Safety Reports Series
No. 39

Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays

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JOINTLY SPONSORED BY THE
INTERNATIONAL ATOMIC ENERGY AGENCY,
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FOREWORD

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) cover the application of ionizing radiation for all practices and interventions and are, therefore, basic and general in nature. Users of radiation sources have to apply those basic requirements to their own particular practices. That requires a degree of 'interpretation' by the user, which can result in varying levels of regulatory compliance and inconsistencies between applications of the BSS to similar practices. In this context, the Preamble of the BSS states that: "The [regulatory body] may need to provide guidance on how certain regulatory requirements are to be fulfilled for various practices, for example in regulatory guideline documents."

In order to guide the user to achieve a good standard of protection and to achieve a consistent national approach to licensing and inspection, some countries have developed practice specific regulatory guidance, while others have practice specific regulations. National regulatory guidance is tailored to a country's own legislation and regulations for obvious reasons. This can lead to problems if the guidance is used in other States without appropriate modification to take local requirements into account. There would appear, therefore, to be scope for producing internationally harmonized guidance, while bearing in mind that the ultimate responsibility for the regulatory documents rests with the State.

Some regions have taken the initiative of preparing guidance to facilitate the regional harmonization of regulatory control of certain common practices (e.g. radiology). In particular, it is felt that States participating in the IAEA's technical cooperation Model Project on Upgrading Radiation and Waste Safety Infrastructure would benefit significantly from the availability of practice specific guidance. Member States could then more readily develop their own guidance tailored to their own requirements and needs. This idea led to the development of the present publication.

The International Action Plan for the Radiological Protection of Patients, approved by the General Conference of the IAEA in September 2002, requires that:

> "The practice-specific documents under preparation should be finalized as guidance rather than regulations, and they should include input from professional bodies, from international organizations and from authorities with responsibility for radiation protection and medical care."

Following this request, the only mandatory statements in this report are quotations from the BSS, including requirements.

There are certain BSS requirements that, when applied to specific practices, can be fulfilled mainly through one practical solution. In such cases, the regulatory body may need to use a 'should' statement, which implies that licensees should choose this solution or, if another option is intended, an equivalent level of safety should be provided. In other cases, there may be more than one option. In those cases, the regulatory body would just mention or describe them.

This guidance is intended for both regulators and users of radiation sources in radiology. Regulators may use it for reviewing applications for authorization and during the inspection of facilities. Registrants/licensees may wish to follow the guidance in order to comply with BSS requirements or equivalent national requirements. Experts recruited on IAEA missions to advise on the implementation of the BSS for the practice of radiology are expected to use this guidance rather than their own national guidance. Working safely is important and contributes to gaining overall confidence and credibility in the practice of radiology itself.

This report has been prepared by the IAEA with the contributions of the International Labour Office, the Pan American Health Organization, the World Health Organization, the International Society of Radiology, the International Society of Radiographers and Radiological Technologists, and the International Organization for Medical Physics.

The IAEA officer responsible for this publication was P. Ortiz López of the Division of Radiation, Transport and Waste Safety.

EDITORIAL NOTE

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS) were published as IAEA Safety Series No. 115 in 1996 [1]. The BSS represent the culmination of efforts over the past decades towards harmonization of radiation protection and safety standards internationally, and are jointly sponsored by the Food and Agriculture Organization of the United Nations (FAO), the IAEA, the International Labour Office (ILO), the OECD Nuclear Energy Agency (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO). The purpose of the standards is to establish basic requirements for protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure (hereinafter called 'radiation safety'). The requirements are based on the principles set out in IAEA Safety Series No. 120 [2].

The standards can only be implemented through an effective radiation safety infrastructure that includes adequate laws and regulations, an efficient regulatory system, supporting experts and services, and a 'safety culture' shared by all those with responsibilities for protection, including both management and workers.

The BSS cover the application of ionizing radiation for all practices and interventions and are, therefore, basic and general in nature. Users of radiation sources have to apply these basic requirements to their own particular practices. In this context, the Preamble of the BSS states that:

> "The [regulatory body] may need to provide guidance on how certain regulatory requirements are to be fulfilled for various practices, for example in regulatory guideline documents."

This report does not contain requirements other than those quoted from the BSS and, therefore, the only mandatory statements in the 'shall' form are those from BSS quotations. Any additional material is in the 'should' form or simply in the present tense, thus indicating a way to comply with the BSS.

1.2. OBJECTIVE

The objective of this report is to assist regulatory authorities in monitoring compliance with the BSS (or equivalent national regulations) with regard to diagnostic radiology and interventional procedures[1] using X rays, and ensuring proper and consistent application of the BSS. This report will therefore also be useful to licensees in meeting the regulatory requirements. Separate reports have been prepared for nuclear medicine and radiotherapy [3, 4].

1.3. SCOPE

This report is applicable to all uses of ionizing radiation sources employed in the practice of diagnostic radiology and interventional procedures using X rays, to the facilities where the sources are located and to the individuals involved. The guidance covers, therefore, occupational, public, medical, potential and emergency exposure situations.

2. PRINCIPAL REQUIREMENTS

2.1. ADMINISTRATIVE REQUIREMENTS

2.1.1. Authorization of practices

The BSS require that legal persons apply to the regulatory body for an authorization, which should take the form of a registration or a licence. The BSS further clarify that practices that are amenable to registration are those for which: (a) safety can largely be ensured by the design of the facilities and equipment; (b) the operating procedures are simple to follow; (c) the safety training requirements are minimal; and (d) there is a history of few problems with safety in operations. Registration is best suited to those practices for which operations do not vary significantly.

[1] Interventional procedures using X rays means the practice of patient care through the integration of clinical and X ray imaging based diagnosis and minimally invasive therapy.

Strictly speaking, the above conditions are generally not met in radiology practice owing to the following three reasons: patient exposure depends on human performance; protection is not largely ensured by design; and the training required is significant. Medical practices are, in principle, better candidates for individualized licensing than for registration. For some practices, such as dental and general radiography, however, it is possible to simplify the authorization process by relying on standardized training and a relatively standardized quality assurance (QA) programme, and by establishing a simple regulatory mechanism to provide evidence of both.

For the purpose of authorization, legal persons have to submit to the regulatory body the relevant information necessary to demonstrate the protection and safety of the practice (see the BSS, paras 2.11–2.14). In the case of the practice in radiology, the relevant information usually includes:

(a) The qualifications in radiation protection of the medical practitioners who are to be so designated by name in the authorization;
(b) A statement that only medical practitioners with the qualifications in radiation protection specified in these regulations, or to be specified in the registration or licence, will be permitted to prescribe medical exposure using the sources to be authorized.

Safety requirements apply to the following stages of the practice in radiology:

(a) Design and construction;
(b) Operation (acceptance, commissioning, clinical use, maintenance);
(c) Modifications;
(d) Decommissioning or cessation of activities (partial or total).

Modification, with possible implications for radiation safety, of the radiology and of procedures, or partial cessation of the practice, requires an amendment to the authorization.

2.1.1.1. Renewal of authorization

Regulatory authorities may require that the authorization be renewed periodically. Periods of renewal are based on safety criteria.[2] The advantages of

[2] The frequency of revalidation is influenced by several factors, described in IAEA-TECDOC-1067 [4], in the view of which a reasonable period for radiology is five years.

a renewal or revalidation approach are described in Refs [5, 6]. Revalidation is also a beneficial reminder to users that they have regulatory obligations to meet and that safety aspects should be kept under review. This is particularly important in cases where on-site inspections are infrequent, owing to limitations on the resources of the regulatory body, as well as to the low risk inherent in certain types of facility.

2.1.1.2. Inspection

To monitor compliance with the BSS, the registrant and licensee have to permit inspection by the regulatory body of the facilities and records.

2.1.1.3. Personal accreditation[3]

The BSS require that:

> "(a) all personnel on whom protection and safety depend be appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgement and according to defined procedures." (BSS, para. 2.30)

In the practice of radiology, the following individuals are responsible for protection and safety by virtue of tasks involving decisions, operation or manipulation of X ray equipment:

(a) Medical practitioners working in radiology (typically radiology specialists, cardiologists and other specialists performing interventions using X rays, and dentists);
(b) Radiographers and radiological technologists;[4]
(c) Qualified experts in radiology physics (medical physicists in radiology physics);
(d) Radiation protection officers (RPOs);
(e) Staff performing special tasks (e.g. type testing of equipment, QC tests).

[3] Regulations in a number of countries require a personal accreditation as formal recognition of the holder's competence to do the job safely. Accreditation is usually provided by the relevant professional bodies. Other countries require a formal personal authorization.

[4] Radiology staff skilled in performing, under medical supervision, radiographic procedures. Under the supervision of the qualified expert in diagnostic radiology physics, he/she carries out basic quality control (QC) tests.

To comply with the BSS requirements given above in relation to the staff mentioned, evidence is required for education and training relevant to their duties in relation to protection and safety. Responsibility for the practice in radiology requires accreditation by the professional body or an educational institution.

Training in radiation protection is necessary, but by no means sufficient, to practise in radiology. As a precondition, qualifications and certification in the profession are indispensable, which are not defined by radiation protection regulations or granted by the regulatory body, but granted by academic institutions and by boards or societies. In the particular case of a qualified expert, the BSS define one as:

> "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,…" (BSS, Glossary)

For radiologists[5] and other medical practitioners, radiographers/radiological technologists, qualified experts in diagnostic radiology physics and RPOs, typical documentary evidence indicated above, i.e. qualifications and credentials, should consist of:

(a) A degree relevant to the profession, academic qualifications issued by the competent education and examining authorities, as required in the country, and certification by appropriate boards or societies;
(b) A course on radiation protection for which the contents, methodology and teaching institution are approved by the regulatory body. This course may be integrated into the curricula of the professional education under (b) provided that it meets the training criteria for radiation protection specified by the regulatory body (with regard to medical exposure, the training criteria should be established by the regulatory body in consultation with relevant professional bodies);
(c) On the job training supervised by accredited professionals with experience, as required in the country, before working without supervision.

[5] The radiologist is responsible for all aspects of imaging procedures to obtain radiological images and for the interpretation of these images. The radiologist holds a nationally accepted medical degree and, in addition, has completed a nationally prescribed programme of training in the discipline of radiology and has credentials that were obtained from a national medical speciality certifying agency.

Courses and syllabuses required in professional education and training are generally defined by the departments of health and/or education in a country, together with professional bodies. It is acceptable for training criteria for radiation protection for medical exposure, specified by the regulatory body in consultation with relevant professional bodies (BSS, Appendix II, para. II.1(f)),[6] be incorporated into professional education and training.

It may be appropriate and convenient for the regulatory body to recognize certain training centres and courses for their quality and suitability in connection with radiation protection requirements. For example, it can identify radiology departments that have been accredited as training centres for the profession (if any) and facilities, syllabuses and qualifying bodies that are responsible for training and accreditation in radiology, and recognize in them the potential for use in radiation protection training as well. Such recognition can be formally conferred by a process of accreditation based on the training criteria referred to above.

Evidence of competence for the maintenance and servicing of medical equipment may consist of the following:

(a) Certification, ideally by the manufacturer, of having completed a training programme on the type of authorized equipment;
(b) A course on radiation protection for which the contents, the methodology and the teaching institution are approved by the regulatory body.

Personal accreditation or authorization may need to be renewed periodically. It could be enough in some cases to ask for evidence of training and continuing education in such a way that the renewal process may not be necessary. The regulatory body should provide guidance on qualification requirements in radiation protection for each job category found in particular practices.

2.1.1.4. Authorization of other practices related to radiology

According to the BSS [1], the following activities also require authorization:

(a) Import, distribution, sale, decommissioning or transfer of X ray systems;
(b) Assembly and maintenance of radiology equipment.

[6] For countries where a national professional body does not exist, regional bodies or international professional organizations may be consulted for advice.

Regulatory authorities may require the licensee of a radiology practice to hire or contract out these services only to those enterprises authorized by the regulatory body. The requirements to carry out these practices would have been established by national regulations complemented by regulatory guidance documents.

2.2. RADIATION PROTECTION REQUIREMENTS

The principles of radiation protection and safety on which the safety standards are based are those developed by the International Commission on Radiological Protection (ICRP). These principles are reflected in the requirements of the BSS:

> **"Justification of practices**
> No practice or source within a practice should be authorized unless the practice produces sufficient benefit to the exposed individuals or to society to offset the radiation harm that it might cause; that is: unless the practice is justified, taking into account social, economic and other relevant factors. (BSS, para. 2.20)
>
> **"Dose limitation**
> The normal exposure of individuals shall be restricted so that neither the total effective dose nor the total equivalent dose to relevant organs or tissues, caused by the possible combination of exposures from authorized practices, exceeds any relevant dose limit specified in Schedule II, except in special circumstances provided for in Appendix I. Dose limits shall not apply to medical exposures from authorized practices. (BSS, para. 2.23)
>
> **"Optimization of protection and safety**
> In relation to exposures from any particular source within a practice, except for therapeutic medical exposures, protection and safety shall be optimized in order that the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures all be kept as low as reasonably achievable, economic and social factors being taken into account, within the restriction that the doses to individuals delivered by the source be subject to dose constraints." (BSS, para. 2.24)

For diagnostic medical exposure, optimization of protection is achieved by keeping the exposure of patients to the minimum necessary to achieve the required diagnostic objective, but dose constraints are not applicable to

patients; instead, guidance levels are established to be an indicator of doses for average sized patients (see BSS, para. 2.27).

Table 1 summarizes the principles as applied to occupational and public exposure and to diagnostic medical exposure.

Dose constraints are used for optimizing protection in the planning stage for each radiation source. Anticipated individual doses should be compared with the appropriate dose constraints and protective measures should be chosen that predict doses below dose constraints. The BSS definition of dose constraint is: "For occupational exposures, dose constraint is a source related value of individual dose used to limit the range of options considered in the process of optimization" (BSS, Glossary, p. 301). When choosing dose constraints for the sources involved in a radiology facility, consideration needs to be given to the fact that medical and paramedical staff often work in more than one hospital, i.e. two institutions in two working shifts.

As indicated in Section 4 on occupational exposure, pregnant workers are required to be protected in a way that ensures that the embryo or foetus is

TABLE 1. PRINCIPLES OF RADIATION PROTECTION AS APPLIED TO OCCUPATIONAL AND PUBLIC EXPOSURE COMPARED WITH MEDICAL EXPOSURE

Principles of protection	
Application in general	Specific application to medical exposure
Justification of practices: A practice that entails exposure to radiation should only be adopted if it yields sufficient benefit to the exposed individuals or to society to outweigh the radiation detriment.	*Justification of practices:* By weighing the diagnostic … 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 radiation exposure.
Dose limitation to individuals (for occupational and public exposure).	*Dose limitation* is not applicable to medical exposure.
Optimization of protection and safety: Providing the best available protection and safety measures under the prevailing circumstances, so that the magnitudes and likelihood of exposures and the numbers of individuals exposed are as low as reasonably achievable.	*Optimization of protection and safety:* In diagnostic medical exposure, keeping the exposure of patients to 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.

afforded the same broad level of protection as required for members of the public. Table 2 summarizes individual dose limits as established in the BSS.

2.3. MANAGERIAL REQUIREMENTS

2.3.1. Managerial commitment and policy statement

The BSS, in para. 2.28, establish that a "safety culture shall be fostered and maintained to encourage a questioning and learning attitude to protection and safety and to discourage complacency". To comply with this requirement, hospital senior management should be committed to an effective protection

TABLE 2. SUMMARY OF DOSE LIMITS (SEE BSS, SCHEDULE II)

	Occupational exposure	Apprentices of 16 to 18 years of age, who are in training for employment and students of 16 to 18 years	Public exposure
Effective dose	20 mSv/a averaged over five consecutive years; 50 mSv in a single year	6 mSv in a year	1 mSv in a year; in special circumstances, an effective dose of up to 5 mSv in a single year provided that the average dose over five consecutive years does not exceed 1 mSv/a
Equivalent dose to the lens of the eye	150 mSv in a year	50 mSv in a year	15 mSv in a year
Equivalent dose to the extremities (hands and feet) or the skin[a]	500 mSv in a year	150 mSv in a year	Equivalent dose to the skin of 50 mSv in a year

[a] The equivalent dose limits for the skin apply to the average dose over 1 cm^2 of the most highly irradiated area of the skin. Skin dose also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.

and safety policy and by demonstrable support for those persons whose responsibility is radiation protection. The commitment can be demonstrated by a written policy that, in addition to recognizing that the objective of the practice is the diagnosis, treatment and well-being of the patients, assigns the required importance to protection and safety in radiology. This unambiguous statement should be made known to the hospital personnel and should be followed by establishing a radiation protection programme, which includes fostering a safety culture in the hospital.

2.3.2. Organization and responsibilities

The BSS, in paras 1.6 and 1.7, establish the following responsibilities:

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

(a) registrants or 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."

The BSS, in para. 1.9, also establish that it is the responsibility of principal parties:

"(b) to develop, implement and document a protection and safety programme commensurate with the nature and extent of the risks associated with the practices…under their responsibility and sufficient to ensure compliance with the requirements of the Standards…"

According to the BSS requirements for medical exposure (see Appendix II.2), the advice of qualified experts in radiology physics is necessary; suitable individuals need to be appointed on a part time or full time basis as required, depending on the size of the radiology department. The tasks of qualified experts include imaging and QA (including technical purchase specifications, acceptance tests, quality control, participation in the Quality Assurance Committee) and optimization of protection, which should involve patient dosimetry.

2.3.3. Quality assurance

The International Organization for Standardization (ISO) defines QA as all planned and systematic actions needed to provide confidence that a structure, system or component will perform satisfactorily in service. Applying this definition to diagnostic radiology, WHO [7] points out that "satisfactory performance in service implies the optimum quality of the entire process, i.e., the consistent production of adequate diagnostic information with minimum exposure of both patient and personnel". A comprehensive QA programme should, therefore, embrace the entire process of radiology.

The BSS establish that:

> "2.29. Quality assurance programmes shall be established that provide, as appropriate:
>
> (a) adequate assurance that the specified requirements relating to protection and safety are satisfied; and
> (b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures."

The BSS, in para. 2.29, require the licensee to have QA programmes that provide "adequate assurance that the specified requirements relating to protection and safety are satisfied" and "quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures."

An effective QA programme demands a strong commitment from the departmental and institutional leadership to provide the necessary resources of time, personnel and budget. The programme should cover the entire process from the initial decision to adopt a particular procedure through to the interpretation and recording of results and should include a systematic control

methodology. A major part of the QA of a radiology department is related to medical exposure, which is dealt with in Section 5.

2.3.4. Human factors

The BSS, in para. 2.30, establish that:

"Provision shall be made for reducing as far as practicable the contribution of human error to accidents and other events that could give rise to exposures, by ensuring that:

(a) all personnel on whom protection and safety depend be appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgement and according to defined procedures".

2.3.4.1. Staffing

To comply with this requirement, the licensee should appoint a number of professionals with personal accreditation for the tasks described in Section 2.1.1.3, sufficient to ensure that all activities relevant to protection and safety are carried out in accordance with regulations and the radiation protection programme. The number of persons should be kept under review, especially as workload increases, or new techniques and new equipment are incorporated.

2.3.4.2. Education and training

A number of requirements in the BSS refer to the availability of qualified personnel, for example, para. 2.14 which states:

"The legal person responsible for a source to be used for medical exposure shall include in the application for authorization:

(a) the qualifications in radiation protection of the medical practitioners who are to be so designated by name in the registration or licence; or
(b) a statement that only medical practitioners with the qualifications in radiation protection specified in the relevant regulations or to be specified in the registration or licence will be permitted to prescribe medical exposure by means of the authorized source."

The BSS, in para. 2.31, require that "Qualified experts shall be identified and made available" and, in particular, in Appendix II, para. II.2, require that:

> "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… radiodiagnostic physics."

And the BSS, in Appendix II, para. II.1(c), require that "medical and paramedical personnel with appropriate training be available as needed."

A typical list of topics for this training is given in Appendix II. The licensee should establish a policy that encourages and provides a continuing professional development programme, with the aim of improving staff skills, maintaining familiarity with current practices and fostering a safety culture throughout the institution. Such training and development schemes can be set up through informal meetings of the radiology department, seminars, accredited continuing education programmes or other means.

The licensee should ensure that only staff with the credentials specified in Section 2.1.1.3 fill these positions and that they are aware of:

(a) The conditions and limitations of the authorization;
(b) The institutional radiation protection policies and procedures;
(c) Their own individual (subsidiary) responsibilities;
(d) The use and operation of equipment;
(e) The local QA programme and QC procedures, which should be in an accessible manual;
(f) Reviews of incidents and accidental exposure, especially for those involved in interventional procedures using X rays;
(g) Instructions provided to patients and care givers.

The professional education and the training to obtain the necessary qualifications mentioned previously need to have been completed before commencement of duties and continued subsequently as part of professional development and as required by the regulatory body. Furthermore, the instruction of personnel is required whenever significant changes occur in duties, regulations, the terms of the licence or radiation safety procedures. Registrants and licensees need to maintain records with respect to the initial and periodic instruction of personnel.

3. SAFETY OF X RAY EQUIPMENT AND FACILITIES

3.1. DESIGN OF MEDICAL EQUIPMENT USING RADIATION

Appendix II, paras II.11–13, of the BSS establish, with regard to the design of equipment, that:[7]

> "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;
> (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.

[7] In many countries it may be difficult for registrants and licensees to influence the design of equipment; they can, however, impose purchasing specifications, which may include conditions to meet these requirements and, in particular, meet International Electrotechnical Commission (IEC) and ISO standards.

"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 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…by using collimating devices aligned with the radiation beam;
(f) the radiation field within the examination…without any radiation beam modifiers…be as uniform as practicable and the non-uniformity be stated by the supplier; and
(g) exposure rates outside the examination…due to radiation leakage or scattering be kept as low as reasonably achievable."

When manufacturers are asked to supply X ray equipment, demonstration of compliance with appropriate IEC standards or the equivalent national standards helps in ensuring compliance with the BSS with respect to equipment design. Therefore, evidence of such compliance should be provided. For type tests,[8] manufacturer's records with the results of the tests for the relevant equipment type and model may be sufficient evidence of compliance. Type tests should be supplemented by acceptance tests for the individual piece of equipment delivered. Reference to the relevant safety tests described in the

[8] Certain tests, termed 'type tests', refer to a type or brand of equipment and do not need to be repeated for all pieces of equipment. Individual tests refer to quality control of every piece of equipment.

IEC standards should be included in the acceptance protocol and be specified in the purchasing conditions.

IEC standards provide for tests to be carried out by the manufacturer for a given type of equipment, and for 'site tests', to be done at the hospital on every individual piece of equipment. The IEC distinguishes between three grades of tests:

(a) *Grade A:* an analysis of the equipment design related to an IEC safety requirement, which results in a written statement included in the technical description with respect to the working principles or the constructional means by which the IEC requirement is fulfilled.
(b) *Grade B:* visual inspection or functional test or measurement. For this test grade, the relevant IEC standard specifies a procedure. The test should then be performed according to the IEC procedure. Grade B tests may include fault conditions, which are achievable only without interference with the circuitry or construction of the equipment.
(c) *Grade C:* functional test or measurement, which may involve interference with circuitry or the construction of the equipment, and should be performed by or under the direct supervision of the manufacturer, or his or her agent.

Compliance with the requirement outlined in Appendix II, paras II.13(b) and (c), of the BSS on the operating and maintenance instructions in a "major world language" which is widely understood by the users, is facilitated by the IEC requirements that "accompanying documents" are considered an essential part of the equipment and its delivery is not complete if the instructions are not provided. This aspect should be taken into account when a purchase contract is being made. This provides a mechanism for users to ensure that instructions which are indispensable to running the facility efficiently and safely are made available by the suppliers.

The relevant IEC standards applicable to radiology are given in Refs [8–15]. Other relevant IEC standards are, for example, those in series 61223 related to evaluation and routine testing in medical imaging departments (general aspects, constancy checks and acceptance tests). Series 61262 covers medical electrical equipment, and characteristics of electro-optical X ray image intensifiers; series 61331 covers protective devices against diagnostic medical X radiation.[9]

[9] A list of IEC standards can be obtained on-line at http://www.iec.ch.

Further, in Appendix II, the BSS establish the following:

"*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 position, 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."

Approaches to ascertain compliance with the BSS, Appendix II, paras II.13 and 14, by registrants and licensees in cooperation with suppliers are given in Ref. [16]. The following is a summary of the general protection features required on radiological equipment that should be measured in acceptance tests. More specific details are given in the IEC standards. A summary of the general protection features required for radiological equipment that should be measured in an acceptance test is given in Appendix III of this report.

3.2. FACILITIES (X RAY ROOM DESIGN)

Provisions for the incorporation of safety features are best made at the facility design stage (X ray rooms and other related rooms). The three factors relevant to dose reduction (time, distance and shielding) can be combined in the design to optimize protection. Larger rooms are preferable to allow easy access for patients on a bed trolley and to reduce exposure of the staff as well as

the public, and at the same time allow for patient positioning and easy movement during the procedure, which in the case of fluoroscopy helps reduce time and exposure. The following are examples of safety features:

(a) A protective barrier should be placed at the control console to shield staff, who should not need to wear protective clothing while at the console.
(b) The design of the room should be such that the X ray beam cannot be directed at any area which is not shielded, i.e. the dose received in this area would be unacceptable.
(c) The X ray room should be designed so as to avoid the direct incidence of the X ray beam on the access doors. The doors should be calculated to act as a protective shield for scattered radiation and be shut when the X ray beam is on.
(d) The operator needs to be able to clearly observe the patient at all times during an X ray diagnostic procedure.
(e) A sign, such as one recommended by the ISO [17], should be posted on each entrance to an X ray room as an indicator of radiation. A sign should also be posted to indicate that the X ray room is a controlled area.
(f) A warning light should be placed at the entrance to any room where fluoroscopy or computed tomography (CT) equipment is in use. The light should be illuminated when the X ray beam is energized.
(g) In rooms with a heavy workload using fluoroscopy with staff close to the patients, such as rooms for interventional procedures, it is advisable that ceiling mounted protective screens and table mounted leaded curtains be installed.

3.2.1. Considerations about shielding calculation

The methodology and data for shielding calculation are given in Refs [18–23]. The nominal design dose[10] parameters in occupied areas is derived by the process of constrained optimization, i.e. selecting a source related dose constraint, with the condition that the individual doses from all relevant sources is well below the dose limits for the persons occupying the area to be shielded. Shielding barriers are calculated by the attenuation they have to provide.

The shielding thickness is obtained from the attenuation factor, which is required to reduce the dose that would be received by staff and the public if

[10] In Ref. [18], this is defined as 'shielding design goals (P)', which are levels of air kerma used in the design calculations and evaluation of barriers for the protection of individuals, at a reference point beyond the barrier.

shielding were not present (a) to a dose value that can be considered as acceptable, as a result of an optimization process, i.e. a nominal design dose derived by a process of optimization (b):

(a) Doses that would be received without shielding are calculated by using tabulated workload values (mAmin per week for the most relevant beam qualities, i.e. kV and filtration), tabulated 'use factors' for a given beam direction (fraction of the total amount of radiation emitted in that direction) and tabulated 'occupancy factors' (fraction of the total exposure that will actually affect individuals at a place, by virtue of the time permanence in that place). For secondary barriers, the 'use factor' is always unity, since scatter and leakage radiation is propagated in all directions all the time.
(b) Once the dose that would be received without shielding is known, it is necessary to calculate the attenuation that is necessary to reduce this dose to a design level or to a level that can be considered 'optimized protection', i.e. a dose below which additional cost and effort in shielding is not warranted by the dose being averted. This would require successive calculations to determine where this level lies.

The nominal design dose in occupied areas is derived by the process of constrained optimization, i.e. selecting a source related dose constraint, with the condition that the individual doses from all relevant sources are well below the dose limits for the individuals occupying the area to be shielded. However, when using constraints for shielding calculations, consideration should be given to the remark made in ICRP Publication 33, that actual dose values to individuals are 1/10 (for equivalent dose) to 1/30 of dose values of effective dose[11] used as shielding design parameters (see Ref. [19], para. 256). This is due to a number of conservative assumptions made in the calculation. Typical conservative assumptions used in shielding design are:

(a) Attenuation by the patient and image receptor is usually not considered;
(b) Workload, use and occupancy factors are overestimated;
(c) Staff members are always in the most exposed place of the room (a conservative assumption);

[11] Since ICRP Publication 33 appeared prior to ICRP Publication 60, the quantities used were 'dose equivalent' and 'effective dose equivalent' rather than 'equivalent dose' and 'effective dose'. The point made that some of the assumptions may be too conservative, however, is equally applicable to the quantities 'equivalent dose' and 'effective dose'.

(d) Distances are the minimum possible all the time;
(e) Leakage radiation is the maximum all the time (corresponding to the least favourable exposure factors);
(f) Field size used for the calculation of scatter radiation is usually over-estimated.
(g) The numerical value of calculated air kerma (in mGy) is directly 'used' to compare with dose limits or constraints (mSv), which are given in terms of effective dose. However, the actual effective dose is substantially lower than the air kerma, given the dose distribution within the body for the beam qualities used in diagnostic radiology.

A full discussion of the methology for shielding calculations can be found in Refs [18–23].

3.3. MAINTENANCE

The registrant or licensee needs to ensure that adequate maintenance (preventive and corrective) is performed as necessary to ensure that X ray systems retain their design specification for image quality, radiation protection and safety for their useful lives. The registrant or licensee should, therefore, establish the necessary arrangements and coordination with the manufacturer's representative or installer before initial operation.

All maintenance procedures should be included in the QA programme at a frequency recommended by the manufacturer of the equipment and the relevant professional body. Servicing should include a report describing the equipment fault, the work done and the pieces replaced and adjustments made, which should be filed as part of the QA programme.

3.3.1. Electrical and mechanical safety

The electrical and mechanical safety aspects of the X ray systems are an important part of the maintenance programme, and can have direct or indirect effects on radiation safety. This work should be performed by authorized persons who are aware of the specification of the X ray systems. Electrical and mechanical maintenance should be included in the QA programme at a frequency recommended by the manufacturer of the X ray system. Servicing should include a written report describing the findings. These reports should be archived as part of the QA programme.

4. OCCUPATIONAL EXPOSURE

Detailed requirements for protection against occupational exposure are given in the BSS and recommendations on how to meet these requirements are given in Refs [24, 25]. In this section, a summary of the guidance most relevant to radiology is given.

4.1. RESPONSIBILITIES AND CONDITIONS OF SERVICE

In Appendix I, the BSS require that:

"I.1. Registrants and licensees and employers of workers who are engaged in activities involving normal exposures or potential exposure shall be responsible for:

(a) the protection of workers from occupational exposure; and
(b) compliance with any other relevant requirements of the Standards.

"I.2. Employers who are also registrants or licensees shall have the responsibilities of both employers and registrants or licensees.

The parties responsible for occupational exposure are, therefore, not only registrants and licensees but also employers. Registrants and licensees and employers of workers are responsible for ensuring that exposure is limited, that protection and safety are optimized and that appropriate radiological protection programmes are set up and implemented [24]. The BSS further require that "[e]mployers, registrants and licensees shall facilitate compliance by workers with the requirements of the Standards." (BSS, Appendix I, para. I.9)

The BSS also establish the subsidiary responsibilities of workers:

"Workers shall:

(a) follow any applicable rules and procedures for protection and safety specified by the employer, registrant or licensee;
(b) use properly the monitoring devices and the protective equipment and clothing provided;

(c) co-operate with the employer, registrant or licensee with respect to protection and safety and the operation of radiological health surveillance and dose assessment programmes;
(d) provide to the employer, registrant or licensee such information on their past and current work as is relevant to ensure effective and comprehensive protection and safety for themselves and others;
(e) abstain from any wilful action that could put themselves or others in situations that contravene the requirements of the Standards; and
(f) accept such information, instruction and training concerning protection and safety as will enable them to conduct their work in accordance with the requirements of the Standards." (BSS, Appendix I, para. I.10)

Workers can by their own actions contribute to the protection and safety of themselves and others. Workers are also responsible for providing feedback to management.[12] The BSS require that:

> "If for any reason a worker is able to identify circumstances that could adversely affect compliance with the Standards, the worker shall as soon as feasible report such circumstances to the employer, registrant or licensee." (BSS, Appendix I, para. I.11)

They also prescribe that management "shall record any report received from a worker that identifies circumstances which could affect compliance with the Standards, and shall take appropriate action" (BSS, Appendix I, para. I.12).

In some cases, the employer and registrant and licensee are the same legal person; in other cases, they may be different. For example, the employer of a maintenance engineer for radiological equipment ('itinerary workers') may be the maintenance company, while maintenance engineers work in many radiology departments, each one under a different licensee. There is a need for cooperation of the employers, the workers and the managements of the hospitals. The BSS require that:

> "If workers are engaged in work that involves or could involve a source that is not under the control of their employer, the registrant or licensee responsible for the source and the employer shall co-operate by the

[12] The responsibilities are placed on the management of the organizations of registrants, licensees or employers. For simplicity, IAEA Safety Standards Series No. RS-G-1.1 [24] uses the word 'management' to denote registrants, licensees or employers.

exchange of information and otherwise as necessary to facilitate proper protective measures and safety provisions." (BSS, Appendix I, para. I.30)

The organizational structure should reflect the assignment of responsibilities and the commitment of the organization to protection and safety. The management structure should facilitate cooperation between the various individuals involved. The radiation protection programme should be designated in such a way that the relevant information is provided to the individuals in charge of the various aspects of the work [24].

A self-employed person is regarded as having the duties of both an employer and a worker, as specified in the BSS definition of 'worker' (see Definitions). This situation is very much applicable to radiology, because of the large number of small, private radiological departments in many countries.

4.2. USE OF DOSE CONSTRAINTS IN RADIOLOGY

Dose constraints can be used for optimizing protection in the planning stage for each radiation source. Anticipated individual doses are then compared with the appropriate dose constraints and only those protective measures are chosen that predict doses below dose constraints. The BSS definition of dose constraint is:

"For occupational exposures, dose constraint is a source related value of individual dose used to limit the range of options considered in the process of optimization" (see Ref. [1], p. 301).

Since dose constraints are source related, it is necessary to specify the sources to which they relate, e.g. when choosing source related dose constraints for the sources involved in a radiology facility, the fact that medical and paramedical members of staff may work in more than one hospital (for example, in one hospital in the morning and in another one in the evening) and are exposed to the sources from more than one radiology department has to be taken into consideration.

4.3. PREGNANT WORKERS

The BSS establish that:

"I.16. A female worker should, on becoming aware that she is pregnant, notify the employer in order that her working conditions may be modified if necessary.

> "I.17. The notification of pregnancy shall not be considered a reason to exclude a female worker from work; however, the employer of a female worker who has notified pregnancy shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus is afforded the same broad level of protection as required for members of the public."

The limitation of the dose to the conceptus does not mean that it is necessary for pregnant women to avoid work with radiation, but it does imply that the employer should carefully review the exposure conditions with regard to both normal exposure and potential exposure. Possible solutions include moving a technician to a position that may have lower ambient dose equivalent, for example, from fluoroscopy to radiography or to CT, if adequate training is provided for the change.

When applying the dose limit of 1 mSv to the foetus, the reading of the dosimeter may overestimate foetal dose by a factor of 10. If the reading corresponds to a dosimeter worn outside a lead apron, the overestimation of foetal dose may rise to a factor of 100 [26]. Counselling for pregnant workers should be available, as discussed in Section 4.11.

4.4. CLASSIFICATION OF AREAS

Relevant areas of a practice can be classified as controlled or supervised (see the requirements outlined in Appendix I of the BSS, paras I.21–I.25). A controlled area is any area in which specific protection measures and safety provisions are or could be required for controlling normal exposures and preventing or limiting the extent of potential exposures. Applying this definition to a radiology facility, all X ray rooms meet the criteria for controlled areas; in addition, areas where mobile X ray units are used can also be categorized as controlled areas during the time in which radiological work is being carried out. In order to avoid uncertainties about the extent of controlled areas, the boundaries should, when possible, be walls and doors.

A *supervised area* is any area not already designated as a controlled area but where occupational exposure conditions need to be kept under review even though specific protection measures and safety provisions are not normally needed. Supervised areas may involve areas surrounding X ray rooms. A typical design of a radiology department includes two basic areas: an area for staff circulation and an area for circulation of patients, which includes reception and waiting rooms, and corridors from which the X ray rooms can be accessed through the dressing cabinets. The staff area includes dark rooms, film

reading room and internal corridors. The control panel may be inside the X ray rooms, separated by structural shielding, or outside the X ray room in the staff area, with visual control of the X ray room. Most of the staff area may be classified as a supervised area, not primarily because of the exposure level, which can be kept very low, but rather owing to the potential for other individuals inadvertently entering the X ray rooms and receiving an exposure.

A frequently asked question is whether the area of the control panel should be considered a controlled or supervised area. From the point of view of the level of normal exposure, it can be kept at low values by appropriate shielding, i.e. making it a controlled area is not required. However, it should be pointed out that this area requires specific measures and restriction of access by unauthorized individuals so as to prevent the distraction of the operator, which might lead to unnecessary exposure or repeated exposures and image retakes.

4.5. LOCAL RULES AND SUPERVISION

Appendix I, paras I.26–27, in the BSS require the following:

"I.26. Employers, registrants and licensees shall, in consultation with workers, through their representatives if appropriate:

(a) establish in writing such local rules and procedures as are necessary to ensure adequate levels of protection and safety for workers and other persons;
(b) include in the local rules and procedures the values of any relevant investigation level or authorized level, and the procedure to be followed in the event that any such value is exceeded;
(c) make the local rules and procedures and the protective measures and safety provisions known to those workers to whom they apply and to other persons who may be affected by them;
(d) ensure that any work involving occupational exposure be adequately supervised and take all reasonable steps to ensure that the rules, procedures, protective measures and safety provisions be observed; and
(e) when required by the [regulatory body], designate a radiation protection officer.

"I.27. Employers, in co-operation with registrants and licensees, shall:

(a) provide to all workers adequate information on the health risks due to their occupational exposure, whether normal exposure or potential exposure, adequate instruction and training on protection and safety, and adequate information on the significance for protection and safety of their actions;
(b) provide to female workers who are liable to enter controlled areas or supervised areas appropriate information on:
  (i) the risk to the embryo or foetus due to exposure of a pregnant woman;
  (ii) the importance for a female worker of notifying her employer as soon as she suspects that she is pregnant; and
  (iii) the risk to an infant ingesting radioactive substances by breast feeding;

…….

(d) keep records of the training provided to individual workers."

These local rules should include procedures for wearing, handling and storing personal dosimeters, and actions to minimize radiation exposure during unusual events. An example of rules for operational safety (local rules) is provided in Appendix IV.

4.6. PROTECTIVE EQUIPMENT AND TOOLS

According to the BSS, employers and licensees shall ensure that "workers be provided with suitable and adequate personal protective equipment" (BSS, Appendix I, para. I.28). For procedures requiring staff to be inside the room during exposure, protective equipment includes lead aprons, thyroid protectors, protective eye wear and gloves. The need for these protective devices should be established by the RPO. Gloves are useful to protect the hands near the beam but may produce the opposite effect during fluoroscopy with automatic brightness control (ABC) when the hands enter the area covered by the sensor of the ABC, because this would drive the exposure to higher levels for both the staff and the patient and would be ineffective in protecting the hands.

Additional protective devices for fluoroscopy and interventional radiology rooms include:

(a) Ceiling suspended protective screens for protecting eyes and the thyroid while keeping visual contact with the patient;
(b) Protective lead curtains mounted on the patient table.

Over-couch tube geometry is not advisable for fluoroscopy if staff members need to stand near the patient, since there is a considerably higher radiation level at the operator position, as compared with under-table geometry. If over-couch geometry is nonetheless used, protective lead curtains are used to reduce scatter radiation to staff. An example of a list of protective clothing is given in Appendix V.

4.7. INDIVIDUAL MONITORING AND EXPOSURE ASSESSMENT

The BSS establish that:

> "I.32. The employer of any worker, as well as self-employed individuals, and the registrants and licensees shall be responsible for arranging for the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that adequate arrangements be made with appropriate dosimetry services under an adequate quality assurance programme.
>
> "I.33. For any worker who is normally employed in a controlled area, or who occasionally works in a controlled area and may receive significant occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible. In cases where individual monitoring is inappropriate, inadequate or not feasible, the occupational exposure of the worker shall be assessed on the basis of the results of monitoring of the workplace and on information on the locations and durations of exposure of the worker.
>
> "I.34. For any worker who is regularly employed in a supervised area or who enters a controlled area only occasionally, individual monitoring shall not be required but the occupational exposure of the worker shall be assessed. This assessment shall be on the basis of the results of monitoring of the workplace or individual monitoring." (BSS, Appendix I, paras I.32–34)

The purpose of monitoring and dose assessment is, inter alia, to provide information about the actual exposure of workers and confirmation of good working practices. It contributes to reassurance and motivation. The BSS require individual monitoring for any worker who is normally employed in a controlled area and may receive significant occupational exposure. These workers are radiologists, medical physicists, radiographers and nurses, and the RPO. Other frequent users of X ray systems, such as endoscopists,

anaesthetists, cardiologists and surgeons, as well as ancillary workers who frequently work in controlled areas, should also be monitored.

Monitoring includes more than just measuring. It includes interpretation, assessment and investigation, which may lead to corrective measures, if needed. Individual external doses are assessed by using individual monitoring devices such as thermoluminescent dosimeters, film badges or other devices. Each dose meter is for use only by the person to whom it is issued. The monitoring device should be worn on the front of the upper torso of the body, between the shoulders and the waist.

According to the BSS:

> "The nature, frequency and precision of individual monitoring shall be determined with consideration of the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposures." (BSS, Appendix I, para. I.35)

The typical monitoring period specified by regulatory authorities in many countries is one month. In addition, the period between the dosimeters being received by the dosimetry provider and return of the dose reports should not exceed one month or as specified by the regulatory body.

The operational dosimetric quantity required in the BSS and in IAEA Safety Standards Series No. RS-G-1.3 [25] is the personal dose equivalent $Hp(d)$. For weakly penetrating and strongly penetrating radiation, the recommended depths are 0.07 mm and 10 mm, respectively. Radiation used in radiology is usually relatively strongly penetrating, and therefore d = 10 mm. Other depths may be appropriate in particular cases, for example 3 mm for the lens of the eye, in cases that dose to the eye is higher than for the rest of the body and requires, therefore, specific assessment. The Safety Guide states that $Hp(10)$ is used to provide an estimate of effective dose that avoids both underestimation and excessive overestimation [25]. In radiology, the overestimation is somewhat larger because of the lower photon penetration from X ray beams in the kV range.

When a lead apron is used, the assessment of effective dose is not straightforward. A single dosimeter placed under the apron provides a good estimate of the contribution to the effective dose by the parts of the body protected by the apron, but underestimates the contribution of the unprotected parts of the body (thyroid, head and neck, and extremities).

For some interventional procedures, in which exposure to the uncovered areas is substantial, i.e. the interventionist's upper part is very close to the area of the patient in which the scattered radiation is produced, the use of two dosimeters, one under the apron and one over the apron, may be a suitable

solution. The effective dose can be assessed by multiplying the reading of each dosimeter by a factor that approximately accounts for the relative importance of both groups of tissues, both protected and unprotected. The NCRP [27] has proposed the following formula, which provides the effective dose with an overestimation of up to the order of 3:

$$\text{Effective dose (estimate)} = 0.5\ H_W + 0.025\ H_N$$

where H_W is the value of the personal dose equivalent given by the dosimeter at waist level under the apron and H_N is the value recorded by a dosimeter worn at neck level outside the apron. This formula takes account of the relatively lower contribution of the uncovered parts by applying a much smaller factor to H_N.

In some facilities and for some individuals with a low level of occupational exposure (e.g. general dental practitioners), area dosimetry to estimate the level of dose per procedure can be an acceptable alternative. Some X ray facilities for dental radiography, or others which use X rays on a limited number of occasions per month, may not require personal dosimeters for all staff involved, and individual exposure monitoring can be performed through area dosimetry or some other individual dose evaluation per procedure, which could allow the RPO to estimate the typical level of exposure.

Individual dosimeters should be kept in an established place when not in use, and protected from damage or from irradiation when not worn by the individual. If an individual's dosimeter is lost, the RPO should perform a dose assessment, record this evaluation of the dose and add it to the worker's dose record. Where there is a national dose registry, it should be informed of the dose estimate. The most reliable method for estimating an individual's dose is to use his or her recent dose history. In those cases where the individual performs non-routine types of work, it may be better to use the doses of co-workers having exposure as the basis for the dose estimate.

Because evaluation of dose is an essential part of the radiation protection programme, it is important that workers return dosimeters on time for processing. Delays in the evaluation of a dosimeter can result in fading of the stored information. Licensees should make every effort to recover any missing dosimeters. Where a worker has more than one employer or licensee, some countries additionally require separate monitors to be issued, each to be used only in one workplace. The dose records are later combined for that worker at a national dose registry.

In the cases for which occupational exposure is carried out from workplace monitoring (see BSS, para. 1.34, quoted previously), the effective dose can be inferred from the ambient dose equivalent $H^*(10)$. ICRP Publication 74 provides

conversion coefficients from ambient dose equivalent to effective dose for different types of radiation and energies [28]. The conversion coefficients for photons are close to unity except for very low energy, such as the energy of scattered photons from a mammography X ray beam.

4.8. MONITORING THE WORKPLACE

The BSS require licensees to develop programmes for monitoring the workplace (Appendix I, paras I.37–I.40), for example:

"I.38. The nature and frequency of monitoring of workplaces shall:

(a) be sufficient to enable:
  (i) evaluation of the radiological conditions in all workplaces;
  (ii) exposure assessment in controlled areas and supervised areas; and
  (iii) review of the classification of controlled and supervised areas; and
(b) depend on the levels of ambient dose equivalent and activity concentration, including their expected fluctuations and the likelihood and magnitude of potential exposures.

"I.39. The programmes for monitoring of the workplace shall specify:

(a) the quantities to be measured;
(b) where and when the measurements are to be made and at what frequency;
(c) the most appropriate measurement methods and procedures; and
(d) reference levels and the actions to be taken if they are exceeded."

Survey meters for external radiation are usually calibrated in terms of ambient dose equivalent; in the case of diagnostic radiology, the quantity is $H^*(10)$. Initial monitoring should be conducted immediately after the installation of new radiology equipment and should include measurements of radiation leakage from equipment, and area monitoring of usable space around radiology rooms. Additional monitoring should be performed whenever modifications are made to the facility or a new X ray tube is installed.

4.9. INVESTIGATION LEVELS FOR STAFF EXPOSURE

The BSS in Appendix IV, paras IV.18–20 establish that:

"IV.18. Registrants and licensees shall conduct formal investigations as specified by the [regulatory body] if:

(a) a quantity or operating parameter related to protection or safety exceeds an investigation level or is outside the stipulated range of operating conditions; or
(b) any equipment failure, accident, error, mishap or other unusual event or circumstance occurs which has the potential for causing a quantity to exceed any relevant limit or operating restriction.

"IV.19. The investigation shall be conducted as soon as possible after the event and a written report produced on its cause, with a verification or determination of any doses received…and recommendations for preventing the recurrence of similar events.

"IV.20. A summary report of any formal investigation relating to events prescribed by the [regulatory body], including exposures greater than a dose limit, shall be communicated to the [regulatory body] as soon as possible and to other parties as appropriate."

Investigation levels are a tool used to provide a 'warning' of the need to review procedures and performance, investigate what is not working as expected and take timely corrective action. The following are examples of levels and their related tasks that are rarely exceeded and, therefore, could be suitable as investigation levels: monthly values higher than, say, 0.5 mSv (for the dosimeter worn under the lead apron) should be investigated. Values higher than, say, 5 mSv per month from the over-apron dosimeter or in hand or finger dosimeters should also be investigated with a view to optimization.

4.10. SPECIFIC ISSUES OF OCCUPATIONAL PROTECTION IN INTERVENTIONAL PROCEDURES USING X RAYS

Interventional radiology procedures tend to be complex and are performed on patients who can be quite ill. As a consequence, more staff will be needed in an interventional room to attend to the patients' individual clinical needs (interventionists, anaesthetists, radiographers, nurses and

sometimes other specialists). Not only will more staff be exposed during interventional procedures, they will also stand close to the patient where dose rates from radiation scattered by the patient are higher [28].

Interventional procedures require specifically designed and dedicated equipment. The radiation field in the vicinity of the patient is lower on the side of beam exit, i.e. with under-couch X ray tubes and over-couch image intensifiers, than with over-couch X ray tubes. If some equipment for general radiology procedures is used, this may increase exposure not only to the patient but also to staff. In some installations, an over-couch X ray tube has been used. This has resulted in high radiation fields in the vicinity of the patient, and hence higher exposure to the staff [30]. Such configurations should be discouraged.

Radiological equipment specifically designed for interventional procedures often incorporates protective devices, such as ceiling suspended lead acrylic viewing screens, under-table shielding attachments to the X ray couch, and personal portable shields. These devices usually afford individuals significant protection, but they can sometimes be cumbersome to use. Nevertheless, even if used only part of the time, significant doses can be averted.

There are simple methods of reducing exposure to staff as a result of operational factors such as altering staff position. Since the patient is the main source of scatter radiation, it is important to remain as far away as practicable from the patient to reduce exposure to staff. This can be done by determining dose maps for the room and planning the procedures as far as possible. If a mobile C-arm fluoroscope is near vertical, the X ray tube should be under the patient. If the X ray tube is near horizontal, the operator should stand on the image intensifier side and avoid direct beam exposure. Standing on the tube side would increase operator dose from patient backscatter.

In two cases of inadequate equipment and procedures, lens injuries to the eyes of two interventionists and two nurses are known to have occurred. Two facilities were using over-couch X ray tubes that caused increased levels of scattered radiation exposure to staff who remained in the room during the procedures. Estimates of the lens doses to the interventionists in these two facilities indicate that the threshold for deterministic effects from protracted exposures was exceeded in less than four years [31, 32]. The US Food and Drug Administration (FDA) has also received some reports of changes or injuries to the skin of the hands of anaesthetists performing an increasing number of procedures for pain relief using fluoroscopically guided spinal stimulation, typically performed with mobile C-arms. Some of the fluoroscopic images indicate that the hands were in the direct beam [29–32].

4.11. HEALTH SURVEILLANCE

According to the BSS, "Employers…and licensees shall make arrangements for appropriate health surveillance in accordance with the rules established by the [regulatory body]." (BSS, Appendix I, para. I.41). The primary purpose of health surveillance is to assess the initial and continuing fitness of employees for their intended tasks. Health surveillance programmes should be based on the general principles of occupational health.

No specific health surveillance related to exposure to ionizing radiation is necessary for staff involved in diagnostic radiology or interventional procedures. Only in the case of overexposed workers at doses much higher than the dose limits (e.g. 0.2–0.5 Sv or higher) would special investigations involving biological dosimetry and further extended diagnosis and medical treatment be necessary (see Ref. [24], para. 7.18). Under normal working conditions, the doses incurred in a radiology department are low and no specific radiation related examinations are normally required for persons who are occupationally exposed to ionizing radiation, as there are no diagnostic tests that yield information relevant to normal exposure. It is, therefore, rare for the radiation component of the working environment of a radiology department to significantly influence the decision about the fitness of a worker to undertake work with radiation or to influence the general conditions of service (see Ref. [24], para. 7.6).

Counselling should be available to workers (see Ref. [24], para. 7.14), such as women who are or may be pregnant, individual workers who have or may have been exposed substantially in excess of dose limits, and workers who may be worried about their radiation exposure. This is particularly necessary for women who are or may be pregnant, such as, for example, female medical practitioners or radiology technologists working in interventional procedures.

4.12. RECORDS

The BSS state that employers and licensees "shall maintain and preserve exposure records for each worker" (see Appendix I, para. I.44). The exposure records should include: information on the general nature of the work involving occupational exposure; information on doses, and the data upon which the dose assessments have been based; when a worker is or has been occupationally exposed while in the employ of more than one employer; information on the dates of employment with each employer and the doses, exposures and intakes in each such employment; and records of any doses due

to emergency interventions or accidents, which should be distinguished from doses during normal work.

Employers and licensees are to provide workers with access to information in their own exposure records; and give due care and attention to the appropriate confidentiality of records.

5. MEDICAL EXPOSURE

The detailed requirements given in Appendix II of the BSS are applicable, in particular, to radiology. In addition, Ref. [16] describes strategies to involve organizations outside the regulatory framework, such as professional bodies, whose cooperation is essential to ensure compliance with the BSS requirements for medical exposures. Examples which illustrate this point include acceptance testing processes for radiation equipment, development and use of guidance levels, and reporting of medical overexposure.

As an overall remark, it is important to note that the principles of justification and optimization of protection requirements also apply to medical exposure.

However, dose limits do not apply — nor do dose constraints that apply to patients. Dose constraints should be specified, however, for the exposure of comforters of patients and for exposure for medical research, in which exposure does not produce direct benefit to the exposed individuals.

5.1. RESPONSIBILITIES

With regard to responsibilities for medical exposure (see Section 5.5), the BSS require the following:

"II.1. Registrants and licensees shall ensure that:

(a) no patient be administered a diagnostic … 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 … procedure that the medical practitioner prescribes;

…….

(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 body] in consultation with relevant professional bodies". (BSS, Appendix II.1)[13]

In addition, as stated in the BSS (see Section 2.3 of the present report), subsidiary parties with responsibilities for compliance with safety standards can also be workers, RPOs, health professionals, or any other party to whom a principal party has delegated specific responsibilities. Each individual should take actions within his or her area of responsibility, as established in the radiation protection programme, to prevent inappropriate exposures to patients. All persons involved in the delivery of medical exposure should:

(a) Follow the applicable rules and procedures for the protection and safety of patients, as specified by the licensee;

(b) Be aware that the prescription of treatment and the treatment plan need to be signed by the medical practitioner prior to the initiation of treatment.

The BSS state that "[r]egistrants and licensees should ensure that for diagnostic uses of radiation the imaging and quality assurance requirements … be fulfilled with the advice of a qualified expert in radiodiagnostic physics", the latter refers, for example, to a medical physicist (see BSS, Appendix II, para. II.2). The current shortage of qualified experts in medical imaging physics in the world may preclude the legal person from naming such an expert on each application for authorization. However, the regulatory body should require that registrants and licensees obtain advice, as required in the BSS. Arrangements can also be made so that a medical physics group from a larger radiology department can provide the required advice to smaller departments:

"Medical practitioners shall promptly inform the registrant or licensee of any deficiencies or needs regarding compliance with the national Regulations with respect to protection and safety of patients and shall

[13] The training criteria refer to training in radiation protection.

take such actions as may be appropriate to ensure the protection and safety of patients." (BSS, Appendix II, para. 11.3)

5.2. JUSTIFICATION

The BSS establish that:

"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, Appendix II, para. II.4)

The medical practitioner should, therefore, consider the efficacy, benefits and risks of alternative diagnostic modalities, e.g. ultrasound or magnetic resonance imaging (MRI).

In justifying each type of diagnostic examination by radiography or fluoroscopy, relevant guidelines will be taken into account, such as those established by WHO [33–35]. Important additional information for the medical practitioner prescribing or conducting radiological examinations is the range of typical doses per examination. This could help in the process of justification. A good way to apply the justification criteria in radiology is to use the referral criteria published by different scientific societies:

"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."

With respect to medical research, the BSS in Appendix II, para. II.8, require that:

> "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 Declaration[16] and follows the guidelines for its application prepared by Council for International Organizations of Medical Sciences (CIOMS)[17] and WHO[18]; 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."
>
> "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."

"[16] Adopted by the 18th World Medical Assembly, Helsinki, 1974, 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)."

As children are at greater risk of incurring stochastic effects, paediatric examinations should require special consideration in the justification process. Thus the benefit of some high dose examinations (e.g. CT, IVU, etc.) should be carefully weighed against the increased risk.

The justification of examinations in pregnant women requires special consideration. Due to the higher radiosensitivity of the foetus, the risk may be substantial. It should be ascertained whether the female patient is pregnant

before performing an X ray examination for diagnosis. The BSS require that "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" (Appendix II, para. II.16(d)). To comply with this requirement, the following should be done.

Before the examination, it should be determined whether a patient is, or may be, pregnant, whether the foetus will be in the direct beam, and whether the procedure is relatively high dose [26]. Advisory notes should be posted, particularly in the reception area and other areas. When a patient has been determined to be pregnant or possibly pregnant, one should ascertain whether the conceptus is going to be in the primary X ray beam. If no, the risk to the foetus is low. It is most important to optimize protection and practise good radiology. Optimization is addressed in Section 5.3 and in Appendix VI.

If the foetus is going to be in the direct beam or very close to the border of the beam, one should ascertain whether it is a low dose procedure (such as single plain radiography) or high dose procedure (involving fluoroscopy and/or multiple images). If the procedure is high dose, it is very important to determine whether another type of procedure not involving ionizing radiation, such as ultrasound, would provide the diagnostic information.

This is particularly important in the case where the foetus is in or near the primary beam (e.g. abdominal examinations and certain complex interventional procedures). European Commission guidelines are a useful source of information [36].

5.3. OPTIMIZATION FOR MEDICAL EXPOSURES IN RADIOLOGY

The BSS require that:

"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." (Appendix II, para. II.16.)

There are a number of ways of optimizing protection to meet these BSS requirements. A summary is provided in Appendix VI. Special consideration requires the optimization of protection in the case of pregnancy. Once the decision to perform the procedure has been made, protection should be

optimized. The most common ways to tailor examinations and reduce foetal dose are to collimate the beam to a very specific area of interest, remove the antiscatter grid if possible, reduce the number of radiographs taken, and use shielding if this does not interfere with the procedure.

A specific foetal dose estimation after the examination is generally not necessary unless the foetus is in the primary beam or very close to the beam in high dose procedures. A specific estimation is required for high dose abdominal or pelvic CT or fluoroscopy procedures. Specific dose assessment is not simple and is subject to a number of uncertainties. They should therefore be performed with the advice of a qualified expert in diagnostic radiology physics.

Any dose to the foetus can lead to apprehension about possible foetal effects. Even though the absorbed dose to the foetus is generally small for most diagnostic radiography, such concern may lead to inappropriate suggestions that additional diagnostic examinations be delayed or withheld or even that the pregnancy should be terminated. ICRP Publication 84 [26] advises that:

> "Termination of pregnancy is an individual decision affected by many factors. Foetal doses below 100 mGy should not be considered a reason for terminating a pregnancy. At foetal doses above this level, there can be foetal damage, the magnitude and type of which is a function of dose and stage of pregnancy."

Foetal doses are usually well below 50 mGy in diagnostic radiology, except in high dose procedures with the patient in the direct X ray beam.

5.3.1. Calibration of patient dosimetry equipment

The BSS require that "[r]egistrants and licensees shall ensure that: (a) the calibration of sources used for medical exposure be traceable to a Standards dosimetry laboratory." (Appendix II, para. II.19.) To achieve this requirement, measuring instruments should be calibrated and traceable to a relevant national standard as appropriate:

(a) Records of calibration measurements and associated calculations should be maintained;
(b) It is important that dosimetry and test equipment be calibrated at selected beam qualities and dose and dose rate ranges that can be taken as representing those used in the practice of radiology.

5.3.2. Clinical dosimetry in radiology: Assessment of exposure to the patient

According to the BSS:

"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." (Appendix II, para. II.20.)

Patient exposure assessment in radiology is necessary for keeping an awareness of exposure, for establishing guidance levels by means of surveys, for using guidance levels as reference to compare with at individual facilities, for applying methods of dose reductions and optimization of protection and for assessment of population doses. Dose assessment is performed at individual facilities and as part of surveys of a representative sample of facilities.

5.3.2.1. Assessment of exposure to the patient at individual X ray facilities

Patient exposure assessment should always be associated with monitoring image information. Exposure alone is not meaningful if they do not correspond to images that provide an acceptable level of confidence in the information for an accurate diagnosis. Patient exposure and image quality assessments at individual facilities should be carried out on a sample of typical patients.

5.3.2.2. Surveys of patient exposure

Surveys of patient doses serve the following purposes:

(a) Establishing guidance levels (reference levels). Surveys provide dose (or air kerma) distributions over a number of hospitals on which local or national guidance levels can be based.
(b) Comparing doses and dose distributions for the same type of examination, done with different exposure parameters or with different equipment, or in different X ray rooms or different hospitals or different countries, or to monitor improvement by making comparisons before and after changes. The comparisons can be made in terms of organ doses obtained from measurable quantities indicated above.
(c) Comparing patient exposure for different types of examinations. This comparison may only be feasible by comparing effective doses, since

organs and tissues exposed in different types of examinations may not be the same. Effective dose is, therefore, used for comparison; however, the application of effective dose for patients requires some caution as indicated by UNSCEAR [37].[14]

(d) Assessing relative contributions to collective doses from various types of examinations or even comparing medical with non-medical radiation exposure of the population. Examples of these comparisons are the UNSCEAR reports.

(e) Analysing trends in the use of radiation, e.g. change in frequency and dose per examination, introduction of new examination techniques or modification of techniques.

5.3.2.3. Quantities and units for patient exposure assessment

The quantities to be used for monitoring patient exposure in radiology need to be relatively easy to measure at facilities but also suitable for inferring from them patient exposure, i.e. deriving organ doses. The quantities that meet these two requirements are entrance surface air kerma, air kerma area product, CT air kerma index, weighted CT air kerma index, and air kerma length product. Organ doses are usually derived from these quantities by using tables of conversion coefficients provided by Monte Carlo codes applied on anatomical models. A list of definitions including the above quantities is included at the end of this report.

For interventional procedures using X rays, in addition to the quantities that are related to stochastic effects, such as air kerma area product, it is critical to monitor cumulative doses to the most exposed skin areas because of the potential for reaching the threshold for deterministic effects for complicated cases.

The determination of the dose to the most exposed area is not straightforward since exposure parameters and projection angle change during the procedure and the most exposed area cannot always be anticipated. This makes the knowledge of the skin dose distribution (sometimes called 'dose mapping' over the skin) necessary. A comprehensive review of approaches to obtain dose mapping and to determine the most exposed area of the skin is given by Balter et al. [38].

[14] UNSCEAR emphasizes that effective doses from medical exposure should not be used for estimating detriment to individuals or populations, because of differences in demographic data (health status, age and sex) between particular populations of patients and those general populations for whom the ICRP derived the risk coefficients. Notwithstanding, for comparative purposes in diagnostic radiology, UNSCEAR summarizes results in terms of effective dose.

The most important methods for dose mapping are low sensitivity X ray films, such as films used in radiotherapy and radiochromic films — reading of the dose is only possible after the procedure. On an experimental basis, there are on-line calculation methods, based on the geometrical information derived from patient size, location, beam projection and exposure parameters, to calculate skin dose distribution in real time [38].

For some procedures, for which the beam projection does not change much, the most exposed area may be known to some degree and a correlation can be found. This may not be straightforward for some common cardiological procedures, such as percutaneous transluminal coronary angioplasty (PTCA), because of changing projections.

5.3.3. Quality assurance for medical exposures in radiology

The BSS establish that:

"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,…taking into account the principles established by the WHO…and the PAHO.

"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…;
(c) written records of relevant procedures and results;
(d) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment…"

Acceptance tests should be performed by the manufacturer's representative in the presence of authorized local personnel (e.g. a qualified expert in radiology physics) representing the user to decide on acceptance. It involves verification of all specifications and features of the equipment, in particular, protection and safety features. After acceptance, commissioning is carried out, usually by the qualified expert in radiology physics, and should include all

parameters and conditions of use that are expected in clinical use. At commissioning, the baseline for constancy tests is established.

In order for a QA programme to be effective, it is important to have a maintenance programme in place that ensures that any malfunction of equipment, revealed by quality controls, is rectified. Tests may need to be performed after maintenance or repairs that may affect its imaging and/or radiation characteristics.

The QA programme should include auditing, both internal and external, as well as continual improvement. These principles need to be linked to the radiation protection programme in order to strengthen safety while at the same time improving quality and efficiency.

5.4. GUIDANCE LEVELS

The principal requirements of the BSS establish that:

"2.27. Guidance levels for medical exposure shall be established for use by medical practitioners. The guidance levels are intended:

(a) to be a reasonable indication of doses for average sized patients;
(b) to be established by relevant professional bodies in consultation with the [regulatory body] following the detailed requirements of Appendix II and the guidance levels given in Schedule III;
(c) to provide guidance on what is achievable with current good practice rather than on what should be considered optimum performance;
(d) to be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgement; and
(e) to be revised as technology and techniques improve."

Appendix II further establishes the following detailed requirements:

"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."[15]

Further:

"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 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." (BSS, Appendix II, para. II.25.)

It is important to illustrate the benefit of establishing and using guidance levels by the achievements of national surveys, such as the Nationwide Evaluation of X-ray Trends (NEXT) in the USA and the National Patient Dose Database (NPDS) in the United Kingdom and regional surveys, such as the programme carried out in the European Union.

The NEXT survey began in 1973 to assess radiation exposure levels for a number of common medical and dental diagnostic examinations: chest, mammography, abdomen, lumbo-sacral spine, upper gastrointestinal tract and cardiac fluoroscopy, CT and dental radiography. NEXT 1999 surveys have shown that optimization does not always lead to dose reduction; it may also lead to improvement in image quality, provided that the information increase is required for the diagnosis [40].

[15] The BSS were written and approved before the more recent Code of Practice for Dosimetry in Radiology and the ICRU 74 report, in which most of these indicators have shifted to air kerma, i.e. quantities in which dosimetry is calibrated and, therefore, traceable.

In the United Kingdom, the first national survey of patient doses was conducted in the mid-1980s and national reference doses were established in collaboration with the Royal College of Radiologists for about a dozen common X ray examinations on adult patients. Based on this experience, a national protocol was developed [41]. Successive surveys performed in the United Kingdom led to an overall dose reduction of 30% followed by a further reduction of 20% five years later.

The European Commission survey has led to a systematic approach to evaluating image information, by using real patient images. Study groups set up by the European Commission developed specific quality criteria for some common radiographic projections and CT examinations on adult and paediatric patients. Criteria include: (a) image criteria; (b) important image details; (c) diagnostic reference levels; and (d) an example of good radiographic technique [42–45].

In summary, through these experiences, radiologists, radiographers and medical physicists were provided with a mechanism for comparing the radiation doses that they deliver to patients with those of other hospitals. This has undoubtedly led to an increased awareness of the radiation doses associated with their practices and has stimulated optimization of protection. For this purpose, it is essential to ensure that guidance levels are not implemented in a way that leads to the detriment of image quality or that may impair the diagnosis. The corrective actions that may follow an investigation triggered by having exceeded guidance levels should include suitable checks to ensure that adequate image quality for the intended diagnostic task is retained after the corrective action has been implemented.

5.5. DOSE CONSTRAINTS FOR RESEARCH VOLUNTEERS AND COMFORTERS OF PATIENTS

Dose constraints are not applicable to the exposure of patients as part of their own diagnosis guidance levels. For exposures for research purposes, which do not produce direct benefit to the exposed individual, the BSS establish that:

> "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." (Appendix II, para. II.26.)

With regard to comforters of patients and visitors, the BSS establish that:

"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." (Appendix II, para. II.27.)

Schedule II, para. II-9, of the BSS establishes that:

"the dose of any such comforter… 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."[16]

5.6. INVESTIGATION OF ACCIDENTAL MEDICAL EXPOSURE IN RADIOLOGY

From the BSS:

"II.29. Registrants and licensees shall promptly investigate…:

…….

(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." (Appendix II, paras II.29–30.)

Accidental exposures to both patients and staff are more likely to occur in interventional procedures, and these are well documented [29, 46, 47]. In Ref. [38], it is reported that relatively high doses at the level of deterministic effects may be inherent to the procedure and, therefore, they are expected to be incurred at a given frequency, which may need to be accepted as 'normal'

[16] The dose of 5 mSv from the BSS, Schedule II, para. II-9, refers to effective dose.

exposures. However, most cases of reported severe radiation injuries involving ulceration and necrotic tissue were associated with unnecessary and extreme exposure conditions, such as: (a) very short distance from X ray focus to the patient; (b) use of high dose-rate mode for a time much longer than necessary; (c) fixed projection exposing the same area of skin; and (d) malfunction of automatic exposure control systems. These situations cannot be considered to be normal, their occurrence can be avoided and their severity can be substantially reduced by optimization; they should be considered accidental medical exposure.

Dissemination of information about these exposures and radiation injuries has greatly contributed to increasing awareness worldwide of methods for avoiding radiation injuries, for example, by the FDA and ICRP Publication 85 [29, 46, 47]. It is advisable to pursue this approach by reporting mechanisms.

5.7. RECORDS

The BSS require that:

"II.31. Registrants and licensees shall keep for a period specified by the [regulatory body] 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." (Appendix II, para. II.31.)

This requirement involves, at least, the number of radiographic exposures, the duration of fluoroscopic examinations, and exposure of volunteers in medical research.

5.8. GRADUAL TRANSITION FROM BASIC TO ADVANCED STAGES OF BSS IMPLEMENTATION WITH REGARD TO MEDICAL EXPOSURE

The requirements of the BSS are comprehensive and need time, organization and resources for full implementation, necessitating a step by step process; the International Action Plan for the Radiological Protection of Patients [48] points out the need to define stages in the implementation of the BSS and to include "advice about the gradual transition from basic to advanced stages of implementation" in this report. It also recognizes that many

developing countries do not have, at present, the resources or expertise necessary for fully meeting such requirements and, therefore, request support to be provided for Member States in this transition.

Full compliance implies having in place requirements equivalent to those in the BSS, Appendix II, in the national regulations and regulatory guidance, performing periodical image quality assessments and retakes; having a full QA programme and arrangements for rectification of equipment malfunction; wide scale surveys of patient exposure; and a mechanism for education and training of medical and paramedical personnel.

The gradual transition to reach this advanced stage should start with the development of the capability for evaluating image quality, retake analysis, searching for causes of poor quality, and preparing the ground for a subsequent QA programme, based on the needs of the country. At this stage, it is also possible to carry out preliminary QC not requiring instrumentation but with very simple tools. For this purpose, the guidance published by the International Society of Radiographers and Radiological Technologists is useful [49] and the educative value of this type of QC should be emphasized. Formal patient exposure assessment may not be feasible at the beginning, but preliminary steps by recording exposure parameters for analysis together with image quality should be carried out in order to develop an awareness of patient exposure conditions. Early stages often have a pilot or experimental character involving a few radiology departments in the country, one of them acting as nodal centre, which would collate reports nationally.

Having taken the preliminary steps described above, it is possible to develop a more comprehensive QA programme, which would emphasize parameters depending on their contribution to image quality, derived from the retake analysis and image quality grading and causes for poor quality films. The programme should include control of equipment, film processing and operator performance. The maintenance and service programme should be developed for rectification of equipment malfunction. The availability of such a service should lead to a report on frequency of malfunctions and actions taken, and their impact on image quality. At this stage, provisions for sustainable training should be made.

Countries achieving this stage would be able to go over to direct measurements on patients on a limited pilot scale, provided that a number of calibrated TLDs, or similar means of measurement, are made available. The results of this activity would be values of patient exposure in a number of cases for each examination, from each hospital participating in deriving guidance levels. At the end of the process, a comprehensive QA programme and a sustainable training mechanism for medical and paramedical staff should be in place.

6. PUBLIC EXPOSURE

6.1. RESPONSIBILITIES

The BSS, Appendix III, para. III.1, require that:

"Registrants and licensees shall apply the requirements of the Standards as specified by the [regulatory body] to any public exposure delivered by a practice or source for which they are responsible…"

The registrant and licensee is, therefore, responsible for controlling public exposure resulting from a radiology practice. Public exposure is controlled by proper shielding design and, in large part, by control of access and by ensuring that keys to the control panel are secured, to prevent unauthorized access or use. The presence of members of the public in and near the radiology department should be considered when designing shielding and flow of persons in the department. In order to control public exposures, the registrant and licensee is responsible for the establishment, implementation and maintenance of the controlled access of visitors and monitoring of public exposure, as discussed in the following sections.

6.2. CONTROLLED ACCESS OF VISITORS

There should be no visitors to radiology equipment rooms while the rooms are in use. Persons allowed to stay in a controlled area are usually family members supporting patients, whose exposure is not a public exposure but a medical exposure.

6.3. MONITORING OF PUBLIC EXPOSURE

The BSS require that:

"Registrants and licensees shall, if appropriate:

(a) establish and carry out a monitoring programme sufficient to ensure that the requirements of the Standards regarding public exposure to

sources of external irradiation be satisfied and to assess such exposure;

…….

(c) keep appropriate records of the results of the monitoring programmes." (Appendix III, para. III.13.)

The programme for monitoring public exposure from radiology should include dose assessment in the areas surrounding radiology facilities, which are accessible to the public. This can be achieved from the shielding calculations in the planning stage, combined by area monitoring at the initial operation of the facility.

Appendix I

ITEMS FOR A RADIATION PROTECTION AND SAFETY PROGRAMME IN DIAGNOSTIC RADIOLOGY AND INTERVENTIONAL PROCEDURES USING X RAYS

This appendix presents a list of major items to assist in appraisals of radiation protection and safety in diagnostic radiology and interventional procedures using X rays. The relative complexity of each facility should be taken into account when assessing compliance. The list is only intended to provide a systematic approach to an appraisal, to ensure consistency in these appraisals and to avoid missing major items. It should not be construed as replacing professional judgement and knowledge of how safety features fit in radiological or interventional procedures using X rays, or of how to avoid interfering with medical care. The list can be used as guidance for self-assessment by the licensee, by peers when performing an appraisal, and by regulators, when checking compliance with the BSS.

I.1. GENERAL INFORMATION ON THE FACILITY

— Patient workload;
— Number of pieces of equipment for use in examinations and types of equipment (describe);
— Number of staff (specify type, specialty and number of each).

I.2. COMPLIANCE WITH ADMINISTRATIVE REQUIREMENTS

— Availability of an authorization granted by the regulatory body to build the facility, to import the source and to operate the radiology practice;
— Specific conditions in the authorization;
— Previous reviews and inspections performed;
— Safety concerns in previous appraisals.

I.3. SECURITY OF SOURCES

— Provisions to keep an inventory of all X ray equipment and facilities;
— Responsibilities assigned for keeping the inventory;

— Means to prevent unauthorized access and use of the X ray equipment.

I.4. RADIATION PROTECTION AND SAFETY PROGRAMME

— Protection and safety programme in place, and supported and signed by the licensee (the legal person);
— Definition of functions and responsibilities (for radiologists and other clinicians using X rays, radiographers, qualified experts in radiology physics, maintenance engineers and RPOs);
— Provisions to ensure that these responsibilities are understood by the persons concerned;
— Provisions to ensure that only qualified and accredited staff assumes the responsibilities for using radiation (radiologists, radiographers, etc.);
— Programme in place for education and training, and continuing professional development (describe).

I.5. RULES AND PROCEDURES

Procedures for:

— Purchasing radiological equipment;
— Use of radiological equipment;
— Individual exposure monitoring (see occupational protection);
— Workplace monitoring (see occupational protection);
— Equipment repairs and return to use.

Protection from occupational exposure

Provisions to inform the workers about their obligations and responsibilities for their own protection and the protection of others against radiation exposure and for the safety of sources.

Conditions of service

Provisions to encourage a pregnant worker to notify her employers of the pregnancy and to adapt her working conditions so as to ensure that the embryo or foetus is afforded the same broad level of protection as required for members of the public, without excluding the female worker from work.

Classification of areas

— Classification of areas: X ray rooms classified as controlled areas;
— Arrangements for classifying areas where mobile equipment is used during the time in which radiological work is being carried out.

Local rules and supervision

— Procedures for ensuring adequate levels of protection and safety of workers;
— Provisions to make sure that these procedures, the protective measures and safety provisions are known to those workers to whom they apply and to other persons who may be affected by them;
— Supervision to ensure observance of the procedures;
— Investigation levels in place.

Personal protective equipment

— Availability of lead aprons;
— Availability of other devices, such as thyroid protection, protective eye wear and gloves for fluoroscopy, protective curtains;
— Availability of protective accessories for protection for interventional fluoroscopy, such as ceiling suspended shielding.

Cooperation between the employer and the licensee

Provisions to exchange information with other employers and use specific exposure restrictions, if staff works in another place using radiation.

Individual monitoring and exposure assessment

— Arrangements to provide individual monitoring provided by an accredited and authorized service;
— Identification of staff members requiring individual monitoring;
— Establishment of the monitoring period, frequency for reading and recording the accumulated doses, and rules for returning and changing dosimeters;
— Arrangements to ensure that details of doses are made available to the staff;
— Rules for estimating the worker's dose if a personal dosimeter is lost or damaged.

Monitoring of the workplace

Provisions for keeping the workplace under supervision and monitoring at a frequency that enables assessment in controlled areas and supervised areas.

Health surveillance

— Arrangements in place for health surveillance according to the rules of the regulatory body;
— Counselling for pregnant women.

Records

Ensuring that exposure and medical surveillance records are available.

I.6. PROTECTION FOR MEDICAL EXPOSURE

Responsibilities

— Assignment of the overall responsibility for patient protection and safety to a medical practitioner. Specify (department head, radiologist, chief medical officer, etc.);
— Assignment of the responsibility for conducting or supervising calibration of beam and sources, clinical dosimetry and QA to a qualified expert on diagnostic radiology physics. Specify type of expert (qualified expert in diagnostic radiology physics, hospital physicist, etc.);
— Documented education and training of all staff;
— Lessons from accidents and their prevention included in the training.

Justification of medical exposure

— Procedure in place for the prescription and administration of medical exposure to ensure that these are justified;
— Provision to justify research involving application of radiation on humans.

Optimization: Consideration of equipment and testing

Acceptance test carried out according to international (such as the IEC) or equivalent national standards for radiological equipment (describe).

Optimization: Operational considerations

Provision for optimization (see the BSS [1]) to ensure that the exposure of patients is the minimum required to achieve the intended diagnostic objective, taking into account relevant information from previous examinations in order to avoid unnecessary additional examinations, and taking into account the relevant guidance levels for medical exposure.

Optimization: Calibration

Provisions to ensure that measurements in X ray beams made with an instrument that is traceable to a standards dosimetry laboratory or with a calibration certificate provided by the manufacturer's accredited laboratory.

Optimization: Clinical dosimetry

Provision to determine representative values for average sized adult patients of entrance doses, dose area products, dose rates[17] or organ doses.

Optimization: Quality assurance

— QA programme in place, based on an accepted and proven protocol;
— Assignment of all tasks of the programme to trained persons;
— Maintenance strategy, arrangements and procedures.

Investigation of accidental medical exposure

— Provision in place to investigate and report: (a) Any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and (b) any equipment failure, accident, error, mishap or other unusual occurrence with the potential to cause a patient exposure which is significantly different from that intended;
— Provision to estimate the doses received, and indicate and implement corrective measures;

[17] The BSS, written before the current ICRU and IAEA Code of Practice on Dosimetry in Radiology, refer to entrance dose and dose area product and dose rates but, in practice, entrance air kerma and kerma area product and air kerma rate should be used.

— Provision for follow-up of patients who received high exposure procedures with the potential for deterministic effects, such as prolonged interventional procedure.

I.7. PROTECTION FROM PUBLIC EXPOSURE

— Shielding design with due consideration of public exposure;
— Control of access of public and visitors in place;
— Design of pathways designed to minimize interference from the public with console control space and radiology rooms to avoid potential exposure.

Appendix II

TRAINING OUTLINE

A list of broad topics is presented in this appendix, related to the BSS requirements for the various professionals in radiology, for example, medical practitioners, radiographers/radiological technologists, medical physicists, RPOs, nurses and maintenance staff. The degree of details for each of these professionals will necessarily differ. Curricula for training must be developed in consultation with the appropriate professional bodies and can be integrated in a modular form into professional education and training.

The training should include the following subjects, outlined in Table 3, as applicable to the duties and responsibilities of the individual. For professionals working in interventional radiology, paediatric radiology and mammography, supplementary and specialized training items are necessary. These topics follow approximately the main structure of the requirements in the BSS, which should be addressed in the training.

TABLE 3. EXAMPLE OF AN OUTLINE FOR TRAINING

Part No.	Part	Objective
I	Radiation physics	To become familiar with basic knowledge in radiation physics. Interaction with matter, dosimetric quantities and units to perform related calculations, different types of radiation detectors and their characteristics, their operating principles and limitations.
II	Biological effects of ionizing radiation, including epidemiological studies and risk assessment	To become familiar with the mechanisms of different types of biological effects following exposure to ionizing radiation, and results of epidemiological studies of exposed population to ionizing radiation. To be aware of the models used to derive risk coefficients for estimating detriment.
III	Principles of radiation protection and the international radiation safety standards (BSS)	To become aware of the ICRP's conceptual framework and the BSS requirements, as well as related IAEA Safety Guides in radiation protection in the medical field.

TABLE 3. EXAMPLE OF AN OUTLINE FOR TRAINING (cont.)

Part No.	Part	Objective
IV	Medical radiation equipment: X ray tube and generator	To become familiar with the physics and technological principles of X ray production.
V	Medical X ray imaging	To become familiar with basic knowledge of the physics and elements that affect image formation.
VI	Safety of sources and design of shielding facilities	To become familiar with the safety requirements for the design of X ray systems and auxiliary equipment, shielding of facilities and relevant international safety standards, e.g. the IEC.
VII	Occupational exposure	To become familiar with the detailed requirement of the BSS for radiation protection of workers in diagnostic radiology and the IAEA Safety Guide on occupational radiation protection [24].
VIII	Medical exposure	To become familiar with the detailed requirements of the BSS for medical exposure and the IAEA Safety Guide on protection for medical exposure [16], in particular diagnostic radiology: responsibilities, justification, optimization, clinical dosimetry (dosimetry of patients), guidance levels, investigation of accidental exposure and records.
IX	Optimization of protection for general radiology: radiography	To be able to apply the principle of optimization of radiation protection to a conventional X ray system to become aware of equipment design, operational considerations, calibration, clinical dosimetry QC.
X	Optimization of protection for general radiology: fluoroscopy	To be able to apply the principle of optimization of radiation protection to a fluoroscopy system including design and operational considerations, clinical dosimetry and QC.
XI	Optimization of protection for interventional radiology	To be able to apply the principle of optimization of radiation protection to interventional radiology, including design and operational considerations, clinical dosimetry and QC.
XII	Optimization of protection for computed tomography	To be able to apply the principle of radiation protection to a CT scanner, including design and operational considerations, clinical dosimetry and QC.

TABLE 3. EXAMPLE OF AN OUTLINE FOR TRAINING (cont.)

Part No.	Part	Objective
XIII	Optimization of protection for mammography	To be able to apply the principle of optimization of radiation protection to a mammography system, including design and operational considerations, clinical dosimetry and QC.
XIV	Optimization of protection for paediatric radiology	To be able to apply the principle of optimization of radiation protection to paediatric radiology, including design and operational considerations, clinical dosimetry and QC.
XV	Optimization of protection for dental radiology	To be able to apply the principle of optimization of radiation protection to a dental radiology system, including design and operational considerations, clinical dosimetry and QC.
XVI	Quality assurance	To become familiar with the concepts of QA, radiation protection in diagnostic radiology and procedures for reviewing and assessing the overall effectiveness of radiation protection.
XVII	Potential and accidental exposures	To become familiar with the modalities that can lead to unwanted exposure, case studies of accidental exposures and lessons learned.
XVIII	Protection of the public	To become aware of the BSS requirements for the protection of the public against exposure and how these are applied in restrictions to the design and operation of a diagnostic radiology unit.

Note: The IAEA, together with other international organizations, has developed a training package that follows this outline.

Appendix III

GENERAL RADIATION PROTECTION FEATURES FOR RADIOLOGICAL EQUIPMENT

Leakage radiation

X ray source assemblies (comprising the X ray tube, the housing and the collimator) should restrict leakage radiation to not exceed an ambient dose equivalent, $H^*(10)$, of 1 mGy in 1 h at 1 m at any rating specified by the manufacturer. This value can be averaged over an area not exceeding 100 cm^2.

Beam filtration

The inherent filtration of every X ray tube assembly should be marked permanently and clearly on the housing. The total filtration includes the inherent filtration, any added filtration and filtration afforded by attenuating material that permanently intercepts the beam, e.g. the mirror of a light beam collimator. For normal diagnostic, the total filtration of the beam should be equivalent to not less than 2.5 mm of aluminium, of which 1.5 mm should be permanent (see Ref. [19]).

Special equipment should be used for procedures, such as mammography, CT, dental radiology and interventional procedures, which require specific values of filtration.

Beam size

The X ray systems should always have a means to restrict the radiation field size to the area of interest, either in the form of adjustable diaphragms or a collimator, or for specific examinations such as mammography and dental radiography in the form of a fixed collimator.

For radiographic equipment (except for dental) there should be a light beam to indicate the position and extent of the radiation beam, visible during normal lighting conditions.

In the case of fluoroscopy, equipment should be provided with the means, preferably automatic, to confine the beam within the image receptor area whatever the distance of the X ray tube from the image receptor. Manual collimation should be possible in addition to automatic collimation.

Image receptors

All fluoroscopy units should preferably use an image intensifier (or equivalent technology). Replacing direct fluoroscopy by image intensified fluoroscopy would achieve substantial dose reductions, but it involves substantial investment. It is for Member States to assign the necessary priority to such replacements and to draw up the necessary plans, which should take medical and financial aspects into account.

With regard to radiography, rare earth (gadolinium oxysulphide) intensifying screens have a higher X ray absorption efficiency and higher light output, thus obtaining the required diagnostic information with a substantially lower radiation dose.

Selection of materials for patient's couch, film cassette, etc.

Attenuation of the X ray beam between the patient and the image receptor should be minimized by the use of suitable materials for the tabletop (in the case of over-couch tubes), the front of the film cassette and the antiscatter grid.

Signals and marking

The X ray systems should indicate at the control panel all the important technical parameters relevant to image quality and patient exposure. The tube voltage (kV), tube current (mA) and exposure time (or tube loading (mAs)) are the minimum parameters to be displayed during radiographic exposure.

Instantaneous values of tube voltage (kV), tube current (mA) and accumulated fluoroscopy time should be available at the control console. The degree of magnification (active area of the image intensifier) and the different fluoroscopy modes (low, normal and high) if they exist should be clearly shown to the operator.

If the fluoroscopy unit is capable of high dose-rate operation, a separate visual or audible warning should be available to the operator.

Exposure switches

Exposure switches on all X ray diagnostic equipment, except computed tomography scanners, should be arranged so that an exposure continues only while continuous pressure is maintained on the switch and terminate if pressure is released (if not previously terminated by other means, for example, at the end of the set exposure time in radiography or by the automatic exposure control).

Control of exposure duration

For radiography, exposure should be terminated automatically after a preset time, electrical charge (mAs) or amount of radiation. Additional means of termination should be provided which is independent of the normal means. The release of an exposure switch may be regarded as additional means. Automatic exposure control should be regarded as an aid to achieve consistent radiographs.

For fluoroscopy, the release of an exposure switch may be regarded as the normal means of termination. An additional means of termination should be provided which operates automatically when a predetermined time not exceeding 10 min has elapsed. An audible warning should be activated 30 s earlier, to enable the operator to reset the device if the exposure needs to be prolonged.

It is advisable that fluoroscopy systems incorporate a 'last image hold' mode, where the last acquired image is displayed as long as required.

Exposure measurement

There are means for monitoring the air kerma area product that are suitable for fluoroscopy, i.e. with changing field size, projection and exposure factors. These devices are particularly useful for teaching and interventional procedures and when continuously installed, help detect equipment malfunction or progressive degradation. In interventional radiology, there is a need for monitoring the peak skin dose. Dose mapping can be done by using radiochromic film and, more recently, on-line computational devices for dose mapping are becoming available. Additionally, iso-kerma maps given by the manufacturer should be included as part of the technical documentation for the equipment.

Scattered radiation for fixed fluoroscopy

All tables and stands used for fluoroscopy should be provided with adequate protection against scatter radiation, including, for example, lead curtains, which should be kept in good condition so as to provide the shielding required.

Appendix IV

EXAMPLES OF RULES FOR OPERATIONAL SAFETY (LOCAL RULES)

The following are examples of local rules for use in a radiology facility. They are to be regarded as basic and sample rules only, and may be added to or modified according to local circumstances and regulatory requirements. Local rules should be written in easily understandable form, and in the language of the radiology staff, and displayed prominently in working areas.

IV.1. PATIENT AND PUBLIC PROTECTION

Shielding of radiosensitive organs such as the gonads, lens of the eye, breast and thyroid has to be provided as appropriate. To do so, lead protective devices either as half aprons or gonad shields should be used to cover the pelvic region on all males and premenopausal females. This applies to every possible examination. The protection should be provided on the surface *facing the primary beam:*

(a) Infants and children presenting for examinations of the hip should have the first series without any protection and all progress examinations with shielding.
(b) Any unnecessary persons accompanying the patient must not be in the room during an examination.
(c) Persons (staff or helper/comforter) aiding an examination should wear a lead apron and avoid the primary beam. If their hands are near the primary beam, they should be provided with lead gloves if appropriate.
(d) Parents whose children require assistance during examination should be encouraged to assist. Adequate protection should be provided, along with clear instructions to the parents.
(e) When dental X rays are being performed, all individuals except the patient should be outside the room when an exposure is made.

IV.2. PREGNANCY AND X RAY EXAMINATIONS

The following measures should be taken to protect all females of reproductive capacity, concentrating especially on those who are known to be

pregnant or who think they may be. Identification of pregnant patients is necessary. The primary responsibility for identification of pregnant patients rests with the referring doctor, while the radiology staff provides a secondary backup.

IV.2.1. Identification of pregnant patients

Female patients of reproductive age should be asked whether they are pregnant or whether they think they may be pregnant. A positive answer to this is expected from women who think they may be pregnant, are trying to become pregnant and those who know they are pregnant. In case of doubt, the patient should be considered to be pregnant. The answer to this question should be recorded.

If the answer to the above question is negative, then caution should still be adopted in radiological procedures involving exposure of the lower abdominal and pelvic regions of women of reproductive capacity to ensure that the radiation dose received is as low as practicable.

IV.2.2. Procedure when patient is pregnant

If the patient is or is suspected to be pregnant, then the case should be referred to a radiologist to decide on whether the examination should proceed. In general, only urgent examinations of the pelvis and lower abdomen should be carried out during pregnancy, especially for relatively high dose procedures and particular care should be taken to avoid exposure of the foetus to the direct beam whenever practicable. Optimization of protection of the foetus should be carried out. All radiographic factors should be recorded so that the foetal absorbed dose can be calculated by the qualified expert in radiology physics and recorded.

IV.2.3. Procedure after exposure of pregnant patients

Occasionally, a female patient will not know that she is pregnant at the time of an X ray examination, and will naturally be very concerned when the pregnancy becomes known. In most cases, there is effectively no risk, as the irradiation will have occurred in the first 21 days following conception. In a few cases, the foetus will be older and the dose involved may be considerable. It is, however, extremely rare for the dose to be large enough to warrant advising the patient to consider termination of the pregnancy. A specific estimation is required for high dose abdominal or pelvic CT or fluoroscopy procedures. Specific dose assessment is not simple and is subject to a number of uncertainties.

They should, therefore, be performed with the advice of a qualified expert in diagnostic radiology physics.

ICRP Publication 84 [24] advises that:

> "Termination of pregnancy is an individual decision affected by many factors. Foetal doses below 100 mGy should not be considered a reason for terminating a pregnancy. At foetal doses above this level, there can be foetal damage, the magnitude and type of which is a function of dose and stage of pregnancy."

IV.3. STAFF PROTECTION

Radiation monitoring badges

- Personal monitoring badges should be issued every four weeks (for example, four weeks for general radiology and eight weeks for dental radiology);
- Workers should wear personnel monitoring devices (dose meters) at all times while working in controlled areas;
- When wearing a lead apron, badges should be worn underneath the apron (or as specified);
- The RPO should inform the staff of radiation monitoring results. This should be posted on the staff noticeboard.

Safe operation of X ray equipment

- The lead glass in the operators' areas is only sufficient to stop scattered radiation. At no time should the X ray tube be pointed at this area;
- The X ray tube should not be used any closer than 1 m to the console area;
- Lead aprons should be worn while operating mobile X ray equipment.

Patient immobilization

- Restraining of patients should not be done by radiographers and, if possible, not by people at all;
- Immobilizing devices should be used whenever possible to minimize exposure to the patient, staff or helper/comforter.

Lead apron testing

All lead aprons should be stored on hangers when not in use. They should never be folded for storage. All aprons should be tested at approximately 12–18 month intervals for shielding integrity. Each apron must be given a permanent individual identification. If damage to an apron is seen or suspected, it should be reported to the chief radiographer immediately, and the apron should not be used until it has been tested and declared safe.

Appendix V

PROTECTIVE CLOTHING

Protective clothing used in radiology includes the following:

— Gowns, aprons and thyroid protectors made from a material (such as vinyl) which contains lead;
— Removable bed shielding made from the same material;
— Gloves or gauntlets made from the same material;
— Glasses (spectacles) with lenses made from leaded glass or leaded plastic;
— Viewing windows (fixed or mobile) made from leaded glass or leaded plastic.

Gowns, aprons and thyroid protectors

These may be manufactured in various forms: a coat which is fixed at the front, a poncho which is fixed at the sides, gowns which are either open at the back or contain less lead at the back, or gowns which are in two parts: a top in the form of a coat, and a bottom which is fixed around the waist.

Protective aprons should be equivalent to at least 0.25 mm lead if the X ray equipment operates up to 100 kV and 0.35 mm lead if it operates above 100 kV. Interventional radiology staff should use 0.5 mm lead equivalent because of the high levels of scattered radiation.

The style chosen depends on the radiology practice for which they will be used. The apron gown should have uniform lead equivalence front and back. It is, however, always better to shield the largest possible area of the body.

In interventional radiology, the thyroid will normally need protection. Some gowns include a collar covering the thyroid, but in most cases, a separate thyroid collar will be required.

Bed shielding

In interventional radiology, the scattered radiation levels can be greatly reduced by attaching removable lead vinyl sheets to the side of the X ray table. As the weight is carried by the bed, higher values of lead equivalence can be used.

Lead gloves or gauntlets

Gauntlets are heavy gloves made from lead vinyl. They have limited value because they are difficult to use. Their use can increase a procedure time and thus dose, in some cases. Gauntlets should, therefore, only be used where appropriate.

It is possible to obtain lightweight leaded gloves similar to surgical gloves. These should be used with great care, as they contain little lead, and are only effective at low tube voltages (less than 60 kVp).

Glasses

In some interventional radiology procedures, it is possible for the lens of the operator's eye to receive annual doses which approach or even exceed the BSS limit of equivalent dose to the lenses of the eye (150 mSv). In these cases, some form of eye protection is essential.

Glasses (spectacles) which have leaded lenses are one solution. However, they must have protection at the sides as well.

Viewing windows

Leaded glass or plastic viewing windows are common in shielding for the X ray control area. They should be marked with the lead equivalence, and the maximum tube voltage (kVp) at which this applies.

For interventional equipment, a movable viewing window is very useful. These typically are mounted on the ceiling, and can be placed in such a position that the operator views the main source of scattered radiation (where the X ray beam enters or leaves the patient) through the window. This then provides protection for both the eyes and thyroid. Frequently, strips of lead vinyl are attached below the window to provide additional protection to the torso.

Quality control testing of protective equipment

All lead vinyl material should be tested both soon after purchase and at regular intervals (at least every two years). If vinyl is not stored correctly (on a coat hanger, for instance), it will eventually crack, causing loss of shielding. The damage will not be seen by visual inspection.

All lead vinyl protective materials can be simply tested with fluoroscopy, at certain given kVp values. Automatic control should not be used if this is possible. Fluoroscopy screening will not measure the lead equivalence, but will

reveal any faults in the shielding. Faulty clothing should be immediately discarded and not used.

It is recommended that each item of protective clothing is given a unique identification, and the details of purchase date and subsequent testing be recorded.

Appendix VI

OPTIMIZATION BY APPLYING METHODS FOR REDUCTION OF PATIENT EXPOSURE WITHOUT LOSING DIAGNOSTIC INFORMATION

There are a number of methods for dose reduction in diagnostic radiology and interventional procedures using X rays. Emphasis should be given to assessing image quality whenever methods for dose reduction are applied so as to ensure that dose reduction is not detrimental to diagnostic confidence. ICRP Publication 34 [50] provides a review of these methods, a summary of which follows.

VI.1. GENERAL RADIOLOGY

Sensitivity of image receptors for radiography

Rare earth (gadolinium oxysulphide, among others) intensifying screens have a higher X ray absorption efficiency and higher light output. The use of this type of fluorescent screen can result in substantial reductions in patient exposure and is probably the most cost effective exposure reduction method.

Image intensifier for fluoroscopy

Direct fluoroscopy is still used in many countries; however, it has many disadvantages, including low luminance requiring that the fluoroscopy room be completely dark and that the radiologist be adapted to the dark for at least 15 min; perception of contrast and visual resolution are poor; and radiation dose levels to the patient and medical staff are high. Therefore, it is desirable to replace direct fluoroscopy with image intensified fluoroscopy as soon as the necessary priority can be assigned to such replacements, taking medical and financial aspects into account.

Patient exposure in fluoroscopy may be further reduced by several methods, including the use of image intensifiers with a high conversion coefficient, and the use of image memories in which the last television frame or frames are displayed (last image hold).

Magnification and high dose modes should be used only when necessary as these can greatly increase the patient and staff exposure. Television monitors should be placed at suitable locations in the room and be visible at ambient light levels. (Room light levels should be reduced to optimize video image visibility and minimize reflections.) An alarm should alert the operator that a

certain fluoroscopy time has elapsed. This is useful in minimizing the use of fluoroscopy, and hence in minimizing patient exposure.

Beam quality (penetration)

X ray beams of a higher mean energy are more penetrating than those with lower mean energy. This means that for the same dose to the image receptor,[18] the entrance surface air kerma on the patient will be lower if an X ray beam of a higher mean energy is used. There are several beam parameters influencing the penetrating power of the beam:

(a) *Generator wave form:* Three phase or constant potential (or multi-pulse) generators produce more X ray photons of a higher energy for the same tube potential than single phase generators.
(b) *Filtration:* Adding filtration to an X ray tube (usually in the form of aluminium filters) selectively removes low energy X ray photons; these are otherwise more likely to be absorbed within the patient, and lead to increased patient dose.
(c) *Tube potential:* Increasing the X ray tube potential increases the mean energy of the X ray photons and provides a substantial reduction in entrance surface dose for a constant dose to the image receptor.

However, the higher the mean energy, the lower the contrast of the image. Image contrast is, therefore, the main consideration when selecting the tube potential, which should be as high as feasible, consistent with sufficient image contrast for the diagnosis.

Antiscatter grids

Antiscatter grids or other means are used to limit the degrading effect of scattered radiation on radiological images. All methods of scattered radiation control (i.e. grids, air gap or moving slit) increase patient exposure for the same film density. Scatter control devices should only be used when necessary. For example, a grid can increase the dose to patient tissue by a factor of between 2 and 5. Scatter control devices are not necessary when the irradiated mass is small and the amount of scattered radiation is acceptable.

[18] The need for a constant dose to the image receptor applies to conventional film-screen radiography. It does not apply for digital radiology image receptors.

Collimation

Collimation reduces the amount of irradiated tissue to the minimum needed for the diagnosis. In addition, the dose to tissues just outside the beam, but close to it, increases rapidly towards the field edge. This is particularly important for certain organs, such as the testes, for which a good collimation may reduce doses by a factor of up to 100, as illustrated in Fig. 1 [50]

Organ shielding

Special devices are available for shielding the gonads. A gonad shield is made of an absorbing material (e.g. 1–2 mm lead equivalent rubber) placed between the X ray tube and the gonads. It should be used whenever the gonads are in the primary X ray beam, provided it does not interfere with the areas of clinical interest to be imaged.

Ovarian shields are more difficult to use, because it is difficult to determine precisely the position of the ovaries. Ovary shields are not suited to fluoroscopy as the shields may affect the automatic dose rate control system.

Focus to skin distance

The X ray beam area increases and the radiation intensity decreases with distance away from the X ray tube focus according to the inverse square law.

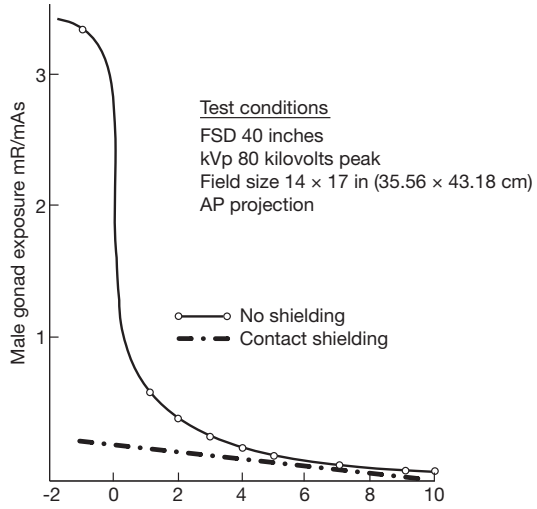

FIG. 1. Male gonad exposure as a function of distance between the edge of the X ray field and the location of the gonads [50].

As a consequence, the entrance dose is greater at short focus to skin distances (FSDs) for the same field size and dose at the plane of the image receptor. The effect of the FSD on entrance dose is illustrated in Fig. 2 [51].

Reducing attenuation between the patient and image receptor

Any material placed between the exit side of the patient and the image receptor, such as the patient couch, grid and cassette, will attenuate some of the useful X ray beam. This attenuation will result in an increase in patient exposure for the air kerma value at the image receptor. It is, therefore, desirable to reduce this attenuation. Patient couches, cassette fronts and grids should be manufactured from low attenuation materials, such as carbon fibre, whenever possible. Compared with plastic materials, carbon fibre results in a dose reduction of between 10 and 30% when used in a cassette front and 14% in a tabletop.

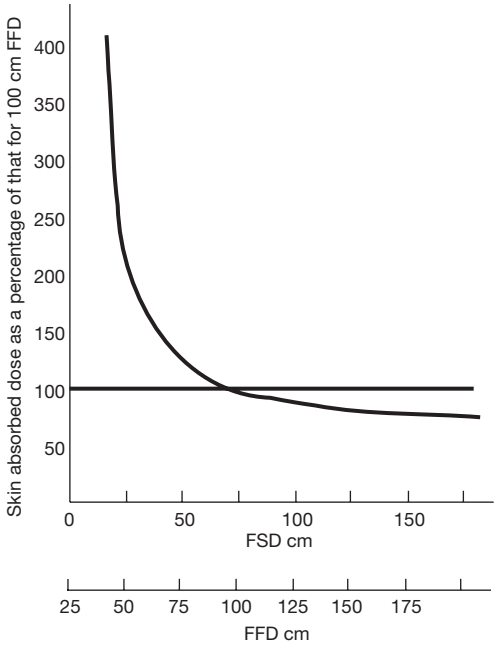

FIG. 2. Effect on skin radiation absorbed dose of altering the focus film distance. Radiation quality and film exposure are assumed to be constant: patient thickness (i.e. distance from the incident skin surface to film) is assumed to be 25 cm. The principle illustrated is applicable to all types of recording device (FSD: focus skin distance; FFD: focus film distance) [51].

Examination technique

Projection direction can influence patient exposure. For instance, in chest radiography the patient should be positioned facing away from the X ray tube to minimize breast dose. (The posterior–anterior projection results in a reduction in the dose to the breast of approximately 20 times.) This is one of the reasons why mobile chest radiography in the ward should be avoided if at all possible.

Film processing

Automatic film processing is preferred. Technical factors, such as developer temperature, developing time and chemistry replenishment, affect the quality of the films and are much more difficult to control in manual processing. Manual processing darkrooms should be equipped with a timer and thermometer, and a time–temperature development table which is followed for processing all films.

VI.2. DIGITAL RADIOLOGY

There are fundamental differences between film screen and digital image receptors. Keeping the average dose at the film screen within a narrow range is a condition in conventional radiography because too dark as well as too light film images are not adequate for diagnosis. In digital radiography, this need to keep a constant dose at the image receptor no longer applies, since it is possible to adjust the grey scale for observation of the image at the image monitor. That is, a higher or lower dose in the image receptor does not result in too dark or too light pictures. Image receptors are generally more sensitive than film screen systems. Thus, they have the potential to reduce exposure. However, an increase in exposure has been the most frequent outcome of digital radiology for the following reasons:

(a) Since images can be obtained with a different receptor dose, this can lead to an increase in the exposure. Higher dose does not mean a too dark image. Rather, it means a low noise image, often lower than necessary for the diagnosis.
(b) As is the case with digital photo cameras, it is easier to take a larger number of pictures than needed and then use only some of them.

(c) Post-processing allows framing of the field size after the picture has been taken. This possibility may lead to less careful collimation, i.e. a field size larger than the one seen by the radiologist after post-processing.

The solution to these problems is proper training for the transition from conventional to digital radiography before undesirable working habits are established, and the development and use of specific guidance (reference) levels.

VI.3. COMPUTED TOMOGRAPHY

Dose reduction in CT can be accomplished through the judicious use of three factors: kVp, mAs, and slice spacing or table incrementation. Increasing kVp reduces patient exposure for reasons similar to those for conventional radiography.

Reducing mAs reduces patient exposure proportionally. Slice spacing is very important in that overlapping slices doubles the dose in the areas of overlap and does not provide a significant improvement in image quality. It is often possible to allow for small spaces between slices, especially with spiral CT, as data are acquired from both sides of the patient so that with small spaces all of the anatomy, and pathology, is imaged.

The primary cause for high doses in CT is the failure to adjust the mAs based on the size of the patient or the body part being imaged. Many facilities use the same kVp and mAs regardless of patient size or anatomy being imaged. For example, for conventional screen film imaging, 0.15 mGy for a chest X ray is used and 3.0 mGy for a lumbar spine image, a factor of 20 difference in patient dose. However, many facilities use the same dose for both chest and abdomen CT. Likewise, many facilities use the same technique for paediatric patients, average sized adults and heavy adults (over 100 kg). CT techniques need to be adjusted based on patient size and body part being imaged in order to optimize radiation doses.

VI.4. MAMMOGRAPHY

The positioning of the patient is critical for the clinical outcome of the examination and mammography radiographers and radiologists should be specially trained in mammography positioning techniques.

A film processor designed for and dedicated to mammography processing is preferable.

Special viewing boxes (with high brightness and collimation) should be installed in a low ambient light level environment.

Dedicated high sensitivity, high resolution mammography screen film combinations or equivalent digital imaging systems need to be used to produce the image quality required at a low dose.

VI.5. INTERVENTIONAL PROCEDURES USING X RAYS

Professionals other than radiologists (cardiologists, urologists, etc.) perform interventional procedures. These professionals may need specific training in radiation protection and the safe use of interventional fluoroscopic equipment.

ICRP Publication 85 [29] has identified the following simple means of keeping doses as low as possible, especially with a view to avoiding radiation injuries from interventional procedures using X rays:

— Keeping beam-on time to a minimum;
— Ensuring that all staff know that the dose rate will be greater and that the skin dose will accumulate faster in larger patients;
— Keeping the tube current as low as possible and the tube potential as high as possible to achieve appropriate compromise between contrast and patient doses;
— Using increased tube filtration to reduce the low energy radiation which is preferentially absorbed by the patient, thereby increasing patient exposure unnecessarily;
— Using pulsed fluoroscopy and last image hold;
— Keeping the X ray tube at the maximal distance from the patient and image intensifier as close as possible to the patient;
— Removing the grid during procedures on small patients or when the image intensifier cannot be placed close to the patient (air gap);
— Considering options for positioning the patients or altering the X ray field or other means to alter beam angulation so that the same area of skin is not continuously in the direct X ray field when procedures are unexpectedly prolonged;
— Keeping in mind that doses can vary as much as tenfold for the same fluoroscopy time, depending on patient size, location of the beam, beam angle and distance of the tube from the patient;
— Using high dose rate modes in fluoroscopy only during the minimum indispensable time necessary to the procedure;

— Reducing the use of magnification imaging modes. If the area imaged is reduced by a factor of two, the dose rate to that area goes up by a factor of between two and four times.

VI.6. PREGNANCY

The most common ways to tailor examinations and reduce foetal exposure are to: collimate the beam to a very specific area of interest; remove the antiscatter grid if possible; use shielding if it does not interfere with the required image; and reduce the number of radiographs to be taken. Increasing kVp also reduces foetal dose, especially if the foetus is in the beam.

Typical examples of dose reduction are given in ICRP Publication 84 [26]:

(a) For CT, it may be possible to limit the scanning to the anatomical area of interest (e.g. the kidneys) rather than to scan the entire abdomen and pelvis. Fortunately, the primary radiation beam is very tightly collimated and location can be precisely controlled. For scans with the uterus in the field of view, the absorbed doses are typically about 10–40 mGy.

(b) For an intravenous urogram, it may be possible to reduce the number of images to be taken. A typical example is a pregnant patient in whom an obstructing distal urethral stone is suspected. Instead of performing a routine intravenous procedure (taking a preliminary film and about seven sequential post-intravenous contrast films), the diagnosis of where the level of obstruction is or the size of the stone can often be obtained with one preliminary film and then a single film 10 min after the contrast administration.

(c) In the case of fluoroscopy of the abdominal or pelvic region, minimizing the fluoroscopy time can reduce the radiation dose. With good technique, foetal dose during a barium enema can be in the range of 3–7 mGy. Because of longer fluoroscopy times, doses from double contrast are often twice as high as those from single contrast studies. If the woman is not aware of the pregnancy and specific attention is not given to limiting fluoroscopy time, foetal dose can approach or exceed 50 mGy, especially if the fluoroscopy time exceeds 7 min.

(d) When the foetus is known to be in the primary X ray beam, the technical factors should be recorded to allow assessment of foetal dose. The relevant factors are whether a grid was used, the value of kVp, fluoroscopy time, a geometrical description and projections used. If dose area product monitoring is available, the value should also be recorded.

VI.7. PAEDIATRIC RADIOLOGY

— Radiographers should undergo specific training in managing paediatric patients, in the appropriate radiographic techniques, and in the use of immobilization devices;
— Wherever possible, dedicated paediatric X ray systems should be used for babies and small children because they have special features, such as special grids, beam quality (special filtration) and they also have the ability to use very short exposure times and thus avoid degradation of the image quality caused by patient movement;
— If conventional (adult) X ray equipment is to be used for babies and small children, the grid should be removed where possible;
— The automatic exposure control for non-dedicated paediatric equipment should be able to accommodate the different size and stature of children of a range of ages.

VI.8. DENTAL RADIOLOGY

— Intra-oral dental radiology should be performed on dedicated equipment operating at tube potentials above 50 kVp, preferably 70 kVp;
— The collimator should provide a focus to skin distance of at least 20 cm and a field size no more than 6 cm in diameter at the collimator end, and preferably limited to the image receptor dimensions;
— Only open-ended collimators should be used;
— E-speed or faster film should be used. The film should be processed according to the manufacturer's instructions, adjusting the processing time appropriately, depending on the developer solution temperature;
— Panoramic dental radiography should only be performed on dedicated X ray equipment. The vertical dimension of the X ray beam in these devices should not exceed the film width;
— Cephalometry should be performed at a focus to skin distance of at least 1 m.

Appendix VII

GUIDANCE LEVELS OF RADIOLOGY (TYPICAL ADULT PATIENTS)

The following tables are taken from the BSS, Schedule III: Guidance levels of dose, dose rate and activity for medical exposure.[19]

"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

[19] At the time the BSS were published, the quantities in use were entrance dose, dose–area product and dose rates. More recently, the ICRU and the IAEA have pointed out that it is impractical to measure absorbed dose to air in situations where there is a lack of secondary electron equilibrium, such as in air–tissue interfaces. It is proposed, therefore, to measure air kerma instead. (ZOETLIEF, J., et al. "Dosimetry in diagnostic and interventional radiology: ICRU and IAEA activities", Standards and Codes of Practice in Medical Radiation Dosimetry (Proc. Symp. Vienna, 2002), IAEA, Vienna (2003)).

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

Examination		Entrance surface dose per radiograph[a] (mGy)
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."

"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 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."

REFERENCES

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

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and the Safety of Radiation Sources, Safety Series No. 120, IAEA, Vienna (1996).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Applying Radiation Safety Standards in Nuclear Medicine, Safety Reports Series No. 40, IAEA, Vienna (2005).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Applying Radiation Safety Standards in Radiotherapy, Safety Reports Series No. 38, IAEA, Vienna (2005).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization and Implementation of a National Regulatory Infrastructure Governing Protection Against Ionizing Radiation and the Safety of Radiation Sources: Interim Report for Comment, IAEA-TECDOC-1067, IAEA, Vienna (1999).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Control of Radiation Sources, IAEA Safety Standards Series No. GS-G-1.5, IAEA, Vienna (2004).

[7] WORLD HEALTH ORGANIZATION, Quality Assurance in Diagnostic Radiology, WHO, Geneva (1982).

[8] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment — Part 2–43: Particular Requirements for the Safety of X-ray Equipment for Interventional Procedures, Rep. IEC-60601-2-43, IEC, Geneva (2000).

[9] INTERNATIONAL ELECTROTECHNICAL COMMISSION, X-ray Tube Assemblies for Medical Diagnosis: Characteristics of Focal Spots, Rep. IEC-60336, IEC, Geneva (1993).

[10] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Determination of the Permanent Filtration of X-ray Tube Assemblies, Rep. IEC-60522, IEC, Geneva (2003).

[11] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment — Part 1: General Requirements for Safety — 3. Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-ray Equipment, Rep. IEC-60601-1-3, IEC, Geneva (1994).

[12] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment — Part 2–7: Part 2: Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-ray Generators, Rep. IEC-60601-2-7, IEC, Geneva (1998).

[13] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment — Part 2: Particular Requirements for the Safety of Associated Equipment of X-ray Equipment, Rep. IEC-60601-2-32, IEC, Geneva (1994).
[14] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment — Part 2: Particular Requirements for the Safety of X-ray Source Assemblies and X-ray Tube Assemblies for Medical Diagnosis, Rep. IEC-60601-2-28, IEC, Geneva (1993).
[15] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment — Part 1: General Requirements for Safety — 3. Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-ray Equipment, Rep. IEC-601-1-3, IEC, Geneva (1994).
[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiological Protection for Medical Exposure to Ionizing Radiation, IAEA Safety Standards Series No. RS-G-1.5, IAEA, Vienna (2002).
[17] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Basic Ionizing Radiation Symbol, ISO 361, ISO, Geneva (1975).
[18] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Structural Shielding Design for Medical X-ray Imaging Facilities, NCRP Report No. 147, NCRP, Bethesda, MD (2004).
[19] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Protection against Ionizing Radiation from External Sources Used in Medicine, Publication 33, Pergamon Press, Oxford (1981).
[20] SIMPKIN, D.J., Evaluation of NCRP Report No. 49, Assumptions on workloads and use factors in diagnostic radiology facilities, Med. Phys. **23** 4 (1996) 577–94.
[21] DIXON, R.L., SIMPKIN, D.J., Primary shielding barriers for diagnostic radiology facilities: A new model, Health Phys. **74** (1998) 117–22.
[22] ARCHER, B.R., et al., Attenuation properties of diagnostic x-ray shielding materials, Med. Phys. **21** 9 (1994).
[23] BRITISH INSTITUTE OF RADIOLOGY, Radiation Shielding for Diagnostic X-Rays, Report of a Joint BIR/IPEM Working Party (SUTTON, D.G., WILLIAMS, J.R., Eds), BIR, London (2000).
[24] INTERNATIONAL ATOMIC ENERGY AGENCY, Occupational Radiation Protection, IAEA Safety Standards Series No. RS-G-1.1, IAEA, Vienna (1999).
[25] INTERNATIONAL ATOMIC ENERGY AGENCY, Assessment of Occupational Exposure Due to External Sources of Radiation, IAEA Safety Standards Series No. RS-G-1.3, IAEA, Vienna (1999).
[26] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Pregnancy and Medical Radiation, Publication 84, ICRP, Elsevier, Oxford and New York (2000).
[27] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Use of Personal Monitors to Estimate Effective Dose and Effective Dose Equivalent to Workers for External Exposure to Low-LET Radiation, NCRP Report No. 122, NCRP, Bethesda, MD (1995).

[28] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Conversion Coefficients for Use in Radiological Protection against External Radiation, Publication 74, Elsevier, Oxford and New York (1997).
[29] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Avoidance of Radiation Injuries from Medical Interventional Procedures, ICRP Publication 85, Elsevier, Oxford and New York (2001).
[30] VAÑÓ, E., et al., Dosimetric and radiation protection considerations based on some cases of patient skin injuries in interventional cardiology, Br. J. Radiol. **71** (1998) 510–16.
[31] VAÑÓ, E., GONZÁLEZ, L., BENEYTEZ, F., et al., Lens injuries induced by occupational exposure in non-optimized interventional radiology laboratories, Br. J. Radiol. **71** (1998) 728–33.
[32] WAGNER, L.K., ARCHER, B.R., Minimizing Risks from Fluoroscopic X-rays: Bioeffects, Instrumentation and Examination, 2nd edn, Partners in Radiation Management, The Woodlands, TX (1998).
[33] WORLD HEALTH ORGANIZATION, A Rational Approach to Radiodiagnostic Investigations, WHO, Geneva (1994).
[34] WORLD HEALTH ORGANIZATION, Rational Use of Diagnostic Imaging in Paediatrics, WHO, Geneva (1987).
[35] WORLD HEALTH ORGANIZATION, Effective Choices for Diagnostic Imaging in Clinical Practice, WHO, Geneva (1988).
[36] COMMISSION OF THE EUROPEAN COMMUNITIES, European Guidelines on Radiation Protection of Unborn Children and Infants Irradiated Due to Parental Medical Exposures, Radiation Protection No. CR-18-98-316-EN-C, Office for Official Publications of the European Communities, Luxembourg (1999).
[37] UNITED NATIONS, Ionizing Radiation: Sources and Biological Effects (Report to the General Assembly), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2000).
[38] BALTER, S., SHOPE, T.B., FLETCHER D.W., KUAN, H.M., SEISSL, H., Techniques to Estimate Radiation Dose to Skin During Fluoroscopically Guided Procedures in Introduction in Intravascular Brachytherapy/Fluoroscopically Guided Interventions, AAPM Monograph 28, 2002, Medical Physics Publishing, Madison WI (2002), 731–64.
[39] WORLD HEALTH ORGANIZATION, Efficacy and Radiation Safety in Interventional Radiology, WHO, Geneva (2000).
[40] SULEIMAN, O.H., STERN, S.H., SPELIC, D.C., Patient dosimetry activities in the United States: The nationwide evaluation of X ray trends (NEXT) and tissue dose handbooks, Appl. Radiat. Isot. **50** (1999) 247–59.
[41] NATIONAL RADIOLOGICAL PROTECTION BOARD, National Protocol for Patient Dose Measurements in Diagnostic Radiology, NRPB, Chilton, UK (1992).

[42] COMMISSION OF THE EUROPEAN COMMUNITIES, European Guidelines on Quality Criteria for Diagnostic Radiographic Images, Rep. EUR 16260, Office for Official Publications of the European Communities, Luxembourg (1996).
[43] COMMISSION OF THE EUROPEAN COMMUNITIES, European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics, Rep. EUR 16261, Office for Official Publications of the European Communities, Luxembourg (1996).
[44] COMMISSION OF THE EUROPEAN COMMUNITIES, European Guidelines on Quality Criteria for Computed Tomography, Rep. EUR 16262, Office for Official Publications of the European Communities, Luxembourg (2000).
[45] COMMISSION OF THE EUROPEAN COMMUNITIES, European Guidelines for Quality Assurance in Mammography Screening (DE WOLF, C.J.M., PERRY, N.M., Eds), 2nd edn, Office for Official Publications of the European Communities, Luxembourg (1996).
[46] FOOD AND DRUG ADMINISTRATION, Avoidance of serious X-ray induced skin injuries to patients during fluoroscopy guided procedures, Med. Bull. **24** 2 (1994) 7–17.
[47] SHOPE, T.B., Radiation-induced skin injuries from fluoroscopy, Radiographics **16** (1996) 1195–99.
[48] International Action Plan for the Radiological Protection of Patients, GOV/2002/36-GC(46)/12, IAEA, Vienna (2002).
[49] INTERNATIONAL SOCIETY OF RADIOGRAPHERS AND RADIOLOGICAL TECHNICIANS, Quality Control Handbook for Technicians in Radiography Using Simple X-ray Equipment and Manual Film Processing (1986).
[50] UNITED STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, Specific Area Gonad Shielding, Publication (FDA) 76 8054, US Government Printing Office, Washington, DC (1976).
[51] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Protection of the Patient in Diagnostic Radiology, Publication 34, Pergamon Press, Oxford and New York (1983).

DEFINITIONS

absorbed dose. The fundamental dosimetric quantity, D, defined as:

$$D = \frac{d\bar{\varepsilon}}{dm}$$

where $d\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to matter in a volume element and dm is the mass of matter in the volume element. The energy can be averaged over any defined volume, the average dose being equal to the total energy imparted in the volume divided by the mass in the volume. The SI unit of absorbed dose is the joule per kilogram ($J \cdot kg^{-1}$), termed gray (Gy) (BSS).

air kerma area product. The air kerma area product, P_{KA}, is the integral of the air kerma over the area of the X ray beam in a plane perpendicular to the beam axis thus:

$$P_{KA} = \int_A K(x,y)dxdy$$

Unit: $J \cdot kg^{-1} \cdot m^2$. The special unit of air kerma area product is $Gy \cdot m^2$.

air kerma entrance dose. The entrance surface air kerma, K_e, is the kerma to air measured on the central beam axis on the patient or phantom entrance surface. Therefore, both the radiation incident on the patient or phantom and the backscattered radiation are included.

air kerma length product. The air kerma length product, $P_{KL,}$ is the integral of the air kerma over a line, L, parallel to the axis of rotation of a CT scanner, thus:

$$P_{KL} = \int_L K(z) \ \ \mathrm{d}z$$

Unit: $J \cdot kg^{-1} \cdot m$. The special unit of air kerma length product is $Gy \cdot m$.

ambient dose equivalent. The quantity $H^*(d)$ at a point in a radiation field, defined as the dose equivalent that would be produced by the corresponding aligned and expanded field in the ICRU sphere at a depth d on the radius opposing the direction of the aligned field. A depth $d = 10$ mm is recommended for strongly penetrating radiation.

approved. Approved by the regulatory body.

authorization. The granting by a regulatory body or other governmental body of written permission to perform specified activities.

authorized. Granted an authorization by the regulatory body.

chronic exposure. Exposure persisting in time.

computed tomography kerma index. The computed tomography kerma index, C_{100}, for a single axial scan is the quotient of the integral of the air kerma along a line parallel to the axis of rotation of a CT scanner over a length of 100 mm and the product of the number of acquired tomographic sections N and the nominal section thickness *T*. The integration range is positioned symmetrically about the volume scanned, thus:

$$C_{100} = \frac{1}{NT}\int_{-50}^{+50} K(z)\ \ dz$$

Unit: joule per kilogram ($J \cdot kg^{-1}$). The special unit for computed tomography kerma index is gray (Gy).

dose constraint. A prospective and source related restriction on the individual dose delivered by the source which serves as a bound in the optimization of protection and safety of the source. For occupational exposures, dose constraint is a source related value of individual dose used to limit the range of options considered in the process of optimization. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source. The exposure to which the dose constraint applies is the annual dose to any critical group, summed over all exposure pathways, arising from the predicted operation of the controlled source. The dose constraint for each source is intended to ensure that the sum of doses to the critical group from all controlled sources remains within the dose limit. For medical exposure the 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.

effective dose. The quantity E, defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_T w_T H_T$$

where H_T is the equivalent dose in tissue T and w_T is the tissue weighting factor for tissue T. From the definition of equivalent dose, it follows that:

$$E = \sum_T w_T \sum_R w_R D_{T,R}$$

where w_R is the radiation weighting factor for radiation R and $D_{T,R}$ the average absorbed dose in the organ or tissue T. The unit of effective dose is joule per kilogram ($J \cdot kg^{-1}$), special name sievert (Sv).

employer. A legal person with recognized responsibility, commitment and duties towards a worker in his or her employment by virtue of a mutually agreed relationship. (A self-employed person is regarded as being both an employer and a worker.)

excluded. Outside the scope of the BSS.

health professional. An individual who has been accredited through appropriate national procedures to practise a profession related to health (e.g. medicine, dentistry, chiropractic, paediatrics, nursing, medical physics, radiation and nuclear medical technology, radiopharmacy, occupational health).

health surveillance. Medical supervision intended to ensure the initial and continuous fitness of workers for their intended task.

kerma. The quantity K, defined as:

$$K = \frac{dE_{tr}}{dm}$$

where dE_{tr} is the sum of the initial kinetic energies of all charged ionizing particles liberated by uncharged ionizing particles in a material of mass dm. The SI unit of kerma is joule per kilogram ($J \cdot kg^{-1}$), termed gray (Gy).

legal person. Any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national

legislation, who or which has responsibility and authority for any action having implications for protection or safety.

licence. A legal document issued by the regulatory body granting authorization to perform specified activities related to a facility or activity.

licensee. The holder of a current licence.

medical exposure. 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.

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 exposure; 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.

member of the public. In a general sense, any individual in the population except, for the purposes of the BSS, when subject to occupational or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, the representative individual in the relevant critical group.

normal exposure. An exposure which is expected to occur under normal operating conditions of a facility or activity, including possible minor mishaps that can be kept under control, i.e. during normal operation and anticipated operation occurrences.

notification. A document submitted to the regulatory body by a legal person to notify an intention to carry out a practice or other use of a source.

occupational exposure. All exposures of workers incurred in the course of their work with the exception of exposures excluded from the BSS and exposures from practices or sources exempt by the BSS.

percutaneous transluminal coronary angioplasty, PTCA. A common non-surgical treatment[s] for opening obstructed coronary arteries.

personal dose equivalent, *Hp(d)*. The dose equivalent in soft tissue below a specified point on the body at the appropriate depth. (The relevant depths for the purposes of the BSS are generally $d = 10$ mm for strongly penetrating radiation and $d = 0.07$ mm for weakly penetrating radiation.)

potential exposure. Exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

practice. Any human activity that introduces additional sources of exposure or exposure pathways, or extends exposure to additional people, or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed.

protection and safety. The protection of people against exposure to ionizing radiation or radioactive materials and the safety of radiation sources, including the means for achieving this, and the means for preventing accidents and for mitigating the consequences of accidents should they occur.

protective action. An intervention intended to avoid or reduce doses to members of the public in chronic or emergency exposure situations.

public exposure. Exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure and the normal local natural background radiation, but including exposure from authorized sources and practices and from intervention situations.

qualified expert in diagnostic radiology physics. 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 radiology physics. The BSS require that for diagnostic uses of radiation (in this case, radiology) the imaging and quality assurance requirements of the BSS be fulfilled with the advice of a qualified expert in radiology physics. In high complexity services, the qualified expert is indispensable; in services of low and medium complexity, at the least, a

medical physicist should be available to provide periodic advisory services.

radiation protection officer, RPO. An individual technically competent in radiation protection matters relevant to a given type of practice who is designated by the registrant or licensee to oversee the application of the requirements of the BSS.

registrant. An applicant who is granted registration of a practice or source and has recognized rights and duties for such a practice or source, particularly in relation to protection and safety.

registration. A form of authorization for practices of low or moderate risks whereby the legal person responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the regulatory body. The practice or use is authorized with conditions or limitations as appropriate. The requirements for safety assessment and the conditions or limitations applied to the practice should be less severe than those for licensing.

regulatory body. An authority or a system of authorities designated or otherwise recognized by a government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety.

risk. A multi-attribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with actual or potential exposures. It relates to quantities, such as the probability that specific deleterious consequences may arise, and the magnitude and character of such consequences.

safety assessment. A review of the aspects of design and operation of a source which are relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations.

safety culture. The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority,

protection and safety issues receive the attention warranted by their significance.

source. Anything that may cause radiation exposure — such as by emitting ionizing radiation or releasing radioactive substances or materials. For example, materials emitting radon are sources in the environment, a sterilization gamma irradiation unit is a source for the practice of radiation preservation of food, an X ray unit may be a source for the practice of radiodiagnosis, and a nuclear power plant is a source for the practice of generating electricity by nuclear power. A complex or multiple installation situated at one location or site may, as appropriate, be considered a single source for the purposes of application of the BSS.

standards dosimetry laboratory. A laboratory designated by the relevant national authority for the purpose of developing, maintaining or improving primary or secondary standards for radiation dosimetry.

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.)

weighted computed tomography air kerma index. The computed tomography kerma index (CTKI) is measured both free-in-air along the axis of rotation of the scanner and in acrylic (or polymethyl methacrylate, PMMA) phantoms. The notations, $C_{100,a}$ and $C_{100,PMMA}$ are used.

The weighted computed tomography kerma index, C_W, is defined as:

$$C_W = \frac{1}{3}\left(C_{100,PMMA,c} + 2 \;\; C_{100,PMMA,p}\right)$$

The quantity $C_{100,PMMA,c}$ is the value of the CTKI measured at the centre of a CT phantom (160 or 320 mm diameter and 100 mm thick) and $C_{100,PMMA,p}$ is the average of values of the CTKI measured at four positions around the periphery of the same phantom.

worker. Any person who works, whether full-time, part-time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection. (A self-employed person is regarded as having the duties of both an employer and a worker.)

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