources, representative absorbed doses to patients; and
- (e) in all radiotherapeutic treatments, the absorbed doses to relevant organs.

II.21. In radiotherapeutic treatments, registrants and licensees shall ensure, within the ranges achievable by good clinical practice and optimized functioning of equipment, that:

- (a) the prescribed absorbed dose at the prescribed beam quality be delivered to the planning target volume; and
- (b) doses to other tissues and organs be minimized.

Quality assurance for medical exposures

II.22. Registrants and licensees, in addition to applying the relevant requirements for quality assurance specified elsewhere in the Standards, shall establish a comprehensive quality assurance programme for medical exposures with the participation of appropriate qualified experts in the relevant fields, such as radiophysics or radiopharmacy, taking into account the principles established by the WHO^{21–23} and the PAHO²⁴.

II.23. Quality assurance programmes for medical exposures shall include:

- (a) measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter;

- (b) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;
- (c) written records of relevant procedures and results;
- (d) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; and
- (e) as far as possible, regular and independent quality audit reviews of the quality assurance programme for radiotherapy procedures.

GUIDANCE LEVELS

II.24. Registrants and licensees should ensure that guidance levels for medical exposure be determined as specified in the Standards, revised as technology improves and used as guidance by medical practitioners, in order that:

- (a) corrective actions be taken as necessary if doses or activities fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients;
- (b) reviews be considered if doses or activities exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice; and
- (c) for diagnostic radiology, including computed tomography examinations, and for nuclear medicine examinations, the guidance levels be derived from the data from wide scale quality surveys which include entrance surface doses and cross-sectional dimensions of the beams delivered by individual facilities and activities of radiopharmaceuticals administered to patients for the most frequent examinations in diagnostic radiology and nuclear medicine respectively.

II.25. In the absence of wide scale surveys, performance of diagnostic radiography and fluoroscopy equipment and of nuclear medicine equipment should be assessed on the basis of comparison with the guidance levels specified in Schedule III, Tables III-I to III-V. These levels should not be regarded as a guide for ensuring optimum performance

²¹ WORLD HEALTH ORGANIZATION, Quality Assurance in Diagnostic Radiology, WHO, Geneva (1982).

²² WORLD HEALTH ORGANIZATION, Quality Assurance in Nuclear Medicine, WHO, Geneva (1982).

²³ WORLD HEALTH ORGANIZATION, Quality Assurance in Radiotherapy, WHO, Geneva (1988).

²⁴ PAN AMERICAN HEALTH ORGANIZATION, Publicación Científica No. 499, Control de Calidad en Radioterapia: Aspectos Clínicos y Físicos, PAHO, Washington, DC (1986).

in all cases, as they are appropriate only for typical adult patients and, therefore, in applying the values in practice, account should be taken of body size and age.

DOSE CONSTRAINTS

II.26. The Ethical Review Committee or other institutional body assigned similar functions on the subject by national authorities shall specify dose constraints to be applied on a case by case basis in the optimization of protection for persons exposed for medical research purposes if such medical exposure does not produce direct benefit to the exposed individual.

II.27. Registrants and licensees shall constrain any dose to individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment, and to visitors to patients who have received therapeutic amounts of radionuclides or who are being treated with brachytherapy sources, to a level not exceeding that specified in Schedule II, para. II-9.

MAXIMUM ACTIVITY IN PATIENTS IN THERAPY ON DISCHARGE FROM HOSPITAL

II.28. In order to restrict the exposure of any members of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and members of the public, such a patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below the level specified in Schedule III, Table III-VI. Written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary.

INVESTIGATION OF ACCIDENTAL MEDICAL EXPOSURES

II.29. Registrants and licensees shall promptly investigate any of the following incidents:

- (a) 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 secondary effects;
- (b) any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and

- (c) any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

II.30. Registrants and licensees shall, with respect to any investigation required under para. II.29:

- (a) calculate or estimate the doses received and their distribution within the patient;
- (b) indicate the corrective measures required to prevent recurrence of such an incident;
- (c) implement all the corrective measures that are under their own responsibility;
- (d) submit to the Regulatory Authority, as soon as possible after the investigation or as otherwise specified by the Regulatory Authority, a written report which states the cause of the incident and includes the information specified in (a) to (c), as relevant, and any other information required by the Regulatory Authority; and
- (e) inform the patient and his or her doctor about the incident.

RECORDS

II.31. Registrants and licensees shall keep for a period specified by the Regulatory Authority and make available, as required, the following records:

- (a) in diagnostic radiology, necessary information to allow retrospective dose assessment, including the number of exposures and the duration of fluoroscopic examinations;
- (b) in nuclear medicine, types of radiopharmaceuticals administered and their activities;
- (c) in radiation therapy, a description of the planning target volume, the dose to the centre of the planning target volume and the maximum and minimum doses delivered to the planning target volume, the doses to other relevant organs, the dose fractionation, and the overall treatment time; and
- (d) the exposure of volunteers in medical research.

II.32. Registrants and licensees shall keep and make available, as required, the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatments.

Annex III

Schedule II. DOSE LIMITS.

DOSE LIMITATION FOR COMFORTERS AND VISITORS OF PATIENTS*

Dose limitation for comforters and visitors of patients

II-9. The dose limits set out in this part shall not apply to comforters of patients, i.e., to individuals knowingly exposed while voluntarily helping (other than in their employment or occupation) in the care, support and comfort of patients undergoing medical diagnosis or treatment, or to visitors of such patients. However, the dose of any such comforter or visitor of patients shall be constrained so that it is unlikely that his or her dose will exceed 5 mSv during the period of a patient's diagnostic examination or treatment. The dose to children visiting patients who have ingested radioactive materials should be similarly constrained to less than 1 mSv.

* Reproduced verbatim from the BSS (Schedule II, p. 93).

Annex IV

Schedule III. GUIDANCE LEVELS OF DOSE, DOSE RATE AND ACTIVITY FOR MEDICAL EXPOSURE*

GUIDANCE LEVELS FOR DIAGNOSTIC RADIOLOGICAL PROCEDURES

TABLE III-I. GUIDANCE LEVELS OF DOSE FOR DIAGNOSTIC RADIOGRAPHY FOR A TYPICAL ADULT PATIENT

Examination	Entrance surface dose per radiograph ^a (mGy)	
Lumbar spine	AP	10
	LAT	30
	LSJ	40
Abdomen, intravenous urography and cholecystography	AP	10
Pelvis	AP	10
Hip joint	AP	10
Chest	PA	0.4
	LAT	1.5
Thoracic spine	AP	7
	LAT	20
Dental	Periapical	7
	AP	5
Skull	PA	5
	LAT	3

Notes: PA: posterior–anterior projection; LAT: lateral projection; LSJ: lumbo–sacral joint projection. AP: anterior–posterior projection.

^a In air with backscatter. These values are for conventional film–screen combination in the relative speed of 200. For high speed film–screen combinations (400–600), the values should be reduced by a factor of 2 to 3.

* Reproduced verbatim from the BSS (Schedule III, pp. 279–284).

TABLE III-II. DOSE GUIDANCE LEVELS FOR COMPUTED TOMOGRAPHY FOR A TYPICAL ADULT PATIENT

Examination	Multiple scan average dose ^a (mGy)
Head	50
Lumbar spine	35
Abdomen	25

^a Derived from measurements on the axis of rotation in water equivalent phantoms, 15 cm in length and 16 cm (head) and 30 cm (lumbar spine and abdomen) in diameter.

TABLE III-III. DOSE GUIDANCE LEVELS FOR MAMMOGRAPHY FOR A TYPICAL ADULT PATIENT

Average mammary glandular dose per cranio-caudal projection ^a 1 mGy (without grid) 3 mGy (with grid)

^a Determined in a 4.5 cm compressed breast consisting of 50% glandular and 50% adipose tissue, for film–screen systems and dedicated Mo-target Mo-filter mammography units.

TABLE III-IV. DOSE RATE GUIDANCE LEVELS FOR FLUOROSCOPY FOR A TYPICAL ADULT PATIENT

Mode of operation	Entrance surface dose rate ^a (mGy/min)
Normal	25
High level ^b	100

^a In air with backscatter.
^b For fluoroscopes that have an optional ‘high level’ operational mode, such as those frequently used in interventional radiology.

GUIDANCE LEVELS FOR
DIAGNOSTIC PROCEDURES IN NUCLEAR MEDICINE

TABLE III-V. GUIDANCE LEVELS OF ACTIVITY FOR PROCEDURES IN NUCLEAR MEDICINE FOR A TYPICAL ADULT PATIENT

Test	Radio-nuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
<i>Bone</i>			
Bone imaging	⁹⁹ Tc ^m	Phosphonate and phosphate compounds	600
Bone imaging by single photon emission computerized tomography (SPECT)	⁹⁹ Tc ^m	Phosphonate and phosphate compounds	800
Bone marrow imaging	⁹⁹ Tc ^m	Labelled colloid	400
<i>Brain</i>			
Brain imaging (static)	⁹⁹ Tc ^m	TcO ₄ ⁻	500
	⁹⁹ Tc ^m	Diethylenetriaminepenta-acetic acid (DTPA), gluconate and glucoheptonate	500
Brain imaging (SPECT)	⁹⁹ Tc ^m	TcO ₄ ⁻	800
	⁹⁹ Tc ^m	DTPA, gluconate and glucoheptonate	800
Cerebral blood flow	⁹⁹ Tc ^m	Exametazime	500
	¹³³ Xe	In isotonic sodium chloride solution	400
	⁹⁹ Tc ^m	Hexamethyl propylene amine oxime (HM-PAO)	500
Cisternography	¹¹¹ In	DTPA	40
<i>Lacrimonal</i>			
Lacrimonal drainage	⁹⁹ Tc ^m	TcO ₄ ⁻	4
	⁹⁹ Tc ^m	Labelled colloid	4
<i>Thyroid</i>			
Thyroid imaging	⁹⁹ Tc ^m	TcO ₄ ⁻	200
	¹²³ I	I ⁻	20
Thyroid metastases (after ablation)	¹³¹ I	I ⁻	400
Parathyroid imaging	²⁰¹ Tl	Tl ⁺ chloride	80

TABLE III-V. (cont.)

Test	Radio-nuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
<i>Lung</i>			
Lung ventilation imaging	⁸¹ Kr ^m	Gas	6000
	⁹⁹ Tc ^m	DTPA-aerosol	80
Lung ventilation study	¹³³ Xe	Gas	400
	¹²⁷ Xe	Gas	200
Lung perfusion imaging	⁸¹ Kr ^m	Aqueous solution	6000
	⁹⁹ Tc ^m	Human albumin (macroaggregates or microspheres)	100
Lung perfusion imaging (with venography)	⁹⁹ Tc ^m	Human albumin (macroaggregates or microspheres)	160
Lung perfusion studies	¹³³ Xe	Isotonic solution	200
	¹²⁷ Xe	Isotonic chloride solution	200
Lung imaging (SPECT)	⁹⁹ Tc ^m	Macroaggregated albumin (MAA)	200
<i>Liver and spleen</i>			
Liver and spleen imaging	⁹⁹ Tc ^m	Labelled colloid	80
Functional biliary system imaging	⁹⁹ Tc ^m	Iminodiacetates and equivalent agents	150
Spleen imaging	⁹⁹ Tc ^m	Labelled denaturated red blood cells	100
Liver imaging (SPECT)	⁹⁹ Tc ^m	Labelled colloid	200
<i>Cardiovascular</i>			
First pass blood flow studies	⁹⁹ Tc ^m	TcO ₄ ⁻	800
	⁹⁹ Tc ^m	DTPA	800
	⁹⁹ Tc ^m	Macroaggregated globulin 3	400
Blood pool imaging	⁹⁹ Tc ^m	Human albumin complex	40
Cardiac and vascular imaging/probe studies	⁹⁹ Tc ^m	Human albumin complex	800
	⁹⁹ Tc ^m	Labelled normal red blood cells	800

TABLE III-V. (cont.)

Test	Radio-nuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
Myocardial imaging/probe studies	⁹⁹ Tc ^m	Phosphonate and phosphate compounds	600
Myocardial imaging	⁹⁹ Tc ^m	Isonitriles	300
	²⁰¹ Tl	Tl ⁺ chloride	100
Myocardial imaging (SPECT)	⁹⁹ Tc ^m	Phosphonate and phosphate compounds	800
	⁹⁹ Tc ^m	Isonitriles	600
<i>Stomach, gastrointestinal tract</i>			
Stomach/salivary gland imaging	⁹⁹ Tc ^m	TcO ₄ ⁻	40
Meckel's diverticulum imaging	⁹⁹ Tc ^m	TcO ₄ ⁻	400
Gastrointestinal bleeding	⁹⁹ Tc ^m	Labelled colloid	400
	⁹⁹ Tc ^m	Labelled normal red blood cells	400
Oesophageal transit and reflux	⁹⁹ Tc ^m	Labelled colloid	40
	⁹⁹ Tc ^m	Non-absorbable compounds	40
Gastric emptying	⁹⁹ Tc ^m	Non-absorbable compounds	12
	¹¹¹ In	Non-absorbable compounds	12
	¹¹³ In ^m	Non-absorbable compounds	12
<i>Kidney, urinary system and adrenals</i>			
Renal imaging	⁹⁹ Tc ^m	Dimercaptosuccinic acid	160
Renal imaging/renography	⁹⁹ Tc ^m	DTPA, gluconate and glucoheptonate	350
	⁹⁹ Tc ^m	Macroaggregated globulin 3	100
	¹²³ I	O-iodohippurate	20
Adrenal imaging	⁷⁵ Se	Selenorcholesterol	8

TABLE III-V. (cont.)

Test	Radio-nuclide	Chemical form ^a	Maximum usual activity per test ^b (MBq)
<i>Miscellaneous</i>			
Tumour or abscess imaging	⁶⁷ Ga	Citrate	300
Tumour imaging	²⁰¹ Tl	Chloride	100
Neuroectodermal tumour imaging	⁹⁹ Tc ^m	Dimercaptosuccinic acid	400
	¹²³ I	Meta-iodo-benzyl guanidine	400
	¹³¹ I	Meta-iodo-benzyl guanidine	20
Lymph node imaging	⁹⁹ Tc ^m	Labelled colloid	80
Abscess imaging	⁹⁹ Tc ^m	Exametazime labelled white cells	400
	¹¹¹ In	Labelled white cells	20
Thrombus imaging	¹¹¹ In	Labelled platelets	20

^a In some countries some of the compounds are considered obsolete.
^b In some countries the typical values are lower than those indicated in the table.

GUIDANCE LEVEL OF
ACTIVITY FOR DISCHARGE FROM HOSPITAL

TABLE III-VI. GUIDANCE LEVEL FOR MAXIMUM ACTIVITY FOR PATIENTS IN THERAPY ON DISCHARGE FROM HOSPITAL

Radionuclide	Activity (MBq)
Iodine-131	1100 ^a

^a In some countries a level of 400 MBq is used as an example of good practice.

GLOSSARY

accident. Any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

diversity. The presence of two or more redundant systems or components to perform an identified function, where the different systems or components have different attributes so as to reduce the possibility of common cause failure.

dose constraint. A prospective restriction on the individual dose delivered by a source, which serves as an upper bound on the dose in optimization of protection and safety for the source.

—For medical exposure, dose constraint levels should be interpreted as guidance levels, except when used in optimizing the protection of persons exposed for medical research purposes or of persons, other than workers, who assist in the care, support or comfort of exposed patients.

ionizing radiation. For the purposes of radiation protection, radiation capable of producing ion pairs in biological material(s). When used in IAEA publications, the term radiation normally refers only to ionizing radiation.

medical exposure. Exposure incurred by patients as part of their own medical or dental diagnosis (diagnostic exposure) or treatment (therapeutic exposure); by persons, other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.

medical practitioner. An individual who: (a) has been accredited through appropriate national procedures as a health professional; (b) fulfils the national requirements on training and experience for prescribing procedures involving medical exposures; and (c) is a registrant or a licensee, or a worker who has been designated by a registered or licensed employer for the purpose of prescribing procedures involving medical exposure.

planning target volume. A geometrical concept used in radiotherapy for planning treatment with consideration of the net effect of movements of the patient and of the tissues to be irradiated, variations in size and shape of the tissue, and variations in beam geometry such as beam size and beam direction.

qualified expert. An individual who, by virtue of certification by appropriate boards or societies, professional licences or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, e.g. medical physics, radiation protection, occupational health, fire safety, quality assurance or any relevant engineering or safety speciality.

quality assurance (QA). Planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy given requirements for quality, for example, those specified in the licence.

— This definition is slightly modified from that in ISO 921:1997 (Nuclear Energy—Vocabulary)¹ to say “an item, process or service” instead of “a product or service” and to add the example. A more general definition of *quality assurance* and definitions of related terms can be found in ISO 8402:1994².

Or: All those planned and systematic actions necessary to provide confidence that a structure, system or component will perform satisfactorily in service.³

quality control (QC). Part of quality assurance intended to verify that structures, systems and components correspond to predetermined requirements. This definition is taken from ISO 921:1997¹. A more general definition of *quality control* and definitions of related terms can be found in ISO 8402:1994².

supplier. Any legal person to whom a registrant or licensee delegates duties, totally or partially, in relation to the design, manufacture, production or construction of a source. (An importer of a source is considered a supplier of the source.)

¹ INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Nuclear Energy — Vocabulary, 2nd edn, ISO 921:1997, ISO, Geneva (1997).

² INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management and Quality Assurance — Vocabulary, ISO 8402:1994, ISO, Geneva (1994).

³ INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Nuclear Power Plants — Quality Assurance, ISO 6215:1980, ISO, Geneva (1980).

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