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Radiation Protection and Safety in Medical Uses of Ionizing Radiation

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DRAFT SAFETY GUIDE DS399



FOREWORD

By Yukiya Amano

Director General

[standard text to be added]

PREFACE

In 2006, the Agency published the Fundamental Safety Principles (IAEA Safety Standards Series No. SF-1), jointly sponsored by the European Atomic Energy Community (EURATOM), the Food and Agriculture Organization of the United Nations (FAO), the IAEA, the International Labour Organization (ILO), the International Maritime Organization, the OECD Nuclear Energy Agency (OECD/NEA), the Pan American Health Organization (PAHO), the United Nations Environment Programme (UNEP) and the World Health Organization (WHO). That publication sets out the fundamental safety objective and the principles of protection and safety. Requirements designed to meet these are established in Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (the BSS), jointly sponsored by the European Commission (EC/Euratom), Food and Agriculture Organization of the United Nations (FAO), IAEA, International Labour Organization (ILO), United Nations Environment Programme (UNEP) and World Health Organization (WHO).

This Safety Guide, prepared jointly by the IAEA, the WHO, the PAHO and the International Labour Office, provides guidance on fulfilling the requirements of GSR Part 3 with respect to medical uses of ionizing radiation. It is aimed primarily at end-users in medical radiation facilities where radiological procedures are performed, including management, radiological medical practitioners, medical radiation technologists, medical physicists, radiation protection officers and other health professionals. It also provides recommendations and guidance to health professionals who refer patients for radiological procedures; to manufacturers and suppliers of medical radiological equipment; and to ethics committees with responsibilities for biomedical research. This publication provides recommendations and guidance on appropriate regulatory activities and infrastructure, and is therefore also applicable to regulatory bodies, health authorities, government agencies in general, and professional bodies.

The Safety Guide addresses all three categories of exposure: occupational exposure for health professionals performing radiological procedures; medical exposure, primarily for the patients undergoing the radiological procedures but also for carers and comforters and for volunteers subject to exposure as part of a programme of medical research; and public exposure for members of the public. A systematic approach should be applied to ensure that there is a balance between being able to utilize the benefits from medical uses of ionizing radiation and minimizing the risk of radiation effects to patients, workers and members of the public.

This Safety Guide supersedes Safety Guide Radiological Protection for Medical Exposure to Ionizing Radiation, RS-G-1.5, Safety Reports Series No. 38 Applying Radiation Safety Standards in Radiotherapy, Safety Reports Series No. 39 Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays, and Safety Reports Series No. 40 Applying Radiation Safety Standards in Nuclear Medicine.

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1. INTRODUCTION

BACKGROUND

1.1. Medical uses of ionizing radiation are amongst the longest established applications of ionizing radiation. Current estimates put the worldwide annual number of diagnostic and interventional radiological procedures at over 3000 million and at over 5 million radiation therapy treatments [1]. These medical uses bring considerable public health benefits.

1.2. However, ionizing radiation can cause harm and a systematic approach should be applied to ensure that there is a balance between being able to utilize the benefits from medical uses of ionizing radiation and minimizing the risk of radiation effects to patients, workers and members of the public.

1.3. Medical uses of ionizing radiation only have a place in the context of medical practice. The system for ensuring radiation protection and safety should fit in with the larger system for ensuring good medical practice. This Safety Guide focuses on the system of radiation protection and safety.

1.4. The International Atomic Energy Agency (IAEA) Fundamental Safety Principles [2] present the fundamental safety objectives and principles of protection and safety. Requirements designed to meet these are established in Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (the BSS), jointly sponsored by the European Commission (EC/Euratom), Food and Agriculture Organization of the United Nations (FAO), IAEA, International Labour Organization (ILO), OECD Nuclear Energy Agency (OECD/NEA), Pan American Health Organization (PAHO), United Nations Environment Programme (UNEP) and World Health Organization (WHO) [3].

1.5. This Safety Guide, prepared jointly by the IAEA, the WHO, the PAHO and the ILO, provides guidance on fulfilling the requirements of GSR Part 3 [3] (the BSS) with respect to medical uses of ionizing radiation.

1.6. The International Commission on Radiological Protection (ICRP) has developed recommendations for a system of radiation protection [4]. These and other current recommendations of the ICRP and the International Commission on Radiation Units and Measurements (ICRU) have been taken into account in preparing this Safety Guide.

1.7. It is assumed in this Safety Guide that the individual State has in place an effective governmental, legal and regulatory infrastructure for radiation safety that covers medical uses of ionizing radiation.

1.8. This Safety Guide supersedes Safety Guide Radiological Protection for Medical Exposure to Ionizing Radiation, RS-G-1.5, Safety Reports Series No. 38 Applying Radiation Safety Standards in Radiotherapy, Safety Reports Series No. 39 Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays, and Safety Reports Series No. 40 Applying Radiation Safety Standards in Nuclear Medicine.

1.9. Unless otherwise stated, terms are used with the meanings ascribed to them in the BSS [3] or the IAEA Safety Glossary (2007 Edition) [5].

OBJECTIVE

1.10. The BSS [3] establish requirements for protection of people from harmful effects of exposure to ionizing radiation, for the safety of radiation sources and for protection of the environment. This Safety Guide recommends how medical uses of ionizing radiation should be carried out safely within the framework of the BSS.

1.11. The purpose of this publication is to provide recommendations and guidance on meeting the requirements for the safe use of radiation in medicine. It is aimed primarily at end-users in medical radiation facilities where radiological procedures are performed, including management, radiological medical practitioners, medical radiation technologists, medical physicists, radiation protection officers and other health professionals. It also provides recommendations and guidance to health professionals who refer patients for radiological procedures; to manufacturers and suppliers of medical radiological equipment; and to ethics committees with responsibilities for biomedical research.

1.12. This publication provides recommendations and guidance on appropriate regulatory activities and infrastructure, and is therefore also applicable to regulatory bodies, health authorities, government agencies in general, and professional bodies.

SCOPE

1.13. This Safety Guide provides recommendations for ensuring radiation protection and safety of radiation sources with regard to patients, workers, carers and comforters, volunteers in biomedical research, and the public in medical uses of ionizing radiation. It covers radiological procedures in diagnostic radiology (including dentistry), image guided interventional procedures, nuclear medicine, and radiation therapy. Some of these radiological procedures may be carried out in other medical specialties, including, but not limited to, cardiology, vascular surgery, urology, orthopaedic surgery, obstetrics and gynaecology, emergency medicine, gastroenterology, anaesthetics and pain management.

1.14. Depending on the laws and regulations in a State, medical uses of ionizing radiation may include the use of ionizing radiation in other health care practices, such as chiropractic, osteopathy and podiatry. These uses are also within the scope of this Safety Guide.

1.15. This Safety Guide does not include recommendations or guidance on human imaging using ionizing radiation for purposes other than medical diagnosis, medical treatment or biomedical research. Such human imaging using ionizing radiation for other purposes includes exposing people to radiation for employment related, legal or health insurance purposes without reference to clinical indications, and human imaging using ionizing radiation for the detection of concealed objects for anti-smuggling purposes or for the detection of concealed objects that could be used for criminal acts that pose a national security threat. These applications will be covered in Safety Guide DS471 [6].

STRUCTURE

1.16. Following this introductory section, Section 2 gives general recommendations for radiation protection and safety in medical uses of ionizing radiation. This includes the application of the principles of protection and safety; the use of the graded approach; roles and responsibilities; education, training, qualification and competence; management systems for protection and safety; and safety assessments.

1.17. Sections 3-5 give recommendations for specific areas of medical uses of ionizing radiation – Section 3 – diagnostic radiology and image guided interventional procedures; Section 4 – nuclear medicine; and Section 5 – radiation therapy. Guidance for hybrid modalities is addressed in the relevant sections, as appropriate.

1.18. Appendix I gives summary guidance on typical causes of and contributing factors to accidental exposures in medical uses of radiation. Appendices II and III give recommendations on the avoidance of pregnancy following radiopharmaceutical therapy and the cessation of breast feeding following administration of radiopharmaceuticals for diagnostic examinations, respectively.

2. GENERAL RECOMMENDATIONS FOR RADIATION PROTECTION AND SAFETY IN MEDICAL USES OF RADIATION

GENERAL ASPECTS

2.1. Medical uses of ionizing radiation take place in a variety of settings, including hospitals, medical centres, health clinics, specialist clinics, and dental practices. Medical radiation facility is the term used in the BSS to cover all the possible settings. Many medical radiation facilities provide services for more than one medical use of radiation. For example, a large hospital typically may have facilities for diagnostic radiology, image guided interventional procedures, nuclear medicine and radiation therapy. The authorization process for medical uses of ionizing radiation varies from State to State. In some States a single authorization may cover all specialties and activities within the facility, whereas others may authorize each specialty or application separately. For example, in one State a hospital may have a single authorization covering all of diagnostic radiology, image guided interventional procedures, nuclear medicine, and radiation therapy, whereas in another State each of these areas or applications may be authorized separately. Despite differences in authorization, the guidance in this Safety Guide remains applicable.

2.2. Traditionally each of the areas of diagnostic radiology, nuclear medicine, and radiation therapy were separate, with little or no combined usage. This has changed, with the so-called hybrid imaging systems involving both diagnostic radiology and nuclear medicine expertise, and with the planning, guidance and verification stages of radiation therapy increasingly involving both imaging and radiation therapy expertise. Cross references are given where appropriate.

2.3. As already noted above in para. 1.3, the setting for this Safety Guide is the practice of medicine (including dentistry, chiropractic, osteopathy and podiatry). The requirements of the BSS for radiation protection and safety of radiation sources apply for the uses of radiation in medicine as elsewhere. The requirements must be met and fitted in with medical structures and processes and in health care pathways, with the objective of improved patient care and patient outcomes.

TYPES OF EXPOSURE SITUATIONS AND CATEGORIES OF EXPOSURE

2.4. The requirements of the BSS are based around the three types of exposure situations: planned exposure situations, existing exposure situations, and emergency exposure situations. Medical uses of ionizing radiation are a planned exposure situation and the requirements of Sections 2 and 3 of the BSS apply, as appropriate. This includes situations of potential exposure that is an exposure that is not expected to occur with certainty, but could result from an accident or from an event or a sequence of events that may occur but is not certain to occur (BSS [3], paragraph 1.20 (a)]. Potential exposure can be applicable to any of occupational, public and medical exposure, where the event, if it occurs, results in an exposure over and above what would be expected normally. Situations when the radiological procedures do not go as planned – that is, unintended and accidental medical exposures should be treated as planned exposure situations (BSS [3], paragraph 3.145]. Chapters 2, 4 and 5 of this safety guide discuss the prevention and mitigation of events leading to a potential exposure. In extreme situations in medical settings when dangerous source is involved (such as a radiotherapy source), emergency exposure situation may occur affecting either workers or member of the public. For preparedness and response for emergency exposure situations requirements of Sections 4 of the BSS and specific safety standard GSR Part 7 apply [7].

2.5. Medical uses of ionizing radiation involve all three categories of exposure: occupational exposure for those involved in the performance of radiological procedures; medical exposure, primarily for the

patients undergoing the radiological procedures but also for carers and comforters and for volunteers subject to exposure as part of a programme of medical research; and public exposure for members of the public, such as in waiting rooms. The requirements for radiation protection and safety differ according to the category of exposure, so it is important that the exposure of persons is categorized correctly. For example, a nurse assisting with image guided interventional procedures would be considered to be occupationally exposed, whereas a nurse working in an in-patient ward where occasional mobile radiography is performed by a medical radiation technologist would not be considered occupationally exposed but rather as subject to public exposure. The term carer and comforter has been introduced into the BSS to cover the persons who, outside an occupational capacity, willingly and voluntarily help in the care, support and comfort of a patient undergoing a radiological procedure. Carers and comforters are subject to medical exposure, whereas a casual acquaintance visiting a patient who has undergone radionuclide therapy would be considered a member of the public and hence subject to public exposure. More extensive guidance is provided in each of the specialty Sections 3 - 5.

2.6. Unintended and accidental medical exposures are covered in detail in Sections 3-5. Such events include the exposure of the wrong person¹.

APPLICATION OF THE RADIATION PROTECTION REQUIREMENTS

2.7. The three general principles of radiation protection, justification, optimization of protection and safety and the application of dose limits, are expressed in safety principles 4, 5, 6 and 10 of the Fundamental Safety Principles [2]. In terms of Requirement 1 of the BSS, those responsible for protection and safety must ensure that the relevant requirements applying these principles are met.

2.8. Medical exposure differs from occupational and public exposure in that persons (primarily patients) are deliberately, directly, and knowingly exposed to radiation for their benefit. In medical exposures applying a 'dose limit' is inappropriate as it may limit the benefit for the patient; consequently, only two of the radiation protection principles apply – justification and optimization. Justification plays the role of gatekeeper, as it will determine whether the exposure will take place or not. If it is to take place, the radiological procedure should be performed in such a way that the radiation protection and safety is optimized.

TABLE 1. SUMMARY OF RADIATION PROTECTION PRINCIPLES AS APPLIED TO OCCUPATIONAL AND PUBLIC EXPOSURES IN COMPARISON WITH MEDICAL EXPOSURE

Application to occupational and public exposure	Application to medical exposure
Justification of practices: A practice that entails	Justification: The diagnostic or therapeutic benefits
exposure to radiation should only be adopted if it	produced by exposures are weighed against the
yields sufficient benefit to the exposed individuals or	radiation detriment they might cause, taking into
to society to outweigh the radiation detriment.	account the benefits and risks of available alternative
	techniques that do not involve medical exposure.

¹ The definition of medical exposure in the BSS [3] was changed from the previous edition to ensure that the event of the 'wrong person' is kept within the radiation protection and safety framework for medical exposure so that it can be investigated by the appropriate people, with corrective actions to minimize recurrence.

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 be as low as reasonably achievable, economic and social factors being taken into account. Optimization of protection and safety: In diagnostic and interventional medical exposure, keeping the exposure of patients to the minimum necessary to achieve the required diagnostic or interventional objective.

In therapeutic medical exposure, keeping the exposure of normal tissue as low as reasonably achievable consistent with delivering the required dose to the planning target volume.

Limitation of doses: Doses to individuals are limited (for occupational and public exposure).

Limitation of doses: Not applicable to medical exposure.

Justification

2.9. Justification in medical uses of ionizing radiation involves consideration of all three categories of exposure – medical, occupational and public exposure.

2.10. From an occupational and public exposure perspective, the practice should be justified. This aspect of justification is the process of determining whether the use of the given radiological procedure is expected to yield benefits to the individuals that undergo the procedure and to society that outweigh the harm (including radiation detriment) resulting from the procedure. In almost all cases the occupational and public considerations in justification are overshadowed by the justification of medical exposures (see para. 2.11). While medical radiological procedure is expected to do more good than harm to the patient, subsidiary account should be taken of the radiation detriment from the exposure of the radiological staff and of other individuals.

2.11. The application of the justification principle to medical exposures requires a special approach, using three levels. As an overarching justification of medical exposures, it is accepted that the proper use of radiation in medicine does more good than harm (level 1). At the second level generic justification of a given radiological procedure should be carried out by the health authority in conjunction with appropriate professional bodies,. The possibility of accidental or unintended exposures should also be considered at this level. This applies to the justification of new technologies and techniques as they evolve, but the decisions should be reviewed from time to time, as more information becomes available about the risks and effectiveness of the existing procedure and about new procedures. For the final level of justification (level 3), the application of the radiological procedure to a given individual should be considered. The specific objectives of the exposure, the clinical circumstances and the characteristics of the individual involved should be taken into account. National or international referral guidelines, developed by professional bodies together with health authorities, should be used (BSS paragraph 3.158). Those radiological procedures that are not justified should be eliminated. The approach to implementing of justification of a procedure for an individual patient (level 3) depends on whether it is a diagnostic procedure, an image guided intervention, or a treatment. Specific guidance on justification in each specialty is given in Sections 3 to 5.

2.12. The level 3 justification of medical exposure for an individual patient does not include considerations of occupational exposure. If the proposed radiological procedure is justified for that

patient, then the participation of particular staff in performing the procedure is governed by the requirements for optimization of occupational radiation protection and safety and occupational dose limitation.

Optimization of protection and safety

2.13. The optimization of protection and safety, when applied to the exposure of workers and of members of the public, and of 'carers and comforters' of patients undergoing radiological procedures, is a process for ensuring that the magnitude and likelihood of exposures and the number of individuals exposed are as low as reasonably achievable, with economic, societal and environmental factors taken into account. This means that the level of protection and safety would be the best possible under the prevailing circumstances.

2.14. As is the case with justification, the application of the requirements for optimization to the medical exposure of patients and to that of volunteers as part of a programme of biomedical research requires a special approach. Too low a radiation dose could be as bad as too high a radiation dose, in that the consequence could be that a cancer is not cured or the images taken are not of suitable diagnostic quality. The medical exposure should always lead to the required clinical outcome.

2.15. Optimization is a prospective and iterative process that requires judgements to be made using both qualitative and quantitative information. Specialty specific guidance on optimization of medical, occupational and public radiation protection and safety is given in Sections 3 to 5.

2.16. Dose constraints are applicable to occupational exposure and to public exposure in medical uses of ionizing radiation. Dose constraints are also used in optimization of protection and safety for 'carers and comforters' and for volunteers subject to exposure as part of a programme of biomedical research. Dose constraints are not applicable to the exposure of patients in radiological procedures for the purposes of medical diagnosis or treatment. See also paras. 2.46 to 2.50. Dose constraints are used, in the planning stage, for optimization of protection and safety, the intended outcome of which is that all exposures are controlled to levels that are as low as reasonably achievable (ALARA), economic, societal and environmental factors being taken into account.

2.17. The dose constraint for each particular source of radiation exposure is intended, among other things, to ensure that the sum of doses from planned operations for all sources under control remains within the dose limits. Dose constraints are not dose limits; exceeding a dose constraint does not represent non-compliance with regulatory requirements, but it might result in follow-up actions.

2.18. In X ray medical imaging, image guided interventional procedures and diagnostic nuclear medicine, diagnostic reference levels (DRLs) are a tool used in optimization of protection and safety. Periodic assessments are to be performed of typical patient doses or, for radiopharmaceuticals, activities administered in a medical radiation facility. Doses in this context may be expressed in one of the accepted dosimetric quantities as described in para 2.40 [8 - 10]. For simplicity sake in this Safety Guide in Sections 3 and 4, the term "dose" will be used when referring generally to medical exposure measurements in radiological imaging, with specific forms of dose or activity used where needed.

2.19. If comparison with established diagnostic reference levels shows that the typical patient doses or activities are either unusually high or unusually low, a local review is to be initiated to ascertain whether protection and safety has been optimized and whether any corrective action is required. DRLs are not dose limits. See also paras. 2.34 to 2.45.

2.20. Other tools used in optimization of protection and safety include, *inter alia*, design and operational considerations and programmes of quality assurance. These are described in detail in the specialty Sections 3 to 5.

Dose limits

2.21. Dose limits apply to occupational exposure and public exposure arising from any use of ionizing radiation, including medical applications. Schedule III of the BSS [3] sets out these dose limits and they are reproduced here for convenience in Table 2. Dose limits do not apply to medical exposure – i.e. exposure of patients, carers or comforters, and volunteers as part of a programme of biomedical research.

2.22. The occupational dose limit for the lens of the eye is lower in the BSS [3] than previously recommended. There are some areas of medical uses of ionizing radiation, such as image guided interventional procedures, where, if good radiation protection practice is not being followed, there is a possibility of exceeding this dose limit. Specific guidance is given in the specialty Sections 3 to 5.

TABLE 2. DOSE LIMITS FOR PLANNED EXPOSURE SITUATIONS (ADAPTED FROMSCHEDULE III OF THE BSS [3])

OCCUPATIONAL EXPOSURE

For occupational exposure of workers over the age of 18 years, the dose limits are:

- (a) An effective dose of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years), and of 50 mSv in any single year;
- (b) An equivalent dose to the lens of the eye of 20 mSv per year averaged over 5 consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;
- (c) An equivalent dose to the extremities (hands and feet) or the skin of 500 mSv in a year.

Additional restrictions apply to occupational exposure for a female worker who has notified pregnancy or is breast-feeding (BSS para. 3.114).

For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are:

- (a) An effective dose of 6 mSv in a year;
- (b) An equivalent dose to the lens of the eye of 20 mSv in a year;
- (c) An equivalent dose to the extremities (hands and feet) or the skin of 150 mSv in a year.

PUBLIC EXPOSURE

For public exposure, the dose limits are:

- (a) An effective dose of 1 mSv in a year;
- (b) In special circumstances, a higher value of effective dose in a single year could apply, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year;
- (c) An equivalent dose to the lens of the eye of 15 mSv in a year;
- (d) An equivalent dose to the skin of 50 mSv in a year.

GRADED APPROACH

2.23. The so-called 'graded approach' is a concept that underpins the application of the system for protection and safety. The BSS in paragraph 2.12 states: "The application of the requirements for the system of protection and safety shall be commensurate with the radiation risks associated with the exposure situation."

2.24. The risks associated with medical uses of ionizing radiation vary significantly, depending strongly on the particular radiological procedure. At the low risk end are dental exposures (excluding cone beam CT), and dedicated bone densitometry (DEXA) studies. At the high risk end is radiation therapy, where the doses involved could be lethal, and image guided interventional procedures, where radiation injuries can occur. Another aspect to consider when implementing a graded approach is the prevalence of a given application – an example is CT, which is increasingly used in imaging.

2.25. The BSS places responsibilities for a graded approach on each of the government, the regulatory body, registrants and licensees, and employers. The government and the regulatory body use the graded approach in setting and enforcing regulatory requirements. For example, it would be expected that regulatory bodies devote fewer resources and less time to regulating dental practices than to regulating the use of radiation in radiation therapy or image guided interventional procedures.

2.26. The registrants or licensees, and employers use the graded approach in the measures they take for protection and safety. For example, the registrant or licensee of a dental practice would not need to implement as comprehensive a quality assurance programme as would a radiation therapy facility in order to meet the requirements of the BSS.

2.27. Guidance incorporating the graded approach is given in the specific guidance for each specialty and the various modalities within those specialties – see Sections 3 to 5.

ROLES AND RESPONSIBILITIES

Government

General

2.28. The roles and responsibilities of the government² with regard to protection and safety are set out in requirement 2 and paragraphs 2.13 to 2.28 of the BSS, with further detailed requirements given in the IAEA Safety Requirements publication "Governmental, Legal and Regulatory Framework for Safety" [10]. These include:

- establishing an effective legal and regulatory framework for protection and safety for all exposure situations;
- establishing legislation that meets specified requirements;
- establishing an independent regulatory body with the necessary legal authority, competence and resources;
- establishing requirements for education and training in protection and safety;

² States have different legal structures, and therefore the term 'government' as used in the IAEA safety standards is to be understood in a broad sense, and is accordingly interchangeable here with the term 'State'.

- ensuring that arrangements are in place for:
 - the provision of technical services (including radiation monitoring services and standards dosimetry laboratories), and
 - education and training services.

All of these are relevant to the safe use of ionizing radiation in medicine.

2.29. As noted above in para. 1.7, this Safety Guide assumes that an effective governmental, legal and regulatory infrastructure for radiation protection and safety is in place. However there are some additional considerations that are important for ensuring radiation protection and safety in medical uses of ionizing radiation.

2.30. Government has a role to facilitate and ensure that the health authority, the relevant professional bodies, and the radiation protection regulatory body communicate and cooperate in working towards establishing the infrastructure necessary for radiation protection and safety in medical uses of ionizing radiation. The role of the health authority typically includes determining policy, which in turn may dictate the resources allocated to the various areas of healthcare, including medical uses of ionizing radiation. Up to date information on developments in medical uses of ionizing radiation, and how that might shape and influence medical practice, should be available so that appropriate policy can be developed and implemented. The professional bodies of the various health professionals associated with radiation in healthcare represent the collective expertise of the given health profession and, as such, can strongly influence the practice of radiation protection and safety. The health authority and the professional bodies should be active working partners with the radiation protection regulatory body to achieve effective regulation of medical uses of ionizing radiation. See paras. 2.52 - 2.68 for more guidance on the health authority and professional bodies.

2.31. Formal recognition of health professionals should be in place to ensure that only persons with the appropriate competencies are allowed to take on particular roles and responsibilities. In medical uses of ionizing radiation, this applies in particular to persons undertaking the role of radiological medical practitioner, medical radiation technologist, or medical physicist. Detailed guidance is given in the sub-section on education, training, qualifications and competence, paras 2.117 to 2.135.

2.32. Other organizations can make a worthwhile contribution to radiation protection and safety in medical uses of ionizing radiation. These include technical standards associations, medical devices regulatory agencies, and health technology assessment agencies, which issue standards or reports that could have direct implications for radiation safety. Not all States have such organizations but, where they exist, the government should ensure that they interact cooperatively with the radiation protection regulatory body, the health authority and the relevant professional bodies. In States that do not have such organizations, the government should consider means to adopt or adapt relevant standards or reports from such organizations in other countries.

2.33. Other organizations can have an indirect, but not necessarily insignificant, effect on radiation protection and safety in medical uses of ionizing radiation. Such organizations include health insurance or re-imbursement companies and standards accreditation bodies. The former, by deciding on what radiological procedures (and other alternative techniques) are covered. The latter, by including radiation protection and safety in its scope, can positively influence how well radiation protection and safety is being implemented in medical facilities seeking accreditation. Again, government should be aware of these players in their country and utilize their influence to improve the practice of radiation protection and safety in medical uses of ionizing radiation.

Diagnostic reference levels

2.34. Diagnostic reference level (DRL) should be used as an important tool for optimization of protection and safety for diagnostic medical exposures , (see para. 2.18). Government has a particular responsibility to ensure that DRLs are established for their country, or regions within their country or, in some cases, regions of several small countries. In establishing values for the DRLs it is preferable that, for common imaging procedures, typical (e.g. average or median) doses³ for patients are obtained from a representative sample of rooms and facilities where these procedures are being performed. In this way a snap shot of current practice in the country or region is obtained, reflecting both good and poor practices, for that particular imaging procedure. The value of the DRL for that particular procedure is typically the rounded 75th percentile of the distribution of the room/facility typical doses [12, 13]. In diagnostic nuclear medicine, an 'optimum' value for a DRL is used also instead of a percentile: a reference level for administrations of activities of radionuclides sufficient to obtain information for standard groups of patients (adults and children), based on the experience of the professional groups ('expert judgement') [12]. In establishing DRLs, it is fundamental to include only radiological procedures whose image quality is adequate for the medical purpose.

2.35. Once established, medical radiation facilities should compare their typical doses (sometimes called "facility reference levels", or "local reference levels") with the relevant DRLs, as described in Sections 3 and 4. Optimization of protection for a particular radiological procedure should be reviewed if the comparison shows that the facility's typical dose exceeds the DRL, or that the facility's typical dose is substantially below the DRL and it is evident that the exposures are not producing images of diagnostic usefulness or are not yielding the expected medical benefit to the patient. The resulting actions aimed to improve optimization of protection and safety will usually, but not necessarily, result in a lower facility typical doses for the procedure or procedures. At some predetermined interval, typically 3 to 5 years, there should be a review of the established national or regional DRL values. A new national or regional survey will result in a new distribution of facility reference levels that will reflect the improvements made as a result of using the existing DRLs. It is likely that the new values of the DRLs will be lower than the previous values. This cycle of establishment of national or regional DRLs, use by imaging facilities, corrective actions by imaging facilities, and periodic review of national or regional DRLs brings about a steady improvement in optimization of protection and safety across the country or region.

2.36. There are several steps to the establishment of DRLs. At the national or regional level decisions should be made whether to use actual patients or phantoms to represent a "standard patient" for each modality. Phantoms avoid most of the issues with variations in patient size (see paras. 2.38 and 2.41). However their use does not truly represent clinical practice with patients and clinical images and, as such, would seem less appropriate for use in establishing DRLs. Nevertheless, a phantom-based approach, in the absence of adequate patient data, can be used to first establish DRLs and then in their utilization [14].

2.37. The imaging procedures, for which DRLs are to be established, should be decided upon at national or regional level. The criteria which may help in this decision are the relative frequencies and the magnitude of the doses of the imaging procedures – the more frequent and higher dose procedures should have a higher priority. Specific consideration should be given to paediatric imaging. Based on

³ The term 'doses' in this subsection on DRLs includes activity for nuclear medicine procedures, as described in para 2.18.

national or regional resources, the actual number of procedures for which DRLs are established will vary [15, 16].

2.38. The next step is to perform preferably a wide-spread or at least a representative survey for the selected procedures. Most imaging radiological procedures are performed on adults, and traditionally national DRLs have been established first for adults. For each room/facility performing the given procedure, typically a sample size of about 20 patients is used. Not all adults are the same size, so many countries [12, 13] have established DRLs for an "standard" adult patient, limiting patient eligibility to the sample on the basis of weight, for example 70 kg \pm 20 kg, and aiming for a sample average in a given weight range, for example 70 kg \pm 5 kg. Other countries adopt a more pragmatic approach, accepting all adults in the initial sample but excluding extreme outliers in terms of weight [17].

2.39. Another consideration with DRLs is whether the procedure is simply defined in terms of the anatomical region being imaged, or whether there should be a further refinement to include the clinical purpose of the examination. For example, a CT of the abdomen may be performed differently depending on the medical question to be answered. For those embarking on establishing DRLs for the first time, it is advisable to take the simpler approach.

2.40. The dose metrics used to represent the dose to the patient should be easily measurable and must follow ICRU recommendations, as stated in the BSS (BSS para 1.46) [8]. The following are commonly used terms in this role: radiography – air kerma-area product, incident air kerma, or entrance surface air kerma (which includes backscatter); fluoroscopy – air kerma-area product; CT – CTDI_{vol}, and DLP; mammography – incident air kerma or entrance surface air kerma and mean glandular dose; dentistry – incident air kerma or entrance surface air kerma and mean glandular dose; dentistry – incident air kerma or entrance surface air kerma for intra-oral radiography and air kerma-area product for panoramic radiography; and image guided interventional procedures – air kerma-area product and air kerma at the interventional reference point. More guidance on dose metrics is given in Section 3 paras 3.193 - 3.195. It is crucial that the dose data collected for each contributing room is for procedures where the image quality was confirmed as adequate for the clinical purpose. For nuclear medicine DRLs are set in activity administered to patient.

2.41. Optimizing protection and safety for average adult patients does not necessarily mean that optimization is being achieved for other size or age groups. Past experience in particular with children undergoing CT examinations has clearly demonstrated that this is not the case. This means that consideration also should be given to establishing DRLs for children undergoing imaging procedures. The same problem of size and weight, as discussed in para. 2.38, also pertains to children. Some countries have adopted a simple age approach – for example, new born, 1, 5, 10, and 15 years – while others normalize patient dose data to particular representative sizes or weights. More guidance on grouping patient for establishing typical doses and DRL is given in Section 3 para 3.204 for diagnostic and interventional radiology and Section 4 para 4.203 for diagnostic nuclear medicine.

2.42. The processes and steps towards establishing DRLs, as described in paras. 2.37 to 2.41, are likely to involve many players including the imaging facilities, the health authority, the professional bodies, and the regulatory body. In particular there should be collective ownership of the DRLs – deciding on: what procedures, what age groups, how to collect the data, who will manage the data, and when to review and update the DRLs. In some countries a national governmental body administers the national patient dose database that underpins the establishing of DRLs. In other countries, this role may be taken by the regulatory body or a professional body. There is no preferred custodian – what is important is that a patient dose database (for DRLs) is established and maintained, DRL values are set, these are promulgated through the regulatory processes, and a process for

periodic review is established. It may be more appropriate to take a regional rather than a national approach to DRLs – either a region in a large country or a region of several small countries.

2.43. The methodology used in performing the initial survey can range from a paper-based approach through to a web-based electronic submission approach. As the interconnectivity of imaging systems, with the availability of patient dose metrics, and radiology and hospital information systems improves, the process of gathering data for DRLs is likely to become easier. Countries embarking on establishing DRLs for the first time should consider the electronic approach.

2.44. The national or regional DRL values should be periodically reviewed and updated, typically with a cycle of 3 to 5 years (see para. 2.35). The review can be performed in many ways, but in all cases there is first a collection phase, followed by analysis of the data collected. The collection of facility reference levels can occur throughout the cycle, or it can be restricted to a shorter time-frame towards the end of the cycle. Pragmatically, the occasion of a medical radiation facility comparing its practice typical doses with the current DRLs would seem to be an appropriate time for the facility to submit their new facility typical doses to the national or regional database being used for the DRLs. At the end of the cycle the analysis of the submitted facility typical doses would take place, and the values of the DRLs updated accordingly. While increased digital connectivity would technically support collection and analysis to be continuous, a given set of DRL values should be stable for a period of time to allow the improvement cycle to take place.

2.45. Finally, if the government in a given country is not able to facilitate the establishment of their own national DRLs or to participate in a regional approach, there is the option for government to facilitate the adoption of another country's or region's DRLs. While such DRLs do not reflect a country's own practice, with judicious choice, the adopted DRLs can still perform the same role of bringing about an improvement in the implementation of optimization of protection and safety in the adopting country. DRLs from countries with significantly different generations of imaging systems should be compared with a care

Dose constraints

2.46. Dose constraints are not dose limits; they are tools for optimization of protection and safety, including considerations of social and economic factors. The role of dose constraints for occupational exposure and for public exposure is introduced above in para. 2.16. In particular the government, typically through the radiation protection regulatory body, has responsibilities with respect to public exposure, where its primary role is to ensure that no member of public can exceed the public dose limit as a result of cumulative public exposure arising from multiple authorized facilities, including medical radiation facilities. A simple approach that can be taken is to set a dose constraint, for public exposure arising from a single facility, at some fraction of the dose limit. Some countries use a dose constraint of approximately one-third of the dose limit – namely an effective dose of 0.3 mSv per year. In establishing such a value the regulatory body should consider the number and type of radiation sources in use in a particular country or region that may expose the public.

2.47. In addition to patients, there are two other groups of people that can incur medical exposure. These are the carers and comforters and the volunteers in biomedical research. Because it is medical exposure, neither of these groups of persons is subject to dose limits for the exposures incurred. Instead, reliance is placed on the use of dose constraints as a means for ensuring optimization of protection and safety takes place (see para. 2.16). For both of these groups of people, the government, through consultation between the health authority, the relevant professional bodies and the radiation

protection regulatory body, has the responsibility to ensure that dose constraints are established so that they can be used.

2.48. For carers and comforters the usual approach is to apply the dose constraints on an "episode by episode" basis – i.e. the dose constraint applies to the cumulative exposure of the carer and comforter over the duration of that person giving care and comfort to a particular patient. In the case of a mother assisting with her child undergoing a diagnostic X ray procedure, the episode is extremely short – simply while the X rays are being produced. In the case of a person having undergone treatment with radiopharmaceuticals, the episode will last several days until such time as the radionuclide has decayed to negligible levels. Consideration should be given to the cumulative dose of a carer or comforter if he/she acts in this role for several distinct episodes. In such cases, a dose constraint per annum may be used in addition.

2.49. In setting dose constraints for carers and comforters consideration should be given to the age of the individual and for a woman the possibility of her being pregnant. A particular issue is that of children being in this role. The definition of a carer or comforter includes that the person "willingly and voluntarily" helps in this role. It could be argued that young children may not understand such concepts. None the less, it is reasonable and likely that the children of a treated parent would want to provide comfort, at least. The framework for radiation protection and safety should accommodate such human wishes. A pragmatic approach often taken is to effectively treat children in this role as members of the public and constrain their medical exposure to an effective dose of 1 mSv per episode. A pregnant carer or comforter presents a similar situation, and consideration should be given to the embryo or fetus. The same approach of constraining the effective dose to the embryo/fetus to 1 mSv per episode is often taken. For an adult carer or comforter, a value of dose constraint smay be used. In any of these cases flexibility with respect to the dose constraint may need to be used.

2.50. In setting dose constraints for diagnostic radiological procedures that are performed on volunteers participating in a programme of biomedical research, the intention is that government, through consultation between the health authority, the relevant professional bodies and the radiation protection regulatory body, provides broad guidance for the ethics committees (see paras. 2.98 - 2.101) who, in turn, would adapt the dose constraints to suit the particular programme of biomedical research under consideration. Typical patient doses and national DRLs would be two considerations in setting such dose constraints.

Criteria and guidelines for release of patients after radionuclide therapy

2.51. Many factors can influence the exposure that members of the public and carers and comforters can incur following the release of a patient who has undergone a therapeutic procedure with unsealed sources or who retains implanted sealed sources. Detailed guidance on these factors for unsealed sources is given in the Safety Report Series No. 63 [18]. The role of government, through consultation between the health authority, the relevant professional bodies and the radiation protection regulatory body, is to ensure that criteria are established, with accompanying guidance, to help simplify the process when individual medical radiation facilities are considering the release of their patients. Guidance for these medical radiation facility actions are given in Sections 4 and 5.

Health authority

2.52. All medical facilities must be authorized by the health authority to ensure that the facility meets the applicable requirements for quality of medical services. When the medical facility uses ionizing radiation, authorization for medical practice and healthcare should be granted by the health authority only if radiation safety requirements are met (para 2.69 - 2.75). As noted in para. 2.30, the health authority should contribute to radiation protection and safety. This includes participation in establishing DRLs, dose constraints for carers and comforters and for volunteers in biomedical research, and criteria and guidance for the release of patients after radionuclide therapy. See guidance in paras. 2.34 to 2.51. Coordination and collaboration between the health authority and the radiation protection regulatory body should ensure radiation protection and overall safety of the medical facility.

2.53. Radiation protection and safety in medical uses of ionizing radiation should be assured by a proper specialization of health professionals – namely that only health professionals with the appropriate competencies can take on roles that include specific responsibilities for radiation protection and safety. The health authority has responsibilities in providing policy and guidance with respect to health profession specialties and their sub-specialties, including scope of practice, and requirements for competence. Guidance on recognition of competence in a specialty is given paras. 2.117 to 2.130.

2.54. Adequate numbers of medical personnel and paramedical personnel should be available for a medical radiation facility to function correctly and safely. This includes sufficient capacity to cover absences of key personnel through sickness, leave or other official reasons. The health authority, through its policy making role, should set clear standards for acceptable medical practice.

2.55. The health authority has particular roles in the application of the radiation protection requirements for justification – namely with respect to:

- generic justification of radiological procedures;
- justification of radiological procedures in health screening programmes; and
- criteria for the justification of radiological procedures for health assessment of asymptomatic individuals intended for the early detection of disease, but not as part of a health screening programme.

2.56. Generic justification of radiological procedures is an on-going process as new procedures become available and as established procedures should be reviewed in the light of new knowledge and developments. It should be decided whether a new radiological procedure should become a new addition to the armamentarium of existing procedures. Conversely, an existing radiological procedure may need to be withdrawn from use because there is evidence that an alternative technique has better efficacy. The health authority, together with relevant professional bodies, should make these decisions.

2.57. The use of radiological procedures as part of a health screening programme involves subjecting asymptomatic populations to radiation exposure. The decision to embark upon such a programme should include consideration of, *inter alia*, the potential of the screening procedure to detect the disease, the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease. Sound epidemiological evidence should provide the basis for such health screening programmes. The health authority, together with relevant professional bodies, should consider all the factors before making a decision.

2.58. The use of radiological procedures on asymptomatic individuals, intended for the early detection of disease but not as part of an approved health screening programme, is now increasingly common. Such radiological procedures are not established medical practice, nor are they being performed as part of a programme of biomedical research. Therefore the health authority, together with relevant professional bodies, has a role in providing guidance on the applicability and appropriateness of such procedures. Such guidance would help the referring medical practitioner and the radiological medical practitioner carry out the justification for an individual patient (see Section 3, paras. 3.135 to 3.137).

2.59. National or international referral guidelines should be used as an important tool in the implementation of justification of medical exposure for an individual patient. The health authority should support the relevant professional bodies in developing and implementing such referral guidelines. See also para. 2.65.

2.60. The health authority should also encourage the development of and promote the implementation of practice guidelines and technical standards⁴ developed by professional bodies.

Professional bodies

2.61. Professional bodies are the collective term used in the BSS and in this Safety Guide to include the various organizations and entities of health professionals within a given State. These include societies, colleges, and associations of health professionals often within a particular specialty. Examples, with direct involvement in the use of ionizing radiation, include representation of radiologists, radiation oncologists, nuclear medicine physicians, medical physicists, medical radiation technologists, and dentists. In large countries, such professional bodies may be regional, within the country. Conversely, there may be regional professional bodies covering several countries. There are also professional bodies in the wider medical arena that still influence some aspects of radiation use. Examples of these include societies, associations and colleges representing specialties such as cardiology, gastroenterology, urology, and neurology, who may use radiation, and other organizations, such as those that represent general practitioners and primary care physicians.

2.62. Professional bodies, as stated in para. 2.30, represent the collective expertise of the given health profession and specialty and, as such, they also should play a role in contributing to radiation protection and safety in medical uses of ionizing radiation. This includes setting standards for education, training, qualifications and competence for a given specialty, and setting technical standards and giving guidance on practice. Further guidance on education, training, qualifications and competence is given in paras. 2.117 to 2.130.

2.63. Relevant professional bodies, in partnership with the health authority and the radiation protection regulatory body, have a role with respect to the establishment of DRLs, dose constraints for carers and comforters and for volunteers in biomedical research, and criteria and guidance for the release of patients after radionuclide therapy, as has been described in paras. 2.42, 2.47, 2.50, and 2.51, respectively.

2.64. The role of the relevant professional bodies with respect to the application of the requirements for justification is described in paras. 2.56 - 2.60.

⁴ The term "practice guidelines and technical standards" is used to represent the range of documents, statements and other publications produced by professional bodies to help educate and guide the respective health professionals to carry out particular aspects of their specialty.

2.65. Professional bodies should take the lead in the development of referral guidelines and appropriateness criteria for use in justification of medical exposure for an individual patient (para 2.59). It may not be possible for every State to develop its own referral guidelines. The significant work of a number of professional bodies around the world could be utilized in many other countries through adoption or adaption by the local professional bodies. See also Section 3 para 3.137 and Section 4 para 4.159.

2.66. With respect to medical imaging, the process of optimization of radiation protection and safety should aim at achieving adequate image quality – not the best possible image quality, but certainly sufficient to ensure that diagnosis or treatment is not compromised. From an operational perspective, there are many factors that influence the image quality versus patient dose relationship for a given procedure. Having standards or norms that specify acceptable image quality is clearly advantageous, and relevant professional bodies have a responsibility in this respect.

2.67. For the implementation of optimization of radiation protection and safety a comprehensive quality assurance programme for medical exposures should be established. As is elaborated elsewhere (para. 2.138), such quality assurance programmes are part of the wider quality management system of the medical radiation facility. Nonetheless, there is considerable benefit in making use of resource material and standards established by professional bodies for particular areas of the programme. For example, many medical physics professional bodies have developed detailed guidance on performance testing aspects of a quality assurance programme. Where such material or standards are lacking in a State, the relevant professional body could adopt or adapt such resources from outside the State.

2. 68. Professional bodies can play a proactive role by encouraging their members to contribute to relevant international or national anonymous and voluntary safety reporting and learning systems, and by contributing to developing of such systems. The large catchment of such databases provides a wealth of information that is educative in helping to minimize unintended and accidental medical exposures. Three such international safety reporting systems are the IAEA's Safety Reporting and Learning System for Radiotherapy, SAFRON [19], and Safety in Radiological Procedures, SAFRAD [20], and the Radiation Oncology Safety Information System (ROSIS) [21].

Regulatory body

2.69. The radiation protection regulatory body must fulfil its regulatory functions, such as establishing requirements and guidelines, authorizing and inspecting facilities and activities, and enforcing legislative and regulatory provisions. Detailed requirements specifying these roles and responsibilities are given in the BSS [3] and in GSR Part 1 [11], and further general guidance in Safety Guide GS-G-1.5 [22]. Guidance on general regulatory body roles and responsibilities with respect to occupational radiation protection and radiation protection of the public are given in the two general safety guides [23, 24]. An pre-requisite for the regulatory body being able to perform its regulatory functions effectively is having staff with appropriate specialist expertise. This is covered in detail in the IAEA Safety Standards [3, 11, 22], but should be emphasized in the context of medical uses of ionizing radiation, where on the one hand persons are being deliberately exposed to radiation and, on the other, health outcome depends on the applicability, availability and use of radiation. The regulatory controls should be applied knowledgeably, and not just as an administrative exercise.

Authorization of medical radiation facilities

2.70. The graded approach to medical uses of ionizing radiation has particular significance for regulatory bodies because, as described in paras. 2.23 to 2.27, there is a wide variation in the complexity of medical radiation facilities. Regulatory bodies should consider what form of authorization is appropriate for a given type of medical radiation facility. Coupled with the type of authorization is the level of complexity in the documentation that should be submitted to the regulatory body prior to the authorization. This includes the degree of detail in the safety assessment (see paras. 2.148 - 2.152). The duration of an authorization is another consideration for the regulatory body – the more complex facilities would warrant a more frequent renewal process.

2.71. Typical 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. These conditions are generally not met in medical uses of ionizing radiation for the following three reasons: patient exposure depends on human performance; radiation protection and safety is not largely ensured by design; and the training required is significant. Medical radiation facilities are, in principle, better candidates for individualized licensing than for registration. It would be expected that licensing would be used for radiation therapy facilities, nuclear medicine facilities, facilities. For some simple forms of diagnostic radiology, such as dental radiography (without cone beam CT) and DEXA, registration may be acceptable. For both forms of authorization, the regulatory body should have standardized forms or templates that help ensure that the correct information is submitted to the regulatory body. See also the paragraphs on safety assessments, paras 2.148 - 2.152.

2.72. No matter what form of authorization is used for a medical radiation facility, a crucial step prior to the granting of the authorization is that the regulatory body ascertains the credentials of key personnel with responsibilities for radiation protection and safety – including the radiological medical practitioners, the medical radiation technologists, the medical physicists and the radiation protection officer. This step cannot be over-emphasized as all aspects of radiation protection and safety in medical uses of ionizing radiation depend ultimately on the competence of the persons involved. See also paras. 2.117 - 2.130.

2.73. Setting up a medical radiation facility may involve the construction of facilities which are difficult to modify at a later time. Regulatory bodies may choose a two-stage process of authorization, i.e. to require an initial application to build a facility before construction begins. At this stage the regulatory body should review the intended medical uses of ionizing radiation, the facility's design, including structural shielding plans⁵, and the planned equipment. This is followed at a later stage by the full regulatory body review and assessment leading to the granting of the authorization. For more complex medical radiation facilities, such as a radiation therapy facility, this latter process should include an inspection by the regulatory body or authorized party.

2.74. Subsequent substantial modifications of a medical radiation facility, including its medical radiological equipment and its procedures, may have safety implications. The regulatory body may require an application for an amendment to the authorization.

⁵ Although not strictly a radiation safety issue, it is important to ensure that the building will support the weight of the structural shielding, for which it may have not been originally designed.

2.75. The regulatory body should require the renewal of an authorization after a set time interval. This allows a review of the findings of inspections and of other information on the safety performance of the medical radiation facility. The frequency of renewal should be based on radiation protection and safety criteria, with consideration given to the frequency of inspections by the regulatory body and the safety record associated with a given type of practice, in general, or with a particular medical radiation facility. A renewal cycle longer than 5 years would seem not appropriate for medical radiation facilities.

2.76. The authorization of a medical radiation facility to use ionizing radiation for medical purposes is a separate exercise to that of the same facility, or the wider medical facility of which it is part, being authorized by the health authority to carry out medicine practice and healthcare (para 2.52). Radiation safety requirements are only a set of requirements before authorization is granted to a medical facility by the health authority. Meeting radiation safety requirements is a condition necessary but not sufficient to obtain an authorization to practice medicine. Coordination and collaboration between the radiation protection regulatory body and the health authority should be in place to ensure radiation protection and overall safety of the medical facility.

Inspection of medical radiation facilities

2.77. On-site inspection by the regulatory body is often the principal means for face-to-face contact with personnel in the medical radiation facility. The regulatory body should have established a system for prioritization and frequency of inspections, based on the risk and complexity associated with the particular medical uses of ionizing radiation. The regulatory body inspection of medical radiation facilities should be performed by staff with the specialist expertise to be able to competently assess the compliance of the facility with the radiation protection regulations and authorization conditions. For further detailed general guidance on inspections see GS-G-1.5 [22].

Particular considerations for the regulatory body with respect to medical, occupational and public exposure

2.78. The regulatory body should ensure that all the BSS requirements with respect to medical, occupational and public exposure are implemented in authorized medical radiation facilities, as described in detail in the relevant subsections of the specialty Sections 3 to 5. To help medical radiation facilities fulfil their obligations, there are some particular areas where the regulatory body should provide specific guidance.

2.79. Calibration of sources that give rise to medical exposure should be in place to ensure radiation safety in medical uses of ionizing radiation, as set out in the BSS paragraph 3.167, and detailed guidance is given in Sections 3 to 5. The regulatory body should specify frequencies for re-calibrations and, in doing so, should make use of applicable guidance given by medical physics professional bodies.

2.80. In the case of the calibration of radiation therapy units, independent verification prior to clinical use should be assured (BSS para. 3.167(c)). The regulatory body should be aware of the limitations on local resources in their State. The ideal independent verification, by different independent medical physicist using different dosimetry equipment, may not be realizable. The regulatory body has the responsibility of not allowing the radiation safety of the radiation therapy unit to be compromised but at the same time not to unnecessarily close down the facility. The regulatory body should decide on acceptable alternatives, such as verification by a second medical physicist with the same equipment or only verification using a second set of equipment, or using a form of verification by postal thermoluminescence, optically stimulated luminescence dosimetry or equivalent.

2.81. Unintended and accidental medical exposures do occur and the regulatory body should require that a system is in place and all practical measures are taken to prevent them, and, if such exposure happens, it is properly investigated and corrective actions are implemented. Arrangements should be in place to respond promptly in order to mitigate any consequences. The regulatory body should require written records to be kept of all unintended and accidental medical exposures and should provide guidelines on what information to be included in these reports. The more significant events should be reported to the regulatory body, (BSS para. 3.181(d)). The regulatory body should provide guidance on what events must be reported to them. One of the reasons for reporting to the regulatory body, in turn, to disseminate information on the event to relevant parties so that the recurrence of similar events is minimized. In addition to mandatory reporting for regulatory purposes, anonymous and voluntary safety reporting and learning systems can significantly contribute to enhance radiation facilities to participate in relevant international or national anonymous and voluntary safety reporting as discussed in para 2.68. Further guidance on this topic is given in the specialty Sections 3 to 5.

2.82. With respect to occupational exposure assessment, the regulatory body should set requirements and provide clear guidance on what form of monitoring should be in place. The BSS (BSS [3], paragraphs 3.99 to 3.102) requires the employers, registrants and licensees to make arrangements for occupational exposure assessment, and in the requirements gives broad criteria for when individual monitoring should be arranged and when workplace monitoring may be sufficient. Occupational exposures vary widely in medical uses of ionizing radiation, ranging from those uses where it is quite clear that individual monitoring should be undertaken, to those uses where workplace monitoring would suffice. It is where uses fall between these two situations that specific direction should be provided from the regulatory body. Further guidance on this topic is given in the specialty Sections 3 to 5.

2.83. The regulatory body has a role as custodian of public radiation protection. Because a member of the public can be subject to exposure arising from any number of authorized medical radiation facilities (or indeed other facilities and activities using radiation), the regulatory body has an oversight role to ensure that the sum or cumulative effect of these multiple pathways does not lead to public exposure greater than the dose limits (see Table 2). Part of this role includes the setting of dose constraints and ensuring that safety assessments include considerations of public and potential public exposure.

2.84. The BSS has many requirements for registrants and licensees, and employers with respect to occupational radiation protection, to maintain and make available records on a wide range of matters. For records pertaining to occupational exposure, the BSS specifies how long such records should be maintained, namely to at least until the worker attains the age of 75 years and for not less than 30 years after cessation of work in which the worker was subject to occupational exposure (BSS, para. 3.104). For all other records, the period for which they should be maintained is deferred to the State's regulatory body. The period of retention will depend on the type of record and its usefulness or relevance after the passage of time. Records relating to a person's health or healthcare arguably should be kept for that persons' lifetime, but there are significant variations around the world. Some States, for example, require medical records to be kept for the lifetime plus 10 years; others require a much shorter period such as 7 to 10 years. Records for activities such as calibrations, dosimetry, quality assurance and investigations of accidents and unintended medical exposures should be kept for a significant period as there is always the possibility that the records will be needed to perform retrospective assessments of medical, occupational or public exposure. A retention period of at least

10 years is recommended for these records. On the other hand, records on personnel education, training, qualification and competence may be of relevance only when that person is working at the medical radiation facility. Further guidance for the regulatory body and for registrants, licensees and employers is given in the IAEA Safety Guide on management systems [25].

Authorization for the installation, maintenance and servicing of medical radiological equipment

2.85. The regulatory body should ensure that persons who install, maintain or service medical radiological equipment are appropriately authorized. See also the sub-sections on responsibilities for suppliers of sources, equipment and software, and for maintenance and servicing organizations, and the guidance on education, training, qualification and competence of servicing engineers and technicians given in para. 2.133.

Authorization of other practices related to medical uses of ionizing radiation

2.86. The regulatory body may also require authorization for other activities related to medical uses of ionizing radiation, including: import, distribution, assembly, sale, transfer or transport of radioactive sources or medical radiological equipment; decommissioning; disposal of radioactive sources, material or waste. The requirements to carry out these practices should have been established by regulations complemented by regulatory guidance documents.

Dissemination of information

2.87. The BSS (BSS [3], paragraph 2.38) requires that the regulatory body has mechanisms in place for the timely dissemination of information - in the context of this Safety Guide - to medical radiation facilities, manufacturers and suppliers, the health authority and professional bodies, on lessons learned for radiation protection and safety resulting from regulatory experience and operating experience, and from incidents and accidents and related findings. Information should be exchanged through the publication of newsletters (paper based or electronic) and the periodic mailing of notices, by presentations at scientific and professional association meetings, by establishing a web site, or by cosponsoring educational seminars and workshops with professional and scientific associations. More rapid actions should be considered in response to actual or potential problems that may result in significant consequences.

Medical radiation facility

2.88. In medical uses of ionizing radiation, the prime responsibility for radiation protection and safety rests with the person or organization responsible for the medical radiation facility – normally referred to as the registrant or licensee. Almost all the requirements in the BSS applicable to a medical radiation facility for ensuring radiation safety in medical uses of ionizing radiation place the responsibility on the registrant or licensee (and on the employer, in the case of occupational radiation protection).

2.89. However medical uses of ionizing radiation involve a multidisciplinary team led by a health professional who often is not the registrant or licensee of the authorized medical radiation facility. Because of the medical setting in which such exposures occur, primary responsibility for radiation protection and safety for patients lies with the health professional responsible for the radiological procedure, who is referred to in the BSS and in this Safety Guide as the 'radiological medical practitioner'. The radiological medical practitioner is the generic term that the BSS uses to refer to a health professional with specialist education and training in medical uses of radiation, who is competent to perform independently or to oversee procedures involving medical exposure in a given specialty. Health professionals that could take on the role of the radiological medical practitioner,

depending on the particular use of radiation and on the laws and regulations in a State, include radiologists, nuclear medicine physicians, radiation oncologists, cardiologists, orthopaedic surgeons, other specialist physicians, dentists, chiropractors and podiatrists. More guidance on the health professionals who could be radiological medical practitioners is given in the specialty Sections 3 to 5. See also paras 2.122 - 2.123 on education and training.

2.90. The net effect of paras. 2.88 and 2.89 is that, for medical exposures, the registrant or licensee must ensure all requirements are implemented. This normally requires that the radiological medical practitioner ensures a given set of actions takes place, usually with the involvement of further health professionals – mainly medical radiation technologists and medical physicists (see paras. 2.91 and 2.92, respectively). The medical exposure sub-sections of the specialty Sections give guidance on the many requirements that come under the responsibility of the radiological medical practitioner.

2.91. The term medical radiation technologist is used in the BSS and this Safety Guide as the generic term for a second group of health professionals. A wide variety of terms are used throughout the world such as radiographer, radiological technologist, nuclear medicine technologist, and radiation therapist. In the BSS, a medical radiation technology, competent to carry out radiological procedures, on delegation from the radiological medical practitioner, in one of more of the specialities of medical radiation technology (e.g. diagnostic radiology, radiation therapy, nuclear medicine). The medical radiation technologist is usually the interface between the radiological medical practitioner and the patient, and his/her skill and care in the choice of techniques and parameters determines to a large extent the practical realization of the optimization of radiation protection and safety for a given patient's exposure in many modalities. More guidance on the roles and responsibilities of medical radiation technologists is given in the specialty Sections 3 to 5. See also paras 2.124 - 2.125 on education and training.

2.92. In the BSS, a medical physicist is a health professional with specialist education and training in the concepts and techniques of applying physics in medicine, and competent to practise independently in one or more of the subfields (specialties) of medical physics, (e.g. diagnostic radiology, radiation therapy, nuclear medicine). The medical physicist provides specialist expertise with respect to radiation protection of the patient. The medical physicist has responsibilities in the implementation of the optimization of radiation protection and safety in medical exposures, including source calibration, clinical dosimetry, image quality and patient dose assessment, and physical aspects of the quality assurance programme, including medical radiological equipment acceptance and commissioning. The medical physicist is also likely to have responsibilities in providing radiation protection and safety training for health professionals. In addition, he/she may also perform the role of the radiation protection. More guidance on the roles and responsibilities of medical physicists is given in the specialty Sections 3 to 5, and in Ref [26]. See also paras 2.126 - 2.127 on education and training.

2.93. There are other health professionals with responsibilities for radiation protection of the patient. These include, for example, radiopharmacists, radiochemists, dosimetrists and biomedical or clinical engineers. Detailed guidance is given in Sections 3 to 5.

2.94. For a medical radiation facility, the radiation protection and safety responsibilities outlined above for the radiological medical practitioner, the medical radiation technologist, the medical physicist and other health professionals with responsibilities for patient radiation protection should be assigned through an authorization (or other regulatory means) issued by the radiation protection regulatory body in that State.

2.95. The radiation protection officer (RPO) is a person technically competent in radiation protection and safety matters relevant for a given type of practice who is designated by the registrant, licensee or employer to oversee the application of relevant requirements [3]. For a medical radiation facility, the RPO oversee the application of requirements for occupational and public radiation protection, and may provide general radiation protection advice to the registrant or licensee. The RPO have no direct responsibilities or roles with respect to patient radiation protection. In many medical radiation facilities, especially smaller facilities with fewer personnel, the role of the RPO and the medical physicist are often performed by the same person who is a medical physicist. However an RPO, unless he or she has recognized competence in medical physics, cannot perform the role of a medical physicist with respect to medical exposure.

2.96. In addition to the above paragraphs, all health professionals involved in the medical uses of ionizing radiation have responsibilities with respect to occupational and public radiation protection. (See the occupational and public radiation protection sub-sections of the specialty Sections 3 to 5.)

2.97. Medical radiation facilities, as they increasingly utilize digital technologies, should assure access to an information technology (IT) specialist⁶ who, through specialized training and experience, would have responsibilities for the maintenance and quality control of information technology software and hardware. The correct functioning of these systems is crucial for radiation protection and safety.

Ethics committees

2.98. Participants in a programme of biomedical research may be either patients, with some disease or ailment, or they may be healthy individuals. Regardless, they must be volunteers. The ethics committee⁷ has a particular responsibility with respect to justification of medical exposure of volunteers exposed as part of a programme of biomedical research (BSS [3] paragraph 3.161). The first part of this responsibility is to decide whether to approve the programme of biomedical research, including the proposed use of radiation. The use of radiation in a programme of biomedical research can include: (a) the use of a diagnostic radiological procedure to assess the efficacy of the treatment under investigation (e.g. ranging from a DEXA scan to measure bone mineral density before, during and after a given treatment regime, to a CT or a PET-CT examination to assess some clinical indicators, again performed before, during and after the treatment); (b) trials being performed to assess a new radiopharmaceutical (i.e. the radiation itself is part of the research, rather than a tool for assessment); (c) trials being performed to assess a new radiotherapy protocol alone or in combination with other therapeutic modalities; (d) trials being performed to compare radiological procedures, for example specificities and sensitivities of different imaging procedures or efficacy of different treatments. In making its decision, the ethics committee should be presented with correct information on the expected doses and estimates of the radiation risks based on the age, gender and health status of the participants. The ethics committee also should obtain information on who will perform the radiological procedures and how. The dose estimates and the associated radiation risks should be

⁶ The IT specialist in this respect is an expert in imaging informatics, with expertise to improve the efficiency, accuracy, usability, reliability and interconnectivity of medical imaging and radiotherapy services within the medical radiation facility and, if relevant, its parent healthcare facility.

⁷ Ethics committee is the term used in the BSS to refer to a committee dedicated to the rights and well-being of research subjects. Other terms such as an Institutional Review Board are used in some States.

assessed by a medical physicist. This information should be then considered by the ethics committee together with the information on the other risks and benefits of the programme.

2.99. The ethics committee has the responsibility to specify any dose constraints that are to be applied to the medical exposures incurred as part of the approved programme of biomedical research. Such dose constraints would be guided by nationally or regionally established dose constraints (see para. 2.50). Dose constraints should be adjusted to the expected benefit of the programme of biomedical research – the lower the benefit to society, the more stringent the dose constraint. The ICRP [27] stratified doses incurred in biomedical research according to radiation risk and in Publication 103 [4] assigned numerical values of dose constraints ranging from less than 0.1 mSv to greater than 10 mSv, as the benefit to society ranged from "minor" through to "substantial". Less stringent dose constraints may be applied to participants with short life expectancy, see for example Ref [28]. Particular attention should be given to setting dose constraints for healthy volunteers who repeatedly take part in biomedical research programs which expose them to increased risks.

2.100. Ethics committees may not be aware of these responsibilities. Therefore it is desirable for the radiation protection regulatory body to act as a facilitator in promoting systems so that ethics committees know about their responsibilities when a proposal for a programme of biomedical research which includes radiation exposure is submitted to the ethics committee. Such a system may include a "box" in the proposal form that asks the question "Will ionizing radiation be used as part of this programme of biomedical research?" And if the answer is yes, the form should then ask for information on radiation doses and risks to be provided, having been first assessed and signed off by a medical physicist.

2.101. In a parallel initiative, the regulatory body should inform the registrants and licensees that radiological procedures requested as part of a programme of biomedical research are only justified if that programme has been approved by an ethics committee, and that such an approval is subject to dose constraints which would then influence how the procedure would be performed.

Suppliers of sources, equipment and software

2.102. Suppliers⁸ of medical radiological equipment and developers of software that could influence the delivery of the medical exposure have responsibilities with respect to design and performance. Generic requirements are given in the BSS paragraph 3.49 and specific requirements in paragraph 3.161.

2.103. A particular issue with medical radiological equipment and software in medical uses of ionizing radiation is that of the language, terminology and icons used on control panels, on software screens and in instruction manuals. English and other major languages dominate. However it is crucial that the person using the equipment or software fully understands the options being presented, and translation into a local language is advisable. A passing knowledge of a major language is not good enough – there are documented instances of unintended or accidental medical exposures arising from incorrect understanding of the displayed language, see for example Ref [29].

2.104. Many items of medical radiological equipment can be configured and supplied with different options. For example, protective tools may be an optional extra, with a higher price. Basic model

⁸ The definition of supplier (of a source) in the BSS [3] includes designers, manufacturers, producers, constructors, assemblers, installers, distributors, sellers, exporters or importers of a source.

versions of a given piece of equipment should include as a default all the relevant protective tools and the features that provide the greatest control over patient radiation protection. Paring the price back by removing radiation protection and safety options in order to gain a sale is not acceptable. Facility management should not be placed in a position of saving money at the expense of compromising radiation safety.

2.105. When medical radiological equipment and software are to be part of a digital network, suppliers should facilitate interconnectivity with other relevant systems.

2.106. After installation of medical radiological equipment or software, the supplier should go through a formal hand-over to the medical radiation facility's registrant or licensee. This should include the acceptance testing, described in more detail in the specialty Sections 3 to 5. It should also include ensuring that specific training in the use of the equipment or software is given to the medical radiation facility's staff, including the radiological medical practitioners, the medical radiation technologists, the medical physicists and the local maintenance engineers. The features of the equipment or software should be fully understood, including their implications for patient radiation protection.

2.107. The radiation protection and safety responsibilities of suppliers of refurbished medical radiological equipment should be no different to the responsibilities for the supply of new equipment. Further guidance on refurbished equipment is given in Refs [30 - 32].

2.108. The radiation protection and safety responsibilities for donors of medical radiological equipment should be no different to those of commercial suppliers for such equipment. See WHO Refs for further guidance on donated equipment [33, 34].

2.109. Regulatory control of engineers and technicians who install medical radiological equipment varies around the world. In many countries they will be licensed to perform installation and servicing and a pre-requisite to obtaining such a licence would be that they have had appropriate radiation protection and safety training. Guidance on education, training, qualification and competence of installation and servicing personnel is given in para. 2.133.

Maintenance and servicing organizations

2.110. Maintenance and servicing of medical radiological equipment is usually performed by an engineer or technician employed either by a company offering such services (who may also be the manufacturer and/or the vendor) or by the medical facility itself (as part of an engineering, biomedical / clinical engineering or service department, for example). In either case, when the medical radiological equipment is being serviced the equipment is not to be used for medical exposures – patients are not to be imaged or treated until service and hand back is completed (see para 2.111). The engineer or technician should follow both the radiation protection and safety rules and procedures established by his or her employer and the relevant rules and procedures of the medical radiation facility, including how to ensure a safe working environment for the service and how to ensure restricted access to the area where the service is taking place. Further guidance on good maintenance service practice is given in Refs [35].

2.111. Maintenance and servicing continues until the medical radiological equipment is ready to be handed back to the medical radiation facility's registrant or licensee. It is recommended that the "hand-over" is formalized. Depending on the maintenance or servicing that has taken place, there may

be a need for quality control tests to be performed by a medical physicist before the hand-over is complete (see Sections 3 - 5, paras. 3.45, 4.58, 5.87, respectively). The engineering service should collaborate with medical physicists and radiological practitioners in setting optimal equipment performance. The engineer or technician also should inform the registrant or licensee of any changes with respect to the medical radiological equipment that may have implications for radiation safety. At this stage the equipment is available for medical use. Pressures to hand medical radiological equipment back for medical use must not be allowed to compromise radiation protection and safety – for example, equipment being used clinically while still in "service mode".

2.112. Regulatory control of servicing engineers and technicians varies around the world. In many countries they will be licensed to perform servicing and a pre-requisite to obtaining such a licence would be that they have had appropriate education and training in radiation protection and safety. Guidance on education, training, qualification and competence of servicing engineers and technicians is given in paragraph 2.133.

Referring medical practitioners

2.113. The health care of the patient is the responsibility of the physician or health professional managing the patient. This physician or health professional may decide that the patient needs to undergo a radiological procedure, at which point a referral to an appropriate medical radiation facility is initiated. "Referring medical practitioner" is the generic term used in the BSS for the health professional who initiates the process that may lead to the radiological procedure being performed. There may be different requirements in different States about who can act in the role of a referring medical practitioner. The referring medical practitioner has a joint responsibility with the radiological medical practitioner to decide on the justification of the proposed radiological procedure. More detailed guidance is given in the specialty Sections 3 to 5.

2.114. Usually the roles of the referring medical practitioner and the radiological medical practitioner are performed by two different persons. However there are some instances where both roles are performed by the same person – often called self-referral. A very common example is the dentist, who decides whether an X ray examination is needed and, if so, performs the examination. Dental professional bodies in many countries have established guidelines for when dental X ray examinations are appropriate or not, and using these guidelines should help the dentist to fulfil both roles acceptably. In other situations, typically involving medical imaging, there may be very strong financial incentives for self-referral because the performance of the radiological procedure generates significant income. Again there is a clear role for professional body guidelines to help minimize potential misuses of self-referral.

Patients

2.115. Patients are being increasingly involved in the decision making processes concerning their own health care, and this includes medical uses of ionizing radiation. The BSS requires that the registrant or licensee for the medical radiation facility ensures that the patient is informed, as appropriate, of both the potential benefit of the radiological procedure and the radiation risks (BSS [3], paragraph 3.151(d). Information should always be provided in an understandable format (e.g. verbally, leaflets, posters, websites), and in a timely manner. The level of information should be commensurate with the complexity, dose and associated risks, and for some radiological procedures informed consent may be

required, written or verbal. Female patients of childbearing potential should be informed about the risk to the embryo or fetus from radiological procedures for either diagnosis or therapy.

2.116. "Self-presenting" patients are individuals demanding a particular radiological procedure on the basis that they believe that this procedure is needed to, for example, detect cancer or heart disease in its early stages before symptoms become manifest. These individuals should be handled in the same way as any other patient – namely through an appropriate referral and the ensuing justification.

EDUCATION, TRAINING, QUALIFICATION AND COMPETENCE

2.117. Medical uses of ionizing radiation involve a number of health professionals performing radiological procedures – diagnostic examinations, interventional procedures or treatment. In each case the radiation protection and safety associated with the radiological procedure depends strongly on the skills and expertise of those health professionals involved as the patient is necessarily and deliberately exposed to radiation. In other words, education, training, qualification and competence of the respective health professionals underpin radiation safety in medical uses of ionizing radiation.

2.118. The BSS places great emphasis on education and training for all persons engaged in activities relevant to protection and safety, with the responsibility placed on government to ensure that requirements for education, training, qualification and competence are established and that arrangements are in place for the provision of the necessary education and training. The development and implementation of a national strategy for education and training⁹ which is based on a national needs assessment can be useful in this context. Further, the regulatory body should ensure the application of the requirements for education, training, qualification and competence in radiation protection. This should take place when an authorization application has been submitted to the regulatory body and during the periodic inspections of the medical radiation facility. Finally, the registrant or licensee of the medical radiation facility has the responsibility to ensure that all the health professionals in that facility with responsibilities for protection and safety have appropriate education, training, qualification and competence.

2.119. In medical uses of ionizing radiation medical exposure occurs, and occupational and public exposure may occur. For the health professionals involved, it is the education, training, qualification and competence in the medical exposure aspects that are the most critical. To this end, the requirements in the BSS for the health professionals involved in performing radiological procedures are quite stringent. For each of the key roles of the radiological medical practitioner, the medical radiation technologist, the medical physicist and the radiopharmacist, the definition in the BSS takes the same form. Namely, that the person is a health professional, that they have specialist education and training in the particular discipline (including radiation protection and safety), and that they have been assessed as being competent to carry out that particular role. See the BSS for the complete definitions (BSS [3], pp 114, 115, 122, 123]). The competence of a person is normally assessed by the State by having a formal mechanism for registration, accreditation or certification of the particular specialized health professional. States that have yet to develop such a mechanism, should assess the education, training and competence of an individual proposed by a licensee to act as a specialized

⁹ IAEA Strategic Approach to Education and Training in Radiation, Transport and Waste Safety, 2011–2020 (IAEA/2010/Note 44)

health professional and to decide, on the basis either of international standards or standards of a State where such a system exists, whether the individual can be considered competent.

2.120. A health professional intending to act in any of the roles of radiological medical practitioner, medical radiation technologist, medical physicist or radiopharmacist can do so only if he or she has the requisite education, training, qualification and competence. It is the prime responsibility of the registrant or licensee to ensure that their staff meets these requirements, and it is the responsibility of the regulatory body to use the authorization, inspection and enforcement processes to ensure that registrants and licensees are discharging their responsibilities in this respect.

2.121. The institutes and organizations that provide education and training in radiation protection to health professionals should use the BSS and its companion Safety Guides as resources on the requirements for radiation protection and safety in medical uses of radiation.

Radiological medical practitioners

2.122. The term radiological medical practitioner is applied to a number of health professionals who independently perform or oversee radiological procedures within a given specialty (see also para. 2.89). Some of these health professionals belong to a specialty with a very long association with medical uses of ionizing radiation, such as radiology, nuclear medicine, radiation therapy and dentistry. In countries where there are well established processes in place for education, training, qualification and competence in these specialties, this includes subjects not only in the specialty itself but also with respect to radiation protection (patient and occupational). Typically these specialists would become registered with the national medical or dental registration board (or a body with a similar function), and competence in the specialty should include competence in radiation protection and safety. It still falls on the regulatory body and the relevant professional body to periodically review the radiation protection and safety aspects of the education and training to ensure that it is still up to date and relevant. In States where there is a lack of infrastructure for education and training in these specialties, a prospective radiological medical practitioner should gain the necessary education, training, and qualification outside the State, both in the specialty itself and in radiation protection and safety. The competence of health professionals trained outside the State should be assessed. In this situation the regulatory body should seek advice from the health authority and the relevant professional body (if it exists), with respect to the adequacy of the specialization of the individual. Assessment of the radiation protection and safety aspects would be performed by the regulatory body. In time this approach should develop into a standardized process for dealing with competence assessments.

2.123. Other specialties, such as orthopaedic surgery and cardiology, have also had a long association with medical uses of ionizing radiations, but radiation protection and safety may not traditionally have been part of the processes for education, training, qualification and competence in the specialty. Still other specialties have a more recent association with medical uses of ionizing radiation, especially with respect to image guided interventional procedures. Radiation protection (patient and occupational) is often not included in the curriculum for education, training, qualification and competence in these specialties. For specialists from these two groups, oftenadditional or separate education and training and credentialing in radiation protection and safety should be arranged, as it applies to their specialty. The relevant professional bodies and the regulatory body should work together in establishing acceptable criteria on education and training in radiation protection. Probably the preferred approach would be for the relevant professional body to administer the process and maintain a register of specialists and their radiation protection and safety credentials. Other possibilities include the
regulatory body taking on the role of overseeing the radiation protection and safety training and recognition processes. An individual medical radiation facility can adopt a 'credentialing and privileging' approach to cover radiation protection and safety education, training, qualification and competence [36]. In this approach the prospective radiological medical practitioner would present all their relevant data regarding training and experience (including in radiation protection and safety), and apply for permission to perform certain medical procedures involving radiological procedures. Detailed guidance on appropriate radiation protection and safety education and training for various specialties involved in medical use of ionizing radiation is given in references [37, 38].

Medical radiation technologists

2.124. Medical radiation technologists should require a programme of education and training in medical radiation technology that usually includes significant components of radiation protection (patient and occupational). On completion of the programme the medical radiation technologist typically would become registered with the national registration board (or a body with a similar function), and this competence in medical radiation technology should include competence in radiation protection and safety.

2.125. Medical radiation technologists may be specialized in various fields and sub-fields. The approach to specialties and sub-specialties vary significantly among countries. In many States, the medical radiation technologist undergoes a programme specific to diagnostic radiology, nuclear medicine or radiation therapy and hence his/her competence would be in that specialty only. Within these specialties there may be specific sub-specialties, where the programme does not necessarily confer competence. For example, the diagnostic radiology programme in a country may not cover CT or image guided interventional procedures to the depth needed for competence. Additional education and training should be arranged to achieve competency in the sub-specialty. The regulatory body, in terms of reviewing the application for an authorization and during its periodic inspections, needs to be aware of issues of specialization and sub-specialization and ensure that only persons with the correct credentials can work in the particular roles. Likewise, the registrant or licensee should ensure that they employ only persons that have the requisite competence.

Medical physicists

2.126. Even though the International Labour Organization has stated that medical physicists working in clinical practice can be considered health professionals [39], the recognition of medical physicists as a specialist group of health professionals is not as widespread as needed. In some countries there are well established processes for education, training and qualification and achieving competence in medical physics, with academic training in medical physics at a university (typically a post-graduate programme), clinical training in a hospital or facility, and finally an assessment of competence. In some States, the professional body administers this whole process, with approved universities for the academic component, approved hospitals or facilities for the clinical placement, and a professional standards board for the competence assessment. More details on education, training, qualification and competence of medical physicists is given by the IAEA [26, 40 – 43]. There are also national and regional requirements and guidance on education, training and recognition of medical physicist with competence only in diagnostic radiology or image guided interventional procedures cannot act in the role of a medical physicist in radiation therapy, and vice versa.

2.127. More difficult is where either the State does not recognize medical physics as a distinct health profession or where there is no infrastructure in place for the education and training of medical physicists. In both cases there is likely to be little in the way of infrastructure for medical physics in

the country. The problem is similar to that described above in the second half of para. 2.123 for radiological medical practitioners. The assessment of education, training, qualification and competence of a person seeking to act in the role of a medical physicist still should take place. Regardless of the educational process, the final competence assessment should be specialty-specific as required by the BSS (BSS [3], para. 3.150).

Radiopharmacists

2.128. A radiopharmacist is usually a pharmacist who has received additional specialist education and training and has competency in the preparation and dispensing of radiopharmaceuticals. Post-graduate courses in radiopharmacy are available in some countries. A few countries have a radiopharmacy professional body, or radiopharmacy can be a specialist sub-group within the national nuclear medicine professional body and/or a pharmacy professional body. More details on education, training, qualification and competence of persons working in a radiopharmacy is given by the IAEA [45]. Even in the absence of a formal infrastructure, the assessment of education, training, qualification and competence of a radiopharmacist still should take place.

Other health professionals in the medical radiation facility

2.129. Other health professionals are involved in medical uses of ionizing radiation. However a distinction should be made between those who have specific responsibilities for patient radiation protection and those whose responsibilities (in terms of radiation protection) are for occupational radiation protection only. Health professionals who fall into the former group, and who are not a radiological medical practitioner, a medical radiation technologist, a medical physicist, or a radiopharmacist, still should have appropriate specialization (as it applies to the radiation use) and the respective radiation protection and safety education, training, qualification and competence. The guidance given above for health professionals where infrastructure is lacking would again be applicable.

2.130. The latter group of health professionals and other professionals involved in medical uses of ionizing radiation include specialist nurses (working in a cardiac investigation suite or theatre or similar), specialist physicians (such as anaesthetists providing support to a patient undergoing an interventional procedure), biomedical engineers, clinical engineers, radiochemists providing support to the performance of the radiological procedure, either directly or indirectly. All these persons should have formal education and training on radiation protection. An example of such training for radiation oncology nurses is given in Ref [46].

Referring medical practitioners

2.131. The referring medical practitioner has a crucial role in the justification of a given radiological procedure for a given patient. The referring medical practitioner would be more effective in this role if he/she has a good understanding of radiation protection and safety as it applies to medical uses of ionizing radiation. Formal processes to require such education and training under a radiation protection and safety framework are difficult to put in place. Instead, a more general approach may be adopted of promoting education and training in radiation protection and safety as part of the general medicine degree curriculum, especially at the time when clinical rotations begin, and/or as part of the corresponding specialty education and training programme.

Radiation protection officers

2.132. As defined in the BSS and stated above in para. 2.95, the RPO should be competent in radiation protection and safety matters with respect to occupational and public radiation protection,

relevant for given medical uses of ionizing radiation [3]. The RPO could come from a range of backgrounds, often in science, engineering, or health. The additional education and training required for the RPO role will depend on the complexity of the technology and practice of the medical radiation facility. In some facilities, the RPO may lead a team, all of whom should have the requisite education and training. As above for the health professionals, in the absence of a third-party recognition process, the regulatory body should liaise with the relevant professional body (if it exists) to set standards to allow assessment of persons seeking authorization to act in the role of RPO. The ILO has recognized the radiation protection expert as an "Environmental and occupational health and hygiene professional" [39].

Suppliers, installation, maintenance and servicing personnel

2.133. Persons who work as engineers or technicians for supply, installation, maintenance and servicing of radiological medical equipment and software should be qualified and competent in such work. Often they will have been trained by their employer specifically for this role. Another aspect of their training should be in the area of radiation protection and safety – not only for their own occupational radiation protection and radiation protection of the staff of the medical radiation facility where they are working, but also they should have a good working knowledge of patient radiation protection in the context of the types of medical radiological equipment and software they are servicing. For the last, this particularly includes understanding the radiation protection and safety implications of the various features of the equipment or software, and how that changes when the features undergo adjustments or revisions. Regulatory control of servicing engineers and technicians varies around the world. In some countries licence may be required to perform servicing and a prerequisite to obtaining such a licence should be that they have had appropriate radiation protection and safety training.

Maintaining competence (CME and CPD)

2.134. The above paragraphs give guidance on the processes for the initial education, training, qualification and competence assessment of the health professional. The health professionals should maintain their core competencies, including radiation protection and safety, and keep abreast of new developments in medical uses of radiation. One way to demonstrate this is through formal continuing medical education (CME) or continuing professional development (CPD) programmes. In many countries, the professional bodies administer such programmes, and maintenance of certification of competence in a specialty is dependent on satisfactory participation in the programme. The registrants and licensees and regulatory bodies can use these programmes as evidence of continuing competence.

Equipment and software specific training

2.135. Specific training should be assured on the actual medical radiological equipment and the software used in the medical radiation facility. This applies in particular to radiological medical practitioners and the medical radiation technologists who work directly with the equipment and software during radiological procedures, and the medical physicist. They should understand how the equipment and software function, including the available options and how to customize these, and their implications for patient radiation protection. Practical training should take place in the medical radiation facility when new equipment or software is installed and when significant modifications are made. From the vendors' side, the servicing engineer, the applications specialist and the IT specialist have a role in providing this specific training for the medical radiation facility.

MANAGEMENT SYSTEM FOR RADIATION PROTECTION AND SAFETY

2.136. The use of radiation in medicine is just one aspect of medical practice. The application of the radiation protection and safety requirements of the BSS should fit in with the wider set of requirements that ensure good medical practice. To this end, in particular, the medical radiation facility and its management should ensure complementarity between the requirements for radiation protection and safety and other healthcare delivery requirements within the medical facility. This is to be achieved through an appropriate management structure and management system.

2.137. The BSS has a specific requirement for radiation protection and safety to be effectively integrated into the overall management system of a given organization (BSS [3], requirement 5). In this Safety Guide, this applies to the medical radiation facility. The BSS has additional detailed requirements on the protection and safety elements of the management system, for promoting a safety culture, and taking into account human factors (BSS [3], paragraphs 2.47 to 2.52). Further detailed requirements for facilities and activities, in general, are given in the IAEA Safety Standards Series No. GS-R-3 [47] and elaborated in the Safety Guide GS-G-3.1 [25]. The requirements for quality management are established in these standards and will not be discussed further in this Safety Guide other than to emphasize that effective management for radiation protection and safety requires commitment from the highest level of management in the medical radiation facility, including the provision of all the required resources. The following guidance is limited to a few particular components of the management system related to radiation protection and safety.

2.138. The BSS has a requirement for a "protection and safety programme" in general (BSS [3], paragraphs 2.42 & 2.43) and a "radiation protection programme" specifically for occupational exposure (BSS [3], requirement 24). In addition the BSS has requirements for a "quality assurance programme for medical exposures" (BSS [3], paragraphs 3.170 - 3.172). All three of these programmes should be part of the overall management system of the medical radiation facility¹⁰. Detailed guidance on the radiation protection programme for occupational exposure and the quality assurance programme for medical exposures is given in the specialty Sections 3 to 5.

2.139. Depending on the size of the medical radiation facility, committees might be formatedto help the implementation of the radiation protection and safety programme aspects of the management system. One such committee might be a radiation safety committee, with the function of advising on safe operation and compliance with radiation protection and safety regulatory requirements. The members of the committee should be at the senior level and would typically include an administrator representing the management, a radiological medical practitioner, a medical radiation technologist, a medical physicist, and the radiation protection officer. For the day-to-day oversight of the radiation protection programme, a radiation protection officer should be appointed, who should report to the committee. The licensee should ensure that the RPO is provided with the resources required to oversee the programme, as well as the authority to communicate with the committee on a periodic basis. The RPO should be able to communicate directly with the licensee, and with the regulatory body as needed, such as in the case of breaches of compliance which may compromise safety.

¹⁰ The medical radiation facility may be a "stand alone" entity, such as a medical imaging centre, or it may be part of a larger organization, such as a hospital. The focus of this section on management systems is at the medical radiation facility level, but it should be recognized that, where the medical radiation facility is part of a larger organization, the medical radiation facility management system should be part of the larger organization's management system.

2.140. Another committee might be the quality assurance committee, with oversight of the quality assurance programme for medical exposures within the medical radiation facility. The committee would determine policy and give direction to the programme, ensure proper documentation is being maintained and review the effectiveness of the programme. The radiation safety and the quality assurance committees have some functions in common, especially with regard to medical exposure, and the health professional representation is likely to be the same. Harmonization of the work of both committees is required to avoid either the duplication of or the inadvertent omission of some functions.

2.141. Any management system should include continuous quality improvement which implies a commitment by staff to strive for continuous improvement in the medical uses of ionizing radiation. Feedback from operational experience and from lessons learned from accidental exposures or near misses should be used systematically, as part of the continuous quality improvement.

2.142. The BSS requires that the medical radiation facility is able to demonstrate effective fulfilment of the requirements for protection and safety in its management system (BSS [3], paragraph 2.50). This will include monitoring, conducted to verify compliance with the requirements for protection and safety (BSS [3], requirement 14, and paragraphs 3.37 and 3.38).

2.143. There are requirements for records to be kept, and made available as needed, in many sections in the BSS. The management system of the medical radiation facility should provide for such record keeping and access. Details on what should be provided are described in Sections 3 to 5.

2.144. Digital information systems are becoming increasingly available to provide various support functions to the management system of the medical radiation facility, including handling requests for radiological procedures, scheduling radiological procedures, tracking patients, and the processing, storage, and transmission of information pertaining to the patient. Further, they may be used for viewing imaging studies and providing reports of study interpretations. Example of systems with some or all of these functions include picture archiving and communication systems (PACSs), radiology information systems (RIS), hospital information systems (HIS), and the electronic health record (EHR). These systems should operate independently, but may also interconnect with each other. Imaging devices and other medical radiological equipment can be interconnected by computer networks and exchange information in accordance with standards such as TCP/IP (Transmission Control Protocol/Internet Protocol, or the Internet protocol suite), DICOM, HL7, and IHE (Integrating the Healthcare Enterprise) [48 - 50]. These information systems are complex and expert implementation and support should be assured. Digital information systems when used appropriately can have a positive effect on the practice of radiation protection and safety in medical uses of ionizing radiation. For example, use of these systems can help avoid performing unnecessary or inappropriate studies and repeat studies by making patient information available to multiple users. Further, connected digital systems should minimize the need for multiple manual data entry, with its associated risks, such as in radiation therapy. These systems can also help in monitoring doses to patients and image receptors, and monitor retakes; the information from this monitoring can help in the implementation of optimization of protection for imaging procedures.

2.145. These digital information systems and procedures for their use should be designed to protect against data loss, which in the context of the medical radiation facility may compromise radiation protection and safety by, for example, having to repeat examinations. It is the responsibility of the medical radiation facility to meet the records retention, security, privacy, and retrieval requirements of the relevant State authorities.

2.146. The management system should include a review cycle. The general principles for audits and reviews are well established [25, 47]. For a medical radiation facility, a possible tool for this is the clinical audit. Clinical audit may be considered as the systematic and critical analysis of the quality of clinical care, including the procedures used for diagnosis and treatment, the associated use of resources and the effect of care on the outcome and quality of life for the patient [50]. A clinical audit looks beyond a strict radiation protection and safety focus, and seeks to assess the quality and efficacy of the medical practice offered in the facility – ultimately the patient health outcome. This should include the radiation protection and safety aspects of medical uses of ionizing radiation and, importantly, keeps these aspects in the context of medical practice, ensuring a common goal. Thus, while the BSS does not require a clinical audit, its use may be seen as fulfilling both the radiation protection and safety of the medical radiation facility's management system. More detailed guidance on clinical audits is given in the three IAEA publications [52 - 54].

2.147. The BSS in the context of medical exposures does require the performance of a radiological review and this should be incorporated into the medical radiation facility's management system ([3], paragraph 3.182). At its simplest, the radiological review includes an investigation and critical review of the current practical application of the requirements for justification and optimization of radiation protection and safety for the radiological procedures that are being performed in the medical radiation facility. The radiological review involves at least the radiological medical practitioners, the medical radiation technologists and the medical physicists at the medical radiation facility.

SAFETY ASSESSMENTS

2.148. In the context of medical uses of ionizing radiation, a safety assessment means an assessment of all relevant aspects of radiation protection and safety for a medical radiation facility, including the siting, design and operation of the facility. The safety assessment can occur before a facility is operational or when a major change in operation is contemplated. The safety assessment deals with finding 'what can go wrong' and how it can be prevented and, in case it occurs, how it can be mitigated. As noted above (paragraph 2.70), the regulatory body has the responsibilities to establish requirements for safety assessments and, once the safety assessment has been submitted, to review and evaluate it prior to granting an authorization (see BSS [3], requirement 13 and paragraph 3.29).

2.149. The BSS gives requirements on: what a safety assessment should include, what the registrant or licensee should take into account, its documentation and placement in the management system, and when additional reviews of the safety assessment should take place (BSS [3], paragraphs 3.30 to 3.36). Further more detailed requirements on safety assessment for facilities and activities, in general, are given in the IAEA Safety Standards Series No. GSR Part 4 [55]. For medical radiation facilities, the safety assessment should include not only considerations of occupational and public exposure, but also medical exposure and the possibility of unintended or accidental medical exposures.

2.150. The BSS specifies two types of safety assessments: generic, and specific to the facility or source. A generic safety assessment is usually sufficient for types of sources with a high degree of uniformity in design. A specific safety assessment is usually required in other cases; however, the specific safety assessment should not include those aspects covered by a generic safety assessment, if a generic safety assessment has been conducted for the source. The safety assessments needed in the context of medical uses of ionizing radiation will range in complexity, but even if the source itself is covered by a generic safety assessment, its placement in the medical radiation facility will nearly

always require some form of specific safety assessment. It is very useful if the regulatory body develops a set of templates [11, 55] to be used by medical radiation facilities for safety assessments for the various modalities and specialties in medical uses of ionizing radiation.

2.151. The BSS requires potential exposure to be considered in the safety assessment of a new facility being planned or a planned modification to an existing facility. Potential exposure refers to prospective exposure that may or may not occur, but could result from an accident or from an event or a sequence of events that may or may not occur. As discussed in paragraph 2.4, in majority of cases in medical use of radiation the potential exposure can be treated as a planned exposure situation. Facilities should have procedures in place to deal with the occurrence of such events.

2.152. The BSS (BSS [3], paragraphs 3.43 and 3.44) requires, if the safety assessment indicates that there is a reasonable likelihood of an emergency affecting either workers or member of the public, an emergency plan to be prepared, including arrangements for the prompt identification of an emergency, and for effective response. Situations that can lead to emergency in medical settings are loss of control over a dangerous radiation therapy source in result of unauthorized or malicious act, or conventional emergencies such as fires and earthquakes. Further more detailed requirements on emergency preparedness and response are given in the GSR Part 7 [7].

3. SPECIFIC RECOMMENDATIONS FOR RADIATION PROTECTION AND SAFETY IN DIAGNOSTIC RADIOLOGY AND IMAGE GUIDED INTERVENTIONAL PROCEDURES

INTRODUCTION

3.1. This chapter covers radiographic and fluoroscopic diagnostic procedures, image-guided interventional procedures, and imaging studies using X-ray radiation which are part of radiation therapy or nuclear medicine processes. These radiological procedures usually take place in permanent facilities but they can also take place in mobile facilities.

3.2. The radiographic procedures aim to image a particular organ or tissue in 2 or 3 dimensions, and include general radiography, computed tomography (CT), cone-beam CT (CBCT), mammography, tomosynthesis, dental radiography (intraoral, panoramic and CBCT) and bone densitometry (dual energy X ray absorptiometry, DEXA).

3.3. Fluoroscopic diagnostic procedures aim to provide real time assessment of the anatomy and pathology of a system or organ. Examples include cardiac, gastrointestinal, urological, and gynaecological examinations.

3.4. During image-guided interventional procedures, fluoroscopy (primarily) or CT is used as an imaging tool to facilitate the diagnosis and treatment of vascular and non-vascular diseases. Examples of vascular procedures include coronary angiography/angioplasty, uterine artery embolizations, aortic valve implantations and aortic endographs. Common non-vascular procedures include, for example, biliary drainage/stenting and liver cytostatic agent injections. Fluoroscopically guided intra-operative procedures include, for example, intramedullary nailing and vertebroplasty.

3.5. The generic term "medical radiation facility" is used widely in Section 2 to mean any medical facility where radiological procedures are performed. In Section 3, the narrower term "radiology facility" is used to cover any medical radiation facility where diagnostic radiology and/or image guided interventional procedures are performed. A radiology facility includes the traditional radiology department in a hospital or medical centre; a stand-alone X ray imaging facility; the interventional cardiology (or other specialty) department, unit or facility, either stand alone or as part of a larger entity; or a dental practice.

3.6. Many different health professionals can take on the role of the radiological medical practitioner (see Section 2 para. 2.89) in diagnostic radiology or image guided interventional procedures, depending *inter alia* on national laws and regulations. They typically include radiologists, cardiologists, orthopaedic surgeons, neurosurgeons, plastic surgeons, vascular surgeons, gastroenterologists, urologists, respiratory and other specialist physicians and surgeons, dentists, chiropractors and podiatrists.

3.7. Section 2 of this Safety Guide provides general guidance on the framework for radiation protection and safety in medical uses of radiation, including roles and responsibilities, education, training, qualification and competence, and the management system for protection and safety. This is relevant to diagnostic radiology and image guided interventional procedures and reference to Section 2 should be made as indicated.

SAFETY OF MEDICAL RADIATION FACILITIES AND MEDICAL RADIOLOGICAL EQUIPMENT

Radiology facilities

Fixed facilities -X ray room design

3.8. The BSS, paragraph 3.51, set out the broad requirements that should be met when choosing a location and designing a radiology facility. Provisions for the incorporation of radiation safety features are best made at the facility design stage (X ray rooms and other related rooms). The siting and layout out should take into account the types of radiological procedures, workload and patient flow, both within the radiology facility and, in cases where the radiology facility is part of a larger hospital or medical centre, with other departments of the wider facility. Guidance on setting up diagnostic radiology and interventional radiology facilities is given in Refs [56 - 58].

3.9. The three factors relevant to dose reduction (time, distance and shielding) can be combined in the design to optimize occupational and public radiation protection. Larger rooms are preferable to allow easy access for patients on a bed trolley. At the same time they allow for easier patient positioning and facilitate both equipment and patient movement during the procedure, which in the case of fluoroscopy and image-guided interventional procedures helps reduce time and exposure. Larger rooms should also reduce the levels of secondary radiation (scatter and leakage) potentially reaching areas occupied by staff and also public areas, typically reducing the level of shielding required.

3.10. Shielding requirements should be individually tailored to suit the practice requirements based on the intended patient workload and the type of examinations to be undertaken. Further assessments

should be undertaken when the intended use of a room changes; X ray equipment is upgraded; or surrounding room occupancy is altered.

3.11. Shielding should consider both structural and ancillary protective barriers at the design stage (see para. 2.73]. In rooms using fluoroscopy with staff working close to the patients, such as rooms for image guided interventional procedures, ceiling mounted protective screens and table mounted leaded curtains should be installed. Such ancillary protective barriers for image guided interventional procedures should be part of the initial facility plan, designed so as to not interfere with the medical procedure, e.g. sterility requirements. Shielding of walls should be at least two metres high, and any doors and viewing windows in walls or doors should have at least the same lead equivalence as the minimum shielding specifications for the shielded wall or barrier in which they are located. Due consideration should be given to the provision of floor and / or ceiling shielding when rooms immediately below and above the X ray installation respectively are occupied. All penetrations and joints in shielding should be arranged so that they are equally as effective in shielding radiation. More details with respect to structural shielding are given in paras 3.17 to 3.23.

3.12. General safety features of radiography, mammography, CT and fluoroscopy rooms include:

- (a) A protective barrier should be placed at the control console to shield staff to the extent that staff should not should wear protective clothing while at the console. This is particularly important in mammography where structural shielding in walls, ceiling and floor may not be necessary.
- (b) For radiography, all possible intended directions of the X ray beam should be taken into consideration in the room design so that the X ray beam cannot be directed at any area which is not shielded and lead to potentially unacceptable doses being received in this area.
- (c) The doors should be calculated to act as a protective shield for secondary radiation and be shut when the X ray beam is on. For radiography, the X ray room should be designed so as to avoid the direct incidence of the X ray beam on the access doors.
- (d) The medical radiation technologist should be able to clearly observe the patient at all times during an X ray diagnostic procedure and be able communicate with him/her.

3.13. Signs and warning lights, preferably positioned at eye level, should be used at the entrances of controlled and supervised areas to prevent inadvertent entry (see also para. 3.270 on control of public access). For controlled areas, the BSS, paragraph 3.90, requires the use of the symbol of the International Organization for Standardization (ISO) [59]. The signs should be clear and easily understandable. Warning lights, such as illuminated and/or flashing signs as appropriate, should be activated when radiation is being produced inside the controlled or supervised area. Door interlocks are not appropriate in X ray diagnostic radiological procedures, because should the X ray beam be stopped, the medical procedure may have to be repeated. However, to prevent unauthorized entry once the procedure has started, some rooms have doors that can be open from the inside only. This particularly is used for rooms in which image guided interventional procedures are performed.

3.14. A stable power supply should be available. An emergency diesel generator may not be sufficiently stable to power a CT or interventional radiology suites and should not be relied upon. Uninterruptible power supply (UPS) or battery backup systems should be installed to capture the active information at time of the outage and to power down all software in a controlled manner. Servers should be programmed to automatically shut down when the power supply is interrupted.

3.15. The design of the facility may should include an air conditioning system sufficient to maintain the temperature in the examination room (and sometimes in areas with computer equipment) within the range defined by the equipment manufacturers.

Mobile facilities

3.16. Mammography and CT "vans" are commonly used in areas where fixed facilities are not available. Other modalities may also be offered via a mobile facility. General safety features of mobile facilities include:

- (a) Mobile facilities should be built so that protection is optimized mainly through shielding as distance is often limited and time depends on the procedure.
- (b) An appropriate power supply should be available with reliable connections.
- (c) Entrance to the mobile facility should be under the control of the mobile facility personnel.
- (d) Waiting areas, if they exist, should be appropriately shielded to afford levels of protection consistent with public exposure limits. Waiting areas are common in mammography mobile facilities, but not in CT.
- (e) To facilitate the imaging procedure, including patient flow, mobile CT facilities are usually operated adjacent to a hospital or clinic, from where they may draw water and electricity, and where patients can use the toilets, waiting and changing rooms and have access to physician offices. Similarly, mammography mobile facilities may also utilize hospital or clinic facilities.

Shielding calculation considerations

3.17. Two widely used methodologies for shielding calculations are given in Refs [60, 61], but other methodologies are also available and used, e.g. Ref [62], as well as specific shielding calculations for the WHIS-RAD X-ray unit¹¹ [63]. 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 is well below the dose limits for the persons occupying the area to be shielded. Nominal design doses 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. Specifications for shielding are calculated on the basis of the attenuation they should provide to satisfy the nominal design doses.

3.18. 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 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 workload values, 'use factors' for a given beam direction (fraction of the total amount of radiation emitted in that direction) and '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. If tabulated figures are used, care should be taken that they reflect the actual usage in the facility and not generic "national" scenarios. Potential practice changes and workload increases should be considered as part of the calculations.
- (b) Once the dose that would be received without shielding is known, attenuation should be calculated 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 may require successive calculations to determine where this level lies.

¹¹ World Health Imaging System is a general purpose X-ray equipment built in accordance with specifications developed by WHO for developing countries.

3.19. When using a shielding methodology to optimize occupational and public radiation protection, decisions should be made about many factors that can greatly influence the final results for the shielding specification. Those decisions may be based on conservative assumptions, which together may lead to an unduly over-conservative shielding specification. Realistic assumptions should be used as much as possible, with some allowance for future changes in use. Adequateness of the shielding specification should be ensured corrective actions after building has been completed will invariably be difficult and expensive. Further, it is likely that the building materials used to provide the shielding will come in specific discrete thicknesses or densities and this can be used to provide a "safety margin" over the calculated shielding values. If using a material other than lead, tabulated values should be used only for materials that exactly match those being considered in terms of chemical composition, density, and homogeneity. The following are some assumptions that will each lead to conservatism in the shielding specification:

- (a) For primary barriers, the attenuation by the patient and image receptor is not considered;
- (b) Workload, use and occupancy factors are overestimated;
- (c) Staff members are always in the most exposed place of the room;
- (d) Distances are always the minimum possible;
- (e) Leakage radiation is the maximum all the time;
- (f) Field sizes used for the calculation of scatter radiation are overestimated;
- (g) Attenuation of the materials is usually considered for the maximum beam quality used;
- (h) The numerical value of calculated air kerma (in mGy) is directly compared with dose limits or constraints (mSv), which are given in terms of effective dose. However, the actual effective dose to personnel or members of the public is substantially lower than the air kerma, given the dose distribution within the body for the beam qualities used in diagnostic and interventional radiology.

3.20. Particular attention should be given to hybrid imaging systems where the shielding should be calculated for each modality and combined as appropriate [58, 64, 65]. See also Section 4, paras. 4.32 -4.35.

3.21. Considerations should be given during the design phase to make sure that radiosensitive equipment and consumables are appropriately shielded, for example computed radiography (CR) cassettes and X ray films. Where used, darkrooms for film processing may require extra shielding to prevent film fogging.

Adequacy of shielding

3.22. Specification of shielding, including calculations, should be prepared by a RPO or medical physicist. In some countries there may be a requirement for shielding plans to be submitted to the regulatory body for review or approval prior to any construction (see also Section 2 para. 2.73).

3.23. The adequacy of the shielding should be verified, preferably during construction, and certainly before the room is placed in clinical use, and similarly after any future structural modifications. Clearly requirements of the regulatory body must be met (Section 2 para. 2.73).

Display and interpretation (reading) rooms design

3.24. To facilitate the interpretation by the radiological medical practitioner, images should be displayed in rooms specifically designed for these purposes. A proper level of ambient light in the viewing room should be ensured. See also paras. 3.40 to 3.41 on image display devices and view boxes.

3.25. Viewing rooms with workstations for viewing digital images should be ergonomically designed to facilitate image processing and manipulation so that reporting can be performed accurately. The viewing monitors of the workstations should meet applicable standards (see para. 3.40).

Medical radiological equipment, software and ancillary equipment

3.26. This sub-section considers medical radiological equipment, including its software, used in diagnostic radiology or image guided interventional procedures, including radiography, fluoroscopy/angiography, CT, cone beam CT (CBCT), mammography, dental radiology, bone mineral densitometry (e.g. DEXA), tomography (including tomosynthesis). It is also applicable to the X ray based component of hybrid imaging modalities, including PET-CT, SPECT-CT, and PET-mammography, and the X ray based component of image-guided radiation therapy systems. Some of this equipment may be used in a nuclear medicine facility or in a radiation therapy facility, rather than a radiology facility.

3.27. The requirements for medical radiological equipment and its software are given in the BSS paragraphs 3.49 and 3.162. The International Electrotechnical Commission (IEC), through its Technical Committee 62 on *Electrical equipment in medical practice* and in particular Sub-committee 62B on *Diagnostic imaging equipment* and Sub-committee 62C on *Equipment for radiotherapy, nuclear medicine and radiation dosimetry*, has published international standards applicable to medical radiological equipment. Current IEC standards relevant to X ray imaging include the following Refs [66 – 110]. For those relevant to the radiopharmaceutical based component of hybrid imaging, see Section 4 para. 4.40. It is recommended that the IEC website is visited to view the most up-to-date list of standards: <u>http://www.iec.ch</u>. The International Organization for Standardization (ISO), through its Technical Committee 85 on *Nuclear energy, nuclear technologies, and radiological protection* and in particular Sub-committee 2 on *Radiological protection*, may publish international standards applicable to view the most up-to-date list of view the most up-to-date list of standards: <u>http://www.iso.org</u>.

3.28. As licensees take responsibility for the radiation safety of medical radiological equipment they use, they should impose purchasing specifications that include conditions to meet relevant international standards of the IEC and ISO and/or equivalent national standards. In some countries there may be a medical devices agency or similar organization that gives type approval to particular makes and models of medical radiological equipment.

3.29. Displays, gauges and instructions on the operating consoles of medical radiological equipment, and accompanying instruction and safety manuals, may be used by staff who may not understand, or who may have a poor understanding of, the manufacturer's original language. In such cases, the accompanying documents should comply with IEC and ISO standards and should be translated into the local language or into a language acceptable by the local staff. The software should be designed so that it can be easily converted into the local language resulting in displays, symbols and instructions that will be understood by the staff. The translations will require a quality assurance process to ensure proper understanding and avoid operating errors. The same applies to maintenance and service manuals and instructions for maintenance and service engineers and technicians, where these persons do not have an adequate understanding of the original language. See also Section 2 para. 2.103.

3.30. All medical radiological equipment should be supplied with all appropriate radiation protection tools as a default, rather than as optional extras. This applies to both patient radiation protection and occupational radiation protection. See also Section 2 para. 2.104.

Design features of medical radiological equipment

3.31. The design of medical radiological equipment should be such that its performance is always reproducible, accurate and predictable, and that it has features that facilitate the appropriate personnel in carrying out the requirement in the BSS for operational optimization of patient protection (paragraph 3.163(b)) – namely that it provides "appropriate techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfil the clinical purpose of the procedure, with account taken of the relevant norms of acceptable image quality" Many design features contribute to the performance of medical radiological equipment and should be considered when purchasing such equipment, as indicated briefly in the following paragraphs. Further details on design features and performance standards of medical radiological equipment used in diagnostic radiology or for image guided interventional procedures are given in Refs [72 – 81, 83, 85 - 91, 103, 105 – 115]. See also later paragraphs on quality assurance and acceptance testing, and in particular para. 3.231.

3.32. General design features for medical radiological equipment used in diagnostic radiology and image guided interventional procedures should consider the following:

- (a) Means to immediately detect any malfunction of a single component of the system that may lead to an inadvertent under- or over-exposure of the patient or exposure of staff so that the risk of any unintended or accidental medical exposure is minimized;
- (b) Means to minimize the frequency and impact of human error in the delivery of unintended or accidental medical exposure;
- (c) Hardware and software controls are incorporated that minimize the likelihood of unintended or accidental medical exposures;
- (d) All operational parameters for radiation generators, such as generating tube potential, filtration, focal spot position and size, source-image receptor distance, field size indication and either tube current and time or their product, should be clearly and accurately shown;
- (e) Radiation beam control mechanisms are provided, including devices that indicate clearly (visually and/or audibly) and in a fail-safe manner when the beam is 'on';
- (f) X ray tubes should have inherent and added filtration adequate to remove low energy component of the X ray beam which do not provide diagnostic information;
- (g) Collimating devices to define the radiation beam; in the case of a light beam diaphragm the light field should align with the radiation field;
- (h) With the exception of mammography and CT equipment, diagnostic and interventional X ray equipment should be fitted with continuously adjustable beam collimating devices. Such devices allow the operator¹² to limit the area being imaged to the size of the selected image receptor or the region of interest, whichever is the smaller;
- (i) When preset protocols are provided, the technique factors being used should be readily accessible and modifiable by appropriate personnel;
- (j) Radiation leakage is kept as low as reasonably achievable and should not exceed 1 mGy in an hour measured at 1 metre from the focal spot, or is less than maximum levels specified in international standards or in local regulations.

3.33. Specific design features for medical radiological equipment used for radiography should include:

¹² The term "operator" is used generically in this section. The operator is usually a medical radiation technologist, but may sometimes be a radiological medical practitioner, such as a radiologist.

- (a) The provision of devices that automatically terminate the irradiation after a preset time, tube current–time product, or dose to the automatic exposure control detector, or the dead man hand switch is released;
- b) Automatic exposure control (AEC) systems are incorporated in radiographic units where practicable. Such AEC systems should be able to compensate for energy dependence, patient thickness and exposure rate, for the expected range of clinical imaging conditions, and be suited to the type of image receptor being used film/screen or digital.

3.34. Specific design features for medical radiological equipment used for CT should include:

- (a) Console display of all CT parameters that directly influence the image acquisition (these may be displayed over a number of screens);
- (b) Console display of estimated volume CT air kerma index (C_{VOL} or $CTDI_{vol}$) and CT air kerma length product ($P_{KL,CT}$ or DLP) for the procedure/acquisition;
- (c) Operator alert if exposure factors are set too high (usually expressed in terms of volume CT air kerma index and/or CT air kerma length product;
- (d) Dose modulation (rotational and z-axis):
- (e) A comprehensive range of beam widths and pitches and other ancillary devices, e.g. dynamic collimation, to ensure over ranging in CT is kept as low as reasonably achievable by facilitating the appropriate choice of beam width and pitch to limit patient dose while maintaining diagnostic image quality;
- (f) Reconstruction algorithms that result in dose reduction without compromising image quality, such as iterative reconstruction algorithms.

3.35. Specific design features for medical radiological equipment used for mammography (both digital and film-screen systems) should include:

- (a) Various anode/filter combinations;
- (b) Compression and immobilization capabilities;
- (c) Magnification views;
- (d) Display on the console of a dose index, for example incident air kerma or mean glandular dose.

3.36. Specific design features for medical radiological equipment used for fluoroscopy should include:

- (a) The provision of a device that energizes the X ray tube only when continuously depressed (such as an exposure footswitch or 'dead man's switch');
- (b) Indication or display of the elapsed time and air kerma area product, and/or entrance surface dose monitors;
- (c) Automatic brightness control;
- (d) Pulsed fluoroscopy and pulsed image acquisition modes;
- (e) Last image hold the capture and display of the last acquired frame;
- (f) Road mapping;
- (g) Interlocks which prevent energizing the X ray beam inadvertently when the image detector is removed from the imaging chain.
- (h) The ability to disconnect the exposure footswitch between cases.

3.37. In addition to those listed in para 3.36, design features for medical radiological equipment used for image guided interventional procedures should include:

- (a) X ray tubes that have high heat capacities to enable operation at high tube currents and short times;
- (b) A generator with capability of at least 80 kilowatts (kW) of power;

- (c) A generator with a large dynamic range of mA levels (to minimize the range of kVp and exposure time needed to compensate for differences in thickness);
- (d) For paediatric work:
 - i. The generator supports an X ray tube with a minimum of three focal spots;
 - ii. The anti-scatter grid is removable;
 - iii. Image acquisition frame rate capability extends up to at least 60 frames per second for small children;
- (e) Transmission chambers installed at the end of the collimators to measure air kerma area product;
- (f) Imaging detectors that allow different fields of view (magnification) to improve the spatial resolution;
- (g) Automatic collimation;
- (h) Dual-shape collimators incorporating both circular and elliptical shutters to be used to modify the field for cardiac contour collimation;
- (i) Additional filtration in the X ray beam (commonly copper filters) that is selectable (often as part of the automatic brightness control system)
- (j) Extra filtration (0.2 mm 0.9 mm) that may be automatically set according to patient weight and angulation of the C-arm;
- (k) Dose per pulse and the number of pulses per second that are selectable;
- (1) Wedge filters that move automatically into the field of view to block areas where there is no tissue and thus no need for imaging;
- (m) Possible manipulation of diaphragms while in 'last image hold';
- (n) Display and recording in a digital format dose report of the following parameters:
 - i. Reference air kerma rate;
 - ii. Cumulative reference air kerma;
 - iii. Cumulative air kerma area product;
 - iv. Cumulative time of fluoroscopy;
 - v. Cumulative number of image acquisitions, (acquisition runs and frames per run);
 - vi. Integrated reference air kerma;
- (o) System for Digital subtraction angiography (DSA).

3.38. All digital medical radiological equipment should have the following additional features:

- (a) Real time dose display and end-of-case dose report (radiation dose structured report (RDSR), DICOM object), including dose metrics export for the purpose of DRLs and individual patient dose calculation;
- (b) Connectivity to RIS/PACS.

3.39. For medical radiological equipment used for performing diagnostic and interventional radiology procedures on children, there should be additional design features that both facilitate successful radiological procedures on patients that are typically uncooperative and suit imaging very small patients. Such features include the capability of very short exposure times for radiography, specifically designed automatic exposure controls, provision of "paediatric modes" for the automatic brightness control systems in fluoroscopy and image guided interventional procedures, and paediatric protocols for CT.

Other equipment

3.40. All equipment used for digital image display should meet appropriate international and/or local standards, for example meeting the performance specifications of the AAPM Task Group 18 [116]. See paras. 3.24 to 3.25 for guidance on reporting rooms.

3.41. View boxes, for viewing films, should have sufficient uniform brightness to facilitate diagnosis, and the colour of view boxes should be matched through the complete set of view boxes. Means should be available (masks) to restrict the illuminated area of the radiograph to avoid dazzling. View boxes used for mammography should have higher luminance performance. Detailed guidance is given in Refs [117 – 122]. See paras. 3.24 to 3.25 for guidance on reporting rooms.

3.42. For radiology facilities where film is being used as an image receptor, film processing plays a crucial role in ensuring the medical exposure results in a diagnostic image. Automatic film processors should meet appropriate standards. Film-screen based mammography should have dedicated film processors with extended processing cycles. If manual processing is being performed, specially designed developer, fixer and washing tanks should be used, with developer temperature-based processing times. The darkroom for processing should meet relevant international and/or local standards for light-tightness and be equipped with an appropriately filtered safe-light, compatible with the film being used. Further details are given in Refs. [86, 117 - 122].

Maintenance

3.43. The BSS (BSS, paragraphs 3.15(i) and 3.41) gives requirements for maintenance to ensure that sources meet their design requirements for protection and safety throughout their lifetime and to prevent accidents as far as reasonably practicable. The registrant or licensee should ensure that adequate maintenance (preventive and corrective) is performed to ensure that medical radiological equipment retain, or improve through appropriate hardware and/or software upgrades, their design specifications for image quality and 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 and on an on-going basis.

3.44. All maintenance procedures should be included in the quality assurance programme at the frequency recommended by the manufacturer of the equipment and relevant professional bodies. Servicing should include a report describing the equipment fault, the work done and the parts replaced and adjustments made, which should be filed as part of the quality assurance programme. A record of maintenance carried out should be kept for each item of equipment: this should include information on any defects found by users (a fault log), remedial actions taken (both interim and subsequent repairs) and the results of testing before equipment is reintroduced to clinical use.

3.45. In line with the guidance in Section 2 para. 2.111, after any modifications or maintenance, the person responsible for maintenance should immediately inform the licensee of the medical radiation facility before it is returned to clinical use. The person responsible for the use of the equipment, in conjunction with the medical physicist, the medical radiation technologist and other appropriate professionals, should decide whether quality control tests are needed with regard to radiation protection, including image quality, and whether changes to protocols are needed.

3.46. The electrical and mechanical safety aspects of the medical radiological equipment should be part of the maintenance programme, and can have direct or indirect effects on radiation safety. Authorized persons who understand the specifications of the medical radiological equipment should perform this work. See also Section 2 paras. 2.110 - 2.112. Electrical and mechanical maintenance should be included in the QA programme at a frequency recommended and preferentially performed by the manufacturer of the medical radiological equipment or authorized agent. Servicing should

include a written report describing the findings. These reports and follow up corrective actions should be archived as part of the QA programme.

OCCUPATIONAL RADIATION PROTECTION

Introduction

3.47. In diagnostic imaging procedures described in paras. 3.1 to 3.4, occupationally exposed individuals are usually the medical radiation technologists and the radiological medical practitioners (including, for example, radiologists and, in dental practices, dentists operating the X ray machine). In a trauma centre, other health professionals such as nurses, emergency department physicians and anaesthetists who may have to be present when using portable or fixed X ray machines, including C-arm fluoroscopes, or who may have to be present in the CT room when the unit is operating may also be considered occupationally exposed.

3.48. In image guided interventional procedures and during surgery, as described in para. 3.4, the occupationally exposed individuals are the radiological medical practitioners who perform the interventions (including but not limited to radiologists, cardiologists, vascular surgeons, orthopaedic surgeons, neurosurgeons, urologists, anaesthetists¹³, respiratory physicians, and gastroenterologists), medical radiation technologists, and other health professionals who are present and part of the interventional team, including the anaesthetist, nurses, and technicians who monitor patient physiological parameters. Some complex and lengthy procedures may require more than one interventionist.

3.49 Additional occupationally exposed personnel may include medical physicists, biomedical, clinical or service engineers and some contractors, depending on their role.

3.50. Other radiology facility workers such as patient porters, orderlies, assistants, cleaners and other service support, for whom radiation sources are not directly related to their work, require the same level of protection as members of the public, as stated in the BSS paragraph 3.78.

3.51. This sub-section contains guidance very specific to diagnostic radiology and image guided interventional procedures. For more general and comprehensive guidance on occupational radiation protection, including guidance on radiation protection programmes, assessment of occupational exposure and providers of dosimetry services, applicable to all areas of radiation use (including non-medical uses), reference should be made to the IAEA Safety Guide *Occupational Radiation Protection* [23].

Arrangements under the radiation protection programme

Classification of areas

3.52. Various areas and rooms in a radiology facility should be classified as controlled or supervised areas, in line with the requirements given in BSS paragraphs 3.88 to 3.92. All other rooms and areas, not so-designated, are considered as "public domain" and levels of radiation in these areas should be low enough to ensure compliance with the dose limits for public exposure.

3.53. All X ray rooms should be designated as 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

¹³ Called anaesthesiologists in some States.

procedures are being carried out. Open plan emergency departments (i.e. an area without fixed walls where curtains or similar are used to create cubicles), with either fixed or mobile X ray units, can also be categorized as controlled areas during the time in which radiological procedures are being carried out. In order to avoid uncertainties about the extent of controlled areas, the boundaries should, when possible, be walls and doors.

3.54. 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 and workstation reading rooms and internal corridors. 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 as a "buffer zone" owing to the potential for other individuals inadvertently entering the X ray rooms and receiving an exposure.

3.55. The control console may be inside the X ray room, separated by structural shielding, or outside the X ray room in the staff area, with visual control of the X ray room and with patient communication. Control console areas should have restricted access to unauthorized individuals to avoid the distraction of the operator, which might lead to unnecessary exposure or repeated exposures. For this reason, control panel areas should be either classified as controlled or supervised, despite the fact that the radiation levels may be very low.

Local rules and procedures

3.56. The BSS, in paragraph 3.93, establishes a hierarchy of preventive measures for protection and safety with engineered controls, including structured and ancillary shielding, being supported by administrative controls and personal protective equipment. To this end, and as required in the BSS paragraph 3.94, written local rules and procedures should be in place in any radiology facility. Their purpose is to ensure protection and safety for workers and other persons. These local rules and procedures should include measures to minimize occupational radiation exposure during both normal work and unusual events. The local rules and procedures also should cover the wearing, handling and storing of personal dosimeters, and specify investigation levels and ensuing follow-up actions (see paras. 3.98 - 3.123).

3.57. Since all personnel involved in using radiation in a radiology facility should know and follow the local rules and procedures, the development and review of these local rules and procedures should include representatives of all health professionals involved in diagnostic radiology and image guided interventional procedures.

3.58. Equipment (hardware and software) should be operated in a manner that ensures satisfactory performance at all times with respect to both the tasks to be accomplished and radiation safety. The manufacturer's operating manual should be used as an important resource in this respect, but additional procedures are likely to be needed. The final documented set of operational procedures should be approved by the radiology facility's licensee, and incorporated into the facility's quality management system (see Section 2, paras. 2.136 - 2.147).

3.59. Radiology facility staff should understand the documented procedures for their work with radiation and for the operation of the equipment with which they are working, including the safety features, and should be trained, with periodic refresher training, in what to do when things go wrong. Additional training should occur when new medical radiological equipment is brought into use in the radiology facility.

3.60. Many local rules and procedures address aspects of some, or all, of occupational radiation protection, patient radiation protection and public radiation protection, either directly or indirectly, as well as ensuring a successful diagnostic examination or intervention. This is the case with the following paragraphs (3.61 to 3.82) – while placed in this section on occupational radiation protection because they are to be followed by workers, the local rules and procedures often also have significance for patient and/or public radiation protection. The following paragraphs (3.61 to 3.82) give recommendations that should be incorporated into the radiology facility's local rules and procedures.

3.61. For those radiological procedures where there is no need for staff to be in the room during an exposure, all attending staff should position themselves in the appropriately shielded areas.

3.62. Immobilization devices (e.g. CT head cradle) should be used whenever possible and as appropriate to minimize exposure to the patient, staff or carer or comforter. Immobilization of patients should not be performed by staff and, if possible, not by any person. If immobilization requires the use of a person, then this should be someone, such as a relative of the patient, who has agreed to be a carer and comforter, and is afforded radiation protection accordingly (see paras. 3. 238 - 3.242).

3.63. For general radiography:

- (a) At no time should the X ray tube be pointed at the control console area;
- (b) Given that the patient is the source of scatter, care should be taken to ensure that the patient position is as far from the control console as is feasible, taking into account the room configuration and accessories, and preferably more than one metre distant from the console.

3.64. For mobile radiography:

- (a) Operators¹⁴ should wear lead aprons and maintain as much distance as possible between themselves and the patient (to minimize exposure to scatter), whilst still maintaining good visual supervision of the patient and being able to communicate verbally with him/her;
- (b) Other staff (e.g., nursing, medical and ancillary staff) are not considered as occupationally exposed workers and hence should be afforded protection as a member of the public. This is achieved by ensuring such persons are as far away from the patient as possible during the exposure (at least 3 meters) or are behind appropriate barriers;
- (c) In those situations where a member of staff needs to be close to the patient, protective aprons should be worn (e.g., an anaesthetist with a ventilated patient or a nurse with an unstable patient);
- (d) Verbal warning of an imminent exposure is given;
- (e) Consideration should be given to other patients who may be nearby. (See also sub-section on public radiation protection, para. 3.269.)

3.65. In many emergency departments, ceiling suspended X ray equipment provides a versatile environment for performing rapid trauma radiography. Appropriate occupational radiation protection can be afforded through the following:

- (a) Lead aprons should be worn by staff members that need to be adjacent to the patient being exposed;
- (b) The primary beam should be directed away from staff and other patients whenever possible;

¹⁴ The term "operator" is used generically in this section. The operator is usually a medical radiation technologist, but may sometimes be a radiological medical practitioner, such as a radiologist.

- (c) Staff should keep as far away as possible from the patient during exposure, whilst still maintaining good visual supervision of the patient;
- (d) Where available, mobile shields should be used;
- (e) Any pregnant staff member (other than radiology staff) should be asked by the medical radiation technologist to leave the vicinity during exposure;
- (f) Verbal warning of imminent exposure is given.

3.66. For CT, when staff need to be in the room during exposures, additional measures should be taken:

- (a) In the case of CT interventions, the interventionist should use appropriate personal protective equipment (protective apron, thyroid shield, protective eye-wear). In addition, care should be exercised to avoid placing hands in the primary beam and immediate notification to the interventionist should be given if this does happen;
- (b) In the case of persons providing medical support, e.g., anaesthetists, a protective apron should be worn and the person should position themselves as far from the gantry as possible, whilst still maintaining good visual supervision of the patient.

3.67. For diagnostic fluoroscopic procedures, when staff need to be in the room, the following measures should be taken:

- (a) The staff member performing the procedure should use personal protective equipment (protective apron, thyroid shield, protective eye-wear, gloves). In addition, care should be exercised to avoid placing hands in the primary beam;
- (b) In the case of persons providing medical support, e.g., anaesthetists, a protective apron should be worn and the person should position themselves as far from the patient as possible during screening.

3.68. For radiological procedures performed with mobile fluoroscopic units (C-arm systems):

- (a) The staff member performing the procedure should use personal protective equipment (protective apron, thyroid shield, protective eye-wear, gloves). In addition, care should be exercised to avoid placing hands in the primary beam and immediate notification to the fluoroscopist should be given if this does happen;
- (b) Only essential staff should remain in the room. All such staff are considered occupationally exposed workers;
- (c) In those situations where a member of staff needs to be close to the patient, protective aprons should be worn (e.g., an anaesthetist with a ventilated patient or a nurse with an unstable patient). At no time should a pregnant staff member take on this role;
- (d) For other practical advice, including X ray tube orientation and positioning, mobile shields, technical parameter selection, see the section on image guided interventional procedures (paras 3.74 to 3.81).

3.69. For mammography, the medical radiation technologist should stand behind the protective barrier attached to the mammography unit when making the exposure.

3.70. For dental facilities with intraoral and panoramic (OPG) equipment, personal protective equipment is not usually needed. Radiation protection is afforded through the use of distance from the patient. Typically, a distance of at least two metres is recommended.

3.71. Cone beam CT (CBCT) is in use in some dental facilities, and should be housed in a room that has been designed and shielded accordingly (see para. 3.34). The staff should be positioned behind the protective barrier at the control console when exposures are being made.

3.72. For DEXA, the radiation levels around the unit are very low and there are no specific precautions that should be taken with respect to occupational radiation protection. Typically the operator can be in the room with the patient when the machine is operating. The operators' desk should be positioned at least 1 m away from a pencil beam, and at least 2 m from a fan-beam system. In the case of fan-beam and cone-beam configurations or if the distances above cannot be accommodated, the use of protective screens should be considered.

3.73. Local rules for pregnant workers and persons under 18 should reflect the guidance given in paras. 3.127 - 3.129 and 3.130 respectively.

Local rules and procedures – image guided interventional procedures

3.74. Image guided interventional procedures, performed either in fluoroscopy rooms or dedicated interventional rooms, tend to be complex and are performed on patients who can be quite ill and/or have a life threatening condition. As a consequence, more staff will be needed in the room to attend to the patients' individual medical needs (e.g., interventionists, anaesthetists, medical radiation technologists, nurses, and sometimes other specialists). Not only will more staff be exposed during interventional procedures, they may also be standing close to the patient where dose rates from radiation scattered by the patient are high.

3.75. Interventional procedures require specifically designed and dedicated equipment. The exposure rate in the vicinity of the patient is lower on the beam exit side of the patient. For a vertical orientation, an under-couch X ray tube with an over-couch image receptor has lower levels of scatter in the area of the operator's trunk and head than an over-couch X ray tube with an under-couch image receptor. A similar situation exists with lateral projections, where the maximum scatter radiation is on the X ray tube side of the patient. Staff should, where practicable, always stand on the image receptor side of the patient during lateral or oblique projections.

3.76. There are simple methods of reducing exposure to staff as a result of operational factors, including choosing where to stand or to be positioned in the room. Since the patient is the main source of scatter radiation, the staff should remain as far away as practicable from the patient when exposures are taking place, to reduce exposure to staff. For the interventionist, taking a step or even half a step back during image acquisition results in a significant reduction in occupational dose. As discussed in para. 3.75, the X ray tube orientation and positioning will determine where it is best to stand in order to be in an area subject to relatively low scatter.

3.77. Staff should never be subject to direct beam exposure. This includes avoiding placing the hands in the beam whenever possible. When hands of the operator are close to the direct beam, an undercouch X ray tube with an over-couch image receptor should be used, because the exposure rate is lower on the beam exit side of the patient and the exposure to the operator's hands is significantly reduced.

3.78. There are many operational factors that affect the patient dose during image guided interventional procedures, and these factors in turn affect staff dose because the dose to the patient determines the amount of scatter being produced. Methods to reduce patient dose are described in paras 3.182 to 3.187, and should always be used to reduce both patient and staff doses.

3.79. Medical radiological equipment specifically designed for image guided interventional procedures often incorporates protective devices, such as ceiling suspended lead acrylic viewing screens, and under-table and lateral shielding attachments to the X ray couch, and personal mobile shields. Alternatively, such devices can be purchased separately. These devices can afford individuals

significant radiation protection, but they can sometimes be cumbersome to use. However, the appropriate use of these devices will result in a significant reduction in staff doses.

3.80. Higher incidence of radiation injuries to the lens of the eye has been reported for interventionists and nurses performing image guided interventional procedures [123]. For this reason it is strongly recommended that interventionists, and other staff who routinely work close to the patient, always use ceiling mounted screens and/or protective eye-wear. This is further reinforced by the requirement to comply with the relatively low dose limit (20 mSv per year) for the lens of the eye. It is quite likely that the dose limit would be exceeded for an interventionist performing several hundred image guided interventional procedures in a year if that person used no protection for the eyes.

3.81. Further specific guidance on interventional radiology and interventional cardiology, endorsed by several regional professional societies, can be found in references [124, 125].

3.82. Some image guided interventional procedures are performed using CT and the guidance given in para 3.66 applies.

Personal protective equipment

3.83. As required in the BSS paragraph 3.93 and 3.95, personal protective equipment and in-room protective equipment should be available and used when structural shielding and administrative controls alone cannot afford the required level of occupational radiation protection. This typically arises when staff are required to be in the room where and when the radiological procedures are taking place, such as with image guided interventional procedures and fluoroscopy, and with mobile radiography. The need for these protective devices should be established by the radiology facility's RPO or medical physicist.

3.84. Personal protective equipment is worn on the person and includes protective aprons, thyroid protectors, protective eye-wear, and protective gloves. Protective aprons are available in many shapes, configurations, materials and lead equivalence, and should be chosen to best suit the intended use. Some aprons require using fully overlapping panels to provide complete coverage. Expert advice on personal protective equipment should be sought from the RPO or medical physicist.

3.85. For image guided interventional procedures, wrap around aprons, preferably consisting of vests and skirts to spread the weight, should be used. They should cover:

- (a) From the neck down to at least 10 cm below the knees;
- (b) The entire breast bone (sternum) and shoulders;
- (c) The sides of the body from not more than 10 cm below the armpits to at least halfway down the thighs;
- (d) The back from the shoulders down to and including the buttocks.

3.86. Protective 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. Even if the fluoroscopy system operates without ABC, leaded gloves may prolong the procedure because they do no afford the necessary tactile sensitivity and thus their value is questionable.

3.87. Protective eye-wear, especially for use in image guided interventional procedures, should cover the entire orbit. This requires lateral protection provided by shielded sides and that the glasses are a close fit.

3.88. The lead-equivalence of personal protective equipment should be specified at the maximum operating X Ray tube potential (kVp) applicable for its intended use.

3.89. Non-lead based personal protective equipment, incorporating shielding materials, such as tin, tungsten, bismuth, and antimony, may be preferable if they are lighter and easier to use. Care should be taken in interpreting claimed lead equivalences for non-lead based protective equipment, and expert advice from the RPO or medical physicist should be sought.

3.90. Protective equipment for pregnant workers should be carefully considered, as wrap around aprons may no longer provide adequate protection for the embryo/fetus to meet BSS requirements (BSS paragraph 3.114). The RPO or medical physicist should be consulted as needed.

3.91. Personal protective equipment, in particular protective aprons, can lose their protective effectiveness if mistreated or not appropriately used or cared for. All personnel that use personal protective equipment have the responsibility for its appropriate use and care, for example ensuring aprons are correctly hung and stored to minimize damage.

3.92. Personal protective equipment should be examined under fluoroscopy at least annually to confirm its shielding integrity.

In-room protective devices

3.93. Additional protective devices for use in fluoroscopy and image guided interventional procedures include:

- (a) Ceiling suspended protective screens for protecting eyes and the thyroid while keeping visual contact with the patient. Technical advances with such screens include systems that move with the operator;
- (b) Protective lead curtains or drapes mounted on the patient table;
- (c) Mobile shields either attached to the table (lateral shields) or mounted on coasters (full body);
- (d) Disposable patient protective drapes.

Monitoring of the workplace

3.94. The BSS, in paragraphs 3.96-3.98, sets out the requirements and responsibilities for workplace monitoring. Workplace monitoring comprises measurements made in the working environment and the interpretation of such results. Workplace monitoring serves several purposes, including routine monitoring, special monitoring for specific occasions, activities or tasks, and confirmatory monitoring to check assumptions made about exposure conditions. Workplace monitoring can be used to verify the occupational doses of personnel whose work involves exposure to predictable low levels of radiation. It should be particularly used for staff members who are not individually monitored. Further general guidance on workplace monitoring is given in Ref [23].

3.95. Workplace monitoring in areas around each of the medical radiological equipment in the radiology facility, when it is being operated, should be carried out when:

- (a) The room and shielding construction has been completed, regardless whether it is a new construction or a renovation, and before the room is first used clinically;
- (b) New or substantially refurbished equipment is commissioned (both direct and indirect radiation such as leakage and scatter should be measured);
- (c) New software for the medical radiological equipment is installed or there is a significant upgrade;
- (d) New techniques are introduced;

(e) Servicing on the medical radiological equipment has been performed, which may have an impact on the radiation delivered.

3.96. Workplace monitoring should be performed and documented as part of the radiology facility's radiation protection programme. The radiology facility's RPO or medical physicist should provide specific advice on the workplace monitoring programme, including any investigations that arise through investigation levels being exceeded (see para. 3.115).

3.97. The survey meters used for radiation monitoring should be calibrated in terms of ambient dose equivalent. For diagnostic radiology and image guided interventional procedures, the quantity is $H^*(10)$ and the unit the Sv and its sub-multiples.

Assessment of occupational exposure and workers' health surveillance

Occupational exposure assessment

3.98. 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 and regulatory compliance. It contributes to reassurance and motivation. The BSS require individual monitoring for any worker who normally works in a controlled area or any worker who occasionally works in a controlled area and is likely to receive significant occupational exposure (see BSS paragraphs 3.99 to 3.102). Workers who may require individual monitoring include radiologists, cardiologists, gastroenterologists, endoscopists, urologists, orthopaedic surgeons, neurosurgeons, respiratory physicians, anaesthetists, medical physicists, biomedical/clinical engineers, medical radiation technologists, nurses, and the RPO.

3.99. Monitoring involves more than just measurement. It includes interpretation, assessment, investigation and reporting, which may lead to corrective measures, if necessary. Individual external doses are assessed using individual monitoring devices that include thermoluminescent dosimeters (TLD), optical stimulated luminescence dosimeters (OSLD), film badges, and electronic dosimeters. Care should be taken when using electronic dosimeters in pulsed X ray fields that they function correctly. Individual monitoring devices must be calibrated, traceable to a standards dosimetry laboratory. For more detailed guidance see Ref [23].

3.100. Each dosimeter is to be used for monitoring only the person to whom it is issued, for work performed at that radiology facility and should not be taken to other facilities where that person may work. For example, if a person is issued with a dosimeter at hospital A it should be worn only at hospital A and not at any other hospitals or medical centres where he/she may also work. Monitoring results can then be interpreted for the person working in a specific radiology facility, and allow appropriate review of the effectiveness of the optimization of protection for that individual in that facility. See also paras. 3.117 to 3.118.

3.101. The monitoring period (period of dosimeter deployment) specified by regulatory bodies in most countries is typically in the range of one to three months. A one month monitoring period is usually used for persons performing procedures associated with higher occupational exposures, such as image guided interventional procedures. A longer monitoring period (two or three months) is more typical for personnel exposed to lower doses, as a one month cycle would usually mean that the actual occupational dose was less than the minimum detection level of the dosimeter resulting in no detectable doses. With a longer cycle it is more likely to obtain a reading. The radiology facility

should send the dosimeters to the dosimetry service provider who should then process the dosimeters and return the dose reports, all in a timely manner. Some regulatory bodies may specify a performance criterion for timely reporting.

3.102. The operational dosimetric quantity used is the personal dose equivalent $H_p(d)$. For weakly penetrating and strongly penetrating radiation, the recommended depths, *d*, are 0.07 mm and 10 mm, respectively. Radiation used in diagnostic radiology and image guided interventional procedures is usually relatively strongly penetrating, and therefore d = 10 mm for dosimeters being used to assess effective dose. $H_p(10)$ is used to provide an estimate of effective dose that avoids both underestimation and excessive overestimation [23]. In diagnostic radiology and image guided interventional procedures, the overestimation is somewhat larger because of the lower photon penetration from X ray beams in the kV range [126, 127]. If a protective apron or thyroid shield is being worn, the relationship between $H_p(10)$ effective dose becomes more complex and additional guidance is given below in para. 3.109.

3.103. For monitoring the skin and extremities, a depth of 0.07 mm (d = 0.07) is recommended, and $H_p(0.07)$ is used to provide an estimate of equivalent dose to the skin and extremities.

3.104. For monitoring the lens of the eye, a depth of 3 mm (d = 3) is recommended, and $H_p(3)$ is used to provide an estimate of equivalent dose to the lens of the eye. In practice, however, the use of $H_p(3)$ has not been widely implemented for routine individual monitoring. In cases where eye doses are a concern, such as in image guided interventional procedures, $H_p(0.07)$, and to a lesser extent $H_p(10)$, can be considered as an acceptable surrogate operational quantity. More guidelines are provided in the IAEA publication [128].

3.105. There are three dose limits applicable to workers in diagnostic radiology and image guided interventional procedures – effective dose; and equivalent dose to the lens of the eye, and to skin and extremities. The dosimeter being worn will be used to estimate one or more of the quantities used for the dose limits. Depending on the work being performed by the person being individually monitored, there may be a preferred position for wearing the dosimeter, and more than one dosimeter may be used.

3.106. For individual monitoring with only one dosimeter in diagnostic radiology and image guided interventional procedures:

- (a) If the monitored worker never wears a protective apron, the dosimeter should be worn on the front of the torso between the shoulders and the waist;
- (b) If the monitored worker sometimes wears a protective apron, the dosimeter should be worn on the front of the torso between the shoulders and the waist, and under the apron when it is being worn;
- (c) If the monitored worker always wears a protective apron, the dosimeter should be worn on the front of the torso at shoulder or collar level outside the apron (see also para. 3.107);
- (d) If the working situation is such that the radiation is always or predominantly coming from one side of the person, such as in image guided interventional procedures, the dosimeter should be placed, in addition to the guidance in (a) to (c), on the front of the torso on the side closest to the source of radiation.

3.107. For individual monitoring with two dosimeters, such as in image guided interventional procedures where the monitored worker always wears a protective apron, one dosimeter should be worn on the front of the torso at shoulder or collar level outside the apron on the side closest to the

source of radiation. The other dosimeter should be worn on the front of the torso between the shoulders and the waist and under the apron, preferably on the side closest to the source of radiation.

3.108. Specialized dosimeters, such as ring dosimeters for monitoring finger doses, will have their own specific wearing instructions which should be followed.

3.109. When a protective apron is being used, the assessment of effective dose may not be straightforward:

- (a) A single dosimeter placed under the apron, reported in $H_p(10)$, 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).
- (b) A single dosimeter worn outside the apron, reported in $H_p(10)$, provides a significant overestimate of effective dose and should be corrected for the protection afforded by the apron by using an appropriate algorithm [123, 127 129].
- (c) Where two dosimeters are worn, one under the apron and the other outside the apron, an algorithm should be applied to estimate effective dose from the two reported values of $H_p(10)$ [127, 129].

3.110. As noted in para. 3.104, dosimeters for reporting $H_p(3)$ are not widely available. A dosimeter worn outside the apron at collar or neck level, reported in either $H_p(0.07)$ or $H_p(10)$, can provide a surrogate estimate for the equivalent dose to the lens of the eye. Whether protective eye-wear was being worn or not should be taken into account to correctly interpret the dose estimate.

3.111. When not in use, individual dosimeters should be kept in an established place and protected from damage or from irradiation. 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 in a timely manner. 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 similar exposure conditions as the basis for the dose estimate.

3.112. In some radiology 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 to individual monitoring. Knowing the typical level of dose per procedure for positions where personnel are placed during exposures and the number of procedures per year, the RPO can estimate personnel doses.

3.113. Similarly, occupational doses can be estimated from the results of workplace monitoring. The effective dose for personnel can be inferred from the measured ambient dose equivalent $H^*(10)$. ICRP Publication 116 provides conversion coefficients from ambient dose equivalent to effective dose for different types of radiation and energies [126]. 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.

3.114. An additional direct reading operational dosimeters, such as appropriately calibrated electronic dosimeters, may be also used in image guided interventional procedures, as these devices can give the worker an instant indication of both the cumulative dose and the current dose rate and are a useful educative tool for the optimization of occupational radiation protection [23].

Investigation levels for staff exposure

3.115. Investigation levels are separate from dose constraints and dose limits; they 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. Exceeding an investigation level should prompt such actions. The following are examples for radiology facilities of levels and their related tasks that should not normally be exceeded and, therefore, could be suitable as investigation levels. For example, monthly values higher than 0.5 mSv (for the dosimeter worn under the protective apron) should be investigated. Values higher than 2 mSv per month [125] from the over-apron dosimeter may indicate that eye doses may be of concern. Values higher than 15 mSv per month for hand or finger dosimeters should also be investigated. Abnormal conditions and/or events should also trigger an investigation. In all cases the investigation is carried out with a view to improve implementation of optimization of occupational protection and results should be recorded. Investigation levels should also be set for workplace monitoring.

3.116. The investigation is to be initiated as soon as possible following the trigger or event and a written report is to be prepared concerning the cause, including determination or verification of the dose, corrective or mitigating actions, and instructions or recommendations to avoid recurrence. Such reports should be reviewed by quality assurance and radiation safety committees, as appropriate, and the holder of the licence should be informed. In some cases, the regulatory body may also need to be informed.

Persons who work in more than one place

3.117. Personnel may work regularly in more than one radiology facility. The facilities may be quite separate entities in terms of ownership and management, or they may have common ownership and management, but be physically quite separate management, or they may have common ownership and management, but be physically quite separate. No matter which, the occupational radiation protection requirements for the particular radiology facility apply when the person is working in that facility. As described above in para. 3.100, a dosimeter issued for individual monitoring should be worn only in the facility for which it is issued as this facilitates effective implementation of optimization of protection in that facility. This approach is logistically more easily implemented as each physical site has its own dosimeters – there is no need to transport dosimeters between facilities, with the risk of either loss or forgetting them. In cases where the facilities are under common ownership it may be seen as an unnecessary financial burden to provide more than one set of dosimeters for staff that work in more than one of its facilities. However the radiation protection advantages of having the dosimeter results linked to a person's work in only one radiology facility remain. See also para. 3.119.

3.118. There is however an additional consideration, namely ensuring compliance with the occupational dose limits. Any person who works in multiple radiology facilities should notify the licensee for each of those facilities. Each licensee, through their RPO, establishes formal contact with the licensees of the other radiology facilities, and their RPOs, so that each facility has an arrangement to ensure that a personal dosimeter is available and that there is an on-going record of the occupational doses for that person in all the facilities where they work.

3.119. Some personnel, such as consultant medical physicists or service engineers, may perform work in many radiology facilities and, maybe as well, other medical radiation facilities. They may be employed by a company or be self-employed, providing contracted services to the radiology and other facilities. In such cases it is simpler for the company or the self-employed person to provide the dosimeters for individual monitoring. In other words, in these cases for each person the same dosimeter is used for work performed in all radiology facilities (and other medical radiation facilities) in the monitoring period.

Records of occupational exposure

3.120. Paragraphs 3.103 to 3.107 of the BSS state the requirements for records of occupational exposure, placing obligations on the employer, registrant and licensee. Apart from demonstrating compliance with legal requirements, records of occupational exposure should be used within the radiology facility for additional purposes, including assessing the effectiveness of the facility's implementation of optimization of protection, and evaluating trends in exposure. National or local regulatory bodies might specify additional requirements for records of occupational exposure and for access to the information contained in those records. Employer shall provide workers with access to records of their own occupational exposure (BSS, para 3.106 (a). Further general guidance on records of occupational exposure is given in [23].

Workers' health surveillance

3.121. The primary purpose of health surveillance is to assess the initial and continuing fitness of employees for their intended tasks, and requirements are given in BSS paragraphs 3.108 to 3.109.

3.122. No specific health surveillance related to exposure to ionizing radiation is necessary for staff involved in diagnostic radiology or image guided interventional procedures, with perhaps the possible exception of initial and periodic eye assessments for visual acuity and contrast resolution for personnel performing significant numbers of image guided interventional procedures. Only in cases of overexposed workers, at doses much higher than the dose limits (e.g. a few hundred millisieverts or higher), would special investigations involving biological dosimetry and further extended diagnosis and medical treatment be necessary [23]. Under normal working conditions, the occupational doses incurred in diagnostic radiology and image guided interventional procedures are low and no specific radiation related examinations are 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 considerations of occupational exposure arising from the working environment of a radiology facility to significantly influence the decision about the fitness of a worker to undertake work with radiation or to influence the general conditions of service [23].

3.123. Counselling should be available to workers who have or may have been exposed in excess of dose limits, and information, advice and, if indicated, counselling should be available to workers who are concerned about their radiation exposure. In diagnostic radiology and image guided procedures, the latter group may include women who are or may be pregnant such as, for example, female medical radiation technologists and nurses working in therapy wards. Counselling should be given by appropriately experienced and qualified practitioners. Further guidance is given in [23].

Information, instruction and training

3.124. All staff involved in diagnostic radiology and image guided interventional procedures should fulfil the respective training and competence criteria described in Section 2, paras. 2.117 to 2.135. This will include general education, training, qualification and competence for occupational radiation protection. Radiological medical practitioners, medical radiation technologists and nurses working with hybrid units (such as PET-CT, SPECT-CT) may have trained exclusively in their original specialty. They should undertake radiation protection training relevant to the additional imaging modality.

3.125. The BSS, in paragraph 3.110, places responsibilities on employers to provide, *inter alia*, specific instruction and training for protection and safety as it pertains to their radiology facilities.

This is not only for new staff but also for all staff as part of their continuing professional development. Specific instruction and training should be provided when new medical radiological procedures, equipment, software and technologies are introduced.

Conditions of service and special arrangements

3.126. As required in BSS paragraph 3.111, no special benefits are to be offered to staff because they are occupationally exposed. It is simply not acceptable to offer benefits as substitutes for measures for protection and safety.

Female workers (pregnant)

3.127. A female worker should notify the licensee that she is pregnant as soon as she knows of her condition, so that radiation protection requirements for the embryo/fetus as a member of the public can be met.

3.128. The limitation of the dose to the embryo/fetus does not mean that pregnant women should 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. A possible solution includes reassigning a pregnant worker to a location that may have lower ambient dose equivalent; for example, from fluoroscopy to radiography or to CT. Adequate training should accompany such reassignments.

3.129. When applying the dose limit of 1 mSv to the fetus, the reading of the dosimeter may overestimate fetal dose by a factor of 10. If the reading corresponds to a dosimeter worn outside a lead apron, the overestimation of fetal dose may rise to a factor of 100 [130]. Counselling for pregnant workers should be available (see also para. 3.123).

Persons under 18

3.130. In many countries there is the possibility of students aged 16 or more, but under 18, commencing their studies and training to become a medical radiation technologist or other health professional that may involve occupational exposure to ionizing radiation. The BSS paragraph 3.116 states the requirements for access to controlled areas and the dose limits for such persons are more restrictive – see Table 2 in this Safety Guide and Schedule III of the BSS.

RADIATION PROTECTION OF PATIENTS, CARERS AND COMFORTERS, AND VOLUNTEERS IN BIOMEDICAL RESEARCH

Introduction

3.131. The section covers what is more formally called 'medical exposure' in radiation protection. Medical exposure is defined in the BSS and described in Section 2, para. 2.5. It concerns radiation protection of the patient, carers and comforters, and volunteers in biomedical research. The term 'patient', when used in the context of medical exposure, means the person undergoing the radiological procedure. Other patients in the radiology facility, including those who may be waiting for their own

radiological procedure, are considered as members of the public and their radiation protection is covered in paras. 3.264 to 3.273.

3.132. As described in Section 2 para. 2.8, there are no dose limits for medical exposure, making it very important that there is effective application of the requirements for justification and optimization.

Justification of medical exposures

3.133. The requirements of the BSS for justification of medical exposure, paragraphs 3.156 to 3.163, incorporate the '3 level approach' to justification [4, 131, 132].

3.134. The roles of the health authority and professional bodies with respect to 'level 2' or generic justification of radiological procedures, justification of health screening programmes, and justification of screening intended for the early detection of disease, but not as part of a health screening programme, are described in Section 2 paras. 2.55 to 2.58, and 2.64.

Justification for the individual patient

3.135. The BSS invokes a joint approach to justification at the individual patient level, with a shared decision involving both the referring medical practitioner (who initiates the request for a radiological procedure) and the radiological medical practitioner. A referral should be regarded as a 'request for a professional consultation or opinion' rather than an 'instruction or order to perform'. The referring medical practitioner brings the knowledge of the medical context and the patient's history to the decision process, while the radiological medical practitioner has the specialist expertise on the radiological procedures. The efficacy, benefits and risks of alternative methods (both involving and not involving ionizing radiation) should be considered. In all cases the justification is informed by national or international referral guidelines, for example Refs [133 – 141]. Ultimate responsibility will be identified by individual member states' regulations.

3.136. The patient also should be informed about the expected benefits, risks and limitations of the proposed radiological procedure(s), as well as the consequences of not undergoing the procedure.

3.137. Justification, which is a radiation protection principle, is implemented more effectively as part of the medical process of determining 'appropriateness'. Appropriateness uses an evidence-based approach to choose the best test for a given clinical scenario, taking into account the diagnostic efficacy of the radiological procedure as well as alternative procedures that do not use ionizing radiation, for example, ultrasound, MRI or endoscopy. Useful tools to support this decision making process include national or international imaging referral guidelines developed by professional societies [133 - 141]. Imaging referral guidelines can be disseminated through electronic requesting systems¹⁵ and clinical decision support tools or systems.

3.138. In determining appropriateness of the radiological procedure for an individual patient, the following questions should be asked by the referring medical practitioner [138];

(a) *Has it been done already?* A radiological procedure that has already been performed within a reasonable time period (depending on the procedure and clinical question) should not be repeated. The results (images and reports) of previous examinations should be available, not only within a given radiology facility but also between different facilities. Digital imaging

¹⁵ Such electronic requesting systems include the so-called CPOE – computerized physician order entry, noting that for imaging such a system should generate a request rather than an order.

modalities and electronic networks should facilitate this process. Individual patient exposure records should facilitate decision making process if available.

- (b) *Is it needed?* The results of the proposed radiological procedure (positive or negative) should influence the patient's management.
- (c) *Is it needed now?* The timing of the proposed radiological procedure in relation to the progression of the suspected disease and the possibilities for treatment, all should be considered as a whole.
- (d) *Is this the best investigation to answer the clinical question?* Advances in imaging techniques are taking place continually, and the referring medical practitioner may need to discuss with the radiological medical practitioner what is currently available for a given problem.
- (e) *Has the clinical problem been explained to the radiological medical practitioner?* The medical context for the requested radiological procedure is crucial to ensure the correct technique is performed with the correct focus.

3.139. For a large percentage of radiological procedures, primarily 'well established' and low dose procedures, the practical implementation of justification may be achieved through the medical radiation technologist, who is effectively representing the radiological medical practitioner with the formal understanding that, if there is uncertainty, the radiological medical practitioner is contacted and the final decision is taken by the radiological medical practitioner in consultation with the referring medical practitioner. Such justification is guided by national or international referral guidelines.

3.140. For the smaller percentage of radiological procedures, primarily because of a combination of complexity, difficult medical context, and higher dose, the justification is likely to be led by the radiological medical practitioner with the referring medical practitioner providing any needed further clarification on the medical context. Again the justification is informed by national or international referral guidelines.

3.141. Two particular groups of patients are identified in the BSS, paragraph 3.157, for special consideration with respect to justification – patients who may be pregnant and paediatrics.

- (a) Due to the higher radiosensitivity of the embryo/fetus, it should be ascertained whether a female patient is pregnant before performing an X ray examination for diagnosis or an image guided interventional procedure. Determining pregnancy status is a requirement in the BSS, paragraph 3.176, for those radiological procedures that could result in significant dose to the embryo or fetus. Pregnancy would then be a factor in the justification process and might influence the timing of the proposed radiological procedure or whether another examination is more appropriate. Confirmation of pregnancy may occur after the initial justification and before the radiological procedure is performed. Repeat justification is required taking into account the additional sensitivity of the pregnant female patient and embryo or fetus.
- (b) As children are at greater risk of incurring radiation-induced stochastic effects, paediatric examinations require special consideration in the justification process.

3.142. Review of the justification may need to take place if circumstances change. For example, the performance of a low dose procedure that has been justified but, at the time of performing the examination, a high dose protocol is needed. Such a case might be the justification for low dose CT for renal colic would have to be reviewed if high-dose enhanced CT urography is actually needed to answer the clinical question.

3.143. 'Self-referral' occurs when a health professional undertakes a radiological procedure for patients as a result of justification based on their own previous clinical assessment. Examples of

acceptable self-referral practice include: dentistry, cardiology, orthopaedics, vascular surgery, urology, and gastroenterology. Relevant professional bodies in many countries develop appropriate guidance for their specialty, for example dental associations [142].

3.144. 'Self-presentation' occurs when a member of the public asks for a radiological procedure without a referral from a health professional. This may have been prompted by media reports or advertising. Examples include 'individual health assessment' which often involves CT procedures in asymptomatic individuals for early detection of cancer (e.g. whole body CT, lung CT or colon CT) and/or quantification of coronary artery calcification (coronary artery CT). Justification is required, as for all radiological procedures. Relevant professional bodies have an important role in considering evidence for developing guidance when new practices are proposed, as for example in the case of CT [143]. Member states may choose to incorporate this into legislation [144].

3.145. Approaches to support the implementation of the requirements for justification for medical exposures should consider the development of means to improve 'awareness, appropriateness and audit'. Awareness of the need for justification underpins the whole process. Means for promoting awareness include traditional education and training, such as at medical school or during specialty training, web-based learning or learning through work flow at the right time,(e.g. junior doctors in the emergency department), and the use of feedback in the reporting process. Appropriateness has been described in paras. 3.137 - 3.138, and the process of audit is used for monitoring and feedback to improve both awareness and appropriateness.

Justification – biomedical research volunteers

3.146. The role of the ethics committee in the justification of medical exposure of volunteers exposed as part of a programme of biomedical research is described in Section 2 para 2.98.

Justification – carers and comforters

3.147. The justification of medical exposure incurred by a carer or comforter is effectively carried out by the radiological medical practitioner or medical radiation technologist involved in the radiological procedure, prior to the performance of the procedure. It depends on the carer or comforter being correctly informed about the radiation doses and risks involved, and his or her understanding of this information and consequent agreement to take on the role of carer or comforter.

Optimization of protection and safety

3.148. In medical exposures, optimization of protection and safety has several components, some applied directly to the radiological procedure about to be performed and others providing the support or framework for the other components. These components of optimization of protection and safety are described in the following paras. 3.149 to 3.243.

Design considerations

3.149. The use of appropriate and well-designed medical radiological equipment underpins any radiological procedure in diagnostic radiology or any image guided interventional procedure. X ray generators and their accessories should be designed and manufactured so as to facilitate the keeping of medical exposures as low as reasonably achievable consistent with obtaining adequate diagnostic information or guidance for the intervention. Extensive guidance on design considerations is given in the sub-section on medical radiological equipment, paras. 3.26 to 3.39. This guidance is applicable to both stand-alone and hybrid systems. Ultimately, as stated in the BSS paragraph 3.162, it is the

responsibility of the radiology facility licensee to ensure that his/her facility uses only medical radiological equipment and software that meets applicable international or national standards.

Operational considerations - general

3.150. Following justification, the diagnostic radiological procedure or image guided interventional procedure is performed in such a way as to optimize patient protection, as required in the BSS paragraph 3.163. The level of image quality sufficient for diagnosis is determined by the radiological medical practitioner and is based on the clinical question posed and the anatomical structures imaged (e.g., the diagnosis of the pattern of sinusitis on CT requires only a low dose procedure as high contrast structures viz. air and bone are being imaged). With image guided interventional procedures, additionally, the level of image quality should be sufficient to guide the intervention.

3.151. The following points apply to all diagnostic radiological procedures or image guided interventional procedures:

- (a) There should be an effective system for correct identification of patients, with at least two forms of verification, for example name, birthday, address, medical record number.
- (b) Patient details should be correctly recorded, such as age, gender, weight, height, pregnancy status.
- (c) Patient clinical history should be reviewed.

3.152. The first step in operational considerations of optimization is to select the appropriate medical radiological equipment. For example, a chest X ray should be performed using dedicated equipment with a generator producing high output enabling the use of a long source to image receptor distance (typically 1.8 m) and a short exposure time to ensure a reproducible diagnostic quality image by minimizing patient respiratory and cardiac motion.

3.153. The volume (area) of the patient that is exposed should bestrictly limited to that of clinical interest. This is achieved through collimation for radiography, mammography, fluoroscopy and image guided interventional procedures, and through choice of scan parameters in CT. For digital radiography image cropping, performed after the exposure, does not achieve the same reduction in exposed volume as collimation. See also the paragraphs below for more specific guidance for the different modalities.

3.154. Patient co-operation should be achieved to produce a diagnostic quality image. This is particularly relevant when imaging children. Good communication helps to achieve this. Verbal interaction between the medical radiological technologist or the medical radiological practitioner and the patient should be in place before, during and after the procedure.

3.155. Optimization of protection for women undergoing radiological procedures during pregnancy should take into account the woman and the embryo/fetus. Routine diagnostic CT examinations of the pelvic region with and without contrast injection can reach lead to a dose of 50 mSv to the uterus which is assumed to be equivalent to the fetal dose in early pregnancy. When CT scanning is indicated in a pregnant patient, Low-dose CT protocols should be used and the scanning area should be reduced to a minimum possible.

3.156. Shielding of radiosensitive organs such as the gonads, lens of the eye, breast and thyroid should be used when appropriate.

3.157. For each modality there are a number of factors which can be adjusted to influence the image quality and patient dose relationship. Written protocols that specify the operational parameters to be

used for common diagnostic radiological procedures should be developed, adopted and implemented in each radiology facility. The protocol 'technique charts' should be posted adjacent to each X ray generator and be specific for each piece of equipment. The protocols should take into account patient habitus, especially mass. The protocols are best developed using guidelines from national or international professional bodies, and hence reflect current best practices, as for example in Refs [145 – 155]. For modern digital equipment many of the factors are automated through menu-driven examination selections on the console. Nevertheless, in setting up these options, significant scope exists for optimization of protection through the appropriate selection of values for the various technical parameters, thereby producing effectively an electronic 'technique chart'.

3.158. Size specific written protocols should be developed for children, from neonates to teenagers, and include additional operational considerations, such as the use of additional filtration or the removal of grids when appropriate [151, 154, 155].

3.159. The BSS paragraph 3. 166 (b) set special requirement to the optimization of protection for individuals subject to medical exposure as part of an approved health screening programme. All aspects should be considered before the approval of the program and during its implementation: selection of X-ray equipment suitable for the particular screening, parameters settings, etc. Dedicated quality assurance program should be implemented to meet screening objectives, as described in more details in paras 3.225 - 3.237.

Operational considerations - radiography

3.160. In developing protocols for radiography, many technique factors should be considered which can influence the image quality and the patient dose for the radiographic projection. Detailed guidance on appropriate choices for those factors is widely available [145, 150, 151, 156 – 162]. Such factors include:

- (a) The tube potential (kV); current (mA); exposure time; focal spot size; filtration; source to image receptor distance (SID, FID or FFD); choice of anti-scatter grids or Bucky device; collimation; image receptor size; patient positioning, immobilisation and compression;
- (b) The number of projections needed (e.g. PA chest X ray rather than PA and lateral X rays);
- (c) Organ shielding where appropriate (e.g. testicular shielding for pelvic radiographs in boys);

3.161. Suitably calibrated and maintained automatic exposure controlled systems (AEC) should be used when available and appropriate. Particular attention should be given to paediatric radiography to ensure that the AEC sensor(s) is(are) within the radiation field. AEC systems are calibrated based on the radiation exposure at the detector required to produce the desired level of optical density (OD) for film-screen systems or a pre-determined acceptable level of signal to noise ratio (SNR), or surrogate, for digital systems. The value for the SNR should be established as part of setting up the protocols for radiographic projections for each particular X ray unit. When AEC is not available, consideration should be made of the patient size and thickness of the body part imaged in determining technique factors.

3.162. For digital systems, users should understand how the selection of "exposure index" (or similar term for exposure indicator) affects patient dose. For some manufacturers, increasing the index lowers the dose; for others, it increases it [163].

3.163. For film-based image acquisition systems, additional factors include: the type (speed and spectral response) of film–screen combination and film processing conditions (e.g. the chemicals used and developing time and temperature).

3.164. Mobile and portable radiographic equipment usually produce images of lower quality compared with fixed units, and should only be used for examinations where it is impractical or not medically acceptable to transfer patients to a fixed unit.

3.165. Patient should be properly positioned and immobilized. In addition, instructions should be clear and in the language understood by the patient (e.g. "Please hold your breath").

Operational considerations - mammography

3.166. In developing protocols for mammography, consideration of radiographic technique factors should be made as for radiography, in para 3.160. Additional factors that should be considered include: adequate compression; tissue composition (e.g. dense glandular breasts identified on previous mammograms); and correct choice of anode and filters. Detailed guidance on appropriate choices for technique factors and additional factors is available [119 - 122, 147, 164 – 166].

3.167. For film-based mammographic systems, additional factors include: the type of film-screen combination and film processing conditions (e.g. the chemicals used, and developing time and temperature), as discussed in Refs [119 - 121].

3.168. Breast tomosynthesis is an evolving technique where guidance for optimization is likely to become available as the modality matures. A review of features that influence image acquisition has been made in Ref. [167].

3.169. Viewing conditions are of paramount importance for both digital and film-based mammography systems, and the operational performance should be meet the conditions described in paras. 3.24, 3.25 and 3.41. Poor viewing conditions not only compromise the reporting of a good quality image, but they may also lead to changes in technique factors, in a mistaken attempt to compensate for the poor viewing conditions, that actually result in sub-optimal image quality. For example, use of low luminance viewing boxes may lead to radiographs being produced that have a low density with insufficient diagnostic content. Although the dose may be reduced, there might be an unacceptable loss of diagnostic information.

Operational considerations - CT

3.170. In developing protocols for CT, many technique factors and features should be considered which can influence the image quality and the patient dose for the examination, including: tube potential; tube current; tube current modulation with noise index; pitch; beam width; total scan length, over-ranging and over-beaming. These and other factors may be optimized through automatic exposure control systems where available. The choice of protocol will be determined by the clinical question to be answered (e.g. for cardiac CT, a low dose protocol is sufficient for stratifying risk in patients with intermediate probability for coronary artery disease, whereas a higher dose contrast enhanced protocol is needed for patients with suspected coronary artery disease). Detailed guidance on appropriate choices for these factors and features is available [65, 146, 152, 153, 155, 157, 160, 161, 168 - 172].

3.171. Careful consideration should be made as to the need for multiple phase studies to answer the clinical question (e.g. CT abdomen portal venous phase only for routine detection of liver metastases rather than triple phase - arterial, portal venous and delayed phase acquisitions). Protocols for optimized CT procedures for common clinical conditions should be agreed, put in place and used. This applies particularly to children where protocols based on size should be used [153, 160, 161].
3.172. Consideration of a spiral or axial technique will depend on the indication and will have an implication on image quality and dose (e.g. for diffuse lung disease a non-contiguous single slice protocol is preferred for high resolution lung CT, and delivers lower patient dose).

3.173. Improved image presentation, reconstruction algorithms and post-processing features to reduce image noise can have the potential to enable the choice of a protocol with reduced patient dose. An example is the use of iterative reconstruction algorithms.

3.174. Proper positioning of the patient and proper setting of the scanned anatomical area of interest should be achieved, e.g. CT thorax with both arms raised or CT of the wrist in the 'superman position' (i.e. with the patient lying prone with the affected arm stretched out above his or her head) are of considerable advantage to avoid artefact and to reduce dose. Immobilizing devices may be used where appropriate. Special attention should be made for proper immobilisation of paediatric patients by use of straps, swaddling clothes, plastic holders for the head or body, foam pads, sponges, sand bags, pillows or other objects.

3.175. Including the lens of the eye in the primary beam should be avoided. This may be achieved in brain scans by using a head cradle or, in some cases, tilting the gantry.

3.176. For CT angiography, use of software to detect the arrival of contrast medium in the relevant vessel to trigger the volume acquisition has image quality advantages and avoids repeat acquisitions (e.g. detecting contrast medium in the pulmonary artery in CT pulmonary angiography).

3.177. For cardiac CT and CT angiography, use of software to control acquisition with respect to the patient electrocardiograph (ECG-gated or ECG triggered studies) should be considered, when appropriate, to reduce radiation dose.

3.178. For hybrid imaging with CT (e.g. PET-CT and SPECT-CT), consideration should be given to the use of a low dose CT protocol to correct for PET or SPECT attenuation, which may necessitate a second diagnostic procedure of the primary area of interest or a higher dose CT protocol (often contrast-enhanced) as part of the hybrid procedure.

3.179. Cone beam CT (CBCT) is used for imaging the head and neck (e.g. sinuses where there is significant artefact from dental amalgam) as well as for dental indications. Operational aspects with respect to optimization are still evolving. Guidance is available [173, 174] and factors that should be considered include: tube potential, tube current-exposure time product, field of view, voxel size, and the number of projections.

Operational considerations - dentistry

3.180. In developing protocols for conventional intra-oral radiography, factors that can influence the image quality and the patient dose include: tube potential (kV); current (mA); exposure time; collimation; focus to skin distance; and for analogue systems, film speed and processing development time and temperature. Detailed guidance on appropriate choices for those factors is available [175, 176].

3.181. In developing protocols for panoramic imaging, additional factors that can influence the image quality and the patient dose include: patient positioning (e.g. jaw open / closed); collimation (e.g. for temporomandibular joint examinations only these areas should be included); and for analogue systems, film/screen speed and processing development time and temperature. Detailed guidance on appropriate choices for those factors is available [175, 176].

Operational considerations - image guided interventional procedures

3.182. The choice of imaging modality for guidance will depend on the clinical scenario (e.g. fluoroscopic guidance for percutaneous coronary intervention, CT guidance for biopsy). Occasionally more than one modality may be used in a single interventional procedure to improve effectiveness and safety. This may result in a lower dose when the second modality is non-ionizing (e.g. ultrasound is used to locate the renal pelvis in percutaneous nephrostomy before fluoroscopic catheter placement). Furthermore the correct selection of equipment with appropriate size (and shape) of flat panel or image intensifier will improve diagnostic image quality.

3.183. Patient co-operation should be ensured for the successful interventions (e.g. movement may compromise accuracy of roadmaps when performing aneurysm embolization in neuro-intervention). It is imperative that patients are briefed about the intervention prior to the commencement of the procedure so that they know what to expect and how to cooperate.

3.184. In developing protocols for fluoroscopically guided interventional procedures, many technique factors and features should be considered which can influence the image quality and the patient dose for the intervention, including: tube potential; tube current; use of pulsed fluoroscopy (hence pulse width and rate); dose rate mode (effectively the image intensifier or flat panel detector input air kerma rate); collimation, and collimation tracking with focus to detector distance; filtration (fixed and variable); use of magnification; total fluoroscopy time for the intervention; image acquisition dose mode (effectively the image intensifier or flat panel detector input air kerma); image acquisition frame rate; number of frames per run and the total number of acquisitions. Detailed guidance on appropriate choices for these factors and features is available [123, 157, 158, 160, 161, 177 - 180].

3.185. Many of the factors in para. 3.182 are automated through an algorithm-driven 'automatic brightness control system' (ABC). Nevertheless, in setting up the algorithm, scope exists for optimization of protection through the selection of values for these parameters. For example, image intensifier or flat panel detector input air kerma rates (for fluoroscopy) and input air kerma per frame (for image acquisition) are set during installation and adjusted thereafter during periodic maintenance and servicing. The values actually used for these settings can vary considerably. High rate dose modes in fluoroscopy should be used only during the minimum indispensable time necessary to the procedure. The use of magnification modes should be kept to a minimum consistent with a successful intervention.

3.186. In the course of the intervention the tube orientation and position may need to be changed – for long procedures the area of skin where the X ray beam is incident upon the patient should be changed during the procedure to avoid deterministic skin effects. As a default from a radiation protection perspective, it is preferable to have the X ray tube under the patient (i.e. "under couch"). Steep oblique projections should be avoided. The distance between the X ray tube and patient should always be maximized to reduce patient dose. Typically for a vertical beam this is achieved by having the table as high as possible for the primary operator. In conjunction with this, the image intensifier or flat panel detector is positioned as close to the patient as possible.

3.187. Particular paediatric considerations include: use of special filtration, removal of the grid; gonad protection.

3.188. In developing protocols for CT guided interventional procedures, technique factors that should be considered, which can influence the image quality and the patient dose for the intervention,

include: tube potential; tube current; and beam width. The number of image acquisitions should be kept to a minimum consistent with a successful intervention.

Operational considerations - fluoroscopy

3.189. See fluoroscopic considerations in the image guided interventional procedures sub-section, paras. 3.184 - 3.187.

Operational considerations - bone densitometry

3.190. Selection of the appropriate site for densitometry will take into account both the anatomical area of clinical concern as well as the likelihood of non-representative images and measurements due artefacts (e.g. massive vertebral osteophytes may obviate the value of lumbar densitometry). Guidance is given in Ref [181].

Operational considerations - emergency radiology

3.191. Special considerations for the emergency department include: judicious patient positioning taking into account injury or disease (e.g. lateral shoot through projection of the hip); and CT protocols with the minimum number of acquisitions (e.g. contrast enhanced CT for polytrauma when one acquisition only is needed for diagnosis and expedience).

Calibration - general

3.192. Following the BSS paragraph 1.46, for diagnostic radiology and image guided interventional procedures the dosimetric quantities and units of ICRU are to be used [8, 182]. Further guidance on dosimetry in diagnostic radiology is given in Refs [9, 183].

3.193. Calibration requirements for medical radiological equipment and dosimetry equipment are given in the BSS paragraph 3.167. Responsibility is assigned to the radiology facility's medical physicist. After the initial calibration, the intervals for periodic calibrations may differ, depending on the complexity of the medical radiological equipment. Related to calibrations are the constancy tests on equipment performance performed as quality control tests. These are described in paras 3.228 and 3.230 - 3.231.

Calibration - medical radiological equipment

3.194. In diagnostic radiology, including medical radiological equipment used for radiation therapy simulation and treatment verification and hybrid imaging systems, and for image guided interventional procedures, 'source calibration' is to be interpreted as the measurement of certain dosimetric quantities which are modality-dependent and should be carried out in reference conditions.

3.195. For diagnostic radiographic and fluoroscopic medical radiological equipment, including conventional radiation therapy simulators, the dosimetric quantities are: incident air kerma, $K_{a,i}$, in Gy, incident air kerma rate, $K_{a,i}$, in Gy.s⁻¹ and air kerma-area product, P_{KA} , in Gy.m² (noting that some manufacturers use μ Gy.m² or mGy.cm² or Gy.cm²).

3.196. In CT, the dosimetric quantities are (see also [8, 9, 182 - 186]):

- (a) CT air kerma index, C_K, usually in mGy. In many countries the more colloquial term computed tomography dose index, CTDI, is used, and has been accepted by ICRU [182];
- (b) Weighted CT air kerma index, C_w, usually in mGy, which is the CT air kerma calculated from measurements at the centre and periphery of a standard PMMA CT head or body phantom. As in (a), this quantity is often simply called weighted CTDI or CTDI_w;

- (c) Volume CT air kerma index, C_{VOL} , usually in mGy which takes into account the helical pitch or axial scan spacing. As in (a), this quantity is often simply called volume CTDI or CTDI_{VOL};
- (d) CT air kerma-length-product, $P_{KL,CT}$, usually in mGy.cm. In many countries the more colloquial term dose-length-product, DLP, is used, and has been accepted by ICRU [182].

3.197. In mammography, three dosimetric quantities are used: incident air kerma, entrance surface air kerma and mean glandular dose, D_G , usually in mGy [8, 9].

3.198. Measurements of these dosimetric quantities, when being used to calibrate or characterize a given X ray, CT or mammography unit output or performance, should be made for a range of representative technique factors used clinically, and following recognized protocols such as in Ref [9].

Calibration – dosimetry instrumentation

3.199. Dosimetry instrumentation used at a radiology facility should be calibrated at appropriate intervals. A period of two to three years is recommended. See also para. 3.235 on associated quality assurance guidance.

3.200. The BSS in paragraph 3.167(d) requires the calibration of dosimetry instrumentation to be traceable to a standards dosimetry laboratory (SDL). Ideally this would be to the national SDL (primary or secondary) in the State concerned, with access either directly or through a duly accredited calibration facility. However, it may be necessary for dosimetry instruments to be sent to another country or state if there is no national SDL in the country or state where the instruments are used. At present only some of the secondary SDLs of the IAEA/WHO network provide calibration services using diagnostic radiology spectra and dose rates representative of clinical practice. However, since dosimetry accuracy is not as critical in diagnostic radiology as in radiation therapy, calibrations with comparable radiation qualities should be sufficient. Alternatively, the regulatory body may accept instrument manufacturer, provided that the manufacturer operates or uses a calibration facility that is itself traceable to a SDL and appropriate calibration conditions have been used. This certificate should state the overall uncertainty of the calibration factors.

3.201. Records of calibration measurements and associated calculations, including uncertainty determinations (budgets), should be maintained as described in para. 3.263. Uncertainty determinations for several radiological examinations have been calculated by the IAEA [9, 161].

3.202. There is a role for cross-calibration of dosimeters, where the radiology facility's dosimeters that have been officially calibrated are used to check or compare with other dosimeters. This is particularly important for field KAP meters which should be calibrated (or cross-calibrated) against a reference KAP meter or air kerma dosimeter *in situ* in the clinical rather than in a SDL environment [9]. It might also occur when a radiology facility has many dosimeters, and to calibrate all dosimeters could be too costly. Cross-calibration can also be utilized as a constancy check, as part of periodic quality control tests.

Dosimetry of patients

3.203. The BSS paragraph 3.168 requires facilities to ensure that patient dosimetry in diagnostic radiology and image guided interventional procedures is performed and typical doses for their radiological procedures are determined. Knowledge of a facility's typical doses forms the basis for applying methods of dose reduction as part optimization of protection. It also enables the radiology facility to use diagnostic reference levels (see paras. 3.217 to 3.224) as another tool for optimization of protection.

3.204. Clearly, the more radiological procedures at the radiology facility for which typical doses are known, the better the basis for optimization of protection. However, pragmatically, the BSS requires typical dose determination for only common radiological procedures in radiology facilities. What is common will vary from facility to facility, and country to country, but in general there are some core common examinations, including:

- (a) Radiography head, chest, abdomen and pelvis;
- (b) CT head, chest, abdomen and pelvis, for specified clinical indications;
- (c) Fluoroscopy barium swallow, barium enema;
- (d) Mammography cranio-caudal, medio-lateral-oblique;
- (e) Dentistry intraoral, panoramic (orthopantomography), cone-beam CT
- (f) Bone densitometry (DEXA) spine and hip.

3.205. For image guided interventional procedures, the facility should ascertain typical doses for the broad types of procedures they perform. For example, an interventional cardiology facility would characterize typical doses for percutaneous coronary interventions, including PTCAs. A facility performing neurological procedures might characterize typical doses for their diagnostic cerebral angiograms and for their embolization interventions. Other image guided interventional procedures might include ERCP (endoscopic retrograde cholangiopancreatography) and TIPS (transjugular intrahepatic portosystemic shunt).

3.206. The term 'typical dose', as used in the BSS paragraph 3.168, means the average or median of the doses for a sample of relatively standard-sized patients, at clinically acceptable image quality. Patient size has a large influence on dose, so some selection or grouping of patients is required. Such groupings include 'average adult', often based around an average weight of 70 kg with a range of \pm 20 kg. Groupings for children have sometimes been based on age, such as new born (0 years), infant (1 year), small child (5 years), child (10 years) and teenager (15 years), but more recently size-specific groupings are being used. The radiology facility should adopt patient size groupings that correspond with the groupings used in their country or state for DRLs. The sample size used for each patient grouping and radiological procedure should be sufficient to assure confidence in the determination of the mean dose. Such sample sizes are typically in the range of 20 patients, but clearly the larger the sample the better the statistics.

3.207. Dose in the term 'typical dose', as used in the BSS paragraph 3.168, means for the given radiological procedure an accepted dosimetric quantity as described in paras. 3.195 - 3.196. For particular reasons, e.g. for risk estimation or for collective dose estimation, organ doses or effective dose can be estimated from typical dose.

3.208. Patient dosimetry to determine typical doses should be carried out in conjunction with an assessment of the diagnostic image quality. Exposure alone is not meaningful if it does not correspond to images that are adequate for an accurate diagnosis. Therefore patients included in the sample used for determining typical doses should be only those whose radiological procedure resulted in acceptable image quality.

3.209. The results of the surveys used to determine typical doses at the radiology facility should be used as part of the facility's on-going review of the implementation of optimization of protection, and that additionally will be used for comparison with established DRLs (see paras. 3.217 to 3.224). The results should also be submitted to the organization in their country or state that is responsible for establishing and reviewing the national or regional DRLs. Patient dosimetry surveys, required by the BSS, should take place at intervals of no more than 5 years and preferably no more than 3 years.

Another trigger for a survey would be the introduction of new equipment or technology into the radiology facility or when significant changes have been made to the protocols or the equipment.

3.210. Sometimes patient dosimetry in diagnostic radiology or image guided interventional procedures may be required for specific individual patients, either through measurements or calculations. Reasons might include an unintended or accidental medical exposure, where estimation of patient doses is required as part of the investigation and report (see para. 3.256) or because there is a need to estimate embryo or fetal doses (see para. 3.155).

3.211. There are several indirect and direct methods to estimate patient dose in diagnostic radiology and image guided interventional procedures. Methodologies for these determinations are explained in detail in Refs [8, 9, 180, 182 - 187] and summarized below:

- (a) Estimations based on incident air kerma $(K_{a,i})$ or entrance surface air kerma $(K_{a,e})$ measurements corrected for the techniques used (X ray tube potential, current and time, source-skin-distance, etc.). This approach can be used for radiography, fluoroscopy and mammography.
- (b) Estimations based on measured air kerma-area product (P_{KA}) . This approach can be used for radiography, fluoroscopy and CBCT.
- (b) Estimations based on measurements of CT air kerma index (C_{VOL}) and CT air kerma-length product ($P_{KL,CT}$). This approach can be used for CT.
- (c) Reported values of dose quantities from DICOM headers or the DICOM radiation dose structured reports. The accuracy of the reported dose quantities should have been validated at acceptance testing and commissioning and during QA procedures as explained in para. 3.235. This approach is applicable to all digital modalities.
- (d) Direct measurements in selected organs such as the skin in interventional procedures. For this purpose thermoluminescent and optically-stimulated dosimeters (TLDs and OSLs) as well as radiochromic or silver halide film can be used.
- (e) In the case of CT, size-specific dose estimates, SSDE, can be made, where C_{VOL} values are corrected taking into consideration the size of the patient using linear dimensions measured on the patient or patient images [182, 187].

3.212. When needed, organ doses can be derived from the quantities mentioned in para. 3.211 by using conversion coefficients derived from Monte Carlo codes applied to anatomical models. Methods for doing this are discussed in Ref [9].

Dosimetry of patients - specific considerations for image guided interventional procedures

3.213. 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 areas of skin because of the potential for reaching the threshold for tissue effects in complicated cases [188, 189].

3.214. The determination of the dose to the most exposed area of skin is not straightforward since exposure parameters and projection angles 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 in Ref [180].

3.215. An established method for dose mapping uses low sensitivity X ray films, such as films used in radiation therapy and radiochromic films. However, determination of the dose is only possible after the procedure.

3.216. The cumulative dose at the interventional reference point $K_{a,r}$, defined as the kerma in air at 15 cm from the isocentre in the direction of the X ray tube [74], either displayed during the procedure and/or obtained from the DICOM header, may be used as a conservative estimate for peak skin dose. The degree of over-estimation depends on several factors, including how often the beam projection was changed. The cumulative dose at the interventional reference point gives the least over-estimation when most of the radiation is delivered in just one beam projection. The accuracy of the reported cumulative dose at the interventional reference point should have been validated at acceptance testing and commissioning and during QA procedures, as explained in para. 3.233.

Diagnostic reference levels

3.217. The BSS, paragraphs 3.168 - 3.169, requires that radiology facilities perform patient dosimetry surveys, as described in paras 3.203 to 3.209, and that these results are compared with the established DRLs for their country or region. The purpose is to ascertain whether the typical dose in the facility for a given radiological procedure compares favourably, or not, with the value of the DRL for that radiological procedure. Guidance on establishing national or regional DRLs in given in Section 2, paras. 2.34 to 2.45.

3.218. A review of optimization of protection for that particular radiological procedure is triggered if the comparison shows that the facility's typical dose exceeds the DRL, or that the facility's typical dose is substantially below the DRL and it is evident that the exposures are not producing images of diagnostic usefulness or are not yielding the expected medical benefit to the patient.

3.219. Given the uncertainties in determining a facility's typical dose (see paras 3.206 and 3.207), questions can arise over whether a DRL has really been exceeded or not. Some countries adopt an algorithmic approach, for example where the facility's typical dose, minus two times its standard error, should be greater than the value of the DRL [13]. A simpler approach, based purely on the facility's typical value, may be sufficient as the purpose is to identify the need for a review, and perhaps it is better to perform more reviews than fewer.

3.220. No individual patient's dose should be compared with a DRL. It is the facility's typical dose, as determined by the representative patient sample, which is compared.

3.221. Further, the comparison is not a case of "Does the radiology facility comply with the DRL?" DRLs are not dose limits. It is mandatory to use them for the comparison exercise to identify practices that warrant further investigation.

3.222. The review of how the given radiological procedure is being performed and its optimization of protection, triggered by the DRL comparison, may conclude that there are valid reasons supported by sound clinical judgement why the radiology facility has a typical dose that exceeds the DRL. These reasons should be documented as part of the facility's QA programme. Adequateness of image quality should be always taken into account. On the other hand, the review may identify areas for improvement resulting in revised protocols for that radiological procedure. The results of the DRL comparison and any ensuing review and actions should be documented as part of the facility's QA programme.

3.223. The fact that a radiology facility's typical dose for a radiological procedure is less than the DRL for that procedure does not mean necessarily that optimization of protection for that radiological procedure has been fully achieved. DRLs are only one of the tools for optimization, aimed specifically at identifying the outliers in performance.

3.224. The regulatory body in a given country may specify frequencies for performing DRL comparisons. Otherwise, the general guidance on patient dosimetry, described above in para. 3.207, would be applicable.

Quality assurance for medical exposures

3.225. The BSS paragraph 3.170 requires radiology facilities to have a comprehensive programme of quality assurance for medical exposures. General guidance on management systems is given in Section 2, paras 2.135 to 2.146, and it is simply re-iterated here that the programme of quality assurance for medical exposures should fit in with, and be part of, the facility's wider management system. The paragraphs in this subsection give guidance on the technical aspects of the programme of quality assurance for medical exposures.

3.226. The purpose of the programme of quality assurance for medical exposures is to help ensure successful implementation of optimization of patient protection in the radiology facility and to minimize the occurrence of unintended and accidental medical exposures.

3.227. The complexity of the programme of quality assurance for medical exposures will depend on the type of facility. A dental practice with intra-oral only radiography will have a simpler programme compared with a facility that offers all modalities of diagnostic radiology as well as image guided interventional procedures. Nonetheless, most of the elements of the programme are common, and it is more in the degree of implementation that there are differences. The BSS paragraph 3.171 establishes the common elements of the programme.

3.228. Measurements on medical radiological equipment are one of the components of the programme. Acceptance tests are required for new or significantly refurbished or repaired equipment, or after the installation of new software or modification of existing software that could affect protection and safety of patients. The acceptance test is followed immediately by commissioning, and then on-going periodic quality control tests, including constancy tests. The purpose is to ensure that, at all times, all medical radiological equipment is performing correctly, accurately, reproducibly and predictably. Acceptance and commissioning tests should be performed in the same way for equipment and/or software that has been donated.

3.229. Depending on the equipment purchase agreement, acceptance tests may be performed by the manufacturer's representative in the presence of the local medical physicist and the radiological medical practitioner representing the user, or, if acceptable to the manufacturer and/or the purchaser, by a medical physicist jointly with the manufacturer's representative. The process involves verification of all specifications and features of the equipment.

3.230. After acceptance and before clinical use on patients, commissioning is carried out by or under the supervision of the medical physicist. Commissioning should include measurements of all parameters and conditions of use that are expected in clinical use, including setting up or validating image acquisition protocols. For most modalities (CT, image guided interventional procedures, tomosynthesis, mammography, DR/CR, fluoroscopy) the medical physicist should be directly involved in the measurements, calculations and interpretation of data to characterize the equipment's performance. For the least complex modalities (dental and DEXA) the medical physicist should provide documented advice on how the commissioning should be performed. At commissioning, the baseline for subsequent constancy tests is established.

3.231. There are many published reports from international and national organizations and national or regional professional bodies giving detailed guidance on the performance tests and quality control

tests that should be performed on the various modalities, including recommended frequencies [111, 112, 117 – 122, 166, 170, 175, 176, 179 – 181, 183, 190 – 211]. In addition, many of these organizations have extensive websites where any new or updated publications on the topic can be found. The regulatory body may have its own specific requirements on the tests that should be performed and their frequencies. It would be expected that such specific requirements would have been established with consultation between the regulatory body and the relevant professional bodies.

3.232. Quality control tests also should be performed on other equipment or devices that have an impact on the successful outcome of the radiological procedure. Such equipment and devices include, but are not limited to: film processors, darkrooms, and cassettes for facilities using film-based imaging; CR plates and CR readers for facilities with CR systems; and view boxes, workstations, and reporting rooms. Many of the references given in para. 3.231 are applicable here.

3.233. The results of the quality control tests should be compared with established tolerance limits. These limits may have been established to ensure compliance with a regulatory requirement for the performance of particular physical parameters or they may be set on the basis of recommended values given in published reports, such as referenced in para. 3.231. As required in the BSS paragraph 3.171(b), if the measured values fall outside the tolerance limits, corrective actions should take place. Such corrective actions are likely to include maintenance or servicing of the equipment, and hence the radiology facility should have a preventive maintenance programme in place. In some cases, the equipment may be outside the tolerance limits by a significant amount and the equipment should be immediately taken out of clinical use and not returned until the servicing has taken place and it has been ascertained that the equipment meets the performance requirements.

3.234. The programme of quality assurance for medical exposures in the radiology facility should include use of "checks and balances" to ensure that the facility's protocols and procedures for imaging and interventional procedures, including radiation protection and safety, are being followed. The periodic review of the protocols and procedures themselves is part of the facility's radiological review (see 3.260 - 3.262). In addition a review of imaging procedures may have been triggered by a comparison with DRLs (see paras. 3.217 to 3.224).

3.235. The BSS paragraph 3.171(e) specifically requires that dosimetry and monitoring equipment are part of the QA programme. This is to ensure that such instrumentation has a current calibration, typically within 2 or 3 years (see para. 3.199), and that it is functioning correctly. The programme of quality assurance for medical exposures should establish a calibration cycle for each instrument and a set of quality control checks on the operation of each instrument to be performed at set intervals. This applies to stand alone dosimetry equipment and to dosimeters integrated into the medical radiological equipment, such as KAP meters in fluoroscopic systems, and to software of the medical radiological equipment itself that calculates, displays and reports dose metrics such as CTDI and DLP in CT and K_{ar} in image guided interventional procedures.

3.236. Maintaining records is a crucial aspect of the programme of quality assurance for medical exposures. This includes the procedures used in the programme, and the results of the quality control tests, the dosimetry surveys, the DRL comparisons, corrective actions and the investigations of unintended and accidental medical exposures. When planning and developing an effective QA programme, licensees should recognize that it demands strong managerial commitment and support in the form of training and time, personnel and equipment resources. The regulatory body, during its inspections of a radiology facility, should review the records of the programme of quality assurance for medical exposures.

3.237. In line with standard practices for quality management, the BSS in paragraph 3.172 requires regular and independent audits of the programme of quality assurance for medical exposures, adding that the frequency of such audits will depend on the complexity of the radiological procedures being performed in the facility. Such audits may be internal or external. Internal audits are usually logistically simpler to implement, while the external audit generally has the advantage of bringing in an outside perspective. The audit of the radiology facility's programme of quality assurance for medical exposures can be incorporated into more comprehensive audits that the facility is performing for its management system. Further, the results of the audit of the programme of quality assurance for medical exposures will be a major input into the radiology facility's radiological review (see paras. 3.260 to 3.262).

Dose constraints – carers and comforters

3.238. Some diagnostic radiological procedures, particularly of children, can be better performed with the assistance of a helper – the carer or comforter, for example a relative in the case of a paediatric patient, or a relative or friend for a disabled or very elderly or very ill patient. In these circumstances, the carer or comforter will be exposed, usually to a low dose.

3.239. The BSS paragraph 3.153 states that a carer or comforter must be informed about the radiation risks involved in helping with the radiological procedure and about the means to be taken to afford appropriate radiation protection to the carer or comforter. The carer or comforter should indicate that he/she has understood the information and is still willing to help with the radiological procedure.

3.240. The radiation protection afforded the carer or comforter should be optimized, and as part of this process dose constraints should be applied, as required in the BSS paragraph 3.173. These are the dose constraints established by government, as a result of consultation with the health authority, relevant professional bodies and the regulatory body, as required by the BSS paragraph 3.149(a)(ii) (see also Section 2, paras, 2.48 to 2.49).

3.241. The radiology facility should have written protocols for the optimization of protection measures for carers and comforters who hold patients during radiological procedures. The measures should utilize the basic methods for radiation protection, i.e., time and distance. The protocol should include the following:

- (a) Methods to avoid the need for holding patients, for example the administration of sedatives (especially for long procedures such as CT examinations) and the use of infant restraints;
- (b) Criteria specifying which carers and comforters are allowed to hold patients, for example friends and relatives, provided that they are not pregnant, but not employees such as porters and nurses (see also Section 2 para. 2.49);
- (c) Methods for positioning and protecting the carer or comforter so that his or her exposure is as low as reasonably achievable, for example by ensuring that the carer or comforter is not in the direct beam of the radiation device and that appropriate personal protective equipment is used, for example a protective apron or ancillary shields of a specified lead equivalence;
- (d) The values of the dose constraints to be applied (see Section 2 para. 2.49) depend on the radiological exam or intervention; a common value may be 5 mSv per event as stated in para 2.49. Although it is unlikely that a child, closely related to the patient, would be a carer or comforter for a diagnostic radiological procedure, in cases where this is unavoidable, his or her dose should be constrained to less than 1 mSv.

3.242. Registrants and licensees should be able to demonstrate that the effective dose to the carer or comforter, by applying the protocol, is unlikely to exceed the dose constraint. It is relatively

straightforward to estimate effective doses to carers and comforters from measurements of the ambient dose equivalent rates at the positions where they will be situated. These determinations should be made in advance to verify that dose constraint will not be exceeded. Therefore, individual dose monitoring is normally not necessary.

Dose constraints – volunteers in biomedical research

3.243. Some individuals will undergo diagnostic radiological procedures as part of their voluntary participation in an approved programme of biomedical research (see Section 2 para. 2.98). Part of the approval process for the biomedical research will have been the setting of dose constraints for the radiological procedures (see Section 2 paras 2.98 - 2.99). When the volunteer presents him/herself at the radiology facility, he/she is to be afforded the same radiation protection as if he/she were a patient ready to undergo a radiological procedure within a normal healthcare pathway, but with the additional restriction that his/her exposure will be subject to a dose constraint, either a nationally established dose constraint or as specified by the ethics committee that approved the biomedical research programme (see Section 2 paras. 2.50, 2.98 and 2.99).

Pregnant female patients

3.244. Female patients who are pregnant form a special sub-group of patients that should be particularly considered with respect to radiation protection. These considerations have been described in para. 3.141(a) for justification and para. 3.155 for optimization. None of these considerations can take place if it is not known that the patient is pregnant. Therefore it is crucial, as is required in the BSS paragraphs 3.175 -3.176, for the radiology facility to have in place means for ensuring that pregnancy status is known for female patients.

3.245. The first approach is through posting of clear signs, in languages easily understood by the range of people using the radiology facility, asking the question "Are you pregnant or possibly pregnant?" and, if so, "Please tell the staff". Such signs should be posted widely in the facility, including waiting rooms and cubicles. The second approach is to ask female patients directly whether they are or might be pregnant. This may not always be so easy given social and cultural sensitivities, but it should be done when needed.

3.246. Neither of the approaches described in para. 3.245 work if the woman does not know if she is or may be pregnant. For this reason, the BSS (paragraph 3.176) has an additional requirement on facilities to have "procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus". Such radiological procedures would include those that involve primary beam irradiation of the abdomen or pelvis area delivering relatively high patient doses directly to the embryo or fetus, or to volumes near the uterus such that significant scattered radiation reaches the embryo or fetus. Cooperation with the referring medical practitioner, through standard requests for pregnancy status for specified radiological procedures, is one approach. In case of doubt, a pregnancy test or hormonal level determination to assess menopausal status may be carried out.

Unintended and accidental medical exposures

Prevention of unintended and accidental medical exposures

3.247. The BSS, paragraphs 3.179 to 3.181, sets out requirements both for minimizing the likelihood of unintended and accidental medical exposures and for the ensuing investigation if such exposures occur. The pathways identified in the BSS for potentially leading to unintended or accidental medical exposures include flaws in the design of medical radiological equipment, failures of medical radiological equipment while in operation, failures and errors in software that control or influence the delivery of the radiation, and human error. General strategies for addressing those pathways include regular maintenance of medical radiological equipment and software, a comprehensive quality assurance programme, and continuing education and training of staff. The lessons learned from events that have occurred should be used for preventing or minimizing unintended and accidental medical exposures, as described in para. 3.257.

3.248. A reduction in the probability of unintended or accidental medical exposures in diagnostic radiology and image guided interventional procedures can be brought about by:

- (a) The introduction of safety barriers at identified critical points in the radiology pathway, with specific quality control checks at these points. Quality control is not confined to physical tests or checks but can include such as actions as correct identification of the patient.
- (b) Actively encouraging a culture of always working with awareness and alertness.
- (c) Providing detailed protocols and procedures for each process in the radiology pathway.
- (d) Education and training, including continuous professional development, of all staff involved in providing radiology services.
- (e) Clear definitions of the roles, responsibilities and functions of staff in the radiology facility that are understood by all staff.

3.249. Preventive measures should include incident and near incident reporting, analysis and feedback including lessons learnt from international experience [123]. Preventive measures should also include each radiology facility checking the robustness of their safety system against reported incidents. ICRP 85 [123] contains a review of case histories from a collection of unintended and accidental medical exposures in image guided interventional procedures.

3.250. Building on the guidance from paras 3.248 to 3.249, the following three-step strategy can help to prevent unintended and accidental medical exposures in the radiology facility:

- (a) allocate responsibilities to appropriately qualified health professionals only and ensure that a quality management system is in place that includes radiation safety;
- (b) use the lessons learned from unintended and accidental medical exposures to test whether the quality management system, including for radiation safety, is robust enough against these types of events;
- (c) identify other latent risks by posing the question "what else could go wrong" or "what other potential hazards might be present" in a systematic, anticipative manner to all steps in the diagnostic and interventional radiology process.

Investigation of unintended and accidental medical exposures

3.251. The events that constitute unintended or accidental medical exposures are detailed in the BSS paragraph 3.180. Unintended and accidental medical exposures may occur in all imaging procedures; however, the consequences in CT may be more severe and in image guided interventional procedures may be even more severe [123, 169].

3.252. Exposure of the wrong patient or wrong body part is always a possibility in a radiology facility. Many patients have similar names, for example, or patients may not have a clear understanding of what procedures are meant to take place. Facilities should have procedures in place that consist of

several independent methods of patient identification, and verification of examination requisition and patient orientation.

3.253. One of the events requiring investigation is when the exposure was "substantially greater than was intended". This situation may occur when the radiological procedure did not go according to plan – for example, the AEC in radiography may not have terminated the exposure when expected because the wrong sensors were selected or there was a hardware malfunction; or one or more of the technique factors in the examination protocol, for example for a CT examination, were incorrectly set giving a much higher dose than intended.

3.254. Another event that should be investigated is the inadvertent exposure of the embryo or fetus in the course of a radiological procedure, where at the time of the procedure it was not known that the woman was pregnant.

3.255. Radiation injuries have and do occur in image guided interventional procedures. A given procedure that may be performed in accordance with the facility's protocol still has the potential to result in tissue effects because there were difficulties with the particular patient. However, most cases of reported severe radiation injuries involving ulceration and necrosis were associated with unnecessary and extreme exposure conditions, such as: (a) very short distance between the X ray source and 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 and investigated with a view to improve. Facilities performing image guided interventional procedures should have systems in place for identifying patients who may be at risk from late radiation injuries, typically based on estimates of peak skin dose, cumulative dose at the interventional reference point or kerma area product. For so-identified patients, information should be added to the patient's medical record so that appropriate observation and follow up is implemented. For example, it is recommended that patients with estimated skin doses of 3 Gy should be followed up 10-14 days after exposure [123]. Further information on trigger levels for patient follow up are available in the IAEA SAFRAD website [20]. Any resulting radiation injury should receive appropriate medical care.

3.256. The BSS, paragraph 3.181, states what should be done in the course of the investigation. This includes calculation or estimation of patient doses, which should be performed by a medical physicist, and notification of the event to the patient's referring medical practitioner. A record of the calculation method and results should also be placed in the patient file. When required, counselling of the patient should be undertaken by someone with appropriate experience and clinical knowledge.

3.257. The investigation of unintended and accidental medical exposures, as required by the BSS paragraphs 3.180 - 3.181, has three main purposes. The first is to assess the consequences for the patient (s) affected and provide remedial and health care actions if necessary. The second is to establish what went wrong and how to prevent or minimize the likelihood of a recurrence in the radiology facility – i.e. the investigation is for the facility's and their patients' benefit. The third purpose is to provide information to other persons or other radiology facilities. Dissemination of information about unintended and accidental medical 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 [123, 188, 212, 213]. This might be through the regulatory body and/or the health authorities for more significant events or as required by a country's regulations, where the regulatory body disseminates information on the event and the corrective

actions to other facilities that might learn from the event. Independently from any legal requirement for reporting to the regulatory body, the implementation of voluntary and anonymous safety reporting and learning systems can significantly contribute to improving safety and safety culture in health care. This includes participation in voluntary international or national databases designed as educative tools. One such database for image guided interventional procedures is the so-called SAFRAD reporting system (Safety in Radiological Procedures) [20]. Facilities performing image guided interventional procedures should participate in SAFRAD or similar databases.

3.258. As noted in para. 3.257, the BSS requires reporting to the regulatory body and to the health authority if appropriate for "significant" events. Further, the regulatory body in a given country may also specify their own requirements for reporting events to them. It is difficult to quantify "significant" – specifying a numerical trigger value immediately creates an artificial distinction between values immediately below that value (and hence should not be reported) and those just above the value (which should be reported). However, the attributes of "significant" events can be elaborated, and events with one or more of these attributes should be reported to the regulatory body and the health authority. Such attributes would include the occurrence of, or the potential for, serious unintended or unexpected health effects due to radiation, the likelihood of a similar event occurring in other radiology facilities, a large number of patients were affected, and gross misconduct or negligence by the responsible health professionals. As stated in para. 3.257 above, one of the roles of the regulatory body for such a reported event is to disseminate information on the event and the lessons learned to all potentially affected parties – typically other radiology facilities and relevant professional bodies, but also in some cases manufacturers, suppliers, and maintenance companies.

3.259. Irrespective of whether the event is also reported to the regulatory body, feedback to staff should be provided in a timely fashion and, where changes are recommended, all staff should be involved in bringing about their implementation.

Records and review

Radiological review

3.260. The BSS in paragraph 3.182 requires the performance of a periodic radiological review at the radiology facility. This involves considering both justification and optimization aspects of radiation protection. For the latter, the results of the programme of quality assurance for medical exposures, including the periodic independent audit, would be a significant input into the process. As described in Section 2, paras. 2.146 and 2.147, the wider clinical audit [52] could include the radiological review with its assessment of the effective application of the requirements for justification and optimization in the facility for the radiological procedures being performed.

3.261. To facilitate compliance with the BSS paragraph 3.182 and to learn from periodic radiological reviews, the methodology used, the original physical, technical and clinical parameters considered, and the conclusions reached should be documented and taken into account prior to any new review that may result in an update of the radiology facility's policies and procedures.

3.262. Radiological reviews should consider changes in patient management that result from the diagnostic or interventional procedure, the effect of introducing new technologies on efficiency and cost, and comparisons of different imaging modalities and of protocols for the same pathologies.

Records

3.263. Records should be in place to demonstrate on-going compliance with radiation protection requirements. The BSS, paragraphs 3.183 to 3.185, specify requirements for keeping personnel records, records of calibration, dosimetry and quality assurance, and records for medical exposure. These records should be kept for the period specified by the country's regulatory body. In the absence of such a requirement, a suggested period for keeping records is 10 years. In the case of children, records should be kept for a longer time.

RADIATION PROTECTION OF THE PUBLIC

Introduction

3.264. Public exposure may arise from the performance of diagnostic radiology and image guided interventional procedures to persons in and around the radiology facility.

3.265. The requirements of the BSS for public protection, paragraphs 3.117 to 3.123, 3.125 to 3.127, and 3.135 to 3.137, apply to radiology facilities. This sub-section contains guidance very specific to radiology facilities. For more general and comprehensive guidance on radiation protection of the public, reference should be made to the IAEA Safety Guide *Radiation Protection of the Public* [24].

Non-occupationally exposed workers and visitors

3.266. Non-occupationally exposed workers are those persons who work at the radiology facility but not in a role that is directly involved in the use of X rays, for example ward nurses, imaging staff who work exclusively with non-radiation imaging modalities (ultrasound or MRI), clerical staff, and cleaning personnel. It also includes those persons who work at the wider medical facility where the radiology facility is located. These persons are to be afforded the same level of radiation protection as any member of the public, as required by the BSS paragraph 3.78.

3.267. Visitors to the radiology facility include those persons who will be undergoing a radiological procedure, for the time during the visit when the radiological procedure is not taking place – for example, while they are sitting in the waiting room. Similarly for carers and comforters – any exposure other than during the radiological procedure in which they are helping will be public exposure. Other visitors, including persons delivering goods or supplies, sales personnel, accompanying persons and escorts, and other patients in the facility, are also considered members of the public.

External exposure

3.268. The primary means for protecting the public (non-occupationally exposed workers and visitors) is to ensure that the shielding of the radiology facility (see paras. 3.17 - 3.23) is sufficient so that public exposure resulting from being in any immediate adjacent area, including rooms above and below, accessible by either non-occupationally exposed workers or visitors would be in compliance with the public dose limits, and preferably less than any dose constraint that the regulatory body may have applied (see Section 2 paras. 2.16 and 2.46.)

3.269. Particular consideration should be given to patients in the radiology facility, who are not undergoing a radiological procedure, but are in the vicinity when mobile radiography is being

performed in their ward or area, or when fixed radiography is being performed in an open area, such as in an emergency department. In these cases a combination of distance, placement of mobile shielding and careful control of the X ray beam direction should ensure that appropriate public radiation protection is being afforded.

Control of access

3.270. Access to areas where radiation is being used should be controlled to provide for controlling doses to visitors and non-occupationally exposed workers. According to the BSS, paragraph 3.128, access of visitors to radiology or interventional rooms or other controlled areas while in use is restricted. Exceptionally, a visitor, for example a health professional from another medical facility, may be accompanied by a staff member who knows the protection and safety measures for the controlled area. The radiology facility should have written procedures specifying when such exceptions can take place and who may do the accompanying. Similarly, the facility should have established the rules regarding non-occupationally exposed workers, especially regarding access to controlled and supervised areas. Particular attention, in all cases, should be made with respect to potentially pregnant women.

3.271. Controlled and supervised areas should be clearly identified to help prevent inadvertent entry to areas where diagnostic radiology or image guided interventional procedures are being performed [59]. See also para. 3.13. Further control can be afforded by the use of keys (or passwords) to restrict access to the control panels of medical radiological equipment to only authorized persons.

Monitoring and reporting

3.272. The BSS, requirement 32 and paragraph 3.137, sets out the requirements that should be met by the radiology facility with respect to monitoring and reporting. In the radiology facility, procedures should be in place to ensure that:

- (a) The requirements regarding public exposure are satisfied and to assess such exposure;
- (b) Appropriate records of the results of the monitoring programmes are kept.

3.273. The programme for monitoring public exposure arising from diagnostic radiology and image guided interventional procedures should include dose assessment in the areas in and surrounding the radiology facility 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 and periodically thereafter. Records of these assessments should be kept for typically 7-10 years, but in any case for periods that meet any relevant regulatory requirements.

PREVENTION AND MITIGATION OF ACCIDENTS

Safety assessments

3.274. To comply with the BSS requirements for safety assessment (paragraphs 3.29 to 3.36), the registrant or licensee should conduct a safety assessment applied to all stages of the design and operation of the radiology facility. The safety assessment report should be submitted to the regulatory body if required. Basically, the safety assessment deals with determining 'what can go wrong' and

how it can be prevented and, in case it occurs, how it can be mitigated. Section 2, paras 2.148 - 2.152, describes general considerations for facilities using ionizing radiation for medical purposes.

3.275. The safety assessment should be systematic and contain information on identification of possible events leading to accidental exposure (see Appendix I for a summary of typical causes and contributing factors to accidental exposures in diagnostic radiology and image guided interventional procedures). The safety assessment should not only cover these events, but also aim at anticipating other events that have not previously been reported. Clearly the safety assessment should be documented.

3.276. The safety assessment should be revised when:

- (a) New or modified medical radiological equipment or their accessories are introduced;
- (b) Operational changes occur, including workload;
- (c) Operational experience or information on accidents or errors indicates that the safety assessment should be reviewed.

Accident prevention

3.277. Accident prevention is clearly the best means for avoiding potential exposure and the BSS, paragraphs 3.39 to 3.41, set out requirements based on good engineering practice and defence in depth, as well as facility-based arrangements, to achieve this. Design considerations for medical radiological equipment and the radiology facility are described in paras 3.8 to 3.46.

3.278. The licensee should incorporate:

(a) Defence in depth measures to cope with identified events, and evaluation of the reliability of the safety systems (including administrative and operational procedures, equipment and facility design).(b) Operational experience and lessons learned from accidents and errors. This information should be incorporated into the training, maintenance and quality assurance programmes.

3.279. For diagnostic radiology and image guided interventional procedures, possible scenarios for potential exposure include flaws in the design of medical radiological equipment, failures of medical radiological equipment while in operation, failures and errors in software that control or influence the delivery of the radiation, and human error. In addition in the radiology facility, another possible scenario is the rupture of radioactive sources, such as those used in dosimetry systems calibration.

3.280. Potential public exposure from a radiation generator may occur if a person (for example a cleaner) enters an interventional or conventional fluoroscopy room in between cases and depresses the exposure footswitch (usually a foot pedal placed on the floor). To prevent such potential exposure equipment should be provided with a special X ray interlock in the control panel to disconnect the exposure footswitch in between cases, as described in para. 3.36(h).

3.281. Inadvertent entry to the room when a patient is undergoing a radiological procedure is another way for potential public exposure. Means for control of entry has been addressed in paras. 3.268-3.269.

3.282. For medical exposure, potential exposure, when it does occur, is manifest as an unintended or accidental medical exposure. Means for preventing or minimizing unintended and accidental medical exposures are described in para. 3.245, and the ensuing investigation and corrective actions are described in paras, 3.251 - 3.257.

Mitigation and contingency plans

3.283. Because the radiation source in almost all cases is an X ray generator and tube, turning the primary electrical source off immediately stops any radiation being produced. All relevant staff should be adequately trained to be able to recognize when medical radiological equipment is not functioning correctly or, for example, when a programming error in the software is suspected. If there are implications for occupational and/or patient protection and if medical considerations allow it, the radiological procedure should be discontinued and the X ray unit turned off.

3.284. Some radiology facilities may have sealed radioactive sources for dosimetry instrument calibration purposes or even possibly I-125 sources for low-intensity X ray imaging scopes (lixiscopes). Source loss or encapsulation rupture may lead to contamination. See Section 4 para. 4.291 for guidance on source loss.

4. SPECIFIC RECOMMENDATIONS FOR RADIATION PROTECTION AND SAFETY IN NUCLEAR MEDICINE

INTRODUCTION

4.1. This chapter covers nuclear medicine, the branch of clinical medicine in which unsealed radioactive materials are administered to patients for diagnosis or treatment of disease, or for clinical or pre-clinical research. Treatment using sealed sources is covered in Section 5. X ray imaging such as CT, which may occur in conjunction with a nuclear medicine procedure such as in hybrid imaging, is mainly covered in Section 3 with appropriate cross-references.

4.2. All nuclear medicine procedures involve the administration of a radiopharmaceutical to the patient. For diagnostic nuclear medicine procedures, trace amounts of compounds are labelled with photon or positron emitters, forming what is called a radiopharmaceutical. For photon emitters, the distribution of the radiopharmaceutical in the human body can be imaged in several ways, such as planar imaging -including whole body imaging- or single photon emission computerized tomography (SPECT). In the case of positron emitters, the detection of annihilation photons allow registering the three-dimensional spatial distribution of the radiopharmaceutical using positron emission tomography (PET). In hybrid imaging, SPECT and PET are combined with an X ray based modality, such as in PET-CT and SPECT-CT, and more recently also with magnetic resonance imaging, such as in PET-MRI. In addition, probes may be used for the intra-operative localization of tumours and lymph nodes or leaks, and for uptake measurements in specific organs, such as the thyroid or lungs. In therapeutic nuclear medicine, therapeutic activities of radiopharmaceuticals are administered that are usually labelled with beta or beta-gamma emitting radionuclides, more recently also with alpha emitters; therapy with Auger electrons is mostly experimental. The nuclear medicine facility may also perform in vitro studies, although these are not a primary focus of this Safety Guide. Some nuclear medicine facilities may also have an associated cyclotron facility for on-site radionuclide production. Detailed guidance for such cyclotron facilities is beyond the scope of this Safety Guide.

4.3. The generic term "medical radiation facility" is used widely in Section 2 to mean any medical facility where radiological procedures are performed. In Section 4, the narrower term "nuclear medicine facility" is used to cover any medical radiation facility where nuclear medicine procedures are performed. A nuclear medicine facility may be a nuclear medicine department inside a wider hospital or medical centre, or may be a stand-alone facility providing nuclear medicine services. In some cases, the nuclear medicine facility may be a mobile facility.

4.4. The defined term "radiological procedure" is used in the BSS to cover all imaging and therapeutic procedures using ionizing radiation. In a nuclear medicine facility both imaging and therapeutic radiological procedures may occur, and this needs to be borne in mind when reading the following guidance in Section 4. In cases where the guidance is specific to one or other of imaging or treatment, additional qualifiers, such as "imaging", "diagnostic", "therapy" or "treatment", are used.

4.5. Different health professionals can take on the role of the radiological medical practitioner in nuclear medicine procedures, depending *inter alia* on national laws and regulations. They primarily include nuclear medicine physicians, but may include other specialists such as radiologists, cardiologists or radiation oncologists.

4.6. Section 2 of this Safety Guide provides general guidance on the framework for radiation protection and safety in medical uses of radiation, including roles and responsibilities, education, training, qualification and competence, and the management system for protection and safety. This is relevant to nuclear medicine and reference to Section 2 should be made as indicated or needed.

SAFETY OF MEDICAL RADIATION FACILITIES AND MEDICAL RADIOLOGICAL EQUIPMENT

Nuclear medicine facilities

4.7. Provisions for the incorporation of radiation safety features are best made at the facility design stage. The siting and layout should take into account workload and patient flow, both within the nuclear medicine facility and, in cases where the nuclear medicine facility is part of a larger hospital or medical centre, with other departments of the wider facility. The nuclear medicine facility is likely to provide services to both inpatients and outpatients, so the location of the facility should give easy access to both groups. Consideration should also be given to provide easy exit routes for patients, after the examination or treatment has been performed, that minimize movement through the facility.

4.8. A typical nuclear medicine facility using unsealed sources¹⁶ requires areas for the following: source storage and preparation (radiopharmacy or radioisotope laboratory or "hot lab"), radiopharmaceutical administration to patient, uptake rooms, imaging (in vivo), sample measurement (in vitro), radioactive waste storage and predisposal processing . For those nuclear medicine facilities performing therapy with radiopharmaceuticals, a dedicated ward for patients undergoing such treatments should be considered. In addition, a nuclear medicine facility requires separate waiting areas for patients before and after radiopharmaceutical administration, changing areas and toilets. The facility will also have areas where radioactive materials are not expected to be found, such as in offices, reporting areas and staff rooms, including cloakrooms, showers and toilets for staff. For detailed guidance on setting up nuclear medicine facilities, including PET-CT facilities, reference should be made to Refs [65, 214 - 219]. The following paragraphs give a general overview.

4.9. For security purposes, nuclear medicine facilities should be located in areas where access by members of the public to the rooms where sources, including generators, and radiopharmaceutical dispensing equipment are used and stored can be restricted. Further, the proximity of source storage facilities to personnel that may respond in the event of a security breach should also be considered.

4.10. As a general rule, the design of the nuclear medicine facility should make provisions for safety systems or devices associated with the equipment and rooms. This includes electrical wiring related to emergency 'off' switches, as well as safety interlocks and warning signals.

4.11. A stable power supply should be available for the facility. Uninterruptible power supply (UPS) or battery backup systems should be installed to capture the active information at time of any outage

¹⁶ In a nuclear medicine facility the only sealed sources present are those used as check sources for calibration of the activity meters and the flood sources to check the uniformity of the gamma cameras.

and to power down all software in a controlled manner. Servers should be programmed to automatically shut down when the power supply is interrupted.

4.12. The design of the facility may include an air conditioning system sufficient to maintain the temperature in the examination room within the parameters defined by the equipment manufacturers. For example, temperature control is needed for uptake rooms in a PET facility to prevent artefacts (brown fat uptake) occurring if room temperatures are too low.

4.13. Issues to be considered for the design of the nuclear medicine facility include: optimizing protection against external radiation and contamination, maintaining low radiation background levels to avoid interference with imaging equipment, meeting radiopharmaceutical requirements (see para. 4.38), and ensuring safety and security of sources (locking and control of access).

4.14. For external exposure, the three factors relevant to dose reduction (time, distance and shielding) should be combined in the design to optimize occupational and public radiation 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 procedures.

4.15. The design of the nuclear medicine facility should include provision for secure and shielded storage for the radioactive sources. Shielding should be appropriate to the type and energy of the emitted radiation. Storage may be provided in a room or a separate space outside the work area or in a locked cupboard, safe, refrigerator or freezer situated in the work area. Separate radiopharmaceutical storage compartments and an area for temporary storage of radioactive waste should be provided with appropriate protection.

4.16. Special consideration should be given to avoiding interference with work in adjoining areas, such as imaging or counting procedures, or where fogging of films stored nearby can occur.

4.17. Signs and warning lights should be available at the entrances of controlled and supervised areas to prevent inadvertent entry (see also paras. 4.266 - 4.267 on control of public access). For controlled areas, the BSS, paragraph 3.90, requires the use of the symbol of the International Organization for Standardization (ISO) [59]. Signs and warning lights should be particularly available at the entrances of source preparation and storage areas, hybrid imaging rooms, and for rooms for hospitalized patients undergoing radiopharmaceutical therapy (see, also below on treatment wards, paras. 4.28 - 4.30). The signs should be clear and easily understandable. Warning lights, such as illuminated and flashing signs, should be activated when CT is being used in hybrid imaging.

4.18. Bathrooms designated for use by nuclear medicine patients should be finished in materials that are easily decontaminated. Nuclear medicine facility staff should not use the patient bathrooms, as it is likely that the floors, toilet seats and sink tap handles will be contaminated.

Mobile facilities

4.19. In some countries, PET-CT scanners are mounted on a truck and this mobile unit provides a service to specific regions of that country. These mobile units should meet the same requirements of the BSS as fixed facilities and the relevant guidance in this Safety Guide is applicable.

Areas where unsealed radioactive materials are handled

4.20. Radiopharmacies or laboratories where unsealed radioactive materials are handled, such as the source preparation area, should have:

(a) Means to prevent access by unauthorized persons;

- (b) Adequate storage space for equipment used in the given room or area to be available at all times, to minimize the potential for spreading contamination to other areas;
- (c) A contained workstation for easy decontamination;
- (d) Shielded storage for radioactive sources;
- (e) Shielded temporary storage for both solid and liquid radioactive waste, and places designated for the authorized discharge of liquid radioactive waste;
- (f) Shielding to protect workers where significant external exposure may occur;
- (g) A wash-up area for contaminated articles, such as glassware;
- (h) An entry area where protective clothing can be stored, put on and taken off, and which is provided with a hand wash-up sink and a contamination monitor;
- (i) Taps and soap dispenser that are operable without direct hand contact and disposable towels or a hot air dryer;
- (j) An emergency eyewash, installed near the hand washing sink; and
- (k) An emergency shower for decontamination of persons.

Detailed guidance is given in Refs [66, 214 – 219].

4.21. Radiopharmacies, laboratories and other work areas for manipulation of unsealed radioactive materials should be provided with equipment kept specifically for this purpose, which should include:

- (a) Tools for maximizing the distance from the source, for example tongs and forceps;
- (b) Syringe shields;
- (c) Containers for radioactive materials, with shielding as close as possible to the source;
- (d) Double walled containers (the outer being unbreakable) for liquid samples;
- (e) Drip trays for minimizing the spread of contamination in the case of spillage;
- (f) Disposable tip automatic pipettes (alternatively, hypodermic syringes to replace pipettes);
- (g) Lead walls or bricks for shielding;
- (h) Lead barriers with lead glass windows;
- (i) Barriers incorporating a low atomic number material (i.e. acrylic) for work with beta emitters;
- (j) Radiation and contamination monitoring equipment (surface and air);
- (k) Carrying containers, wheeled if necessary, for moving radioactive materials from place to place;
- (1) Equipment to deal with spills (decontamination kits).

4.22. Drainpipes from sinks in the radiopharmacy or laboratory should go as directly as possible to the main building sewer and should not connect with other drains within the building, unless those other drains also carry radioactive material. This is to minimize the possibility of a 'backup' contaminating other non-controlled, areas. The final plans of the drainage system, which are supplied to maintenance personnel, should clearly identify the drains from radiopharmacies and laboratories. Pipelines through which radioactive materials flow should be marked to ensure that monitoring precedes any maintenance.

4.23. Some countries require that drainpipes from a nuclear medicine facility and especially from radionuclide therapy wards terminate in a delay tank. Requirements on this issue differ very much among countries but each nuclear medicine facility should comply with their country's regulations.

4.24. The floors of areas with the potential for contamination should be finished in an impermeable material which is washable and resistant to chemical change, curved to the walls, with all joints sealed and glued to the floor. The walls should be finished in a smooth and washable surface, for example painted with washable, non-porous paint. The surfaces of the room where unsealed radioactive materials are used or stored, such as benches, tables, seats, and door and drawer handles, should be smooth and non-absorbent, so that they can be cleaned and decontaminated easily. Supplies (for

example, gas, electricity and vacuum equipment) should not be mounted on bench tops, but on walls or stands.

4.25. The floor and benches, including worktops, should be strong enough to support the weight of any necessary shielding materials or of radionuclide generators. The need for lifting equipment for radionuclide generators should be assessed.

4.26. Radiopharmacies or laboratories in which radioactive aerosols or gases may be produced or handled should have an appropriate ventilation system that includes a fume hood, laminar air flow cabinet or glove box. The fume hood should be constructed of material that is smooth, impervious, washable and resistant to chemicals. The working surface should have a slightly raised lip to contain any spills. The ventilation system should be designed such that the radiopharmacy or laboratory is at negative pressure relative to surrounding areas.

4.27. The airflow should be from areas of minimal likelihood of airborne contamination to areas where such contamination is likely. All air from the radiopharmacy or laboratory should be vented through a fume hood and should not be recirculated either directly, in combination with incoming fresh air in a mixing system, or indirectly, as a result of proximity of the exhaust to a fresh air intake. For reasons of asepsis, some radiopharmacies may require a positive rather than a negative pressure. In this case, the pressure gradient can be obtained by placing other workstations requiring negative pressure next to the radiopharmacy workstation.

Treatment rooms and wards

4.28. Floors and other surfaces of rooms designated for patients undergoing radiopharmaceutical therapy should be covered with smooth, continuous and non-absorbent materials that can be easily cleaned and decontaminated. Shielding should be designed using appropriate dose constraints for staff and public. Secure areas should be provided with bins for the temporary storage of linen and waste contaminated with radioactive materials. Storage areas should be clearly marked, using the radiation sign.

4.29. Rooms designated for patients undergoing radiopharmaceutical therapy should have separate toilet and washing facilities. A sign requesting patients to flush the toilet at least twice and wash their hands should be displayed to ensure adequate dilution of excreted radioactive materials and minimize contamination. The facilities should include a wash-up sink as a normal hygiene measure. For guidance on bathrooms and their use see para. 4.18.

4.30. The design of safe and comfortable accommodation for carers and comforters (see also paras. 4.232 - 4.236) should be considered for nuclear medicine facilities with radiopharmaceutical therapy patients.

Shielding calculation considerations

4.31. The shielding should be designed to meet the requirements for optimization of protection and taking into consideration the classification of the areas within the facility, the type of work to be done and the radionuclides (and their activity) intended to be used. Shielding should consider both structural and ancillary protective barriers at the design stage (see para 2.73). It is convenient to shield the source, where possible, rather than the room or the person. The need for wall shielding should be assessed, for example in the design of therapy and of PET-CT facilities to reduce occupational and public exposure to acceptable levels. Wall shielding may be needed in the design of rooms housing sensitive instruments (to keep a low background), such as well counters, probes and imaging equipment (gamma cameras and PET scanners). In designing such wall shielding, consideration

should be given to the height of the wall to ensure scattered radiation, such as from a CT scanner, does not pass over the wall into the area being protected.

4.32. Methodologies and data for shielding calculations for nuclear medicine facilities are given in Refs [58, 64, 215], and reference should be made to Section 3, paras 3.17 - 3.21) for shielding with respect to X ray imaging systems (e.g. CT) used as part of hybrid imaging equipment. 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 persons occupying the area to be shielded. Nominal design doses 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. Specifications for shielding are calculated on the basis of the attenuation they should provide to satisfy the nominal design doses. Potential practice changes and workload increases should be considered.

4.33. Care should be taken to avoid multiplication of conservative assumptions which can lead to unrealistic overestimates of required shielding. Typical conservative assumptions are: attenuation by the patient is usually not considered; decay of short-lived radionuclides, such as ¹⁸F, is not considered; workload, use and occupancy factors are overestimated; and the persons to be protected are considered as remaining permanently in the most exposed place of the adjacent roomTherefore, a balanced decision should be achieved and accumulation of overly conservative measures that may go beyond optimization should be avoided.

4.34. Specification of shielding, including calculations, should be performed by a RPO or medical physicist. In some countries there may be a requirement for shielding plans to be submitted to the regulatory body for review or approval prior to any construction (see also Section 2 para 2.66).

4.35. The adequacy of the shielding should be verified, preferably during construction, and certainly before the facility, room or area comes into clinical use. Clearly requirements of the regulatory body must be met (Section 2 para. 2.73).

Display and interpretation (reading) rooms design

4.36. To facilitate the interpretation by the radiological medical practitioner, images should be displayed in rooms specifically designed for these purposes. A low level of ambient light in the viewing room should be achieved. See also Section 3, paras. 3.40 - 3.41 on image display devices and view boxes.

4.37. Viewing rooms with workstations for viewing digital images should be ergonomically designed to facilitate image processing and manipulation so that reporting can be performed accurately. The viewing monitors of the workstations should meet applicable standards (see Section 3, para. 3.40).

Radiopharmaceuticals

4.38. Radiopharmaceuticals should be manufactured according to good manufacturing practice following relevant international standards [217, 218, 222 - 224] for:

- (a) Radionuclide purity;
- (b) Specific activity;
- (c) Radiochemical purity;
- (d) Chemical purity;
- (e) Pharmaceutical aspects: toxicity, sterility and pyrogenicity.

Medical radiological equipment, software and ancillary equipment

4.39. This sub-section considers medical radiological equipment, including its software, used in a nuclear medicine facility. Such equipment falls into two categories – those that detect ionizing radiation from the unsealed or sealed sources and those that generate ionizing radiation. The former includes probes, gamma cameras, SPECT scanners, and PET scanners, since these have an influence on the activity to be administered to the patient in order to obtain the desired diagnosis. The latter includes CT, typically as part of a hybrid imaging system such as a PET-CT or SPECT-CT scanner. Some hybrid equipment utilizes MRI, and although these are not generating ionizing radiation and are outside the scope of this Safety Guide, their performance can influence the efficacy of the nuclear medicine procedure and hence such equipment should meet relevant IEC standards or equivalent.

4.40. The requirements for medical radiological equipment and its software are given in the BSS paragraphs 3.49 and 3.161. The International Electrotechnical Commission (IEC), through its Technical Committee 62 on *Electrical equipment in medical practice* and in particular Sub-committee 62B on *Diagnostic imaging equipment* and Sub-committee 62C on *Equipment for radiotherapy, nuclear medicine and radiation dosimetry*, has published international standards applicable to medical radiological equipment. Current IEC standards relevant to nuclear medicine include the following Refs [225 – 234]. For those relevant to the X ray based component of hybrid imaging, see Section 3 para. 3.27. It is recommended that the IEC website is visited to view the most up-to-date list of standards: <u>http://www.iec.ch</u>. The International Organization for Standardization (ISO), through its Technical Committee 85 on *Nuclear energy, nuclear technologies, and radiological protection* and in particular Sub-committee 2 on *Radiological protection*, may publish international standards applicable to view the most up-to-date list of view the most up-to-date list of standards: <u>http://www.iec.ch</u>. It is recommended that the ISO website is visited to view the ISO website is visited to view the most up-to-date list of standards: <u>http://www.iec.ch</u>.

4.41. As the licensees take responsibility for the radiation safety of medical radiological equipment they use, they should impose purchasing specifications that include conditions to meet relevant international standards of the IEC and ISO and/or equivalent national standards. In some countries there may be a medical devices agency or similar organization that gives type approval to particular makes and models of medical radiological equipment.

4.42. Some nuclear medicine facilities may operate a cyclotron for on-site radionuclide production. As the cyclotrons are not directly involved in the exposure of the patient, they should not comply with the BSS requirements for medical radiological equipment. Nevertheless, they should comply with the more general requirements of the BSS for radiation generators (requirement 17 and paragraphs 3.49 - 3.60), as well as additional regulatory requirements, in a given Member State, for the preparation and control of radiopharmaceuticals.

4.43. Displays, gauges and instructions on operating consoles of medical radiological equipment, and accompanying instruction and safety manuals, may be used by staff who may not understand, or who may have a poor understanding of, the manufacturer's original language. In such cases, the accompanying documents should comply with IEC and ISO standards and should be translated into the local language. The software should be designed so that it can be easily converted into the local language resulting in displays, symbols and instructions that will be understood by the staff. The translations will require a quality assurance process to ensure proper understanding and avoid operating errors. The same applies to maintenance and service manuals and instructions for maintenance and service engineers and technicians, where these persons do not have an adequate understanding of the original language. See also Section 2 para. 2.103.

Design features for medical radiological equipment

4.44. The performance of probes, gamma cameras, SPECT systems and PET scanners determine the efficacy of the diagnostic radiological procedures and hence can influence the amount of radioactivity needed to be administered to the patient, even whether the procedure is diagnostically successful. Many design features contribute to their performance and should be considered when purchasing such equipment, as indicated briefly in the next paragraphs and detailed in Refs [192, 210, 211, 219, 225 – 241].

4.45. Design features for probes used for uptake measurements that should be considered include energy response, energy resolution, sensitivity, counting precision, linearity of count rate response and geometrical dependence.

4.46. Design features for probes used intra-operatively that should be considered include energy resolution, background count rate, sensitivity in scatter, sensitivity to scatter, shielding (side and back), counting precision, linearity of count rate response (with scatter), and count rate recorded by visual display and by an audible sound, the intensity of which is proportional to the count rate.

4.47. Design features for gamma and SPECT cameras as well as their accessories that should be considered include:

- (a) Detector performance;
- (b) Detector head and gantry design;
- (c) Detector head motion;
- (d) Automatic patient-detector distance sensing;
- (e) Collimators;
- (f) Pulse height analysis;
- (g) Imaging table and attachments;
- (h) Data acquisition, including:
 - a. General acquisition features;
 - b. Static acquisition;
 - c. Dynamic acquisition;
 - d. List mode acquisition;
 - e. Gated cardiac acquisition;
 - f. Whole body imaging;
 - g. Tomography.
- (i) Data processing system, including data display, image manipulation, region of interest (ROI) generation and display, curve generation, display and arithmetic, processing of SPECT data, quality control software and test data;
- (j) Accessories that include physiological triggering, anatomical landmarking, and phantoms.

4.48. Design features for PET scanners that should be considered include:

- (a) Detector design and performance;
- (b) Spatial resolution;
- (c) Scatter fraction, count losses and random events;
- (d) Sensitivity;
- (e) Accuracy;
- (f) Time of flight capability;
- (g) Data acquisition, including 2D and 3D whole body imaging, and cardiac and respiratory gating;
- (h) Data processing system, including image reconstruction algorithms and image manipulation.

4.49. Guidance on medical radiological equipment using X rays, used for imaging as part of nuclear medicine, is given in Section 3, paras. 3.26 - 3.39.

4.50. All digital medical radiological equipment should have connectivity to RIS/PACS.

Ancillary equipment

4.51. All equipment used for digital image display should meet appropriate international and/or local standards, for example meeting the performance specifications of the AAPM Task Group 18 [115]. Workstations and image processing and display software should be specifically designed for nuclear medicine, ensuring DICOM conformance, and network interconnectivity. Guidance on DICOM image and data management for nuclear medicine is given in Ref [242]. See paras. 4.36 - 4.37 for guidance on reporting rooms.

4.52. The nuclear medicine facility should have equipment, instruments and test objects for measurements, dosimetry and quality control which may include liquid scintillation counters, well counters, activity meters, dose calibrators, check sources, flood sources, phantoms, geometry and mechanical test tools. Where applicable, such instrumentation should adhere to relevant IEC standards or national equivalents. Further guidance on appropriate equipment, instruments and test objects is given in Refs [227, 240, 243].

4.53. The nuclear medicine facility should be equipped with radiation monitoring, including survey meters and portable contamination monitors.

4.54. Radiopharmaceutical dispensing equipment should adhere to relevant IEC standards or national equivalents.

Security of sources

4.55. The objective of source security is to ensure continuity in the control and accountability of each source at all times in order to meet the requirement in BBS paragraph 3.53. In the nuclear medicine facility the sources include unsealed radiopharmaceuticals as well as radionuclide generators, radiopharmaceutical dispensing equipment, and sealed sources used for calibration or QC tests. Requirements for the identification and documentation of unsealed radioactive uses are given by ISO [228]. Situations that are particularly critical with respect to source security in the nuclear medicine facility include receipt of radiopharmaceuticals, storage of sources, movement of sources within the facility, and storage of radioactive waste. The nuclear medicine facility licensee should develop procedures to ensure the safe receipt and movement of radioactive sources within the institution and establish controls to prevent theft, loss, unauthorized withdrawal of radioactive materials or entrance of unauthorized personnel to the controlled areas. An inventory of sources should be maintained, with procedures in place to check and confirm the sources are in their assigned locations and are secure. Procedures to stimulate proactive behaviour should be in writing, for example, to trigger a search when a delivery of radiopharmaceuticals is not received at the expected time.

Maintenance

4.56. The BSS (BSS, paragraphs 3.15(i) and 3.41) gives requirements for maintenance to ensure that sources meet their design requirements for protection and safety throughout their lifetime and to prevent accidents as far as reasonably practicable. The licensee should ensure that adequate maintenance (preventive and corrective) is performed as necessary to ensure that medical radiological equipment used in the nuclear medicine facility retains, or improves through appropriate hardware and/or software upgrades, its design specification for image quality, radiation protection and safety for its useful life. The licensee should, therefore, establish the necessary arrangements and coordination with the manufacturer's representative or installer before initial operation and on an on-going basis.

4.57. All maintenance procedures should be included in the quality assurance programme at the frequency recommended by the manufacturer of the equipment and relevant professional bodies. Servicing should include a report describing the equipment fault, the work done and the parts replaced and adjustments made, which should be filed as part of the quality assurance programme. A record of maintenance carried out should be kept for each item of equipment: this should include information on any defects found by users (a fault log), remedial actions taken (both interim and subsequent repairs) and the results of testing before equipment is reintroduced to clinical use.

4.58. In line with the guidance in Section 2, para. 2.111, after any modifications or maintenance, the person responsible for maintenance should immediately inform the licensee of the nuclear medicine facility before it is returned to clinical use. The person responsible for the use of the equipment, in conjunction with the medical physicist, the medical radiation technologist and other appropriate professionals, should decide whether quality control tests are needed with regard to radiation protection, including image quality, and whether changes to protocols are needed, especially in the amount of administered activity.

4.59. The electrical and mechanical safety aspects of the medical radiological equipment are an important part of the maintenance programme, and can have direct or indirect effects on radiation safety. Authorized persons who understand the specifications of the medical radiological equipment should perform this work. See also Section 2 paras. 2.110 - 2.112. Electrical and mechanical maintenance should be included in the QA programme at a frequency recommended and preferentially performed by the manufacturer of the medical radiological equipment. Servicing should include a written report describing the findings. These reports should be archived as part of the QA programme.

OCCUPATIONAL RADIATION PROTECTION

Introduction

4.60. In nuclear medicine, described in paras. 4.1 to 4.5, occupationally exposed individuals are usually the medical radiation technologists, the radiological medical practitioners (including, for example, nuclear medicine physicians), the radiopharmacists and the medical physicists. Other health professionals such as nurses, particularly in nuclear medicine facilities providing therapy services, may also be considered occupationally exposed.

4.61. Additional occupationally exposed personnel may include biomedical, clinical or service engineers and some contractors, depending on their role.

4.62. Other nuclear medicine facility workers such as administrative personnel, patient porters, orderlies, assistants, cleaners and other service support personnel, for whom radiation sources are not directly related to their work, require the same level of protection as members of the public, as stated in the BSS paragraph 3.78.

4.63. This sub-section contains guidance very specific to nuclear medicine. For more general and comprehensive guidance on occupational radiation protection, including guidance on radiation protection programmes, assessment of occupational exposure and providers of dosimetry services,

applicable to all areas of radiation use (including non-medical uses), reference should be made to the IAEA Safety Guide *Occupational Radiation Protection* [23].

Arrangements under the radiation protection programme

Classification of areas

4.64. Various areas and rooms in a nuclear medicine facility should be classified as controlled or supervised areas, in line with the requirements given in BSS paragraphs 3.88 and 3.91, respectively. Once designated, these areas should meet the requirements detailed in the BSS paragraphs 3.89 to 3.90 (for controlled areas) and 3.92 (for supervised areas), including requirements for area delineation, signage, protection and safety measures, control of access, provision of personal protective equipment, provision of individual and area monitoring, provision of equipment for monitoring for contamination, and provision of personal decontamination facilities. All other rooms and areas, not so-designated, are considered as "public domain" and levels of radiation in these areas should be low enough to ensure compliance with the dose limits for public exposure.

4.65. In a nuclear medicine facility, rooms for radiopharmaceutical preparation (i.e. radiopharmacies or hot labs), injection of the radiopharmaceuticals and for storage and decay of radiopharmaceuticals meet the criteria for controlled areas and should be so designated. Imaging rooms, particularly those housing radiopharmaceutical dispensing equipment (i.e. PET radiopharmaceutical and radioactive gas and aerosol dispenser devices), should also be considered controlled areas. Rooms with patients undergoing radiopharmaceutical therapy should be controlled areas. Rooms housing hybrid machines that have an X ray component (SPECT-CT, PET-CT) should be considered controlled areas when the X ray unit is energized. A warning light at the entry to the room should indicate the machine is on to prevent unintended passage.

4.66. Supervised areas may include examination rooms (with probes, gamma cameras and SPECT and PET systems) and waiting rooms dedicated to patients who have been injected with radiopharmaceuticals (e.g. uptake rooms in a PET facility).

4.67. The area around the control panel of hybrid imaging equipment (e.g. PET-CT and SPECT-CT) should be classified as either a controlled or a supervised area, even though the radiation levels may be very low due to the shielding design. In either case, this should ensure restricted access and hence, among other things, avoid distraction of the operator which may lead to accidental or unintended medical exposure of patients. See also Section 3, para. 3.55.

4.68. In order to avoid uncertainties about the extent of controlled and supervised areas, the boundaries should, when possible, be walls and doors or other physical barriers, clearly marked or identified with 'radiation area' signs.

Local rules and procedures

4.69. The BSS, in paragraph 3.93, establishes a hierarchy of preventive measures for protection and safety with engineered controls, including structured and ancillary shielding, specific physical barriers, signs and interlocks, being supported by administrative controls and personal protective equipment. To this end, and as required in the BSS paragraph 3.94, written local rules and procedures should be established in a nuclear medicine facility. Their purpose is to ensure protection and safety for workers and other persons. These local rules and procedures should include measures to minimize occupational radiation exposure during both normal work and unusual events. The local rules and

procedures should also cover the wearing, handling and storing of personal dosimeters, and specify investigation levels and ensuing follow-up actions (see paras. 4.117 - 4.131).

4.70. Since all personnel involved in using radiation in nuclear medicine should know and follow the local rules and procedures, the development and review of these local rules and procedures should include representatives of all health professionals involved in nuclear medicine.

4.71. Equipment (hardware and software) should be operated in a manner that ensures satisfactory performance at all times with respect to both the tasks to be accomplished and radiation safety. The manufacturer's operating manual is an important resource in this respect, but additional procedures should be also considered. The final documented set of operational procedures should be approved by the nuclear medicine facility's licensee, and incorporated into the facility's quality management system (see Section 2, paras. 2.136 - 2.147).

4.72. Nuclear medicine staff should understand the documented procedures for their work with radiopharmaceuticals and for the operation of the equipment with which they are working, including the safety features, and should be trained, with periodic refresher training, in what to do when things go wrong. Additional training should occur when new radiopharmaceuticals or devices are brought into nuclear medicine practice.

4.73. Many local rules and procedures address aspects of some, or all, of occupational radiation protection, patient radiation protection and public radiation protection, either directly or indirectly, as well as ensuring a successful diagnostic examination or application of the treatment. This is the case with the following paragraphs (4.74 to 4.108) – while placed in this section on occupational radiation protection because they are to be followed by workers, the local rules and procedures often also have significance for patient and/or public radiation protection. These following paragraphs (4.74 to 4.108) give recommendations that should be incorporated into the nuclear medicine facility's local rules and procedures. In addition, reference should also be made to para. 4.55 on the security of sources.

4.74. Work procedures should be formulated so as to minimize exposure from external radiation and contamination, to prevent spillage from occurring and, in the event of spillage, to minimize the spread of contamination (surface and airborne). For instance, all manipulation for dispensing radioactive materials should be carried out over a drip tray. Work with unsealed sources should be restricted to a minimum number of specifically designated areas.

4.75. No food or drink, cosmetic or smoking materials, crockery or cutlery should be brought into an area where unsealed radioactive materials are used. An exception to this is when food is radiolabelled for patient studies. Food or drink should not be stored in a refrigerator used for unsealed radioactive materials. Personal cell phones and handkerchiefs should never be used in these areas; an adequate supply of paper tissues should be provided. Before a person enters an area where radioactive material is handled, any cut or break in the skin should be covered by a waterproof dressing.

4.76. In areas classified as controlled, protective clothing should be worn as determined by prior risk assessment of potential contamination. Protective clothing is unlikely to be necessary for persons accompanying patients into gamma camera rooms. On leaving the controlled area, protective clothing that is contaminated should be placed in an appropriate container. The method of removing gloves should be based on the surgical technique, in order to avoid transferring activity to the hands.

4.77. Staff leaving a controlled area, classified as such on account of the potential for contamination, should, after removal of their protective clothing, wash their hands and then monitor their hands, clothing and body. Liquid soap should be provided unless aseptic considerations require an alternative

cleaner. Non-abrasive nail brushes should only be used if contamination persists after simple washing. See also paras. 4.104 - 4.108 below on decontamination of persons.

4.78. Pipettes should never be operated by mouth. Syringes used for handling radioactive liquids should be appropriately shielded wherever practicable. The distance between the fingers and the radioactive liquid should be as large as can be achieved.

4.79. The work area should be kept tidy and free from articles not required for work. A monitoring and cleaning programme should be established to ensure minimal spread of contamination. Cleaning and decontamination can be simplified by covering benches and drip trays with disposable material such as plastic backed absorbent paper.

4.80. All containers used for radioactive material should be clearly labelled, indicating the radionuclide, chemical form and activity at a given date and time. Batch number and expiry date and time should be added as appropriate. All such containers are to be adequately sealed and shielded at all times. Except for very small activities, containers are not to be handled directly and, if possible, tongs or forceps for vials and syringe shields should be used. Records of stocks, administrations and pre-disposal waste management should be kept.

4.81. The amount of shielding material required can be minimized by positioning it close to the source. A variety of materials can be used for this purpose, such as lead, tungsten, lead glass and lead composite. Shielding incorporating acrylic is more suitable for beta emitters, as it lowers the amount of bremsstrahlung produced. Lead should be coated to provide a cleanable surface.

4.82. The attenuation by lead aprons at the typical gamma energies used in nuclear medicine is modest, and even less for non-lead based protective aprons. Automatic dispensers and injectors, and mobile shields are preferred alternatives.

4.83. The following protective approaches can reduce occupational exposure significantly:

- (a) For preparation and dispensing of radiopharmaceuticals, working behind a lead glass bench shield, using shielded vials and syringes, and using disposable gloves.
- (b) During examinations, when the distance to the patient is short, using a movable transparent shield.

4.84. All radioactive sources should be returned to safe storage immediately when no longer required.

4.85. All operations involving radioactive gases or aerosols should be carried out in a fume hood or similar ventilated device to prevent airborne contamination. Exhaust vents should be situated well away from air intakes. The administration of aerosols to patients, such as for ventilation studies, should be performed using a mouthpiece or mask for the patient.

4.86. Glassware and implements for use in the radiopharmacy should be appropriately marked and under no circumstances removed from that area.

4.87. Packaging and containers for radioactive material should be checked for contamination on opening.

4.88. Containers, lead pots, etc., that no longer contain radioactive material and require to be managed as non-radioactive waste should have any radiation warning labels removed or obliterated before removing them from regulatory control.4.89. For X ray based imaging (e.g. CT) in the nuclear medicine facility, reference should be made to the guidance, where appropriate, in Section 3, paras. 3.61 - 3.73.

4.90. Local rules for pregnant workers and persons under 18 should reflect the guidance given in paras. 4.144 - 4.148 and 4.149 respectively.

Specific local rules and procedures for radiopharmaceutical therapy

4.91. Administration is normally by the oral route, intravenous injection (systemic), intra-arterial injection (locoregional) or instillation into closed joints (intra-articular/radiosynoviorthesis) or body cavities (intracavitary).

- (a) Shielded syringes should be utilized during the intravenous or intra-arterial administration of radiopharmaceuticals as necessary to ensure extremity doses are maintained below occupational dose constraints. Absorbent materials or pads should be placed underneath an injection or infusion site. The facility RPO should be consulted to determine the necessity of other protective equipment (e.g., shoe covers, step-of-pads, etc.) for particular radiopharmaceutical therapies.
- (b) For intravenous or intra-arterial administrations by bolus injections, when dose-rates warrant, the syringe should be placed within a syringe shield (plastic for beta-emitting radionuclides to minimize bremsstrahlung, high atomic number materials for photon-emitting radionuclides) with a transparent window to allow for visualization of the material in the syringe. For intravenous administrations by slower drip or infusions, the activity container should be placed within a suitable shield. For high-energy photons, a significant thickness of lead or other high atomic number material may need to be used. In addition, consideration should be given for shielding pumps and lines.
- (c) For oral administrations of therapeutic radiopharmaceuticals, the radioactive material should be placed in a shielded, spill-proof container. Care should be taken to minimize the chance for splashing liquid, or for dropping capsules. Appropriate long-handled tools should be utilized when handling unshielded radioactive materials.

4.92. Patients hospitalized for therapy with radiopharmaceuticals should be attended by staff (physicians, nurses, aids, cleaning staff) trained in radiation protection. This also includes night staff. The training should cover radiation protection and specific local rules, in particular, for situations where there is a risk of significant contamination from urine, faeces or vomiting. Ward nurses should be informed when a patient may pose a radioactive hazard.

4.93. Local rules should be established concerning the type of nursing that can be performed according to the level of ambient dose equivalent. In general, non-essential nursing should be postponed to take advantage of the reduction of activity by decay and excretion. Blood and urine analyses should be performed prior to therapy Procedures should be established for the handling of any potentially contaminated item (bed linen, clothing, towels, crockery, etc.).

4.94. As described above in para. 4.65, rooms occupied by patients treated with radiopharmaceuticals should be controlled areas, and both a radiation sign and a warning sign should be posted. Access should be restricted and a list of relevant contacts (such as nuclear medicine and on-call physicians, medical radiation technologists, radiation protection officer) should be provided. Protective clothing, such as laboratory coats, gloves and shoe covers, should be available at the entrance to the room. The nursing staff should be familiar with the implications of the procedures for controlled areas, the time and date of administration, and any relevant instructions to carers and comforters.

4.95. Values of ambient dose equivalent at suitable distances should be determined by the RPO or medical physicist. This information will assist in deriving appropriate arrangements for entry by staff and by carers and comforters. These arrangements should be made in writing in the local rules.

4.96. On leaving the work area, staff should remove any protective clothing and wash their hands.

4.97. Patients treated with radiopharmaceuticals should use designated toilets. Measures to minimize contamination should be implemented (such as laying plastic backed absorbent paper on the floor around the toilet bowl, sitting down when using the toilet and instructions to flush the toilet at least twice in the absence of delay tanks).

4.98. Particular attention and measures to limit spread of contamination are required in the case of incontinent patients and in the risk of vomiting after oral administration of the radiopharmaceutical. Plastic backed absorbent paper on the bed and floor can help reduce spread of contamination. Contaminated bedding and clothing should be changed promptly and retained for monitoring.

4.99. Crockery and cutlery may become contaminated. Local rules should specify washing up and segregation procedures, and the management of single use dishes, cutlery and food waste.

4.100. Nursing care items should be covered when possible to prevent contamination. For example, the stethoscope can be covered with a glove. The blood pressure cuff and the thermometer should remain in the room until the release of patient, and then checked for contamination before being returning to regular use again.

4.101. The staff should be informed about the treatment procedure and any relevant medical history. If the medical condition of a patient deteriorates such that intensive care becomes necessary, the advice of the RPO should be sought immediately. While urgent medical care is a priority and should not be delayed, it may be necessary to restrict the maximum time that individual health professionals spend with a patient.

Specific local rules and procedures in PET facilities

4.102. PET imaging personnel can receive relatively large annual occupational radiation doses compared to their counterparts in general nuclear medicine. The main contribution to the occupational dose for personnel comes from patient handling. PET radiopharmacists, at facilities performing radiopharmaceutical synthesis and unit dose preparations, can receive significant hand and body doses, even where heavily shielded 'hot cells' are available to moderate dose. For these reasons, local rules and procedures for PET facilities should emphasize the means described above for minimizing the dose to personnel when handling radiopharmaceuticals and the injected patient.

4.103. Radiopharmaceuticals should be stored and transported in lead or tungsten containers specifically designed to limit external radiation levels from radionuclides used for PET. An additional plastic shield inside a lead or tungsten syringe shield will absorb positrons before striking the tungsten, minimizing unwanted production of bremsstrahlung radiation. The use of tongs to handle unshielded radiopharmaceutical vials markedly reduces hand doses. Automatic systems are available which allow safe and quick radiopharmaceuticals dispensing into syringes, thus minimizing operators' actions.

Decontamination of persons

4.104. Hands should be washed on completing work with unsealed radioactive materials and on leaving an area that is controlled, because of potential contamination. If detectable contamination remains on the hands after simple washing, use of a surfactant or chelating agent specific to the chemical form of the contaminant agent may be more successful. A decontamination kit and procedures for its use shoul be available on site.

4.105. The RPO should be consulted when contamination of parts of the body other than the hands is suspected, or when the procedures for decontamination of the hands are ineffective. Special care

should be taken in the decontamination of the face to restrict entry of radioactive material into the eyes, nose or mouth.

4.106. If the skin is broken or a wound is sustained under conditions where there is a risk of radioactive contamination, the injury should be irrigated with water as soon as appropriate, taking care not to wash contamination into the wound. As soon as the first aid measures have been taken, the person should seek further treatment, including decontamination if necessary The RPO should be consulted as needed.

4.107. Contaminated clothing should be removed as soon as practicable, taking care not to spread contamination.

4.108. All staff working with unsealed sources should be trained in the procedures for dealing with accidents, spills or contaminated persons, with refresher training at appropriate intervals. This includes instructions on appropriate use of showering and eye washing.

Personal protective equipment and in-room protective devices

4.109. The BSS, paragraphs 3.93 and 3.95, requires that personal protective equipment and in-room protective equipment are available and used when structural shielding and administrative controls alone cannot afford the necessary level of occupational radiation protection. The need for this protective equipment should be established by the nuclear medicine facility's RPO or medical physicist.

4.110. In a nuclear medicine facility, protective equipment includes the following:

- (a) Shields for bench tops, vials, syringes, activity meters and for the preparation of the radiopharmaceuticals (i.e. L-blocks and side blocks) of a material and thickness appropriate to the type and energy of the radiation. Particular considerations for the choice of shield include:
 - a. Alpha emitters such as ²¹¹At may need to be shielded by high atomic number materials because of their characteristic X rays and high-energy gamma components;
 - b. ²²³Ra does not need a high atomic number shield because the gamma component does not contribute significantly to the dose;
 - c. Solutions containing pure low-energy beta emitters such as ¹⁴C and ⁹⁰Sr require a plastic shield to attenuate the beta particles;
 - d. Solutions containing high-energy beta emitters such as ³²P and ⁹⁰Y require a plastic shield to attenuate the beta particles followed by a high atomic number material shield for the bremsstrahlung radiation;
 - e. Solutions containing radionuclides which have both beta and gamma radiations (such as ⁸⁹Sr, ¹⁵³Sm, ¹⁶⁹Er, ¹⁷⁷Lu, and ¹⁸⁶Re) may need in addition a lead shield to attenuate the high-energy gamma components;
 - f. Gamma emitters always require high-Z material shielding.
- (b) Protective clothing should be used in work areas where there is a likelihood of contamination, such as radiopharmaceutical preparation areas. The protective clothing may include laboratory gowns, waterproof gloves (made of latex or non-latex such as neoprene, polyvinyl chloride or nitrile), overshoes, and caps and masks for aseptic work. The clothing serves both to protect the body of the wearer and to help to prevent the transfer of contamination to other areas. The clothing should be monitored and removed before leaving designated areas; however, when moving between supervised areas such as the camera room and the injection area, it may not be necessary to change the protective clothing unless a spill is suspected. Protective clothing should be removed prior to going to other areas such as staff rooms.
- (c) When lower energy beta emitters are handled, the gloves should be thick enough to protect against external beta radiation.

- (d) Lead aprons should be worn when entering a room with hybrid imaging (e.g. PET-CT) if the X rays are about to be used and the staff member needs to be in the room with the patient. Lead aprons may also be worn when preparing and administering high activities of ^{99m}Tc, although their use is not recommended, as other protective measures are more effective.
- (e) Tools for remote handling of radioactive material, including tongues and forceps.
- (f) Containers for radioactive waste and radioactive source transportation.
- (g) Fume hoods, fitted with appropriate filters, should be used with volatile radiopharmaceuticals such as ¹³¹I, ¹³³Xe and ²¹¹At. The sterility of the intravenous radiopharmaceuticals should be preserved.

Monitoring of the workplace

4.111. The BSS, in paragraphs 3.96-3.98, sets out the requirements and responsibilities for workplace monitoring. Workplace monitoring comprises measurements made in the working environment and the interpretation of such results. Workplace monitoring serves several purposes, including routine monitoring, special monitoring for specific occasions, activities or tasks, and confirmatory monitoring to check assumptions made about exposure conditions. Workplace monitoring can be used to verify the occupational doses of personnel whose work involves exposure to predictable low levels of radiation. It is particularly important for staff members who are not individually monitored. In the nuclear medicine facility, workplace monitoring should address both external exposure and contamination. Further general guidance on workplace monitoring is given in Ref [23].

4.112. Laboratories and other areas in which work with unsealed sources is undertaken should be monitored, both for external radiation and for surface contamination, on a systematic basis. Contamination monitoring is required for:

- (a) All working surfaces (including the interior of enclosures), tools, equipment and devices (including dosimetry systems, computers and peripherals, and stress testing units), the floor and any items removed from these areas;
- (b) Contained workstations, ventilation systems and drains during maintenance;
- (c) Protective and personal clothing, and shoes, particularly when leaving an area that is controlled due to the risk of contamination (monitors should be available near the exit);
- (d) Clothing, bedding and utensils used by radiopharmaceutical therapy patients.

4.113. Periodic monitoring with a survey meter and contamination monitor or by wipe tests should be conducted for controlled and supervised areas. Continuous monitoring with an area monitor should be considered for source storage and handling areas. If a package containing radioactive sources is damaged upon arrival, a survey of removable contamination and the external radiation field should be carried out.

4.114. Workplace monitoring with respect to X ray based imaging systems used in nuclear medicine should follow the guidance given in Section 3, para. 3.95.

4.115. Workplace monitoring should be performed and documented as part of the nuclear medicine facility's radiation protection programme. The nuclear medicine facility's RPO or medical physicist should provide specific advice on the workplace monitoring programme, including any investigations that arise when investigation levels are being exceeded (see paras. 4.130 - 4.131).

4.116. The survey meters used for external radiation monitoring should be calibrated in terms of ambient dose equivalent. For nuclear medicine, the quantity is $H^*(10)$ and the unit the Sv and its submultiples. Contamination monitors should be calibrated in appropriate operational quantities. See also further guidance on calibration in paras. 4.195 – 4.200. Assessment of occupational exposure and workers' health surveillance

Occupational exposure assessment

4.117. 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 and regulatory compliance. It contributes to reassurance and motivation. The BSS require individual monitoring for any worker who normally works in a controlled area or who occasionally works in a controlled area and is likely to receive significant occupational exposure (see BSS paragraphs 3.99 to 3.102). Workers who may require individual monitoring include nuclear medicine physicians, other specialist doctors, medical radiation technologists, medical physicists, the RPO, radiopharmacists and any other persons involved in the preparation, dispensing and administering of radiopharmaceuticals to patients for diagnosis and therapy, staff dealing with radioactive waste, biomedical engineers, maintenance and servicing personnel, and any nursing or other staff who need to spend time with nuclear medicine patients or work in controlled areas.

4.118. Monitoring involves more than just measurement. It includes interpretation, assessment, investigation and reporting, which may lead to corrective measures, if needed. Individual external doses are assessed by using individual monitoring devices that include thermoluminescent dosimeters (TLD), optical stimulated luminescence dosimeters (OSLD), film badges, and electronic dosimeters. Individual monitoring devices must be calibrated, traceable to a standards dosimetry laboratory. For more detailed guidance see Ref [23].

4.119. Each dosimeter is to be used for monitoring only the person to whom it is issued, for work performed at that nuclear medicine facility and should not be taken to other facilities where that person may work. For example, if a person is issued with a dosimeter at hospital A it should be worn only at hospital A and not at any other hospitals or medical centres where he/she may also work. Monitoring results can then be interpreted for the person working in a specific nuclear medicine facility and allow appropriate review of the effectiveness of the optimization of protection for that individual in that facility. See also paras. 4.132 to 4.134.

4.120. The monitoring period (period of dosimeter deployment) specified by regulatory bodies in most countries is typically in the range of one to three months. It is determined by such factors as service availability, work load and type of work. A one month monitoring period is usually used for persons performing procedures associated with higher occupational exposures. A longer monitoring period (two or three months) is more typical for personnel exposed to lower doses, as a one month cycle would usually mean that the actual occupational dose was less than the minimum detection level of the dosimeter resulting in no detectable doses. With a longer cycle it is more likely to obtain a reading. In certain circumstances (e.g. introduction of new procedures, high dose rate work) shorter monitoring periods may be needed. In these situations, the supplementary use of electronic dosimeters may be appropriate. Unnecessary delays in the return, reading and reporting of dosimeters should be avoided – the nuclear medicine facility should send the dosimeters to the dosimetry service provider who should then process the dosimeters and return the dose reports, all in a timely manner. Some regulatory bodies may specify a performance criterion for timely reporting.

4.121. The operational dosimetric quantity used for external radiation is the personal dose equivalent $H_p(d)$. For weakly penetrating and strongly penetrating radiation, the recommended depths, *d*, are 0.07 mm and 10 mm, respectively. Both weakly penetrating and strongly penetrating radiation are used in
nuclear medicine. $H_p(10)$ is used to provide an estimate of effective dose that avoids both underestimation and excessive overestimation [23].

4.122. For monitoring the skin and extremities, a depth of 0.07 mm (d = 0.07) is recommended, and $H_p(0.07)$ is used to provide an estimate of equivalent dose to the skin and extremities. When there is a possibility of high exposure to the hands, such as in the preparation and administration of radiopharmaceuticals, extremity dosimeters should be worn (if compatible with good clinical practice).

4.123. For monitoring the lens of the eye, a depth of 3 mm (d = 3) is recommended, and $H_p(3)$ is used to provide an estimate of equivalent dose to the lens of the eye. In practice, however, the use of $H_p(3)$ has not been widely implemented for routine individual monitoring. In nuclear medicine it would generally be expected that the dose to the lens of the eye is not higher than for the rest of the body. A possible exception is during the handling of sources for preparation and administration, but with accepted practices (as described in 4.69 to 4.90) the lens of the eyes should be adequately protected. Nonetheless, monitoring of eyes doses may need to be considered.

4.124. There are three dose limits applicable to workers in nuclear medicine – effective dose, and equivalent dose to the lens of the eye, and to skin and extremities. However, in nuclear medicine, exposures from both external radiation and internal contamination are relevant. The dosimeter being worn will measure external radiation only and will be used to estimate one or more of the quantities used for the dose limits. Depending on the work being performed by the person being individually monitored, there may be a preferred position for wearing the dosimeter, and more than one dosimeter may be used. In nuclear medicine, dosimeters are usually worn on the front of the upper torso (and under any protective clothing), as occupational exposure arising from most nuclear medicine procedures results in the whole body being fairly uniformly exposed. See para. 4.122 for when extremity dosimeters should be worn.

4.125. When a protective apron is being used, the assessment of effective dose may not be straightforward:

- (a) A single dosimeter placed under the apron, reported in $H_p(10)$, 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).
- (b) A single dosimeter worn outside the apron, reported in $H_p(10)$, provides a significant overestimate of effective dose and should be corrected for the protection afforded by the apron by using an appropriate algorithm [123, 127 129].
- (c) In nuclear medicine, a single dosimeter under the apron provides an estimate of the effective dose that is sufficient for radiation protection purposes.

4.126. In nuclear medicine, certain workers may be at risk of both surface (skin) contamination and internal contamination by ingestion, inhalation or adsorption of radioactive material. Employers are responsible (BSS paragraph 3.102) to identify those persons and arrange appropriate monitoring. This requirement is typically met by monitoring the thyroid with an external detector assessing the iodine uptake for individuals handling radioiodine and by monitoring the hands after the protective gloves have been removed. In some special cases, it may be required to measure the activity of urine samples. The committed effective dose should be calculated as part of the worker's total effective dose [23].

4.127. When not in use, individual dosimeters should be kept in an established place and protected from damage or from irradiation. 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 in a timely manner. 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 similar exposure conditions as the basis for the dose estimate.

4.128. In some cases occupational doses may be estimated from the results of workplace monitoring. The effective dose for personnel can be inferred from the measured ambient dose equivalent $H^*(10)$, provided the dose gradient in the workplace is relatively low. ICRP [125] provides conversion coefficients from ambient dose equivalent to effective dose for different types of radiation and energies.

4.129. The use of additional direct reading operational dosimeters, such as electronic dosimeters, should be considered for use in a nuclear medicine facility, e.g. in a new department or with the introduction of new procedures, as these devices can give the worker an instant indication of both the cumulative and the current dose rate and also allow pre-setting of an alarm to alert when a given level has been reached [23]. These dosimeters are also useful for staff involved in radiopharmaceutical therapies and for pregnant workers where a 'real-time' radiation exposure reading is recommended.

Investigation levels for staff exposure

4.130. Investigation levels are separate from dose constraints and dose limits; they 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. Exceeding an investigation level should prompt such actions. In nuclear medicine, one could use predetermined values such as 0.5 mSv per month for effective dose or 15 mSv per month for finger dose. Suitable alternatives may be doses that exceed an appropriate fraction (e.g. 25%), pro rata per monitoring period, of the annual dose limits or a pre-set value above a historical average. Abnormal conditions and/or events should also trigger an investigation. In all cases the investigation is with a view to improve implementation of optimization of occupational protection and results should be recorded. Investigation levels should also be set for workplace monitoring.

4.131. The investigation is to be initiated as soon as possible following the trigger or event and a written report is to be prepared concerning the cause, including determination or verification of the dose, corrective or mitigating actions, and instructions or recommendations to avoid recurrence. Such reports should be reviewed by quality assurance and radiation safety committees, as appropriate, and the holder of the licence should be informed. In some cases, the regulatory body should also be informed.

Persons who work in more than one place

4.132. Personnel may work in more than one nuclear medicine facility. The facilities may be quite separate entities in terms of ownership and management, or they may have common ownership but separate management, or they may even have common ownership and management, but be physically quite separate. No matter which, the occupational radiation protection requirements for the particular nuclear medicine facility apply when the person is working in that facility. As described above in para. 4.119, a dosimeter issued for individual monitoring should be worn only in the facility for which it is issued as this facilitates effective implementation of optimization of protection in that facility. This approach is logistically more easily implemented as each physical site has its own dosimeters –

there is no need to transport dosimeters between facilities, with the risk of losing them or forgetting them. In cases where the facilities are under common ownership it may be seen as an unnecessary financial burden to provide more than one set of dosimeters for staff that work in more than one of its facilities. However the radiation protection advantages of having the dosimeter results linked to a person's work in only one nuclear medicine facility remain. See also para. 4.134.

4.133. There is however an additional consideration, namely ensuring compliance with the occupational dose limits. Any person who works in more than one nuclear medicine facility should notify the licensee for each of those facilities. Each licensee, through their RPO, establishes formal contact with the licensees of the other nuclear medicine facilities, and their RPOs, so that each facility has an arrangement to ensure that a personal dosimeter is available and that there is an on-going record of the occupational doses for that person in all the facilities where they work.

4.134. Some personnel, such as consultant medical physicists or service engineers, may perform work in many nuclear medicine facilities and, maybe as well, other medical radiation facilities. They may be employed by a company or be self-employed, providing contracted services to the nuclear medicine and other facilities. In such cases it is simpler for the company or the self-employed person to provide the dosimeters for individual monitoring. In other words, in these cases for each person the same dosimeter is used for his/her work performed in all nuclear medicine facilities (and other medical radiation facilities) in the monitoring period.

Records of occupational exposure

4.135. Paragraphs 3.103 to 3.107 of the BSS state the detailed requirements for records of occupational exposure, placing obligations on the employer, registrant and licensee. Apart from demonstrating compliance with legal requirements, records of occupational exposure should be used within the nuclear medicine facility for additional purposes, including assessing the effectiveness of the facility's implementation of optimization of protection, and evaluating trends in exposure. National or local regulatory bodies might specify additional requirements for records of occupational exposure and for access to the information contained in those records. Further general guidance on records of occupational exposure is given in [23].

Workers' health surveillance

4.136. The primary purpose of health surveillance is to assess the initial and continuing fitness of employees for their intended tasks, and requirements are given in BSS paragraphs 3.108 to 3.109.

4.137. No specific health surveillance related to exposure to ionizing radiation is necessary for staff involved in nuclear medicine. Under normal working conditions, the occupational doses incurred in nuclear medicine are low and no specific radiation related medical surveillance is required as there are no diagnostic tests that yield information relevant to low dose exposure. It is, therefore, rare for considerations of occupational exposure arising from the working environment of a nuclear medicine facility to significantly influence the decision about the fitness of a worker to undertake work with radiation or to influence the general conditions of service [23].

4.138. Only in cases of overexposed workers, at doses much higher than the dose limits (e.g. a few hundred millisieverts or higher), would special investigations involving biological dosimetry and further extended diagnosis and medical treatment be necessary [23]. In case of internal contamination, additional investigations to determine uptake and retention may be required. Interventions to facilitate excretion or limit uptake of the radioactive agent should be considered, as appropriate.

4.139. Counselling should be available to workers who have or may have been exposed in excess of dose limits, and information, advice and, if indicated, counselling should be available to workers who are concerned about their radiation exposure. In nuclear medicine, the latter group may include women who are or may be pregnant. Counselling should be given by appropriately experienced and qualified practitioners. Further guidance is given in [23].

Information, instruction and training

4.140. All staff involved in nuclear medicine should fulfil the respective training and competence criteria described in Section 2, paras. 2.117 to 2.135. This will include general education, training, qualification and competence for occupational radiation protection in nuclear medicine. Nuclear medicine physicians, medical radiation technologists, medical physicists and nurses may not have been trained with respect to the X ray based component of hybrid imaging systems, such as PET-CT, and as such should undertake radiation protection training relevant to the additional imaging modalities in their nuclear medicine facility.

4.141. The BSS, in paragraph 3.110, places responsibilities on employers to provide, inter alia, specific instruction and training for protection and safety as it pertains to their nuclear medicine facilities. This is not only for new staff but also for all staff as part of their continuing professional development. Specific instruction and training should be provided when new radiopharmaceuticals, medical radiological equipment, software and technologies are introduced.

4.142. Information on potential contamination risks should be given to ancillary staff, including information technology specialists, and contractors doing occasional work in a nuclear medicine facility and/or radiopharmaceutical laboratory.

Conditions of service and special arrangements

4.143. As required in BSS paragraph 3.111, no special benefits are to be offered to staff because they are occupationally exposed. It is simply not acceptable to offer benefits as substitutes for measures for protection and safety.

Special arrangements – female workers (pregnant or breast-feeding)

4.144. A female worker should notify the licensee that she is pregnant as soon as she knows of her status, or if she is breast feeding, so that radiation protection requirements for the embryo/fetus and baby as a member of the public can be met respectively.

4.145. Limitation of the dose to the embryo/fetus does not mean that pregnant women should avoid working with radiation, but it does imply that the employer should carefully review the exposure conditions with regard to both normal exposure and potential exposure. For example, a pregnant worker may be restricted from spending a lot of time in the radiopharmacy or working with solutions of radioiodine [130]. The main risk with radioiodine is that it crosses the placental barrier and concentrates in the fetal thyroid.

4.146. Other possible solutions include reassigning a pregnant worker to duties where the likelihood of an accident or incident is unlikely or to a location that may have lower ambient dose equivalent. Adequate training should accompany such reassignments. A further consideration is to avoid having

pregnant workers respond to an incident or accident such as a radioactive spill (see also paras. 4.291 - 4.296).

4.147. The use of personal electronic dosimeters are valuable in assessing radiation doses to pregnant workers and subsequently the embryo/fetus. See also para. 4. 129.

4.148. When applying the dose limit of 1 mSv to the embryo/fetus, embryo/fetal doses are not likely to exceed 25% of the personal dosimeter measurement of external exposure. This value depends on the penetration of the radiation, i.e. on the photon energy of the radionuclides in use. Information, advice and, if indicated, counselling for pregnant workers should be available (see also para. 4.139).

Special arrangements – persons under 18

4.149. In many countries there is the possibility of students aged 16 or more, but under 18, commencing their studies and training to become a medical radiation technologist or other health professional that may involve occupational exposure to ionizing radiation. The BSS paragraph 3.116 states the requirements for access to controlled areas, and the dose limits for such persons are more restrictive – see Table 2 in this Safety Guide and Schedule III of the BSS.

Protection of workers responding to incidents in the nuclear medicine facility

4.150. The practice of nuclear medicine is a planned exposure situation, and when circumstances result in incidents that lead to, or could lead to, unintended or accidental exposures of patients or staff, they are still within the framework of a planned exposure situation. The potential occurrence of such should be considered in advance in the facility's safety assessment and contingency plans developed accordingly – see guidance in paras. 4.280 - 4.297 in the section on prevention and mitigation of accidents.

4.151. Occupational exposure of staff responding to these incidents is still subject to the occupational dose limits and the contingency plans for incidents should include considerations for the optimization of protection for the responding workers. The contingency plans should also include allocation of responsibilities and provide for the training of the relevant staff in executing the mitigation measures, which should be periodically rehearsed. Most of these situations, for example spillage of radioactive materials on work surfaces, can be executed in a planned manner so that doses can be kept low. There may be cases with high doses, for example in medical emergencies involving immediate care of patients in the case of a stroke or cardiac arrest, when large amounts of radioactive material have been incorporated (e.g. 2 GBq of 131 I), but in these events the dose is justified because the procedure is lifesaving. However, even in the case of urgent surgery, rotation of personnel may be utilized if the surgical procedure is lengthy, to help maintain optimized occupational radiation protection for this situation. The advice of the facility's RPO is needed for these situations. See the guidance in paras. 4.295 – 4.296 for more details.

RADIATION PROTECTION OF PATIENTS, CARERS AND COMFORTERS, AND VOLUNTEERS IN BIOMEDICAL RESEARCH

Introduction

4.152. This section covers what is more formally called 'medical exposure' in radiation protection. Medical exposure is defined in the BSS and described in Section 2, para. 2.5. It concerns radiation protection of the patient, carers and comforters, and volunteers in biomedical research. The term 'patient', when used in the context of medical exposure, means the person undergoing the radiological procedure. Other patients in the nuclear medicine facility, including those who may be waiting for their own radiological procedure, are considered as members of the public and their radiation protection is covered in paras. 4.260 - 4.269.

4.153. As described in Section 2 para. 2.8, there are no dose limits for medical exposure, making it very important that there is effective application of the requirements for justification and optimization.

Justification of medical exposures

4.154. The requirements of the BSS for justification of medical exposure, BSS paragraphs 3.155 to 3.161, incorporate the '3 level approach' to justification [4, 131, 140].

4.155. The roles of the health authority and professional bodies with respect to 'level 2' or generic justification of radiological procedures, justification of health screening programmes, and justification of screening intended for the early detection of disease, but not as part of a health screening programme, are described in Section 2 paras. 2.55 - 2.59 and 2.64 - 2.65.

Justification for the individual patient

4.156. The BSS invokes a joint approach to justification at the individual patient level, with a shared decision involving both the referring medical practitioner (who initiates the request for a radiological procedure) and the radiological medical practitioner. A referral for a nuclear medicine procedure should be regarded as a 'request for a professional consultation or opinion' rather than an 'instruction or order to perform'. The referring medical practitioner brings the knowledge of the medical context and the patient's history to the decision process, while the radiological medical practitioner has the specialist expertise on the radiological procedures. The efficacy, benefits and risks of alternative methods (both involving and not involving ionizing radiation, such as for example CT or ultrasound) should be considered. Ultimate responsibility for justification will be identified by individual member states' regulations.

4.157. In the case of radiopharmaceutical therapy, the requirements for justification are implemented more effectively as part of the medical process of determining the best approach to treatment. When a patient is referred by a referring medical practitioner for treatment, careful consideration should be made by a multidisciplinary team, including such specialists as radiation oncologists or endocrinologists, regarding whether to treat the patient with radiopharmaceutical therapy or some other form of radiation therapy, another modality, a combined treatment approach (sequential or concomitant) or not to be treated at all. Ideally every treatment decision should be discussed and documented in a tumour board or equivalent multidisciplinary meeting.

4.158. The patient also should be informed about the expected benefits, risks and limitations of the proposed radiological procedure(s), as well as the consequences of not undergoing the procedure.

4.159. In nuclear medicine imaging, requirements for justification are applied more effectively as part of the medical process of determining 'appropriateness'. Appropriateness uses an evidence-based approach to choose the best test for a given clinical scenario, taking into account diagnostic efficacy and justification as well as alternative procedures that do not use ionizing radiation, for example, ultrasound or MRI. Useful tools to support this decision making process include national or international imaging referral guidelines developed by professional societies [133 - 140, 245], in some cases disseminated through electronic requesting systems¹⁷ and clinical decision support tools or systems.

4.160. In determining appropriateness of the nuclear medicine imaging procedure for an individual patient, the following questions should be asked by the referring medical practitioner [138];

- (a) Has it been done already? A radiological procedure that has already been performed within a reasonable time period (depending on the procedure and clinical question) should not be repeated. In some cases an alternative procedure may have already been performed in another facility, making the proposed radiological procedure unnecessary for example a CTPA performed recently in one facility for a patient who presents as a potential V/Q patient at another facility. The results (images and reports) of previous examinations should be available, not only within a given nuclear medicine facility but also between different facilities. Digital imaging modalities and electronic networks should facilitate this process.
- (b) *Is it needed?* The results of the proposed radiological procedure (positive or negative) should influence the patient's management.
- (c) *Is it needed now?* The timing of the proposed radiological procedure in relation to the progression of the suspected disease and the possibilities for treatment, all should be considered as a whole.
- (d) *Is this the best investigation to answer the clinical question?* Advances in imaging techniques are taking place continually, and the referring medical practitioner may need to discuss with the radiological medical practitioner what is currently available for a given problem.
- (e) *Has the clinical problem been explained to the radiological medical practitioner?* The medical context for the requested radiological procedure is crucial to ensure the correct technique is performed with the correct focus.

4.161. Three particular groups of patients are identified in the BSS, paragraph 3.157, for special consideration with respect to justification in nuclear medicine – patients who may be pregnant or breast-feeding, and paediatric patients.

- (a) Due to the higher radiosensitivity of the embryo/fetus, it should be ascertained whether a female patient is pregnant before performing a nuclear medicine procedure. Determining pregnancy status is a requirement in the BSS, paragraph 3.176, for those radiological procedures that could result in significant dose to the embryo or fetus. Pregnancy would then be a factor in the justification process and might influence the timing of the proposed radiological procedure or whether another examination or treatment is more appropriate. Care should be taken to ascertain that the examination is indeed indicated for a medical condition that requires prompt medical treatment. Confirmation of pregnancy may occur after the initial justification and before the radiological procedure is performed. Repeat justification is required taking into account the additional sensitivity of the pregnant woman and embryo or fetus.
 - a. Most diagnostic procedures with ^{99m}Tc do not cause high fetal doses. For radionuclides that do not cross the placenta, fetal dose is derived from the radioactivity in maternal tissues. Some radiopharmaceuticals, or their breakdown

¹⁷ Such electronic requesting systems include the so-called CPOE – computerized physician order entry, noting that for imaging such a system should generate a request rather than an order.

components, that do cross the placenta and concentrate in a specific organ or tissue can pose a significant risk to the fetus. Particular attention should be drawn to radiopharmaceuticals labelled with iodine isotopes. Radiopharmaceuticals labelled with other radionuclides, in particular positron emitters, need special consideration. In all these instances the medical physicist should estimate the fetal dose. Detailed information on doses to the embryo and fetus from intakes of radionuclides by the mother is given by the ICRP [246].

- b. As a rule, a pregnant woman should not be subject to radioiodine therapy unless the application is lifesaving. Otherwise, the therapeutic application should be deferred until after the pregnancy and after any period of breast feeding [130, 247]. In particular, radioiodine will easily cross the placenta, and the fetal thyroid begins to accumulate iodine at about ten weeks of gestation.
- (b) In breast feeding patients excretion through the milk and potentially enhanced breast dose should be considered in the justification process. Detailed information on doses to infants from the ingestion of radionuclides in mother's milk is given by the ICRP [248] and can be calculated using available software, for example [249].
- (c) As children are at greater risk of incurring radiation-induced stochastic effects, paediatric examinations require special consideration in the justification process [245].

4.162. 'Self-referral' occurs when a health professional undertakes a radiological procedure for patients as a result of justification based on their own previous clinical assessment. Most examples of acceptable self-referral practice occur with X ray imaging, such as dentistry, and relevant professional bodies in many countries develop appropriate guidance for their specialty (see Section 3 para. 3.143). Self-referral in nuclear medicine, if it occurs, would need to be guided by such professional guidelines.

4.163. 'Self-presentation', including 'individual health assessment', occurs when a member of the public asks for a radiological procedure without a referral from a health professional. This may have been prompted by media reports or advertising. Self-presentation for nuclear medicine procedures is not widely prevalent, but for any such case justification is required, as for all radiological procedures. Relevant professional bodies have an important role in considering evidence for developing guidance when new practices are proposed. Member states may choose to incorporate this approach into legislation [144].

4.164. Approaches to support applications of the requirements for justification for medical exposures should consider the development of means to improve 'awareness, appropriateness and audit'. Awareness of the need for justification underpins the whole process. Means for promoting awareness include traditional education and training, such as at medical school or during specialty training, web-based learning or learning through work flow at the right time, (e.g. junior doctors in the emergency department), and the use of feedback in the reporting process. Appropriateness has been described in paras. 4.159 to 4.161, and the process of audit is used for monitoring and feedback to improve both awareness and appropriateness.

Justification – biomedical research volunteers

4.165. The role of the ethics committee in the justification of medical exposure of volunteers exposed as part of a programme of biomedical research is described in Section 2 para 2.98.

Justification – *carers and comforters*

4.166. The justification of medical exposure incurred by a carer or comforter is effectively carried out by the radiological medical practitioner or delegated to the medical radiation technologist involved in the radiological procedure, prior to the performance of the procedure. It depends on the carer or comforter being correctly informed about the radiation doses and risks involved, and his or her understanding of this information and consequent agreement to take on the role of carer or comforter.

Optimization of protection and safety

4.167. In medical exposures, optimization of protection and safety has several components, some applied directly to the radiological procedure(s) about to be performed and others providing the support or framework for the other components. These components of optimization of protection and safety are described in the following paras. 4.168 to 4.236.

Design considerations

4.168. The use of appropriate and well-designed medical radiological equipment and associated software underpins any nuclear medicine procedure. Gamma cameras, SPECT-CT and PET-CT scanners and their accessories should be designed and manufactured so as to facilitate the keeping of medical exposures as low as reasonably achievable consistent with obtaining adequate diagnostic information. Guidance on design considerations is given in the sub-section on medical radiological equipment, paras. 4.44 to 4.50. Guidance on design considerations applicable for X ray imaging systems as part of hybrid systems is given in Section 3, paras. 3.31 to 3.39. Ultimately, as stated in the BSS paragraph 3.162, it is the responsibility of the nuclear medicine facility licensee to ensure that his/her facility uses only medical radiological equipment and software that meets applicable international or national standards.

Operational considerations - general

4.169. Following justification, the nuclear medicine procedure is performed in such a way as to optimize patient protection, as required in the BSS paragraph 3.163 for diagnostic procedures and in paragraph 3.166 for radiopharmaceutical therapy procedures. The level of image quality sufficient for diagnosis is determined by the radiological medical practitioner and is based on the clinical question posed.

4.170. The following points apply to all nuclear medicine patients, whether undergoing diagnostic or therapeutic procedures:

- (d) There should be an effective system for correct identification of patients, with at least two forms of verification, for example name, birthday, address, medical record number.
- (e) Patient details should be correctly recorded, such as age, gender, weight, height, pregnancy and breast-feeding status, current medications, allergies.
- (f) Patient clinical history should be reviewed.

Operational considerations – diagnostic imaging

4.171. The nuclear medicine facility should have a written protocol for each diagnostic procedure performed in the facility, designed to maximize the clinical information to be obtained from the study, taking into consideration the appropriate diagnostic reference level for the procedure (see Section 2 paras. 2.34 - 2.45). These protocols are best developed using guidelines from national or international professional bodies, and hence reflect current best practices, as for example in Refs [65, 214, 215, 250 – 255]. For modern digital equipment many of the factors are automated through menu-driven selections on the equipment console. Nevertheless, in setting up these options, significant scope exists

for optimization of protection through the appropriate selection of values for the various technical parameters, thereby producing effectively an electronic protocol. Protocols should be periodically reviewed in line with the requirements for quality assurance and radiological reviews (see paras. 4.231 and 4.256 - 4.258).

4.172. Deviations from such protocols may be necessary owing to the special needs of a particular patient or because of the local unavailability of components for a test. In these cases the radiological medical practitioner should record a valid reason for his or her decision.

4.173. Equipment should be operated within the conditions established in the technical specifications, and in any licence conditions, ensuring that it will operate satisfactorily at all times, in terms of both the tasks to be accomplished and radiation safety, so that optimal image acquisition and processing can be achieved with the minimum of patient exposure.

4.174. Many factors influence the relationship between image quality and patient dose in diagnostic nuclear medicine procedures. Detailed guidance on appropriate choices for those factors is widely available and should be followed [65, 214, 215, 219, 250 - 255]. Such factors include:

- (a) Appropriate selection of the best available radiopharmaceutical and its activity, noting the special requirements for children and for patients with impairment of organ function;
- (b) Adherence to patient preparation requirements specific to the study to be performed. Examples include:
 - a. Use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable;
 - b. Correct hydration.
- (c) The storage or retention of radiopharmaceuticals within specific organs can be influenced by drugs such as diuretics or gall bladder stimulants, whenever they do not interfere adversely with the procedure. This method is sometimes used to increase the specificity of the examination, but has also a positive influence on radiation protection – e.g. the use of diuretic challenge in renography.
- (d) For children undergoing diagnostic procedures, the amount of activity administered should be chosen utilizing methodologies described in international or national guidelines [66, 214, 215, 219, 251, 252, 256 258].
- (e) Using appropriate image acquisition parameters:
 - a. For nuclear medicine with a gamma camera, this may include selection of collimator, acquisition matrix, energy windows, acquisition zoom, time per frame, imaging distance;
 - b. For PET systems, this may include 2D and 3D acquisitions, matrix size, field of view, time of flight, attenuation correction, slice overlap, scatter correction, coincidence timing;
- (f) Using appropriate reconstruction parameters such as algorithm, matrix, filters, scatter correction, zoom factor,
- (g) Utilizing quantitative and qualitative capabilities, such as the generation of region-of-interest (ROI) analysis, time-activity curve generation, image reformatting, or tissue uptake ratios, specific for the clinical need.

4.175. Many radionuclides are excreted by the kidneys. Bladder doses can be minimized by drinking plenty of fluid and frequent bladder emptying. Patients, particularly in the case of children, should be encouraged to void frequently, especially in the immediate interval following the examination.

4.176. While most adults can maintain the required position without restraint or sedation during nuclear medicine examinations, it may be necessary to immobilize or sedate children so that the examination can be completed successfully. Increasing the administered activity to reduce the examination time is an alternative that can be used in elderly patients with pain.

4.177. In some cases, if the patient is healthy and cooperative, activity might be reduced and scan times increased - e.g. lung scans for pregnant women. In all cases, however, diagnostic information produced should not be compromised by reduction in activity.

4.178. Care should be taken to ensure that there is no contamination on the collimator surface or elsewhere as this might impair the quality of the images.

Operational considerations – radiopharmaceutical therapy

4.179. The nuclear medicine facility should have written protocols for each type of radiopharmaceutical therapy performed in the facility, designed to meet the requirements of the BSS paragraph 3.165. These protocols are best developed using guidelines from national or international professional bodies, and hence reflect current best practices, as for example in Refs [214, 215, 250 – 254, 259, 260]. For modern digital equipment many of the factors are automated through menu-driven selections on the equipment console. Nevertheless, in setting up these options, significant scope exists for optimization of protection through the appropriate selection of values for the various technical parameters, thereby producing effectively an electronic protocol. Protocols should be periodically reviewed in line with the requirements for quality assurance and radiological reviews (see paras. 4.231 and 4.256 - 4.258).

4.180. In addition to the guidance in paras. 4.169 - 4.171 (for both diagnostic and therapy nuclear medicine procedures), the following provisions should be in place:

- (a) Verbal and written information and instructions to patients about their radiopharmaceutical therapy and about how to minimize exposure to family members and the public, and advice on pregnancy and contraception after therapy. For detailed guidance, including sample information sheets, see Refs [214, 18, 261, 262];
- (b) Special attention to preventing spread of contamination due to patient vomit and excreta;
- (c) A protocol for the release of patients after administration of the rapeutic doses of radiopharmaceuticals (see guidance in paras. 4.243 - 4.245).

4.181. The BSS, paragraph 3.165, gives requirements concerning the activity of the therapeutic radiopharmaceutical to be administered. Algorithms for determining appropriate activities for a given patient based on radiation doses to critical organs do exist, but there is no standardized algorithm. Methodologies are discussed in Refs [214, 251, 263-268]. Typically, therapeutic radiopharmaceuticals are administered at standard fixed activities (in gigabecquerel or millicurie), standard fixed activities per unit body mass (MBq kg⁻¹ or mCi kg⁻¹) or standard fixed activities per unit body surface area (MBq m⁻² or mCi m⁻²), based on the results of toxicity and side effects in clinical trials.

4.182. For female patients, their pregnancy and breast-feeding status should be evaluated before administration of a therapy dose (see also paras. 4.238 - 4.242). Immediately prior to administration of a therapeutic radiopharmaceutical, the following information, as applicable, should be verified preferably by two individuals:

- (a) Dose on the radiopharmaceutical label matches the prescription;
- (b) Identification of the patient by two independent means;

- (c) Identity of the radionuclide;
- (d) Identity of the radiopharmaceutical;
- (e) Total activity;
- (f) Date and time of calibration.

4.183. The administered activity should be verified in an activity meter (dose calibrator) or other suitable device to ensure that the total activity does not deviate significantly from the prescribed administered activity (e.g. < 10 % deviation), and the measured value recorded. Corrections should be calculated for residual activity in the syringe, cups, tubing, inline filter, or other materials used in the administration.

4.184. Radiopharmaceutical therapy patients should be informed in advance that it will be necessary for medical personnel to minimize close or direct contact, so that this precaution will not be interpreted as a lack of concern.

4.185. Both females and male patients should be advised about avoiding conception after therapeutic administrations. Data on the periods during which conception should be avoided after administration of a radiopharmaceutical to females for therapeutic purposes are given in Appendix II, with further guidance in Ref. [251]. These times have been derived with a view to the need for further therapy, which may be compromised if the patient becomes pregnant.

4.186. The administration of therapeutic doses of relatively long lived radionuclides in ionic chemical forms to males is a possible source of concern because of the appearance of larger quantities of these radionuclides in ejaculate and in sperm. It may be prudent to advise sexually active males who have been treated with for example ³²P (phosphate), ⁸⁹Sr (strontium chloride), ¹³¹I (iodide), ²²³Ra (chloride), to avoid fathering children for a period of four months after treatment. The period of four months is suggested as this is longer than the life of a sperm cell [251, 269].

Operational considerations – pregnant female patients

4.187. Administration of radiopharmaceuticals for therapy to female patients who are pregnant or might be pregnant should be generally avoided. There may be exceptions when the treatment is lifesaving. See also paras. 4.161 on justification and 4.238 - 4.240 on the need to ascertain pregnancy status.

4.188. Diagnostic nuclear medicine procedures with ^{99m}Tc and radiopharmaceuticals that do not cross the placenta do not cause high fetal doses. Protection of the fetus can be optimized by using smaller administered activities and longer imaging times. This is feasible if the patient is able to remain still.

4.189. Specific assessment of individual fetal doses is not usually necessary after diagnostic nuclear medicine studies involving ^{99m}Tc radiopharmaceuticals. In the case of other radiopharmaceuticals (such as iodine or gallium), calculation of dose to the individual fetus and risk estimation may be necessary.

4.190. In the case of radiopharmaceuticals that are rapidly eliminated by the maternal kidneys, the urinary bladder is the major source of fetal irradiation. After the administration of such radiopharmaceuticals, maternal hydration and frequent voiding should be encouraged. Some radiopharmaceuticals, for example radioactive iodides, including those administered for diagnostic purposes, cross the placenta freely and are taken up by the fetal tissues, for example the thyroid. Failure to ascertain whether a patient is pregnant when administering ¹³¹I for a scan, for example, may lead to a severe accidental exposure of the fetus.

4.191. Of special concern is also the use of CT in PET-CT or SPECT-CT examinations. Routine diagnostic CT examinations of the pelvic region with and without contrast injection can lead to a dose of 50 mSv to the uterus, which is assumed to be equivalent to the fetal dose in early pregnancy. When PET-CT or SPECT-CT scanning is indicated in a pregnant patient, low-dose CT protocols should be used and the scanning area should be reduced to a minimum. See also Section 3, paras. 3.170 - 3.178.

4.192. If FDG is being used for the PET component of hybrid imaging, a lower activity of FDG should be used. Further guidance is given in Refs [65, 270].

Operational considerations – breast feeding

4.193. Female patients should be advised that breast feeding is generally contraindicated after therapeutic administration of some radiopharmaceuticals, because of both the external irradiation of the suckling baby and the potential excretion of radioactivity through the breast milk. See also paras. 4.161 on justification and 4.241 - 4.242 on the need to ascertain breast-feeding status.

4.194. Depending on the radiopharmaceutical, breast feeding may need to be interrupted for a period or even stopped following its administration for a diagnostic procedure. More specific advice is given in Appendix III and Refs. [214, 247, 251].

Calibration

4.195. Requirements for calibration of sources and instruments used for dosimetry of patients are given in the BSS paragraph 3.167. For nuclear medicine, responsibility is assigned to the nuclear medicine facility's medical physicist. Unsealed sources for nuclear medicine procedures should be calibrated in terms of activity of the radiopharmaceutical to be administered, with the activity being determined and recorded at the time of administration. Detailed guidance on acceptable protocols for making activity measurements can be found in the following references [243, 271].

4.196. Radionuclides should be checked for radioactive impurities when these are liable to be present. This applies particularly to short lived radionuclides, as longer- lived impurities may be present and could deliver a significant fraction of the absorbed dose.

4.197. The calibration of X ray based imaging devices that are part of hybrid imaging systems, such as CT in PET-CT or SPECT-CT, should follow the guidance for such modalities in Section 3. See also Section 5 for hybrid imaging systems used in radiation therapy simulation and treatment planning.

4.198. In the nuclear medicine facility, instruments used for dosimetry of patients, such as activity meters (dose calibrators), also should be calibrated at appropriate intervals using calibrated reference sources that cover the energy range used in clinical practice. After the initial calibration, the intervals for periodic calibrations may differ, depending on the availability of calibration radioactive sources in the department. A period of one to two years is recommended.

4.199. The BSS in paragraph 3.167(d) requires the calibration of dosimetry instrumentation to be traceable to a standards dosimetry laboratory (SDL). Ideally this would be to the national SDL (primary or secondary) in the State concerned, with access either directly or through a duly accredited calibration facility. However, it may be necessary for instruments used for dosimetry of patients to be sent to another country or state if there is no national SDL in the country or state where the instruments are used.

4.200. Records of calibration measurements and associated calculations, including uncertainty determinations (budgets), should be maintained as described in para. 4.230.

Dosimetry of patients – diagnostic procedures

4.201. The BSS paragraph 3.168 requires nuclear medicine facilities to ensure that patient dosimetry is performed and typical doses for their diagnostic radiological procedures are determined. Knowledge of a facility's typical doses forms the basis for applying methods of optimization of protection. It also enables the nuclear medicine facility to use diagnostic reference levels (see paras. 4.210 to 4.217) as another tool for optimization of protection. Administered activity (in MBq) is the most widely used surrogate for dose in diagnostic nuclear medicine, however organ doses and effective doses can be calculated from activity using established methodologies – see para 4.208.

4.202. Clearly, the more radiological procedures at the nuclear medicine facility for which typical doses are known, the better the basis for optimization of protection. However, pragmatically, the BSS requires only common radiological procedures for diagnostic medical exposures. What is common will vary from facility to facility, and country to country, but in general there are some core common examinations, including: thyroid scans, bone scans, myocardial perfusion imaging, FDG-PET/CT in oncology, renal scans, and lung scans.

4.203. The term 'typical dose', as used in the BSS paragraph 3.168, refers to the average or median dose or activity for a particular size of patients. Patient size has a large influence on doses, so some selection or grouping of patients is required. Such groupings include 'average adult', often based around an average weight of 70 kg with a range of \pm 20 kg. Groupings for children have sometimes been based on age, such as new born (0 years), infant (1 year), small child (5 years), child (10 years) and teenager (15 years), but more recently size-specific groupings are being used. The nuclear medicine facility should adopt patient size groupings that correspond with the groupings used in their country or state for DRLs. The sample size used for each patient grouping and radiological procedure should be of sufficient size to assure confidence in the determination of the mean dose. Such sample sizes are typically in the range 10 to 20 patients, but clearly the larger the sample the better the statistics.

4.204. Dose in the term 'typical dose' means for the given procedure the effective dose, organ doses, or, in the case of X ray imaging, an accepted dosimetric quantity as described in Section 3 paras. 3.195 - 3.196. For combining doses from radiopharmaceuticals and X rays, organ doses will need to be used.

4.205. Patient dosimetry to determine typical doses in diagnostic nuclear medicine should be carried out in conjunction with an assessment of the diagnostic image quality. Exposure alone is not meaningful if it does not correspond to images that are sufficient for an accurate diagnosis. Therefore patients included in the sample used for determining typical doses should be only those whose radiological procedure resulted in acceptable image quality.

4.206. The results of the surveys used to determine typical doses at the nuclear medicine facility should be used as part of the facility's on-going review of the implementation of optimization of protection, and additionally will be used for comparison with established DRLs (see paras. 4.210 to 4.217). The results should also be submitted to the organization in their country or state that is responsible for reviewing the national or regional DRLs. With these considerations in mind, the patient surveys of administered activities, from which patient doses can be calculated as required by the BSS, should take place at intervals of no more than 5 years and preferably no more than 3 years. Another trigger for a survey would be the introduction of new radiopharmaceuticals, equipment or

technology into the nuclear medicine facility or when significant changes have been made to the protocols or the equipment.

4.207. Sometimes patient dosimetry in diagnostic nuclear medicine procedures may be required for specific individual patients. Reasons might include an unintended or accidental medical exposure where an estimation of patient doses is required as part of the investigation and report (see para. 4.252), or there may be the need to estimate embryo or fetal doses (see para. 4.189).

4.208. There are several indirect and direct methods to estimate patient dose in diagnostic nuclear medicine procedures. In the case of hybrid systems, the contribution from each of X rays and radionuclides should be calculated and combined. Methodologies and data for the determination of doses from radiopharmaceuticals are given in Refs [232, 234, 240, 241, 255 – 259] and for methodologies for X ray imaging see Section 3, paras. 3.211.

Dosimetry of patients – radiopharmaceutical therapy procedures

4.209. The BSS paragraph 3.168 requires nuclear medicine facilities to determine typical absorbed doses to patients for their therapeutic radiological procedures. As in para. 4.208, methodologies for the determination of doses from therapy radiopharmaceuticals are explained in detail in Refs [249, 251, 257, 258, 272 - 278].

Diagnostic reference levels

4.210. The BSS, paragraphs 3.168 - 3.169, requires that nuclear medicine facilities perform patient dosimetry surveys for their diagnostic procedures, as described in paras 4.201 to 4.208, and that these results are compared with the established DRLs for their country or region. The purpose is to ascertain whether the typical dose or activity in the facility for a given diagnostic nuclear medicine procedure compares favourably, or not, with the value of the DRL for that nuclear medicine procedure. Guidance on establishing national or regional DRLs in given in Section 2, paras. 2.34 to 2.45.

4.211. A review of optimization of protection for that particular nuclear medicine procedure is triggered if the comparison shows that the facility's typical dose or activity exceeds the DRL, or that the facility's typical dose or activity is substantially below the DRL and it is evident that the exposures are not producing images of diagnostic usefulness or are not yielding the expected medical benefit to the patient.

4.212. Given the uncertainties in determining a facility's typical dose or activity, questions can arise over whether a DRL has really been exceeded or not. Some countries adopt an algorithmic approach, for example where the facility's typical dose or activity, minus two times its standard error, should be greater than the value of the DRL [13]. A simpler approach, based purely on the facility's typical value, may be sufficient as the purpose is to identify the need for a review, and perhaps it is better to perform more reviews than fewer [12, 13].

4.213. No individual patient's dose or activity should be compared with a DRL. It is the facility's typical dose or activity, as determined by the representative patient sample, which is compared.

4.214. Further, the comparison is not a case of "Does the nuclear medicine facility comply with the DRL?" DRLs are not dose limits. It is mandatory to use them for the comparison exercise to identify practices that warrant further investigation.

4.215. The review of how the given nuclear medicine procedure is being performed and its optimization of protection, triggered by the DRL comparison, may conclude that there are valid

reasons supported by sound clinical judgement why the nuclear medicine facility has a typical dose or activity that exceeds the DRL. These reasons should be documented as part of the facility's QA programme. On the other hand, the review may identify areas for improvement resulting in revised protocols for that nuclear medicine procedure. The results of the DRL comparison and any ensuing review and actions should be documented as part of the facility's QA programme.

4.216. The fact that a nuclear medicine facility's typical dose or activity for a nuclear medicine procedure is less than the DRL for that procedure does not mean necessarily that optimization of protection for that nuclear medicine procedure has been fully achieved. DRLs are only one of the tools for optimization, aimed specifically at identifying the outliers in performance.

4.217. The regulatory body in a given country may specify frequencies for performing DRL comparisons. Otherwise, the general guidance on patient dosimetry, described above in para. 4.206, would be applicable.

Quality assurance for medical exposures

4.218. The BSS paragraph 3.170 requires nuclear medicine facilities to have a comprehensive programme of quality assurance for medical exposures. General guidance on management systems is given in Section 2, paras 2.136 to 2.147, and it is simply re-iterated here that the programme of quality assurance for medical exposures should fit in with, and be part of, the facility's wider management system. The paragraphs in this subsection give guidance on the technical aspects of the programme of quality assurance for medical exposures.

4.219. The purpose of the programme of quality assurance for medical exposures is to help ensure successful implementation of optimization of patient protection in the nuclear medicine facility and to minimize the occurrence of unintended and accidental medical exposures.

4.220. The complexity of the programme of quality assurance for medical exposures will depend on the type of nuclear medicine facility. A facility with only limited diagnostic procedures will have a simpler programme compared with a facility that offers a comprehensive diagnostic service, including PET-CT imaging, radiopharmaceutical therapy, and that has a radiopharmacy. Nonetheless, most of the elements of the programme are common, and it is more in degree of implementation that there are differences. The BSS paragraph 3.171 establishes the common elements of the programme.

4.221. Measurements on medical radiological equipment are one of the components of the programme. Acceptance tests are required for new or significantly refurbished or repaired equipment, or after the installation of new software or modification of existing software that could affect protection and safety of patients. The acceptance test is followed immediately by commissioning, and then on-going periodic quality control tests, including constancy tests. The purpose is to ensure that, at all times, all medical radiological equipment is performing correctly, accurately, reproducibly and predictably. Acceptance and commissioning tests should be performed in the same way for equipment and/or software that has been donated.

4.222. Depending on the equipment purchase agreement, acceptance tests may be performed by the manufacturer's representative in the presence of the local medical physicist and the radiological medical practitioner representing the user, or, if acceptable to the manufacturer and/or the purchaser, by a medical physicist jointly with the manufacturer's representative. The process involves verification of all specifications and features of the equipment; in particular, protection and safety features including displayed and reported dose metrics.

4.223. After acceptance and before clinical use on patients, commissioning is carried out by or under the supervision of the medical physicist. Commissioning should include measurements of all parameters and conditions of use that are expected in clinical use. For most situations the medical physicist should be directly involved in the measurements, calculations and interpretation of data to characterize the equipment's performance. In some simple situations it may be sufficient for the medical physicist to provide documented advice on how the commissioning should be performed. At commissioning, the baseline for subsequent constancy tests is established.

4.224. There are many published reports from international and national organizations and national or regional professional bodies giving detailed guidance on the quality control tests that should be performed in nuclear medicine, including recommended frequencies [192, 193, 197, 210, 211, 214, 215, 217, 225 – 241, 243, 271, 277, 279 – 281]. In addition, many of these organizations have extensive websites where any new or updated publications on the topic will be able to be found. The regulatory body may have its own specific requirements on the tests that should be performed and their frequencies.

4.225. For guidance on the quality control tests for X ray imaging devices used in nuclear medicine, see Section 3, para. 3.231.

4.226. In nuclear medicine there is the additional factor of the radiopharmaceuticals themselves. The quality assurance programme for medical exposures should ensure that radiopharmaceuticals intended for administration to patients are prepared in a manner that meets clinical needs and satisfies both radiation safety and pharmaceutical quality requirements [214, 217, 218]. Therefore, radiopharmacist should be involvemed.

4.227. The BSS paragraph 3.171(e) specifically requires that dosimetry and monitoring equipment are part of the QA programme. This is to ensure that such instrumentation has a current calibration, typically within 2 years (see para. 4.198), and that it is functioning correctly. The programme of quality assurance for medical exposures should establish a calibration cycle for each instrument and a set of checks on the operation of each instrument to be performed at set intervals. This applies to stand alone dosimetry equipment and to equipment software related to dosimetry – e.g. software used to calculate "specific uptake values (SUV)" from which doses can be estimated. Detailed guidance on quality control tests for such nuclear medicine instrumentation is given in [192, 193, 197, 210, 211, 214, 215, 217, 225 – 241, 243, 271, 277, 279 – 281].

4.228. The results of the quality control tests should be compared with established tolerance limits. These limits may have been established to ensure compliance with a regulatory requirement for the performance of particular physical parameters or they may be set on the basis of recommended values given in published reports, such as referenced in para. 4.224. As required in the BSS paragraph 3.171(b), if the measured values fall outside the tolerance limits, corrective actions should take place. Such corrective actions are likely to include maintenance or servicing of the equipment, and hence the nuclear medicine facility should have a maintenance programme in place. In some cases, the equipment may be outside the tolerance limits by a significant amount and the equipment should be immediately taken out of clinical use and not returned until the servicing has taken place and it has been ascertained that the equipment now meets the performance requirements.

4.229. The programme of quality assurance for medical exposures in nuclear medicine should include use of "checks and balances" to ensure that the facility's protocols and procedures for imaging and therapy, including radiation protection and safety, are being followed. The periodic review of the protocols and procedures themselves is part of the facility's radiological review (see 4.256 - 4.258).

In addition a review of imaging procedures may have been triggered by a comparison with DRLs (see paras. 4.210 to 4.217).

4.230. Maintaining records is a crucial aspect of the programme of quality assurance for medical exposures. This includes the procedures used in the programme, and the results of the quality control tests including trend analysis, the dosimetry surveys, the DRL comparisons, corrective actions and the investigations of unintended and accidental medical exposures. When planning and developing an effective QA programme, licensees should recognize that it demands strong managerial commitment and support in the form of training and time, personnel and equipment resources. The regulatory body, during its inspections of a nuclear medicine facility, should review the records of the programme of quality assurance for medical exposures.

4.231. In line with standard practices for quality management, the BSS in paragraph 3.172 requires regular and independent audits of the programme of quality assurance for medical exposures, adding that the frequency of such audits will depend on the complexity of the radiological procedures being performed in the facility. Such audits may be external or internal. Internal audits are usually logistically simpler to implement, while the external audit generally has the advantage of bringing in an outside perspective. The audit of the nuclear medicine facility's programme of quality assurance for medical exposures can be incorporated into more comprehensive audits that the facility is performing for its management system. Further, the results of the audit of the programme of quality assurance for medical exposures will have a major input into the nuclear medicine facility's radiological review (see paras. 4.256 to 4.258).

Dose constraints – carers and comforters

4.232. Some diagnostic radiological procedures in nuclear medicine, particularly of children, can be better performed with the assistance of a carer or comforter, for example a relative in the case of a paediatric patient, or a relative or friend for a disabled patient. In these circumstances, the carer or comforter will be exposed. This is usually to a low dose, such as when caring for a child undergoing a renal examination, but in some cases the dose is not insignificant e.g. staying with a child during a PET examination. Further, in nuclear medicine there is also the additional consideration of exposure of carers and comforters after the diagnostic procedure, or in the case of radiopharmaceutical therapy with radioiodine, their exposure during the course of the treatment. This exposure is defined as medical exposure (see the BSS) and as such is not subject to dose limits. However the BSS, paragraphs 3.153 and 3.173, requires that such carers and comforters are afforded radiation protection through the application of the requirements for optimization of protection and safety and, in particular, the use of dose constraints in this process. These are the dose constraints established by government, as a result of consultation with the health authority, relevant professional bodies and the regulatory body, as required by the BSS paragraph 3.149(a)(ii). Guidance on setting dose constraints, including considerations for children and pregnant women, is given in Section 2, paras, 2.48 to 2.49.

4.233. The nuclear medicine facility should have written protocols for implementing measures for the optimization of protection for carers and comforters of patients during or after nuclear medicine procedures. The measures should utilize the basic methods for radiation protection, i.e. shielding, time and distance (proximity), and measures to minimize spread of contamination. The protocol should include the following:

- (a) Criteria specifying who would be acceptable for acting as a carer or comforter;
- (b) Methods for ensuring that the carer or comforter receives a dose that is as low as reasonably acceptable;
- (c) The values of the dose constraints to be applied (see Section 2 para. 2.49).

4.234. Licensees should be able to demonstrate that the effective dose to the carer or comforter, by applying the protocol, is unlikely to exceed the dose constraint. In some cases it is relatively straightforward to estimate effective doses to carers and comforters from measurements of the ambient dose equivalent rates at the positions where they will be situated. These determinations should be made in advance to verify that dose constraint will not be exceeded. Therefore, individual dose monitoring is normally not necessary. For carers and comforters in a therapy ward, consideration may be given to the use of electronic dosimeters.

4.235. The BSS paragraph 3.153 states that a carer or comforter must be informed about the radiation risks involved in helping with the radiological procedure and about the means to be taken to afford appropriate radiation protection to the carer or comforter. The carer or comforter should indicate that he/she has understood the information and is still willing to provide support, care and comfort to the patient that is or has undergone a nuclear medicine procedure. In the case of radiopharmaceutical therapy with iodine, for both patients still in the hospital and for those that have been released (see also para. 4.245), appropriate written instructions should be provided to the carer or comforter of the patient (including for example, time and proximity to the patient, minimizing physical contact and not sharing food or drinks). Further guidance is given in Refs [18, 261].

4.236. Guidance applicable to carers and comforters supporting patients undergoing X ray imaging radiological procedures as part of the nuclear medicine procedure in the nuclear medicine facility is given in Section 3 paras. 3.236 to 3.240.

Dose constraints – volunteers in biomedical research

4.237. Some individuals will undergo diagnostic nuclear medicine procedures as part of their voluntary participation in an approved programme of biomedical research (see Section 2 para. 2.98). Part of the approval process for the biomedical research will have been the setting of dose constraints for the nuclear medicine procedures (see Section 2 para. 2.99). When the volunteer presents at the nuclear medicine facility, they are to be afforded the same radiation protection as if they were a patient presenting for a nuclear medicine procedure within a normal health care pathway, but with the additional measure that their exposure will be subject to a dose constraint, either a nationally established dose constraint or as specified by the ethics committee that approved the biomedical research programme (see Section 2 paras. 2.50 and 2.99).

Pregnant female patients

4.238. Female patients who are pregnant form a special sub-group of patients that should be particularly considered with respect to radiation protection. These considerations have been described in para. 4.161 for justification and paras. 4.187 - 4.192 for optimization. None of these considerations can take place if it is not known that the patient is pregnant. Therefore it is crucial, as is required in the BSS paragraphs 3.175 - 3.176, for the nuclear medicine facility to have in place means for ensuring that pregnancy status is known for female patients.

4.239. The first approach is through posting of clear signs, in languages easily understood by the range of people using the nuclear medicine facility, asking the question "Are you pregnant or possibly pregnant?" and, if so, "Please tell the staff". Such signs should be posted widely in the facility, including waiting rooms and cubicles. The second approach is to ask female patients directly whether they are or might be pregnant. This may not always be so easy given social and cultural sensitivities, but it may should be done when needed.

4.240. Neither of the approaches described in para. 4.239 will work if the woman does not know if she is or may be pregnant. For this reason, the BSS (paragraph 3.176) has an additional requirement on facilities to have "procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus". In nuclear medicine, pregnancy status should be ascertained for all radiopharmaceutical therapy and it is advisable for all diagnostic procedures, in particular for those radiopharmaceuticals that are known to cross the placental barrier. Cooperation with the referring medical practitioner, through standard requests for pregnancy status for specified procedures, is one approach. In case of doubt, a pregnancy test or hormonal level determination to assess menopausal status may be carried out.

Breast-feeding patients

4.241. As above for pregnant women, breast-feeding patients form a special sub-group of patients that should be particularly considered with respect to radiation protection in nuclear medicine. These considerations have been described in para. 4.161 for justification and paras. 4.193 - 4.194 for optimization. None of these considerations can take place if it is not known that the patient is breast-feeding. Therefore it is crucial, as is required in the BSS paragraphs 3.175 - 3.176, for the nuclear medicine facility to have in place means for ensuring that breast-feeding status is known for female patients.

4.242. The first approach is through posting of clear signs, in languages able to be understood by the range of people using the nuclear medicine facility, simply asking the question "Are you breast feeding?" and, if so, informing staff. Such signs should be posted widely in the facility, including waiting rooms and cubicles. The second approach is to directly ask female patients whether they are breast feeding. This may not always be so easy given social and cultural sensitivities, but it may should be done when needed.

Release of patients after radiopharmaceutical therapy

4.243. As required in the BSS paragraph 3.178, a nuclear medicine facility should have arrangements in place to manage the release of patients who have undergone radiopharmaceutical therapy. Once the patient is released, two groups of persons should be afforded appropriate radiation protection – the general public with whom the patient may encounter or interact, and members of the patient's family and close friends who may be viewed simply as also being members of the public or as carers and comforters. Exposure of members of the public is subject to the public dose limits (see Section 2 Table 2), while exposure of carers and comforters is not subject to dose limits but is instead controlled through dose constraints (see paras. 4.232 - 4.236). Further, as discussed in para 2.46, public exposure arising from a single "source", such as a patient who has undergone radiopharmaceutical therapy, should be subject to dose constraints set at some fraction of the dose limits.

4.244. The nuclear medicine facility's medical physicist or radiation protection officer should establish prior to the release of a patient that the retained radioactivity in the patient is such that the doses that could be received by members of the public would not exceed public dose limits, and would be unlikely to exceed the relevant dose constraints for both members of the public and carers and comforters. An acceptable method to estimate the acceptable retained activity for patients being discharged from hospitals is to calculate the time integral of the ambient dose equivalent rate,

considering the activity, energy and the effective half-life of the radionuclides. When deciding on the discharge for a particular patient, the living conditions of the patient, such as the extent to which he or she can be isolated from other family members, in particular children and pregnant women, should also be considered. Safe management of the patient's contaminated excreta should be addressed. Special consideration should be given to the case of incontinent patients. In the case of carers and comforters, the assumptions made for the calculations should be consistent with the written instructions that will be given at the time the patient is discharged from the facility. Published data would suggest that systematic dose monitoring is not necessary. For detailed guidance on all aspects pertaining to the release of patients see the Refs [18, 261].

4.245. As indicated in 4.244, the patient or legal guardian of the patient should be provided with written instructions on how to keep doses to members of the public and carers and comforters as low as reasonably achievable. Areas of particular concern are children and pregnant partners of patients. Detailed guidance, including sample information sheets, is given in the Refs [18, 261].

Unintended and accidental medical exposures

Prevention of unintended and accidental medical exposures

4.246. The BSS, paragraphs 3.179 to 3.181, sets out requirements both for minimizing the likelihood of unintended and accidental medical exposures and for the ensuing investigation if such exposures occur. The pathways identified in the BSS for potentially leading to unintended or accidental medical exposures include flaws in the design of medical radiological equipment, failures of medical radiological equipment while in operation, failures and errors in software that control or influence the delivery of the radiation, and human error. General strategies for addressing those pathways include regular maintenance of medical radiological equipment and software, a comprehensive quality assurance programme, and continuing education and training of staff. The lessons learned from events that have occurred should be usedfor preventing or minimizing unintended and accidental medical exposures, as described below in para. 4.248.

4.247. A reduction in the probability of unintended or accidental medical exposures in nuclear medicine can be brought about by:

- (f) The introduction of safety barriers at identified critical points in the nuclear medicine pathway, with specific quality control checks at these points. Quality control is not confined to physical tests or checks but can include such as actions as double checks of the radiopharmaceutical and activity to be administered, and correct identification of the patient.
- (g) Actively encouraging a culture of always working with awareness and alertness.
- (h) Providing detailed protocols and procedures for each process in the nuclear medicine pathway.
- (i) Education and training, including continuous professional development, of all staff involved in providing nuclear medicine services.
- (j) Clear definitions of the roles, responsibilities and functions of staff in the nuclear medicine facility that are understood by all staff.

4.248. Preventive measures should include incident and near incident reporting, analysis and feedback including lessons learnt from international experience [282]. Preventive measures should also include each nuclear medicine facility checking the robustness of their safety system against reported incidents. IAEA Safety Reports Series No. 17 [282] contains reviews of case histories from an

extensive collection of accidental medical exposures, including examples relevant to nuclear medicine.

4.249. Building on the guidance from paras 4.247 to 4.248, the following three-step strategy can help to prevent unintended and accidental medical exposures in nuclear medicine:

- (d) allocate responsibilities to appropriately qualified health professionals only and ensure that a quality management system is in place that includes radiation safety;
- (e) use the lessons learned from unintended and accidental medical exposures to test whether the quality management system, including for radiation safety, is robust enough against these types of events;
- (f) identify other latent risks by posing the question "what else could go wrong" or "what other potential hazards might be present" in a systematic, anticipative manner to all steps in the nuclear medicine process.

Investigation of unintended and accidental medical exposures

4.250. The events that constitute unintended or accidental medical exposures are detailed in the BSS paragraph 3.180, and for a nuclear medicine facility include those associated with diagnostic procedures and with radiopharmaceutical therapy. For diagnostic procedures, reference should also be made to Section 3 paras. 3.249 - 3.252, for aspects relating to X ray imaging. Unintended and accidental medical exposures may occur at any stage in the nuclear medicine process. For radiopharmaceutical therapy, unintended or accidental medical exposures may be either underexposures or overexposures. The events in the BSS paragraph 3.180 also include 'near misses', and these should be considered in the same way as actual events.

4.251. One of the events identified in the BSS paragraph 3.180 is when the activity administered in radiopharmaceutical therapy was "substantially different from (over or under)" the prescribed dose. Consensus recommendations regarding the level of activity difference that would be considered as substantially different appear to be lacking, but a pragmatic approach for use within the nuclear medicine facility might be deviations greater than 10%. The nuclear medicine facility should have in place a system with clear procedures for identifying when this type of event occurs.

4.252. The BSS, paragraph 3.181, states what should be done in the course of the investigation. This includes calculation or estimation of patient doses, which should be performed by a medical physicist. A record of the calculation method and results should also be placed in the patient file. When required, counselling of the patient should be undertaken by someone with appropriate experience and clinical knowledge.

4.253. The investigation of unintended and accidental medical exposures, as required by the BSS paragraphs 3.180 - 3.181, has three main purposes. The first is to assess the consequences for the patient (s) affected and provide remedial and health care actions if necessary. The second is to establish what went wrong and how to prevent or minimize a recurrence in the nuclear medicine facility – i.e. the investigation is for the facility's and their patients' benefit. The third purpose is to provide information to other persons or other nuclear medicine facilities. Dissemination of information about unintended and accidental medical exposures and radiation injuries has greatly contributed to improving methods for minimizing their occurrence. This might be through the regulatory body and/or the health authorities for more significant events or as required by a country's regulations, where the regulatory body disseminates information on the event and the corrective actions to other facilities that might learn from the event. Independently from any legal requirement for reporting to the regulatory body, the implementation of voluntary and anonymous safety reporting

and learning systems can significantly contribute to improve safety and safety culture in health care. This includes participation in voluntary international or national databases designed as educative tools, as is the case for image guided interventional procedures and radiation therapy – see Sections 3 and 5, paras. 3.257 and 5.272, respectively.

4.254. As noted in 4.253, the BSS requires reporting to the regulatory body and to the health authority if appropriate for "significant" events. Further, the regulatory body in a given country may also specify their own requirements for reporting events to them. It is difficult to quantify "significant" – specifying a numerical trigger value immediately creates an artificial distinction between values immediately below that value (and hence should not be reported) and those just above the value (which should be reported). However, the attributes of "significant" events can be elaborated, and events with one or more of these attributes should be reported to the regulatory body. Such attributes would include the occurrence of, or the potential for, serious unintended or unexpected health effects due to radiation (in this case the health authority should be also informed), the likelihood of a similar event occurring in other nuclear medicine facilities, a large number of patients were affected, and gross misconduct or negligence by the responsible health professionals. As stated in 4.253 above, one of the roles of the regulatory body for such a reported event is to disseminate information on the event and the lessons learned to all potentially affected parties – typically other nuclear medicine facilities and relevant professional bodies, but also in some cases manufacturers, suppliers, and maintenance companies.

4.255. Irrespective of whether the event also reported to the regulatory body, feedback to staff should be provided in a timely fashion and, where changes are recommended, all staff should be involved in bringing about their implementation.

Records and review

Radiological review

4.256. The BSS in paragraph 3.182 requires the performance of a periodic radiological review at the nuclear medicine facility. This involves considering both justification and optimization aspects of radiation protection. For the latter, the results of the programme of quality assurance for medical exposures, including the periodic independent audit, would be a significant input into the process. As described in Section 2, paras. 2.146 - 2.147, the wider clinical audit could include the radiological review with its assessment of the application of the requirements for justification and optimization in the facility for the nuclear medicine procedures being performed [53].

4.257. To facilitate compliance with the BSS paragraph 3.182 and to learn from periodic reviews, the methodology used, the original physical, technical and clinical parameters considered, and the conclusions reached should be documented and taken into account prior to any new review that may result in an update of institutional policies.

4.258. Radiological reviews should consider changes in patient management that result from the diagnostic nuclear medicine procedures, and the effect of introducing new technologies or radiopharmaceuticals on efficiency and cost. In radiopharmaceutical therapy, reviews should consider patient outcome (survival, acute and late side effects, etc.), and the effect of introducing new radiopharmaceuticals on efficiency and cost. The nuclear medicine facility should have a system for the on-going collection of relevant data to support such reviews.

Records

4.259. Records should be in place to demonstrate on-going compliance with radiation protection requirements. The BSS, paragraphs 3.183 to 3.185, specify requirements for keeping personnel records, records of calibration, dosimetry and quality assurance, and records of medical exposure. These records should be kept for the period specified by the country's regulatory body. In the absence of such a requirement, a suggested period for keeping records is 10 years. In the case of children, records should be kept for a longer time.

RADIATION PROTECTION OF THE PUBLIC

Introduction

4.260. Public exposure may arise from the performance of nuclear medicine, to persons in and around the nuclear medicine facility, but also in the wider public domain. The latter can occur as a result of the release from the nuclear medicine facility of patients with some remaining radioactivity. Persons who may be so exposed fall into three categories – those who work at the nuclear medicine facility but not in a role that is directly involved in the use of radiation, those who are visitors to the facility, and the wider public. Radiation exposure of carers and comforters while performing that role is considered occupational exposure and not public exposure and is not covered by this section. See paras. 4.232 - 4.236 for guidance on carers and comforters. In addition there is the possibility, albeit low, of public exposure from pathways associated with the discharge of radioactive waste.

4.261. The requirements of the BSS for public protection, paragraphs 3.117 to 3.123, 3.125 to 3.127, and 3.135 to 3.137, apply to nuclear medicine facilities. This sub-section contains guidance very specific to nuclear medicine facilities. For more general and comprehensive guidance on radiation protection of the public, reference should be made to the IAEA Safety Guide *Radiation Protection of the Public* [24].

Non-occupationally exposed workers and visitors

4.262. Non-occupationally exposed workers are those persons who work at the nuclear medicine facility but not in a role that is directly involved in the use of radiation, for example non-nuclear medicine ward nurses, clerical staff, and cleaning personnel. It also includes those persons who work at the wider medical facility where the nuclear medicine facility is located. These persons are to be afforded the same level of radiation protection as any member of the public, as required by the BSS paragraph 3.78.

4.263. Visitors to the nuclear medicine facility include those persons who will be undergoing nuclear medicine procedures, for the time during the visit when their treatment or diagnostic procedure is not taking place – for example, while they are sitting in the "cold" waiting room. Similarly for carers and comforters – any exposure other than that arising from the nuclear medicine procedure with which they are helping will be public exposure. Other visitors, including persons delivering goods or supplies, sales personnel, accompanying persons and escorts, and other patients in the facility, are also considered members of the public.

External exposure and contamination

4.264. The primary means for protecting the public (non-occupationally exposed workers and visitors) from external exposure is to ensure that the shielding of the nuclear medicine facility (see paras. 4.31 – 4.35) is sufficient so that public exposure resulting from being in any immediate adjacent areas, including rooms above and below, accessible by either non-occupationally exposed workers or visitors would be in compliance with the public dose limits, and preferably less than any dose constraint that the regulatory body may have applied (see Section 2 paras. 2.16 and 2.46.)

4.265. Patients that have been administered radiopharmaceuticals may expose members of the public in the nuclear medicine facility and upon release. For the latter situation (release) see paras. 4.243 to 4.245. In the nuclear medicine facility, the RPO should establish rules to ensure that the exposure of any member of the public will be less than the public dose limit and, preferably, lower than any applicable dose constraint. At the design stage of the nuclear medicine facility, consideration should given to the respective flow of patients and visitors in the facility so that their contact or proximity is minimized, thereby reducing the potential for both external exposure and spread of contamination.

Control of access

4.266. Following adequate shielding, access to areas where radiation is being used should be control to provide forcontrolling doses to visitors and non-occupationally exposed workers. This is effective against both external exposure and contamination. Visitors should not be allowed to enter controlled areas, in particular radiopharmaceutical therapy wards. Exceptionally, a visitor may enter, but he/she should be accompanied to some controlled areas by a staff member who knows the protection and safety measures for the controlled area. The nuclear medicine facility should have written procedures specifying when such exceptions can take place and who may do the accompanying. Similarly, the facility should have established the rules regarding non-occupationally exposed workers, especially regarding access to controlled and supervised areas. Particular attention, in all cases, should be made with respect to potentially pregnant women.

4.267. Controlled and supervised areas should be clearly identified to help prevent inadvertent entry. This includes areas such as toilets designated for nuclear medicine patients. Further control can be afforded by the use of keys (or passwords) to restrict access to the control panels of medical radiological equipment to only authorized persons.

Members of the public in the wider public domain

4.268. Usually there are no restrictions with respect to public exposure for the release of patients that have undergone diagnostic nuclear medicine procedures. Patients should be advised on measures to enhance elimination of the residual radioactivity (such as hydration and frequent voiding) and to avoid prolonged contact with sensitive members of the public (young children, pregnant women), if appropriate.

4.269. The exposure of other persons, in the wider public domain, by patients who have received radiopharmaceutical therapy can occur through external irradiation of persons close to the patient, such as on public transport, and through internal contamination of persons as a result of excreted or exhaled radionuclides. The RPO of the nuclear medicine facility should establish rules to ensure that the exposure of any member of the public, following release of a radiopharmaceutical therapy patient, will be less than the public dose limit and, preferably, lower than any applicable dose constraint. As stated in para. 4.245, the patient should have been given written instructions that include means for avoiding external and internal exposure of the public. An acceptable method to estimate the acceptable retained activity for patients being discharged is described in para. 4.244. Results of the

calculations should be recorded. When deciding on the appropriate discharge activity for a particular patient, the licensee and RPO should take into account the transport and the living conditions of the patient, such as the extent to which the patient can be isolated from other family members and the safe management of the patient's excreta and body fluids. Detailed guidance on release of radiopharmaceutical therapy patients and public radiation protection is given in Refs [18, 261].

Death of a patient who has undergone a nuclear medicine procedure

4.270. Precautions may be required after the death of a patient to whom radiopharmaceuticals have been administered, particularly in the case of radiopharmaceutical therapy. This applies to the immediate handling of the dead patient, both in the hospital and in home or other place, but also with respect to autopsy, embalming, burial or cremation. The radiation protection precautions should be determined by the RPO, based on a generic safety assessment of the need for monitoring personnel who carry out these procedures, the need for monitoring the premises and the need for minimizing external radiation exposure and the potential for contamination. In addition to whole body monitoring, finger monitoring may be required for autopsy and embalming personnel, as contamination and radioactive waste are likely to be generated. A particular problem is the cremation of patients injected with bone-seeking radiopharmaceuticals such as ⁸⁹Sr for pain management of skeletal metastases. Because of the relatively long half-life of this radionuclide (50 days), the crematorium should store the ashes until adequate decay is achieved before releasing them to the family. Detailed guidance is given in Refs [18, 261]. Other considerations, e.g. cultural o legal, may prevail over the radiation protection considerations.

Radioactive waste

4.271. Another potential pathway for public exposure is radioactive waste and hence there should be systems and procedures in place to manage radioactive waste and its discharge, as stated in the BSS, requirement 31 and paragraphs 3.131 to 3.134. Detailed guidance on the management of radioactive waste, applicable to nuclear medicine facilities, is given in Ref [283].

4.272. Most radioactive waste from nuclear medicine is short lived radionuclides, and it is feasible to consider them as non-radioactive waste either directly or after some time for decay. A formal mechanism should be in place, including rigorous control measures, to demonstrate compliance with regulatory requirements in respect of release of radioactive waste from regulatory control. Further guidance is given in Ref [283].4.273. Since waiting for decay until the waste meets the regulatory criteria for clearance or authorized discharge is an essential method in nuclear medicine, a room for interim storage of radioactive waste should be available. The room should be locked, properly marked and ventilated. Records should be kept from which the origin of the waste can be identified. The process requires grouping (segregation) radionuclides according to the expected time for their decay (initial activity and physical half-life) and their physical form. Examples of different physical forms include: vials that may contain residual radioactivity, biological waste which may undergo decomposition, infectious waste requiring sterilization, broken glassware, syringes, and needles requiring collection in separate containers to prevent personnel being injured, radionuclide generators, bed linen and clothing from hospital wards (therapeutic applications), and liquid scintillation solutions. Containers to allow segregation of different types of radioactive waste should be available in areas where the waste is generated. The containers should be suitable for their purpose (for example, in volume, shielding and leak tightness).

4.274. In practice, it is mainly ¹³¹I and the waste from radiopharmaceutical therapy patients that require special precautions. Appropriate storage of radioactive materials to allow for decay will minimize the environmental impact of the release. The majority of diagnostic studies are performed using ^{99m}Tc, which has a physical half-life of 6 h. Following storage of 2.5 days (10 half-lives, i.e. a decay of a factor of more than 1000) most of this waste can be treated conventionally. The technetium generators contain ⁹⁹Mo with a half-life of 2.75 days; depending on their initial activity, the decay time at the nuclear medicine facility is 1.5–2 months.

4.275. ¹⁸F is the most commonly used radionuclide in PET. The short physical half-life of 110 minutes generally allows discharge within 24 hours.

4.276. Management of radioactive waste containing longer-lived radionuclides should consider initial activity and half-life. The nuclear medicine facility's RPO should give advice in these situations.

4.277. Following the above considerations, a summary of practical advice for specific situations in nuclear medicine can be given:

- (a) Technetium generators. There are two options: (1) returning to the supplier after use, ensuring compliance with regulations for transport of radioactive materials (see paras. 4.298 4.300), and (2) waiting for decay. After 1.5–2 months, the generator can be dismantled and the elution column removed, as the material is considered non-radioactive. Labels should then be removed.
- (b) Used syringes and needles. These can be collected in a shielded container in the rooms used for preparation and injection of radiopharmaceuticals. When the container is full, it should be sealed and the expected date of release from regulatory control be marked on it. After this time, the external dose rate can be monitored. The container can be released from regulatory controlwhen the external ambient dose equivalent rate is the same as the background or in line with national/local regulations.
- (c) *Vials containing residues of* ^{99m}*Tc*, ⁶⁷*Ga*, ¹¹¹*In and* ²⁰¹*Tl*. A similar procedure should be established as for the syringes, but segregation based on the physical half-life is needed. Caution should be exercised in storing waste containing very low levels of longer lived residues such as ⁶⁸Ge (half-life 271 days) as these could over time accumulate to activities where they should be considered as radioactive waste and could require prolonged storage before release from regulatory control.
- (d) Gloves and cover paper. These should be collected in plastic bags in the rooms used for preparation and injection of radiopharmaceuticals. When a bag is filled, it should be sealed. After waiting for decay or with appropriate monitoring, they can be released from control and treated as ordinary waste.
- (e) *Sealed sources* for calibration of activity meters, quality control of gamma cameras and counters, and anatomical marking of images are released from regulatory controlas determined by the RPO in accordance with national regulations and authorization by the regulatory body (clearance).
- (f) *Small activities of* ³*H and* ¹⁴*C in organic solutions* can usually be treated as non-radioactive waste. In certain instances, because of their potential toxicity, special precautions may apply, and appropriate bio-hazard precautions taken.
- (g) Patients' excreta, such as urine with ¹³¹I. For diagnostic patients there is no need for collection of excreta and ordinary toilets can be used. For therapy patients, policies vary for different countries, but in principle follow the dilution and decay methodologies to meet national or local requirements. Some precautions may be required where sewerage systems allow rapid processing of effluent with subsequent usage for irrigation of land used for growing vegetables.

Monitoring and reporting

4.278. The BSS, requirement 32 and paragraph 3.137, sets out the requirements that should be met by the nuclear medicine facility with respect to monitoring and reporting. In the nuclear medicine facility, procedures should be in place to ensure that:

- (c) The requirements regarding public exposure are satisfied and such exposure is assessed;
- (d) The requirements regarding discharge of radioactive materials to the environment are satisfied;
- (e) Appropriate records of the results of the monitoring programmes are kept.

4.279. The programme for monitoring public exposure arising from nuclear medicine should include dose assessment in the areas in and surrounding the nuclear medicine facility, which are accessible to the public. This can be achieved from the shielding calculations in the planning stage, combined with area monitoring and contamination monitoring at the initial operation of the facility and periodically thereafter. Records of these assessments should be kept for typically 7-10 years, but in any case for a period that meets any relevant regulatory requirements.

PREVENTION AND MITIGATION OF ACCIDENTS

Safety assessments

4.280.To comply with the BSS requirements for safety assessment (BSS, paragraphs 3.29 to 3.36), , the the registrant or licensee should conduct a safety assessment applied to all stages of the design and operation of the nuclear medicine facility. The safety assessment report should be submitted to the regulatory body if required. Basically, the safety assessment deals with determining 'what can go wrong' and how it can be prevented and, in case it occurs, how it can be mitigated. Section 2, paras 2.148 - 2.152, describes general considerations for facilities using ionizing radiation for medical purposes.

4.281. The safety assessment should be systematic and contain information on identification of possible events leading to accidental exposure (see Appendix I for a summary of typical causes and contributing factors to accidental exposures in nuclear medicine). The safety assessment should not only cover these events, but also aim at anticipating other events that have not previously been reported. Clearly the safety assessment should be documented.

4.282. The safety assessment should be revised when:

- (d) New or modified radiopharmaceuticals, equipment, or their accessories are introduced;
- (e) Operational changes occur, including workload;
- (f) Operational experience or information on accidents or errors indicates that the safety assessment is to be reviewed.

4.283. Safety assessments in nuclear medicine include consideration of all the steps in the use of radiopharmaceuticals for diagnosis and treatment in the nuclear medicine facility. The steps include ordering, transport and receipt of radiopharmaceuticals, unpacking, storage, preparation and

administration of the radiopharmaceuticals to the patient, examination or treatment, care of therapy patients with high amounts of radioactivity, and storage and handling of radioactive waste.

Accident prevention

4.284. Accident prevention is clearly the best means for avoiding potential exposure and the BSS, paragraphs 3.39 to 3.41, set out requirements based on good engineering practice, defence in depth, and facility-based arrangements, to achieve this. Design considerations for the nuclear medicine facility, medical radiological equipment and ancillary equipment are described in paras 4.7 to 4.58.

4.285. The licensee should incorporate:

(a) Defence in depth measures to cope with identified events, and evaluation of the reliability of the safety systems (including administrative and operational procedures, equipment and facility design). For example, theft of sources can be minimized through multiple layers of security including having sources locked up in a safe within a locked room, in an area that has a restricted access with camera surveillance and is routinely patrolled.

(b) Operational experience and lessons learned from accidents and errors. This information should be incorporated into the training, maintenance and quality assurance programmes.

Mitigation and contingency plans

4.286. On the basis of events identified by the safety assessment for the nuclear medicine facility, contingency plans should be prepared for events associated with potential exposure, including allocation of responsibilities and resources, the development and implementation of procedures, and the provision of training and periodic retraining of the relevant staff in executing the mitigation measures. Contingency plans in a nuclear medicine facility should, as a minimum, cover the following:

- (a) Predictable incidents and accidents, and measures to deal with them;
- (b) The persons responsible for taking actions, with full contact details;
- (c) The responsibilities of individual personnel in an accident or emergency procedures (for example, nuclear medicine physicians, medical physicists, nuclear medicine technologists, the RPO);
- (d) Equipment and tools necessary to carry out the emergency procedures;
- (e) Training and periodic rehearsals;
- (f) Recording and reporting systems;
- (g) Immediate measures to avoid unnecessary radiation doses to patients, staff and the public;
- (h) Measures to prevent access of persons to the affected area;
- (i) Measures to prevent spread of contamination, including leakage from fume hoods and room ventilation systems.

4.287. Kits should be kept readily available for use in a nuclear medicine incident. These may include the following:

- (a) Protective clothing, for example overshoes and gloves;
- (b) Decontamination materials for the affected areas, including absorbent materials for wiping up spills;
- (c) Decontamination materials for persons;

- (d) Warning notices and barrier tape;
- (e) Portable monitoring equipment;
- (f) Bags for waste, tape, labels and pencils.

4.288. The exposure of workers involved in such nuclear medicine events cannot be considered an unexpected exposure and whether deliberate or not should be controlled, and the dose limits for workers in planned exposure situations should apply.

4.289. For medical exposure, potential exposure when it does occur is manifest as an unintended or accidental medical exposure. Means for preventing or minimizing unintended and accidental medical exposures in nuclear medicine are described in para. 4.246 - 4.249, and the ensuing investigation and corrective actions are described in paras, 4.250 - 4.255.

4.290. The BSS, paragraphs 3.43 to 3.44, sets out the requirements for emergency preparedness and response. It is unlikely that emergency exposure situation can arise from nuclear medicine practice, but if the safety assessment identified the need, an emergency plan should be prepared according to the requirements in the GSR Part 7 and guidelines by the regulatory authority [7].

Lost sources

4.291. It is critical for this type of event that an up-to-date inventory exists (see para. 4.55) so that it can be determined immediately when a source is missing, what its type and activity are, when and where it was last known to be, and who last took possession of it. A proactive attitude is recommended for the case that sources are ordered and not received at the expected time. Making a check for the arrival of a source at the expected receipt time should be part of the procedures. The actions to be part of the contingency plans in this case include:

- (a) Obtain assistance from the RPO when needed.
- (b) Conduct a local search.
- (c) Check and ensure security and control of the other sources if a theft in the facility is suspected.
- (d) If the source is not found, call the supply company and inform them of the loss so that they can trace the shipment and find out where the radioactive material is.
- (e) If not found, report the loss of the material according to the rules given by the regulatory body.

Damage to radionuclide generators

4.292. Radionuclide generators, such as for ⁸²Rb, ^{99m}Tc and ⁶⁸Ga, contain a relatively large amount of activity. In the event of a generator being damaged, the measures to be taken should include:

- (a) Evacuate the area immediately and institute measures to prevent entry to the area.
- (b) Inform the RPO, who should confirm the spillage, define the safety boundaries and supervise the decontamination and monitoring procedures, including when restrictions to enter the area can be lifted.
- (c) Record the event and make a report according to the rules given by the regulatory body.

Spillage of small amounts of radioactivity

4.293. After a spillage of a small amount of radioactivity, for example low volumes of non-toxic radiopharmaceuticals which are easily removed, such as 10 MBq of ^{99m}Tc or ¹⁸F, the following actions should be taken:

(a) Use protective clothing and disposable gloves.

- (b) Quickly blot the spill with an absorbent pad to keep it from spreading.
- (c) Remove the pad from the spill.
- (d) Wipe with a tissue from the edge of the contaminated area towards the centre.
- (e) Monitor the tissue for residual activity, for example using a contamination monitor or performing a wipe test.
- (f) Continue the cycle of cleaning and monitoring until the measurements indicate that the spill has been removed, trying to keep the volume of contaminated waste as small as possible. In some cases, such as with short-lived radionuclides, it may be simpler to "quarantine" the area for sufficient time to allow decay e.g. cover the spill site, such as with a laboratory coat, and prevent access to the area.
- (g) Use a plastic bag to hold contaminated items. Suitable bags should be always available, as well as damp paper towels.
- (h) If the decontamination process is not successful, the RPO should be contacted.
- (i) Monitor all people involved in the spill for contamination when leaving the room, particularly the monitoring of shoes if the spill was on the floor.

Spillage of large amounts of radioactivity

4.294. After a spillage of a large amount of radioactivity, for example if a patient undergoing ¹³¹I therapy vomits shortly after administration, the following actions should be taken:

- (a) Throw absorbent pads over the spill to prevent further spread of contamination.
- (b) All people not involved in the spill should leave the area immediately.
- (c) The RPO should immediately be informed and directly supervise the clean-up.
- (d) Monitor all people involved in the spill for contamination when leaving the room.
- (e) If clothing is contaminated, remove and place it in a plastic bag labelled 'RADIOACTIVE'.
- (f) If contamination of skin occurs, wash the area immediately.
- (g) If contamination of an eye occurs, flush with large quantities of water.
- (h) When the contamination is contained, the procedures outlined for cleaning small spills may be followed, taking particular care that the contaminated waste bags are appropriately labelled and stored.

Medical emergencies involving patients who have received therapeutic radiopharmaceuticals

4.295. There may be medical emergencies, such as in the case of a stroke or cardiac arrest, involving immediate care of patients who have been administered large amounts of radioactive material (e.g. of the order of several GBq of ¹³¹I) for radiopharmaceutical therapy. In these cases dose rates near the patient are high, and attendant medical personnel may receive significant doses. However, the dose will be acceptable because the procedure is lifesaving. Measures should be used to minimize such doses. All members of the emergency team should wear impermeable protective gloves. Medical staff should be informed and trained on how to deal with such patients. Rehearsals of the procedures should be held periodically.

Need for urgent patient attention, including surgery

4.296. Radiation protection considerations should not prevent or delay lifesaving operations in the event that surgery is required on a patient who has been administered radiopharmaceuticals. The following precautions should be observed:

- (a) Notify the operating room staff.
- (b) Modify operating procedures under the supervision of the RPO to minimize exposure and spread of contamination.

- (c) Use protective equipment as long as efficiency and speed are not affected.
- (d) Rotate personnel as needed if the surgical procedure is lengthy.
- (e) Measure personnel doses.

Fires, earthquakes and other disasters affecting the nuclear medicine facility

4.297. The normal facility drill should be observed, providing for safe evacuation of patients, visitors and staff. When the first responders (for example the fire brigade) attend, they should be informed of the presence of radioactive material. No one, other than emergency responders, should re-enter the building until it has been checked for contamination by the RPO or by the radiation safety staff of the agency in charge of emergency response.

SAFETY IN THE TRANSPORT OF RADIOACTIVE MATERIALS

4.298. The BSS paragraph 2.25 sets out the requirements for the transport of radioactive materials, invoking in particular the IAEA Regulations for the Safe Transport of Radioactive material [283]. The IAEA Regulations for the Safe Transport of Radioactive material use the defined terms "consignor" to mean any person, organization or government that prepares a consignment for transport, and "consignee" to mean any person, organization or government that is entitled to take delivery of a consignment. "Consignment" is also a defined term, meaning any package or packages, or load of radioactive material, presented by a consignor for transport.

4.299. The licensee of a nuclear medicine facility may be both a consignee and a consignor, and hence may have responsibilities for both receipt and shipment of radioactive materials. Receipt of radioactive materials will be a regular occurrence for all nuclear medicine facilities. Shipments may take place when the facility has a cyclotron or laboratory that sends radiopharmaceuticals to other sites, or when expired generators, old sealed calibration sources or radioactive liquids (for example ¹⁴C solutions) should be returned to the supplier or disposed off-site, as applicable.

4.300. The detailed requirements for the safe transport of radioactive material, including general provisions, activity limits and classification, requirements and controls for transport, requirements for radioactive material and for packagings and packages, test procedures, and approval and administrative requirements, are given in the IAEA Regulations for the Safe Transport of Radioactive material [284]. Emergency arrangements during the transport of radioactive material should be in place, in line with the requirements in the GSR Part 7 and guidelines by the regulatory authority [7]. The licensee and the RPO of the nuclear medicine facility should be familiar with these regulations to ensure that their transport of radioactive materials will be in compliance.

5. SPECIFIC RECOMMENDATIONS FOR RADIATION PROTECTION AND SAFETY IN RADIATION THERAPY

INTRODUCTION

5.1. This chapter covers radiation therapy, the branch of clinical medicine that uses ionizing radiation (teletherapy and brachytherapy), either alone or in combination with other modalities, for the treatment of patients with malignancies or other diseases. It includes responsibility for the treatment decision, treatment preparation and planning, treatment delivery, follow-up and supportive care of the patient as an integral part of the multidisciplinary management of patients. Treatment using unsealed sources is covered in Section 4. Imaging studies used in treatment preparation, planning, verification and delivery are covered in Section 3, with appropriate cross-references.

5.2. External beam radiation therapy (teletherapy) is mainly performed with linear accelerators (Linacs), superficial and orthovoltage units, tomotherapy units incorporating a CT, or radioactive source based equipment (primarily using cobalt-60). In the case of Linacs, both photons and electrons are widely used and, for each, a range of energies can be utilized. External beam radiation therapy can be delivered using a wide range of techniques including: 2D, 3D conformal radiotherapy (3DCRT), intensity modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic radiotherapy (SRT), volumetric-modulated arc therapy (VMAT), Rapid Arc, and intraoperative radiotherapy (IORT). More recently, proton and heavy ion therapy has become available in some facilities.

5.3. Brachytherapy can be performed by implanting radioactive sources directly into the patient or using after-loading devices that allow for the sources – either manually or remotely – to be placed into catheters that then are inserted in the body. Techniques can be interstitial, intracavitory, surface or intraoperative and a range of sources are used. Low dose rate (LDR), medium dose rate (MDR), high dose rate (HDR) and pulsed dose rate (PDR) brachytherapy techniques are used.

5.4. The generic term "medical radiation facility" is used widely in Section 2 to mean any medical facility where radiological procedures are performed. In Section 5, the narrower term "radiation therapy facility" is used to cover any medical radiation facility where radiation therapy is being performed. A radiation therapy facility may be a radiation therapy department inside a wider hospital or medical centre, or it may be a stand-alone facility.

5.5. The defined term "radiological procedure" is used in the BSS to cover all imaging and therapeutic procedures using ionizing radiation. In a radiation therapy facility both imaging and therapeutic radiological procedures occur, and this should be borne in mind when reading the following guidance in Section 5. In cases where the guidance is specific to one of either imaging or treatment, additional qualifiers, such as "imaging" or "treatment", are used.

5.6. The health professionals that can take on the role of the radiological medical practitioner in radiation therapy depend *inter alia* on national laws and regulations. Most typically this will be a radiation oncologist, but may also include other specialists – for example, neurosurgeons in the case of stereotactic radiosurgery.

5.7. Section 2 of this Safety Guide provides general guidance on the framework for radiation protection and safety in medical uses of radiation, including roles and responsibilities, education,

training, qualification and competence, and the management system for protection and safety. This is relevant to radiation therapy and reference to Section 2 should be made as indicated or needed.

SAFETY OF MEDICAL RADIATION FACILITIES AND MEDICAL RADIOLOGICAL EQUIPMENT

Radiation therapy facilities

Location and site

5.8. A radiation therapy facility should be located on a site that gives ready access for in-patients and outpatients, and that at the same time makes fulfilling radiation protection requirements as simple as possible. Operational efficiency, initial cost, as well as provision for future expansion and/or increased workload, should be considered when locating a new radiation therapy facility. Radiation therapy facilities are often located on the periphery of the hospital complex to minimize radiation protection problems arising from treatment rooms being adjacent to high occupancy areas. The option of being able to construct rooms below ground level, with the potential for a reduced need for substantial shielding, may also influence the choice of site. Further guidance on location and site of radiation therapy facilities is given in Refs [285 - 288].

5.9. In addition to on-site considerations, surrounding environment should be also considered. This includes presence of, and implications for, adjacent residential or industrial areas, and the level of general public access to, and use of, the area. This relates to ensuring that public exposure outside – and above and below if there are occupied areas – the radiation therapy facility is consistent with public exposure requirements.

5.10. When considering expansion of an existing radiation therapy facility consideration should be given to the areas beside, above and below the proposed expansion site.

5.11. For physical security purposes, radiation therapy facilities using sealed radioactive sources should be located in areas where access by members of the public to the rooms where sources are used and stored can be restricted.

Design of rooms within the radiation therapy facility – general considerations

5.12. A typical radiation therapy facility consists of 5 main functional areas: reception, clinical consulting areas, external beam radiation therapy, brachytherapy, and imaging and treatment planning. Within these areas there are several types of rooms and, depending on the treatment modalities being provided, may include rooms or areas for patient imaging, treatment simulation, treatment planning, treatment control, treatment delivery, mould preparation, and patient examination, as well as patient changing cubicles, public waiting rooms, operating theatres and source storage and preparation rooms. Provisions for the incorporation of radiation safety features into these areas and rooms are best made at the facility design stage. (See para. 2.73). Because the structural shielding of radiotherapy facilities is very heavy, care should be taken that the shielding weight can be supported by the building structure, especially in cases when machines are replaced by higher energy ones, such as is the case of a cobalt-60 unit being replaced by a linear accelerator. The layout should take into account workload and staff and patient flow, both within the radiation therapy facility and, in cases where the radiation therapy facility is part of a larger hospital or medical centre, with other departments and wards of the wider facility. Wherever possible, treatment rooms should be surrounded with rooms that have low or controlled occupancy. Physical signage giving information on where different areas are located and designating hazardous areas is beneficial here and should be preferably in both word and picture format. Colour coding of different areas is also very helpful. General guidance on radiation therapy facility design is given in Refs. [285 – 289].

5.13. The three factors relevant to dose reduction for workers and the public (namely, time, distance and shielding) should be combined in the design to optimize occupational and public radiation protection.

5.14. Access to the radiation therapy facility and its treatment, imaging, consultation and patient preparation rooms should be considered. This includes provision for the delivery of equipment and for ease of access for patients undergoing clinical assessment and daily treatment. Patients may arrive in wheelchairs or on trolleys or beds.

5.15. As a general rule, the design of the radiation therapy facility should make provisions for safety systems or devices associated with the equipment and room. This includes ventilation, electrical wiring related to emergency 'off' switches, as well as standby lighting, safety interlocks and warning signals.

5.16. A reliable and stable power supply should be available for all modern equipment and information technology systems. An emergency diesel generator alone is generally not sufficiently stable to power a linear accelerator or orthovoltage unit and should not be used in this way. Uninterruptible power supply (UPS) or battery backup systems should be installed to capture the active information at the time of an outage and to power down all software in a controlled manner. Servers should be programmed to automatically shut down when the power supply is interrupted. Diesel generators could be used to run systems that depend only on timers, such as in the case of cobalt-60 teletherapy units.

5.17. The design of the facility should include an air conditioning system sufficient to maintain the temperature in the treatment room within the parameters defined by the equipment manufacturers.

5.18. Room lights should be dimmable so that the alignment lasers and the field defining lights can be seen easily to facilitate patient set up. It is useful to be able to control the treatment and imaging room lights and lasers from the control pendant in the respective room. When the field light is switched on, the room lights should dim to a pre-set (but adjustable) level, and the alignment lasers should also be switched on. Since fluorescent lights do not dim very satisfactorily, it is recommended that incandescent lights are used for the dim level. Four alignment lasers are recommended. Three lasers projecting across: two aligned with the gantry positions of 90° and 270°, and one mounted in the ceiling directly above the isocentre. A fourth laser should project a sagittal line along the gantry axis. This laser is usually mounted on an angled bracket on the wall opposite the gantry. The laser switching should be controlled from the hand pendant, but it is also useful to be able to switch them off independently for quality control tests.

5.19. In addition to interlocks, as described in para 5.29, signs and warning lights should be placed at the entrances of controlled areas to prevent inadvertent entry (see also para. 5.287 on control of public access). The BSS, paragraph 3.90, requires the use of the symbol of the International Organization for Standardization (ISO) [59]. An illuminated warning sign should be displayed at the entrance to the maze or treatment room as well as several inside the treatment room. It should be possible to see a warning sign from any position within the treatment room. These signs should be interlocked with the treatment unit control. The illuminated signs may have two or three stages. For a two stage sign, the first stage will be illuminated when there is power to the treatment unit, and the second stage will illuminate when the beam or the source is on. For a three stage sign, stage one will be illuminated when there is power to the treatment unit is programmed to deliver a radiation beam and stage three will illuminate when the beam or the source is on. Other rooms which are also controlled
areas, such as imaging, simulator and source storage rooms, also should have appropriate signs and warning lights.

5.20. Radiation therapy facilities that use radioactive sources should implement technical measures so that unauthorized access to sources can be detected in a timely fashion, including afterhours. These technical measures should be independent of any interlocks that terminate the radiation beam during normal operation. Such measures could include a video camera that provides continuous remote surveillance of the device, a photoelectric beam or motion detector system installed in the maze and/or treatment room, or a door interlock. If these devices indicate the potential presence of an unauthorized person, an alarm should indicate this locally and remotely so that personnel can respond in a timely fashion. Further guidance on security provisions for teletherapy sources, and HDR, PDR, MDR and LDR brachytherapy sources is given in Ref. [286]. See also para. 5.84.

5.21. Firefighting equipment should be available in all areas. For example, in brachytherapy this is in order to preserve the integrity of radioactive sources in the event of a fire. Further guidance is available in Ref [287].

Design of rooms within the radiation therapy facility – treatment rooms for external beam radiation therapy and afterloading brachytherapy

5.22. External beam radiation therapy and HDR/PDR brachytherapy should be carried out within the radiation therapy facility in treatment rooms designed for that purpose.

5.23. A shielded treatment room should not be shared between HDR brachytherapy and external beam radiation therapy, as this can negatively influence procedure flow and efficiency. Further guidance is given in Ref [285].

5.24. The size of the treatment room will depend on many factors, including the treatment equipment and the intended techniques of the treatments. The room should be large enough to allow full extension of the couch in any direction, with sufficient space for staff to walk around it. The design should also take account of the need for larger treatment rooms to allow for specific procedures. For example, total body irradiation (TBI) will require a larger treatment distance to one wall; IORT procedures require additional support staff and equipment, and the room may need to be larger. Imaging systems for image guided radiation therapy (IGRT), especially CT-on-rails, also need extra space. Easy access for patients on a bed or trolley, correct storage of accessory equipment such as electron applicators or breast positioning boards, and ease of patient positioning and staff movement during the setup procedures may be better facilitated with a larger room. Careful placement of accessory equipment within the room can help minimize the walking distance for each patient set up. Further guidance is given in Refs [285 – 287].

5.25. Care should be taken when a new machine or unit is to be introduced into an existing treatment room or bunker. The room size and shielding specification should be consistent with the new equipment and practices. This can be particularly relevant in the case of IMRT or the installation of a non-isocentric unit, for instance.

5.26. Some current or future equipment integrations, such as MRI/Cobalt/ MRI or MRI/Linac/ MRI, may have particular requirements that should be considered in the room design to ensure both efficient and effective operation and radiation safety.

5.27. The treatment and imaging room designs should include an open access conduit for the control panel, and monitoring and dosimetry equipment cables. This duct should not be aligned with the primary beam.

5.28. Entrance to the treatment room may be through a shielded door or via a maze or a combination of both. A maze reduces the need for a heavy shielded door and provides a route for ventilation ducts and electrical conduits without compromising the shielding. However a maze requires more room. More guidance on mazes and entrances is given in Refs [286, 287, 289].

5.29. Access to the treatment room should be furnished with a visible signal indicating whether the radiation source is 'on' or 'off'. An interlock barrier to prevent unauthorized access should be provided. This could include a light beam or a physical barrier such as a gate or door. Preferably two such interlock barriers should be in place. The interruption of irradiation should be maintained until the interlock is reset after it has been verified that no person but the patient is inside the room and that the patient setup has not changed. After an interruption, provided no operating parameters are changed or reselected, it should be possible to resume irradiation, but only from the equipment's control panel. See also para. 5.68.

5.30. The design should be such that access to the treatment (and imaging) rooms should be visible to the operators at all times. Further, the controls should be installed in such a way that access to the treatment room can be monitored at all times.

5.31. A safety system, such as the 'last man out button', should be in place to ensure that all staff have left the room prior to treatment commencement.

5.32. One or more emergency off switches should be conveniently placed inside the treatment room, in addition to those on the control panel and the equipment itself, to allow interruption of the irradiation from inside the treatment room.

5.33. Adequate systems, audio-visual devices or other means should be provided to allow staff to have communication with and a clear and full view of the patient. Oral communication from the control panel should be possible with the patient in the treatment (and imaging) room using an intercom or other communication system.

5.34. When using sealed sources a power fail-safe radiation area monitor (audio-visual) should be visible upon entering the room.

5.35. Provision should be made in each treatment room to enable the safe removal of the patient in the event of a power outage (e.g. availability of flashlights or torches). This also means manual operation of heavy doors should be possible.

5.36. Enclosed patient changing cubicles should not be located within the treatment room.

Design of rooms within the radiation therapy facility – rooms for manual brachytherapy

5.37. Typical radiation safety features for rooms used for the storage and preparation of sealed radioactive sources for manual brachytherapy include:

- (a) The room should be provided with a lockable door to control access and maintain source security (see also paras. 5.11 and 5.84).
- (b) There should be shielded storage (e.g. a safe) for all sources, the outer surface of which should be made of fireproof materials. The safe should be located near the preparation workbench to reduce the exposure of personnel during handling and transfer of sources if applicable.
- (c) The safe should have compartments for different source activities. Each compartment should be marked so as to permit immediate and easy identification of its contents from the outside with a minimum of exposure.

- (d) Sources should be readily identifiable by sight. When radioactive sources of the same appearance but of different activities or activity distribution are used, they should be distinguishable, e.g. by different coloured threads or beads.
- (e) The workbench should be provided with L block shielding, and with a lead glass viewing window and a magnifying glass.
- (f) The working surface for source preparation should be smooth and seamless to avoid losing small sources such as ¹⁹²Ir wire fragments or small ¹²⁵I seeds.
- (f) The source handling area should be well illuminated and a magnifying glass in a fixed mounting should be available for viewing, in order to handle sources efficiently and with a minimum of radiation exposure.
- (g) Devices for handling sources, typically forceps, should be available. They should be as long as practicable, compatible with efficient source handling. A device should be provided for threading sources expeditiously with the fingers protected by distance.
- (h) The source storage and preparation laboratory should have a sink with a filter or trap to prevent sources being lost into the sewerage system.
- (j) There should be a clear indication of the radiation level in terms of ambient dose equivalent. This should be achieved either by an area radiation monitor that should be visible on entering the room and during any handling of the unshielded sources, or by a survey meter that should be available and in use during source handling.
- (k) Hand carried transport containers should be provided with long handles. The lid of the container should be securely fastened to prevent tipping and dropping of sources during transport. Containers should bear the radiation symbol as well as a warning sign.
- (1) Space should be available for source transport trolleys.

5.38. It is preferable that patients' rooms be single and adjacent to one another. Where this is not possible, appropriate shielding between patients is necessary to minimize to the external exposure from other patients in the room. Within patients' rooms, whenever possible movable shielding for the nurses and potential visitors should be provided (see also para. 5.146).

5.39. The treatment room should contain a shielded storage container (large enough to accept the applicators if necessary) and a remote handling tool (forceps) in the event of a dislodged source.

5.40. An area monitor should be placed at the entrance so as to detect when a source or a patient with a source is leaving the room or the controlled area. In order to ensure that after the treatment no source remains within the patient, clothes or bed linen, or anywhere in the area, a portable monitor should be available for monitoring these items.

Design of rooms within the radiation therapy facility – imaging and other non-treatment rooms

5.41. Patient preparation and imaging areas where radiation is used, such as simulator rooms (CT, PET-CT, conventional), together with their console areas and patient changing areas should be designed to ensure that requirements for occupational and public protection are met. Details are given in the appropriate sub-sections of Sections 3 and 4, paras. 3.8 - 3.15 and paras. 4.7 - 4.27, respectively, and further guidance is given in Ref [285, 287].

Design of rooms within the radiation therapy facility – shielding considerations

5.42. Radiation therapy facilities typically require significant shielding, especially for the treatment rooms, to ensure that the requirements for occupational and public radiation protection are met. 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 be well below the dose limits for the persons occupying the area to be shielded. The following paragraphs (5.43 to 5.50) highlight some considerations with respect to shielding design, but a full discussion and details on methodologies and data for shielding calculations for treatment rooms are presented in Refs. [286, 290, 291].

5.43. Care should be taken to avoid multiplication of conservative assumptions which can lead to unrealistic overestimates of required shielding. Typical conservative assumptions are: workload, use and occupancy factors are overestimated; and the persons to be protected are permanently in the most exposed place of the adjacent room. A balanced decision should be achieved and accumulation avoided of overly conservative measures that may go beyond optimization.

5.44. However, from the other perspective, since corrections or additions after radiation therapy facilities are completed can be difficult and expensive, it is also advisable that the design includes consideration of possible future needs for new equipment and changes in practice or use, increased workloads, and changes in the occupancy of adjacent, above and below spaces.

5.45. The design and specification for the radiation shielding should be performed by a medical physicist or RPO to ensure that the required level of occupational and public radiation protection is achieved. The medical physicist or RPO should be involved from the very beginning because shielding requirements may influence decisions on where to site treatment and imaging rooms, and the type of building construction. The medical physicist or RPO should be provided with all relevant information regarding the proposed medical radiological equipment and its use, type of building construction, and occupancy of nearby areas. The shielding assumptions and specifications should be documented and signed off by the medical physicist or RPO and all documentation, including calculations, should be archived for the lifetime of the facility. Depending on a Member State's regulatory requirements, it may also be necessary to submit the final shielding specifications to the radiation protection regulatory body for review prior to construction.

5.46. The shielding of the radiation treatment room should be so constructed that the integrity of the radiation protection is not compromised by joints, by openings for ducts, pipes or other objects passing through the barriers, or by conduits, service boxes, or other structural elements embedded in the barriers.

5.47. Treatment room door and/or maze design for high-energy machines requires special consideration to ensure adequate radiation protection without sacrificing operational efficiency.

5.48. Whenever and wherever possible, there should be site visits by the medical physicist or RPO during construction to ensure that there has been, from the radiation safety perspective, the correct positioning of the joins in the structure and to ensure that the concrete has been poured to avoid gaps or cracks in the shielding and that the ducting does not go through the primary shielding or is aligned with the primary beam.

5.49. A final assessment of the adequacy of the shielding should be performed by the medical physicist or RPO after construction or installation of the equipment has been completed.

5.50. Shielding considerations for imaging and simulator rooms, depending on the modalities used, are given in Sections 3 and 4, paras. 3.17 - 3.23 and 4.31 - 4.35, respectively.

Medical radiological equipment, software and ancillary equipment

5.51. This sub-section considers medical radiological equipment, software and ancillary equipment used in a radiation therapy facility, including for diagnosis, simulation, treatment planning, treatment delivery, verification and follow up. For treatment pre-planning and simulation, the equipment used may include C-arms, conventional simulators, CT scanners, PET-CT, SPECT-CT, MRI, and ultrasound units. Medical radiological equipment used for external beam therapy includes superficial units (including units using Grenz or Bucky rays), orthovoltage units, gamma-ray teletherapy units, linear accelerators, and proton or heavy ion accelerators. While the radiological equipment used for external beam therapy falls into two main camps - linac-based and cobalt-based - the techniques used and hence how the equipment is constructed, its features and configurations vary enormously depending on whether treatment is via conventional external beam radiation therapy, SRS, stereotactic body radiation therapy (SRBT), 3-dimensional conformal radiation therapy, IMRT, VMAT, intensity modulated arc therapy (IMAT), Rapid Arc, or some other technique. Some hybrid external beam radiation therapy units incorporate imaging systems, such as radiography, fluoroscopy, CT, cone beam CT or MRI, and can perform IGRT. Brachytherapy may be manual or remote and is characterized by contact, intracavitary, or interstitial applications, which may be temporary or permanent. Almost all brachytherapy is performed with sealed radioactive sources but electronic brachytherapy systems with miniature X ray tubes are available [292, 293]. Radiation therapy with unsealed sources is covered in Section 4.

5.52. The requirements for medical radiological equipment and its software are given in the BSS paragraphs 3.49 and 3.162. The International Electrotechnical Commission (IEC), through its Technical Committee 62 on *Electrical equipment in medical practice* and in particular Sub-committee 62C on *Equipment for radiotherapy, nuclear medicine and radiation dosimetry*, has published international standards applicable to medical radiological equipment used in radiation therapy. Current IEC standards relevant to radiation therapy include the following Refs [289, 294 – 310]. For those relevant to the X ray based imaging systems used in radiation therapy see Section 3 para. 3.27, and for those relevant to radiopharmaceutical based imaging used in radiation therapy, see Section 4 para. 4.40. It is recommended that the IEC website is visited to view the most up-to-date list of standards: <u>http://www.iec.ch</u>. The International Organization for Standardization (ISO), through its Technical Committee 85 on *Nuclear energy, nuclear technologies, and radiological protection* and in particular Sub-committee 2 on *Radiological protection*, publishes international standards applicable to medical radiological equipment used in radiation therapy. Current ISO standards relevant to radiation therapy. Standards: http://www.isc.org.

5.53. Guidance on X ray based medical radiological equipment used for imaging as part of pretreatment simulation, IGRT or for follow-up assessment, as described in para 5.51, is given in Section 3, paras. 3.26 - 3.39.

5.54. As the licensee takes responsibility for the radiation safety of medical radiological equipment to be used in the radiation therapy facility, he/she should impose purchasing specifications that include conditions to meet relevant international standards of the IEC and ISO and/or equivalent national standards. In some countries there may be a medical devices agency or similar organization that gives type approval to particular makes and models of medical radiological equipment. Radiation sources, including radioactive material, equipment and accessories, should be purchased only from suppliers who meet national requirements for such dealings.

5.55. Displays, gauges and instructions on operating consoles of medical radiological equipment, and accompanying instruction and safety manuals, may be used by staff who may not understand, or who have a poor understanding of, the manufacturer's original language. In such cases, the accompanying

documents should comply with IEC and ISO standards and should be translated into the local language. Software, either used in conjunction with medical radiological equipment or as part of treatment planning (see also para. 5.75) should be designed so that it can be easily converted into the local language resulting in displays, symbols and instructions that will be easily understood by the staff. The translations will require a quality assurance process to ensure accuracy of the technical content to avoid operating errors. The same should apply to maintenance and service manuals and instructions for maintenance and service engineers and technicians, if these persons do not have an adequate understanding of the original language.

5.56. Procedures for the purchase, installation, acceptance, commissioning, use, maintenance and quality control of all equipment (hardware and software) should be developed with the involvement of a medical physicist together with other radiation therapy professionals as appropriate (for example, medical radiological practitioner, medical radiation technologist, biomedical engineer, information technology specialist) and the radiation therapy facility's radiation protection committee and quality assurance committee.

5.57. For medical radiological equipment in use, specific criteria of acceptability should be defined in order to indicate when remedial action should be taken, including, if appropriate, taking the equipment out of service. Examples of remedial and suspension criteria are given in Ref. [193]. A strategy or transition period for replacement based on social and economic factors is helpful. See also paras. 5.224 - 5.243 on quality assurance programmes for medical exposure.

Design features of medical radiological equipment – general considerations

5.58. The design of medical radiological equipment should be such that its performance is always reproducible, accurate and predictable, and that it has features that facilitate staff in carrying out the requirements in the BSS for operational considerations of optimization of patient protection (BSS, paragraph 3.163 - 3.164). Many design features contribute to the performance of medical radiological equipment and should be considered when purchasing such equipment, as indicated briefly in the following paragraphs. Further details on design features and performance standards of medical radiological equipment used in radiation therapy are given in Refs [294 – 299, 301 - 309, 311]. See also later paragraphs on quality assurance and acceptance testing, and in particular para. 5.236.

5.59. Medical radiological equipment should include provisions for selection, reliable indication and confirmation (when appropriate and to the extent feasible) of operational parameters such as type of radiation, indication of energy, beam modifiers (such as filters and wedges), treatment distance, field size, beam orientation and either treatment time or pre-set dose.

5.60. As noted in para. 5.52, radioactive sources for either teletherapy or brachytherapy should meet relevant international standards [311- 313].

5.61. Units under software control that are designed to operate within certain tolerances should have interruption mechanisms that stop the radiation when the tolerances are exceeded (for example, tumour tracking and respiratory gating). The equipment design should include the ability to override the software control, but only by appropriate persons that have been authorized by the radiation therapy facility's licensee. When dynamic treatments are interrupted due to being outside defined tolerances, there should be a system/method available to resume and complete the treatment.

5.62. Medical radiological equipment using radioactive sources should be fail-safe in the sense that the source will be automatically retracted to its shielded position in the event of an interruption of

power and will remain shielded until the beam control mechanism is reactivated from the control panel.

5.63. Medical radiological equipment used for radiation therapy should be provided with safety systems capable of preventing its use by unauthorized personnel. A key should be required to energize the system, access to which should be restricted to authorized staff.

5.64. External beam radiation therapy equipment containing radioactive sources and high dose rate brachytherapy (HDR/PDR) equipment should be provided with a device to return sources manually to the shielded position in the case of a failure of the source to retract. For SRS and SBRT units it should be possible to close the shielding door manually.

5.65. The design of safety interlocks should be such that operation of the medical radiological equipment during maintenance procedures, if interlocks are bypassed, can be performed only under direct control of the maintenance personnel using appropriate devices, codes or keys.

5.66. Record and verify systems (RVSs) and their related interfaces with imaging systems, treatment planning systems, treatment delivery systems, and image and administrative data storage systems (e.g. PACS, RIS, OIS) should be systematically verified for all their functionalities and data integrity. The RVSs should be able to store complete sets of information, including the patient's identification, prescription, treatment plan, and field parameters, allowing this information to be entered and called upon accurately for each treatment. The details about the treatment equipment, including coordinates, scales, and angles conventions used, beam energies, available field sizes, and other parameters and limitations should be entered, or their entry supervised, by the medical physicist. The system should be subject to periodic quality assurance because, if these parameters are incorrectly introduced into the RVS, systematic treatment errors will occur. Detailed guidance on RVSs is given in [309, 314].

5.67. Data transfer and data integrity, including patient information, should be maintained throughout the radiation therapy facility's network. Thus the information technology specialist should be familiar with the radiation therapy process and work in close cooperation with the radiological oncology team (radiological medical practitioner, medical radiation technologist and medical physicist).

Design features of medical radiological equipment – external beam therapy

5.68. Medical radiological equipment used for external beam therapy should meet the specifications given in relevant IEC standards [294 - 297, 301, 302, 305, 306, 308] and should follow the guidance on design specifications and performance in Refs [285, 315 - 317], as appropriate. In addition to the recommendations given in paras. 5.58 - 5.67, the following considerations should also be included:

- (a) Safety interlocks or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel should be provided.
- (b) Equipment design should permit interruption of the treatment from the control panel; after the interruption, resumption of treatment should be possible only from the control panel.
- (c) Radiation beam control mechanisms should be provided, including devices that indicate clearly and in a fail-safe manner whether the beam is 'on' or 'off'. See also para. 5.19.
- (d) The radiation field within the treatment area in the absence of any radiation beam modifiers (such as wedges or multileaf collimators) should be as uniform as practicable and the nonuniformity be stated by the supplier. The non-uniformity of flattening filter free (FFF) beams also should be specified by the supplier.
- (e) The design of the unit should lead to exposure rates outside the treatment area due to radiation leakage or scattering being kept as low as reasonably achievable.

(f) If primary shielding is incorporated into the equipment, electrical or mechanical interlocks should be provided to avoid the beam being directed towards secondary barriers if the primary shielding is not intercepting the beam.

5.69. Manufacturers should design accelerators to minimize neutron production, for example by avoiding the use of aluminium and other materials which have a high neutron-capture cross section.

Design features of medical radiological equipment – brachytherapy

5.70. Medical radiological equipment used for brachytherapy should meet the specifications given in Refs [298] and should follow the guidance in [285, 318], as appropriate.

5.71. Both LDR and HDR sources should be accompanied by a source certificate specifying:

- (a) The source strength in terms of reference air kerma rate (RAKR) or the air kerma rate constant defined by the ICRU [300]. See also para. 5.206(b));
- (b) The quality control tests applied to the source.

5.72. Applicators for brachytherapy should be manufactured specifically for the source to be used or be compatible with it. Use of reusable LDR radioactive sources after the working lifetime recommended by the manufacturer should be continued only after leak testing by the medical physicist or RPO and approval by the regulatory body.

5.73. Where manual brachytherapy sources incorporating ²²⁶Ra or encapsulated ¹³⁷Cs are still in use, efforts should be made to replace them as soon as practicable with modern afterloading systems. In no case should sources be left in applicators (pre-loaded applicators) in between clinical procedures, to avoid encapsulation and/or applicator rupture due to radiation damage.

5.74. Sources using beta emitters, such as ⁹⁰Sr and ¹⁰⁶Ru in ophthalmic applicators, should be provided with low atomic number shielding to minimize bremsstrahlung while they are in storage and in preparation for use.

Design features of treatment planning systems

5.75. The capabilities of treatment planning systems (TPS) have evolved in parallel with advances in computers and computing. Depending on the TPS, these capabilities may include complex three- or four-dimensional image manipulation and dose calculations. The design features of the TPS should meet the clinical goals of the radiation therapy facility. TPSs should meet the standards given in Ref [307], and should follow the guidance on TPSs, including specifications and performance given in [285, 320 - 322].

Design features of simulators and imaging equipment

5.76. The role of radiation therapy simulators, as distinct from imaging devices, has changed in recent years with wide bore CT scanners becoming more prevalent and integral to the treatment planning and follow-up. Where more conventional simulators are used these should meet the specifications given in IEC standards [299, 303, 304] and should follow the recommendations of Refs [285, 323]. The CT scanners used as virtual simulators should be designed so that patients can be simulated in the treatment position. As noted above in para. 5.53, guidance on medical radiological equipment used for imaging as part of radiation therapy, either pre-treatment, during treatment (IGRT) or for follow-up, is given in Section 3, paras. 3.26 - 3.39 and Section 4, paras. 4.44 - 4.50, with specific guidance for IGRT in Ref [324].

5.77. Guidance applicable to C-arm imaging devices used in brachytherapy is given in Section 3, paras. 3.36 - 3.37.

Ancillary equipment

5.78. The radiation therapy facility should have equipment, instruments and test objects for dosimetry and quality control which may include ionization chambers (thimble, plane- parallel and well-type), solid-state detectors, detectors for small-field dosimetry, electrometers, thermometers, barometers, phantoms, geometry and mechanical test tools. Further guidance on appropriate equipment, instruments and test objects is given in [285, 298, 310, 317, 325, 326].

5.79. The radiation therapy facility should have a mould room (also known as a patient preparation area or workshop) that is equipped to prepare beam modifiers, positioning aids and immobilization devices (e.g. blocks, compensators, bolus, etc.). Immobilization devices are now more commonly prepared in the simulation area and multileaf collimators remove the requirement for shielding blocks in most of the cases. Where blocks are still prepared, electronic transfer of data from the TPS to the automatic cutting and milling machines would represent an advantage in terms of accuracy.

5.80. In addition to laser positioning beams, the radiation therapy facility may need to have other positioning devices, including surface optical scanners, RF systems, GPS transmitters and ultrasound units.

5.81. For manual brachytherapy, the radiation therapy facility should be equipped with radiation safety and source handling equipment including a magnifying glass, source manipulators (such as forceps, tweezers or tongs), clippers or wire-cutters, and several shielded containers.

5.82. For afterloading brachytherapy, the radiation therapy facility should be equipped for source handling in the case of a failure of the afterloading unit, including: a storage container present in the treatment room, to serve as an emergency source container in case of failure of the afterloader in retracting the source; a remote manipulator; and a rod mounted GM detector for source localization.

5.83. The radiation therapy facility should be equipped with radiation monitoring instruments (area detectors and portable/survey meters), including Geiger counters, ionization chambers with electrometers or scintillators. For accelerators with energies of 15 MV and above, access to a neutron measuring instrument may be needed.

Security of sources

5.84. The objective of source security is to ensure continuity in the control and accountability of each source at all times in order to meet the requirement in BBS paragraph 3.53. In the radiation therapy facility the sources include sealed sources used in teletherapy and brachytherapy, and sealed sources used for calibration or QC tests. Situations that are particularly critical with respect to source security in the radiation therapy facility include receipt of sources, storage of sources, and movement of sources within the facility. The radiation therapy facility licensee should develop procedures to ensure the safe receipt and movement of radioactive sources within the institution and establish controls to prevent theft, loss, unauthorized withdrawal of radioactive materials or entrance of unauthorized personnel to the controlled areas. An inventory of sources should be maintained, with procedures in place to check and confirm the sources are in their assigned locations and are secure.

Maintenance

5.85. The BSS (BSS, para 3.15(i) and 3.41) gives requirements for maintenance to ensure that sources meet their design requirements for protection and safety throughout their lifetime and to prevent

accidents as far as reasonably practicable. Therefore the licensee of the radiation therapy facility should establish the necessary arrangements and coordination with the manufacturer's representative before initial operation and on an on-going basis. This can be achieved through a maintenance contract (preventive and corrective) with the manufacturer, or by in-house staff or third party contractor only if appropriately trained and authorized (see also Section 2, para. 2.112).

5.86. Maintenance includes not just the medical radiological equipment and its hardware, but also software, networks, data bases and other supporting systems in the radiation therapy facility, for example, PACS, HIS and RIS.

5.87. In addition to the guidance in Section 2, paras 2.110 - 2.111, the licensee of the radiation therapy facility should ensure that the process of removal from, and return to, clinical service of radiation therapy medical radiological equipment for maintenance or source exchange includes:

- (a) A record of maintenance carried out should be kept for each item of equipment: this should include information on any defects found by users (a fault log), remedial actions taken (both interim and subsequent repairs) and the results of testing before equipment is reintroduced to clinical use.
- (b) Where maintenance of the therapy and imaging equipment or treatment planning equipment may affect the accuracy of the physical or clinical dosimetry or the safe operation of the equipment, a radiation therapy medical physicist should perform specific tests or measurements in order to determine that the equipment is operating satisfactorily before it is used to treat patients (see BSS paragraph 3.167(b)).

5.88. The electrical and mechanical safety aspects of the medical radiological equipment are an important part of the maintenance programme, and can have direct or indirect effects on radiation safety. This work should be performed by appropriately authorized persons who understand the specifications of the medical radiological equipment. Electrical and mechanical maintenance should be included in the QA programme at a frequency recommended and preferentially performed by the manufacturer of the medical radiological equipment. Servicing should include a written report describing the findings. These reports should be archived as part of the QA programme.

OCCUPATIONAL RADIATION PROTECTION

Introduction

5.89. In radiation therapy radiological procedures, as described in paras. 5.1 to 5.6, occupationally exposed individuals are usually the medical radiation technologists, the radiological medical practitioners (typically the radiation oncologists) and the medical physicists. In some radiation therapy facilities, other health professionals such as nurses may also be considered occupationally exposed.

5.90. Additional occupationally exposed personnel may include dosimetrists and biomedical or service engineers and some contractors, depending on their role.

5.91. Other radiation therapy facility workers such as social workers, dieticians, physiotherapists, patient porters, orderlies, assistants, cleaners and other service support personnel, for whom radiation sources are not directly related to their work, require the same level of protection as members of the public, as stated in the BSS paragraph 3.78.

5.92. This sub-section contains guidance very specific to radiation therapy. For more general and comprehensive guidance on occupational radiation protection, including guidance on radiation protection programmes, assessment of occupational exposure and providers of dosimetry services, applicable to all areas of radiation use (including non-medical uses), reference should be made to the IAEA Safety Guide *Occupational Radiation Protection* [23].

Arrangements under the radiation protection programme

Classification of areas

5.93. Various areas and rooms in a radiation therapy facility should be classified as controlled or supervised areas, in line with the requirements given in BSS paragraphs 3.88 to 3.92. All other rooms and areas, not so-designated, are considered as "public domain" and levels of radiation in these areas should be low enough to ensure compliance with the dose limits for public exposure.

5.94. In a radiation therapy facility, all treatment rooms for external beam radiation therapy and remote afterloading brachytherapy, operating theatres used during brachytherapy procedures with radioactive sources, brachytherapy patient rooms, radioactive source storage and handling areas, and rooms where imaging or simulation procedures are performed meet the criteria for controlled areas and should be so designated.

5.95. Supervised areas may include the areas surrounding brachytherapy patients' rooms or around radioactive source storage and handling areas.

5.96. The area around the control panel for all medical radiological equipment used in radiation therapy should be classified as either a controlled or a supervised area, even though the radiation levels may be very low due the shielding design. In either case, this area should have restricted access, among other things to avoid distraction of staff which may lead to accidental medical exposure of patients.

5.97. In order to avoid uncertainties about the extent of controlled and supervised areas, the boundaries should, when possible, be walls and doors, partitions or other physical barriers, clearly marked or identified with 'radiation area' signs.

Local rules and procedures – general

5.98. The BSS, in paragraph 3.93, establishes a hierarchy of preventive measures for protection and safety with engineered controls, including structured and ancillary shielding, specific physical barriers, signs and interlocks, being supported by administrative controls and personal protective equipment. To this end, and as required in the BSS paragraph 3.94, written local rules and procedures should be established in a radiation therapy facility. Their purpose is to ensure protection and safety for workers and other persons. These local rules and procedures should include measures to minimize occupational radiation exposure during both normal work and unusual events. The local rules and procedures also should cover the wearing, handling and storing of personal dosimeters, and specify investigation levels and ensuing follow-up actions (see also paras. 5.155 - 5.167).

5.99. Since all personnel involved in using radiation in radiation therapy should know and follow the local rules and procedures, the development and review of these local rules and procedures should include representatives of all health professionals involved in radiation therapy.

5.100. Equipment (hardware and software) should be operated in a manner that ensures satisfactory performance at all times with respect to both the tasks to be accomplished and radiation safety. The manufacturer's operating manual is an important resource in this respect, but additional procedures should be also considered. The final documented set of operational procedures should be approved by the radiation therapy facility's licensee, and incorporated into the facility's quality management system (see Section 2, paras. 2.136 - 2.147).

5.101. Radiation therapy staff should understand the documented procedures for operation of the equipment with which they are working, including the safety features, and should be trained, with periodic refresher training, in what to do when things go wrong. Additional education and training should occur when new devices or techniques are introduced into radiation therapy practice.

5.102. Many local rules and procedures address aspects of some or all of occupational radiation protection, patient radiation protection and public radiation protection, either directly or indirectly, as well as ensuring a successful application of the treatment. This is the case with the following paragraphs (5.103 to 5.142) – while placed in this section on occupational radiation protection because they are to be followed by workers, the local rules and procedures often also have significance for patient and/or public radiation protection. The following paragraphs (5.103 to 5.142) give recommendations that should be incorporated into the radiation therapy facility's local rules and procedures.

5.103. No one should be in the treatment room during the delivery of treatment, except the patient. All attending personnel should be in appropriately shielded areas.

5.104. Safety features such as interlocks, presence of accessories such as the T-bar for manual Co-60 source retraction and survey meters functionality should be checked daily prior to patient treatment. More detail is given in Ref [285], and see also para. 5.236 on quality control tests in general.

5.105. Sealed sources should be subject to leak tests prior to their first use and at regular intervals thereafter, in conformity with international standards [312]. Leak tests should be sufficiently sensitive to be able to detect the presence of very small amounts of removable contamination, for example 0.2 kBq.

5.106. Area surveys should be performed periodically around all treatment units and check sources, including cobalt 60-units, shielded safes and source storage facilities for LDR and HDR sources.

5.107. Local rules for pregnant workers and persons under 18 should reflect the guidance given in paras. 5.178 - 5.181 and 5.182, respectively.

Local rules and procedures – external beam radiation therapy

5.108. Safe operation of external beam radiation therapy units requires procedures for area surveys, interlock checks, wipe tests (for sealed sources) and procedures for contingencies such as a source becoming stuck in the on or partially on position. Such procedures require that the necessary equipment be available, calibrated and in working order, including:

- (a) A radiation monitor;
- (b) Wipe test capabilities (for radioactive sources);
- (c) Personal alarm dosimeters, especially for unplanned exposures.

5.109. The procedures for the use of radiation monitoring equipment should recognize that some instruments will "lock up" in a high radiation field and give erroneous readings, and that this phenomenon, if it occurs, can be identified by starting the monitoring from outside the room in which the source is located, i.e. monitoring from the lower to the higher dose rate areas.

5.110. The presence of other staff in the area of the control panel should be kept to the minimum necessary so as to avoid distraction to the medical radiation technologist, as stated in para. 5.96.

5.111. As described in para 5.105, regular wipe tests should be performed for sealed sources. For external beam therapy the method to be used is the indirect wipe test of the nearest accessible surface.

5.112. Irradiations that involve long uses of high energy X rays, such as beam calibration, dosimetry and quality control measurements, should be scheduled to take place at the end of the day's clinical roster so that neutron activated radionuclides (especially the longer-lived ones) can decay significantly overnight.

Local rules and procedures – brachytherapy – general considerations

5.113. Source inventories should be maintained, giving the radionuclide, location and activity with reference date of each source at the facility as well as its serial or batch number, and a unique identifier. The unique identifier may be either a colour coded or an alphanumeric identifier.

5.114. Sources should never be left on preparation surfaces. They should be either in storage, in transit or in use.

5.115. As described in para 5.105, regular wipe tests should be performed for sealed sources. For long-lived LDR brachytherapy sources the typical method is the direct moist wipe test, while for remote controlled brachytherapy the method to be used is the indirect wipe test of the nearest accessible surface. For an HDR/PDR unit, the wipe tests should be only carried out on the afterloading drive assembly and transport containers, since the source itself has too high a dose rate to allow this type of test.

5.116. As stated in para 5.106, area surveys should be performed periodically around the source storage facilities for LDR and HDR/PDR sources.

5.117. The source storage facilities should be marked to indicate that they contain radioactive materials, and instructions given on how to contact the radiation protection officer, medical physicist or other responsible radiation safety individual in the event of an emergency.

5.118. Source storage rooms should be kept locked at all times.

5.119. After every brachytherapy treatment, all brachytherapy sources should be removed from the patient, except in the case of permanent implants. The patient should be monitored with a radiation survey meter to ensure that no radioactive source remains in or on the patient. Linen, dressings, clothing, waste and equipment should be kept within the room where the removal of sources takes place until all sources are accounted for, and should be monitored with a radiation detector. Mobile containers and portable equipment containing radioactive sources should be removed to storage or to a secure place when not in use.

5.120. Sterilization processes in brachytherapy should be appropriate for preventing damage to sources and applicators that could affect safety.

Local rules and procedures – brachytherapy – additional for LDR sources

5.121. In the case of temporary LDR brachytherapy applications, both manual as well as remotely controlled, the following information should be displayed at the entrance to the treatment room: identification of the patient, sources, date and time of insertion and removal, nursing required, time/distance allowance for nurses and visitors, and concise instructions for unplanned source and applicator removal and for dealing with an emergency, including contact details. A patient with a removable source in or on his or her body should only leave the room in exceptional circumstances and would should be accompanied by an attendant from the radiation therapy facility at all times.

5.122. Reusable sources should be inspected visually for possible damage after each use, by means of magnifying viewers and a leaded viewing window in a shielded work area.

5.123. There should be a diagram at the source storage safe that shows the exact location of each source within the safe, thus reducing the time taken to locate and identify a source.

5.124. Sources should only be handled with long forceps or tongs.

5.125. When transporting sources, a mobile shielded container should be available and the shortest route possible should be used. The container should have a long handle and/or a long handled trolley should be used.

5.126. Reusable sources that come into direct contact with body tissues will require cleaning and sterilization after each use. This can subject the sources to possible damage from heat, abrasion, chemicals and mechanical stresses. Therefore, these sources should be inspected after every use.

5.127. Work surfaces should be continuous, easy to clean and brightly lit to make it easy to find any sources that have been dropped.

5.128. If the source storage and preparation room is also the applicator loading room, there should be a sink for cleaning the applicators. However, a sink can also lead to a loss of sources to the sewage system when a source is left in the applicator or a patient removes a source and puts it in the sink. These situations are preventable by placing a filter in the sink's drain.

Local rules and procedures – brachytherapy – additional for HDR/PDR sources

5.129. The HDR/PDR afterloader should undergo routine quality assurance tests at the beginning of each treatment day [327].

5.130. Among other safety checks, the couplings and transfer tubes should be checked before each HDR treatment, to ensure that there are no obstacles to prevent motion of the source. Further details on safety checks are given in Ref [327].

5.131. Emergency safety precautions require the availability of an emergency container in the treatment room, as well as an emergency kit containing surgical clamps and long handled forceps for manipulation of the source guide tubes and applicators if the source fails to return to the safe, or for other source retrieval actions. The emergency container should be placed close to the patient and should be sufficiently large that it can accept the entire applicator assembly containing the source removed from any patient.

5.132. Manufacturers provide suggested contingency procedures if the source fails to return to the safe. These generally consist of a short single page synopsis, suitable for posting in an appropriate place, of the necessary sequential steps involved in the emergency procedure. They assume that the physical integrity of the applicator is maintained. These procedures are specific to the actual afterloading unit, but, in general, each step assumes that if the previous action fails to lead to recovery, then the following actions are required. The general sequence is:

- (a) Observation at the console of an error message and emergency indicators (audible and visible alarms);
- (b) Recovery at the console (e.g. pressing an emergency 'off' button);
- (c) Entry into the room with a portable radiation survey meter (opening the door activates the interlock that retracts the source);
- (d) Observation of radiation levels in the room (by mounted monitors or portable survey meters);
- (e) Recovery at the afterloading unit (pressing an emergency 'off' button on the remote afterloading unit);
- (f) Manual retraction of the source (using a hand crank);
- (g) Patient survey and the afterloader survey (confirming that the source is in the safe);
- (h) Applicator removal and placement in the emergency container;
- (i) Patient survey and emergency container survey (to confirm that the source is not in the patient and that it is in the emergency container);
- (j) Removal of the patient from the vault with subsequent redundant survey monitoring.

Local rules and procedures – remote control afterloading brachytherapy

5.133. Remote afterloading equipment requires specific contingency procedures, as these are especially critical for HDR brachytherapy. These procedures are dealt with in paras. 5. 310 - 5.313. A shielded container large enough to accommodate the largest applicator set should be kept next to the unit in case the source gets stuck.

Local rules and procedures – manual brachytherapy

5.134. For implants with sources of different activities, after verification of the source strength, the source or source holder should be marked with unique identifiers (for example, a pre-established colour which cannot be compromised by body fluids), to facilitate visual recognition and prevent the possibility of confusion between different sources or batches. Containers utilized for transport of radioactive sources should conform to the requirements established in the IAEA's Regulations for the Safe Transport of Radioactive Material [284] – see also paras 5.318 - 5.320.

5.135. The movements of the sources from the time they leave the safe until their return (if applicable) should be recorded, with the signature of the person responsible for the move (using forms or a log book). A person should be assigned to be in charge of accountability for the sources. This person should keep a record of the source order and of issuance from and return to the safe, with signatures. See also para. 5.84.

5.136. Reusable sources should be inspected visually for possible damage after each use by means of magnifying viewers and a leaded viewing window in a shielded work area.

5.137. Sources should only be handled with long forceps or tongs, never directly with the fingers.

5.138. A mobile shielded container should be available for transport of sources and the shortest route possible should be used. The container should have a long handle and/or a long handled trolley used.

5.139. Reusable sources which come into direct contact with body tissues require cleaning and sterilization after each use; this can subject the sources to possible damage from heat, abrasion, chemical attack and mechanical stresses. Therefore, these sources should be inspected after every use.

5.140. Available safety features listed in para. 5.37 should be effectively used.

5.141. Precautions to be observed during the cutting and handling of 192 Ir wires should include ensuring that:

- (a) Appropriate tools and equipment such as forceps, cutting devices, magnifying glasses and good illumination of the work surface are available and used and that, if ¹⁹²Ir wires are cut off for immediate use, a container to hold cut lengths is provided and labelled;
- (b) Radioactive waste is collected and stored in adequate containers, and properly transferred to an authorized waste disposal facility (see also paras. 5.288 5.289);
- (c) Surfaces and tools are properly decontaminated.

Local rules – imaging and simulation

5.142. Local rules and procedures for performing imaging procedures as part of pre-planning and simulation should follow the guidance, where appropriate, given in Sections 3 and 4, paras. 3.56 - 3.82 and 4.69 - 4.103, respectively. Additional information relevant to local rules specific to using imaging equipment as part of IGRT is given in Ref [324].

Personal protective equipment and in-room protective devices

5.143. The BSS, paragraphs 3.93 and 3.95, requires that personal protective equipment and in-room protective equipment are available and used when structural shielding and administrative controls alone cannot afford the necessary level of occupational radiation protection. The need for this protective equipment should be established by the radiation therapy facility's RPO or medical physicist.

5.144. For current external beam treatment procedures in radiation therapy, personal protective equipment is not usually needed. However, during patient preparation, source implantation or manual afterloading techniques in brachytherapy, and in the simulation/preplanning phase when imaging equipment is in use, e.g. C-arm, CT, PET-CT, the relevant recommendations given in the Sections 3 and 4 covering these procedures should be applied (see paras. 3.83 - 3.93 and 4.109 - 4.110).

5.145. In the case of manual handling of sources for brachytherapy, protective equipment such as shielding blocks on the workbench and lead glass screen should be used, as well as appropriate devices for handling sources (see para. 5.138 and 5.141).

5.146. For nursing of brachytherapy patients with either temporary (137 Cs or 192 Ir) or permanent implants (125 I seeds) consideration should be given to the use of movable shielding in the ward. Further advice is given in Ref [328].

5.147. Protective equipment for emergencies in brachytherapy, e.g. a stuck source in HDR, should include an emergency container suitable for applicators/sources. See also the sub-section covering procedures for contingencies (paras. 5.310 - 5.313).

Monitoring of the workplace

5.148. The BSS, in paragraphs 3.96-3.98, sets out the requirements and responsibilities for workplace monitoring. Workplace monitoring comprises measurements made in the working environment and the interpretation of such results. Workplace monitoring serves several purposes, including routine monitoring, special monitoring for specific occasions, activities or tasks, and confirmatory monitoring to check assumptions made about exposure conditions. Workplace monitoring can be used to verify the occupational doses of personnel whose work involves exposure to predictable low levels of radiation. It is particularly important for staff members who are not individually monitored. Further general guidance on workplace monitoring is given in Ref [23].

5.149. Workplace monitoring in areas around each of the medical radiological equipment (therapy and imaging) in the radiation therapy facility, when it is being operated, should be carried out when:

- (a) The room and shielding construction has been completed, either new or renovation, and before the room is first used clinically;
- (b) New or substantially refurbished equipment is commissioned;
- (c) Source replacements have taken place in teletherapy or remote controlled brachytherapy;
- (c) New software for the medical radiological equipment is installed or there is a significant upgrade;
- (d) New techniques are introduced;
- (e) Servicing on the medical radiological equipment has been performed, which may have an impact on the radiation delivered.

5.150. Initial workplace monitoring includes measurements of radiation leakage from the equipment and of scattered radiation using suitable phantoms, and area monitoring of accessible areas around, above and below irradiation rooms. This initial monitoring should be performed as part of acceptance tests, prior to clinical use of equipment.

5.151. In addition, exposure levels in teletherapy rooms with radioactive sources and high dose rate brachytherapy treatment rooms should be continuously monitored through the use of permanently installed area monitors. The source storage and handling area should be monitored with a survey meter immediately following the removal from, or return to, storage of brachytherapy sources.

5.152. For treatment rooms where the possibility of induced activity exists, e.g. with protons, heavy ions and high energy X ray beams (>10 MV), consideration should be given to the use of appropriate area monitors to detect the presence of neutrons and other radiation being from emitted from induced radionuclides in the treatment room [329].

5.153. Workplace monitoring should be done in association with brachytherapy procedures. Soon after implantation of the sources a survey of exposure rates in the vicinity of the patient is necessary.

5.154. All survey meters used for workplace monitoring should be calibrated in terms of ambient dose equivalent. For radiation therapy procedures, the quantity is $H^*(10)$ and the unit the Sv and its submultiples. The calibration should be traceable to a standards dosimetry laboratory. The meters should be subject to regular quality control tests. See also para. 5.241. Assessment of occupational exposure and workers' health surveillance

Occupational exposure assessment

5.155. The purpose of monitoring and dose assessment is, inter alia, to provide information about the actual exposure of workers and confirmation of good work practices and regulatory compliance. It contributes to reassurance and motivation. As stated in the BSS, paragraphs 3.99 to 3.102, individual monitoring is required for any worker who normally works in a controlled area and is likely to receive significant occupational exposure. Workers who may require individual monitoring include radiation oncologists, medical physicists, medical radiation technologists, the radiation protection officer, biomedical engineers, maintenance and servicing personnel, and any nursing or other staff who should spend time with patients who contain sources.

5.156. Monitoring involves more than just measurement. It includes interpretation, assessment, investigation and reporting, which may lead to corrective measures, if needed. Individual external doses can be assessed by using individual monitoring devices that include thermoluminescent dosimeters (TLDs), optical stimulated luminescence dosimeters (OSLDs), film badges and electronic dosimeters. Individual monitoring devices must be calibrated, and be traceable to a standards dosimetry laboratory. For more detailed guidance see Refs [23].

5.157. Each dosimeter is to be used for monitoring only the person to whom it is issued, for work performed at that radiation therapy facility and should not be taken to other facilities where that person may work. For example, if a person is issued with a dosimeter at hospital A it should be worn only at hospital A and not at any other hospitals or medical centres where he/she may also work. Monitoring results can then be interpreted for the person working in a specific radiation therapy facility, and allow appropriate review of the effectiveness of the optimization of protection measures for that individual in that facility. See also paras. 5.168 - 5.170.

5.158. The monitoring period specified by regulatory bodies in most countries is typically in the range of one to three months. A one month monitoring period is usually used for persons performing procedures associated with higher occupational exposures. A longer monitoring period (two or three months) is more typical for personnel exposed to lower doses, as a one month cycle would usually mean that the actual occupational dose was less than the minimum detection level of the dosimeter resulting in no detectable doses. With a longer cycle it is more likely to obtain a reading. Unnecessary delays in the return, reading and reporting of dosimeters should be avoided – the radiation therapy facility should send the dosimeters to the dosimetry service provider who should then process the dosimeters and return the dose reports, all in a timely manner. Some regulatory bodies may specify a performance criterion for timely reporting.

5.159. The operational dosimetric quantity used is the personal dose equivalent $H_p(d)$. For weakly penetrating and strongly penetrating radiation, the recommended depths, *d*, are 0.07 mm and 10 mm, respectively. Radiation used in radiation therapy is usually strongly penetrating and therefore d = 10 mm, except in the case of use of beta sources for brachytherapy. $H_p(10)$ is used to provide an estimate of effective dose that avoids both underestimation and excessive overestimation [18].

5.160. For monitoring the skin and extremities, a depth of 0.07 mm (d = 0.07) is recommended, and $H_p(0.07)$ is used to provide an estimate of equivalent dose to the skin and extremities. When the possibility of substantial exposure to the hands exists, such as in the handling of brachytherapy sources, extremity dosimeters should be worn (if this is compatible with clinical practice).

5.161. For monitoring the lens of the eye, a depth of 3 mm (d = 3) is recommended, and $H_p(3)$ is used to provide an estimate of equivalent dose to the lens of the eye. In practice, however, the use of $H_p(3)$ has not been widely implemented for routine individual monitoring. In radiation therapy it would generally be expected that the dose to the lens of the eye is not significantly higher than for the rest of the body. A possible exception is during the handling of sources for preparation and insertion, but the accepted practice of using a workbench provided with L block shielding with a lead glass viewing window should adequately protect the eyes. Nonetheless, monitoring of eyes doses may be considered in these or similar cases.

5.162. There are three dose limits applicable to workers in radiation therapy – effective dose; and equivalent dose to the lens of the eye, and to skin and extremities. The dosimeter being worn can be used to estimate one or more of the quantities used for the dose limits. Depending on the work being performed by the person being individually monitored, there may be a preferred position for wearing the dosimeter, and more than one dosimeter may be used. In radiation therapy, dosimeters are usually worn on the front of the upper torso, as occupational exposure arising from most radiation therapy procedures results in the whole body being fairly uniformly exposed. If specialized dosimeters, such as ring dosimeters for monitoring finger doses, are needed, the manufacturer's specific wearing instructions should be followed.

5.163. When not in use, individual dosimeters should be kept in an established place and protected from damage or from irradiation. 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, information of the dose estimate should be provided in a timely manner. 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 similar exposure conditions as the basis for the dose estimate.

5.164. In some cases occupational doses may be estimated from the results of workplace monitoring. The effective dose for personnel can be inferred from the measured ambient dose equivalent $H^*(10)$, provided the dose gradient in the workplace is relatively low. ICRP [125] provides conversion coefficients from ambient dose equivalent to effective dose for different types of radiation and energies. The conversion coefficients for photons are close to unity except for very low energy, such as the energy of scattered photons from an X ray beam generated at a low kilovoltage.

5.165. The use of additional direct reading operational dosimeters, such as electronic dosimeters, should be considered for use in a radiation therapy facility, e.g. in a new department or with the introduction of new modalities or procedures, as these devices can give the worker an instant indication of both the cumulative and the current dose rate and also allow pre-setting of an alarm [23].

Investigation levels for staff exposure

5.166. 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 should not normally be exceeded and, therefore, could be suitable as investigation levels. In radiation therapy, for example, pro rata monthly values higher than 0.5 mSv (for the dosimeter worn on the torso) should be investigated. If additional dosimeters are being used, then values higher than 2 mSv per month for a dosimeter monitoring the lens of the eye may indicate that eye doses may be of concern. Values higher than 15 mSv per month for hand or finger dosimeters should also be investigated. Abnormal conditions and/or events should also trigger an investigation. In all cases the investigation is with a view to improve implementation of

optimization of occupational protection and results should be recorded. Investigation levels should also be set for workplace monitoring.

5.167. The investigation is to be initiated as soon as possible following the trigger or event and a written report is to be prepared concerning its cause, including determination or verification of any doses received, corrective or mitigating actions, and instructions or recommendations to avoid recurrence. Such reports should be reviewed by quality assurance and radiation safety committees, as appropriate, and the holder of the licence should be informed. It is recommended that the report is submitted to an international or national educational safety reporting system, for example ROSIS (Radiation Oncology Safety Information System) [21]. In some cases, the regulatory body should also be informed.

Persons who work in more than one place

5.168. Personnel may work in more than one radiation therapy facility. The facilities may be quite separate entities in terms of ownership and management, or they may have common ownership but separate management, or they may even have common ownership and management, but be physically quite separate. No matter which, the occupational radiation protection requirements for the particular radiation therapy facility apply when the person is working in that facility. As described above in para. 5.157, a dosimeter issued for individual monitoring should be worn only in the facility for which it is issued as this facilitates effective implementation of optimization of protection measures in that facility. This approach is logistically more easily implemented as each physical site has its own dosimeters – there is no need to transport dosimeters between facilities, with the risk of losing them or forgetting them. In cases where the facilities are under common ownership it may be seen as an unnecessary financial burden to provide more than one set of dosimeters for staff that work in more than one of its facilities. However the radiation protection advantages of having the dosimeter results linked to a person's work in only one radiation therapy facility remain. See also para. 5.170.

5.169. There is however an additional consideration, namely ensuring compliance with the occupational dose limits. Any person who works in more than one radiation therapy facility should notify the licensee for each of those facilities. Each licensee, through their RPO, establishes formal contact with the licensees of the other radiation therapy facilities, and their RPOs, so that each facility has an arrangement to ensure that a personal dosimeter is available and that there is an on-going record of the occupational doses for that person in all the facilities where they work.

5.170. Some personnel, such as consultant medical physicists or service engineers, may perform work in many radiation therapy facilities and, maybe as well, other medical radiation facilities. They may be employed by a company or be self-employed, providing contracted services to the radiation therapy and other facilities. In such cases it is simpler for the company or the self-employed person to provide the dosimeters for individual monitoring. In other words, in these cases for each person the same dosimeter is used for work performed in all radiation therapy facilities (and other medical radiation facilities) in the monitoring period.

Records of occupational exposure

5.171. Paragraphs 3.103 to 3.107 of the BSS state the detailed requirements for records of occupational exposure, placing obligations on the employer, registrant and licensee. Apart from demonstrating compliance with legal requirements, records of occupational exposure should be used within the radiation therapy facility for additional purposes, including assessing the effectiveness of the facility's implementation of optimization of protection measures, and evaluating trends in exposure. Further general guidance on records of occupational exposure is given in [23].

Workers' health surveillance

5.172. The primary purpose of health surveillance is to assess the initial and continuing fitness of employees for their intended tasks, and requirements are given in BSS paragraphs 3.108 to 3.109.

5.173. No specific health surveillance related to exposure to ionizing radiation is necessary for staff involved in radiation therapy. Only in cases of overexposed workers, at doses much higher than the dose limits (e.g. a few hundred millisieverts or higher), would special investigations involving biological dosimetry and further extended diagnosis and medical treatment be necessary [23]. Under normal working conditions, the occupational doses incurred in radiation therapy are low. 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 such normal exposure. It is, therefore, rare for considerations of occupational exposure arising from the working environment of a radiation therapy facility to significantly influence the decision about the fitness of a worker to undertake work with radiation or to influence the general conditions of service [23].

5.174. Counselling should be available to workers who have or may have been exposed substantially in excess of dose limits, and information, advice and, if indicated, counselling should be available to workers who are concerned about their radiation exposure. In radiation therapy, the latter group may include women who are or may be pregnant. Counselling should be given by appropriately experienced and qualified practitioners. Further guidance is given in Refs. [23, 330].

Information, instruction and training

5.175. All staff involved in radiation therapy should fulfil the respective training and competence criteria described in Section 2, paras. 2.117 to 2.135. This will include education, training, qualification and competence for occupational radiation protection in radiation therapy. Radiation oncologists, medical radiation technologists, medical physicists and nurses may not have been trained with respect to imaging or pre-planning systems, such as CT, PET-CT, and as such should undertake radiation protection and safety training relevant to the additional imaging modalities in their radiation therapy facility.

5.176. The BSS, in paragraph 3.110, places responsibilities on employers to provide, *inter alia*, specific instruction and training for protection and safety as it pertains to their radiation therapy facilities. This is not only for new staff but also for all staff as part of their continuing professional development. Specific instruction and training should be provided when new medical radiological equipment, software and techniques are introduced.

Conditions of service and special arrangements

5.177. As required in BSS paragraph 3.111, no special benefits are to be offered to staff because they are occupationally exposed. It is simply not acceptable to offer benefits as substitutes for measures for protection and safety.

Special arrangements – female workers (pregnant)

5.178. A female worker should notify the licensee that she is pregnant as soon as she knows of her condition, so that radiation protection requirements for the embryo/fetus as a member of the public can be met.

5.179. Limitation of the dose to the embryo/fetus does not mean that pregnant women should avoid working with radiation, but it does imply that the employer should carefully review the exposure conditions with regard to both normal exposure and potential exposure. For example, the dose to the fetus for workers involved in source handling in manual brachytherapy, under normal conditions, may reach the dose limit for members of the public (see Section 2, Table 2). To prevent this from happening, rigorous time, shielding and distance restrictions should be implemented.

5.180. Other possible solutions include reassigning a pregnant worker to duties where the likelihood of an accident or incident is unlikely or to a location that has a lower ambient dose equivalent. Adequate education and training should accompany such reassignments. A further consideration is to avoid using pregnant workers in responding to an incident or emergency such as those described in paras. 5.304 - 5.314, for example, with a cobalt unit or an HDR brachytherapy unit.

5.181. When applying the dose limit to the embryo/fetus, the reading of the dosimeter may overestimate embryo/fetal dose by a factor depending on the energy and type of the incident radiation (by a factor 10 for low energy X rays and about 2 for Co-60 and MeV X rays). Information, advice and, if indicated, counselling for pregnant workers should be available (see also para. 5.174).

Special arrangements – persons under 18

5.182. In many countries there is the possibility of students aged 16 or more, but under 18, commencing their studies and training to become a medical radiation technologist or other health professional that may involve occupational exposure to ionizing radiation. The BSS paragraph 3.116 states the requirements for access to controlled areas and the dose limits for such persons are more restrictive – see Table 2 in this Safety Guide and Schedule III of the BSS.

Protection of workers responding to incidents in the radiation therapy facility

5.183. The practice of radiation therapy is a planned exposure situation, and when circumstances result in incidents that lead to, or could lead to, unintended or accidental exposures of patients or staff, they are still within the framework of a planned exposure situation. The potential occurrence of such should be considered in advance and contingency plans developed accordingly – see guidance in paras. 5.301 - 5.317 in the section on potential exposure, mitigation and contingency plans.

5.184. Occupational exposure of staff responding to these incidents is still subject to the occupational dose limits, and the contingency plans for incidents should include considerations for the optimization of protection for the responding workers. The contingency plans also should include allocation of responsibilities and provide for the education and training of the relevant staff in executing the mitigation measures, which should be periodically rehearsed. Most of these situations, for example the retraction of a stuck cobalt-60 source, can be executed in a planned manner so that doses received can be kept low.

RADIATION PROTECTION OF PATIENTS, CARERS AND COMFORTERS, AND VOLUNTEERS IN BIOMEDICAL RESEARCH

Introduction

5.185. This section covers what is more formally called 'medical exposure' in radiation protection. Medical exposure is defined in the BSS and described in Section 2, para. 2.5. It concerns radiation protection of the patient, carers and comforters, and volunteers in biomedical research. The term 'patient', when used in the context of medical exposure, means the patient undergoing the radiological procedure. Other patients in the radiation therapy facility or wider medical facility, including those who may be waiting for their own radiological procedure, are considered as members of the public and their radiation protection is covered in paras. 5.278 - 5.291.

5.186. As described in Section 2 para. 2.8, there are no dose limits for medical exposure, making it very important that there is application of the requirements for justification and optimization.

Justification of medical exposures

5.187. The requirements of the BSS for justification of medical exposure, BSS paragraphs 3.155 to 3.161, incorporate the '3 level approach' to justification [4, 131, 140].

5.188. The roles of the health authority and professional bodies with respect to 'level 2' or generic justification of radiological procedures in radiation therapy are described in Section 2 paras. 2.55 - 2.56 and 2.64, respectively.

Justification for the individual patient

5.189. The BSS invokes a joint approach to justification at the individual patient level, with a shared decision involving both the referring medical practitioner (who initiates the request for a radiological procedure or procedures) and the radiological medical practitioner. In the case of radiation therapy, the requirements for justification are applied more effectively as part of the medical process of determining the best approach to treatment. When a patient is referred by a referring medical practitioner for treatment, careful consideration should be made by the multidisciplinary oncology team regarding whether to treat the patient either by radiation therapy, another modality, a combined treatment approach (sequential or concomitant) or not to be treated at all. Ideally every treatment decision should be discussed and documented in a tumour or similar board.

5.190. From the radiation protection perspective, not only the radiation therapy treatment should be justified, but all the imaging radiological procedures prior to, during and after the treatment also should be justified. This includes consideration of the expected benefits that the imaging brings to improving the treatment outcome. For example, requesting PET-CT for improved target delineation or daily IGRT.

5.191. Two particular groups of patients are identified in the BSS, paragraph 3.157, for special consideration with respect to justification – patients who may be pregnant and paediatrics.

(a) Due to the higher radiosensitivity of the embryo/fetus, it should be ascertained whether a female patient is pregnant. Determining pregnancy status is a requirement in the BSS,

paragraph 3.176, for those radiological procedures that could result in significant dose to the embryo or fetus. Pregnancy is a factor in the justification process and might influence the timing of the proposed treatment or whether another approach to treatment is more appropriate. Confirmation of pregnancy may occur after the initial justification and before the treatment commences or during treatment, in which case repeat justification is required taking into account the additional sensitivity of the embryo or fetus.

(b) As children may be at greater risk of incurring radiation-induced stochastic effects, paediatric treatments require special consideration in the justification process.

5.192. The decision of the multidisciplinary oncology team should be conveyed to the patient or their legal authorized representative. The patient, or their legal authorized representative, also should be informed about the expected benefits, risks and limitations of the proposed treatment, as well as the consequences of not undergoing the treatment. Women of fertile age should be aware of the possibility of becoming pregnant during treatment and the risk that this entails. Consent for treatment should be obtained before any further patient management action is initiated.

Justification – biomedical research volunteers

5.193. The role of the ethics committee in the justification of medical exposure of volunteers exposed as part of a programme of biomedical research is described in Section 2 para 2.98.

Justification – carers and comforters

5.194. The justification of medical exposure incurred by a carer or comforter is effectively carried out by the radiological medical practitioner or medical radiation technologist involved in the treatment or imaging together with the carer or comforter, prior to the giving of care or comfort. It depends on the carer or comforter being correctly informed about the radiation doses and risks involved, and his or her understanding of this information and consequent agreement to take on the role of carer or comforter.

Optimization of protection and safety

5.195. In medical exposures, optimization of protection and safety has several components, some applied directly to the radiological procedure(s) about to be performed and others providing the support or framework for the other components. These components of optimization of protection and safety are described in the following paras. 5.196 - 5.249.

Design considerations

5.196. The use of appropriate and well-designed medical radiological equipment and associated software underpins any treatment in radiation therapy. Linear accelerators, X ray generators, radioactive source based equipment (teletherapy and brachytherapy) and their associated technologies and accessories (including treatment planning systems) should be designed and manufactured so as to facilitate the aim of ensuring that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances. Extensive guidance on design considerations is given in the sub-section on medical radiological equipment in radiation therapy, paras. 5.51 to 5.77. Guidance on design considerations for imaging systems, such as used in radiation therapy for simulation, patient preparation, image-guidance and follow up procedures, is given in section 3, paras 3.26 to 3.39, and Section 4 paras. 4.39 - 4.50. Ultimately, as stated in the BSS para. 3.162, it is the responsibility of the radiation therapy facility licensee to ensure that his/her facility

uses only medical radiological equipment and software that meets applicable international or national standards.

Operational considerations

5.197. Following justification, the treatment planning and the treatment delivery are performed in such a way as to optimize patient protection, as required in the BSS paragraph 3.164. The treatment goal is to deliver the correct absorbed dose to the correct volume within the overall prescribed time while keeping the dose to normal tissue and organs at risk within the established tolerances and as low as reasonably achievable. Accurate treatment planning is a crucial precursor to achieving this treatment goal.

5.198. Each radiation therapy facility should have written procedures and protocols for the delivery of radiation therapy consistent with the above goal. Protocols should be consistent with current best radiation therapy practice, published by the relevant professional bodies – national, regional or international, for example [331 - 336].

5.199. Advanced radiation therapy techniques (for example, IMRT, SRS, HDR brachytherapy, and ion beam therapy) have resulted in the possibility of high conformity to target volumes or subvolumes and therefore dose delivery has very small margins for error. When delivering radiation therapy in this way, the radiation therapy facility should utilize high quality imaging and delivery equipment and, where applicable, immobilization devices.

5.200. The use of advanced technology has led to the delivery of higher doses to the target volume, and frequently uses more complex and unconventional field or source arrangements. When moving to more complex modes of delivery, there is a greater risk of error and the radiation therapy facility should have all the necessary expertise and resources available before implementing these techniques.

5.201. Calculation of the dose to the embryo/fetus before the treatment of a pregnant patient should be part of the treatment plan. The distance from the field edge to the embryo/fetus is the most important factor in embryo/fetal dose, together with other factors such as field size, angle and radiation energy [130, 337].

5.202. Specific protocols for the use of imaging equipment (e.g. CT, PET-CT) in the pre-planning stage (simulation) of external beam radiation therapy should be used to ensure appropriate optimization of protection. In addition to the relevant guidance given in Section 3 paras. 3.170 - 3.179, these should include the following:

- (a) A medical radiation technologist specialized in radiation therapy should always be present when images for external beam radiation therapy planning are acquired in a diagnostic imaging facility;
- (b) Patients should be in the treatment position for all images acquired for external beam radiation therapy planning;
- (c) The geometry of the imaging modality should be sufficiently accurate to minimize errors in dose calculation and target delineation;
- (d) When used as a virtual simulator, a CT scanner should have a large enough bore so that images can be acquired with the patient in the treatment position;
- (e) A flat table top or flat inserts should be used when images are acquired for external beam radiation therapy planning;
- (f) A reference system consistent with those in the treatment rooms should be used when acquiring images for external beam radiation therapy planning. The treatment planning system reference point and the patient treatment reference point should be correlated;

(g) Imaging protocols for radiation therapy should include the specific technical parameters required for the simulation. For example, with CT this would include Hounsfield number calibration for dose computation accuracy, slice thickness for optimum planning, the scan length necessary to encompass the potential volume and other parameters that may influence the image quality for radiation therapy planning.

5.203. Specific protocols for the use of imaging equipment in IGRT should be used to ensure appropriate optimization of protection. In addition to the relevant guidance given in Section 3 paras. 3.170 to 3.179, more specific guidance is given in Ref. [324].

Calibration – medical radiological equipment

5.204. The BSS, paragraph 3.167(a), states the requirements for calibration of sources giving rise to medical exposure. For radiation therapy, all external beam medical radiological equipment and brachytherapy sources used in the radiation therapy facility should be calibrated, as follows:

- (a) External beam radiation therapy medical radiological equipment should be calibrated in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions; the recommended quantity is absorbed dose to water [319, 338]. The calibrations should be for at least the clinically used energies and qualities.
- (b) Sealed sources used for brachytherapy should be calibrated in terms of reference air kerma rate in air or equivalent quantity as recommended by the ICRU, at a specified distance, for a specified date [319].
- (c) Internationally or nationally accepted calibration protocols should be used. Examples of such protocols include Refs. [327, 338 344].
- (d) For brachytherapy, a distinction can be made between removable and permanent implants. For removable implants each source should be calibrated individually. For permanent implants when a large number of sources are being used, a representative sample may be assessed, for example 10% of the sources [341 – 344].
- (e) Particular attention should be paid to the calibration of sources used for special radiation therapy procedures (e.g. radiosurgery, IORT, stereotactic radiotherapy, tomotherapy, total body irradiation) which may require adaptation of the existing international codes of practice and introduce additional uncertainties associated with making measurements in non-reference conditions. A particular consideration is small field dosimetry – guidance is given in Ref [345].
- (f) Imaging devices used in the radiation therapy process, such as conventional simulators, CT scanners, CBCT, fluoroscopy, radiography and hybrid imaging systems (PET-CT, SPECT-CT) should be calibrated following the relevant recommendations in Sections 3 and 4, paras 3.194 3.198 and 4.195 4.200, respectively. Guidance for MV imaging devices is given in Refs [346, 347].

5.205. The BSS, paragraphs 3.154(d) and 3.167, places the responsibility for calibration in radiation therapy on the medical physicist, with either direct fulfilment or by supervision. Correct calibration in radiation therapy is fundamental and, with increasing complexity in technology and software, the need for the direct presence and involvement of the medical physicist is fundamental. See also sub-sections on patient dosimetry and the quality assurance programme for medical exposures, below.

5.206. The BSS, paragraph 3.167(b), specifies when these calibrations should occur. In addition to the initial calibration prior to clinical use and calibration after major maintenance or upgrade, periodic calibrations should occur. The intervals for these calibrations may differ, depending on the type of source and unit. For example, linear accelerators should be calibrated at least yearly. These intervals

will be specified by the regulatory body in each Member State. Constancy checks are addressed in paras. 5.224 - 5.243.

5.207. The BSS, paragraph 3.167(c), requires independent verification of radiation therapy equipment calibrations, prior to clinical use, because miscalibration of a radiation therapy source can result in inappropriate treatment involving many patients and can lead to very serious consequences. Independent verification ideally means verification by a different, independent medical physicist using different dosimetry equipment. However, other options, such as verification by a second medical physicist or only verification using a second set of equipment, or using a remote dosimetry audit (e.g. the IAEA/WHO TLD dosimetry audit) could be acceptable. In checking for compliance, the regulatory body should be aware of the limitations of local resources, but nevertheless some form of independent verification should take place.

5.208. The licensee of the radiation therapy facility should ensure that independent verification of all radiation therapy equipment calibrations is performed at least once every two years through participation in a national, regional or international programme. One of the simplest mechanisms for independent verifications of external beam calibration or physical dosimetry is participation in the IAEA/WHO thermoluminescent dosimetry postal dose quality audit. The regulatory body should encourage licensees to participate in this or similar programmes.

5.209. Sealed sources used for external beam and brachytherapy will also have a calibration certificate provided by the manufacturer, in accordance with Ref. [311] or its national equivalent standards. While important, this does not replace the calibrations required by the BSS paragraph 3.167 and described above in paras. 5.204 - 5.208.

5.210. New brachytherapy sources should be calibrated and differences of more than 5% from the manufacturer's certified reference air kerma rate should be investigated. The sources should not be used for patient treatment until such differences have been investigated and resolved. Further guidance on resolving differences in calibrations is given in Ref [343].

Calibration – dosimetry instrumentation

5.211. Dosimetry instrumentation used at a radiation therapy facility should be calibrated at appropriate intervals. Detailed guidance is given in Ref [338]. A period of not more than three years is recommended for the reference instruments.

5.212. The BSS in paragraph 3.167(d) requires the calibration of dosimetry instrumentation to be traceable to a standards dosimetry laboratory (SDL). Ideally this would be to the national SDL (primary or secondary) in the State concerned, with access either directly or through a duly accredited calibration facility. However, it may be necessary for dosimetry instruments to be sent to another country or state if there is no national SDL in the country or state where the instruments are used. To ensure the calibration is maintained, the calibrated dosimeter should be checked for consistency periodically in the facility against a reference check source.

5.213. Given the expenses involved in calibrating dosimeters, it is helpful if the radiation therapy facility keeps the calibrated dosimeter as its "local standard" and uses it only for primary calibrations. Relative calibrations can be done with instruments intercompared with the "local standard" on a periodic basis.

5.214. Records of calibration measurements and associated calculations, including uncertainty determinations (budgets), should be maintained as described in para. 5.276.

Dosimetry of patients

5.215. The BSS, paragraph 3.168, gives the requirements for dosimetry of patients in radiation therapy. Dosimetry is required for each patient undergoing external beam radiation therapy or brachytherapy. There are two aspects to the patient dosimetry – absorbed doses to the planning target volume(s) and absorbed doses to specific organs and tissues that have been identified as being at risk by the radiological medical practitioner (radiation oncologist).

5.216. For external beam radiation therapy, the final doses delivered to a patient are the result of a multi-stage process, commencing with the treatment prescription, dated and signed by the medical radiological practitioner (radiation oncologist), which should contain the following information: the location of the treatment site(s), total dose, dose per fraction, fractionation and overall treatment period of each course per site. The treatment prescription should indicate whether the radiation therapy will be given alone or in combination, either concomitantly or sequentially, with chemotherapy and the timing of other local treatments such as surgery. The normal tissues or organs that may receive significant radiation should be identified and the maximum doses to, and if possible and necessary the volumetric distribution of dose in, these organs or tissues at risk should be stated. Such tissues or organs may be in the irradiated volume or they may receive doses as a consequence of leakage or scattered radiation. The treatment prescription is then used as the basis for treatment planning, followed by delivery and dose verification. The requirements of the BSS can be met by determining the absorbed doses to the planning target volume(s) and the absorbed doses to specific tissues and organs that have been identified as being at risk.

5.217. There are many different terms, concepts and approaches in use for different aspects of prescribing, recording and reporting of external beam radiation therapy. For example, there are many specifications of volumes, including gross tumour volume, clinical target volume, planning target volume, organ at risk, planning organ at risk volume. Radiation therapy facilities should use the international recommendations of the ICRU for the specification of volumes and the prescribing, recording and reporting of doses in external beam radiation therapy [348 - 355]. Further guidance on dosimetry in external beam radiation therapy is given in Refs. [326, 337 - 340, 354 - 360].

5.218. For brachytherapy, the process also begins with the treatment prescription, dated and signed by the radiological medical practitioner (radiation oncologist). The treatment prescription should contain the following information: the total dose to a reference point and to organs at risk, the size of the reference dose volume, the number of sources and their dose distribution, the radionuclide and the source strength at a reference date. As with 5.219, the specification of volumes and the prescribing, recording and reporting of doses should follow the recommendations of the ICRU [361 – 363]. Further guidance on dosimetry in brachytherapy is given in Refs. [359, 364 - 371].

5.219. Absorbed doses to organs as a result of imaging procedures carried out as part of the radiation therapy process should be considered both in the irradiated volume and in the critical organs. While this estimation does not need to have the accuracy required in the determination of the doses to the target volumes and normal tissues or organs at risk, these absorbed doses can be considerable and they should then be accounted for and added as appropriate. Guidance specific to imaging doses during IGRT is given in Ref [372].

5.220. Absorbed doses arising from neutrons when using high energy photon beams should be considered when determining doses to the irradiated volume and to the critical organs. Methodologies for this are still being developed [373].

5.221. Whenever appropriate, radiobiological considerations should be incorporated into the treatment decisions, for example by calculation of biologically effective doses [374]. Examples are when doses from external beam radiation therapy and brachytherapy are added, or when the patient has missed some fractions due to clinical or technical reasons.

5.222. Treatment planning systems in radiation therapy continue to become more and more complex and, at the same time, they are used to predict the doses that the patient will receive. Therefore, the radiation therapy facility should have means to verify the dose to selected points, independent from the treatment planning systems calculations, for example by performing by manual calculations or case-specific QA measurements in a phantom. [321, 375, 376].

5.223. The radiation therapy facility medical physicist should perform phantom and/or in vivo measurements as appropriate. An example is to verify lung dose distributions for total body irradiation with photons.

Quality assurance for medical exposures

5.224. The BSS paragraph 3.170 requires radiation therapy facilities to have a comprehensive programme of quality assurance for medical exposures. General guidance on management systems is given in Section 2, paras 2.136 to 2.147, and it is simply re-iterated here that the programme of quality assurance for medical exposures should fit in with, and be part of, the facility's wider management system. The paragraphs in this subsection give guidance on the technical aspects of the programme of quality assurance for medical exposures.

5.225. When planning and developing an effective quality assurance programme for medical exposures, licensees should recognize that it demands strong managerial commitment and support in the form of training and allocation of time, personnel and equipment resources.

5.226. The purpose of the programme of quality assurance for medical exposures is to help ensure successful implementation of optimization of patient protection in the radiation therapy facility and to minimize the occurrence of unintended and accidental medical exposures. The BSS paragraph 3.171 establishes the elements of the programme.

5.227. By the very nature of radiation therapy, the facility's programme of quality assurance for medical exposures will be complex and should encompass the entire radiation therapy process, including the treatment decision, tumour localization, patient positioning and immobilization, image acquisition for treatment planning, treatment planning, treatment delivery, treatment verification and follow up. With respect to equipment, instrumentation and systems, it should include both the hardware and software.

5.228. Measurements on medical radiological equipment used in radiation therapy are an important component of the programme. Acceptance tests are required for new or significantly refurbished or repaired equipment, or after the installation of new software or modification of existing software that could affect protection and safety of patients. The acceptance test is followed immediately by commissioning, and then on-going periodic quality control tests, including constancy tests. The purpose is to ensure that, at all times, all medical radiological equipment is performing correctly, accurately, reproducibly and predictably. Acceptance and commissioning tests should be performed in the same way for equipment and/or software that has been donated.

5.229. Acceptance tests and commissioning should not be restricted to radiation emitting equipment or sources, but should also be conducted for any system that has implications for safety, such as

treatment planning systems (TPSs) and other software integral to or supporting any stage of the radiation therapy process. Insufficient understanding of TPSs at the commissioning stage and thereafter was involved in several accidental medical exposures [377 - 379].

5.230. After equipment or software installation has been completed, acceptance testing should verify conformance with the technical specifications given by the manufacturer and stated in the purchase agreement, and should verify compliance with relevant safety requirements from IEC or other recognized standards [294 – 309]. Depending on the equipment purchase agreement, acceptance tests may be performed by the manufacturer's representative in the presence of the local medical physicist representing the user, or, if acceptable to the manufacturer and/or the purchaser, by a medical physicist jointly with the manufacturer's representative. The tests to be performed as part of the acceptance testing should be specified in the purchasing conditions, where the responsibility of the manufacturer or supplier for resolving issues of non-conformity identified during acceptance testing should be clearly established.

5.231. Acceptance tests should ensure that equipment and/or software is compatible with the other equipment with which it will have to interface. The accuracy and integrity of data including during transfer processes should be verified.

5.232. After acceptance and before starting clinical use, commissioning of equipment (hardware and software) is performed – i.e. and radiation sources and radiation beams are characterized and software is customized for clinical use. The commissioning process is also a very important stage for familiarization of the staff with the equipment (hardware and software) and for gaining a full understanding of the equipment's capabilities and limitations. The process is critical, and therefore essential, to safety as shown in reports on unintended and accidental medical exposures involving a large number of patients [23, 380, 381]. During commissioning the medical physicist identifies, measures and compiles all data required for clinical use. This is followed by validation of the data [285, 314, 320].

5.233. During commissioning the quantities and measures including tolerances and action levels are defined for the periodic quality control tests, setting the baseline for subsequent constancy tests (see also 5.238 below).

5.234. If there has been a major repair or modification or a source replacement that may affect the radiation protection and safety of patients, no treatment can take place until the necessary QC tests have been completed and checked by the medical physicist who has confirmed that the equipment is safe for use. Significant unintended and accidental medical exposure has occurred because appropriate tests were not performed following a repair [282, 380, 382].

5.235. As noted above in para. 5.228, the quality assurance programme, with acceptance, commissioning and on-going quality control tests should include software – installation, upgrade, or modification. A particular case is the software upgrade of a treatment planning system where the necessary actions may range from full commissioning to a partial verification of the relevant parameters. The medical physicist should be involved in this process. Where remote software modifications are possible, a protocol should be in place that ensures the medical physicist is informed prior to any modifications being carried out so that appropriate QC tests can take place prior to reintroduction of treatment.

5.236. There are many published reports from international and national organizations and national or regional professional bodies giving detailed guidance on the range of acceptance, commissioning and

quality control tests that should be performed on the various equipment and software used in the different modalities in, and aspects of, radiation therapy, how they should be performed, tolerances and action levels, and recommended frequencies [193, 285, 314 - 316, 318, 320 - 322, 324, 325, 327, 328, 331 - 334, 341, 346, 375, 376, 383 - 401]. In addition, many of these organizations and professional bodies have websites where new or updated publications on the topic can be found. The regulatory body may have its own specific requirements on the tests that should be performed and their frequencies.

5.237. The quality assurance programme for medical exposures should include testing of sealed sources for leakage at regular intervals, as required by the regulatory body. The quality assurance programme should also include regular inventories of all radiation sources, at intervals determined by the regulatory body.

5.238. For guidance with respect to imaging medical radiological equipment see Sections 3 and 4, paras. 3.229 and 4.224, respectively. A diagnostic and a radiation therapy medical physicist should be present. Radiotherapy specific parameters that should be considered include, for example, Hounsfield number calibration for CT and geometric accuracy.

5.239. The results of the quality control tests should be compared with established tolerance limits. These limits may have been established to ensure compliance with a regulatory requirement for the performance of particular physical parameters or they may be set on the basis of recommended values given in published reports, such as referenced in para. 5.236. As required in the BSS paragraph 3.170(b), if the measured values fall outside the tolerance limits, corrective actions should take place. Such corrective actions are likely to include maintenance or servicing of the equipment, and hence the radiation therapy facility should have a maintenance programme in place. In some cases, the equipment may be outside the tolerance limits by a significant amount and the equipment should be immediately taken out of clinical use and not returned until the servicing has taken place and it has been ascertained by the medical physicist that the equipment now meets the performance requirements for clinical use.

5.240. The programme of quality assurance for medical exposures in radiation therapy should include use of "checks and balances" to ensure that the facility's protocols and procedures for treatment, including radiation protection and safety, are being followed – for example, geometric and dosimetric verification of the treatment. The periodic review of the protocols and procedures themselves is part of the facility's radiological review (see paras. 5.273 - 5.275).

5.241. The BSS paragraph 3.171(e) specifically requires that dosimetry and monitoring equipment are part of the programme of quality assurance for medical exposures. This includes instrumentation used for the purposes of calibration and clinical dosimetry, such as ion chambers, detectors, electrometers, and beam scanners. The requirement is to ensure that such instrumentation has a valid calibration (see paras. 5.211 - 5.214), and that it is functioning correctly. Instrumentation for calibration and clinical dosimetry in radiation therapy should undergo acceptance testing and regular quality control. The programme of quality assurance for medical exposures should establish a calibration cycle for each instrument (see also para. 5.211) and a set of quality control tests on the operation of each instrument to be performed at regular intervals, such as recommended internationally [338]. Preventive maintenance procedures should be carried out on a regular basis.

5.242. Maintaining records is a crucial aspect of the programme of quality assurance for medical exposures. This includes the procedures used in the programme and all ensuing results. In particular, all data related to acceptance, commissioning, calibration and dosimetry should be documented,

including independent verification. Records also should be kept for the results of the periodic quality control tests, and corrective actions. The regulatory body, during its inspections of a radiation therapy facility, should review the records of the programme of quality assurance for medical exposures.

5.243. In line with standard practices for quality management, the BSS in paragraph 3.172 requires regular and independent audits of the programme of quality assurance for medical exposures. Because of the complexity of the radiological procedures being performed in a radiation therapy facility, such audits should be performed relatively frequently, perhaps every two years for a radiation therapy facility performing complex radiation therapy treatments. Such audits may be external or internal. Internal audits are usually logistically simpler to implement, while the external audit generally has the advantage of bringing in an outside perspective. The audit of the radiation therapy facility's programme of quality assurance for medical exposures can be incorporated into more comprehensive audits that the facility is performing for its management system. Further, the results of the audit of the programme of quality assurance for medical exposures will be a major input into the radiation therapy facility's radiological review (see paras. 5.273 - 5.275). If indicated from the audit, the programme of quality assurance for medical exposures should be updated or modified, accordingly. Further, feedback from operational experience and lessons learned from accidents or near misses (see also para 5.270) can help identify potential problems and correct deficiencies, and therefore should be used systematically in improving the quality assurance programme [17, 19].

Dose constraints – carers and comforters

5.244. In radiation therapy, the potential for persons to act in the role of a carer or comforter (as defined in the BSS) is generally limited as accompanying a patient during external beam radiation therapy or access to HDR brachytherapy patients during treatment is generally not allowed. However, since LDR brachytherapy treatments last 2-3 days, visits by close relatives could be allowed, provided dose constraints for these carers or comforters are established and implemented. Similarly, brachytherapy treatments that involve permanent implants of sealed sources may also lead to the exposure of persons who, in the role of carers or comforters, provide care, comfort and support to the patient. This exposure of carers and comforters is defined as medical exposure (see the BSS) and as such is not subject to dose limits. However the BSS, paragraphs 3.153 and 3.173, requires that such carers and comforters are afforded radiation protection through the application of the requirements for optimization of protection and safety and, in particular, the use of dose constraints in this process. These are the dose constraints established by government, as a result of consultation with the health authority, relevant professional bodies and the regulatory body, as required by the BSS paragraph 3.149(a)(ii). Guidance on setting dose constraints, including considerations for children and pregnant women, is given in Section 2, paras, 2.48 - 2.49.

5.245. The radiation therapy facility should have written protocols for implementing measures for the optimization of protection for carers and comforters of LDR brachytherapy patients or patients with permanent implants. The measures should utilize the basic methods for radiation protection, i.e. shielding, time and distance. The protocol should include the following:

- (a) Criteria specifying who would be acceptable as acting as a carer or comforter;
- (b) Methods for ensuring that the carer or comforter receives a dose that is as low as reasonably acceptable;
- (c) The values of the dose constraints to be applied (see Section 2 para. 2.49).

5.246. Licensees should be able to demonstrate that the effective dose to the carer or comforter, by applying the protocols, is unlikely to exceed the dose constraints. It is relatively straightforward to estimate effective doses to carers and comforters from measurements of the ambient dose equivalent

rates at the positions where they will be situated with respect to the patient. These determinations should be made in advance to verify that dose constraints will not be exceeded. Therefore, individual dose monitoring is normally not necessary.

5.247. The BSS paragraph 3.153 states that a carer or comforter must be informed about the radiation risks involved in providing care, comfort and support to the patient, and about the means to be taken to afford appropriate radiation protection to the carer or comforter. The carer or comforter should indicate that he/she has understood the information and is still willing to care, comfort and support the patient. Appropriate written instructions should be available and provided to the carer or comforter.

5.248. Guidance applicable to carers and comforters supporting patients under imaging radiological procedures as part of the treatment process in the radiation therapy facility is given in Section 3 paras. 3.236 to 3.240.

Dose constraints – volunteers in biomedical research

5.249. Participants in a programme of biomedical research may undergo radiation therapy as part of the research programme. Guidance on the role of the ethics committee in approving such programmes is given in Section 2, para 2.98, and this normally includes the setting of applicable dose constraints (Section 2 para. 2.99).

Pregnant females patients

5.250. Female patients who are pregnant form a special sub-group of patients that should be particularly considered with respect to radiation protection. These considerations have been described in para. 5.191 for justification and para. 5.201 for optimization. None of these considerations can take place if it is not known that the patient is pregnant. Therefore it is crucial, as is required in the BSS paragraphs 3.175 -3.176, for the radiation therapy facility to have in place means for ensuring that pregnancy status is known for female patients.

5.251. The first approach is through posting of clear signs, in languages able to be understood by the range of people using the radiation therapy facility, simply asking the question "Are you pregnant or possibly pregnant?" and, if so, asking them to inform staff. Such signs should be posted widely in the facility, including waiting rooms and cubicles. The second approach is to directly ask female patients whether they are or might be pregnant. This may not always be so easy given social and cultural sensitivities, but it should be done when needed.

5.252. Neither of the approaches described in para. 5.251 work if the woman does not know if she is or may be pregnant. For this reason, the BSS paragraph 3.176 has an additional requirement on facilities to have "procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus". In radiation therapy this situation is likely to occur, in particular when it includes treatment of the abdomen or pelvis area and treatment to volumes near the uterus such that significant leakage and/or scattered radiation reaches the embryo or fetus. Cooperation with the referring medical practitioner, through standard requests for pregnancy status for specified treatments, is one approach. In case of doubt, a pregnancy test or hormonal level determination to assess menopausal status may be carried out.

Release of patients after permanent brachytherapy implants

5.253. As required in the BSS paragraph 3.178, a radiation therapy facility should have arrangements in place to manage the release of patients who have permanent brachytherapy implants. Once the patient is released, two groups of persons should be afforded appropriate radiation protection – the general public with whom the patient may encounter or interact, and members of the patient's family and close friends who may be viewed simply as also being members of the public or as carers and comforters. Exposure of members of the public is subject to the public dose limits (see Section 2, Table 2), while exposure of carers and comforters is not subject to dose limits but is instead controlled through dose constraints (see Section 2 paras. 2.46 - 2.49 and Section 5 paras. 5.244 - 5.248). Further, as discussed in para 2.46, public exposure arising from a single "source", such as the patient with the implants, should be subject to dose constraints set at some fraction of the dose limits.

5.254. The radiation therapy facility's medical physicist or radiation protection officer should establish prior to the release of a patient that the radioactivity of the implants is such that the doses that could be received would not exceed public dose limits, for members of the public, and would be unlikely to exceed the relevant dose constraints for both members of the public and carers and comforters. An acceptable method to estimate the acceptable activity of permanent implants for patients being discharged from hospitals is to calculate the time integral of the ambient dose equivalent rate, considering the activity, energy and half-life of the radionuclides. In the case of carers and comforters, the assumptions made for the calculations should be consistent with the written instructions that will be given at the time the patient is discharged from the facility. Published data would suggest that systematic dose monitoring, at least in the case of permanent brachytherapy implanted sources for prostate cancer, is not necessary [342, 402].

5.255. As indicated in 5.256, the patient or legal guardian of the patient should be provided with written instructions on how to keep doses to members of the public and carers and comforters as low as reasonably achievable. Areas of particular concern are children and pregnant partners of patients. Detailed guidance, including a sample information sheet, has been given by the ICRP for implanted sources for prostate cancer [402].

5.256. There is a low probability of an implanted seed being expelled, for example with prostate treatment. The written instructions should cover this possibility and give guidance on what to do and what not to do. Again detailed advice is given by the ICRP [402].

5.257. The patient with permanent brachytherapy implants should be informed that if he/she is to undergo subsequent surgery, then the surgeon should be informed of the presence of the implants – for example, a prostate cancer patient undergoing subsequent pelvic or abdominal surgery. A wallet card with all relevant information about the implant is useful [402].

5.258. Information also should be provided to the patient on radiation risks, including guidance with respect to fertility in the case of implants for prostate cancer [402].

Unintended and accidental medical exposures

Prevention of unintended and accidental medical exposures

5.259. The BSS, paragraphs 3.179 to 3.181, sets out requirements both for minimizing the likelihood of unintended and accidental medical exposures and for the ensuing investigation if such exposures occur. The pathways identified in the BSS for potentially leading to unintended or accidental medical

exposures include flaws in the design of medical radiological equipment, failures of medical radiological equipment while in operation, failures and errors in software that control or influence the delivery of the radiation, and human error. General strategies for addressing those pathways include regular maintenance of medical radiological equipment and software, a comprehensive quality assurance programme, continuing education and training of staff, and the promotion of a safety culture. The lessons learned from events that have occurred should be used for preventing or minimizing unintended and accidental medical exposures, as described below in para. 5.270.

5.260. A reduction in the probability of unintended or accidental medical exposures in radiation therapy can be brought about by:

- (k) The introduction of safety barriers at identified critical points in the radiation therapy pathway, with specific quality control checks at these points. Quality control is not confined to radiological equipment physical tests or checks, and can include actions such as checks of the treatment plan or dose prescription by independent professionals.
- (1) Actively encouraging a culture of always working with awareness and alertness.
- (m) Providing detailed protocols and procedures for each process in the radiation therapy pathway.
- (n) Education and training, including continuing professional development, of all staff involved in the preparation and delivery of radiation therapy.
- (o) Clear definitions of the roles, responsibilities and functions of staff in the radiation therapy facility that are understood by all staff.

5.261. Unusual and complex treatments should always trigger an extra warning and each staff member should be aware and alert in these situations. The use of 'time-out' where staff take time to review what has been planned, prior to delivering treatment, should be considered.

5.262. As noted in 5.262 above, comprehensive protocols and procedures covering the various steps in the process should exist for the major part of the department's activity [331 - 336, 396, 403 - 409]. Checklists detailing actions, and signed by the responsible parties at each step, are very helpful [410]. For the most critical steps, such as commissioning and calibration of equipment, there should always be a review, either internally or preferably through an external independent audit.

5.263. Preventive measures should include incident and near incident reporting, analysis and feedback including lessons learnt from international experience [19, 21, 282, 378, 380, 381, 411 – 414]. Preventive measures should also include each radiation therapy facility checking the robustness of their safety system against reported incidents. IAEA Safety Reports Series No. 17 [282] and ICRP Publications 86 and 112 [380, 411] contain reviews of case histories from an extensive collection of accidental medical exposures.

5.264. Proactive risk assessment should also be carried out to try to pre-empt incidents or potential incidents. The tools used to carry out this type of analysis in radiation therapy include, for example, process maps or failure trees to facilitate the identification of possible failure modes, and then the use of prospective analyses, such as failure mode and effect analysis (FMEA), root cause analysis (RCA), and risk matrix to assess the probability and likely consequences of such unacceptable events. Detailed guidance on some of these tools and approaches is given by the ICRP [411] and the European Commission [405].

5.265. Before introducing a new technology into a radiation therapy facility, general lessons obtained from established technologies may still be useful but there will be no specific lessons to share and to apply. In this case, a proactive assessment is even more necessary. This can be combined with an

early collection and sharing of experience and events by the first users of the new technology, such as through participation in SARON, ROSIS or similar [19, 21].

5.266. Building on the guidance from paras 5.259 to 5.265, the following three-step strategy can help to prevent unintended and accidental exposures in radiation therapy:

- (g) allocate responsibilities to appropriately qualified health professionals only and ensure that a quality management system that includes radiation safety is in place;
- (h) use the lessons learned from unintended and accidental medical exposures to test whether the quality management system, including for radiation safety, is robust enough against these types of events;
- (i) identify other latent risks by posing the question "what else could go wrong" or "what other potential hazards might be present" in a systematic, anticipative manner to all steps in the radiation therapy process, using for example the proactive methods briefly described in para. 5.264.

Investigation of unintended and accidental medical exposures

5.267. The events that constitute unintended or accidental medical exposures are detailed in the BSS paragraph 3.180, and for a radiation therapy facility include those associated with imaging and with treatment. For the former, reference should also be made to Section 3, paras. 3.251 - 3.255 and Section 4, paras. 4.250 - 4.251. Unintended and accidental medical exposures may occur at any stage in the radiation therapy process. It needs to be stressed that for treatment in radiation therapy, unintended or accidental medical exposures may be either underexposures or overexposures. It also needs to be stressed that the events in the BSS paragraph 3.180 also include 'near misses', and these nshould be considered in the same way as actual events.

5.268. One of the events identified in the BSS paragraph 3.180 is when the dose or dose fraction delivered was "substantially different from (over or under)" the prescribed dose. Guidance regarding the level of dose difference that would be considered as substantially different can be found in international or regional recommendations [380, 404]. The radiation therapy facility should have in place a system with clear procedures for identifying when this type of event occurs. For example, unintended or accidental medical exposures involving a total dose 10% or more over that prescribed should be detectable in most cases by the radiation oncologist or relevant health professional, based on an unusually high incidence of adverse patient reactions [380], and the radiation therapy facility's procedures should include such patient monitoring to act as a trigger for further investigation. Clinical identification of situations of under dose is more difficult, but may become manifest through poor tumour control – again, such monitoring should be part of the radiation therapy facility's procedures. In addition to the clinically based approaches to identifying doses that were substantially different from that prescribed, other approaches should be used in parallel, including the review processes that are part of quality assurance.

5.269. Each radiation therapy facility should have a system in place to manage the investigation of unintended and accidental medical exposures, and the ensuing actions and reporting. The BSS, paragraph 3.181, states what should be done in the course of the investigation. This includes calculation or estimation of patient doses, which should be performed by a medical physicist, identification and implementation of corrective actions, records of the investigation and for the radiological medical practitioner to inform the patient and the patient's referring medical practitioner. A record of the calculation method and results should also be placed in the patient file. When required, counselling of the patient should be undertaken by someone with appropriate experience and clinical knowledge.
5.270. The investigation of unintended and accidental medical exposures, as required by the BSS paragraphs 3.180 - 3.181, has three main purposes. The first is to assess the consequences for the patient (s) affected and provide remedial and health care actions if necessary. The second is to establish what went wrong and how to prevent or minimize a recurrence in the radiation therapy facility – i.e. the investigation is for the facility's and their patients' benefit. The second purpose is to provide information to other persons or other radiation therapy facilities. Dissemination of information about unintended and accidental medical exposures and radiation injuries has greatly contributed to improving methods for minimizing their occurrence. This might be through the regulatory body and/or the health authority for more significant events or as required by a country's regulations, where the regulatory body disseminates information on the event and the corrective actions to other facilities that might learn from the event (see also para. 5.271). Another approach, independent from any legal requirement for reporting to the regulatory body, is to participate in voluntary international or national databases designed as educative tools. Two international such databases for radiation therapy are the SAFRON and ROSIS reporting systems [19, 21]. Facilities performing radiation therapy should be active participants and users of SAFRON, ROSIS or similar international databases or equivalent national ones [415, 416].

5.271. As noted in para. 5.270, the BSS requires reporting to the regulatory body, and to the health authority if appropriate, for "significant" events. Further, the regulatory body in a given country may also specify their own requirements for reporting events to them. It is difficult to quantify "significant" – specifying a numerical trigger value immediately creates an artificial distinction between values immediately below that value (and hence should not be reported) and those just above the value (which should not be reported). However, the attributes of "significant" events can be elaborated, and events with one or more of these attributes should be reported to the regulatory body. Such attributes would include the occurrence of, or the potential for, serious unintended or unexpected health effects due to radiation, the likelihood of a similar event occurring in other radiation therapy facilities, a large number of patients were affected, and gross misconduct or negligence by the responsible health professionals. As stated in para 5.270 above, one of the roles of the regulatory body for such a reported event is to disseminate information on the event and the lessons learned to all potentially affected parties – typically other radiation therapy facilities and relevant professional bodies, but also in some cases manufacturers, suppliers, and maintenance companies.

5.272. Irrespective of whether the event is also reported to the regulatory body, feedback to staff should be provided in a timely fashion and, where changes are recommended, all staff should be involved in bringing about their implementation.

Records and review

Radiological review

5.273. The BSS in paragraph 3.182 requires the performance of a periodic radiological review at the radiation therapy facility. This involves considering both justification and optimization aspects of radiation protection. For the latter, the results of the programme of quality assurance for medical exposures, including the periodic independent audit, would be a significant input to the process. As described in Section 2, paras. 2.146 - 2.147, the wider clinical audit could include the radiological review with its assessment of the application of the requirements for justification and optimization in the facility for the radiation therapy being performed [54, 417].

5.274. To facilitate compliance with the BSS, paragraph 3.182, and to learn from periodic reviews, the methodology used, the original physical, technical and clinical parameters considered, and the conclusions reached should be documented and taken into account prior to any new review that may result in an update of institutional policies.

5.275. In radiation therapy, reviews should consider patient outcome (survival, control of disease, acute and late side effects, etc.), the effect of introducing new technologies on efficiency and cost, such as, for example, the introduction of hypofractionation either for curative or palliative intent. The radiation therapy facility should have a system for the on-going collection of relevant data to support such reviews.

Records

5.276. Records should be in place to demonstrate on-going compliance with radiation protection requirements. The BSS, paragraphs 3.183 to 3.185, specify requirements for keeping personnel records, records of calibration, dosimetry and quality assurance, and records for medical exposure. These records should be kept for the period specified by the country's regulatory body. In the absence of such a requirement, a suggested period for keeping records is 10 years. In the case of children, records should be kept for a longer time.

5.277. In the case of records for a radiation therapy facility, care should be taken to also retain the records of the imaging radiological procedures (X ray and nuclear medicine) performed while preparing, planning, treating and verifying the treatment.

RADIATION PROTECTION OF THE PUBLIC

Introduction

5.278. Public exposure may arise, from the performance of radiation therapy, to persons in and around the radiation therapy facility.

5.279. The requirements of the BSS for public protection, paragraphs 3.117 - 3.123, 3.125 - 3.127, and 3.135 - 3.137, apply to radiation therapy facilities. This sub-section contains guidance very specific to radiation therapy facilities. For more general and comprehensive guidance on radiation protection of the public, reference should be made to the IAEA Safety Guide *Radiation Protection of the Public* [24].

Non-occupationally exposed workers and visitors

5.280. Non-occupationally exposed workers are those persons who work at the radiation therapy facility but not in a role that is directly involved in the use of radiation, for example clerical staff, and cleaning personnel. It also includes those persons who work at the wider medical facility where the radiation therapy facility is located. These persons are to be afforded the same level of radiation protection as any member of the public, as required by the BSS paragraph 3.78.

5.281. Visitors to the radiation therapy facility include those persons who will be undergoing radiation therapy but refers to the time during the visit when the treatment or other radiological procedure is not taking place. Similarly for carers and comforters – any exposure other than during the radiological procedure in which they are helping will be public exposure. Other visitors, including persons delivering goods or supplies, sales personnel, accompanying persons and escorts, and other patients in the facility, are also considered members of the public.

External exposure and contamination

5.282. The primary means for protecting the public (non-occupationally exposed workers and visitors) is to ensure that the shielding of the radiation therapy facility (see paras. 5.42 - 5.50) is sufficient so that public exposure resulting from being in any immediate adjacent areas, including rooms above and below, accessible by either non-occupationally exposed workers or visitors, would be in compliance with the public dose limits, and preferably less than any dose constraint that the regulatory body may have applied (see Section 2 paras. 2.16 - 2.17 and 2.46.)

5.283. Patients receiving permanent implants may expose members of the public in the radiation therapy facility and upon discharge. Patients receiving temporary implants may also expose members of the public in the radiation therapy facility. In the radiation therapy facility, the RPO should establish rules to ensure that the exposure of any member of the public will be less than the public dose limit and, preferably, lower than any applicable dose constraint. An acceptable method to estimate the acceptable retained activity for patients being discharged is described in para. 5.254. Assumptions made in these calculations with regard to time and distance should be consistent with the instructions given to patients at the time of discharge of the patient from the radiation therapy facility. Results of the calculations should be recorded. Examples of such calculations are given in Ref. [418].

5.284. When deciding on the appropriate activity at discharge for a particular patient, the licensee and RPO should take into account the transport and the living conditions of the patient, such as the extent to which the patient can be isolated from other family members and the need to manage safely the patient's excreta and body fluids that may contain a migrating source. In some cases, such as for elderly or child patients, it may be necessary to discuss the precautions to be taken with other family members.

5.285. Radiation protection precautions may be required after the death of a patient with permanent implants, for autopsy, embalming, burial or cremation. These precautions should be determined by the RPO, based on a generic safety assessment of the need for monitoring personnel who carry out these procedures, the need for monitoring the premises and the need for minimizing external radiation exposure and the potential for contamination. Whole body monitoring and finger monitoring may be required for autopsy and embalming personnel, as contamination and radioactive waste are likely to be generated [383]. Other considerations, such as cultural or ethical concerns, should be taken into account. A particular example is the cremation of patients with permanent implants, where strict radiation protection considerations would indicate the need to store the ashes until adequate decay has been achieved before releasing them to the family.

Control of access

5.286. Access to areas where radiation is being used should be controlled to provide for controlling doses to visitors and non-occupationally exposed workers. Visitors should not be allowed to enter treatment rooms or other controlled areas while in use. Exceptionally, a visitor may be permitted to enter a controlled or supervised area, accompanied at all times by a staff member who knows the protection and safety measures for the area. The radiation therapy facility should have written

procedures specifying when such exceptions can take place and who may do the accompanying. Similarly, the facility should have established the rules regarding non-occupationally exposed workers, especially regarding access to controlled and supervised areas. Particular attention, in all cases, should be made with respect to potentially pregnant women.

5.287. Controlled and supervised areas should be clearly identified to help prevent inadvertent entry to areas where treatment or other radiological procedures are being performed. See also para. 5.19. Further control can be afforded by the use of keys (or passwords) to restrict access to the control panels of medical radiological equipment to only authorized persons.

Radioactive sources no longer in use

5.288. When radioactive sources in the radiation therapy facility become surplus to requirements or are no longer viable for their medical purpose, the licensee should ensure that the sources are either transferred or disposed of, appropriately. The licensee retains responsibility for the sources until the time of their transfer to another appropriate licensee or to an authorized waste disposal facility. Detailed guidance on the management of radioactive waste, applicable to radiation therapy facilities, is given in Ref [283].

5.289. Specifically for radioactive source teletherapy equipment, the licensee should:

(a) Notify the regulatory body of any intention to transfer or decommission ⁶⁰Co teletherapy equipment prior to initiating an action. Depleted uranium used as shielding material should also be treated as radioactive waste. For example, a ⁶⁰Co teletherapy head may contain depleted uranium and is to be managed appropriately.

(b) Ensure that resources for the disposal of the sources will be made available when the teletherapy equipment is to be decommissioned.

5.290. Regulatory bodies may need to require applicants for licences to have in place a programme for safe disposal or return of the radioactive sources when their use is discontinued, before authorization for the import or purchase of equipment or radiation sources is given. A contract with the manufacturer or representative for the return of sources is acceptable evidence of such a programme.

Monitoring and reporting

5.291. The programme for monitoring public exposure arising from radiation therapy should include dose assessment in the areas in and surrounding the radiation therapy facility 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 and periodically thereafter. Records of these assessments should be kept for typically 7-10 years, but in any case for a period that meets any relevant regulatory requirements.

PREVENTION AND MITIGATION OF ACCIDENTS

Safety assessments

5.292. To comply with the BSS requirements for safety assessment (paragraphs 3.29 to 3.36), , the registrant or licensee should conduct a safety assessment applied to all stages of the design and

operation of the radiotherapy facility. The safety assessment report should to be submitted to the regulatory body if required. Basically, the safety assessment deals with determining 'what can go wrong' and how it can be prevented and, in case it occurs, how it can be mitigated. Section 2, paras 2.148 - 2.152, describes general considerations for facilities using ionizing radiation for medical purposes.

5.293. The safety assessment should be systematic and contain information on identification of possible events leading to accidental exposure. Information on events, causes and contributing factors identified from reported accidents is available in Refs. [282, 378, 380, 381, 405, 406, 411 - 414] (see also Appendix I for a summary of typical causes and contributing factors to accidental exposures in radiation therapy). The safety assessment should not only cover these events, but also aim at anticipating other events that have not previously been reported. Clearly the safety assessment should be documented.

5.294. The safety assessment should be revised when:

- (a) New or modified radiation sources are introduced including equipment and new or renovated facilities
- (b) Operational changes occur, including workload;

(c) Operational experience or information on accidents or errors indicates that the safety assessment is to be reviewed.

5.295. Safety assessments in radiation therapy facilities performing brachytherapy or teletherapy with sealed sources should consider additional steps associated with sealed sources, including ordering, transport and receipt of sealed sources, unpacking, storage, preparation and handling of the sources prior to the use in the treatment of the patient, care of patients with high amounts of activity, and storage and handling of sources after removal and the management of unused radioactive seeds.

5.296. The performance of safety assessments in radiation therapy can be complemented by participation in international networks to share information, such as SAFRON and ROSIS [18, 20] or national ones such as ROILS and NRLS [415, 416]. In order to ensure that the safety assessment is comprehensive and is not restricted to past events but also anticipates other possible events, consideration should also be given to using systematic techniques, e.g. fault and event trees and probabilistic safety assessment technique, such as described for unintended or accidental medical exposure of patients in paras 5.264.

5.297. For radiation therapy, as discussed in para 5.259, possible scenarios for potential exposure include flaws in the design of medical radiological equipment, failures of medical radiological equipment while in operation, failures and errors in software that control or influence the delivery of the radiation, and human error. Potential exposure can also arise from imaging during patient preparation, simulation in treatment planning and guidance during.

Accident prevention

5.298. Accident prevention is clearly the best means for avoiding potential exposure and the BSS, paragraphs 3.39 to 3.41, set out requirements based on good engineering practice, defence in depth, and facility-based arrangements to achieve this. Design considerations for medical radiological equipment, ancillary equipment and the radiation therapy facility are described in paras 5.8 to 5.83.

5.299. The licensee should incorporate:

(a) Defence in depth measures to cope with identified events, and evaluation of the reliability of the safety systems (including administrative and operational procedures, equipment and facility design).(b) Operational experience and lessons learned from accidents and errors [282, 380, 411]. This information should be incorporated into the education and training, maintenance and quality assurance programmes.

Mitigation and contingency plans

5.300. On the basis of events identified by the safety assessment for the radiotherapy facility, contingency plans should be prepared for events associated with potential exposure, including allocation of responsibilities and resources, the development and implementation of procedures, and the provision of training and periodic retraining of the relevant staff in executing the mitigation measures. Such contingency plans should be based on the events identified by the safety assessment for the radiation therapy facility.

5.301. The exposure of workers involved in such radiation therapy events cannot be considered an unexpected exposure and whether deliberate or not should be controlled, and the dose limits for workers in planned exposure situations should apply.

5.302. For medical exposure, potential exposure when it does occur is manifest as an unintended or accidental medical exposure. Means for preventing or minimizing unintended and accidental medical exposures in radiation therapy are described in paras. 5.259 - 5.266, and the ensuing investigation and corrective actions are described in paras. 5.267 - 5.272.

5.303. The BSS, paragraphs 3.43 to 3.44, sets out the requirements for emergency preparedness and response. Situations that may be treated as emergency should be identified in the safety assessment, and emergency plan should be prepared according to the requirements in the GSR Part 7 and guidelines by the regulatory authority [7]. Potential situations that can lead to emergency in radiotherapy department settings are loss of control over a dangerous radiation therapy source in result of unauthorized or malicious act, or conventional emergencies such as fires and earthquakes.

Stuck sources, general

5.304. Contingency procedures should be short, concise, unambiguous and, if necessary, illustrated with drawings without explanatory text. They should be able to be read at 'first sight' and followed. It should be made clear that the first sight procedures refer to actions to be taken immediately to prevent or limit serious overexposures, or take other lifesaving actions [396]. Further actions to recover the sources, to repair and test the equipment for returning it to use, are not directly part of the contingency response. The occupational protection requirements, including dose limits, will apply to these subsequent actions.

5.305. In radiation therapy, however, the patient is directly in the radiation beam or brachytherapy sources are placed inside the patient; for this reason some of the contingency response actions coincide with source recovery actions, for example the retrieval of remote control brachytherapy sources from the patient to the safe, either manually, electrically or using the manual crank.

Stuck sources, cobalt 60

5.306. Contingency procedures should be posted at the treatment unit. These procedures should ensure that the patient is removed from the primary beam as quickly and efficiently as possible whilst minimizing unnecessary exposure to the involved personnel.

5.307. In the case of an event, the first step is to note the time, and immediately use the source driving mechanism to return the source to the shielded position. If there is a patient on the treatment couch, the patient should be removed from the area and the area should be secured from further entry. Emphasis should be placed on avoiding exposure of personnel to the primary beam. The medical physicist or radiation protection officer should notified and take control of the situation, including deciding when it is safe to re-enter the room. Before resuming patient treatment, the medical physicist should check the calibration of the radiation therapy and verify that it has not changed, particularly the timer error in Co-60 teletherapy units.

5.308. Actions are to be performed only by personnel that have been educated and trained in the contingency actions understand them and have regularly rehearsed the procedures. The actions required should be performed within seconds. Therefore personnel present in all procedures, i.e. the staff on the unit, should be educated and trained in these actions.

5.309. After the contingency actions, the following should be done:

(a) The maintenance or service engineer should be contacted to perform an inspection of the machine;

(b) The medical physicist should assess the patient doses and clear the use of the machine after the ensuing maintenance;

(c) The radiation protection officer should assess the doses to personnel as a result of the contingency actions and recovery operations;

(d) A record should be kept of all actions;

(e) The regulatory body may need to be notified, depending on the country's regulations;

(f) Information should be sent to an international safety learning system such as SAFRON or ROSIS [20, 22] or national ones [415, 416].

Stuck sources, remote control brachytherapy units

5.310. Contingency plans require having an emergency container available in the treatment room, as well as an emergency kit containing long handled forceps for manipulation of the source guide tubes, and applicators if the source fails to return to the safe, as stated in paras. 5.129 and 5.131. The emergency container should be placed close to the patient and should be sufficiently large to accept the entire applicator assembly containing the source which has been removed from a patient.

5.311. In HDR applications the short response time required for contingency actions (minutes) imposes the need for the immediate availability of a radiological medical practitioner, a medical physicist and a medical radiation technologist during all applications. Each one of these professionals should be educated and trained in contingency procedures and actions.

5.312. Manufacturers usually provide suggested contingency procedures if the source fails to return to the safe. They assume that the physical integrity of the applicator is maintained. These procedures are specific to the actual afterloading unit but generally involve a standard sequence, as detailed in para. 5.132.

5.313. After the contingency actions have been successful, the following should be done:

(a) The maintenance or service engineer should be contacted to perform an inspection and, if necessary, repair the machine;

(b) The medical physicist should make an assessment of the patient doses arising from the incident, and clear the re-use of the machine after the ensuing maintenance;

(c) The radiation protection officer should make an assessment of the dose to personnel involved in the contingency actions and recovery operations;

(d) The assessments should be recorded;

(e) The regulatory body may need to be notified, depending on the country's regulations.(f) Information should be sent to an international safety learning system such as SAFRON or ROSIS [19, 21] or national ones [415, 416].

Incidents during source replacement

5.314. Only trained and authorized maintenance or servicing personnel should handle incidents during a source change of external beam therapy and remote control brachytherapy units. If the participation of radiation therapy personnel is necessary for any of these actions, the scope of this participation should be limited to operating the equipment. The respective responsibilities of radiation therapy personnel and maintenance or servicing personnel for these specific situations should be clearly defined.

Contamination

5.315. Although ²²⁶Ra has been removed from most radiation therapy facilities, encapsulated ¹³⁷Cs sources used in manual afterloading still exist, and there is always a possibility that the encapsulation may rupture. In the case of a contamination event the area should be closed to further entry and that all who were in the area remain to be surveyed and decontaminated if necessary. If there are windows or other ventilation systems, these should be closed or turned off. The radiation protection officer should be contacted immediately once the possibility of contamination is suspected. Contact details for the radiation protection officer should be posted throughout the radiation therapy facility.

Lost radiation therapy sources

5.316. A detailed, up to date inventory of all sources should be maintained by the RPO of the radiation therapy facility so that it can be determined immediately which sources are missing, their type and activity, their last known location, and who last had possession of them. The area where the sources were last known to be should be closed to entry and exit until after a survey. This search should be performed with the most sensitive radiation detection survey meter available.

5.317. When the source cannot be located and it is suspected that it is off site, emergency plan should be followed, according to the requirements in the BSS ([3], Section 4) for emergency exposure situations. Thee regulatory body should be informed immediately. These situations typically require actions by national intervention organizations [7].

SAFETY IN THE TRANSPORT OF RADIOACTIVE MATERIALS

5.318. The BSS paragraph 2.25 sets out the requirements for the transport of radioactive materials, invoking in particular the IAEA Regulations for the Safe Transport of Radioactive material [266]. The IAEA Regulations for the Safe Transport of Radioactive material use the defined terms "consignor" to mean any person, organization or government that prepares a consignment for transport, and "consignee" to mean any person, organization or government that is entitled to take delivery of a consignment. "Consignment" is also a defined term, meaning any package or packages, or load of radioactive material, presented by a consignor for transport.

5.319. The licensee of a radiation therapy facility may be both a consignee and a consignor, and hence may have responsibilities for both receipt and shipment of radioactive sources – for example, external beam sources and brachytherapy sources.

5.320. The detailed requirements for the safe transport of radioactive material, including general provisions, activity limits and classification, requirements and controls for transport, requirements for radioactive material and for packagings and packages, test procedures, and approval and administrative requirements, are given in the IAEA Regulations for the Safe Transport of Radioactive material [283]. Emergency arrangements during the transport of radioactive material should be in place, in line with the requirements in the GSR Part 7 and guidelines by the regulatory authority [7]. The licensee and the RPO of the radiation therapy facility should be familiar with these regulations to ensure that their transport of radioactive materials will be in compliance.

APPENDIX I

SUMMARY OF TYPICAL CAUSES OF AND CONTRIBUTING FACTORS TO ACCIDENTAL EXPOSURES IN MEDICAL USES OF IONIZING RADIATION

DIAGNOSTIC RADIOLOGY AND INTERVENTIONAL PROCEDURES

I.1. Problems leading to accidental exposures associated with using radiation in diagnostic radiology and image guided interventional procedures that have been identified from reported events include:

- Equipment not meeting IEC or equivalent national standards;
- Maintenance errors;
- Errors in the identification of patients and examination sites;
- Inappropriate or lack of examination protocols.

I.2. Factors that may influence the frequency and severity of accidental exposures include:

- Insufficient training and expertise of radiological medical practitioners (in particular interventionists), medical physicists or medical radiation technologists;
 - Lack of knowledge about the equipment being used and its features and options;
 - Lack of knowledge about optimization of protection for patients;
 - Lack of knowledge about optimization of protection for staff;
- No reassessment of staffing requirements after purchasing new equipment or increasing workload;
- Inadequate quality assurance and lack of defence in depth;
 - Dose rates for interventional equipment set too high;
 - AEC malfunction;
- Lack of a programme for acceptance tests and commissioning of equipment;
- Lack of a maintenance programme;
- Poor, misunderstood or violated procedures;
- Lack of operating documents in a language understandable to users;
- Lack of dose or dose rate display during a procedure;
- Lack of dose alerts if selected factors seem inappropriate;
- Lack of radiation protection tools and devices in the examination room;
- Misunderstanding of displays or software messages;
- Inattention;
- Inconsistent use of different quantities and units.

I.3. In most accidental exposures there was a combination of several contributing factors, which can be summarized as:

- Lack of commitment of the licensee (medical facility and/or radiology facility administrators and managers);
- Staff insufficiently trained;
- Insufficient quality assurance.

NUCLEAR MEDICINE

I.4. Problems leading to accidental exposures associated with using radiation in nuclear medicine that have been identified from reported events include:

- Communication errors, faulty transmission of information, misunderstanding of prescriptions and protocols, or use of obsolete protocols;
- Errors in the identification of the patient;
- Use of the wrong source, the wrong radiopharmaceutical or the wrong activity;
- Calibration errors;
- Maintenance errors.

I.5. Factors that may influence the frequency and severity of accidental exposures include:

- Insufficient training and expertise of radiological medical practitioners (nuclear medicine physicians), medical physicists or medical radiation technologists (nuclear medicine technologists);
- No reassessment of staffing requirements after purchasing new equipment, hiring new medical radiation technologists or increasing workload;
- Inadequate quality assurance and lack of defence in depth;
- Lack of a programme for acceptance tests and commissioning of equipment;
- Lack of a maintenance programme;
- Poor, misunderstood or violated procedures;
- Lack of operating documents in a language understandable to users;
- Misunderstanding of displays or software messages;
- Inattention;
- Inconsistent use of different quantities and units.

I.6. In most accidental exposures there was a combination of several contributing factors, which can be summarized as:

- Lack of commitment of the licensee (medical facility and/or nuclear medicine facility administrators and managers);
- Staff insufficiently briefed or trained;
- Insufficient quality assurance.

RADIATION THERAPY

I.7. Problems leading to accidental exposures associated with using radiation in radiation therapy that have been identified from reported events include:

Common to external beam radiation therapy and brachytherapy:

- Equipment not meeting IEC or equivalent national standards;
- Maintenance errors;
- Errors in the identification of patients and treatment sites;
- Conflicting signals and displays misinterpreted or not followed up;
- Communication errors, transmission of information and misunderstanding of prescriptions and protocols, or use of obsolete protocols;
- Use of obsolete files and forms which were still accessible.

External beam radiation therapy:

- Errors in acceptance tests and commissioning or lack of tests of both radiation equipment and sources and TPSs;
- Errors in the calibration of radiotherapy beams;
- Errors in the preparation of tables and curves from which the treatment time is calculated;
- Errors in the use of TPSs for individual patients.

Brachytherapy:

- Using an incorrect source or incorrect units of source strength;
- Dislodging of HDR brachytherapy sources;
- Mistakes in source handling by nurses during brachytherapy treatment;
- Leakage of sealed sources;
- Sources left in patients and loss of radiation sources.

I.8. The following contributing factors allowed these errors to remain undetected until they became accidental medical exposures:

- Insufficient education of the radiological medical practitioner (radiation oncologist), medical physicist, medical radiation technologist (radiotherapy technologist), maintenance engineers and brachytherapy nurses;
- Overloaded staff when new equipment was purchased or workload increased;
- Insufficient quality assurance and lack of independent checks for safety critical activities, such as beam calibration;
- Lack of a programme for acceptance testing and commissioning;
- Lack of a maintenance programme;
- Poor, misunderstood or violated procedures;
- Lack of operating documents in a language understandable to the users;
- Inattention (environment prone to distraction);
- Inconsistent use of quantities and units.

I.9. In a number of the reported accidents there was a combination of several of the above contributing factors. Concurrent occurrence of several contributing factors may be indicative of a more general problem involving:

- Lack of commitment of the licensee (medical facility and/or radiation therapy facility administrators and managers);
- Insufficiently educated or trained staff;
- Insufficient quality assurance and defence in depth.

APPENDIX II AVOIDANCE OF PREGNANCY FOLLOWING RADIOPHARMACEUTICAL THERAPY

II.1 The periods for which it is recommended to avoid pregnancy following radiopharmaceutical therapy with long-lived radionuclides are given in Table 3, adapted from Ref [251].

TABLE 3. RECOMMENDATIONS FOR AVOIDANCE OF PREGNANCY FOLLOWING RADIOPHARMACEUTICAL THERAPY

Nuclide and form	Disease	All activities up to* (MBq)	Avoid pregnancy (months)
³² P-phosphate	Polycythaemia and related disorders	200	3
⁸⁹ Sr-chloride	Bone metastases	150	24
90Y-colloid	Arthritic joints	400	0
90Y-colloid	Cancer	4000	1
¹³¹ I-iodide	Thyrotoxicosis/non-toxic goitre	800	6 (at least)
¹³¹ I-iodide	Thyroid cancer	6000	6 (at least)
¹³¹ I MIBG	Phaeochromocytoma	7500	3
¹⁵³ Sm-colloid	Bone metastases	2600	1
¹⁶⁹ Er-colloid	Arthritic joints	400	0

* Note: The administration of activities smaller than those indicated in column 3 does not imply that the advisory period specified in column 4 may be reduced.

APPENDIX III CESSATION OF BREAST FEEDING

III.1. Recommendations for cessation of breast feeding following administration of various radiopharmaceuticals for diagnostic procedures are given in Table 4, adapted from the recommendations of Refs. [214, 247, 251]. In addition, it is recommended that there is a cessation period of 4 hours for breast-feeding patients undergoing a PET procedure with ¹⁸F-FDG, taking into account both exposure from breast milk and external exposure to the baby while being fed [65].

TABLE 4. RECOMMENDATIONS FOR CESSATION OF BREAST FEEDING FORRADIOPHARMACEUTICALS IN DIAGNOSTIC EXAMINATIONS

Radiopharmaceutical	Administered activity to the mother, MBq (mCi)	Need for counselling	Advice
³² P-phosphate	Any	Yes	Cessation
⁵¹ Cr-EDTA	1.85 (0.05)	No	
⁶⁷ Ga-citrate	185 (5.0)	Yes	Cessation
^{81m} Kr-gas	6000 (160)	No	
99mTc-DISIDA	300 (8)	No	
^{99m} Tc-DMSA	80 (2)	No	
^{99m} Tc-DTPA	740 (20)	No	
^{99m} Tc-exametazime	500 (14)	No	
^{99m} Tc-glucoheptonate	740 (20)	No	
^{99m} Tc-HAM	300 (8)	No	
99mTc-MAA	148 (4)	Yes	Cessation for 12 hours
^{99m} Tc-MDP	740 (20)	No	
^{99m} Tc-MIBI	1110 (30)	No	
^{99m} Tc-pertechnetate	800 (20)	Yes	Cessation for 40 hours
^{99m} Tc-PYP	740 (20)	No	
^{99m} Tc-RBCs in vitro	740 (20)	No	
99mTc-RBCs in vivo	740 (20)	Yes	Cessation for 12 hours
^{99m} Tc-sulphur colloid	444 (12)	No	

^{99m} Tc-DTPA aerosol	37 (1)	No	
99mTc-MAG3	370 (10)	No	
^{99m} Tc-WBCs	185 (5)	Yes	Cessation for 48 hours
¹¹¹ In-WBCs	18.5 (0.5)	No	
¹²³ I-MIBG	370 (10)	Yes	Cessation for 48 hours
¹²³ I-NaI	14.8 (0.4)	Yes	Cessation
¹²³ I-OIH	74 (2)	No	
¹²⁵ I-fibrinogen	Any	Yes	Cessation
¹²⁵ I-HSA	Any	Yes	Cessation
¹²⁵ I-OIH	0.37 (0.01)	No	
¹³¹ I-NaI	5550 (150)	Yes	Cessation
¹³¹ I-OIH	11.1 (0.3)	No	
²⁰¹ Tl	111 (3)	Yes	Cessation for 96 hours

Note: The abbreviations used in this table are as follows:

DISIDA, di-isopropyl-iminodiacetic acid;

DMSA, dimercaptosuccinic acid;

DTPA, diethylene-triamine-penta-acetic acid;

EDTA, ethylene-diamine-tetra-acetic acid;

HAM, human albumin microsphere;

HAS, human serum albumin;

MAA, macro-aggregated albumin;

MAG3, mercapto-acetyl-triglycine;

MDP, methylene diphosphonate;

MIBG, meta-iodo-benzyl-guanidine;

MIBI, methoxy-isobutyl-isonitrile;

OIH, ortho-iodo-hippurate;

PYP, pyrophosphate;

RBCs, red blood cells;

WBCs, white blood cells;

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