IAEA Safety Standards

for protecting people and the environment

Radiation Protection and Safety in Medical Uses of Ionizing Radiation

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Specific Safety Guide

No. SSG-46

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International Atomic Energy Agency

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IAEA SAFETY STANDARDS

Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

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The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at: Vienna International Centre, PO Box 100, 1400 Vienna, Austria.

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Security related publications are issued in the **IAEA Nuclear Security Series**.

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RADIATION PROTECTION AND SAFETY IN MEDICAL USES OF IONIZING RADIATION

The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

IAEA SAFETY STANDARDS SERIES No. SSG-46

RADIATION PROTECTION AND SAFETY IN MEDICAL USES OF IONIZING RADIATION

SPECIFIC SAFETY GUIDE

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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2018

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FOREWORD

by Yukiya Amano
Director General

The IAEA's Statute authorizes the Agency to "establish or adopt… standards of safety for protection of health and minimization of danger to life and property" — standards that the IAEA must use in its own operations, and which States can apply by means of their regulatory provisions for nuclear and radiation safety. The IAEA does this in consultation with the competent organs of the United Nations and with the specialized agencies concerned. A comprehensive set of high quality standards under regular review is a key element of a stable and sustainable global safety regime, as is the IAEA's assistance in their application.

The IAEA commenced its safety standards programme in 1958. The emphasis placed on quality, fitness for purpose and continuous improvement has led to the widespread use of the IAEA standards throughout the world. The Safety Standards Series now includes unified Fundamental Safety Principles, which represent an international consensus on what must constitute a high level of protection and safety. With the strong support of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its standards.

Standards are only effective if they are properly applied in practice. The IAEA's safety services encompass design, siting and engineering safety, operational safety, radiation safety, safe transport of radioactive material and safe management of radioactive waste, as well as governmental organization, regulatory matters and safety culture in organizations. These safety services assist Member States in the application of the standards and enable valuable experience and insights to be shared.

Regulating safety is a national responsibility, and many States have decided to adopt the IAEA's standards for use in their national regulations. For parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by regulatory bodies and operators around the world to enhance safety in nuclear power generation and in nuclear applications in medicine, industry, agriculture and research.

Safety is not an end in itself but a prerequisite for the purpose of the protection of people in all States and of the environment — now and in the future. The risks associated with ionizing radiation must be assessed and controlled without unduly limiting the contribution of nuclear energy to equitable and sustainable development. Governments, regulatory bodies and operators everywhere must ensure that nuclear material and radiation sources are used beneficially, safely and ethically. The IAEA safety standards are designed to facilitate this, and I encourage all Member States to make use of them.

PREFACE

In 2006, the IAEA published the Fundamental Safety Principles (IAEA Safety Standards Series No. SF-1), which 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 (GSR Part 3, 2014).

This Safety Guide provides recommendations and guidance on fulfilling the requirements of GSR Part 3 with respect to medical uses of ionizing radiation, addressing all three categories of exposure: medical exposure, primarily of patients undergoing the radiological procedures but also of carers and comforters and of volunteers subject to exposure as part of a programme of medical research; occupational exposure of health professionals performing radiological procedures; and exposure of members of the public. Recommendations and guidance are provided on applying a systematic approach to ensure that there is a balance between utilizing the benefits from medical uses of ionizing radiation and minimizing the risk of radiation effects on patients, workers and members of the public.

This Safety Guide supersedes Radiological Protection for Medical Exposure to Ionizing Radiation (RS-G-1.5, 2002) and three publications of the Safety Reports Series: namely Applying Radiation Safety Standards in Radiotherapy (No. 38, 2006); Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays (No. 39, 2006); and Applying Radiation Safety Standards in Nuclear Medicine (No. 40, 2005).

This Safety Guide is jointly sponsored by the IAEA, the International Labour Office, the Pan American Health Organization and the World Health Organization. The IAEA gratefully acknowledges the contribution of experts from the European Society for Radiotherapy and Oncology, the International Organization for Medical Physics, the International Society of Radiographers and Radiological Technologists, the International Society of Radiology and the World Federation of Nuclear Medicine and Biology to the drafting and review of the text.

THE IAEA SAFETY STANDARDS

BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care, and are expected to fulfil their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property, and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation, and to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and security measures[1] have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1).

Safety Fundamentals

Safety Fundamentals present the fundamental safety objective and principles of protection and safety, and provide the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. Requirements, including numbered ‘overarching’ requirements, are expressed as ‘shall’ statements. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

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[1] See also publications issued in the IAEA Nuclear Security Series.

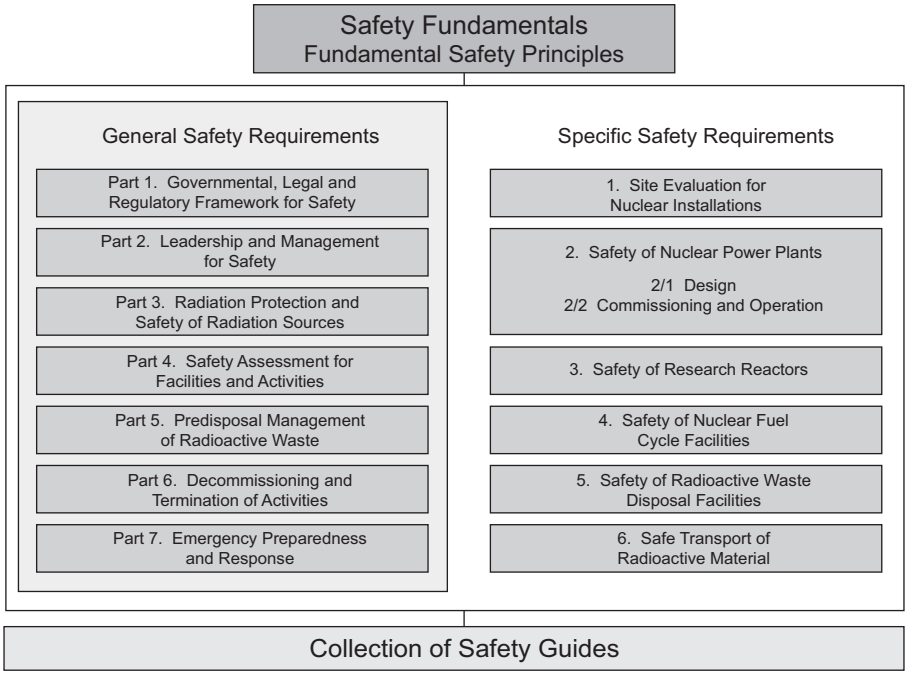

FIG. 1. The long term structure of the IAEA Safety Standards Series.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as 'should' statements.

APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including the development of educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to be assessed at the national level. For example, many of the IAEA safety standards, in particular those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and five safety standards committees, for emergency preparedness and response (EPReSC) (as of 2016), nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of

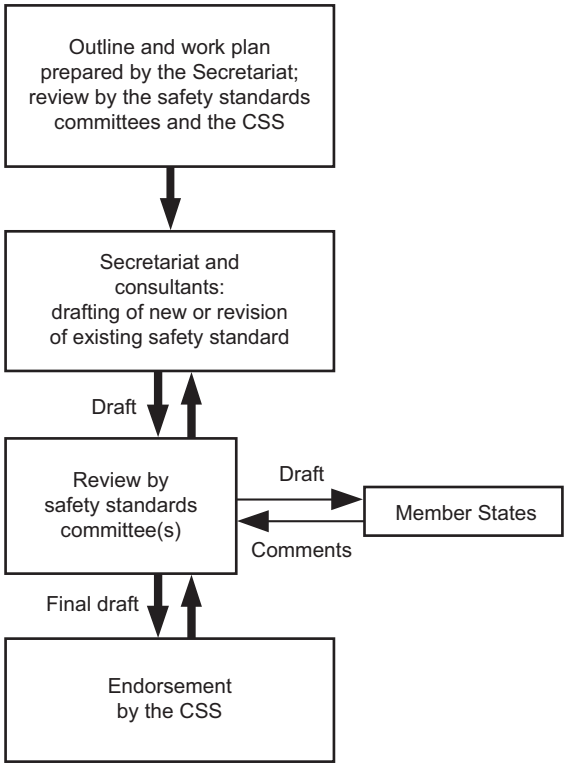

FIG. 2. The process for developing a new safety standard or revising an existing standard.

the Commission on Safety Standards is appointed by the Director General and includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards. It articulates the mandate of the IAEA, the vision for the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international

expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

INTERPRETATION OF THE TEXT

Safety related terms are to be understood as defined in the IAEA Safety Glossary (see http://www-ns.iaea.org/standards/safety-glossary.htm). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard in the IAEA Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text, and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. Annexes and footnotes are not integral parts of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material under other authorship may be presented in annexes to the safety standards. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

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1. INTRODUCTION

BACKGROUND

1.1. Medical uses of ionizing radiation are among the longest established applications of ionizing radiation. In 2008, the estimated worldwide annual number of diagnostic and interventional radiological procedures (including dental) was 3.6 billion, the estimated number of nuclear medicine procedures was over 30 million, and the estimated number of radiation therapy procedures was over 5 million [1]. The number of such procedures has continued to increase since then. 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 utilizing 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 have a place only in the context of medical practice. The system for ensuring radiation protection and safety should form part of the larger system for ensuring good medical practice. This Safety Guide focuses on the system of radiation protection and safety.

1.4. IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [2], presents the fundamental safety objective and principles of protection and safety. Requirements designed to meet this objective and these principles are established in IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [3].

1.5. This Safety Guide provides guidance on fulfilling the requirements of GSR Part 3 [3] 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 protection and safety that covers medical uses of ionizing radiation.

1.8. This Safety Guide supersedes IAEA Safety Standards Series No. RS-G-1.5, Radiological Protection for Medical Exposure to Ionizing Radiation, issued in 2002, and several Safety Reports issued by the IAEA in 2005 and 2006.[1]

1.9. Unless otherwise stated, terms in this publication are to be understood as defined and explained in GSR Part 3 [3] or the IAEA Safety Glossary [5].

OBJECTIVE

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

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 as established in GSR Part 3 [3], and these publications should be used together. This Safety Guide is aimed primarily at end-users in medical radiation facilities in which radiological procedures are performed, including managers, radiological medical practitioners, medical radiation technologists, medical

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[1] INTERNATIONAL ATOMIC ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Radiological Protection for Medical Exposure to Ionizing Radiation, IAEA Safety Standards Series No. RS-G-1.5, IAEA, Vienna (2002).
EUROPEAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Applying Radiation Safety Standards in Radiotherapy, Safety Reports Series No. 38, IAEA, Vienna (2006).
INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS, INTERNATIONAL SOCIETY OF RADIOLOGY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays, Safety Reports Series No. 39, IAEA, Vienna (2006).
INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, INTERNATIONAL ORGANIZATION FOR MEDICAL PHYSICS, PAN AMERICAN HEALTH ORGANIZATION, WORLD FEDERATION OF NUCLEAR MEDICINE AND BIOLOGY, WORLD HEALTH ORGANIZATION, Applying Radiation Safety Standards in Nuclear Medicine, Safety Reports Series No. 40, IAEA, Vienna (2005).

physicists, radiation protection officers (RPOs) and other health professionals. It also provides recommendations and guidance to: health professionals who refer patients for radiological procedures; manufacturers and suppliers of medical radiological equipment; and ethics committees with responsibilities for biomedical research. National requirements may vary, being stricter in some States; the related national regulations and guidelines should be known and followed.

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, gastroenterology, obstetrics and gynaecology, emergency medicine, anaesthetics and pain management.

1.14. Depending on the laws and regulations in the 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.[2]

STRUCTURE

1.16. Following this introductory section, Section 2 provides 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 provide recommendations for specific areas of medical uses of ionizing radiation: Section 3 covers diagnostic radiology and image guided interventional procedures; Section 4 covers nuclear medicine; and Section 5 covers radiation therapy. Guidance for hybrid modalities is addressed in the relevant sections, as appropriate.

1.18. Appendix I provides summary guidance on typical causes of, and contributing factors to, accidental exposure in medical uses of radiation. Appendices II and III provide recommendations on the avoidance of pregnancy following radiopharmaceutical therapy and on the cessation of breast-feeding following administration of radiopharmaceuticals for nuclear medicine, respectively.

1.19. It is important to note that the sections on specific areas (Sections 3–5) should always be read in conjunction with Section 2. In addition, each section should be considered in its entirety.

[2] A Safety Guide on non-medical human imaging is in preparation. Guidance on the justification of non-medical human imaging is provided in IAEA Safety Standards Series No. GSG-5, Justification of Practices, Including Non-medical Human Imaging [6].

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

GENERAL

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. A medical radiation facility is the term used in GSR Part 3 [3] to cover all such possible settings. A medical radiation facility may provide services for one or more medical uses of radiation. For example, a large hospital typically has 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 such 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 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. Within this Safety Guide, cross-references are provided where appropriate when such systems are addressed.

2.3. As stated in paras 1.13 and 1.14, the setting for this Safety Guide is the practice of medicine (including dentistry, chiropractic, osteopathy and podiatry). The requirements of GSR Part 3 [3] for radiation protection and safety of radiation sources apply to the uses of radiation in medicine as for elsewhere. The requirements should be met and included within medical structures and processes and in medical guidelines, with the objective of improved patient care and patient outcomes.

TYPES OF EXPOSURE SITUATION AND CATEGORIES OF EXPOSURE

2.4. The requirements of GSR Part 3 [3] are structured according to the three types of exposure situation: 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 GSR Part 3 [3] apply, as appropriate. This includes situations of potential exposure, which is defined in para. 1.20(a) of GSR Part 3 [3] as 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". Potential exposure can be applicable for any occupational, public and medical exposure where the event, if it occurs, results in an exposure over and above what would be expected normally. Unintended and accidental medical exposures should be treated as planned exposure situations (para. 3.145 of GSR Part 3 [3], see Table 1). Sections 2–5 of this Safety Guide cover the prevention and mitigation of the consequences of events leading to a potential exposure. In extreme situations in medical facilities of emergency preparedness category III [7] (such as a radiation therapy facility), an emergency exposure situation may occur that affects either workers or members of the public. For preparedness and response for emergency exposure situations, the applicable requirements include section 4 of GSR Part 3 [3] and IAEA Safety Standards Series Nos GSR Part 7 [7], GSG-2 [8] and GS-G-2.1 [9].

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. A nurse working on an inpatient ward where occasional mobile radiography is performed by a medical radiation technologist would also be considered to be occupationally exposed; however, because in this case the radiation source is not required by or directly related to the work, this nurse should be provided with the same level of protection as members of the public (see para. 3.78 of GSR Part 3 [3]). The term 'carer and comforter' is defined in GSR Part 3 [3] as: "Persons who willingly and voluntarily help (other than in their occupation) in the care, support and comfort of patients undergoing radiological procedures for medical diagnosis or medical treatment." 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 of this Safety Guide.

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

Application to occupational exposure and public exposure	Application to medical exposure
Justification of practices: Adopting a practice that entails exposure to radiation only if it yields sufficient benefit to the exposed individuals or to society to outweigh the radiation detriment.	Justification of practices: The diagnostic or therapeutic benefits of exposure are weighed against the radiation detriment they might cause, with account taken of the benefits and risks of available alternative techniques that do not involve medical exposure.
Optimization of protection and safety: Providing the best available protection and safety measures under the prevailing circumstances, so that the magnitudes and likelihood of exposures and the numbers of individuals exposed are as low as reasonably achievable, 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 exposure and public exposure).	Limitation of doses: Does not apply to medical exposure.

2.6. Unintended and accidental medical exposures are covered in detail in Sections 3–5. Such events include any medical treatment or diagnostic procedure in which the wrong individual is exposed.[3]

[3] The definition of medical exposure in GSR Part 3 [3] was changed from that used previously to ensure that the event of the wrong individual being exposed 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.

APPLICATION OF THE RADIATION PROTECTION REQUIREMENTS

2.7. The three general principles of radiation protection, namely justification, optimization of protection and safety, and the application of dose limits, are expressed in Principles 4–6 and 10 of the Fundamental Safety Principles [2]. In terms of Requirement 1 of GSR Part 3 [3], those responsible for protection and safety are required to 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 exposure, 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 or not the exposure will take place. If it is to take place, the radiological procedure should be performed in such a way that radiation protection and safety is optimized.

Justification

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

2.10. From an occupational exposure 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 who undergo the procedure and to society that outweigh the harm (including radiation detriment) resulting from the procedure. In almost all cases, the occupational exposure and public exposure considerations in justification are overshadowed by the justification of medical exposure (see para. 2.11). While a medical radiological procedure is expected to do more good than harm to the patient, account should also be taken of the radiation detriment from the exposure of the staff of the medical radiation facility and of other individuals.

2.11. The application of the justification principle to medical exposure requires a special approach, using three levels (the three-level approach). As an overarching justification of medical exposure, it is accepted that the proper use of radiation in medicine does more good than harm (level 1). At the next level (level 2), generic justification of a given radiological procedure should be carried out by the health

authority in conjunction with appropriate professional bodies. This applies to the justification of current technologies and techniques and new technologies and techniques as they evolve. 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. Those radiological procedures that are no longer justified should be removed from medical practice. The possibility of accidental or unintended exposure should also be considered at level 2. For the final level of justification (level 3), the application of the radiological procedure to a given individual patient 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, are required to be used (para. 3.158 of GSR Part 3 [3]). The approach to the implementation 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 3–5.

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 limitation of occupational dose.

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 the medical exposure 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 3–5.

2.16. Dose constraints are used in the planning stage in the optimization of protection and safety. Dose constraints are applicable for occupational exposure and for public exposure in medical uses of ionizing radiation. Dose constraints are also used in the 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 for the exposure of patients in radiological procedures for the purposes of medical diagnosis or treatment (see also paras 2.46–2.50).

2.17. One of the purposes of establishing a dose constraint for each particular source of radiation exposure is 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 the optimization of protection and safety. Periodic assessments are required to be performed of typical patient doses or, for radiopharmaceuticals, of activities administered in a medical radiation facility (para. 3.169 of GSR Part 3 [3]). Doses in this context may be expressed in one of the accepted dosimetric quantities as described in para. 2.40 [10–12]. For simplicity, the term ‘dose’ in Sections 3 and 4 will be used when referring generally to measurements of medical exposure in radiological imaging, with specific forms of dose or activity used where necessary.

2.19. If comparison with established DRLs shows that the typical doses or activities to patients are either unusually high or unusually low, a local review is required 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 2.34–2.45).

2.20. Other tools used in the optimization of protection and safety applied to all three categories of exposure include, inter alia, design and operational

considerations and programmes of quality assurance. These are described in detail in the specialty Sections 3–5.

Dose limits

2.21. Dose limits apply to occupational exposure and public exposure arising from any use of ionizing radiation. Schedule III of GSR Part 3 [3] sets out these dose limits, which are reproduced here for convenience (see Box 1). 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 GSR Part 3 [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 Sections 3–5.

GRADED APPROACH

2.23. The graded approach is a concept that underpins the application of the system for protection and safety. Paragraph 2.12 of GSR Part 3 [3] 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 computed tomography, CBCT), and dedicated bone densitometry studies (dual energy X ray absorptiometry, DXA). 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.

2.25. GSR Part 3 [3] places responsibilities for a graded approach on the government, the regulatory body, registrants and licensees, and employers. The government and the regulatory body are required to use a 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.

BOX 1: DOSE LIMITS FOR PLANNED EXPOSURE SITUATIONS

OCCUPATIONAL EXPOSURE

III.1. 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[66] (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 five 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 to the skin[67] of 500 mSv in a year.

Additional restrictions apply to occupational exposure for a female worker who has notified pregnancy or is breast-feeding (para. 3.114 of [GSR Part 3]).

III.2. 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 to the skin[67] of 150 mSv in a year.

PUBLIC EXPOSURE

III.3. For public exposure, the dose limits are:

(a) An effective dose of 1 mSv in a year;
(b) In special circumstances[68], 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.

Source: Schedule III of GSR Part 3 [3].

[66] The start of the averaging period shall be coincident with the first day of the relevant annual period after the date of entry into force of these Standards, with no retrospective averaging.

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

[68] For example, in authorized, justified and planned operational conditions that lead to transitory increases in exposures.

2.26. The registrants, or licensees, and employers are required to use a 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 a quality assurance programme that is as comprehensive as the programme implemented for a radiation therapy facility in order to meet the requirements of GSR Part 3 [3].

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

ROLES AND RESPONSIBILITIES

Government

General

2.28. The roles and responsibilities of the government[4] with regard to protection and safety are established in Requirement 2 and paras 2.13–2.28 of GSR Part 3 [3], with further detailed requirements established in IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [13]. These include:

(a) Establishing an effective legal and regulatory framework for protection and safety in all exposure situations.
(b) Establishing legislation that meets specified requirements.
(c) Establishing an independent regulatory body with the necessary legal authority, competence and resources.
(d) Establishing requirements for education and training in protection and safety.
(e) Ensuring that arrangements are in place for:
   — The provision of technical services (including radiation monitoring services and standards dosimetry laboratories);
   — Education and training services.

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

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

2.29. As noted 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. The government has a responsibility 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 health care, 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 health care 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 in achieving effective regulation of medical uses of ionizing radiation (see paras 2.52–2.69 for more guidance on the health authority and professional bodies).

2.31. Mechanisms for formal recognition of health professionals should be put 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 provided in paras 2.119–2.137, on education, training, qualifications and competence.

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, regulatory bodies for medical devices and health technology assessment agencies that issue standards and reports that could have direct implications for radiation protection and 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 States.

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, and 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, the government should be aware of these organizations and should utilize their influence to improve the practice of radiation protection and safety in medical uses of ionizing radiation.

Diagnostic reference levels

2.34. DRLs are an important tool and should be used for optimization of protection and safety for diagnostic medical exposure (see para. 2.18). The government has a particular responsibility to ensure that DRLs are established for the State. DRLs can also be established for a region within the State or, in some cases, regions of several small States. In establishing values for the DRLs, typical (e.g. median or average) doses[5] 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 State 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 typical doses for the room or facility [14–17]. In establishing DRLs, it is important to include only radiological procedures whose image quality is adequate for the medical purpose (for further guidelines, see para. 3.215 for diagnostic and interventional radiology and para. 4.207 for nuclear medicine).

2.35. Once DRLs have been 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. The use of the median value rather than the average value of the distribution of data collected from a representative sample of standard sized patients should be preferred for comparison with DRLs, as the average value could be substantially

[5] The term ‘doses’ in paras 2.34–2.45, on DRLs, includes activities in nuclear medicine procedures, as described in para. 2.18.

affected by a few high or low values (see also Ref. [14]). Optimization of protection and safety 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 at improving optimization of protection and safety will usually, but not necessarily, result in lower facility typical doses for the procedure or procedures. At some predetermined interval, typically three to five years, there should be a review of the established national or regional DRL values. More frequent surveys may be necessary when substantial changes in technology, new imaging protocols or image post-processing become available. A new national or regional survey will result in a new distribution of facility typical doses, which will reflect the improvements made as a result of using the existing DRLs. After initial evaluations, 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, their use by imaging facilities, corrective actions by imaging facilities, and periodic review of national or regional DRLs brings about a steady improvement in the optimization of protection and safety across the State or region. After several cycles, it would be expected that the value of the DRL would stabilize. However, a DRL may increase if there is a major change in technologies or techniques in which the relationship between the diagnostic content of the image and the dose changes.

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. Whenever possible, DRLs should be established on the basis of surveys of procedures performed on an appropriate sample of patients. The use of phantoms avoids most of the issues with variations in patient size indices (e.g. mass, height and body mass index) (see paras 2.39 and 2.41). However, their use does not truly represent clinical practice with patients and clinical images and, as such, it would seem less appropriate for use in establishing DRLs. Nevertheless, a phantom based approach, in the absence of adequate patient data, can be used first to establish DRLs and then later in their application [14, 17].

2.37. The imaging procedures for which DRLs are to be established should be decided upon at a national or regional level. The criteria that may help in this decision are the relative frequencies of the imaging procedures and the magnitude of the doses incurred. A graded approach may be used to select procedures for which DRLs are to be established for adults and children — the more frequent

and higher dose procedures should have a higher priority. Specific consideration should be given to paediatric imaging. Depending on national or regional resources, the actual number of procedures for which DRLs are established will vary[6] [18]. It is beneficial if the health authority and professional bodies adopt a common terminology for procedures.

2.38. 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 (e.g. indication based protocols). For example, a CT of the abdomen may be performed differently depending on the diagnostic purpose. For those embarking on establishing DRLs for the first time, it is advisable to define the procedure simply in terms of the anatomical region being imaged.

2.39. The next step is to perform, for the selected procedures, a representative survey — preferably widespread in terms of the types and sizes of facility (rural, urban, private and public), the equipment and the geographical locations. Most imaging radiological procedures are performed on adults, and traditionally national DRLs have been established first for adults. For each room or facility in which the given procedure is performed, the sample size depends on the frequency of the imaging procedure and variability in patient doses, but clearly a larger sample size will reduce the statistical uncertainties (for further guidelines, see para. 3.213 for diagnostic and interventional radiology and para. 4.205 for nuclear medicine). Not all adults are the same size, so many States have established DRLs for a standard adult patient, limiting patient eligibility to the sample on the basis of mass, for example 70 ± 20 kg, and aiming for a sample average in a given mass range, for example 70 ± 5 kg (see Refs [14–16]). Other States have adopted a more pragmatic approach, accepting all adults in the initial sample but excluding extreme outliers in terms of patient size indices.[7]

2.40. The dose metrics used to represent the dose to the patient should be easily measurable and should be in accordance with the recommendations of the ICRU, as established in para. 1.46 of GSR Part 3 [3]. The following are commonly used terms for diagnostic and interventional radiology [10, 11]:

(a) In radiography: air kerma–area product, incident air kerma or entrance surface air kerma (which includes backscatter).
(b) In fluoroscopy: air kerma–area product.

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[6] See www.eu-alara.net/index.php/surveys-mainmenu-53/36-ean-surveys/156-drls.html
[7] See www.arpansa.gov.au/research/surveys/national-diagnostic-reference-level-service

(c) In CT: CT air kerma index and CT air kerma–length product.
(d) In mammography and tomosynthesis: incident air kerma or entrance surface air kerma and mean glandular dose.
(e) In dentistry: incident air kerma for intraoral radiography and air kerma–area product for panoramic radiography and CBCT.
(f) In image guided interventional procedures: air kerma–area product and cumulative reference air kerma at the patient entrance reference point.

Further guidance on dose metrics is given in paras 3.202–3.204. It is crucial that the dose data for each contributing facility is only collected for procedures where the image quality was confirmed as adequate for the clinical purpose. In nuclear medicine, DRLs are set in activity administered to the patient and in activity per unit of body mass (MBq/kg) (see paras 4.205 and 4.206).

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. Experience, in particular with children undergoing CT examinations, has clearly demonstrated that this is not the case [19]. This means that consideration should also be given to establishing DRLs for children undergoing imaging procedures. The same problem of size and mass, as stated in para. 2.39, also pertains to children. Patient age has been used to define groups of children for the purpose of establishing paediatric DRLs. Some States or regions have adopted a simple age approach, for example newborn, 1, 5, 10 and 15 years, while others use age bands, for example less than 1 year, 1–5 years, 5–10 years and 10–15 years. Because the size of children, and hence the dose level, significantly varies not only across different ages but also at any given age, this alone is not a good indicator, and patient mass or patient equivalent thickness should also be considered. When DRLs for several mass, size or age groups are defined, the groups should be defined unambiguously by using intervals (e.g. body mass bands). The number of groups chosen should take into account the practical difficulty in collecting a sufficient number of patient dose data in each group. In nuclear medicine, administered activities should be adjusted on the basis of agreed factors linked to size or mass. More guidance on grouping patients for establishing typical doses and DRL is given in para. 3.213 for diagnostic and interventional radiology, in para. 4.205 for diagnostic nuclear medicine and in Ref. [14]. In addition, guidelines on DRLs for paediatric imaging are also being prepared by the European Commission.[8]

[8] See www.eurosafeimaging.org/pidrl

2.42. The processes and steps towards establishing DRLs, as described in paras 2.36–2.41, are likely to involve many parties, including the imaging facilities, the health authority, professional bodies and the regulatory body. In particular, there should be collective ownership of the DRLs in deciding which procedures and age groups will be used, how the data will be collected, who will manage the data, and when the DRLs should be reviewed and updated. In some States, a national governmental body administers the national patient dose database that underpins the establishing of DRLs. In other States, 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 and then 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 (see para. 2.34).

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 (HISs) improves, the process of gathering data for DRLs is likely to become easier. States embarking on establishing DRLs for the first time should consider applying an electronic submission approach.

2.44. The national or regional DRL values should be periodically reviewed and updated, typically with a cycle of three to five 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 typical doses 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 facility typical doses with the current DRLs would seem to be an appropriate time for the facility to submit its new facility typical doses to the national or regional database being used for the DRLs. At the end of the cycle, an analysis of the submitted facility typical doses would take place, and the values of the DRLs would be updated accordingly. While increased digital connectivity would technically support the continuous collection and analysis of data, a given set of DRL values should be kept stable for a period of time to allow the improvement cycle to take place.

2.45. Finally, if the State is not able to facilitate the establishment of its own national DRLs or to participate in a regional approach, there is the option to facilitate the adoption of the DRLs from another State or region. While such

DRLs might not reflect the State's own practice, with judicious selection, the adopted DRLs can still perform the same role of bringing about an improvement in the optimization of protection and safety in the adopting State. Care is needed when comparing DRLs from States that use significantly different generations of imaging systems.

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 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 the 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 States use a dose constraint of approximately one third of the dose limit, namely an effective dose of 0.3 mSv per year [20]. In establishing such a dose constraint, the regulatory body should consider the number and type of radiation sources used in a particular State or region that may result in public exposure.

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

2.48. For carers and comforters, the usual approach is to apply dose constraints on an episode by episode basis — that is, the dose constraint applies to the cumulative exposure of the carer or comforter over the duration of that person giving care and comfort to a patient. In the case of a parent assisting with his or her child undergoing a diagnostic X ray procedure, the episode is the time in which the X rays are being produced, which is extremely short. In the case of a carer or comforter for a person having undergone treatment with radiopharmaceuticals, the episode will last several days until the radionuclide has

decayed to negligible levels. Consideration should be given to the cumulative dose of a carer or comforter acting in this role for several distinct episodes. In such cases, a dose constraint per annum may be used in addition to an episode based dose constraint.

2.49. In setting dose constraints for carers and comforters, consideration should be given to the age of the individual and the possibility of pregnancy. A particular issue is that of children 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 might not understand such concepts. Nonetheless, it is reasonable and likely that the children of a parent undergoing treatment would want to provide and receive comfort. The framework for radiation protection and safety should accommodate such wishes. A pragmatic approach is often taken, whereby children in this role are effectively treated as members of the public and their medical exposure is constrained 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 or fetus to 1 mSv per episode is often taken. For an adult carer or comforter, a value of dose constraint commonly used is 5 mSv effective dose per episode. For elderly persons, more lenient dose constraints may be used. In any of these cases, flexibility may need to be applied with respect to the dose constraint.

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 with the health authority, the relevant professional bodies and the radiation protection regulatory body, provides broad guidance for the ethics committees (see paras 2.99–2.102) 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 the 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 (for detailed information on these factors for unsealed sources, see Ref. [21]). The role of government, through consultation with 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 to simplify the process when individual medical radiation facilities are considering the release of a patient. Guidance for such actions of the medical radiation facility is given in Sections 4 and 5.

Health authority

2.52. All medical facilities should 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 health care should be granted by the health authority only if the radiation safety requirements are met (paras 2.70–2.76). 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 the guidance in paras 2.34–2.51). 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 the 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 subspecialties, including on the scope of practice, and requirements for competence. Guidance on recognition of competence in a specialty is given in paras 2.119–2.133.

2.54. Adequate numbers of radiological medical practitioners, medical radiation technologists, medical physicists and other health professionals with responsibilities for patient radiation protection 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 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:

(a) Generic justification of radiological procedures;
(b) Justification of radiological procedures in health screening programmes;

(c) 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 ongoing process as new procedures become available and as established procedures are 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 existing procedures. Conversely, an existing radiological procedure may need to be withdrawn from use if there is evidence that an alternative modality or technology has greater 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 a particular 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 reaching 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 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 process of justification for an individual patient (see paras 3.141–3.143).

2.59. National or international referral guidelines should be used as an important tool in the application of the process of justification of medical exposure for an individual patient. The health authority should support the relevant professional bodies in developing and implementing evidence based 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 standards[9] developed by professional bodies.

Professional bodies

2.61. Professional bodies is the collective term used in GSR Part 3 [3] and in this Safety Guide to include the various organizations and groups of health professionals. These include societies, colleges and associations of health professionals, often for a particular specialty. Examples of professional bodies with direct involvement in the use of ionizing radiation include societies, colleges and associations of radiologists, radiation oncologists, nuclear medicine physicians, medical physicists, medical radiation technologists and dentists. In large States, such professional bodies might be regional within the State. Conversely, there can be regional professional bodies covering several States. 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, vascular surgery, orthopaedic surgery 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 should also 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 2.119–2.133.

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 is described in paras 2.42, 2.47–2.50 and 2.51, respectively.

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[9] The term ‘practice guidelines and technical standards’ is used to represent the range of documents, statements and publications produced by professional bodies to help to educate and guide health professionals in the conduct of their specialty.

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.

2.65. Professional bodies should take the lead in the development of referral guidelines (also called appropriateness criteria in some States) for use in justification of medical exposure for an individual patient (para. 2.59). It might 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 by many other States through adoption or adaptation by the local professional bodies (see also paras 3.143 and 4.160).

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 relationship between image quality and patient dose. Having standards or norms that specify acceptable image quality is clearly advantageous, and relevant professional bodies have a role in establishing and promoting such criteria.

2.67. For the optimization of radiation protection and safety, a comprehensive programme of quality assurance for medical exposure is required. Such programmes should be part of the wider management system of the medical radiation facility (see para. 2.140). Nonetheless, there is considerable benefit in making use of resource material and standards established by professional bodies for particular areas of the programme of quality assurance. For example, many medical physics professional bodies have developed detailed guidance on performance testing aspects of a programme of quality assurance. 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 should encourage their members to perform proactive risk assessment, especially in radiotherapy. They can also play an active 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. Such databases provide a wealth of information that can help to minimize unintended and accidental medical exposures. Examples of international safety reporting systems are the IAEA safety reporting systems Safety in Radiation Oncology (SAFRON) and Safety in Radiological Procedures (SAFRAD), and the Radiation Oncology Safety Education and Information System (ROSEIS).

2.69. Professional bodies have a role in disseminating information on standards and guidance relevant to radiation protection and safety.

Regulatory body

2.70. The radiation protection regulatory body should 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 GSR Part 3 [3] and GSR Part 1 (Rev. 1) [13], and further general guidance is provided in IAEA Safety Standards Series No. GS-G-1.5, Regulatory Control of Radiation Sources [22]. Guidance on general regulatory body roles and responsibilities with respect to occupational radiation protection and radiation protection of the public are given in IAEA Safety Standards Series Nos GSG-7, Occupational Radiation Protection [23], and GSG-8, Radiation Protection of the Public and the Environment [24]. A prerequisite 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 GSR Part 3 [3], GSR Part 1 (Rev. 1) [13] and GS-G-1.5 [22], and applies in the context of medical uses of ionizing radiation. The regulatory controls should be applied knowledgeably and not just as an administrative exercise.

Authorization of medical radiation facilities

2.71. The graded approach to medical uses of ionizing radiation has particular significance for regulatory bodies because, as described in paras 2.23–2.27, there is a wide variation in the complexity of medical radiation facilities. Regulatory bodies should consider which form of authorization is appropriate for a given type of medical radiation facility. Coupled with the type of authorization is the level of complexity of 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 2.150–2.154). The duration for which the authorization is granted is another consideration for the regulatory body; more complex facilities would warrant a more frequent renewal process.

2.72. Typical practices that are amenable to registration are those for which: (i) safety can largely be ensured by the design of the facilities and equipment; (ii) the operating procedures are simple to follow; (iii) the safety training requirements are minimal; and (iv) historically, there have been 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 amount of 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 performing image guided interventional procedures and for most diagnostic radiology facilities. For some simple forms of diagnostic radiology, such as dental radiography (without CBCT) and DXA, authorization through registration may be acceptable. For both forms of authorization, the regulatory body should develop standardized forms or templates that help to ensure that the correct information is submitted to the regulatory body (see also paras 2.150–2.154 on safety assessment).

2.73. No matter which form of authorization is used for a medical radiation facility, a crucial step prior to the granting of it is that the regulatory body ascertains the credentials of key personnel with responsibilities for radiation protection and safety, including radiological medical practitioners, medical radiation technologists, medical physicists and RPOs. This step cannot be overemphasized, as all aspects of radiation protection and safety in medical uses of ionizing radiation depend ultimately on the competence of the personnel involved (see also paras 2.119–2.137).

2.74. Setting up a medical radiation facility may involve the construction of facilities that are difficult to modify at a later time. Regulatory bodies may choose a two stage process of authorization; that is, to require an initial application to build a facility to be submitted 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 plans[10], and the planned equipment. This is followed at a later stage by the full review and assessment by the regulatory body, 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.

2.75. Subsequent, substantial modifications of a medical radiation facility, including its medical radiological equipment and its procedures, may have safety

[10] Although not strictly a radiation protection and safety issue, it is important to ensure that the building can support the weight of the structural shielding, for which it may have not been originally designed.

implications. The regulatory body may require an application for an amendment to the authorization.

2.76. 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 five years would normally not be appropriate for medical radiation facilities.

2.77. The authorization of a medical radiation facility to use ionizing radiation for medical purposes is a separate exercise to the authorization of the same facility, or the wider medical facility of which it is part, by the health authority to carry out medicine practice and health care (see para. 2.52). Meeting radiation safety requirements is a condition that is 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 take place to ensure radiation protection and overall safety of the medical facility.

Inspection of medical radiation facilities

2.78. 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 establish a system for prioritization and frequency of inspections, based on the risk and complexity associated with the particular medical uses of ionizing radiation. The inspection by the regulatory body of medical radiation facilities should be performed by staff with the specialist expertise to be able to assess competently the compliance of the facility with the radiation protection regulations and authorization conditions. Further guidance on inspections is given in GS-G-1.5 [22].

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

2.79. The regulatory body should ensure that all the requirements of GSR Part 3 [3] with respect to medical exposure, occupational exposure and public exposure are applied in authorized medical radiation facilities, as described in detail in the relevant subsections of Sections 3–5. To help medical radiation

facilities fulfil their obligations, there are some particular areas for which the regulatory body should provide specific guidance.

2.80. Arrangements for the calibration of sources giving rise to medical exposure are required to be in place to ensure radiation protection and safety in medical uses of ionizing radiation, as established in para. 3.167 of GSR Part 3 [3], and detailed guidance is given in Sections 3–5. The regulatory body should specify frequencies for re-calibration of equipment and, in doing so, should make use of applicable guidance given by professional bodies of medical physics.

2.81. In the case of the calibration of radiation therapy units, independent verification prior to clinical use is required to be assured (para. 3.167(c) of GSR Part 3 [3]). The regulatory body should be aware of the limitations on local resources in their State. An 'ideal' independent verification — for example by independent medical physicist using different dosimetry equipment — might not be feasible. The regulatory body has the responsibility to ensure that the radiation safety of the radiation therapy unit is not compromised and at the same time the facility is not unnecessarily closed down. The regulatory body should decide on acceptable alternatives, such as verification by a different medical physicist with the same equipment or verification by using a different set of equipment, or using a form of verification by postal dosimetry using thermoluminescent, optically stimulated luminescent dosimeters or equivalent.

2.82. Unintended and accidental medical exposures do occur, and the regulatory body is required to ensure that a system is put in place and all practical measures are taken to prevent such exposures, and, if such an exposure does occur, that it is properly investigated and corrective actions are taken (Requirement 41 of GSR Part 3 [3]). Arrangements should be put 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 is to be included in these reports. The more significant events are required to be reported to the regulatory body (para. 3.181(d) of GSR Part 3 [3]). The regulatory body should provide guidance on which events should be reported to them. One of the reasons for reporting to the regulatory body is to enable the regulatory body, in turn, to disseminate information on the event to relevant parties so that the recurrence of similar events can be minimized. In addition to mandatory reporting for regulatory purposes, anonymous and voluntary safety reporting and learning systems can significantly contribute to enhanced radiation protection and safety and quality in health care. The regulatory body should be proactive and encourage medical radiation facilities to participate in relevant international or national anonymous

and voluntary safety reporting and learning systems, as stated in para. 2.68. Further guidance is given in Sections 3–5.

2.83. With respect to assessment of occupational exposure, the regulatory body should establish requirements and provide clear guidance on which form of monitoring should be in place. Paragraphs 3.99–3.102 of GSR Part 3 [3] require employers, registrants and licensees to make arrangements for assessment of occupational exposure, and provide 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 uses where it is quite clear that individual monitoring should be undertaken, to uses where workplace monitoring would suffice. It is where uses fall between these two situations that specific direction should be provided by the regulatory body. Further guidance is given in Sections 3–5.

2.84. The regulatory body has a role as the 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 cumulative effect of these multiple exposure pathways does not lead to public exposure greater than the dose limits (see Box 1). Part of this role includes setting dose constraints and ensuring that safety assessments include considerations of public exposure and potential public exposure.

2.85. GSR Part 3 [3] establishes many requirements for registrants, licensees and employers with respect to occupational radiation protection to maintain and make available records on a wide range of matters. GSR Part 3 [3] requires that:

> "3.104. Records of occupational exposure for each worker shall be maintained during and after the worker's working life, at least until the former worker attains or would have attained the age of 75 years, and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure."

For all other records, the period for which they should be maintained is deferred to the 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 health care should be kept for that person's lifetime, but there are significant variations around the world. In some States, for example, medical records are required to be kept for the lifetime of the person plus ten years; in others, retention for a much shorter period, such as seven to ten years, is

required. Records for activities such as calibrations, dosimetry, quality assurance and investigations of accidents and unintended medical exposures should be kept for a significant period of time, as there is always the possibility that the records will be needed to perform retrospective assessments of medical exposure, occupational exposure or public exposure. A retention period of at least ten years may be appropriate for such records. On the other hand, records on education, training, qualification and competence of individuals 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 IAEA Safety Standards Series No. GS-G-3.1, Application of the Management System for Facilities and Activities [25].

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

2.86. The regulatory body should ensure that the activities to install, maintain or service medical radiological equipment are appropriately authorized (see also paras 2.103–2.111 on responsibilities for suppliers of sources, equipment and software, paras 2.112–2.114 maintenance and servicing organizations, and para. 2.135 on education, training, qualification and competence of servicing engineers and technicians).

Authorization of other practices relating to medical uses of ionizing radiation

2.87. The regulatory body may also require authorization for other activities relating to medical uses of ionizing radiation, including: the import, distribution, assembly, sale, transfer and transport of radioactive sources or medical radiological equipment; decommissioning; and disposal of radioactive sources and waste. The requirements to carry out these practices should be established by regulations, and complementary regulatory guidance documents should be provided.

Dissemination of information

2.88. Paragraph 2.33 of GSR Part 3 [3] requires that the regulatory body ensures that mechanisms are 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 for radiation protection and safety resulting from regulatory experience and operating experience, and from incidents, including accidents, and related findings. Information should be exchanged through the publication of newsletters and the

periodic mailing of notices, by presentations at scientific meetings and meetings of professional associations, by establishing a web site, or by co-sponsoring 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

2.89. 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 of GSR Part 3 [3] applicable to a medical radiation facility for ensuring radiation protection and 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).

2.90. 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 GSR Part 3 [3] and in this Safety Guide as the radiological medical practitioner. The term 'radiological medical practitioner' is the generic term that GSR Part 3 [3] 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 Sections 3–5 and in paras 2.124 and 2.125 on education and training.

2.91. The net effect of paras 2.89 and 2.90 is that, for medical exposure, the registrant or licensee should ensure all requirements are applied. This normally requires that the radiological medical practitioner ensure a given set of actions take place, usually with the involvement of further health professionals, mainly medical radiation technologists and medical physicists (see paras 2.92 and 2.93, respectively). The medical exposure subsections of Sections 3–5 provide

guidance on meeting the many requirements that come under the responsibility of the radiological medical practitioner.

2.92. The term ‘medical radiation technologist’ is used in GSR Part 3 [3] 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 for such health professionals, such as radiographer, radiological technologist, nuclear medicine technologist and radiation therapist. In GSR Part 3 [3], a medical radiation technologist is a health professional with specialist education and training in medical radiation technology, competent to perform radiological procedures, on delegation from the radiological medical practitioner, in one or more of the specialties of medical radiation technology (e.g. diagnostic radiology, radiation therapy and nuclear medicine). The medical radiation technologist is usually the interface between the radiological medical practitioner and the patient, and his or 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. The medical radiation technologists may also have a role in education and training. More guidance on the roles and responsibilities of medical radiation technologists is given in Sections 3–5 and in paras 2.126 and 2.127 on education and training.

2.93. In GSR Part 3 [3], 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 and nuclear medicine). The medical physicist provides specialist expertise with respect to radiation protection of the patient. The medical physicist has responsibilities in 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 programme of quality assurance, 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 or she may also perform the role of the RPO, whose responsibilities are primarily in occupational and public radiation protection. More guidance on the roles and responsibilities of medical physicists is given in Sections 3–5, in Ref. [26], and in paras 2.128 and 2.129 on education and training.

2.94. 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 3–5.

2.95. 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.

2.96. The RPO is: "A person technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant, licensee or employer to oversee the application of regulatory requirements" [3]. For a medical radiation facility, the RPO oversees the application of requirements for occupational and public radiation protection, and may provide general radiation protection advice to the registrant or licensee. The RPO has no direct responsibilities or roles with respect to patient radiation protection. 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.

2.97. In addition, all health professionals involved in medical uses of ionizing radiation have responsibilities with respect to occupational and public radiation protection. (See the occupational and public radiation protection subsections in Sections 3–5).

2.98. Medical radiation facilities, as they increasingly utilize digital technologies, should ensure access to an IT specialist[11] who, through specialized training and experience, has competence in the maintenance and quality control of IT software and hardware. The correct functioning of these systems is crucial for radiation protection and safety.

Ethics committee

2.99. Participants in a programme of biomedical research may be either patients, with some disease or ailment, or they may be healthy individuals. Regardless,

[11] The IT specialist in this respect is an expert in imaging informatics, with expertise in improving the efficiency, accuracy, usability, reliability and interconnectivity of medical imaging and radiotherapy services within the medical radiation facility and, if relevant, its parent health care facility.

they should be volunteers. The ethics committee[12] has a particular responsibility with respect to justification of medical exposure of volunteers exposed as part of a programme of biomedical research (para. 3.161 of GSR Part 3 [3]). 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 DXA scan to measure bone mineral density before, during and after a given treatment regime, to a CT or a positron emission tomography (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;
(e) Trials being performed to assess physiological and/or biochemical processes in healthy individuals.

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, sex and health status of the participants. The ethics committee should also obtain information on who will perform the radiological procedures and how. The dose estimates and the associated radiation risks should be 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.

2.100. The ethics committee has the responsibility to specify any dose constraints that are to be applied to the doses 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

[12] The ethics committee is the term used in GSR Part 3 [3] to refer to a committee dedicated to the rights and well-being of research subjects. Other terms, such as institutional review board, are used in some States.

biomedical research: the lower the benefit to society, the more stringent the dose constraint. The ICRP stratifies doses incurred in biomedical research according to radiation risk [27] and in Ref. [4] assigns 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 for participants with short life expectancy (e.g. see Ref. [28]). Particular attention should be given to setting dose constraints for healthy volunteers who repeatedly take part in biomedical research programmes that expose them to increased risks.

2.101. Ethics committees might not be aware of these responsibilities. Therefore, the radiation protection regulatory body should act as a facilitator in promoting systems so that the ethics committee knows about its responsibilities when a proposal for a programme of biomedical research that includes radiation exposure is submitted to the ethics committee. Such a system may include a standardized proposal form that includes the question 'Will ionizing radiation be used as part of this programme of biomedical research?' If the answer is yes, the form should then request information on radiation doses and risks to be provided, having been first assessed and signed off by a medical physicist.

2.102. In parallel, the regulatory body should inform the registrants and licensees that radiological procedures requested as part of a programme of biomedical research are justified only if that programme has been approved by the 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

2.103. Suppliers[13] 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 established in para. 3.49 of GSR Part 3 [3] and specific requirements in para. 3.162 of GSR Part 3 [3].

2.104. 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

[13] The definition of supplier (of a source) in GSR Part 3 [3] includes designers, manufacturers, producers, constructors, assemblers, installers, distributors, sellers, importers and exporters of a source.

and other widely spoken languages dominate. The person using the equipment or software should fully understand the options being presented, and translation into a local language is strongly recommended. It is not appropriate to assume that partial knowledge of other languages is sufficient; there are documented instances of unintended or accidental medical exposures arising from incorrect understanding of the displayed language (e.g. see Ref. [29]).

2.105. 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 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 protection and safety.

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

2.107. After installation of medical radiological equipment or software, the supplier should go through a formal handover to the medical radiation facility's registrant or licensee. This should include acceptance testing, described in more detail in Sections 3–5.

2.108. Specific training in the use of the equipment or software should be given to the staff of the medical radiation facility, 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 radiation protection of patients and personnel.

2.109. 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, 31].

2.110. The radiation protection and safety responsibilities for donors of medical radiological equipment should be no different to those of commercial suppliers for such equipment. Further guidance on donated equipment is given in Refs [32, 33].

2.111. Regulatory control of engineers and technicians who install medical radiological equipment varies around the world. In many States, they will be licensed to perform installation and servicing and a prerequisite to obtaining such a licence should 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. 2.135.

Maintenance and servicing organizations

2.112. 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 (e.g. as part of an engineering, biomedical or clinical engineering, or service department). In either case, when the medical radiological equipment is being serviced, the equipment should not be used for medical exposures; patients should not be imaged or treated until service and hand back is completed (see para. 2.113). 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 rules and procedures on how to ensure a safe working environment for the service and how to ensure restricted access to the area where the servicing is taking place. Further guidance on good practice in maintenance is given in Ref. [34].

2.113. Maintenance and servicing continues until the medical radiological equipment is ready to be handed back to the medical radiation facility's registrant or licensee. The handover to the registrant or licensee should be 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 handover is complete (see paras 3.49, 4.59 and 5.91). The engineering service should collaborate with medical physicists, medical radiation technologists and radiological medical practitioners in ensuring optimal performance of the equipment. The engineer or technician should also inform the registrant or licensee of any changes with respect to the medical radiological equipment that may have implications for radiation protection and safety. At this stage, the equipment is available for medical use. Pressures to hand medical radiological equipment back for medical use should not be allowed to compromise radiation protection and safety; for example, equipment should not be used clinically while it is still in a 'service mode'.

2.114. Regulatory control of servicing engineers and technicians varies around the world. In many States, they will be licensed to perform servicing and a prerequisite to obtaining such a licence should 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 para. 2.135.

Referring medical practitioners

2.115. 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 GSR Part 3 [3] for the health professional who may refer individuals for a radiological medical procedure. 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 Sections 3–5.

2.116. Usually the roles of the referring medical practitioner and the radiological medical practitioner are performed by two different people. However, there are some instances in which both roles are performed by the same person, often called self-referral. A very common example is a dentist, who decides whether an X ray examination is necessary and, if so, performs the examination. Dental professional bodies in many States have established guidelines for when dental X ray examinations are appropriate or not, and use of 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 to minimize potential misuses of self-referral.

Patients

2.117. Patients are increasingly being involved in the decision making processes concerning their own health care, and this includes medical uses of ionizing radiation. Paragraph 3.151(d) of GSR Part 3 [3] requires that the registrant or licensee for the medical radiation facility ensure that the patient be informed, as appropriate, of both the potential benefit of the radiological procedure and

the radiation risks. Information should be provided in an understandable format (e.g. verbally, leaflets, posters and web sites) 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, either written or verbal. Female patients of reproductive capacity should be informed about the risk to the embryo or fetus from radiological procedures for either diagnosis or therapy.

2.118. 'Self-presenting' patients are individuals demanding a particular radiological procedure on the basis that they believe that this procedure is needed, for example, to 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

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

2.120. GSR Part 3 [3] 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 training (see Ref. [35]) that is based on a national needs assessment can be useful in this context. Furthermore, the regulatory body is required to ensure the application of the requirements for education, training, qualification and competence in radiation protection. Such verification should take place when an application for an authorization 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.

2.121. In medical uses of ionizing radiation, medical exposure occurs and occupational and public exposure might occur. For the health professionals involved, it is their education, training, qualification and competence in the medical exposure aspects that are the most critical. To this end, the requirements of GSR Part 3 [3] 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 GSR Part 3 [3] 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 Definitions in GSR Part 3 [3] for complete descriptions). The competence of a person is normally assessed by the State through 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 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.

2.122. 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 responsibility of the registrants and licensees to ensure that their staff meet 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 discharge their responsibilities in this respect.

2.123. The institutes and organizations that provide education and training in radiation protection to health professionals should use GSR Part 3 [3] and this Safety Guide as resources on the requirements for radiation protection and safety in medical uses of radiation.

Radiological medical practitioners

2.124. 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. 2.90). Some radiological medical practitioners 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 States where there are well established processes in place for education, training, qualification and competence in these specialties, such education, training, qualification and competence includes subjects not only in the specialty itself but also with respect to radiation protection (patient protection and occupational protection). Radiological medical practitioners would typically 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. The regulatory body and the relevant professional body should 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 radiological medical practitioners 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 and assessment of the individual's competence with respect to radiation protection and safety may need to be performed by the regulatory body. In time, this approach should develop into a standardized process for dealing with competence assessments.

2.125. Other specialties, such as orthopaedic surgery and cardiology, have also had a long association with medical uses of ionizing radiation, but radiation protection and safety might 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 protection and occupational protection) is often not included in the curriculum for education, training, qualification and competence in these specialties. For specialists from these two groups, additional or separate education and training and credentialing in radiation protection and safety, as it applies to their specialty, may need to be arranged. The relevant professional bodies and the regulatory body should work together in establishing acceptable criteria on education and training in radiation protection and safety, and the means for recognition of competence in radiation protection. The preferred approach is for the relevant professional body to administer the process and to maintain a register of specialists and their radiation protection and safety credentials. Another

possibility is the regulatory body taking on the role of overseeing the radiation protection and safety training and recognition processes. A medical radiation facility can adopt a 'credentialing and privileging' approach to cover education, training, qualification and competence in radiation protection and safety [36]. In this approach, the prospective radiological medical practitioner would present all their relevant data on 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 education and training in radiation protection and safety for various specialties involved in medical use of ionizing radiation is given in Refs [37, 38].

Medical radiation technologists

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

2.127. Medical radiation technologists may be specialized in various fields and subfields. The approach to specialties and subspecialties vary significantly among States. In many States, the medical radiation technologist undergoes a programme of education and training specific to diagnostic radiology, nuclear medicine or radiation therapy and hence his or her competence would be in that specialty only. Within these specialties, there may be specific subspecialties for which the general programme of education and training does not necessarily confer competence. For example, the diagnostic radiology programme in a State might 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 subspecialty. The regulatory body, in terms of reviewing an application for an authorization and during its periodic inspections, needs to be aware of issues of specialization and subspecialization and ensure that only persons with the correct credentials can work in the particular roles. Similarly, the registrant or licensee should ensure that only persons that have the requisite competence are employed.

Medical physicists

2.128. Even though the International Labour Organization has stated that medical physicists working in clinical practice can be considered health professionals [39], medical physicists are not well recognized as a specialist group of health professionals. In some States, 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 postgraduate 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 physics experts [44]. GSR Part 3 [3] requires specialization for the medical physicist, so, for example, a 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.

2.129. It is more difficult 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 State. The problem is similar to that described in the second half of para. 2.124 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 should still take place. Regardless of the educational process, the final competence assessment for medical physicists should be specialty specific, as required by para. 3.150 of GSR Part 3 [3].

Radiopharmacists

2.130. A radiopharmacist is a health professional, usually a pharmacist, who has received additional specialist education and training, and has competency in the preparation and dispensing of radiopharmaceuticals. Postgraduate courses in radiopharmacy are available in some States. A few States have a radiopharmacy professional body, or a radiopharmacy can be a specialist subgroup within the national nuclear medicine professional body or a pharmacy professional body. More details on education, training, qualification and competence of persons

working in a radiopharmacy are given in Ref. [45]. Even in the absence of a formal infrastructure, the assessment of education, training, qualification and competence of a person seeking to act in the role of a radiopharmacist should still take place.

Other health professionals in the medical radiation facility

2.131. Other health professionals are involved in the 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. A health professional who falls into the former group, and who is not a radiological medical practitioner, a medical radiation technologist, a medical physicist or a radiopharmacist, should still have appropriate specialization (as it applies to the particular use of radiation) and the respective radiation protection and safety education, training, qualification and competence. The guidance given in paras 2.124, 2.127, 2.129 and 2.130 for health professionals in States where infrastructure is lacking would again be applicable.

2.132. The latter group of health professionals and other professionals involved in medical uses of ionizing radiation includes specialist nurses (working in a cardiac investigation suite or theatre), specialist physicians (such as anaesthetists[14] providing support to a patient undergoing an interventional procedure), biomedical engineers, clinical engineers and 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

2.133. The referring medical practitioner has a crucial role in the justification of a given radiological procedure for a given patient. The referring medical practitioner will be more effective in this role if he or 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

[14] Also called anaesthesiologists in some States.

curriculum, especially at the time when clinical rotations begin, or as part of the corresponding specialty education and training programme.

Radiation protection officers

2.134. 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. The RPO's technical expertise 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. Similar to other health professionals, in the absence of a process for recognition by a third party, the regulatory body should liaise with the relevant professional body (if it exists) to set standards to enable assessment of persons seeking authorization to act in the role of RPO. The International Labour Organization recognizes the radiation protection expert as an "environmental and occupational health and hygiene professional" [39].

Suppliers, installation, maintenance and servicing personnel

2.135. Persons who work as engineers or technicians for the 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 they should also 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 latter, 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 States, a licence may be required to perform servicing and a prerequisite to obtaining such a licence should be that such engineers or technicians have had appropriate radiation protection and safety training.

Maintaining competence

2.136. Paragraphs 2.119–2.133 provide guidance on the processes for the initial education, training, qualification and competence assessment of health professionals. Health professionals should maintain their core competencies, including radiation protection and safety, and should keep abreast of new developments in medical uses of radiation. One way to achieve this is through formal continuing medical education or continuing professional development programmes. In many States, the professional bodies administer such programmes, and maintenance of certification of competence in a specialty is dependent on satisfactory participation in the programme. Registrants, licensees and the regulatory body can use these programmes as evidence of continuing competence.

Specific training on equipment and software

2.137. Specific training should take place using the actual medical radiological equipment and 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 (see also paras 2.104 and 2.108). From the vendors' side, the servicing engineer, the applications specialist and the IT specialist have a role in providing specific training for the medical radiation facility. It is important to ensure that equipment and software specific training is given in a manner that can be readily understood by local staff.

MANAGEMENT SYSTEM FOR RADIATION PROTECTION AND SAFETY

2.138. The use of radiation in medicine is just one aspect of medical practice. The application of the radiation protection and safety requirements of GSR Part 3 [3] should complement the wider set of requirements that ensure

good medical practice. In particular, the medical radiation facility[15] and its management should ensure complementarity between the requirements for radiation protection and safety and other health care delivery requirements within the medical facility. This is achieved through an appropriate management structure and management system.

2.139. Requirement 5 of GSR Part 3 [3] establishes a specific requirement for radiation protection and safety to be effectively integrated into the overall management system of a given organization. In this Safety Guide, this applies to the medical radiation facility. Paragraphs 2.47–2.52 of GSR Part 3 [3] establish additional detailed requirements on the protection and safety elements of the management system, for promoting a safety culture and for taking into account human factors. Further detailed requirements for facilities and activities in general are established in IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [47], and elaborated in GS-G-3.1 [25]. The requirements for quality management are established in those safety 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 guidance in paras 2.140–2.149 is limited to a few particular components of the management system relating to radiation protection and safety.

2.140. Paragraphs 2.42 and 2.43 of GSR Part 3 [3] establish a requirement for a "protection and safety programme", in general, and Requirement 24 of GSR Part 3 [3] establishes arrangements under a "radiation protection programme" specifically for occupational exposure. In addition, paras 3.170–3.172 of GSR Part 3 [3] establish requirements for a "comprehensive programme of quality assurance for medical exposures". All three of these programmes should be part of the overall management system of the medical radiation facility. Detailed guidance on the radiation protection programme for occupational exposure and the programme of quality assurance for medical exposures is given in Sections 3–5.

[15] 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 paras 2.138–2.149 on the management system is at the medical radiation facility level, but, where the medical radiation facility is part of a larger organization, the management system of the medical radiation facility will be part of the larger organization's management system.

2.141. Depending on the size of the medical radiation facility, committees might be formed to help the implementation of the aspects of the management system pertaining to the radiation protection and safety programme. 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 RPO. The RPO should carry out day to day oversight of the radiation protection programme and should report to the radiation safety 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 that may compromise safety.

2.142. Another committee might be a quality assurance committee, with oversight of the programme of quality assurance 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 committee and the quality assurance committee have some functions in common, especially with regard to medical exposure, and the representation of health professionals on each is likely to be the same. The work of both committees should be harmonized to avoid either the duplication or the inadvertent omission of some functions.

2.143. The management system should promote continuous improvement, which implies a commitment by staff to strive for continuous improvement in medical uses of ionizing radiation. Feedback from operational experience and from lessons identified from accidental exposures or near misses should be applied systematically, as part of the process of continuous improvement.

2.144. Paragraph 2.50 of GSR Part 3 [3] requires that the medical radiation facility "be able to demonstrate the effective fulfilment of the requirements for protection and safety in the management system." This will include monitoring, performed to verify compliance with the requirements for protection and safety (Requirement 14 and paras 3.37 and 3.38 of GSR Part 3 [3]).

2.145. There are requirements for records to be kept, and made available as needed, in many sections of GSR Part 3 [3]. 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 3–5.

2.146. Digital information systems are becoming increasingly available to provide various support functions to the management system of the medical radiation facility, including the handling of requests for radiological procedures, the scheduling of radiological procedures, the tracking of patients, and the processing, storage and transmission of information pertaining to the patient. Furthermore, digital information systems can be used for viewing imaging studies and obtaining reports of study interpretations. Example of systems with some or all of these functions include picture archiving and communication systems (PACSs), radiology information systems (RISs), HISs, electronic health records (EHRs) and any other commercially available dose management systems. These systems should operate independently, but they can also interconnect with each other. Imaging devices and other medical radiological equipment can be interconnected by computer networks and can exchange information in accordance with standards such as the Transmission Control Protocol/Internet Protocol (TCP/IP or the Internet protocol suite), Digital Imaging and Communication in Medicine (DICOM)[16], Health Level Seven (HL7)[17] and Integrating the Healthcare Enterprise (IHE)[18]. These information systems are complex, and users should ensure that they are expertly implemented and supported. 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 to avoid the performance of unnecessary or inappropriate studies and repeat studies by making patient information available to multiple users. Furthermore, 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 monitoring image retakes; the information from such monitoring can help in the optimization of protection and safety for imaging procedures.

2.147. Such digital information systems and the procedures for their use should be designed to protect against data loss, which in the context of the medical radiation facility might compromise radiation protection and safety by, for

[16] See http://dicom.nema.org
[17] See www.hl7.org
[18] See www.ihe.net

example, necessitating repeat examinations. It is the responsibility of the medical radiation facility to meet the requirements of the relevant State authorities for the retention, security, privacy and retrieval of records.

2.148. The management system should include a review cycle. The general principles for audits and reviews are well established (see GS-G-3.1 [25] and GSR Part 2 [47]). For a medical radiation facility, a possible tool for this is the clinical audit. Clinical audits can be considered as a 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. 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, should keep these aspects in the context of medical practice, ensuring a common goal. Thus, while GSR Part 3 [3] does not require a clinical audit, its use can be seen as fulfilling both the radiation protection and safety and the medical aspects of the medical radiation facility's management system. More detailed guidance on clinical audits is given in Refs [48–50].

2.149. GSR Part 3 [3], in the context of medical exposure, requires the performance of a radiological review and this should be incorporated into the medical radiation facility's management system (see para. 3.182 of GSR Part 3 [3]). 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 ASSESSMENT

2.150. 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. As noted in para. 2.70, the regulatory body has the responsibility 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 Requirement 13 and para. 3.29 of GSR Part 3 [3]).

2.151. Paragraphs 3.30–3.35 of GSR Part 3 [3] establish requirements on what a safety assessment is to include, what the registrant or licensee is to take into account, its documentation and placement in the management system, and when additional reviews of the safety assessment are to take place. More detailed requirements on safety assessment (for all facilities and activities) are given in IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities [51]. 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.

2.152. GSR Part 3 [3] specifies two types of safety assessment: generic and specific to the practice or source. A generic safety assessment is usually sufficient for types of source with a high degree of uniformity in design. A specific safety assessment is usually required in other cases; however, the specific safety assessment need not include those aspects covered by a generic safety assessment if a generic safety assessment has been conducted for the source. The safety assessments for 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 to be used by medical radiation facilities for safety assessments for the various modalities and specialties in medical uses of ionizing radiation [13, 51].

2.153. GSR Part 3 [3] requires that potential exposure 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 might occur, but could result from an accident or from an event or a sequence of events that might occur. As stated in Requirement 15 of GSR Part 3 [3]: "Registrants and licensees…shall take all practicable measures to prevent accidents and to mitigate the consequences of those accidents that do occur."

2.154. Paragraph 3.43 of GSR Part 3 [3] states that:

> "If the safety assessment indicates that there is a reasonable likelihood of an emergency affecting either workers or members of the public, the registrant

or licensee shall prepare an emergency plan for the protection of people and the environment. As part of this emergency plan, the registrant or licensee shall include arrangements for the prompt identification of an emergency, and for determining the appropriate level of the emergency response….”

Situations that can lead to an emergency in a medical setting are loss of control over the source as a result of technical failure, human error, a nuclear security event, or conventional emergencies such as fires and earthquakes. More detailed requirements and guidance on emergency preparedness and response are given in GSR Part 7 [7], GSG-2 [8] and GS-G-2.1 [9].

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

GENERAL

3.1. This section covers radiographic and fluoroscopic diagnostic procedures, image guided interventional procedures, and imaging studies using X ray radiation that are part of the processes of radiation therapy or nuclear medicine. These radiological procedures usually take place in facilities that are in a fixed location, but they can also take place in mobile facilities.

3.2. The radiographic procedures aim to image or quantify a particular organ or tissue in two, three or four dimensions, and include general radiography, CT, CBCT, mammography, tomosynthesis, dental radiography (intraoral, panoramic and CBCT) and bone densitometry (DXA).

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 or angioplasty, uterine artery embolization, aortic valve

implantation and aortic endografts. Common non-vascular procedures include, for example, biliary drainage or stenting, and injecting cytostatic agents into the liver. Fluoroscopically guided intraoperative procedures include, for example, intramedullary nailing and vertebroplasty. Some image guided interventional procedures involve the use of sealed or unsealed radiation sources, for example in intracoronary radiation therapy to prevent coronary artery restenosis.

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. Radiology facilities include: a traditional radiology department in a hospital or medical centre; a stand alone X ray imaging facility; an interventional cardiology (or other specialty) department, unit or facility, either stand alone or as part of a larger entity; and a dental practice.

3.6. Different health professionals can take on the role of the radiological medical practitioner (see para. 2.90) in diagnostic radiology and 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, osteopaths and podiatrists.

3.7. As stated in para. 2.92, the term ‘medical radiation technologist’ is used in GSR Part 3 [3] and this Safety Guide as a generic term for the health professional known by several different terms in different States; such terms include radiographer, radiological technologist and others. Clearly, each State will use its own term in its own jurisdiction.

3.8. 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 guidance is relevant to diagnostic radiology and image guided interventional procedures, and reference to Section 2 should be made as necessary.

SAFETY OF MEDICAL RADIATION FACILITIES AND MEDICAL RADIOLOGICAL EQUIPMENT

Radiology facilities

Fixed facilities: Design of X ray rooms

3.9. Paragraph 3.51 of GSR Part 3 [3] establishes the broad requirements to be met when choosing a location to use a radiation generator, and these are relevant to the design of a radiology facility. Provisions for the incorporation of radiation protection and safety features are best made at the facility design stage (e.g. for X ray rooms and other related rooms). The siting and layout should take into account the types of radiological procedure, 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, within other departments of the facility. Guidance on setting up diagnostic radiology and interventional radiology facilities is given in Refs [52–55].

3.10. The three factors relevant to dose reduction (time, distance and shielding) should be combined in the design to optimize occupational radiation protection and public radiation protection. Larger rooms are preferable to allow easy access for patients on bed trolleys. 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 to reduce time and exposure. Larger rooms will also reduce the levels of secondary radiation (due to scattering and leakage) potentially reaching areas occupied by staff and public areas, typically reducing the level of shielding required.

3.11. Shielding requirements should be tailored to meet any national requirements and to suit the practice requirements based on the intended patient workload and the types of examination to be performed. Further assessments should be undertaken when the intended use of a room changes, X ray equipment is upgraded, underlying procedures or patient workload changes, or the surrounding room occupancy is altered.

3.12. At the design stage, the use of both structural and ancillary protective barriers to provide shielding should be considered. 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, and should be designed so as not to interfere with the medical procedure (e.g. sterility requirements). Wall shielding should be at least 2 m 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 ceiling shielding when rooms immediately below and above the X ray installation 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 3.18–3.24.

3.13. General safety features of radiography, mammography, CT and fluoroscopy rooms include the following:

(a) A barrier should be placed at the control console to shield staff to the extent that they do not need to wear protective clothing while at the console. This is particularly important in mammography, where structural shielding in walls, ceiling and floor might not be deemed necessary.
(b) In 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 that is not shielded and which could lead to potentially unacceptable doses being received in this area.
(c) The doors should provide protective shielding for secondary radiation and should be shut when the X ray beam is on. In 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 and communicate with the patient at all times during an X ray diagnostic procedure.

3.14. Signs and warning lights, preferably positioned at eye level, should be used at the entrances of controlled areas and supervised areas to prevent inadvertent entry (see also paras 3.279 and 3.280 on control of access). For controlled areas, para. 3.90(c) of GSR Part 3 [3] requires the use of the basic ionizing radiation symbol recommended by the International Organization for Standardization (ISO) [56]. The signs should be clear and easily understandable. Warning lights, such as illuminated or flashing signs, as appropriate, should be activated when radiation is being produced inside the controlled area or supervised area. Door interlocks are not appropriate in X ray diagnostic radiological procedures because if the X ray beam is stopped, the medical procedure may have to be repeated.

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

3.16. The design of the facility should include an air conditioning system sufficient to maintain the temperature in the examination room (and sometimes in areas with computer equipment and detectors) within the parameters defined by the equipment manufacturers, but consistent with health and safety requirements for temperature and humidity.

Mobile facilities

3.17. 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 the following:

(a) Mobile facilities should be built so that protection is optimized mainly through shielding (in all relevant directions during use), as providing protection through distance is often limited and exposure time is determined by the procedure being performed.
(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 for mobile mammography facilities but not for mobile CT facilities.
(e) To facilitate the imaging procedure, including patient flow, mobile CT facilities are usually operated adjacent to a hospital or clinic, from where they can draw water and electricity, and where patients can use the toilets, waiting rooms and changing rooms and have access to physician offices. Similarly, mobile mammography facilities may also utilize hospital or clinic facilities.

Shielding calculations

3.18. Two widely used methodologies for shielding calculations are given in Refs [57, 58], but other methodologies are also available and used (e.g. see Refs [55, 59]), as well as specific shielding calculations for the WHIS-RAD X ray unit[19] [60]. The nominal design dose in an occupied area is derived by the process of constrained optimization (i.e. selection of a source related dose constraint), with the condition that each individual dose from all relevant sources is well below the dose limit for a person 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 that the shielding needs to provide to ensure that the nominal design doses are met.

3.19. The shielding thickness is obtained from the attenuation factor required to reduce the dose that would be received by staff and the public if shielding were not present to a dose value considered acceptable. This nominal design dose should be derived by a process of optimization:

(a) The dose that would be received without shielding is calculated by using workload values, use factors for a given beam direction (the fraction of the total amount of radiation emitted in that direction) and occupancy factors (the fraction of the total exposure that will actually affect individuals at a place, by virtue of the time spent by an individual 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 changes in practice and increases in workload 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 that meets national regulations and that can be considered optimized protection; that is, 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.

[19] The World Health Imaging System is general purpose X ray equipment built in accordance with specifications developed by the World Health Organization for developing countries.

3.20. When a shielding methodology is applied to optimize occupational and public radiation protection, decisions will need to 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 specification of the shielding. Realistic assumptions should be used as much as possible, with some allowance for future changes in use. Adequacy of the shielding specification should be ensured as corrective actions after building has been completed will invariably be difficult and expensive. Furthermore, it is likely that the building materials used to provide the shielding will be supplied in specific discrete thicknesses or densities and this can be used to provide a safety margin over the calculated shielding values. If a material other than lead is to be used, tabulated values should be used only for materials that match those being considered (in terms of their chemical composition, density and homogeneity) as closely as possible. The following are some assumptions that would 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 dose constraints (in 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.

3.21. Particular attention should be given to hybrid imaging systems, where the shielding should be calculated for each modality and combined as appropriate [54, 61, 62] (see also paras 4.32–4.35).

3.22. Consideration should be given in the design stage to making sure that radiosensitive equipment and consumables, for example computed radiography (CR) cassettes and X ray films, are appropriately shielded. Where used, darkrooms for film processing may require extra shielding to prevent film fogging.

3.23. Specification of shielding, including calculations, should be performed by a medical physicist or a qualified expert in radiation protection. In some States, 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 para. 2.74).

3.24. 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 should be met (para. 2.74).

Design of display and interpretation (reading) rooms

3.25. To facilitate their interpretation by the radiological medical practitioner, images should be displayed in rooms specifically designed for such purposes. A low level of ambient light in the viewing room should be ensured (see also paras 3.45 and 3.46 on image display devices and view boxes).

3.26. 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. 3.46).

Medical radiological equipment, software and ancillary equipment

3.27. This subsection considers medical radiological equipment, including its software, used in diagnostic radiology and image guided interventional procedures, including radiography, fluoroscopy and angiography, CT, CBCT, mammography, dental radiology, bone mineral densitometry (e.g. DXA) and tomography (including tomosynthesis). It is also applicable to the X ray based component of hybrid imaging modalities, including PET–CT, single photon emission computed tomography (SPECT)–CT, and PET–mammography, and the X ray based component of image guided radiation therapy (IGRT) systems. Some of this equipment might be used in a nuclear medicine facility or in a radiation therapy facility, rather than a radiology facility.

3.28. The requirements for medical radiological equipment and its software are established in paras 3.49 and 3.162 of GSR Part 3 [3]. The International Electrotechnical Commission (IEC) has published international standards applicable to medical radiological equipment. Current IEC standards relevant to X ray imaging include Refs [63–103] (for those relevant to the radiopharmaceutical based component of hybrid imaging, see para. 4.41). It

is recommended that the IEC web site be visited to view the most up to date list of standards. ISO publishes international standards applicable to medical radiological equipment. It is recommended that the ISO web site be visited to view the most up to date list of standards.

3.29. 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 or equivalent national standards. In some States, there may be an agency with responsibilities for medical devices or a similar organization that gives type approval to particular makes and models of medical radiological equipment.

3.30. Displays, gauges and instructions on operating consoles of medical radiological equipment, and accompanying instruction and safety manuals, might be used by staff who do 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 or into a language acceptable to 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 should be subject to a quality assurance process to ensure proper understanding and to avoid operating errors. The same applies to maintenance and service manuals and instructions for maintenance and service engineers and technicians who do not have an adequate understanding of the original language (see also paras 2.104 and 2.137).

3.31. 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 para. 2.105).

Design features for medical radiological equipment

3.32. 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 meeting the requirement of para. 3.163(b) of GSR Part 3 [3] for operational optimization of patient protection, 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 radiological procedure, with account taken of 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 (see paras 3.33–3.41). Further details on design features and performance standards of medical radiological equipment used in diagnostic radiology and image guided interventional procedures are given in Refs [67–74, 76, 78–83, 98–108] (see also paras 3.232–3.246 on quality assurance and acceptance testing, in particular para. 3.236).

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

(a) Means to detect immediately any malfunction of a single component of the system that may lead to an inadvertent underexposure or overexposure 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 of human error and its impact on the delivery of unintended or accidental medical exposure.
(c) Hardware and software controls that minimize the likelihood of unintended or accidental medical exposures.
(d) Operating parameters for radiation generators, such as the generating tube potential, filtration, focal spot position and size, source to image receptor distance, field size indication and either tube current and time or their product, that are clearly and accurately shown.
(e) Radiation beam control mechanisms, including devices that indicate clearly (visually and/or audibly) and in a fail-safe manner when the beam is on.
(f) X ray tubes with inherent and added filtration adequate to remove low energy components 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, dental X ray and CT equipment, diagnostic and interventional X ray equipment that is fitted with continuously adjustable beam collimating devices. Such devices allow the operator[20] 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, technique factors that are readily accessible and modifiable by adequately trained personnel.

[20] The term ‘operator’ is used in a general sense in this section. The operator is usually a medical radiation technologist, but may sometimes be a radiological medical practitioner.

(j) Design of the X ray tube to keep radiation leakage as low as reasonably achievable and not exceeding 1 mGy in an hour measured at 1 m from the focal spot, and less than maximum levels specified in international standards or in local regulations.

3.34. Specific design features for medical radiological equipment used in radiography should include the following:

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

3.35. Specific design features for medical radiological equipment used for dental radiography should include the following:

(a) A minimum tube potential of 60 kV_p;
(b) For intraoral dental systems, an open-ended (preferably rectangular) collimator providing a focus to skin distance of at least 20 cm and a field size at the collimator end of no more than 4 cm × 5 cm if rectangular or 6 cm in diameter if cylindrical, and limitation of field size to the dimensions of the image receptor;
(c) For panoramic dental systems, limitation of field size to the area required for diagnosis by means of programmed field size trimming and the 'child imaging mode';
(d) For dental CBCT, adjustable X ray tube potential and tube current–exposure time product, and a choice of volume sizes and voxel sizes.

3.36. Specific design features for medical radiological equipment used for CT should include the following:

(a) Console display of all CT parameters that directly influence the image acquisition (these can be displayed over a number of screens);

(b) Console display of estimated volume CT air kerma index and CT air kerma–length product for the procedure or image acquisition;
(c) Operator alert if exposure factors are set too high (usually expressed in terms of the volume CT air kerma index and/or the CT air kerma–length product);
(d) Means for dose modulation (rotational and z-axis), and means for selection of noise index or equivalent;
(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;
(g) A range of selectable tube potentials, tube current–exposure time products, and filters to facilitate the optimization of protocols, especially for children.

3.37. Specific design features for medical radiological equipment used for mammography (both digital systems and film–screen systems) should include the following:

(a) Various anode and 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;
(e) An image receptor or image receptors to accommodate all breast sizes.

3.38. Specific design features for medical radiological equipment used for fluoroscopy should include the following:

(a) The provision of a device that energizes the X ray tube only when continuously depressed (such as an exposure foot switch or 'dead man' switch);
(b) Indications or display (both at the control console and on monitors) of the elapsed time, air kerma–area product, and cumulative reference air kerma;
(c) Automatic brightness control (ABC) or automatic dose rate control (ADRC);
(d) Pulsed fluoroscopy and pulsed image acquisition modes;
(e) The capture and display of the last acquired frame (last image hold);

(f) Interlocks that prevent inadvertent energizing of the X ray beam when the image detector is removed from the imaging chain;
(g) The capability to deactivate the exposure foot switch between cases;
(h) The provision of a timer and an alarm that sounds at the end of a pre-set interval (typically 5 min).

3.39. In addition to those listed in para. 3.38, design features for medical radiological equipment used for image guided interventional procedures should include the following:

(a) X ray tubes that have high heat capacities to enable operation at high tube currents and short times.
(b) A radiation generator with a capability of at least 80 kW.
(c) A radiation generator with a large dynamic range of tube current and tube potential (to minimize the pulse width necessary to accommodate differences in patient attenuation).
(d) For paediatric work:
   — A radiation generator that supports an X ray tube with a minimum of three focal spots;
   — An anti-scatter grid that is removable;
   — An image acquisition frame rate that extends up to at least 60 frames per second for small children.
(e) A real time display of air kerma–area product and cumulative reference air kerma.
(f) Imaging detectors that allow different fields of view (magnification) to improve spatial resolution.
(g) Automatic collimation.
(h) Dual-shape collimators incorporating both circular and elliptical shutters to be used to modify the field for collimation along cardiac contours.
(i) System specific variable filtration in the X ray beam that is applied according to patient attenuation (often as part of the ADRC system).
(j) Selectable dose per pulse and selectable number of pulses per second.
(k) Wedge filters that move automatically into the field of view to attenuate the beam in areas where there is no tissue and thus no need for imaging.
(l) Possible means for manipulation of diaphragms while in ‘last image hold’.
(m) The option of the automatic display of the last acquired image run.
(n) Display and recording in a dose report in digital format of the following parameters:
   — Reference air kerma rate;
   — Cumulative reference air kerma;
   — Cumulative air kerma–area product;

— Cumulative time of fluoroscopy;
— Cumulative number of image acquisitions (acquisition runs and frames per run);
— Integrated reference air kerma;
— Option for digital subtraction angiography;
— Road mapping, which is a technique used for navigation of the catheter or wire in endovascular procedures.

3.40. 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, DICOM object), including export of dose metrics for the purpose of DRLs and individual patient dose calculation;
(b) Connectivity to RIS and to PACS.

3.41. 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 who may be uncooperative and suit the imaging of very small patients. Such features include the following:

(a) Capability of very short exposure times for radiography;
(b) Specifically designed AEC systems;
(c) Provision of 'paediatric modes' for the automatic brightness and/or dose rate control systems in fluoroscopy and image guided interventional procedures;
(d) Paediatric protocols for CT;
(e) Child imaging mode for dental panoramic and CBCT equipment.

Other equipment

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 an acceptable 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 processing times based on the developer temperature. The darkroom for processing should meet relevant international and national standards for light tightness and should be equipped with an appropriately filtered safe-light,

compatible with the film being used. Further details are given in Refs [79, 109–114].

3.43. For radiology facilities where film is the medium from which the image is read (e.g. a printed digital image), the printing process plays a crucial role in ensuring the medical exposure delivered results in a diagnostic image. The resolution of the printer should not be less than the resolution of the detector, so that the image quality of the final image is not limited or compromised.

3.44. The characteristics of image receptors (film–screen, phosphor plates for CR or flat detectors for digital radiography (DR)) should be appropriate for the diagnostic imaging task. For example, high resolution is needed for breast imaging, and high sensitivity detectors are needed for paediatric imaging.

3.45. 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. Detailed guidance is given in Refs [109–114] (see paras 3.25 and 3.26 for guidance on display and interpretation rooms).

3.46. All equipment used for digital image display should meet appropriate international and national standards, for example meeting the performance specifications in Ref. [115].

Maintenance

3.47. Paragraphs 3.15(i) and 3.41 of GSR Part 3 [3] establish 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 is required to ensure that adequate maintenance (preventive maintenance and corrective maintenance) is performed as necessary to ensure that medical radiological equipment retains, or improves through appropriate hardware and software upgrades, its design specifications for image quality and radiation protection and safety for its useful life. The registrant or licensee should, therefore, establish the necessary arrangements and coordination with the manufacturer or installer before initial operation and on an ongoing basis.

3.48. All maintenance procedures should be included in the comprehensive programme of quality assurance and should be carried out 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 programme of quality assurance. 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 repairs and subsequent repairs) and the results of testing before equipment is reintroduced to clinical use.

3.49. In line with the guidance provided in para. 2.113, after any modifications or maintenance, the person responsible for maintenance should immediately inform the licensee of the medical radiation facility before the equipment 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.

3.50. The electrical safety and mechanical safety aspects of the medical radiological equipment are an important part of the maintenance programme, as these can have direct or indirect effects on radiation protection and safety. Authorized persons who understand the specifications of the medical radiological equipment should perform this work (see also paras 2.112–2.114). Electrical and mechanical maintenance should be included in the programme of quality assurance and should be performed, preferably by the manufacturer of the medical radiological equipment or an authorized agent, at a frequency recommended by the manufacturer. Servicing should include a written report describing the findings. These reports and follow-up corrective actions should be archived as part of the programme of quality assurance.

OCCUPATIONAL RADIATION PROTECTION

3.51. In the diagnostic imaging procedures described in paras 3.1–3.4, occupationally exposed individuals are usually the medical radiation technologists and the radiological medical practitioners (e.g. including radiologists and, in dental practices, dentists operating X ray machines). In a trauma centre, other

health professionals such as nurses, emergency department physicians and anaesthetists who may have to be present when portable or fixed X ray machines, including C-arm fluoroscopes, are used or who may have to be present in the CT room when the unit is operating may also be considered occupationally exposed.

3.52. 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, anaesthetists, 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 the physiological parameters of the patient. Some complex and lengthy procedures may require more than one interventionist.

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

3.54. Other radiology facility workers, such as ward nurses, imaging staff who work exclusively with imaging modalities without ionizing radiation (ultrasound or magnetic resonance imaging (MRI)), patient porters, orderlies, assistants, cleaners and other service support personnel, for whom radiation sources are not required by, or directly related to, their work, are required to have the same level of protection as members of the public, as established in para. 3.78 of GSR Part 3 [3]. Consequently, the recommendations provided in paras 3.277–3.280 are also applicable in respect of such workers. Rules should be established for these workers, especially with regard to access to controlled areas and supervised areas.

3.55. This subsection contains guidance very specific to diagnostic radiology and image guided interventional procedures. More general and comprehensive guidance on occupational radiation protection is given in GSG-7 [23], 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).

Arrangements under the radiation protection programme

Classification of areas

3.56. Various areas and rooms in a radiology facility should be classified as controlled areas or supervised areas, in line with the requirements established in paras 3.88–3.92 of GSR Part 3 [3]. All other rooms and areas that are not so designated are considered as being in the public domain, and levels of radiation in these areas should be low enough to ensure compliance with the dose limits for public exposure. Paragraphs 3.57–3.59 give general guidance, and it would be expected that final decisions by the licensee for a given medical radiation facility would be based on the expert advice of the medical physicist, a qualified expert in radiation protection or the RPO.

3.57. 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 procedures are being carried out. Open plan emergency departments (i.e. areas without fixed walls where curtains 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.

3.58. Supervised areas may involve areas surrounding X ray rooms. A typical design of a radiology department includes two basic areas: one for patient circulation, which includes the reception, waiting rooms and corridors from which the X ray rooms can be accessed through the dressing cabinets; and another for staff circulation, which 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 to enter the X ray rooms inadvertently and be exposed.

3.59. 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. Access of unauthorized individuals to control console areas should be restricted to avoid the distraction of the operator, which might lead to unnecessary or repeated exposures. Control panel areas are not in the public domain and therefore should be classified as either controlled areas or supervised areas.

Local rules and procedures

3.60. Paragraph 3.93 of GSR Part 3 [3] 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 established in para. 3.94 of GSR Part 3 [3], local rules and procedures are required to be established in writing in any radiology facility. Their purpose is to ensure protection and safety for workers and other persons. Such local rules and procedures should include measures to minimize occupational radiation exposure both for normal work and in unusual events. The local rules and procedures should also cover the wearing, handling and storing of personal dosimeters, and should specify investigation levels and ensuing follow-up actions (see paras 3.104–3.129).

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

3.62. Equipment (both 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 protection and safety. The manufacturer's operating manual is an important resource in this respect, but additional procedures are likely to be needed. The final documented set of operational procedures should be subject to approval by the licensee of the radiology facility, and should be incorporated into the facility's management system (see paras 2.138–2.149).

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

3.64. Many local rules and procedures address some or all aspects of occupational radiation protection, patient radiation protection and public radiation protection, either directly or indirectly, as well as providing for a successful diagnostic examination or intervention. Paragraphs 3.65–3.88 give recommendations that should be incorporated into the radiology facility's local rules and procedures. They are placed in this section on occupational radiation protection because they

are to be followed by workers, but they will often also have significance for patient and public radiation protection.

3.65. 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.

3.66. In general, there should be no need for occupationally exposed staff to hold, or have close contact with, patients during a radiological procedure. If such holding or contact is indeed necessary, then the person to be used in that role should be considered a carer or comforter of the patient, and should be afforded the appropriate radiation protection described in paras 3.247–3.251.

3.67. Immobilization devices (e.g. a CT head cradle) should be used whenever possible and as appropriate to minimize exposure of the patient, the staff member or the 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 or comforter and is afforded radiation protection accordingly (see paras 3.247–3.251).

3.68. For general radiography:

(a) The X ray tube should not be pointed at the control console area.
(b) Given that the patient is the source of scatter radiation, care should be taken to ensure that the position of the patient is as far from the control console as is feasible, with account taken of the room configuration and accessories, and preferably more than 1 m distant from the console.

3.69. For mobile radiography:

(a) Operators should wear lead aprons and should maintain as much distance as possible between themselves and the patient (to minimize exposure to scatter radiation), whilst still maintaining good visual supervision of the patient and being able to communicate verbally with him or 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 (typically at least 3 m) or are behind appropriate barriers.

(c) In situations in which 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 should be given.
(e) Consideration should be given to other patients nearby (see also para. 3.276 on public radiation protection).

3.70. 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 who need to be adjacent to the patient being exposed.
(b) The primary beam should be directed away from staff and other patients whenever possible.
(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 should be given.

3.71. 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 (a protective apron, a thyroid shield and protective eyewear). In addition, care should be exercised to avoid the placing of hands in the primary beam and immediate notification to the interventionist should be given if this happens.
(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.

3.72. 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 (a protective apron, a thyroid shield, protective eyewear and

gloves). In addition, care should be exercised to avoid the placing of hands in the primary beam and immediate notification to the fluoroscopist should be given if this happens.

(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 exposure.

3.73. For radiological procedures performed with mobile fluoroscopic units (C-arm systems), the following measures should be taken:

(a) The staff member performing the procedure should use personal protective equipment (a protective apron, a thyroid shield, protective eyewear and gloves). In addition, care should be exercised to avoid the placing of hands in the primary beam and immediate notification to the fluoroscopist should be given if this happens.

(b) Only essential staff should remain in the room. All such staff are considered occupationally exposed workers.

(c) In situations in which 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.

For other practical advice, including X ray tube orientation and positioning, mobile shields, technical parameter selection, see paras 3.79–3.87 on image guided interventional procedures.

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

3.75. For dental facilities with intraoral and panoramic equipment, the following measures should be taken:

(a) 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 2 m is recommended.

(b) The operator should not hold the image receptor during the exposure.

(c) Handheld portable X ray equipment for intraoral radiography should be used only for examinations where it is impractical or not medically acceptable to transfer patients to a fixed unit or to use a mobile unit (e.g. in nursing homes, residential care facilities or homes for persons with

disabilities; in forensic odontology; or for military operations abroad without dental facilities) [116].

3.76. CBCT is used in some dental facilities, and should be housed in a room that has been designed and shielded accordingly. Staff should be positioned behind the protective barrier at the control console when exposures are made.

3.77. For DXA, 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 operator's 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.

3.78. Local rules for pregnant workers and persons under the age of 18 should reflect the guidance given in paras 3.133–3.135 and 3.136, respectively.

Specific local rules and procedures for image guided interventional procedures

3.79. 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 very ill 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 other specialists). Not only will more staff be exposed during interventional procedures, but they may also be standing close to the patient, where dose rates from radiation scattered by the patient are high.

3.80. Interventional procedures require specifically designed and dedicated equipment. The dose 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 radiation 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.

3.81. There are simple methods of reducing exposure of staff by means of operational factors, including choosing where to stand in the room. Since the

patient is the main source of scatter radiation, staff members should remain as far away as practicable from the patient when exposures take place to reduce exposure of staff. For the interventionist, taking a step or even half a step back during image acquisition will result in a significant reduction in occupational dose. As stated in para. 3.80, the orientation and positioning of the X ray tube will determine where it is best to stand in order to be in an area subject to relatively low amounts of scatter radiation. Automatic contrast media injectors should be used when feasible to allow personnel to move away from the patient, ideally behind a shield.

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

3.83. There are many operational factors that affect 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 radiation being produced. Methods to reduce patient dose are described in paras 3.189–3.195, and should always be used to reduce both patient and staff doses.

3.84. 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 degree of 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.

3.85. A higher incidence of radiation injuries to the lens of the eye has been reported for interventionists and nurses performing image guided interventional procedures [117]. For this reason interventionists, and other staff who routinely work close to the patient, should always use ceiling mounted screens or protective eyewear. This is further reinforced by the relatively low dose limit (20 mSv per year) for the lens of the eye (see para. 2.22 and Box 1). 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 did not use any protection for the eyes. Protective shielding devices are effective only when they

are interposed between the source of radiation and the eye. Care should be taken in the proper positioning of the imaging displays to ensure optimum benefit is derived from the use of screens and protective eyewear.

3.86. Further specific guidance on interventional radiology and interventional cardiology, endorsed by several regional professional societies, can be found in Refs [117, 118].

3.87. Some image guided interventional procedures are performed using CT, and the guidance given in para. 3.71 applies.

3.88. For image guided interventional procedures involving intracoronary implantation of unsealed and sealed radiation sources, reference should be made to the guidance, where appropriate, in paras 4.75–4.89 and paras 5.117–5.145, respectively.

Personal and in-room protective devices

3.89. Paragraphs 3.93 and 3.95 of GSR Part 3 [3] require that personal protective equipment and in-room protective devices 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 during radiological procedures, such as with image guided interventional procedures and fluoroscopy, and with mobile radiography. The need for this protective equipment should be established by the RPO or the medical physicist at the radiology facility.

3.90. Personal protective equipment is worn on the person and includes protective aprons, thyroid shields, protective eyewear 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.

3.91. 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.

3.92. Protective gloves are useful for protecting the hands near the beam, but can produce the opposite effect during fluoroscopy with ABC or ADRC when the hands enter the area covered by the sensor of the ABC or ADRC, 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 or ADRC, leaded gloves can prolong the procedure because they do not afford the necessary tactile sensitivity and thus their value is questionable.

3.93. Protective eyewear, especially for use in image guided interventional procedures, should cover the entire orbit. This means that lateral protection should be provided by shielded sides and the glasses should be a close fit.

3.94. The lead equivalence of personal protective equipment should be specified at the maximum operating X ray tube potential applicable for its intended use.

3.95. Non-lead based personal protective equipment, incorporating shielding materials, such as tin, tungsten, bismuth and antimony, can 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.

3.96. Protective equipment for pregnant workers should be carefully considered, as wrap around aprons may no longer provide adequate protection for the embryo or fetus (para. 3.114 of GSR Part 3 [3]). The RPO or medical physicist should be consulted as necessary.

3.97. Items of 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 by ensuring aprons are correctly hung and stored to minimize damage.

3.98. Personal protective equipment should be examined under fluoroscopy or radiography periodically to confirm its shielding integrity.

3.99. 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 protective drapes for the patient.

Workplace monitoring

3.100. Paragraphs 3.96–3.98 of GSR Part 3 [3] establish the requirements and responsibilities for workplace monitoring. Workplace monitoring comprises measurements made in the working environment and the interpretation of the 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 GSG-7 [23].

3.101. Workplace monitoring in areas around each item of 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 of 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 radiation 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 of the medical radiological equipment has been performed, which could have an impact on the radiation delivered.

3.102. 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 are triggered when investigation levels are exceeded (see paras 3.121 and 3.122).

3.103. The survey meters used for radiation monitoring should be calibrated in terms of ambient dose equivalent. The calibration should be current, and should be traceable to a standards dosimetry laboratory. For diagnostic radiology and image guided interventional procedures, the quantity is the ambient dose equivalent, $H^*(10)$, and the unit is the sievert (Sv) and its submultiples (for more detailed guidance, see GSG-7 [23]).

Assessment of occupational exposure and health surveillance for workers

Assessment of occupational exposure

3.104. The purpose of monitoring and dose assessment is, inter alia, to provide information about the exposure of workers and to confirm good working practices and regulatory compliance. Paragraph 3.100 of GSR Part 3 [3] establishes the requirement of individual monitoring for "any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure". Workers who may require individual monitoring include radiologists, cardiologists, gastroenterologists, endoscopists, urologists, orthopaedic surgeons, neurosurgeons, respiratory physicians, anaesthetists, medical physicists, biomedical and clinical engineers, medical radiation technologists, nurses and the RPO.

3.105. Monitoring involves more than just measurement. It includes interpretation, assessment, investigation and reporting, which may lead to corrective measures, if necessary. Individual external doses can be assessed by using individual monitoring devices, which include thermoluminescent dosimeters, optical stimulated luminescent dosimeters, radiophotoluminiscent dosimeters, film badges and electronic dosimeters. When electronic dosimeters are used in pulsed X ray fields, care should be taken to ensure that they are functioning correctly. Individual monitoring devices should be calibrated and should be traceable to a standards dosimetry laboratory (for more detailed guidance, see GSG-7 [23]).

3.106. Each dosimeter should be used for monitoring only the person to whom it is issued, for work performed at that radiology facility, and it should not be

taken to other facilities where that person may also 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 or she also works. Monitoring results can then be interpreted for the person working in a specific radiology facility, and this will allow appropriate review of the effectiveness of the optimization of protection and safety for that individual in that facility. However, national regulatory requirements may differ from this advice, and they would need to be followed in those jurisdictions in which they apply (see also paras 3.123–3.125).

3.107. The monitoring period (period of dosimeter deployment) specified by regulatory bodies in most States 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 exposure, 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 is less than the minimum detection level of the dosimeter, resulting in no detectable doses. With a longer cycle, it is more likely that a reading can be obtained. Dosimeters should be sent from the radiological facility to the dosimetry service provider, which 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.

3.108. The operational dosimetric quantity used is the personal dose equivalent $H_p(d)$. For weakly penetrating radiation 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 [119, 120]. If a protective apron or thyroid shield is being worn, the relationship between $H_p(10)$ and effective dose becomes more complex; additional guidance is given in para. 3.115.

3.109. 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.

3.110. 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 (see Ref. [121] for further information).

3.111. There are three dose limits applicable to workers in diagnostic radiology and image guided interventional procedures: the limit for effective dose, and the limits for equivalent dose to the lens of the eye and to the 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 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. For image guided interventional procedures, two dosimeters should be worn.

3.112. For individual monitoring with only one dosimeter in diagnostic radiology and image guided interventional procedures the following recommendations are made:

(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. 3.113), except if national regulations require the dosimeter to be worn under the apron.
(d) If the working situation is such that the radiation always or predominantly comes from one side of the person, such as in image guided interventional procedures, the dosimeter should be placed on the front of the torso on the side closest to the source of radiation; the guidance in (a) to (c) should also be followed in this case.

3.113. 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.

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

3.115. When a protective apron is being used, the assessment of effective dose might 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 of the parts of the body protected by the apron, but underestimates the contribution of the unprotected parts of the body (the thyroid, the head and neck, and the 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 [120, 122, 123].
(c) Where two dosimeters are worn, one under the apron and the other outside the apron, an algorithm should be applied to estimate the effective dose from the two reported values of $H_p(10)$ [120, 122].

3.116. As noted in para. 3.110, 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 or not protective eyewear was worn should be taken into account to interpret the dose estimate correctly.

3.117. When not in use, individual dosimeters should be kept in a dedicated place and should be protected from damage or from irradiation. If an individual loses his or her dosimeter, the individual should inform the RPO, who should perform a dose assessment, record this evaluation of the dose and add it to the individual's dose record. Where there is a national dose registry, it should be updated with 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 cases where the individual performs non-routine types of work, it may be better to use the doses of co-workers experiencing similar exposure conditions as the basis for the dose estimate.

3.118. 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. With knowledge of 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.

3.119. 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 $H^*(10)$. The ICRP [119] provides conversion coefficients from ambient dose equivalent to effective dose for different types of radiation and energy. The conversion coefficients for photons are close to unity except for very low energy photons, such as photons scattered from a mammography X ray beam.

3.120. An additional direct reading operational dosimeter, such as an appropriately calibrated electronic dosimeter, can also be 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 tool for the optimization of occupational radiation protection [23].

Investigation levels for staff exposure

3.121. Investigation levels are different from dose constraints and dose limits; they are a tool used to provide a warning of the need to review procedures and performance, to investigate what is not working as expected and to take timely corrective action. The exceeding of an investigation level should prompt such actions. For example, for diagnostic radiology and image guided interventional procedures, monthly values higher than 0.5 mSv (for a dosimeter worn under a protective apron) could be investigated. Values higher than 2 mSv per month [118] from an over-apron dosimeter might indicate that eye doses are of concern. Values higher than 15 mSv per month for hand or finger dosimeters should also be investigated [117, 118]. Abnormal conditions and events should also trigger an investigation. In all cases, the investigation should be carried out with a view to improving the optimization of occupational protection, and the results should be recorded. Investigation levels should also be set for workplace monitoring, with account taken of exposure scenarios and the predetermined values adopted for investigation levels for workers. Details on investigation levels are provided in GSG-7 [23].

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

Persons who work in more than one place

3.123. Some individuals might work 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 but separate management, or they may even have common ownership and management but be physically quite separate. Regardless of the ownership and management structure, the occupational radiation protection requirements for the particular radiology facility apply when the person is working in that facility. As described in para. 3.106, a dosimeter issued for individual monitoring should be worn only in the facility for which it is issued, as this facilitates the effective optimization of protection and safety in that facility. This approach is logistically more easily implemented, since each physical site has its own dosimeters, and so there is no need to transport dosimeters between facilities, with the risk of losing 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. 3.125).

3.124. There is, however, an important additional consideration, namely the need to ensure compliance with the occupational dose limits. Any person who works in more than one radiology facility should notify the licensee for each of those facilities. Each licensee, through its RPO, should establish 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 ongoing record of the occupational doses for that person in all the facilities where he or she works.

3.125. Some individuals, such as consultant medical physicists or service engineers, might perform work in many radiology facilities and, in addition, in other medical radiation facilities. They can be employed by a company or be self-employed, providing contracted services to the radiology facility and the

other facilities. In such cases, it is simpler for the company or the self-employed person to provide the dosimeters for individual monitoring. Therefore, in these cases, a worker uses the same dosimeter for work performed in all radiology facilities (and other medical radiation facilities) in the monitoring period.

Records of occupational exposure

3.126. Paragraphs 3.103–3.107 of GSR Part 3 [3] establish the detailed requirements for records of occupational exposure and place obligations on employers, registrants and licensees. In addition to 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 optimization of protection and safety at the facility 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. Employers are required to provide workers with access to records of their own occupational exposure (para. 3.106(a) of GSR Part 3 [3]). Further general guidance on records of occupational exposure is given in GSG-7 [23].

Health surveillance for workers

3.127. 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 paras 3.108 and 3.109 of GSR Part 3 [3].

3.128. No specific health surveillance relating to exposure to ionizing radiation is necessary for staff involved in diagnostic radiology and image guided interventional procedures, with perhaps the possible exception of initial eye assessment 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 influence significantly the

decision about the fitness of a worker to undertake work with radiation or to influence the general conditions of service [23].

3.129. Counselling should be made available to workers who have or may have been exposed in excess of dose limits, and information, advice and, if indicated, counselling should be made 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. Counselling should be given by appropriately experienced and qualified practitioners. Further guidance is given in GSG-7 [23].

Information, instruction and training

3.130. All staff involved in diagnostic radiology and image guided interventional procedures should meet the respective training and competence criteria described in paras 2.119–2.137. 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 and SPECT–CT) may have trained exclusively in their original specialty. They should undertake radiation protection and safety training relevant to the additional imaging modality.

3.131. Paragraph 3.110 of GSR Part 3 [3] places responsibilities on the employer to provide adequate information, instruction and training for protection and safety as it pertains to the radiology facility. 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

3.132. Paragraph 3.111 of GSR Part 3 [3] requires that no special benefits be offered to staff because they are occupationally exposed. It is not acceptable to offer benefits as substitutes for measures for protection and safety.

Pregnant workers

3.133. There is no requirement in GSR Part 3 [3] for a worker to notify the licensee that she is pregnant, but it is necessary that female workers understand the importance of making such notifications so that their working conditions can be modified accordingly. Paragraph 3.113(b) of GSR Part 3 [3] establishes

the requirement that employers, in cooperation with registrants and licensees, provide female workers with appropriate information in this regard.

3.134. Paragraph 3.114 of GSR Part 3 [3] states that:

> "The employer of a female worker, who has been notified of her suspected pregnancy…shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or fetus…is afforded the same broad level of protection as is required for members of the public."

The limitation of the dose to the embryo or fetus does not mean that pregnant women should avoid work with radiation, but it does mean that the employer should carefully review the exposure conditions with regard to both normal exposure and potential exposure. A possible solution includes reassignment of a pregnant worker to a location that may have lower ambient dose equivalent; for example, from fluoroscopy to radiography or to CT. Such reassignments should be accompanied by adequate training.

3.135. With regard to the dose limit of 1 mSv for the embryo or fetus, the reading of a dosimeter can overestimate the dose to the embryo or fetus by a factor of 10. If the reading corresponds to a dosimeter worn outside a lead apron, the overestimation can rise to a factor of 100 [124]. The dose to the embryo or fetus should be assessed using an appropriately positioned additional dosimeter (see also GSG-7 [23]). Information, advice and, if indicated, counselling for pregnant workers should be made available (see also para. 3.129).

Persons under 18

3.136. In many States, 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 can involve occupational exposure to ionizing radiation. Paragraph 3.116 of GSR Part 3 [3] establishes the requirements for access to controlled areas and the dose limits for such persons are more restrictive (see Box 1 of this Safety Guide and Schedule III of GSR Part 3 [3]).

RADIATION PROTECTION OF INDIVIDUALS UNDERGOING MEDICAL EXPOSURE

3.137. This section covers radiation protection of patients, 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 members of the public and their radiation protection is covered in paras 3.273–3.282.

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

Justification of medical exposure

3.139. The requirements for justification of medical exposure (paras 3.155–3.161 of GSR Part 3 [3]) incorporate the three-level approach to justification (see para. 2.11) [4, 125, 126].

3.140. The roles of the health authority and professional bodies with respect to a 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 paras 2.55–2.60.

Justification of medical exposure for the individual patient

3.141. GSR Part 3 [3] requires a joint approach to justification at the level of an individual patient, 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 specialist expertise on the radiological procedure. The efficacy, benefits and risks of alternative methods (both methods involving ionizing radiation and methods not involving ionizing radiation) should be considered. In all cases, the justification is required to take into account national or international referral guidelines (para. 3.158 of GSR Part 3 [3]). For examples of such

guidelines, see Refs [127–133].[21] The ultimate responsibility for justification will be specified in the individual State's regulations.

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

3.143. Justification, which is a principle of radiation protection, is implemented more effectively as part of the medical process of determining the 'appropriateness' of a radiological procedure. The process of determining appropriateness is an evidence based approach to choosing the best test for a given clinical scenario, with account taken of the diagnostic efficacy of the proposed radiological procedure as well as of 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 [127–133]. Imaging referral guidelines can be disseminated or utilized through electronic requesting systems[22] and clinical decision support tools or systems. It should be ensured that such systems correctly apply the regulatory requirements for justification, in particular with respect to roles and responsibilities.

3.144. In determining the appropriateness of the radiological procedure for an individual patient, the following questions should be asked by the referring medical practitioner [132]:

(a) Has it already been done? A radiological procedure that has already been performed within a reasonable time period (depending on the procedure and clinical question) should not be repeated (unless the clinical scenario indicates the appropriateness of repeating the procedure). The results (images and reports) of previous examinations should be made available, not only at a given radiology facility but also for consultation at different facilities. Digital imaging modalities and electronic networks should facilitate this process. Individual patient exposure records should be used to facilitate the decision making process if available.
(b) Is it needed? The anticipated outcome of the proposed radiological procedure (positive or negative) should influence the patient's management.

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[21] Other guidelines are available at http://gbu.radiologie.fr, www.imagingpathways.health.wa.gov.au and www.myesr.org/esriguide

[22] Such electronic requesting systems include the computerized physician order entry (CPOE) system; such a system is expected to generate a request for imaging rather than an order.

(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 should all 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 for ensuring the correct technique is performed with the correct focus.

3.145. For some radiological procedures, primarily 'well established' procedures and low dose procedures, the practical implementation of justification in many States is carried out by 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. It should be noted that, in all cases, the responsibility for justification lies with the radiological medical practitioner and the referring medical practitioner.

3.146. For a small 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 necessary further clarification on the medical context. Again, the justification should take into account national or international referral guidelines.

3.147. Two particular groups of patients identified in para. 3.157 of GSR Part 3 [3] for special consideration with respect to justification are patients who are pregnant or are paediatric.

(a) Owing to the higher radiosensitivity of the embryo or fetus, it should be ascertained whether a female patient is pregnant before an X ray examination for diagnosis or an image guided interventional procedure is performed. Paragraph 3.176 of GSR Part 3 [3] requires that procedures be "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". Pregnancy

would then be a factor in the justification process and might influence the timing of the proposed radiological procedure or a decision as to whether another approach to treatment is more appropriate. Confirmation of pregnancy could occur after the initial justification and before the radiological procedure is performed. Repeat justification is then necessary, with account taken of the additional sensitivity of the pregnant patient and embryo or fetus.

(b) As children are at greater risk of incurring radiation induced stochastic effects, paediatric examinations necessitate special consideration in the justification process.

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

3.149. A 'self-referral' occurs when a health professional undertakes a radiological procedure for patients as a result of justification on the basis of his or her own clinical assessment. Examples of acceptable self-referral practice occur in dentistry, cardiology, orthopaedics, vascular surgery, urology and gastroenterology. Relevant professional bodies in many States develop appropriate guidance for their specialty, for example dental associations [134].

3.150. '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 assessments' which often involves CT procedures in asymptomatic individuals for early detection of cancer (e.g. whole body CT, lung CT or colon CT) and 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 [135]. States may choose to incorporate such guidance into legislation [136].

3.151. Means to improve awareness, appropriateness and auditing should be developed to support the application of the requirement for justification of medical exposure. Awareness of the need for justification underpins the whole process of justification. Means for promoting awareness include traditional education and training, such as at medical school or during specialty training, Internet based

learning or learning 'on the job' (e.g. junior doctors in an emergency department), and the use of feedback in the reporting process. Appropriateness is described in paras 3.143 and 3.144, and the audit process is used for monitoring and feedback to improve both awareness and appropriateness.

Justification of medical exposure for biomedical research volunteers

3.152. 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 para. 2.99.

Justification of medical exposure for carers and comforters

3.153. The three-level approach to justification is not applicable for carers and comforters. Instead, para. 3.155 of GSR Part 3 [3] establishes the requirement to ensure that there be some net benefit arising from the exposure, for example the successful performance of a diagnostic procedure on a child. The crucial component in the justification of medical exposure of carers and comforters is their knowledge and understanding about radiation protection and the radiation risks for the procedure being considered. To this end, the radiological medical practitioner or medical radiation technologist involved in the radiological procedure, prior to the performance of the procedure, has the responsibility to ensure that the carer or comforter is correctly informed about radiation protection and the radiation risks involved, and that the carer or comforter understands this information and consequently agrees to take on the role of carer or comforter.

Optimization of protection and safety

3.154. In medical exposure, optimization of protection and safety has several components, some applicable 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 paras 3.155–3.252. Key personnel in the optimization process are the radiological medical practitioner, the medical radiation technologist and the medical physicist.

Design considerations

3.155. The use of appropriate and well designed medical radiological equipment and associated software 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 doses in medical exposure as low as reasonably achievable consistent with obtaining adequate diagnostic information or guidance for the intervention. Guidance on design considerations is given in the subsection on medical radiological equipment in paras 3.32–3.41. This guidance is applicable to both stand alone and hybrid systems. Ultimately, as established in para. 3.162 of GSR Part 3 [3], it is the responsibility of the licensee of the radiology facility to ensure that the facility uses only medical radiological equipment and software that meets applicable international or national standards.

Operational considerations: General

3.156. Following justification, the diagnostic radiological procedure or image guided interventional procedure is required to be performed in such a way as to optimize patient protection (para. 3.163 of GSR Part 3 [3]). 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, namely air and bone, be imaged). With image guided interventional procedures, the level of image quality should be sufficient to guide the intervention.

3.157. 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, preferably three, forms of verification, for example name, date of birth, address and medical record number.
(b) Patient details should be correctly recorded, such as age, sex, body mass, height, pregnancy status, current medications and allergies.
(c) The clinical history of the patient should be reviewed.

3.158. The first step in operational considerations of optimization is selection of the appropriate medical radiological equipment. For example, a chest X ray should be performed using dedicated equipment with a radiation 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 image of diagnostic quality by minimizing patient respiratory motion and cardiac motion.

3.159. The volume (area) of the patient that is exposed should be strictly limited to that of clinical interest. This is achieved through collimation in radiography, mammography, fluoroscopy and image guided interventional procedures, and through the choice of scan parameters in CT. For diagnostic radiology, image cropping performed after the exposure does not achieve any reduction in the exposed volume.

3.160. Cooperation of the patient should be ensured to achieve an image of diagnostic quality. 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 take place before, during and after the procedure.

3.161. Optimization of protection and safety for a woman undergoing a radiological procedure during pregnancy should take into account the woman and the embryo or fetus. 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 the same as the dose that would be received by the fetus in early pregnancy. When CT scanning is indicated for a pregnant patient, low dose CT protocols should be used and the scanning area should be reduced to a minimum (see also paras 3.176–3.185).

3.162. Shielding of radiosensitive organs, such as the gonads, the lens of the eye, the breast and the thyroid, should be used when appropriate. Care should be taken in the anatomical placement of such shields, the impact of shielding on image quality (artefacts), and the use of AEC devices and the consequences for patient dose.

3.163. For each modality, there are a number of factors that can be adjusted to influence the relationship between image quality and patient dose. Written protocols that specify the operating parameters to be used for common diagnostic radiological procedures should be developed, adopted and applied in each radiology facility. Such protocol ‘technique charts’ should be posted adjacent to each X ray generator and should be specific for each piece of equipment. The protocols should take into account the anatomical region, as well as patient mass and size. The protocols should be developed using guidelines from national or international professional bodies, and hence should reflect current best practices (e.g. see Refs [137–147]). For modern digital equipment, many of the factors are automated through the menu driven selection of options on the console. Nevertheless, in setting up these options, significant scope exists for the optimization of protection and safety through the appropriate selection of values

for the various technical parameters, thereby effectively creating an electronic technique chart.

3.164. Size specific written protocols should be developed for children, from neonates to teenagers, and should include additional operational considerations, such as the use of additional filtration or the removal of grids when appropriate [143, 145, 146].

3.165. Paragraph 3.166(b) of GSR Part 3 [3] establishes a special requirement for the optimization of protection and safety for individuals subject to medical exposure as part of an approved health screening programme. All aspects of protection should be considered before the approval of the programme and during its implementation, such as the selection of X ray equipment suitable for the particular screening and parameters settings. A dedicated, comprehensive programme of quality assurance should be implemented to meet screening objectives, as described in more detail in paras 3.232–3.246. It should set requirements for the education and training of the medical professionals involved in the health screening programme, for adequate quality management for the whole screening chain and for documentation and evaluation of the results.

Operational considerations: Radiography

3.166. 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 (see Refs [137, 142, 143, 148–153]). Such factors include: the tube potential; current; exposure time; focal spot size; filtration; source to image receptor distance; choice of anti-scatter grids or Bucky device; collimation; image receptor size; positioning, immobilization and compression of the patient; the number of projections needed (e.g. a posterior–anterior chest X ray rather than posterior–anterior and lateral X rays); and organ shielding where appropriate (e.g. testicular shielding for pelvic radiographs in male patients).

3.167. Suitably calibrated and maintained AEC systems should be used when available and appropriate. Particular attention should be given in paediatric radiography to ensuring that AEC sensors are within the radiation field [152]. AEC systems are calibrated on the basis of the radiation exposure at the detector required to produce the desired level of optical density for film–screen systems or a predetermined acceptable level of signal to noise ratio, or surrogate, for digital systems. The value for the signal to noise ratio should be established as part of setting up the protocols for radiographic projections for each particular X ray

unit. In determining technique factors when AEC is not available, consideration should be given to the patient's size and the thickness of the body part to be imaged.

3.168. For digital systems, users should understand how the selection of the 'exposure index' (or other exposure indicator) affects the patient dose. For some systems, increasing the index lowers the dose; for others, it increases it [154].

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

3.170. 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.

3.171. The patient should be properly positioned and immobilized. In addition, instructions should be clear and in the language understood by the patient.

Operational considerations: Mammography

3.172. In developing protocols for mammography, consideration of radiographic technique factors should be made as for radiography (see para. 3.166). Additional factors that should be considered include: adequate compression of the breast; 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 (see Refs [111–114, 139, 155, 156]).

3.173. For film based mammographic systems, additional factors include the type of film–screen combination and the film processing conditions (e.g. the chemicals used and developing time and temperature), as described in Refs [111–113].

3.174. Breast tomosynthesis is an evolving technique for which guidance for optimization is likely to become available as the modality matures. A review of features that influence image acquisition has been made in Refs [157, 158].

3.175. 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 3.25, 3.26 and 3.45. Poor viewing conditions not only compromise the reporting of a good quality image, but they may, in a mistaken attempt to compensate for the poor viewing conditions, also lead to changes in technique factors that actually result in suboptimal image quality. For example, the 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 have been reduced, there might be an unacceptable loss of diagnostic information.

Operational considerations: Computed tomography

3.176. 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; and total scan length, over ranging and over beaming for the scan. These and other factors may be optimized through the AEC system 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 of coronary artery disease; whereas a higher dose contrast enhanced protocol is necessary for patients with suspected coronary artery disease). Detailed guidance on appropriate choices for these factors and features is available (see Refs [19, 62, 138, 144, 145, 147, 150, 152, 159–163]).

3.177. Careful consideration should be made as to the need for multiple phase studies to answer the clinical question (e.g. in abdominal CT imaging for routine detection of liver metastases, and the use of portal venous phase acquisitions only, rather than triple phase acquisitions, namely arterial, portal venous and delayed phase acquisitions). Protocols for optimized CT procedures for common clinical conditions should be agreed, put in place and used.

3.178. Consideration of use of a spiral or axial technique will depend on the indication and will have implications for image quality and dose (e.g. for diffuse lung disease a non-contiguous single slice protocol is preferred for high resolution lung CT, and it also delivers a lower patient dose).

3.179. Special attention should be given to developing protocols for children adapted to body size and age [19, 145, 152]. The use of adult protocols for scanning children is inappropriate.

3.180. Improved image presentation, reconstruction algorithms and post-processing features to reduce image noise can potentially result in a protocol with reduced patient dose. An example is the use of iterative reconstruction algorithms. Care should be taken with the introduction of such algorithms to ensure that the radiation protection of the patient is optimized.

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

3.182. Irradiating the lens of the eye within 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.

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

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

3.185. 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.

3.186. CBCT, also known as flat panel CT, C-arm CT, cone beam volume CT and digital volume tomography, is used in medical applications (diagnostic and interventional radiology, and IGRT) and dental applications. Operational aspects with respect to optimization are still evolving. Guidance is available (see Refs [164, 165]), 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

3.187. In developing protocols for conventional intraoral radiography, factors that can influence the image quality and the patient dose include: tube potential; current; 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 (see Refs [166, 167]).

3.188. 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 or closed); collimation (e.g. for examinations of the temporomandibular joint, only those areas should be included); and for analogue systems, film speed or screen speed, and processing development time and temperature. Detailed guidance on appropriate choices for those factors is available (see Refs [166, 167]).

Operational considerations: Image guided interventional procedures

3.189. The choice of imaging modality for guidance of interventional procedures will depend on the clinical scenario (e.g. fluoroscopic guidance for percutaneous coronary intervention and 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 placement of a catheter). Furthermore, the correct selection of equipment with appropriate size (and shape) of flat panel or image intensifier will improve the diagnostic image quality.

3.190. Successful interventions are heavily reliant upon patient cooperation (e.g. movement may compromise the accuracy of roadmaps in the performance of aneurysm embolization in neuro-intervention). Patients should be briefed about the intervention prior to the commencement of the procedure so that they know what to expect and how to cooperate.

3.191. 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 the distance from the focus to the detector; filtration (fixed and variable); use of magnification; total fluoroscopy time for the intervention; image acquisition dose mode (effectively input air kerma per frame for the image intensifier or flat panel detector); 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 (see Refs [19, 117, 140, 146, 150, 152, 168–171]).

3.192. Many of the factors in para. 3.191 are automated through an algorithm driven ADRC system. Nevertheless, in setting up the algorithm, scope exists for the optimization of protection and safety through the selection of values for these parameters. For example, the input air kerma rates (for fluoroscopy) and input air kerma per frame (for image acquisition) for the image intensifier or flat panel detector 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.

3.193. In the course of the intervention, the tube orientation and position may need to be changed. For long procedures, the area of skin upon which the X ray beam is incident 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, this is achieved for a vertical beam by having the table as high as possible for the primary operator. In conjunction with this, the image intensifier or flat panel detector should be positioned as close to the patient as possible.

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

3.195. 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 (tube rotations) should be kept to a minimum consistent with a successful intervention.

Operational considerations: Fluoroscopy

3.196. Recommendations in paras 3.190–3.194 also apply to fluoroscopy used in diagnostic radiology.

Operational considerations: Bone densitometry

3.197. 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 owing to artefacts (e.g. massive vertebral osteophytes may obviate the value of lumbar densitometry). Information on best practices is given in Ref. [172].

Operational considerations: Emergency radiology

3.198. Special considerations for the emergency department include: judicious patient positioning that takes into account the injury or disease (e.g. a 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

3.199. In accordance with para. 1.46 of GSR Part 3 [3], the dosimetric quantities and units of the ICRU are to be used for diagnostic radiology and image guided interventional procedures [10, 12]. Information on best practices in dosimetry in diagnostic radiology is given in Refs [11, 173, 174].

3.200. Calibration requirements for medical radiological equipment and dosimetry equipment are established in para. 3.167 of GSR Part 3 [3]. Responsibility is assigned to the radiology facility's medical physicist. After the initial calibration, the intervals for periodic calibrations might differ, depending on the complexity of the medical radiological equipment. Relating to calibrations are the constancy tests on equipment performance performed as quality control tests. These are described in paras 3.235, 3.237 and 3.238.

Calibration: Medical radiological equipment

3.201. In diagnostic radiology, including the use of medical radiological equipment for simulation of radiation therapy, treatment verification systems and hybrid imaging systems, and for image guided interventional procedures,

‘source calibration’ is to be interpreted as the measurement of certain dosimetric quantities that are modality dependent and which should be carried out in reference conditions.

3.202. For diagnostic radiographic and fluoroscopic medical radiological equipment, including conventional radiation therapy simulators, the dosimetric quantities are: incident air kerma, in Gy; incident air kerma rate, in $Gy \cdot s^{-1}$; and air kerma–area product, in $Gy \cdot m^2$ (some manufacturers use $\mu Gy \cdot m^2$ or $mGy \cdot cm^2$ or $Gy \cdot cm^2$).

3.203. In CT, the dosimetric quantities are (see also Refs [10–12, 173–176]):

(a) CT air kerma index, usually in mGy. In many States, the more colloquial term computed tomography dose index (CTDI) is used, and is accepted by the ICRU [12].
(b) Weighted CT air kerma index, usually in mGy, which is the CT air kerma calculated from measurements at the centre and periphery of a standard polymethylmethacrylate CT head or body phantom. As in (a), this quantity is often simply called the weighted CTDI.
(c) Volume CT air kerma index, 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.
(d) CT air kerma–length product, usually in mGy·cm. In many States, the more colloquial term dose–length product is used, and is accepted by the ICRU [12].

3.204. In mammography, the three dosimetric quantities used are incident air kerma, entrance surface air kerma and mean glandular dose, usually in mGy [10, 11].

3.205. 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 those in Ref. [11].

Calibration: Dosimetry instrumentation

3.206. Dosimetry instrumentation used at a radiology facility should be calibrated at appropriate intervals. A period of not more than two years is recommended (see also para. 3.244 on quality assurance).

3.207. Paragraph 3.167(d) of GSR Part 3 [3] requires that the calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory. Ideally, this would be the national standards dosimetry laboratory (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 State or region if there is no national standards dosimetry laboratory in the State or region where the instruments are used. At present, only some of the secondary standards dosimetry laboratories of the IAEA/WHO Network of Secondary Standards Dosimetry Laboratories (SSDL 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 might accept instrument manufacturers' calibrations as described in the 'certificate of calibration' issued by the instrument manufacturer, provided that the manufacturer operates or uses a calibration facility that is itself traceable to a standards dosimetry laboratory and appropriate calibration conditions have been used. This certificate should state the overall uncertainty of the calibration coefficient.

3.208. Records of calibration measurements and associated calculations, including uncertainty determinations (uncertainty budgets), should be maintained as described in para. 3.272. Information on best practices in performing uncertainty determinations for several modalities is given in Refs [11, 152].

3.209. 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 air kerma–area product meters, which should be calibrated (or cross-calibrated) against a reference air kerma–area product meter or air kerma dosimeter in situ in the clinical environment rather than in a standards dosimetry laboratory environment [11]. It might also be done 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 test as part of periodic quality control tests.

Dosimetry of patients: General

3.210. Paragraph 3.168 of GSR Part 3 [3] requires that registrants and licensees of radiology facilities ensure that patient dosimetry be performed in diagnostic radiology and image guided interventional procedures and that typical doses to patients for radiological procedures be determined. Knowledge of the typical

doses at a facility forms the basis for applying methods of dose reduction as part of optimization of protection and safety. It also enables the radiology facility to use DRLs (see paras 3.224–3.231) as another tool for the optimization of protection and safety.

3.211. Clearly, the more radiological procedures at the radiology facility for which typical doses are known, the better the basis for the optimization of protection and safety. GSR Part 3 [3] requires determination of typical doses for common radiological procedures in radiology facilities. The procedures that are considered to fall into this category will vary from facility to facility, and State to State, but common core examinations generally include the following:

(a) Radiography: head, chest, abdomen and pelvis.
(b) CT: head, chest, abdomen and pelvis, for specified clinical indications.
(c) Fluoroscopy: barium swallow and barium enema.
(d) Mammography: craniocaudal and mediolateral oblique.
(e) Dentistry: intraoral, panoramic and CBCT.
(f) Bone densitometry (DXA): spine and hip.

3.212. For image guided interventional procedures, typical doses for the broad types of procedure performed at the facility should be ascertained. For example, an interventional cardiology facility would characterize typical doses for percutaneous coronary interventions, including percutaneous transluminal coronary angioplasty. A facility performing neurological procedures might characterize typical doses for diagnostic cerebral angiograms and for embolization interventions. Other image guided interventional procedures might include endoscopic retrograde cholangiopancreatography and transjugular intrahepatic portosystemic shunt.

3.213. The term ‘typical dose’, as used in para. 3.168 of GSR Part 3 [3], is the median or average dose for a representative sample of normal size patients, at clinically acceptable image quality. Patient size has a large influence on dose, so some selection or grouping of patients is recommended. Such groupings include ‘standard adult’, often based on an average mass of 70 kg with a range of ±20 kg. Groupings for children have sometimes been based on age, such as newborn (0 years), infant (1 year), small child (5 years), child (10 years) and teenager (15 years), but more recently size specific groupings are being recommended and used, for example by using body mass intervals [14]. Patient size groupings should be adopted that correspond to the groupings used for the DRLs in the State or region. The sample size used for each patient grouping and radiological procedure should be of sufficient size to assure confidence in the

determination of the typical dose. A representative sample of 10–20 patients per procedure type is needed for non-complex examinations such as radiography and CT, preferably 20–30 patients for complex procedures such as fluoroscopy and fluoroscopically guided procedures, and 50 patients for mammography [14] (see also paras 2.39–2.41).

3.214. The dose in the term 'typical dose', as used in para. 3.168 of GSR Part 3 [3], means, for the given radiological procedure, an accepted dosimetric quantity as described in paras 2.40 and 3.202–3.204. For particular reasons (e.g. for risk estimation or for collective dose estimation), the dose to a particular organ or the effective dose can be estimated from the typical dose.

3.215. 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 only be those whose radiological procedure resulted in acceptable image quality.

3.216. The results of the surveys used to determine typical doses at the radiology facility should be used as part of the ongoing review of the optimization of protection and safety at the facility, and should be used for comparison with established DRLs (see paras 2.34, 2.45 and 3.224–3.231). The results should also be submitted to the organization in the State or region that is responsible for establishing and reviewing national or regional DRLs. Patient dosimetry surveys, required by GSR Part 3 [3], should take place at intervals of no more than five years and preferably no more than three 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.

3.217. 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 an estimation of patient doses is required as part of the investigation and report (see para. 3.265), or because there is a need to estimate the dose to an embryo or fetus (see para. 3.161).

3.218. 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 [10–12, 171, 173–178] and are summarized in the following:

(a) Estimations based on incident air kerma or entrance surface air kerma measurements corrected for the techniques used (e.g. X ray tube potential, current and time, and source–skin distance). This approach can be used in radiography (medical and dental), fluoroscopy and mammography.
(b) Estimations based on measured air kerma–area product. This approach can be used in radiography (medical and dental), fluoroscopy and CBCT.
(c) Estimations based on measurements of CT air kerma index and CT air kerma–length product. This approach can be used for CT.
(d) 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 in acceptance testing and commissioning and by means of quality assurance procedures as explained in para. 3.244. This approach is applicable to all digital modalities.
(e) Direct measurements for selected organs, such as the skin for interventional procedures. For this, thermoluminescent dosimeters and optical stimulated luminescent dosimeters as well as radiochromic or silver halide film can be used.
(f) In the case of CT, size specific dose estimates can be made, where CT air kerma index values are corrected by taking into consideration the size of the patient using linear dimensions measured on the patient or patient images [12, 177].

3.219. When necessary, organ doses can be derived from the quantities mentioned in para. 3.218 by using conversion coefficients derived from Monte Carlo codes applied to anatomical models. Methods for doing this are described in Ref. [11].

Dosimetry of patients: Specific considerations for image guided interventional procedures

3.220. For interventional procedures using X rays, in addition to the quantities that relate to stochastic effects, such as air kerma–area product, the cumulative doses to the most exposed areas of skin should be monitored because of the potential for reaching the threshold for tissue effects in complicated cases [179, 180].

3.221. 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 knowledge of the distribution of the dose over the skin (sometimes called ‘dose mapping’ over the skin) necessary. A comprehensive review of approaches

to dose mapping and to determining the most exposed area of the skin is given in Ref. [171].

3.222. 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.

3.223. The cumulative reference air kerma at the patient entrance reference point, defined as the kerma in air at 15 cm from the isocentre in the direction of the X ray tube [69], either displayed during the procedure or obtained from the DICOM header, may be used as a conservative estimate for peak skin dose. The degree of overestimation depends on several factors, including how often the beam projection was changed. The cumulative reference air kerma gives the least overestimation when most of the radiation is delivered in just one beam projection. The accuracy of the reported cumulative reference air kerma should have been validated in acceptance testing and commissioning and by means of quality assurance procedures, as explained in para. 3.244.

Diagnostic reference levels

3.224. Paragraphs 3.168 and 3.169 of GSR Part 3 [3] require that patient dosimetry surveys be performed for the diagnostic procedures at a radiology facility, as described in paras 3.210–3.219, and that these results be compared with the established DRLs for the State or region. The purpose is to ascertain whether or not the typical dose for the facility for a given radiological procedure compares favourably with the value of the DRL for that radiological procedure. Guidance on establishing national or regional DRLs is given in paras 2.34–2.45.

3.225. A review of optimization of protection and safety for that particular radiological procedure is triggered if the comparison shows that the typical dose for the facility exceeds the DRL, or that the typical dose for the facility 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.

3.226. Given the uncertainties in determining the typical dose for a facility (see paras 3.213 and 3.214), questions can arise over whether or not a DRL has really been exceeded. Some States adopt an algorithmic approach, for example where the typical dose for the facility, minus two times its standard error, should be greater than the value of the DRL [16]. A simpler approach, based purely on the

typical value for the facility, may be sufficient, as the purpose is to identify the need for a review.

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

3.228. Furthermore, the comparison should not simply determine whether the radiology facility complies with the DRL. DRLs are not dose limits. DRLs should be used for the comparison exercise in the review process of optimization of protection and safety to identify practices that warrant further investigation.

3.229. The review of how the given radiological procedure is being performed and of the optimization of protection and safety, triggered by the DRL comparison, might 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 programme of quality assurance. Adequateness of image quality should always be taken into account. On the other hand, the review might 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 programme of quality assurance.

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

3.231. The regulatory body in a given State may specify frequencies for performing DRL comparisons. Otherwise, the general guidance for patient dosimetry, described in para. 3.216, would be applicable.

Quality assurance for medical exposures

3.232. Paragraph 3.170 of GSR Part 3 [3] requires that radiology facilities have in place a comprehensive programme of quality assurance for medical exposures. General guidance on the management system is given in paras 2.138–2.149, and it is reiterated here that the programme of quality assurance for medical exposures should fit in with, and be part of, the wider management system at the facility.

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

3.234. The complexity of the programme of quality assurance for medical exposures will depend on the type of facility. A dental practice with only intraoral 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 application that there are differences. Paragraph 3.171 of GSR Part 3 [3] establishes the common elements of the programme.

3.235. Measurements on medical radiological equipment are one of the components of the comprehensive programme of quality assurance. 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. The acceptance test should be followed immediately by commissioning, and then ongoing periodic quality control tests, including constancy tests. The purpose is to ensure that, at all times, all medical radiological equipment performs correctly, accurately, reproducibly and predictably. Acceptance and commissioning tests should be performed in the same way for equipment and software that has been donated.

3.236. Depending on the equipment purchase agreement, acceptance tests can be performed by the manufacturer in the presence of the local medical physicist and the radiological medical practitioner representing the user, or, if acceptable to the manufacturer and the purchaser, by a medical physicist jointly with the manufacturer. The process should involve verification of all specifications and features of the equipment.

3.237. After acceptance and before clinical use on patients, commissioning should be 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 and validating image acquisition protocols. For most modalities (CT, image guided interventional procedures, tomosynthesis, mammography, radiography and 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 radiography and DXA), the medical physicist should provide documented advice on how the commissioning should be

performed. During commissioning, the baseline for subsequent constancy tests is established.

3.238. In addition to the acceptance testing and commissioning, para. 3.171 of GSR Part 3 [3] requires, periodically and after any major maintenance procedure or upgrade, the measurement of physical parameters of medical radiological equipment. There are many published reports from international and national organizations and national and 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 (see Refs [104, 105, 109–114, 156, 161, 166, 167, 170–173, 181–201]). In addition, many of these organizations and professional bodies publish on their web sites new or updated publications on the topic. The regulatory body may have its own specific requirements for the tests that should be performed, their frequencies and the competence of the specialists involved. Such specific requirements should be established with consultation between the regulatory body and the relevant professional bodies.

3.239. While traditional approaches to constancy testing are based on measurements of technical parameters for the system or using test objects and phantoms, it is likely that in the future clinically derived data could be used in the monitoring of equipment and in ensuring consistency in clinical practice. For example, a particular region of an anatomical image could be analysed to produce an index of noise performance.

3.240. Quality control tests should also 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; flat detectors for DR systems; CR imaging plates and CR readers for facilities with CR systems; and view boxes, workstations, and display and interpretation rooms. Many of the references given in para. 3.238 are applicable here.

3.241. 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 those referenced in para. 3.238. Paragraph 3.171(b) of GSR Part 3 [3] requires the implementation of corrective actions if the measured values fall outside established tolerance limits. Such corrective actions are likely to include maintenance or servicing of the equipment, and hence a

preventive maintenance programme should be put in place at the radiology facility. In some cases, the equipment might be outside the tolerance limits by a significant amount and the equipment should be immediately taken out of clinical use and not returned until servicing has taken place and it has been ascertained that the equipment now meets the performance requirements.

3.242. The programme of quality assurance for medical exposures in the radiology facility should include the use of checks 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 radiological review at the facility (see paras 3.269–3.271). In addition, a review of imaging procedures may have been triggered by a comparison with DRLs (see paras 3.224–3.231).

3.243. As part of the programme of quality assurance for medical exposure, 'repeat and reject analysis' should be performed on a periodic basis. Further guidance is given in Refs [48, 111, 153].

3.244. Paragraph 3.171(e) of GSR Part 3 [3] specifically requires that periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment be part of the programme of quality assurance. This is to ensure that such instrumentation has a current calibration, typically conducted within the last two years (see para. 3.206), and that it is functioning correctly. The programme of quality assurance for medical exposures should establish a frequency for calibration 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 air kerma–area product meters in fluoroscopic systems, and to software of the medical radiological equipment itself that calculates, displays and reports dose metrics such as CT air kerma index and air kerma–length product in CT and reference air kerma at the patient entrance reference point in image guided interventional procedures. Phantoms used in quality assurance and dosimetry should fulfil the requirements specified in the corresponding international standards.

3.245. 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, the corrective actions, and the investigations of unintended and accidental medical exposures. When planning and developing an effective programme of quality assurance, the licensee should recognize that it demands

strong managerial commitment and support in the form of training and allocation of time, personnel and equipment resources. The regulatory body, in its inspections of a radiology facility, should review the records of the programme of quality assurance for medical exposures.

3.246. In line with standard practices for quality management, para. 3.172 of GSR Part 3 [3] requires that "regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks." Such audits may be external audits or internal audits. Internal audits are usually logistically simpler to conduct, while an external audit generally has the advantage of bringing in an outside perspective. The audit of the programme of quality assurance for medical exposures can be incorporated into more comprehensive audits of the management system performed by the licensee. Furthermore, the results of the audit of the programme of quality assurance for medical exposures will be a major input into the radiological review performed at the facility (see paras 3.269–3.271).

Dose constraints: Carers and comforters

3.247. Some diagnostic radiological procedures, 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 or very elderly or very ill patient. In these circumstances, the carer or comforter will be exposed, usually to a low dose.

3.248. Paragraph 3.153 of GSR Part 3 [3] states that:

> "Registrants and licensees shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure…."

The carer or comforter should indicate that he or she is still willing to provide support, care and comfort to the patient that is undergoing the radiological procedure.

3.249. The radiation protection afforded the carer or comforter should be optimized, and, as part of this process, dose constraints are required to be applied (para. 3.173 of GSR Part 3 [3]). 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 para. 3.149(a)(i) of GSR Part 3 [3] (see also paras 2.48 and 2.49).

3.250. Written protocols should be drawn up for implementing measures for the optimization of protection and safety for carers and comforters who hold patients during radiological procedures. The measures should utilize the basic methods for radiation protection (i.e. time, distance and shielding). The protocols 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 of the facility, such as porters and nurses (see also 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 para. 2.49) depend on the radiological exam or intervention; a common value is 5 mSv per event, as stated in para. 2.49. Although it is unlikely that a child, such as 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.

3.251. The licensee should be able to demonstrate that the effective dose to the carer or comforter, by applying the protocols, 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 ensure that dose constraint is not exceeded. Therefore, individual dose monitoring is normally not necessary.

Dose constraints: Volunteers in biomedical research

3.252. Some individuals will undergo diagnostic radiological procedures as part of their voluntary participation in an approved programme of biomedical

research (see para. 2.99). Part of the approval process for the biomedical research will have been the setting of dose constraints for the radiological procedures (see para. 2.100). When the volunteer presents himself or herself at the radiology facility, he or she is to be afforded the same radiation protection as if he or she were a patient ready to undergo a radiological procedure, but with the additional restriction that his or her exposure will be subject to a dose constraint, either a nationally established dose constraint or a dose constraint specified by the ethics committee that approved the biomedical research programme (see paras 2.50, 2.99 and 2.100).

Pregnant patients

3.253. Patients who are pregnant form a special subgroup of patients that should be given particular consideration with respect to radiation protection. These considerations are described in para. 3.147(a) with respect to justification and para. 3.161 with respect to optimization. None of these considerations can take place if it is not known whether the patient is pregnant. Therefore, it is crucial, as is required in paras 3.175 and 3.176 of GSR Part 3 [3], for the radiology facility to have in place means for ensuring that the pregnancy status of patients is known.

3.254. The first approach is through the posting of clear signs (possibly including a pictorial representation of pregnancy) in languages easily understood by the people using the radiology facility, posing 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 in waiting rooms and cubicles. The second approach is to ask patients directly whether they are or might be pregnant. This might not always be so easy given social and cultural sensitivities, but it should be done when necessary.

3.255. Neither of the approaches described in para. 3.254 will work if the patient does not know whether she is pregnant. For this reason, para. 3.176 of GSR Part 3 [3] has an additional requirement on facilities to "ensure that there are 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 scatter radiation reaches the embryo or fetus. Cooperation with the referring medical practitioner, through standard requests for pregnancy status for specified procedures, is one approach. The referral form should include a 'tick box'

for pregnancy status. In case of doubt, a pregnancy test or a determination of hormone levels to assess menopausal status can be carried out.

Unintended and accidental medical exposures

Prevention of unintended and accidental medical exposures

3.256. Paragraph 3.179 of GSR Part 3 [3] states that:

> "Registrants and licensees…shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error."

Paragraph 3.180 of GSR Part 3 [3] requires that the registrants and licensees promptly investigate if such exposures occur. General strategies for addressing those problems include the regular maintenance of medical radiological equipment and software, a comprehensive programme of quality assurance, continuing education and training of staff, and the promotion of a safety culture. Lessons identified from events that have occurred should be used for preventing or minimizing unintended and accidental medical exposures, as described in para. 3.266.

3.257. Minimization of the likelihood 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 process, with specific quality control checks at these points. Quality control should not be confined to physical tests or checks but can include actions such as the 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.
(d) Providing sufficient staff who are educated and trained to the appropriate level, and an effective organization, ensuring reasonable patient throughput.
(e) Continuous professional development and practical training and training in applications for all staff involved in providing radiology services.
(f) Clear definitions of the roles, responsibilities and functions of staff in the radiology facility that are understood by all staff.

3.258. Preventive measures should include reporting of incidents and near incidents, analysis and feedback, including lessons from international experience [123]. Preventive measures should also include checking of the robustness of the safety system of the facility against reported incidents (see Ref. [123] for a review of case histories from a collection of unintended and accidental medical exposures in image guided interventional procedures).

3.259. In addition to the guidance in paras 3.256–3.258, the following three-step strategy (commonly called 'prospective risk management') can help to prevent unintended and accidental medical exposures in a radiology facility:

(a) Allocation of responsibilities to appropriately qualified health professionals only and ensuring that a management system is in place that includes radiation protection and safety;
(b) Use of the lessons from unintended and accidental medical exposures to test whether the management system, including for radiation protection and safety, is robust enough against these types of event;
(c) Identification of other latent risks by posing the questions 'What else could go wrong?' or 'What other potential hazards might be present?' in a systematic, anticipative manner for all steps in the diagnostic and image guided interventional radiology process.

Investigation of unintended and accidental medical exposures

3.260. The events that constitute unintended or accidental medical exposures are detailed in para. 3.180 of GSR Part 3 [3]. Unintended and accidental medical exposures can 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, 159, 160].

3.261. Exposure of the wrong patient or the wrong body part is always a possibility in a radiology facility. Many patients have similar names, for example, or patients might not have a clear understanding of what procedures are meant to take place. Procedures should be put in place that consist of several independent methods of patient identification, and verification of requisition of the examination and of the orientation of the patient.

3.262. One of the events requiring investigation is when the exposure was substantially greater than was intended. This situation might occur when the radiological procedure did not go according to plan, for example: the AEC in radiography might not have terminated the exposure when expected because the

wrong sensors had been selected or there had been a hardware malfunction; or one or more of the technique factors in the examination protocol, for example for a CT examination, had been incorrectly set, giving a much higher dose than intended.

3.263. 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.

3.264. Radiation injuries will continue to occur in image guided interventional procedures. A given procedure performed in accordance with the facility's protocol still has the potential to result in tissue effects because of difficulties with the particular patient. However, most reported cases of severe radiation injuries involving ulceration and necrosis have been associated with unnecessary and extreme exposure conditions, such as: (i) a very short distance between the X ray source and the patient; (ii) the use of a high dose rate mode for much longer than necessary; (iii) a fixed projection exposing the same area of skin; and (iv) a malfunction of the AEC system. 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 exposures and should be investigated. Facilities at which image guided interventional procedures are performed should have systems in place for identifying patients who may be at risk of late radiation injuries, typically based on estimates of peak skin dose, cumulative reference air kerma or air kerma–area product, which take account of the fact that patients have different sensitivities to radiation. For these patients, information should be added to their medical records so that appropriate observation and follow-up is ensured. 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 on the SAFRAD web site.[23] Any resulting radiation injury should receive appropriate medical attention.

3.265. Paragraph 3.181 of GSR Part 3 [3] establishes what is required during 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's file. When required,

[23] See www.iaea.org/resources/rpop/resources/databases-and-learning-systems/safrad

counselling of the patient should be undertaken by an individual with appropriate experience and clinical knowledge. In the particular case of inadvertent exposure of the embryo or fetus, further detailed advice is given in Ref. [124].

3.266. The investigation of unintended and accidental medical exposures, as required by paras 3.180 and 3.181 of GSR Part 3 [3], has three main purposes. The first is to assess the consequences for the patients affected and to 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 benefit and the 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 (e.g. see Refs [123, 179, 202, 203]) has greatly contributed to increasing awareness and improving methods for minimizing the occurrence of radiation injuries. The regulatory body and/or the health authorities could disseminate information on significant events reported to them and on the corrective actions taken, so that other facilities might learn from these events. 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 SAFRAD reporting system. Facilities performing image guided interventional procedures should participate in SAFRAD or similar databases.

3.267. Paragraph 3.181 of GSR Part 3 [3] establishes requirements for the reporting (in writing) of significant events to the regulatory body and, if appropriate, to the relevant health authority. The regulatory body may specify its own requirements for the reporting of events by registrants and licensees. It is difficult to quantify the term 'significant': specification of a numerical trigger value immediately creates an artificial distinction between values immediately below that value (and hence would not be reported) and those just above the value (which would 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 exposure, the likelihood of a similar event occurring in other radiology facilities, a large number of patients having been affected, and gross misconduct or negligence by the responsible health professionals. As stated in para. 3.266, one of the roles of the regulatory body for such a reported

event is to disseminate information on the event and any lessons identified to all potentially affected parties, typically other radiology facilities and relevant professional bodies, but also in some cases manufacturers, suppliers and maintenance companies.

3.268. 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

3.269. Paragraph 3.182 of GSR Part 3 [3] requires that radiological reviews be performed periodically 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, will be a significant input to the process. As described in paras 2.148 and 2.149, the wider clinical audit 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 [48].

3.270. To facilitate compliance with para. 3.182 of GSR Part 3 [3] 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.

3.271. 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

3.272. Records should be in place to demonstrate ongoing compliance with radiation protection requirements. Paragraphs 3.183–3.185 of GSR Part 3 [3] establish the requirements for maintaining personnel records, records of calibration, dosimetry and quality assurance, and records of medical exposure.

These records are required to be kept for the period specified by the regulatory body. In the absence of such a requirement, a suggested period for keeping records is ten years. In the case of children, records should be kept for a longer time.

RADIATION PROTECTION OF THE PUBLIC

3.273. Public exposure can arise from the performance of diagnostic radiology and image guided interventional procedures for persons in and around the radiology facility.

3.274. The requirements for public protection established in paras 3.117–3.123, 3.125–3.129 and 3.135–3.137 of GSR Part 3 [3] apply to radiology facilities. This subsection contains guidance that is specific to radiology facilities. More general and comprehensive guidance on radiation protection of the public is given in GSG-8 [24].

3.275. Persons who will be undergoing a radiological procedure are also considered members of the public during the time 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 incurred other than during the radiological procedure in which they are involved will be public exposure.

3.276. Members of the public also include visitors, such as persons delivering goods or supplies, sales personnel, accompanying persons and other patients in the facility.

External exposure

3.277. The primary means for protecting the public from external exposure is the shielding in place at the radiology facility (see paras 3.18–3.24), which should be sufficient so that public exposure resulting from being in any immediately adjacent areas, including accessible rooms above and below, is in compliance with the public dose limits, and preferably less than any dose constraint that the regulatory body may have applied (see paras 2.16 and 2.46).

3.278. Particular consideration should be given to persons 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

3.279. Access to areas where radiation is being used should be controlled to ensure doses to visitors are below the dose limits and constraints for the public. Paragraph 3.128 of GSR Part 3 [3] requires that access of visitors to controlled areas or supervised areas be restricted. In exceptional cases, a visitor may be permitted to enter a controlled area, but he or she should be accompanied at all times by a staff member who knows the protection and safety measures for the area. Written procedures should be drawn up specifying when such exceptions can take place and who may accompany the visitor. Particular consideration, in all cases, should be given with respect to women who are or may be pregnant.

3.280. Controlled areas and supervised areas should be clearly identified to help to prevent inadvertent entry to areas where diagnostic radiology or image guided interventional procedures are being performed [56] (see also para. 3.14). Further control can be afforded by the use of keys (or passwords) to restrict access to the control panels of medical radiological equipment to authorized persons only.

Monitoring and reporting

3.281. Requirement 32 and para. 3.137 of GSR Part 3 [3] establish the requirements to be met by the radiology facility with respect to monitoring and reporting. At the radiology facility, procedures are to be in place to ensure that:

(a) The requirements for public exposure are satisfied and such exposure is assessed;
(b) Appropriate records of the results of the monitoring programmes are kept.

3.282. 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 that are accessible to the public. Doses can be derived from the shielding calculations in the planning stage, combined with the results from area monitoring at the initial operation of the facility and periodically thereafter. Records of dose assessments should be kept for a period that meets any relevant regulatory requirements. In

the absence of such requirements, a suggested period for keeping records is seven to ten years.

PREVENTION AND MITIGATION OF ACCIDENTS

Safety assessments of potential exposure

3.283. To comply with the requirements for safety assessments established in paras 3.29–3.36 of GSR Part 3 [3], the registrant or licensee is required to conduct a safety assessment applied to all stages of the design and operation of the radiology facility. Furthermore, para. 3.29 of GSR Part 3 [3] states that: "the responsible person or organization shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body." Paragraphs 2.150–2.154 describe general considerations for facilities using ionizing radiation for medical purposes.

3.284. The safety assessment of potential exposure should be systematic, should identify unintended events that can lead to potential exposure, and should consider their likelihood and potential consequences (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 cover not only these events, but should also aim at anticipating other events that have not previously been reported. Clearly, the safety assessment should be documented.

3.285. The safety assessment should be revised when:

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

Prevention of accidents

3.286. Accident prevention is clearly the best means for avoiding potential exposure, and paras 3.39–3.42 of GSR Part 3 [3] establish the requirements for good engineering practice, defence in depth and facility based arrangements to achieve this. Design considerations for medical radiological equipment and the radiology facility are described in paras 3.9–3.50.

3.287. The licensee should incorporate:

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

3.288. Potential exposure of the public from a radiation generator can occur if a person (e.g. a cleaner) enters an interventional or conventional fluoroscopy room in between cases and depresses the exposure foot switch (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 foot switch in between cases, as described in para. 3.38(g).

3.289. Inadvertent entry into the room when a patient is undergoing a radiological procedure is another way for potential public exposure to occur. Means for control of entry are addressed in paras 3.279 and 3.280.

3.290. Means for preventing or minimizing unintended and accidental medical exposures are described in paras 3.256–3.259, and the ensuing investigation and corrective actions are described in paras 3.260–3.268.

Mitigation of the consequences of accidents

3.291. Because the radiation source in almost all cases is an X ray generator and tube, turning off the primary electrical source 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 protection and/or patient protection, and if medical considerations allow it, the radiological procedure should be discontinued and the X ray unit turned off.

3.292. Some interventional radiology facilities may use sealed or unsealed radioactive sources for implantation or administration as part of the image guided interventional procedure. Loss of a source, rupture of the encapsulation or spillage of radioactivity can lead to contamination. For use of unsealed sources, the relevant guidance in paras 4.290–4.301 applies; and for use of sealed sources, the relevant guidance in paras 5.306–5.323 applies.

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

GENERAL

4.1. This section 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 can 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 with different modalities, such as planar imaging (including whole body imaging) or SPECT. In the case of positron emitters, the detection of annihilation photons allows registering of the 3-D spatial distribution of the radiopharmaceutical using 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 MRI, such as in PET–MRI. In addition, probes may be used for the intraoperative 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 and/or gamma emitting radionuclides, more recently also with alpha emitters; therapy with Auger electrons is mostly experimental. The nuclear medicine facility might also perform in vitro studies, although these are not a primary focus of this Safety Guide. Some nuclear medicine facilities might 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 larger hospital or medical centre, or it 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 GSR Part 3 [3] 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 guidance in Section 4. In cases where the guidance is specific to one of either 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 (see para. 2.90) in nuclear medicine procedures, depending, inter alia, on national laws and regulations. They primarily include nuclear medicine physicians, but they may include other specialists such as radiologists, cardiologists and radiation oncologists.

4.6. As stated in para. 2.92, the term 'medical radiation technologist' is used in GSR Part 3 [3] and this Safety Guide as a generic term for the health professional known by several different terms in different States; such terms include radiographer, radiological technologist and others. Clearly, each State will use its own term in its own jurisdiction.

4.7. 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 guidance is relevant to nuclear medicine, and reference to Section 2 should be made as necessary.

SAFETY OF MEDICAL RADIATION FACILITIES AND MEDICAL RADIOLOGICAL EQUIPMENT

Nuclear medicine facilities

4.8. Provisions for the incorporation of radiation protection and safety features should be 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, within other departments of the 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 providing easy exit routes for patients, after the examination or treatment has been performed, that minimize movement through the facility.

4.9. A typical nuclear medicine facility using unsealed sources[24] will have areas for the following: source storage and preparation (radiopharmacy, radioisotope laboratory or 'hot lab'), radiopharmaceutical administration to patients, uptake rooms, imaging (in vivo), sample measurement (in vitro), waiting areas, changing areas and toilets, radioactive waste storage and predisposal processing. Separate waiting areas for patients before and after radiopharmaceutical administration should be considered. For those nuclear medicine facilities at which therapy with radiopharmaceuticals is performed, a dedicated ward for patients undergoing such treatments should be considered. 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. Detailed guidance on setting up nuclear medicine facilities, including PET–CT facilities, is given in Refs [62, 204–210].

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

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

4.12. A stable power supply should be available for the facility. An uninterruptible power supply or battery backup systems should be installed to capture the active information at the time of the outage and to shut down all software in a controlled manner. Servers should be programmed to shut down automatically when the power supply is interrupted.

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[24] In a nuclear medicine facility, sealed sources are also present, such as those used as check sources for the calibration of activity meters and nuclear flood sources to check the uniformity of gamma cameras and for the quality assurance and calibration of PET scanners.

4.13. The design of the facility should include an air conditioning system sufficient to maintain the temperature in the examination room within the parameters defined by the equipment manufacturers. Alternatively, in the case of PET scanners, water cooling can also be used, depending on the equipment. In addition, temperature control is necessary for uptake rooms in a PET facility to prevent artefacts (e.g. brown fat uptake) occurring if room temperatures are too low.

4.14. Issues to be considered for the design of the nuclear medicine facility include: optimization of protection and safety against external radiation and contamination; maintaining of low radiation background levels to avoid interference with imaging equipment; meeting requirements for radiopharmaceuticals (see para. 4.39); and ensuring safety and security of sources (locking and control of access).

4.15. For external exposure, the three factors relevant to dose reduction (time, distance and shielding) should be combined in the design to optimize occupational radiation protection and public radiation protection. Larger rooms are preferable to allow easy access for patients on bed trolleys and to reduce exposure of staff as well as the public. Larger rooms also allow for easier patient positioning and movement during the procedures. For internal exposure, the principles of control, containment and radiation protection by means of barriers should also be considered in the design, to optimize occupational radiation protection and public radiation protection (see paras 4.21 and 4.22).

4.16. The design of the nuclear medicine facility should include provision for secure and shielded storage for radioactive sources. Facility design personnel and engineers should be consulted with regard to floor-loading requirements, with account taken of factors such as radiation shielding, imaging and ancillary equipment. 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 storage compartments for radiopharmaceuticals and an area for temporary storage of radioactive waste should be provided, with appropriate protective barriers.

4.17. 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.

4.18. Signs and warning lights should be used at the entrances of controlled areas and supervised areas to prevent inadvertent entry (see also paras 4.269 and 4.270 on control of access). For controlled areas, para. 3.90(c) of GSR Part 3 [3] requires the use of the basic ionizing radiation symbol recommended by ISO [56]. Signs should also be available at the entrances to areas for source preparation and storage, hybrid imaging rooms and rooms for hospitalized patients undergoing radiopharmaceutical therapy (see also the guidance on treatment rooms and wards, in paras 4.29–4.31). 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 procedures.

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

Mobile facilities

4.20. In some States, PET–CT scanners are mounted on a truck and this mobile unit provides a service to specific regions of that State. These mobile units should meet the same requirements of GSR Part 3 [3] as fixed facilities and the relevant guidance in this Safety Guide is applicable.

Areas where unsealed radioactive materials are handled

4.21. 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 effluent;
(f) Shielding to protect workers where significant external exposure might 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 washing 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;
(k) An emergency shower for decontamination of persons.

Detailed guidance is given in Refs [62, 204–210].

4.22. 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 (with an unbreakable outer wall) 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) Shielded carrying containers, wheeled if necessary, for moving radioactive materials from place to place;
(l) Equipment to deal with spills (decontamination kits).

4.23. Drainpipes from sinks in a 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 the drainage system ‘backing up’ and contaminating other, non-controlled, areas. The final plans of the drainage system, which should be 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.

4.24. Some States 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 States, but each nuclear medicine facility should comply with the State's regulations (see para. 4.280(g)).

4.25. The floors of areas with the potential for contamination should be finished in an impermeable material that 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 (e.g. gas, electricity and vacuum equipment) should not be mounted on bench tops, but on walls or stands.

4.26. 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.

4.27. Radiopharmacies or laboratories in which radioactive aerosols or gases are produced or handled should have an appropriate ventilation system that includes a fume hood, laminar airflow cabinet or glove box. The fume hood should be constructed of material that is smooth, impervious, washable and resistant to chemicals, and it should exhibit a negative flow rate. The work 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 and should be adequate to the radioisotopes used [210].

4.28. The airflow should be from areas of minimal likelihood of airborne contamination to areas where such contamination is likely. Room air from a radiopharmacy or radiochemistry laboratory should be vented through a filtration system or other mechanism for trapping airborne radioactive materials and should not be recirculated, neither directly, in combination with incoming fresh air in a mixing system, nor indirectly, as a result of proximity of the exhaust to a fresh air intake. The possibility for competitive airflow should be considered in the design. For reasons of asepsis, some radiopharmacies may need a positive rather than a negative pressure. In this case, the pressure gradient can be obtained by

locating other workstations requiring negative pressure next to the radiopharmacy workstation.

Treatment rooms and wards

4.29. 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 workers and the public. Bins for the temporary storage of linen and waste contaminated with radioactive materials should be located in secure areas. Storage areas should be clearly marked, using the basic ionizing radiation symbol recommended by ISO [56].

4.30. Rooms designated for patients undergoing radiopharmaceutical therapy should have separate toilets and washing facilities. A sign requesting patients to flush the toilet at least twice and to wash their hands should be displayed to ensure adequate dilution of excreted radioactive materials and to minimize contamination. The facilities should include a hand washing sink as a normal hygiene measure (see para. 4.19 for guidance on bathrooms and their use).

4.31. The design of safe and comfortable accommodation for carers and comforters (see also paras 4.235–4.239) should be considered for nuclear medicine facilities with radiopharmaceutical therapy patients.

Shielding calculations

4.32. The shielding should be designed to meet the requirements for the optimization of protection and safety and should take 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. It is convenient to shield the source, where possible, rather than the room or the person. The need for wall, floor and ceiling shielding should be assessed, for example in the design of therapy facilities 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 that scatter radiation, such as from a CT scanner, does not pass over the wall into the area being protected.

4.33. Methodologies and data for shielding calculations for nuclear medicine facilities are given in Refs [54, 61, 205] (see also paras 3.18–3.22) for shielding with respect to X ray imaging systems (e.g. CT) used as part of hybrid imaging equipment. The nominal design dose in an occupied area is derived by the process of constrained optimization (i.e. selection of a source related dose constraint), with the condition that each individual dose from all relevant sources is well below the dose limit for a person 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 that the shielding needs to provide to ensure that the nominal design doses are achieved. Potential changes in practice and increases in workload should be considered.

4.34. Care should be taken to avoid multiplication of conservative assumptions, which can lead to unrealistic overestimates of the shielding required. Typical conservative assumptions are: attenuation by the patient is not considered; decay of short lived radionuclides, such as ^{18}F, 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 room. Therefore, a balanced decision should be achieved and accumulation of overly conservative measures that may go beyond optimization should be avoided.

4.35. Specification of shielding, including calculations, should be performed by a medical physicist or a qualified expert in radiation protection. In some States, 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 para. 2.74).

4.36. 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 should be met (para. 2.74).

Design of display and interpretation (reading) rooms

4.37. To facilitate their interpretation by the radiological medical practitioner, images should be displayed in rooms specifically designed for such purposes. A low level of ambient light in the viewing room should be ensured (see also paras 3.45 and 3.46 on image display devices and view boxes).

4.38. 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. 3.46).

Radiopharmaceuticals

4.39. Radiopharmaceuticals should be manufactured according to good manufacturing practice following relevant international standards [207, 208, 210–214] for:

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

Medical radiological equipment, software and ancillary equipment

4.40. This subsection 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 unsealed or sealed sources and those that generate ionizing radiation. The former includes probes, gamma cameras (planar and SPECT systems) and PET scanners, since these have an influence on the activity that needs 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 MRI does not generate ionizing radiation and so is outside the scope of this Safety Guide, the performance of MRI can influence the efficacy of the nuclear medicine procedure, and hence such equipment should meet relevant IEC standards or equivalent national standards.

4.41. The requirements for medical radiological equipment and its software are established in paras 3.49 and 3.162 of GSR Part 3 [3]. The IEC has published international standards applicable to medical radiological equipment. Current IEC standards relevant to nuclear medicine include Refs [215–221] (for those relevant to the X ray based component of hybrid imaging, see para. 3.28). It is recommended that the IEC web site be visited to view the most up to date list of standards. ISO publishes international standards applicable to medical radiological equipment. It is recommended that the ISO web site be visited to view the most up to date list of standards.

4.42. 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 or equivalent national standards. In some States, there may be an agency with responsibilities for medical devices or a similar organization that gives type approval to particular makes and models of medical radiological equipment.

4.43. Some nuclear medicine facilities operate a cyclotron for on-site radionuclide production. As the cyclotrons are not directly involved in the exposure of the patient, they need not comply with the requirements of GSR Part 3 [3] for medical radiological equipment. Nevertheless, they should comply with the more general requirements of GSR Part 3 [3] for radiation generators (Requirement 17 and paras 3.49–3.60 of GSR Part 3 [3]), as well as additional regulatory requirements, in a given State, for the preparation and control of radiopharmaceuticals.

4.44. Displays, gauges and instructions on operating consoles of medical radiological equipment, and accompanying instruction and safety manuals, might be used by staff who do 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 or into a language acceptable to 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 should be subject to a quality assurance process to ensure proper understanding and to avoid operating errors. The same applies to maintenance and service manuals and instructions for maintenance and service engineers and technicians who do not have an adequate understanding of the original language (see also paras 2.104 and 2.137).

Design features for medical radiological equipment

4.45. The performance of probes, gamma cameras (planar and SPECT systems) and PET scanners determines the efficacy of the diagnostic radiological procedures and hence can influence the amount of radioactive material that needs to be administered to the patient, or even whether the procedure is diagnostically successful. Many design features contribute to the performance of such equipment and should be considered when purchasing such equipment, as indicated briefly in paras 4.46–4.51 and described in detail in Refs [183, 200, 201, 209, 215–228].

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

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

4.48. Design features that should be considered for gamma cameras (planar and SPECT systems) as well as their accessories include:

(a) Detector features:
  — Pulse height analysis;
  — Uniformity;
  — Spatial resolution and linearity;
  — Energy resolution;
  — Sensitivity;
  — Count rate performance;
  — Detector head shielding leakage.
(b) Detector head motion.
(c) Automatic patient–detector distance sensing.
(d) Collision detection and emergency stops.
(e) Collimators and collimator exchange mechanisms.
(f) Imaging table and attachments.
(g) Data acquisition features:
  — General acquisition features;
  — Static acquisition;
  — Dynamic acquisition;
  — List mode acquisition;
  — Gated cardiac acquisition;
  — Whole body imaging;
  — Tomography.
(h) Data processing system:
  — Data display;
  — Image manipulation;
  — Region of interest generation and display;
  — Curve generation;
  — Display and arithmetic;

— Processing of SPECT data;
— Quality control software;
— Test data.

(i) Accessories, such as features for physiological triggering, anatomical landmarking and phantoms.

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

(a) Detector features:
— Spatial resolution;
— Sensitivity;
— Scatter fraction, count losses and random measurements;
— Energy resolution;
— Image quality and accuracy of attenuation, and scatter correction and quantitation;
— Coincidence timing resolution for time of flight PET accuracy.

(b) Time of flight capability.

(c) Data acquisition features, including 2-D and 3-D whole body imaging, and cardiac and respiratory gating.

(d) Data processing system, including image reconstruction algorithms, image manipulation and image correction.

(e) Emergency stop.

4.50. Guidance on medical radiological equipment using X rays, used for imaging as part of nuclear medicine, is given in paras 3.27–3.41.

4.51. All digital medical radiological equipment should have connectivity to RIS and to PACS.

Ancillary equipment

4.52. All equipment used for digital image display should meet appropriate international or national standards, for example meeting the performance specifications in Ref. [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. [229] (see paras 4.37 and 4.38 for guidance on display and interpretation rooms).

4.53. The nuclear medicine facility should have equipment, instruments and test objects for measurements, dosimetry and quality control. This may include liquid

scintillation counters, well counters, activity meters (dose calibrators), probes, check sources, flood sources, phantoms, and geometry and mechanical test tools. Where applicable, such instrumentation should adhere to relevant IEC standards or equivalent national standards. Further guidance on appropriate equipment, instruments and test objects is given in Refs [215, 224, 227, 230].

4.54. The nuclear medicine facility should be equipped with properly calibrated workplace monitoring instruments, including survey meters and portable contamination monitors.

4.55. Radiopharmaceutical dispensing equipment should adhere to relevant IEC standards or equivalent national standards.

Security of sources

4.56. 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 of para. 3.53 of GSR Part 3 [3]. In a nuclear medicine facility, the sources include unsealed radiopharmaceuticals as well as radionuclide generators, radiopharmaceutical dispensing equipment and sealed sources used for calibration or quality control tests. Standards for the identification and documentation of unsealed radioactive substances are issued by ISO [231]. Situations that are particularly critical with respect to security of sources in a nuclear medicine facility include receipt of radiopharmaceuticals, storage of sources, movement of sources within the facility and storage of radioactive waste (see Ref. [232]). The licensee of the nuclear medicine facility should develop procedures to ensure the safe receipt and movement of radioactive sources within the facility and should establish controls to prevent the theft, loss and unauthorized withdrawal of radioactive materials or the entrance of unauthorized personnel to controlled areas. An inventory of sources should be maintained, and procedures should be put in place to check and confirm that the sources are in their assigned locations and are secure. Written procedures should be developed to encourage proactive behaviour, for example to trigger a search when a delivery of radiopharmaceuticals is not received at the expected time.

Maintenance

4.57. Paragraphs 3.15(i) and 3.41 of GSR Part 3 [3] establish 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 is required to ensure that adequate

maintenance (preventive maintenance and corrective maintenance) is performed as necessary to ensure that medical radiological equipment used in the nuclear medicine facility retains, or improves through appropriate hardware and software upgrades, its design specifications for image quality and radiation protection and safety for its useful life. The registrant or licensee should, therefore, establish the necessary arrangements and coordination with the manufacturer or installer before initial operation and on an ongoing basis.

4.58. All maintenance procedures should be included in the programme of quality assurance and should be carried out 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 programme of quality assurance. 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 repairs and subsequent repairs) and the results of testing before equipment is reintroduced to clinical use.

4.59. In line with the guidance provided in para. 2.113, after any modifications or maintenance, the person responsible for maintenance should immediately inform the licensee of the nuclear medicine facility before the equipment 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.

4.60. The electrical safety and mechanical safety aspects of the medical radiological equipment are an important part of the maintenance programme, as these can have direct or indirect effects on radiation protection and safety. Authorized persons who understand the specifications of the medical radiological equipment should perform this work (see also paras 2.112–2.114). Electrical and mechanical maintenance should be included in the programme of quality assurance and should be performed, preferably by the manufacturer of the medical radiological equipment or an authorized agent, at a frequency recommended by the manufacturer. Servicing should include a written report describing the findings. These reports and follow-up corrective actions should be archived as part of the programme of quality assurance.

4.61. In nuclear medicine, as described in paras 4.1–4.6, occupationally exposed individuals are usually medical radiation technologists, radiological medical practitioners (including, e.g., nuclear medicine physicians), radiopharmacists and medical physicists. Other health professionals such as nurses and other support staff involved in the management of patients who have been administered with radiopharmaceuticals, particularly in nuclear medicine facilities providing therapy services, may also be considered occupationally exposed.

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

4.63. Other nuclear medicine facility workers such as administrative personnel and other service support personnel, cleaning personnel, and workers in the wider medical facility where the nuclear medicine facility is located, for whom radiation sources are not required by, or directly related to, their work, are required to have the same level of protection as members of the public, as established in para. 3.78 of GSR Part 3 [3]. Consequently, the recommendations provided in paras 4.267–4.270 are also applicable in respect of such workers. Rules should be established for these workers, especially with regard to access to controlled areas and supervised areas.

4.64. This subsection contains guidance very specific to nuclear medicine. More general and comprehensive guidance on occupational radiation protection is given in GSG-7 [23], 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).

Arrangements under the radiation protection programme

Classification of areas

4.65. Various areas and rooms in a nuclear medicine facility should be classified as controlled areas or supervised areas, in line with the requirements established in paras 3.88–3.92 of GSR Part 3 [3]. Once designated, these areas should meet the requirements established in paras 3.89 and 3.90 (for controlled areas) and 3.91 and 3.92 (for supervised areas) of GSR Part 3 [3], 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 that are not so designated are considered as being in the public domain, and levels of radiation in these areas should be low enough to ensure compliance with the dose limits for public exposure. Classification of areas in a nuclear medicine facility should be based on the analysis of the process as a whole, and not only on the location of the equipment and the radiation sources. Paragraphs 4.66–4.69 give general guidance, and it would be expected that final decisions by the licensee for a given medical radiation facility would be based on the expert advice of the medical physicist, a qualified expert in radiation protection or the RPO.

4.66. In a nuclear medicine facility, rooms for preparation of radiopharmaceuticals (i.e. radiopharmacies or hot labs), for injection of radiopharmaceuticals and for storage and decay of radiopharmaceuticals meet the criteria for a controlled area and should be so designated. Imaging rooms, particularly those housing radiopharmaceutical dispensing equipment (i.e. PET radiopharmaceutical and radioactive gas and aerosol dispenser devices), as well as waiting rooms dedicated to patients who have been injected with radiopharmaceuticals (e.g. uptake rooms in a PET facility) should also be designated as controlled areas. Rooms for patients undergoing radiopharmaceutical therapy should be designated as controlled areas. Rooms housing hybrid machines that have an X ray component (PET–CT and SPECT–CT) should be designated as controlled areas. A warning light at the entry to the room should be used to indicate when the machine is on to prevent unintended entry.

4.67. Supervised areas may include examination rooms with probes, corridors and other areas where there are patients who have been administered with radiopharmaceuticals.

4.68. The area around the control panel of hybrid imaging equipment (e.g. PET–CT and SPECT–CT) should be classified as a supervised area, even though the radiation levels may be very low owing to the shielding design. Classification of this area as a supervised area will ensure restricted access and hence, inter alia, avoid distraction of the operator, which could lead to accidental or unintended medical exposure of patients (see also para. 3.59).

4.69. In order to avoid uncertainties about the extent of controlled areas and supervised areas, the boundaries of such areas should, when possible, be walls and doors or other physical barriers, clearly marked or identified with suitable warning signs.

Local rules and procedures

4.70. Paragraph 3.93 of GSR Part 3 [3] 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 established in para. 3.94 of GSR Part 3 [3], local rules and procedures are required to be established in writing in any nuclear medicine facility. Their purpose is to ensure protection and safety for workers and other persons. Such local rules and procedures should include measures to minimize occupational radiation exposure both for normal work and in unusual events. The local rules and procedures should also cover the wearing, handling and storing of personal dosimeters, and should specify investigation levels and ensuing follow-up actions (see paras 4.118–4.140).

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

4.72. Equipment (both 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 to radiation protection and safety. The manufacturer's operating manual is an important resource in this respect, but additional procedures should also be considered. The final documented set of operational procedures should be subject to approval by the licensee of the nuclear medicine facility, and should be incorporated into the facility's management system (see paras 2.138–2.149).

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

4.74. Many local rules and procedures address some or all aspects of occupational radiation protection, patient radiation protection and public radiation protection, either directly or indirectly, as well as providing for a successful diagnostic examination or application of the treatment. Paragraphs 4.75–4.109 give recommendations that should be incorporated into the nuclear medicine facility's

local rules and procedures. They are placed in this section on occupational radiation protection because they are to be followed by workers, but they will often also have significance for patient and public radiation protection (see also para. 4.56 on the security of sources).

4.75. 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 and/or plastic backed absorbent pad. Work with unsealed sources should be restricted to a minimum number of specifically designated areas.

4.76. 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 food that 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 not be used in such areas (with respect to the latter, 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 with a waterproof dressing.

4.77. In areas classified as controlled areas, protective clothing should be worn as determined by the safety assessment. 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.

4.78. 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 for residual contamination. 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 4.105–4.109 on decontamination of persons).

4.79. 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. Needles that have been used to inject patients should not be recapped. In other circumstances, needles should be recapped when working with radioactive liquids to maintain containment. Specific recapping tools should be used to prevent injuries from needles.

4.80. 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.

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

4.82. The amount of shielding material required can be minimized by positioning the shielding material 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 usually more suitable for beta emitters, as it lowers the amount of bremsstrahlung produced. Lead should be coated to provide a cleanable surface.

4.83. The attenuation by lead aprons at the typical gamma energies used in nuclear medicine is modest and is even less for non-lead based protective aprons. More effective ways for dose reduction are automatic dispensers and injectors, and mobile shields.

4.84. 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 wearing disposable gloves;
(b) During examinations, when the distance to the patient is short, using a movable transparent shield.

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

4.86. 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 and nose clip or mask for the patient. The placing of extracting devices close to the patient could be considered to improve radiation protection.

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

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

4.89. Items such as containers and lead pots that no longer contain radioactive material are required to be managed as non-radioactive waste. They should have any radiation warning labels removed or obliterated before removing them from regulatory control.

4.90. For X ray based imaging (e.g. CT) in the nuclear medicine facility, reference should be made to the guidance, where appropriate, in paras 3.65–3.77.

4.91. Local rules for pregnant workers and persons under the age of 18 should reflect the guidance given in paras 4.145–4.149 and 4.150, respectively.

Specific local rules and procedures for radiopharmaceutical therapy

4.92. Administration of radiopharmaceuticals 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 RPO at the facility should be consulted to determine the necessity of

other protective equipment (e.g. shoe covers and step off pads) for particular radiopharmaceutical therapies.

(b) For intravenous or intra-arterial administration by bolus injection, when dose rates warrant, the syringe should be placed within a syringe shield (usually a plastic shield for beta emitting radionuclides to minimize bremsstrahlung or a shield of high atomic number material for photon emitting radionuclides) with a transparent window to allow the material in the syringe to be seen. For intravenous administration by slower drip or infusion, the container containing the radioactive material 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 to the shielding of pumps and lines.

(c) For oral administration of therapeutic radiopharmaceuticals, the radioactive material should be placed in a shielded, spill-proof container. Care should be taken to minimize the chance of splashing liquid or of dropping capsules. Appropriate long handled tools should be utilized when handling unshielded radioactive materials.

4.93. Patients hospitalized for therapy with radiopharmaceuticals should be attended by staff (physicians, nurses, aides and 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 vomit. Ward nurses should be informed when a patient may pose a radioactive hazard.

4.94. Local rules should be established concerning the type of nursing that can be performed according to the level of the radiation hazard. 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 (e.g. bed linen, clothing, towels, crockery and bed pans).

4.95. As described in para. 4.66, rooms occupied by patients treated with radiopharmaceuticals should be designated as controlled areas, and both the basic ionizing radiation symbol recommended by ISO [56] and a warning sign should be posted. Access should be restricted and a list of relevant contacts (such as nuclear medicine physicians and on-call physicians, medical radiation technologists and the RPO) should be provided. Protective clothing, such as laboratory coats, gloves and shoe covers, should be made 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 the radiopharmaceuticals were administered, and any relevant instructions to carers and comforters.

4.96. Values of ambient dose equivalent rates 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 and included in the local rules.

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

4.98. 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, and instructions to sit down when using the toilet and to flush the toilet at least twice in the absence of delay tanks).

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

4.100. 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.

4.101. Nursing care items should be covered when possible to prevent contamination. For example, a 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 returned to regular use.

4.102. 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 for PET facilities

4.103. Personnel carrying out PET imaging 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 doses. For these reasons, local rules and procedures for PET facilities should emphasize the means described in paras 4.75–4.102 for minimizing the dose to personnel when handling radiopharmaceuticals and patients containing radiopharmaceuticals.

4.104. 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 that allow the safe and quick dispensing of radiopharmaceuticals into syringes, thus minimizing the operator's actions.

Decontamination of persons

4.105. Hands should be washed on completing work with unsealed radioactive materials and on leaving an area that is classified as controlled because of possible 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 can be more successful. Guidance for monitoring the contamination level should be made available. A decontamination kit and procedures for its use should be available on the site.

4.106. 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.

4.107. If the skin is broken or a wound is sustained under conditions where there is a risk of radioactive contamination, the injury should be flushed with water as soon as appropriate, and care should be taken 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.

4.108. Contaminated clothing should be removed as soon as practicable, and care should be taken not to spread contamination.

4.109. 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 showering and eye washing.

Personal protective equipment and in-room protective devices

4.110. Paragraphs 3.93 and 3.95 of GSR Part 3 [3] require that personal protective equipment and in-room protective devices be available and used when structural shielding and administrative controls alone cannot afford the required level of occupational radiation protection. The need for this protective equipment should be established by the RPO at the nuclear medicine facility or by the medical physicist.

4.111. 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 the following:
   - Alpha emitters may need to be shielded by high atomic number materials because of their characteristic X rays and high energy gamma components.
   - ^{223}Ra does not need a high atomic number shield because the gamma component does not contribute significantly to the dose.
   - Solutions containing pure low energy beta emitters, such as ^{14}C, require a plastic shield to attenuate the beta particles.
   - Solutions containing high energy beta emitters, such as ^{32}P and ^{90}Y, require a plastic shield to attenuate the beta particles followed by a high atomic number material shield for the bremsstrahlung radiation.
   - Solutions containing radionuclides that have both beta radiation and gamma radiation, such as ^{169}Er, ^{177}Lu, ^{186}Re and ^{153}Sm, may need lead shielding to attenuate the high energy gamma photons.

— Gamma emitters always require shielding by high atomic number materials.

(b) Protective clothing should be used in work areas where there is a likelihood of contamination, such as in areas for radiopharmaceutical preparation and administration. The protective clothing may include laboratory gowns, waterproof gloves (made of latex or non-latex material 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 the wearer leaves a designated area. When moving between supervised areas such as the camera room and the injection area, the wearer might not need to change the protective clothing unless a spill is suspected. It is good practice to change gloves after each manipulation. Protective clothing should be removed before entering other areas, such as staff rooms.

(c) When lower energy beta emitters are handled, 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 either a carer or comforter or a 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 (see para. 4.83).

(e) Tools for remote handling of radioactive material, including tongues and forceps.

(f) Containers for the transport of radioactive waste and radioactive sources.

(g) Fume hoods, fitted with appropriate filters and adequate ventilation, should be used with volatile radiopharmaceuticals, such as ^{131}I and ^{133}Xe. The sterility of the intravenous or intra-arterial radiopharmaceuticals should be preserved.

Workplace monitoring

4.112. Paragraphs 3.96–3.98 of GSR Part 3 [3] establish the requirements and responsibilities for workplace monitoring. Workplace monitoring comprises measurements made in the working environment and the interpretation of the 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 GSG-7 [23].

4.113. 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 work 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) Workstations, ventilation systems and drains, when any of these needs to be accessed for maintenance purposes;
(c) Protective and personal clothing, and shoes, particularly when the wearer is leaving a controlled area (monitors should be available near the exit);
(d) Clothing, bedding and utensils used by radiopharmaceutical therapy patients.

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

4.115. Workplace monitoring with respect to X ray based imaging systems used in nuclear medicine should follow the guidance given in paras 3.100–3.103.

4.116. 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 are triggered when investigation levels are exceeded (see paras 4.131 and 4.132).

4.117. The survey meters used for external radiation monitoring should be calibrated in terms of the relevant operational quantities. In nuclear medicine, the relevant quantity is normally the ambient dose equivalent, $H^*(10)$, and the unit is the sievert (Sv) and its submultiples. Contamination monitors should be calibrated in appropriate quantities (see also further guidance on calibration in paras 4.197–4.202).

Assessment of occupational exposure and health surveillance for workers

Assessment of occupational exposure

4.118. The purpose of monitoring and dose assessment is, inter alia, to provide information about the exposure of workers and to confirm good working practices and regulatory compliance. Paragraph 3.100 of GSR Part 3 [3] establishes the requirement of individual monitoring for "any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure". 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 preparing, dispensing and administering of radiopharmaceuticals to patients for diagnosis and therapy, staff dealing with radioactive waste, biomedical and clinical engineers, maintenance and servicing personnel, and any nursing or other staff who need to spend time with nuclear medicine patients or who work in controlled areas.

4.119. Monitoring involves more than just measurement. It includes interpretation, assessment, investigation and reporting, which may lead to corrective measures, if necessary. Individual external doses can be assessed by using individual monitoring devices, which include thermoluminescent dosimeters, optical stimulated luminescent dosimeters, radiophotoluminiscent dosimeters, film badges and electronic dosimeters. Individual monitoring devices should be calibrated and should be traceable to a standards dosimetry laboratory (for more detailed guidance, see GSG-7 [23]).

4.120. With the exception of electronic dosimeters used sequentially by several workers with individual doses recorded separately, each personal dosimeter should be used for monitoring only the person to whom it is issued, for work performed at that nuclear medicine facility, and it should not be taken to other facilities where that person may also 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 or she also works. Monitoring results can then be interpreted for the person working in a specific nuclear medicine facility, and this will allow appropriate review of the effectiveness of the optimization of protection and safety for that individual in that facility. However, national regulatory requirements may differ from this advice, and they would need to be followed in those jurisdictions in which they apply (see also paras 4.133–4.135).

4.121. The monitoring period (period of dosimeter deployment) specified by regulatory bodies in most States 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 exposure. 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 is less than the minimum detection level of the dosimeter, resulting in no detectable doses. With a longer cycle, it is more likely that a reading can be obtained. In certain circumstances (e.g. the introduction of new procedures, and work at high dose rates), shorter monitoring periods may be necessary. In these situations, the supplementary use of electronic dosimeters may be appropriate. Unnecessary delays in the return, reading and reporting of the recorded dose on dosimeters should be avoided. Dosimeters should be sent from the nuclear medicine facility to the dosimetry service provider, which 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.

4.122. The operational dosimetric quantity used for external radiation is the personal dose equivalent $H_p(d)$. For weakly penetrating radiation and strongly penetrating radiation, the recommended depths, d, are 0.07 mm and 10 mm, respectively. Both weakly penetrating radiation 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].

4.123. 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 of the hands, such as in the preparation and administration of radiopharmaceuticals, extremity dosimeters should be worn (if this is compatible with good clinical practice).

4.124. 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 is generally 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 in the handling of sources for preparation and administration, but with accepted practices (as described in paras 4.70–4.91) the lens of the eye should be adequately protected. Nonetheless, monitoring of dose to the lens of the eye may need to be considered.

4.125. There are three dose limits applicable to workers in nuclear medicine: the limit for effective dose, and the limits for equivalent dose to the lens of the eye and to the skin and extremities. However, in nuclear medicine, both exposure from external radiation and exposure from 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 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. 4.123 for guidance on when extremity dosimeters should be worn).

4.126. When a protective apron is being used, the assessment of effective dose might 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 of the parts of the body protected by the apron, but underestimates the contribution of the unprotected parts of the body (the thyroid, the head and neck, and the 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 [120, 122].
(c) Notwithstanding (a) and (b), in nuclear medicine, a single dosimeter under the apron provides an estimate of the effective dose that is sufficient for radiation protection purposes.

4.127. 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 for identifying those persons and for arranging for appropriate monitoring (para. 3.102 of GSR Part 3 [3]). This requirement is typically met by monitoring the thyroid with an external detector that assesses 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].

4.128. When not in use, individual dosimeters should be kept in a dedicated place and should be protected from damage or from irradiation. If an individual loses his or her dosimeter, the individual should inform the RPO, who should perform a dose assessment, record this evaluation of the dose and add it to the individual's dose record. Where there is a national dose registry, it should be updated with 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 cases where the individual performs non-routine types of work, it may be better to use the doses of co-workers experiencing similar exposure conditions as the basis for the dose estimate.

4.129. In some cases, 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 $H^*(10)$, provided the dose gradient in the workplace is relatively low. The ICRP [119] provides conversion coefficients from ambient dose equivalent to effective dose for different types of radiation and energy.

4.130. Additional direct reading operational dosimeters, such as electronic dosimeters, should be considered for use in a nuclear medicine facility, for example in a new facility or with the introduction of new procedures, as these devices can give the worker an instant indication of both the cumulative dose 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' reading of the dose is recommended.

Investigation levels for staff exposure

4.131. Investigation levels are different from dose constraints and dose limits; they are a tool used to provide a warning of the need to review procedures and performance, to investigate what is not working as expected and to take timely corrective action. The exceeding of 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 can 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 events should also trigger an investigation. In all cases, the investigation should be carried out with a view to improving the optimization of occupational protection, and the results should be recorded. Investigation levels should also be set for workplace monitoring, with

account taken of exposure scenarios and the predetermined values adopted for investigation levels for workers. Details on investigation levels are provided in GSG-7 [23].

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

Persons who work in more than one place

4.133. Some individuals might 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. Regardless of the ownership and management structure, the occupational radiation protection requirements for the particular nuclear medicine facility apply when the person is working in that facility. As described in para. 4.120, a dosimeter issued for individual monitoring should be worn only in the facility for which it is issued, as this facilitates the effective optimization of protection and safety in that facility. This approach is logistically more easily implemented, since each physical site has its own dosimeters, and so there is no need to transport dosimeters between facilities, with the risk of losing 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. 4.135).

4.134. There is, however, an important additional consideration, namely the need to ensure 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 its RPO, should establish 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 ongoing record of the occupational doses for that person in all the facilities he or she works.

4.135. Some individuals, such as consultant medical physicists or service engineers, might perform work in many nuclear medicine facilities and, in addition, in other medical radiation facilities. They can be employed by a company or be self-employed, providing contracted services to the nuclear medicine facility and the other facilities. In such cases, it is simpler for the company or the self-employed person to provide the dosimeters for individual monitoring. Therefore, in these cases, a worker uses the same dosimeter for work performed in all nuclear medicine facilities (and other medical radiation facilities) in the monitoring period.

Records of occupational exposure

4.136. Paragraphs 3.103–3.107 of GSR Part 3 [3] establish the detailed requirements for records of occupational exposure and place obligations on employers, registrants and licensees. In addition to 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 optimization of protection and safety at the facility and evaluating trends in exposure. The regulatory body might specify additional requirements for records of occupational exposure and for access to the information contained in those records. Employers are required to provide workers with access to records of their own occupational exposure (para. 3.106(a) of GSR Part 3 [3]). Further general guidance on records of occupational exposure is given in GSG-7 [23].

Health surveillance for workers

4.137. 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 paras 3.108 and 3.109 of GSR Part 3 [3].

4.138. No specific health surveillance relating 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 examinations are required, as there are no diagnostic tests that yield information relevant to exposure at low doses. It is, therefore, rare for considerations of occupational exposure arising from the working environment of a nuclear medicine facility to influence significantly the decision about the fitness of a worker to undertake work with radiation or to influence the general conditions of service [23].

4.139. 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.

4.140. Counselling should be made available to workers who have or may have been exposed in excess of dose limits, and information, advice and, if indicated, counselling should be made 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 GSG-7 [23].

Information, instruction and training

4.141. All staff involved in nuclear medicine should meet the respective training and competence criteria described in paras 2.119–2.137. 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 they should undertake radiation protection and safety training relevant to the additional imaging modalities in their nuclear medicine facility.

4.142. Paragraph 3.110 of GSR Part 3 [3] places responsibilities on the employer to provide, inter alia, adequate information, instruction and training for protection and safety as it pertains to the nuclear medicine facility. 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.

4.143. Information on potential contamination risks should be given to ancillary staff, including IT specialists, and contractors performing occasional work in a nuclear medicine facility or radiopharmaceutical laboratory.

Conditions of service and special arrangements

4.144. Paragraph 3.111 of GSR Part 3 [3] requires that no special benefits be offered to staff because they are occupationally exposed. It is not acceptable to offer benefits as substitutes for measures for protection and safety.

Pregnant or breast-feeding workers

4.145. There is no requirement in GSR Part 3 [3] for a worker to notify the licensee that she is pregnant, but it is necessary that female workers understand the importance of making such notifications so that their working conditions can be modified accordingly. Paragraph 3.113(b) of GSR Part 3 [3] establishes the requirement that employers, in cooperation with registrants and licensees, provide female workers with appropriate information in this regard.

4.146. Paragraph 3.114 of GSR Part 3 [3] establishes the requirement that:

> "The employer of a female worker, who has been notified of her suspected pregnancy or that she is breast-feeding, shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or fetus or the breastfed infant is afforded the same broad level of protection as is required for members of the public."

The limitation of the dose to the embryo or fetus does not mean that pregnant women should avoid work with radiation, but it does mean that the employer should carefully review the exposure conditions with regard to both normal exposure and potential exposure. For example, a pregnant worker might be restricted from spending a lot of time in the radiopharmacy or working with solutions of radioiodine [124]. The main risk with radioiodine is that it crosses the placental barrier and concentrates in the fetal thyroid.

4.147. Other possible solutions include reassignment of a pregnant worker to duties where the likelihood of an accident is lower or to a location that has a lower ambient dose equivalent. Such reassignments should be accompanied by adequate training. A further consideration is the need to avoid having pregnant workers respond to an accident such as a radioactive spill (see also paras 4.294–4.298).

4.148. The dose to the fetus should be monitored using an additional dosimeter appropriately positioned (see also GSG-7 [23]). Personal electronic dosimeters are valuable in assessing radiation doses to pregnant workers and subsequently the embryo or fetus (see also para. 4.130).

4.149. With regard to the dose limit of 1 mSv for the embryo or fetus, the dose to the embryo or fetus is 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 made available (see also para. 4.140).

Persons under 18

4.150. In many States, 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 can involve occupational exposure to ionizing radiation. Paragraph 3.116 of GSR Part 3 [3] establishes the requirements for access to controlled areas and the dose limits for such persons are more restrictive (see Box 1 of this Safety Guide and Schedule III of GSR Part 3 [3]).

Protection of workers responding to incidents in a nuclear medicine facility

4.151. 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 incidents should be considered in advance in the safety assessment for the facility and mitigatory procedures should be developed accordingly (see the guidance in paras 4.283–4.301 on prevention and mitigation of accidents).

4.152. Occupational exposure of staff responding to such incidents is still subject to the occupational dose limits, and the mitigatory procedures for incidents should include considerations for the optimization of protection and safety for the responding workers. The mitigatory procedures should also include allocation of responsibilities and should provide for the education and training of the relevant staff in executing the mitigatory measures, which should be periodically exercised. Most of these situations, for example the response to spillage of radioactive materials on work surfaces, can be executed in a planned manner so that doses can be kept low. There may be situations 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 to maintain optimized occupational radiation protection for this situation. The advice of the facility's RPO should be sought for these situations (see the guidance in paras 4.299 and 4.300 for more details).

RADIATION PROTECTION OF INDIVIDUALS UNDERGOING MEDICAL EXPOSURE

4.153. This section covers radiation protection of patients, 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 members of the public and their radiation protection is covered in paras 4.263–4.272.

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

Justification of medical exposure

4.155. The requirements for justification of medical exposure (paras 3.155–3.161 of GSR Part 3 [3]) incorporate the three-level approach to justification (see para. 2.11) [4, 125, 126].

4.156. The roles of the health authority and professional bodies with respect to a 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 paras 2.55–2.60.

Justification of medical exposure for the individual patient

4.157. GSR Part 3 [3] requires a joint approach to justification at the level of an individual patient, 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

in performing the radiological procedure. The efficacy, benefits and risks of alternative methods (both methods involving ionizing radiation and methods not involving ionizing radiation) should be considered. The ultimate responsibility for justification will be specified in the individual State's regulations.

4.158. In the case of radiopharmaceutical 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 a multidisciplinary team, including such specialists as radiation oncologists or endocrinologists, on 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 within the team and documented at a 'tumour board' or equivalent multidisciplinary meeting.

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

4.160. In nuclear medicine imaging, requirements for justification are applied more effectively as part of the medical process of determining the 'appropriateness' of a radiological procedure. The process of determining appropriateness is an evidence based approach to choosing the best test for a given clinical scenario, with account taken of 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 [127–133, 233]. Imaging referral guidelines can be disseminated or utilized through electronic requesting systems[25] and clinical decision support tools or systems.

4.161. In determining the appropriateness of the nuclear medicine imaging procedure for an individual patient, the following questions should be asked by the referring medical practitioner [132]:

(a) Has it already been done? A radiological procedure that has already been performed within a reasonable time period (depending on the procedure

[25] Such electronic requesting systems include the CPOE system; such a system is expected to generate a request for imaging rather than an order.

and clinical question) should not be repeated (unless the clinical scenario indicates the appropriateness of repeating the procedure). In some cases, an alternative procedure may have already been performed in another facility, making the proposed radiological procedure unnecessary, for example a patient who has recently undergone a CT pulmonary angiography in one facility might be referred for a ventilation/perfusion scan at another facility. The results (images and reports) of previous examinations should be made available, not only at a given nuclear medicine facility but also for consideration at different facilities. Digital imaging modalities and electronic networks should be used to facilitate this process.

(b) Is it needed? The anticipated outcome 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 should all 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 for ensuring the correct technique is performed with the correct focus.

4.162. The three particular groups of patients identified in para. 3.157 of GSR Part 3 [3] for special consideration with respect to justification in nuclear medicine are patients who are pregnant or breast-feeding or are paediatric.

(a) Owing to the higher radiosensitivity of the embryo or fetus, it should be ascertained whether a female patient is pregnant before a nuclear medicine procedure is performed. Paragraph 3.176 of GSR Part 3 [3] requires that procedures be "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". Pregnancy would then be a factor in the justification process and might influence the timing of the proposed radiological procedure or a decision as to whether another approach to treatment is more appropriate. Care should be taken to ascertain that the examination or treatment selected is indeed indicated for a medical condition that requires prompt medical treatment. Confirmation of pregnancy could occur after the initial justification and before the radiological procedure is performed. Repeat justification is then

necessary, with account taken of the additional sensitivity of the pregnant patient and embryo or fetus.

(i) Most diagnostic procedures with ^{99m}Tc do not cause high fetal doses. For radionuclides that do not cross the placenta, the fetal dose is derived from the radioactivity in maternal tissues. Some radiopharmaceuticals, or their breakdown 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 given 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 or fetus from intakes of radionuclides by the mother is given by the ICRP [234].

(ii) As a rule, a pregnant patient 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 [124, 235, 236]. 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 possibly enhanced dose to the breast should be considered in the justification process. Detailed information on doses to infants from the ingestion of radionuclides in breast milk is given by the ICRP [237].

(c) As children are at greater risk of incurring radiation induced stochastic effects, paediatric examinations necessitate special consideration in the justification process [233].

4.163. A ‘self-referral’ occurs when a health professional undertakes a radiological procedure for patients as a result of justification on the basis of his or her own clinical assessment. Most examples of acceptable self-referral practice occur with X ray imaging, such as in dentistry, and relevant professional bodies in many States develop appropriate guidance for their specialty (para. 3.149). Self-referral in nuclear medicine, if it occurs, would need to be guided by such professional guidelines.

4.164. ‘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. States may choose to incorporate such guidance into legislation [136].

4.165. Means to improve awareness, appropriateness and auditing should be developed to support the application of the requirement for justification of medical exposure. Awareness of the need for justification underpins the whole process of justification. Means for promoting awareness include traditional education and training, such as at medical school or during specialty training, Internet based learning or learning 'on the job' (e.g. junior doctors in an emergency department), and the use of feedback in the reporting process. Appropriateness is described in paras 4.160 and 4.161, and the audit process is used for monitoring and feedback to improve both awareness and appropriateness.

Justification of medical exposure for biomedical research volunteers

4.166. 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 para. 2.99.

Justification of medical exposure for carers and comforters

4.167. The three-level approach to justification is not applicable for carers and comforters. Instead, para. 3.155 of GSR Part 3 [3] establishes the requirement to ensure that there be some net benefit arising from the exposure, for example the successful performance of a diagnostic procedure on a child. The crucial component in the justification of medical exposure of carers and comforters is their knowledge and understanding about radiation protection and the radiation risks for the procedure being considered. To this end, the radiological medical practitioner or medical radiation technologist involved in the radiological procedure, prior to the performance of the procedure, has the responsibility to ensure that the carer or comforter is correctly informed about radiation protection and the radiation risks involved, and that the carer or comforter understands this information and consequently agrees to take on the role of carer or comforter.

Optimization of protection and safety

4.168. In medical exposure, optimization of protection and safety has several components, some applicable 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 paras 4.169–4.240. Key personnel in the optimization process are the radiological medical practitioner, the medical radiation technologist and the medical physicist.

Design considerations

4.169. 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 doses from medical exposure as low as reasonably achievable consistent with obtaining adequate diagnostic information. Guidance on design considerations is given in the subsection on medical radiological equipment in paras 4.45–4.51. Guidance on design considerations applicable for X ray imaging systems as part of hybrid systems is given in paras 3.32–3.41. Ultimately, as established in para. 3.162 of GSR Part 3 [3], it is the responsibility of the licensee of the nuclear medicine facility to ensure that the facility uses only medical radiological equipment and software that meets applicable international or national standards.

Operational considerations: General

4.170. Following justification, the nuclear medicine procedure is required to be performed in such a way as to optimize patient protection (para. 3.163 of GSR Part 3 [3] for diagnostic procedures and para. 3.165 of GSR Part 3 [3] 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.

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

(a) There should be an effective system for correct identification of patients, with at least two, preferably three, forms of verification, for example name, date of birth, address and medical record number.
(b) Patient details should be correctly recorded, such as age, sex, body mass, height, pregnancy and breast-feeding status, current medications and allergies.
(c) The clinical history of the patient should be reviewed.

4.172. A written protocol should be drawn up for each diagnostic procedure performed in the facility, designed to maximize the clinical information to be obtained from the study, with consideration given to the appropriate DRL for the procedure (see paras 2.34 and 2.45). Such protocols are best developed using guidelines from national or international professional bodies, and hence will reflect current best practices, as for example in Refs [62, 137, 142–147, 204, 205, 238–240]. 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 the optimization of protection and safety through the appropriate selection of values for the various technical parameters, thereby effectively creating an electronic protocol. Protocols should be periodically reviewed in line with the requirements for quality assurance and radiological reviews (see paras 4.234 and 4.259–4.261).

4.173. 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 such cases, the radiological medical practitioner should record a valid reason for the decision.

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

4.175. Many factors influence the relationship between image quality and patient dose in diagnostic nuclear medicine procedures. Detailed guidance on appropriate choices for these factors is widely available and should be followed [62, 204, 205, 209, 238–240]. Such factors include the following:

(a) Appropriate selection of the best available radiopharmaceutical and its activity, with account taken of special requirements for children and for patients with impaired organ function.
(b) Adherence to patient preparation requirements specific to the study to be performed. Examples include:
   — Use of methods for blocking the uptake in organs not under study and for accelerated excretion, when applicable.
   — Withdrawal of medications, food or substances that might interfere with the outcome of the procedure.

— 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 adversely interfere with the procedure. This method is sometimes used to increase the specificity of the examination, but has also a positive influence on radiation protection, for example the use of a 'diuretic challenge' in renography.

(d) For children undergoing diagnostic procedures, the amount of activity administered should be chosen by utilizing methodologies described in international or national guidelines [62, 204, 205, 209, 238, 241–243].

(e) Use of appropriate image acquisition parameters:
   — In nuclear medicine and with a gamma camera (planar and SPECT systems), this may include selection of the collimator, acquisition matrix, energy windows, acquisition zoom, time per frame and imaging distance.
   — For PET systems, this may include 2-D and 3-D acquisitions, matrix size, field of view, time of flight, attenuation correction, slice overlap, scatter correction and coincidence timing.

(f) Use of appropriate reconstruction parameters (e.g. algorithm, matrix, filters, scatter correction and zoom factor), and application of appropriate image corrections (e.g. attenuation and scatter correction, and, in the case of PET systems, random correction).

(g) Utilization of quantitative and qualitative capabilities, such as the generation of region of interest analysis, time–activity curve generation, image reformatting, or tissue uptake ratios, specific to the clinical need.

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

4.177. 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 for elderly patients who are in pain.

4.178. In some cases, if the patient is healthy and cooperative, activity can be reduced and scan times can be increased, for example for lung scans for pregnant patients. In all cases, however, the diagnostic information produced should not be compromised by a reduction in activity.

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

Operational considerations: Radiopharmaceutical therapy

4.180. Protocols should be established in writing for each type of radiopharmaceutical therapy performed in the facility, designed to meet the requirements of para. 3.165 of GSR Part 3 [3]. Such protocols are best developed using guidelines from national or international professional bodies, and hence should reflect current best practices, as for example in Refs [204, 205, 244, 245]. Protocols should be periodically reviewed in line with the requirements for quality assurance and radiological reviews (see paras 4.234 and 4.259–4.261).

4.181. In addition to the guidance in paras 4.170–4.180 (for both diagnostic nuclear medicine procedures and therapeutic nuclear medicine procedures), the following provisions should be put in place:

(a) Verbal and written information and instructions should be provided to patients about their radiopharmaceutical therapy and about how to minimize exposure of family members and the public, and advice should be provided on pregnancy and contraception after therapy (for detailed guidance, including sample information sheets, see Refs [21, 204, 246–249]).
(b) Special attention should be given to preventing the spread of contamination due to patient vomit and excreta.
(c) A protocol should be drawn up for the release of patients after the administration of therapeutic doses of radiopharmaceuticals (see the guidance in paras 4.246–4.248).
(d) A protocol should be drawn up for the actions to be taken when the dose incurred is above or below the value prescribed by the radiological medical practitioner as required by para. 3.180 of GSR Part 3 [3].

4.182. Paragraph 3.165 of GSR Part 3 [3] establishes the requirement that the type and activity of the therapeutic radiopharmaceuticals that are administered to each patient are appropriate. Although algorithms for determining appropriate activities for a given patient on the basis of radiation doses to critical organs exist, there is no standardized algorithm. Methodologies are described in Refs [250–256]. Ideally, the administered activity should be based on the results of a pre-therapeutic dosimetry. Typically, therapeutic radiopharmaceuticals are administered at standard fixed activities (GBq), standard fixed activities per unit body mass (MBq/kg) or standard fixed activities per unit body surface area

(MBq/m^2), based on the results of toxicity studies and evaluation of side effects in clinical trials.

4.183. For female patients, their pregnancy and breast-feeding status should be evaluated before administration of a therapeutic dose (see also paras 4.241–4.245).

4.184. Immediately prior to administration of a therapeutic radiopharmaceutical, the following information, as applicable, should be verified, preferably by two individuals:

(a) The dose on the radiopharmaceutical label matches the prescription;
(b) The identity of the patient by two independent means;
(c) The identity of the radionuclide;
(d) The identity of the radiopharmaceutical;
(e) The total activity;
(f) The date and time of calibration.

4.185. The administered activity should be verified by means of 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. <5% deviation), and the measured value should be recorded. Corrections should be calculated for residual activity in the syringe, cups, tubing, inline filter or other materials used in the administration.

4.186. Patients undergoing radiopharmaceutical therapy 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.

4.187. Both female and male patients should be advised about avoidance of pregnancy after therapeutic administrations. Data on the periods during which conception should be avoided after administration of a radiopharmaceutical to a female patient for therapeutic purposes are given in Appendix II, with further guidance provided in Ref. [238].

4.188. The administration of therapeutic doses of relatively long lived radionuclides in ionic chemical forms to male patients is a possible source of concern because of the presence of larger quantities of these radionuclides in ejaculate and in sperm. It may be prudent to advise sexually active men who have been treated with, for example, ^{32}P (phosphate), ^{89}Sr (chloride), ^{131}I (iodide), ^{223}Ra (chloride) to avoid fathering children for a period of four months after

treatment, and to have protected intercourse for a period of time to be defined by the medical practitioner. The period of four months is suggested, as this is longer than the sperm regeneration cycle [238, 249, 257].

Operational considerations: Pregnant patients

4.189. Administration of radiopharmaceuticals for therapy to patients who are or might be pregnant should be generally avoided. There may be exceptions when the treatment is lifesaving (see also paras 4.162 on justification and 4.241–4.243 on the need to ascertain pregnancy status).

4.190. 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.

4.191. 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 the dose to the fetus and estimation of risk might be necessary.

4.192. In the case of radiopharmaceuticals that are rapidly eliminated by the maternal kidneys, the bladder is the major source of fetal irradiation. After the administration of such radiopharmaceuticals, drinking plenty of fluid and frequently emptying the bladder should be encouraged. Some radiopharmaceuticals, for example radioactive iodides, including those administered for diagnostic purposes, cross the placenta freely and are taken up by fetal tissue, for example the thyroid. Failure to ascertain whether a patient is pregnant when administering ^{131}I for a scan, for example, may lead to a severe accidental exposure of the fetus.

4.193. 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 for a pregnant patient, low dose CT protocols should be used and the scanning area should be reduced to a minimum (see also paras 3.176–3.185).

4.194. In the use of fluorodeoxyglucose (FDG) or other radiopharmaceuticals in PET imaging with patients who are or might be pregnant, a lower activity of

FDG should be considered. Protection of the fetus can be optimized by using smaller administered activities and longer imaging times. Further guidance is given in Refs [62, 258].

Operational considerations: Breast-feeding

4.195. Female patients should be advised that breast-feeding is generally contraindicated after administration of some radiopharmaceuticals, due to both the external irradiation of the suckling baby and the potential excretion of radioactivity through the breast milk (see also paras 4.162 on justification and 4.244 and 4.245 on the need to ascertain breast-feeding status).

4.196. Depending on the radiopharmaceutical, breast-feeding may need to be interrupted for a period or even stopped following its administration. The milk expressed during the interruption period should be discarded. More specific advice is given in Appendix III and Refs [235, 236, 238, 259].

Calibration

4.197. Requirements for the calibration of sources and instruments used for dosimetry of patients are given in para. 3.167 of GSR Part 3 [3]. In nuclear medicine, responsibility for calibration is assigned to the nuclear medicine facility's medical physicist. Unsealed sources for nuclear medicine procedures should be calibrated in terms of the 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 Refs [230, 260].

4.198. Radionuclides should be checked for radioactive impurities when these are liable to be present. This particularly applies to examining short lived radionuclides for the presence of longer lived impurities that could deliver a significant fraction of the absorbed dose.

4.199. 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 paras 3.201, 3.203 and 3.205.

4.200. In the nuclear medicine facility, instruments used for dosimetry of patients, such as activity meters (dose calibrators), should also 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 might differ, depending on the availability at the facility of radioactive sources for calibration. A period of not more than two years is recommended.

4.201. Paragraph 3.167(d) of GSR Part 3 [3] requires that the calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory. Ideally, this would be the national standards dosimetry laboratory (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 State or region if there is no national standards dosimetry laboratory in the State or region where the instruments are used.

4.202. Records of calibration measurements and associated calculations, including uncertainty determinations (uncertainty budgets), should be maintained as described in para. 4.262.

Dosimetry of patients: Diagnostic procedures

4.203. Paragraph 3.168 of GSR Part 3 [3] requires that registrants and licensees of nuclear medicine facilities ensure that patient dosimetry be performed and that typical doses to patients for diagnostic radiological procedures be determined. Knowledge of the typical doses at a facility forms the basis for applying methods of dose reduction as part of optimization of protection and safety. It also enables the nuclear medicine facility to use DRLs (see paras 4.213–4.220) as another tool for the optimization of protection and safety. 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. 4.210).

4.204. Clearly, the more radiological procedures at the nuclear medicine facility for which typical doses are known, the better the basis for optimization of protection and safety. GSR Part 3 [3] requires determination of typical doses for common diagnostic radiological procedures. The procedures that are considered to fall into this category will vary from facility to facility, and State to State, but common examinations generally include thyroid scans, bone scans, myocardial perfusion imaging, FDG–PET/CT in oncology, renal scans and lung scans.

4.205. The term ‘typical dose’, as used in para. 3.168 of GSR Part 3 [3], refers to the median or average dose or activity for a particular size of patients. In nuclear medicine, DRLs are set in activity administered to the patient (MBq) or in activity per unit of body mass (MBq/kg). Patient size has a large influence

on dose, so some selection or grouping of patients is required. Such groupings include 'standard adult', often based on an average mass of 70 kg with a range of ±20 kg. Groupings for children have sometimes been based on age, such as newborn (0 years), infant (1 year), small child (5 years), child (10 years) and teenager (15 years), but more recently size specific groupings are being recommended and used, for example by using body mass intervals. Patient size groupings should be adopted that correspond to the groupings used for the DRLs in the State or region. The sample size used for each patient grouping and radiological procedure should be of sufficient size to assure confidence in the determination of the typical dose. Such sample sizes are typically in the range of 10–20 patients: the larger sample size the lower the statistical uncertainties (see also paras 2.39–2.41 and Refs [14, 242]).

4.206. The dose in the term 'typical dose', as used in para. 3.168 of GSR Part 3 [3], means, for the given diagnostic nuclear medicine procedure, the activity administered to the patient (MBq) or the activity per unit of body mass (MBq/kg), or, in the case of X ray imaging, an accepted dosimetric quantity as described in paras 3.202 and 3.203. For combined doses from radiopharmaceuticals and X rays, the dose to the organ concerned should be used.

4.207. 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 adequate for an accurate diagnosis. Therefore, patients included in the sample used for determining typical doses should only be those whose radiological procedure resulted in acceptable image quality.

4.208. The results of the surveys used to determine typical doses at the nuclear medicine facility should be used as part of the ongoing review of the optimization of protection and safety at the facility, and should be used for comparison with established DRLs (see paras 4.213–4.220). The results should also be submitted to the organization in the State or region that is responsible for establishing and reviewing 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 GSR Part 3 [3], should take place at intervals of no more than five years and preferably no more than three 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.

4.209. 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. 4.255), or there may be the need to estimate the dose to an embryo or fetus (see para. 4.191).

4.210. 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 [238, 259, 261–265] and methodologies for X ray imaging in para. 3.218.

Dosimetry of patients: Radiopharmaceutical therapy procedures

4.211. Paragraph 3.168 of GSR Part 3 [3] requires that nuclear medicine facilities determine typical absorbed doses to patients for their therapeutic radiological procedures. Methodologies for the determination of doses from therapy radiopharmaceuticals are explained in detail in Refs [238, 252, 254–256, 266–272].

4.212. Radiopharmaceutical toxicity in therapeutic nuclear medicine depends on the absorbed dose to critical organs (e.g. to the haematopoietic system), and the efficacy of the treatment depends on the absorbed dose received by target tissues. In current clinical practice, the nuclear medicine therapeutic treatment is usually delivered on the basis of an administered activity prescription, in some cases with adjustments made for body mass or surface area. Ideally, a pre-treatment calculation of the absorbed doses received by organs at risk and target tissues would allow for an accurate prediction of toxicity and efficacy of the treatment. The dosimetry calculations performed in this context should take into account individual patient pharmacokinetics and anatomy.

Diagnostic reference levels

4.213. Paragraphs 3.168 and 3.169 of GSR Part 3 [3] require that patient dosimetry surveys be performed for the diagnostic procedures at a nuclear medicine facility, as described in paras 4.203–4.210, and that these results be compared with the established DRLs for the State or region. The purpose is to ascertain whether or not the typical dose or activity for the facility for a given diagnostic nuclear medicine procedure compares favourably with the value of the

DRL for that nuclear medicine procedure. Guidance on establishing national or regional DRLs is given in paras 2.34–2.45.

4.214. A review of optimization of protection and safety for that particular nuclear medicine procedure is triggered if the comparison shows that the typical dose or activity for the facility exceeds the DRL, or that the typical dose or activity for the facility 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. However, future advances in technology might result in typical doses or activities substantially below the DRLs, and still produce images of diagnostic usefulness.

4.215. Given the uncertainties in determining the typical dose or activity for a facility, questions can arise over whether or not a DRL has really been exceeded. Some States adopt an algorithmic approach, for example where the typical dose or activity for the facility, minus two times its standard error, should be greater than the value of the DRL [16]. A simpler approach, based purely on the typical value for the facility, may be sufficient, as the purpose is to identify the need for a review [14–16].

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

4.217. Furthermore, the comparison should not simply determine if the nuclear medicine facility complies with the DRL. DRLs are not dose limits. DRLs should be used for the comparison exercise in the review process of optimization of protection and safety to identify practices that warrant further investigation.

4.218. The review of how the given nuclear medicine procedure is being performed and of the optimization of protection and safety, triggered by the DRL comparison, might 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 programme of quality assurance. On the other hand, the review might 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 programme of quality assurance.

4.219. The fact that the typical dose or activity for a nuclear medicine procedure at a nuclear medicine facility is less than the DRL for that procedure does not necessarily mean that optimization of protection and safety for that nuclear medicine procedure has been fully achieved. DRLs are only one of the tools for optimization, and are aimed specifically at identifying the outliers in performance.

4.220. The regulatory body in a given State may specify frequencies for performing DRL comparisons. Otherwise, the general guidance for patient dosimetry, described in para. 4.208, would be applicable.

Quality assurance for medical exposures

4.221. Paragraph 3.170 of GSR Part 3 [3] requires that nuclear medicine facilities have in place a comprehensive programme of quality assurance for medical exposures. General guidance on the management system is given in paras 2.138–2.149, and it is reiterated here that the programme of quality assurance for medical exposures should fit in with, and be part of, the wider management system at the facility.

4.222. The purpose of the programme of quality assurance for medical exposures is to help to ensure successful optimization of protection and safety in the nuclear medicine facility and to minimize the occurrence of unintended and accidental medical exposures.

4.223. 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 the degree of application that there are differences. Paragraph 3.171 of GSR Part 3 [3] establishes the common elements of the programme.

4.224. Measurements on medical radiological equipment are one of the components of the programme of quality assurance. 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. The acceptance test should be followed immediately by commissioning, and then ongoing periodic quality control tests, including constancy tests. The purpose is to ensure that, at all times, all medical radiological

equipment performs correctly, accurately, reproducibly and predictably. Acceptance and commissioning tests should be performed in the same way for equipment and software that has been donated.

4.225. Depending on the equipment purchase agreement, acceptance tests can be performed by the manufacturer in the presence of the local medical physicist and the radiological medical practitioner representing the user, or, if acceptable to the manufacturer and the purchaser, by a medical physicist jointly with the manufacturer. The process should involve verification of all specifications and features of the equipment, in particular, protection and safety features including displayed and reported dose metrics.

4.226. After acceptance and before clinical use on patients, commissioning should be 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. During commissioning, the baseline for subsequent constancy tests is established.

4.227. In addition to the acceptance testing and commissioning, para. 3.171 of GSR Part 3 [3] requires, periodically and after any major maintenance procedure or upgrade, the measurement of physical parameters of medical radiological equipment. There are many published reports from international and national organizations and national and regional professional bodies giving detailed guidance on the quality control tests that should be performed in nuclear medicine, including recommended frequencies [183, 184, 187, 200, 201, 204, 205, 215–228, 230, 260, 266, 273–275]. In addition, many of these organizations and professional bodies publish on their web sites new or updated publications on the topic. The regulatory body may have its own specific requirements for the tests that should be performed, their frequencies and the competence of the specialists involved. Such specific requirements should be established with consultation between the regulatory body and the relevant professional bodies.

4.228. Guidance on the quality control tests for X ray imaging devices used in nuclear medicine is provided in the references listed in para. 3.238.

4.229. In nuclear medicine, there is an additional factor of the radiopharmaceuticals themselves. The programme of quality assurance for

medical exposures should ensure that radiopharmaceuticals intended for administration to patients are prepared in a manner that meets clinical needs and that satisfies both radiation protection and safety and pharmaceutical quality requirements [204, 207, 208]. Therefore, in complex nuclear medicine facilities, radiopharmacists and radiochemists, in conjunction with other health professionals as appropriate, should be involved.

4.230. Paragraph 3.171(e) of GSR Part 3 [3] specifically requires that periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment be part of the programme of quality assurance. This is to ensure that such instrumentation has a current calibration, typically conducted within the last two years (see para. 4.200), and that it is functioning correctly. The programme of quality assurance for medical exposures should establish a frequency for calibration 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 software relating to dosimetry (e.g. software used for calculating specific uptake values from which doses can be estimated).

4.231. 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 those referenced in para. 4.227. Paragraph 3.171(b) of GSR Part 3 [3] requires the implementation of corrective actions if the measured values fall outside established tolerance limits. Such corrective actions are likely to include maintenance or servicing of the equipment, and hence a maintenance programme should be put in place at the nuclear medicine facility. In some cases, the equipment might be outside the tolerance limits by a significant amount and the equipment should be immediately taken out of clinical use and not returned until servicing has taken place and it has been ascertained that the equipment now meets the performance requirements.

4.232. The programme of quality assurance for medical exposures in nuclear medicine should include the use of checks 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 radiological review at the facility (see paras 4.259–4.261). In addition, a review of imaging procedures may have been triggered by a comparison with DRLs (see paras 4.213–4.220).

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

4.234. In line with standard practices for quality management, para. 3.172 of GSR Part 3 [3] requires that "regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks." Such audits may be external audits or internal audits. Internal audits are usually logistically simpler to conduct, while an external audit generally has the advantage of bringing in an outside perspective. The audit of the programme of quality assurance for medical exposures can be incorporated into more comprehensive audits of the management system performed by the licensee. Furthermore, the results of the audit of the programme of quality assurance for medical exposures will be a major input into the radiological review performed at the facility (see paras 4.259–4.261).

Dose constraints: Carers and comforters

4.235. Some diagnostic nuclear medicine procedures, 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 or very elderly or very ill 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, for example in the case of staying with a child during a PET examination. Furthermore, 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 and as such is not subject to dose limits. However, paras 3.153 and 3.173 of GSR Part 3 [3] require that such carers and comforters be afforded radiation protection through the application of the requirements for the 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 para. 3.149(a)(i) of GSR Part 3 [3]. Guidance on setting dose constraints, including considerations for children and pregnant women, is given in paras 2.48 and 2.49.

4.236. Written protocols should be drawn up for implementing measures for the optimization of protection and safety for carers and comforters of patients during or after nuclear medicine procedures. The measures should utilize the basic methods for radiation protection (i.e. time, distance and shielding, and measures to minimize spread of contamination). The protocols 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 achievable;
(c) The values of the dose constraints to be applied (see para. 2.49).

4.237. The licensee should be able to demonstrate that the effective dose to the carer or comforter, by applying the protocols, 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 ensure that dose constraint is not 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.

4.238. Paragraph 3.153 of GSR Part 3 [3] states that:

> "Registrants and licensees shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure."

The carer or comforter should indicate that he or she is still willing to provide support, care and comfort to the patient that is undergoing or has undergone a nuclear medicine procedure. In the case of radiopharmaceutical therapy with iodine, both for patients still in the hospital and for those that have been released (see also para. 4.248), appropriate written instructions should be provided to the

carer or comforter of the patient (including for example, instructions on time spent with the patient and proximity to the patient, minimizing of physical contact and not sharing food or drinks). Further guidance is given in Refs [21, 246].

4.239. 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 paras 3.247–3.251.

Dose constraints: Volunteers in biomedical research

4.240. Some individuals will undergo diagnostic nuclear medicine procedures as part of their voluntary participation in an approved programme of biomedical research (see para. 2.99). Part of the approval process for the biomedical research will have been the setting of dose constraints for the nuclear medicine procedures (see para. 2.100). When the volunteer presents himself or herself at the nuclear medicine facility, he or she is to be afforded the same radiation protection as if he or she were a patient ready to undergo a nuclear medicine procedure, but with the additional restriction that his or her exposure will be subject to a dose constraint, either a nationally established dose constraint or a dose constraint specified by the ethics committee that approved the biomedical research programme (see paras 2.50, 2.99 and 2.100).

Pregnant patients

4.241. Patients who are pregnant form a special subgroup of patients that should be given particular consideration with respect to radiation protection. These considerations are described in para. 4.162(a) with respect to justification and paras 4.189–4.194 with respect to optimization. None of these considerations can take place if it is not known whether the patient is pregnant. Therefore, it is crucial, as is required in paras 3.175 and 3.176 of GSR Part 3 [3], for the nuclear medicine facility to have in place means for ensuring that the pregnancy status of patients is known.

4.242. The first approach is through the posting of clear signs (possibly including a pictorial representation of pregnancy) in languages easily understood by the people using the nuclear medicine facility, posing 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 in waiting rooms and cubicles. The second approach is to ask patients directly whether they are or might be pregnant. This might not always be so easy given social and cultural sensitivities, but it should be done when necessary.

4.243. Neither of the approaches described in para. 4.242 will work if the patient does not know whether she is pregnant. For this reason, para. 3.176 of GSR Part 3 [3] has an additional requirement on facilities to "ensure that there are 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. The referral form should include a 'tick box' for pregnancy status. In case of doubt, a pregnancy test or a determination of hormone levels to assess menopausal status can be carried out.

Breast-feeding patients

4.244. Breast-feeding patients form a special subgroup of patients that should be given particular consideration with respect to radiation protection in nuclear medicine. These considerations have been described in para. 4.162(b) with respect to justification and paras 4.195 and 4.196 with respect to optimization. None of these considerations can take place if it is not known whether the patient is breast-feeding. Therefore, it is crucial, as is required in paras 3.175 and 3.176 of GSR Part 3 [3], for the nuclear medicine facility to have in place means for ensuring that the breast-feeding status of patients is known.

4.245. The first approach is through the posting of clear signs, in languages able to be understood by the people using the nuclear medicine facility, posing the question 'Are you breast-feeding?' and 'If so, please tell the staff'. Such signs should be posted widely in the facility, including in waiting rooms and cubicles. The second approach is to directly ask patients directly whether they are breast-feeding. This might not always be so easy given social and cultural sensitivities, but it should be done when necessary.

Release of patients after radiopharmaceutical therapy

4.246. Paragraph 3.178 of GSR Part 3 [3] requires that a nuclear medicine facility 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 whom the patient may encounter or with whom the patient may 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 Box 1), while exposure of carers and comforters is not subject to dose limits but is instead controlled through dose constraints (see paras 4.235–4.239). Furthermore, as stated 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.

4.247. The medical physicist or RPO at the nuclear medicine facility 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 of estimating 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 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 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 suggest that systematic dose monitoring is not necessary (for detailed guidance on all aspects pertaining to the release of patients, see Refs [21, 246, 247]).

4.248. As indicated in para. 4.247, the patient or the 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. Individuals of particular concern are children and pregnant partners of patients (for detailed guidance, including sample information sheets, see Refs [21, 246, 247]).

Unintended and accidental medical exposures

Prevention of unintended and accidental medical exposures

4.249. Paragraph 3.179 of GSR Part 3 [3] states that:

> "Registrants and licensees…shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical

exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error."

Paragraph 3.180 of GSR Part 3 [3] requires that the registrants and licensees promptly investigate if such exposures occur. General strategies for addressing those problems include the regular maintenance of medical radiological equipment and software, a comprehensive programme of quality assurance, continuing education and training of staff, and the promotion of a safety culture. Lessons identified from events that have occurred should be used for preventing or minimizing unintended and accidental medical exposures, as described in para. 4.251.

4.250. Minimization of the likelihood of unintended or accidental medical exposures in nuclear medicine can be brought about by:

(a) The introduction of safety barriers at identified critical points in the process, with specific quality control checks at these points. Quality control should not be confined to physical tests or checks but can include actions such as double checks of the radiopharmaceutical and activity to be administered, and the 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.
(d) Providing sufficient staff who are educated and trained to the appropriate level, and an effective organization, ensuring reasonable patient throughput.
(e) Continuous professional development and practical training and training in applications for all staff involved in providing nuclear medicine services.
(f) Clear definitions of the roles, responsibilities and functions of staff in the nuclear medicine facility that are understood by all staff.

4.251. Preventive measures should include reporting of incidents and near incidents, analysis and feedback, including lessons from international experience [276]. Preventive measures should also include checking of the robustness of the safety system of the facility against reported incidents (see Ref. [276] for a review of case histories from an extensive collection of accidental medical exposures, including examples relevant to nuclear medicine).

4.252. In addition to the guidance in paras 4.249–4.251, the following three-step strategy (commonly called 'prospective risk management') can help to prevent unintended and accidental medical exposures in nuclear medicine:

(a) Allocation of responsibilities to appropriately qualified health professionals only and ensuring that a management system is in place that includes radiation protection and safety;
(b) Use of the lessons from unintended and accidental medical exposures to test whether the management system, including for radiation protection and safety, is robust enough against these types of event;
(c) Identification of other latent risks by posing the questions 'What else could go wrong?' or 'What other potential hazards might be present?' in a systematic, anticipative manner for all steps in the nuclear medicine process.

Investigation of unintended and accidental medical exposures

4.253. The events that constitute unintended or accidental medical exposures are detailed in para. 3.180 of GSR Part 3 [3], and for a nuclear medicine facility such events include those associated with diagnostic procedures and with radiopharmaceutical therapy. For diagnostic procedures, reference should also be made to paras 3.260–3.264 for aspects relating to X ray imaging. Unintended and accidental medical exposures can occur at any stage in the nuclear medicine process. For radiopharmaceutical therapy, unintended or accidental medical exposures can be either underexposures or overexposures. The events identified in para. 3.180 of GSR Part 3 [3] also include near misses, and these should be considered in the same way as actual events.

4.254. One of the events identified in para. 3.180 of GSR Part 3 [3] is a dose administered in radiopharmaceutical therapy differing substantially from (over or under) the prescribed dose. Consensus recommendations on 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 the specification of deviations greater than 10% as being substantially different. A system with clear procedures should be put in place for identifying when this type of event occurs.

4.255. Paragraph 3.181 of GSR Part 3 [3] establishes what is required during 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's file. When required, counselling of the patient should be undertaken by an individual with appropriate experience and clinical knowledge.

4.256. The investigation of unintended and accidental medical exposures, as required by paras 3.180 and 3.181 of GSR Part 3 [3], has three main purposes. The first is to assess the consequences for the patients affected and to 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 nuclear medicine facility (i.e. the investigation is for the facility's benefit and the 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. The regulatory body and/or the health authorities could disseminate information on significant events reported to them and on the corrective actions taken, so that other facilities might learn from these events. 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, as is the case for image guided interventional procedures and radiation therapy (see paras 3.266 and 5.274, respectively).

4.257. Paragraph 3.181 of GSR Part 3 [3] establishes requirements for the reporting (in writing) of significant events to the regulatory body and, if appropriate, to the relevant health authority. The regulatory body may also specify its own requirements for the reporting of events by registrants and licensees. It is difficult to quantify the term 'significant': specification of a numerical trigger value immediately creates an artificial distinction between values immediately below that value (and hence would not be reported) and those just above the value (which would 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 exposure (in this case the health authority should also be informed), the likelihood of a similar event occurring in other nuclear medicine facilities, a large number of patients having been affected, and gross misconduct or negligence by the responsible health professionals. As stated in para. 4.256, one of the roles of the regulatory body for such a reported event is to disseminate information on the event and any lessons identified to all potentially affected parties, typically other nuclear medicine facilities and relevant professional bodies, but also in some cases manufacturers, suppliers and maintenance companies.

4.258. 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

4.259. Paragraph 3.182 of GSR Part 3 [3] requires that radiological reviews be performed periodically 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, will be a significant input to the process. As described in paras 2.148 and 2.149, the wider clinical audit could include the radiological review with its assessment of the effective application of the requirements for justification and optimization in the facility for the nuclear medicine procedures being performed [49].

4.260. To facilitate compliance with para. 3.182 of GSR Part 3 [3] 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 institutional policies and procedures.

4.261. 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, radiological reviews should consider patient outcome (survival, acute side effects or late side effects), and the effect of introducing new radiopharmaceuticals on efficiency and cost. A system for the ongoing collection of relevant data to support such reviews should be in place at the facility.

Records

4.262. Records should be in place to demonstrate ongoing compliance with radiation protection requirements. Paragraphs 3.183–3.185 of GSR Part 3 [3] establish the requirements for maintaining personnel records, records of calibration, dosimetry and quality assurance, and records of medical exposure. These records are required to be kept for the period specified by the regulatory

body. In the absence of such a requirement, a suggested period for keeping records is ten years. In the case of children, records should be kept for a longer time.

RADIATION PROTECTION OF THE PUBLIC

4.263. Public exposure can arise from the performance of nuclear medicine for persons in and around the nuclear medicine facility and 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. Radiation exposure of carers and comforters while performing that role is considered medical exposure and not public exposure and is not covered here (see paras 4.235–4.239 for guidance on carers and comforters). In addition, there is the possibility, albeit low, of public exposure from exposure pathways associated with the management of radioactive waste.

4.264. The requirements for public protection established in paras 3.117–3.137 of GSR Part 3 [3] apply to nuclear medicine facilities. This subsection contains guidance that is specific to nuclear medicine facilities. More general and comprehensive guidance on radiation protection of the public is given in GSG-8 [24].

Members of the public in the medical facility

4.265. Persons who will be undergoing a nuclear medicine procedure are also considered members of the public during the time when the treatment or diagnostic procedure is not taking place, for example, while they are sitting in the waiting room before being administered radiopharmaceuticals. Similarly for carers and comforters, any exposure incurred other than that arising from the nuclear medicine procedure in which they are involved will be public exposure.

4.266. Members of the public also include visitors, such as persons delivering goods or supplies, sales personnel, accompanying persons and other patients in the facility.

External exposure and contamination

4.267. The primary means for protecting the public from external exposure is the shielding in place at the nuclear medicine facility (see paras 4.32–4.36), which should be sufficient so that public exposure resulting from being in any

immediately adjacent areas, including accessible rooms above and below, is in compliance with the public dose limits, and preferably less than any dose constraint that the regulatory body may have applied (see paras 2.16 and 2.46).

4.268. Patients that have been administered radiopharmaceuticals could expose members of the public in the nuclear medicine facility and upon release (see paras 4.246–4.248). 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 be 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

4.269. Access to areas where radiation is being used should be controlled to ensure doses to visitors are below the dose limits and constraints for the public. This is effective against both external exposure and contamination. Paragraph 3.128 of GSR Part 3 [3] requires that access of visitors to controlled areas or supervised areas be restricted. In exceptional cases, a visitor may be permitted to enter a controlled area, but he or she should be accompanied at all times by a staff member who knows the protection and safety measures for the area. Written procedures should be drawn up specifying when such exceptions can take place and who may accompany the visitor. Particular consideration, in all cases, should be given with respect to women who are or may be pregnant or breast-feeding.

4.270. Controlled areas and supervised areas should be clearly identified to help to 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 authorized persons only.

Members of the public in the wider public domain

4.271. There are usually 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 drinking plenty of fluid and frequently emptying the bladder) and to avoid prolonged contact with sensitive members of the public (young children and pregnant women), if appropriate.

4.272. 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 the 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. 4.248, the patient should be 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. 4.247. Results of the calculations should be recorded. When deciding on the appropriate discharge activity for a particular patient, the licensee and the 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 (for detailed guidance on the release of radiopharmaceutical therapy patients and radiation protection of the public, see Refs [21, 246, 247]).

Death of a patient who has undergone a nuclear medicine procedure

4.273. 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 body, both in the hospital and in the home or other place, but also with respect to autopsy, embalming, burial or cremation. The radiation protection precautions should be determined by the RPO, on the basis of 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 individuals carrying out autopsies or embalming, as contamination and radioactive waste are likely to be generated. The situation for patients injected with bone seeking radiopharmaceuticals such as ^{89}Sr for pain management of skeletal metastases is more of a problem because of the relatively long half-life of this radionuclide (50 days). Storage of the body is impractical. In the case of cremation, depending on the family's intention for the ashes, storage may be needed in order to comply with local regulations (for detailed guidance,

see Refs [21, 246]). Other considerations, such as cultural or ethical concerns, should be taken into account. Regulatory bodies should provide guidance in such situations.

Radioactive waste

4.274. Another potential pathway for public exposure is from radioactive waste; and hence, Requirement 31 and paras 3.131–3.134 of GSR Part 3 [3] require that systems and procedures be put in place to manage radioactive waste and discharges of radioactive material. Detailed guidance on the management of radioactive waste applicable to nuclear medicine facilities is given in IAEA Safety Standards Series No. SSG-45, Predisposal Management of Radioactive Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education [277].

4.275. Most radioactive waste from nuclear medicine is waste containing short lived radionuclides, and it is feasible to consider such waste as non-radioactive waste, either immediately or after some time to allow for decay. A formal mechanism should be put in place, including rigorous control measures, to demonstrate compliance with regulatory requirements in respect of the release from regulatory control of radioactive material that is no longer are considered radioactive waste. Further guidance is given in SSG-45 [277].

4.276. Since waiting for decay until the radioactive material meets the regulatory criteria for clearance or authorized discharge is an essential method in nuclear medicine, a room for the interim storage of radioactive waste should be made 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 the grouping (segregation) of the waste in accordance to the expected time for the decay of the radionuclides (initial activity and physical half-life) and the physical form of the waste. Examples of different physical forms include the following:

(a) Vials that might contain residual radioactivity;
(b) Biological waste that will undergo decomposition;
(c) Infectious waste requiring sterilization;
(d) Broken glassware, syringes and needles requiring collection in separate containers to prevent personnel being injured;
(e) Radionuclide generators, bed linen and clothing from hospital wards (therapeutic applications);
(f) Liquid scintillation solutions.

Containers to allow segregation of different types of radioactive waste should be provided in areas where the waste is generated. The containers should be suitable for their purpose (e.g. in terms of volume, shielding and leaktightness).

4.277. In practice, it is mainly ^{131}I and the waste from radiopharmaceutical therapy patients that require special precautions. Appropriate storage of radioactive material 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 hours. 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 as conventional waste. Technetium generators contain ^{99}Mo with a half-life of 2.75 days; depending on the initial activity of such generators, the time allowed for decay at the nuclear medicine facility should be 1.5–2 months.

4.278. The most commonly used radionuclide in PET is ^{18}F. The short physical half-life of 110 minutes generally allows for discharge of the radioactive material after 24 hours.

4.279. Management of radioactive waste containing longer lived radionuclides should take into account the initial activity and the half-life. The nuclear medicine facility's RPO should give advice in these situations.

4.280. Following the considerations in paras 4.274–4.279, a summary of practical advice for specific situations in nuclear medicine can be given as follows:

(a) Technetium generators: The two options are (i) returning to the supplier after use, ensuring compliance with regulations for the transport of radioactive material (see paras 4.302–4.304) or (ii) waiting for decay. After 1.5–2 months, the generator can be dismantled and the elution column can be removed, as the material is considered non-radioactive. The generator column should be check for long half-life radionuclide contaminants before disposal. Labels should then be removed.
(b) Used syringes and needles: These can be collected in a shielded container in the rooms used for the preparation and injection of radiopharmaceuticals. When the container is full, it should be sealed and the expected date of release from regulatory control should be marked on it. After this time, the external dose rate can be monitored. The container can be released from regulatory control when the external ambient dose equivalent rate is the same as the background or in line with national or local regulations.

(c) Vials containing residues of ^{99m}Tc, ^{67}Ga, ^{111}In, ^{123}I, ^{131}I, ^{32}P, ^{89}Sr and ^{201}Tl: A similar procedure should be established as for the syringes, but segregation should be based on the physical half-life of the radionuclide. Caution should be exercised in storing waste containing very low levels of longer lived residues such as ^{68}Ge (half-life 271 days), as such residues could accumulate over time to activities at which they need to 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 the preparation and injection of radiopharmaceuticals. When a bag is filled, it should be sealed. After waiting for decay or with appropriate monitoring, these can be released from regulatory control and treated as ordinary, non-radioactive waste.

(e) Sealed sources for calibration: These sources used for calibrating activity meters, for the quality control of gamma cameras and counters, and for the anatomical marking of images should be released from regulatory control as determined by the RPO and in accordance with national regulations and authorization by the regulatory body (clearance).

(f) Carbon and hydrogen isotopes: Small activities of ^{14}C and ^{3}H 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 biohazard precautions need to be taken.

(g) Patients' excreta, such as urine containing ^{131}I: For diagnostic patients, there is no need for the collection of excreta and ordinary toilets can be used. For therapy patients, policies vary for different States, but in principle the approaches used follow the dilution or decay methodologies (e.g. either by collecting and storing excreta or by designing facilities with drainpipes terminating in a delay tank). In most situations, it is better to dilute and disperse the waste activity in a continuous sewerage system, rather than to concentrate and store excreta for decay. Some precautions may be required where sewerage systems allow rapid processing of effluent with subsequent mixing with river water or usage for irrigation of land used for growing vegetables (see also Refs [21, 246, 278]).

(h) Waste management at home following the release of patient after radionuclide therapy: Patient should be advised to flush the toilet after use, avoid splashing and clean the toilet after use. The shower and bathtub should be rinsed well after use. Contaminated fabrics such as, clothing and bedding, should be laundered separately (see also Refs [21, 246, 247]).

Monitoring and reporting

4.281. Requirement 32 and para. 3.137 of GSR Part 3 [3] establish the requirements to be met by the nuclear medicine facility with respect to monitoring and reporting. At the nuclear medicine facility, procedures are to be in place to ensure that:

(a) The requirements for public exposure are satisfied and such exposure is assessed;
(b) The requirements for discharge of radioactive materials to the environment are satisfied;
(c) Appropriate records of the results of the monitoring programmes are kept.

4.282. The programme for monitoring public exposure arising from nuclear medicine should include dose assessment in the areas in and surrounding the nuclear medicine facility that are accessible to the public. Doses can be derived from the shielding calculations in the planning stage, combined with the results from area monitoring and contamination monitoring at the initial operation of the facility and periodically thereafter. Records of dose assessments should be kept for a period that meets any relevant regulatory requirements. In the absence of such requirements, a suggested period for keeping records is seven to ten years.

PREVENTION AND MITIGATION OF ACCIDENTS

Safety assessments of potential exposure

4.283. To comply with the requirements for safety assessments established in paras 3.29–3.36 of GSR Part 3 [3], the registrant or licensee is required to conduct a safety assessment applied to all stages of the design and operation of the nuclear medicine facility. Furthermore, para. 3.29 of GSR Part 3 [3] states that: “the responsible person or organization shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body.” Paragraphs 2.150–2.154 describe general considerations for facilities using ionizing radiation for medical purposes.

4.284. The safety assessment of potential exposure should be systematic, should identify unintended events that can lead to potential exposure, and should consider their likelihood and potential consequences (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 should also aim at anticipating other events that have not previously been reported. Clearly, the safety assessment should be documented.

4.285. The safety assessment should be revised when:

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

4.286. Safety assessments in nuclear medicine should include consideration of all the steps in the use of radiopharmaceuticals for diagnosis and treatment in the nuclear medicine facility. The steps include the following:

(a) Ordering, transport and receipt of radiopharmaceuticals, including unpacking and storage;
(b) Preparation and administration of radiopharmaceuticals to patients;
(c) Examination, treatment and care of therapy patients receiving large amounts of radioactive material;
(d) Storage and handling of radioactive waste.

Prevention of accidents

4.287. Accident prevention is clearly the best means for avoiding potential exposure, and paras 3.39–3.42 of GSR Part 3 [3] establish the requirements for 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 4.8–4.55.

4.288. Registrants and licensees should incorporate:

(a) Defence in depth measures to cope with events identified in the safety assessment, 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 restricted access with camera surveillance and is routinely patrolled.

(b) Operational experience and lessons from accidents and errors. This information should be incorporated into the training, maintenance and quality assurance programmes.

4.289. Means for preventing or minimizing unintended and accidental medical exposures in nuclear medicine are described in paras 4.249–4.252, and the ensuing investigation and corrective actions are described in paras 4.253–4.258.

Mitigation of the consequences of accidents

4.290. Paragraph 1.20 of GSR Part 3 [3] states that:

> "If an event or a sequence of events that has been considered in the assessment of potential exposure does actually occur, it may be treated either as a planned exposure situation or, if an emergency has been declared, as an emergency exposure situation."

On the basis of events identified in the safety assessment for the nuclear medicine facility, mitigatory procedures should be prepared for events associated with potential exposure, including the 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 mitigatory measures.

4.291. Paragraph 3.43 of GSR Part 3 [3] states that:

> "If the safety assessment indicates that there is a reasonable likelihood of an emergency affecting either workers or members of the public, the registrant or licensee shall prepare an emergency plan for the protection of people and the environment."

Emergency arrangements and procedures commensurate with the hazard and the potential consequences are required to be established, as appropriate, in accordance with GSR Part 7 [7], GSG-2 [8] and GS-G-2.1 [9].

4.292. Mitigatory procedures in a nuclear medicine facility should cover, but not be limited to, the following:

(a) Accidents, including those of low probability, and actions to deal with them;
(b) Persons responsible for taking actions in the event of an accident, with full contact details;

(c) Responsibilities of individual personnel in implementing mitigatory procedures and emergency procedures (e.g. nuclear medicine physicians, medical physicists, nuclear medicine technologists and the RPO);
(d) Equipment and tools necessary for carrying out the mitigatory procedures and emergency procedures;
(e) Training and periodic exercises;
(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 the spread of contamination, including leakage from fume hoods and room ventilation systems.

4.293. Kits should be kept readily available for implementing mitigatory procedures and emergency procedures. These should 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, together with tape, labels and pencils.

4.294. The exposure of workers involved in such nuclear medicine events or in emergency response should be kept below the dose limits for occupational exposure in planned exposure situations. However, if it is justified that these dose limits are exceeded, emergency workers should be protected in accordance with the requirements and guidance for emergency exposure situations contained in section 4 of GSR Part 3 [3], and GSR Part 7 [7] and GSG-7 [23].

Lost sources

4.295. An up to date inventory should be maintained (see para. 4.56) 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 in the case that sources are ordered and not received at the expected time. Confirming that a source has arrived at

the expected time should be part of the procedures. The actions to be part of the emergency plans and procedures in this case should include the following:

(a) Obtain assistance from the RPO when necessary;
(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 supplier and inform them of the loss so that they can trace the shipment;
(e) If the source is not found, notify the relevant authorities of the loss, consistently with GSR Part 7 [7] and GS-G-2.1 [9].

Damage to radionuclide generators

4.296. Radionuclide generators, such as generators for ^{68}Ga, ^{82}Rb and ^{99m}Tc, contain a relatively large amount of activity. In the event of a radionuclide generator being damaged, the measures to be taken should include the following:

(a) Evacuate the area immediately and implement 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 report to the relevant authorities.

Spillage of small amounts of radioactive material

4.297. After a spillage of a small amount of radioactive material, for example low volumes of non-toxic radiopharmaceuticals that can easily be removed, such as up to 10 MBq of ^{18}F or ^{99m}Tc, the following actions should be taken:

(a) Use protective clothing and disposable gloves.
(b) Quickly blot the spill with an absorbent pad to prevent it spreading.
(c) Remove the pad from the spill and dispose of it.
(d) Wipe with a tissue or paper towel from the edge of the contaminated area towards the centre.
(e) Monitor the paper towel 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, and try to keep the volume of contaminated waste as small as possible. In some cases, such as with short

lived radionuclides, it can be simpler to quarantine the area for a sufficient time to allow for decay, for example 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 and paper towels should be readily available.
(h) If the decontamination process is not successful, contact the RPO.
(i) Monitor all people involved in the spill for contamination when leaving the room; in particular, monitor shoes if the spill is on the floor.

Spillage of large amounts of radioactive material

4.298. After a spillage of a large amount of radioactive material, for example if a patient undergoing ^{131}I 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) Evacuate people not involved in the spill from the area immediately.
(c) Inform the RPO immediately and conduct clean-up under his or her direct supervision.
(d) Monitor all people involved in the spill for contamination when leaving the room.
(e) If necessary, perform a thyroid bioassay of all people involved.
(f) If clothing is contaminated, remove it and place it in a plastic bag labelled 'RADIOACTIVE'.
(g) If contamination of the skin occurs, wash the area immediately.
(h) If contamination of the eye occurs, flush with large quantities of water.
(i) When the contamination is contained, the procedures outlined for cleaning small spills may be followed, with particular care that the contaminated waste bags are appropriately labelled and stored.
(j) Restrict the entry to the contaminated area until decontamination has been completed and the area has been released by the RPO.

Medical emergencies involving patients who have received therapeutic radiopharmaceuticals

4.299. 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 ^{131}I) 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 (see GSR Part 3 [3] and GSR Part 7 [7]). Measures should be used to minimize such doses. All members of the medical team should wear impermeable protective gloves. Medical staff should be informed and trained on how to deal with such patients. Exercises of the procedures should be held periodically.

Need for urgent patient attention, including surgery

4.300. 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 necessary if the surgical procedure is lengthy;
(e) Determine the doses of the people involved in the procedure.

Fires, earthquakes and other disasters affecting the nuclear medicine facility

4.301. The normal facility drill should be observed, providing for safe evacuation of patients, visitors and staff. When first responders (e.g. 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 (see para. 2.154). Requirements and guidance for the arrangements to deal with such emergencies can be found in GSR Part 7 [7] and GS-G-2.1 [9].

SAFETY IN THE TRANSPORT OF RADIOACTIVE MATERIAL

4.302. Paragraph 2.25 of GSR Part 3 [3] establishes the requirements for the transport of radioactive material, invoking in particular IAEA Safety Standards Series No. SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material, 2018 Edition [279]. SSR-6 (Rev. 1) [279] uses 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.

4.303. The licensee of a nuclear medicine facility may be both a consignee and a consignor, and hence may have responsibilities for both the receipt and the shipment of radioactive material. Receipt of radioactive material will be a regular occurrence for all nuclear medicine facilities. Shipments may take place if the facility has a cyclotron or laboratory that sends radiopharmaceuticals to other sites, or when expired radiation generators, old sealed calibration sources or radioactive liquids (e.g. ^{14}C solutions) need to be returned to the supplier or disposed of off the site, as applicable.

4.304. 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 established in SSR-6 (Rev. 1) [279]. Emergency arrangements for the transport of radioactive material should be put in place, in line with the requirements of GSR Part 7 [7] and the guidelines of the regulatory body. The licensee and the RPO of the nuclear medicine facility should be familiar with these regulations to ensure that the transport of radioactive material for which they are responsible complies with the regulations.

5. SPECIFIC RECOMMENDATIONS FOR RADIATION PROTECTION AND SAFETY IN RADIATION THERAPY

GENERAL

5.1. This section 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 cancer 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, also known as teletherapy, is performed with photon, electron and hadron beams. Photon beams (gamma rays) are produced by radioactive sources such as ^{60}Co. High energy (megavoltage, MV) photon and electron beams are produced by linear accelerators (linacs). Low and medium energy X rays are produced by kilovoltage (kV) units. For protons and ion beams, cyclotrons or synchrotons are used. External beam radiation therapy can be delivered using a wide range of techniques, including: 2-D conventional radiotherapy, 3-D conformal radiotherapy, 4-D radiotherapy (motion management), intensity modulated radiation therapy (IMRT), stereotactic radiosurgery (SRS), stereotactic radiotherapy (SRT), stereotactic body radiotherapy (SBRT), volumetric modulated arc therapy (VMAT), robotic radiotherapy and intraoperative radiotherapy (IORT).

5.3. Verification of patient positioning and target localization can be performed with film–screen cassettes or CR cassettes, and with treatment beam (MV) portal images using an electronic portal imaging device (EPID). EPIDs can also monitor doses on-line [280]. Other in-room IGRT devices that use ionizing radiation are low energy X ray sources (kV) that can produce DR, MVCT, MV-CBCT and kV-CBCT. Non-ionizing devices used for IGRT are MRI units, radiofrequency transponders, ultrasound or hybrid systems and optical surface tracking devices. All these IGRT devices are either gantry mounted or room mounted.

5.4. Brachytherapy can be performed by placing radioactive sources or electronic brachytherapy devices directly into or on the patient. A brachytherapy implant can be temporary or permanent. Afterloading devices allow the sources to be placed into catheters that have been already inserted in the body. In some instances, the sources may be introduced manually. Techniques can be interstitial, intracavitary, surface or intraluminal, 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.

5.5. The generic term ‘medical radiation facility’ is used widely in Section 2 to mean any medical facility where radiological procedures are performed. In Section 5, the narrower term ‘radiation therapy facility’ is used to cover any medical radiation facility where radiation therapy is performed. A radiation therapy facility may be a radiation therapy department inside a larger hospital or medical centre, or it may be a stand alone facility.

5.6. The defined term radiological procedure is used in GSR Part 3 [3] to cover all imaging and therapeutic procedures using ionizing radiation. In a radiation therapy facility, both imaging and therapeutic radiological procedures occur, and

this needs to be borne in mind when reading the 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.

5.7. Different health professionals can take on the role of the radiological medical practitioner (see para. 2.90) in radiation therapy, depending, inter alia, on national laws and regulations. Typically, this will be a radiation oncologist, but it may also include other specialists, for example neurosurgeons in the case of SRS.

5.8. As stated in para. 2.92, the term 'medical radiation technologist' is used in GSR Part 3 [3] and this Safety Guide as a generic term for the health professional known by several different terms in different States; such terms include radiographer, radiological technologist and others. Clearly, each State will use its own term in its own jurisdiction.

5.9. 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 guidance is relevant to radiation therapy, and reference to Section 2 should be made as necessary.

SAFETY OF MEDICAL RADIATION FACILITIES AND MEDICAL RADIOLOGICAL EQUIPMENT

Radiation therapy facilities

Location and site

5.10. A radiation therapy facility should be located on a site that gives ready access for inpatients 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, the need for replacement of units with higher energy units and future increases in 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 exposure 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 the location and site of radiation therapy facilities is given in Refs [281–284].

5.11. In addition to considerations of the site, the surrounding environment should also be considered. This includes the 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 protection of the public outside the radiation therapy facility, and above and below the radiation therapy facility if these areas are occupied, is consistent with radiation protection requirements.

5.12. When considering expansion of an existing radiation therapy facility, consideration should be given to the areas beside, above and below the proposed expansion site.

5.13. 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

5.14. A typical radiation therapy facility consists of six main functional areas: reception area, clinical consulting areas, and areas for external beam radiation therapy, brachytherapy, imaging and treatment planning. Within these areas there are several types of room and, depending on the treatment modalities being provided, the facility 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. Provision for the incorporation of radiation protection and safety features into these areas and rooms should be made at the facility design stage. Because the structural shielding of radiotherapy facilities is very heavy, care should be taken that the weight of the shielding 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 ^{60}Co unit being replaced by a linac. 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, within other departments of the facility. Wherever possible, treatment rooms should be surrounded with rooms that have low or controlled occupancy. Physical signage should give information on where different areas are located and should designate hazardous areas; such signs should be preferably in both word and picture format. Colour coding of different areas is also very helpful. General guidance on the design of a radiation therapy facility is given in Refs [281–284].

5.15. The three factors relevant to dose reduction for workers and the public (time, distance and shielding) should be combined in the design to optimize occupational exposure and public exposure.

5.16. 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.

5.17. As a general rule, the design of the radiation therapy facility should make provision for safety systems or devices associated with the equipment and rooms. This includes ventilation systems, electrical wiring relating to emergency off switches, and standby lighting, safety interlocks and warning signs and signals.

5.18. A reliable and stable power supply should be available for all modern equipment and IT systems. An emergency diesel power generator alone is generally not sufficiently stable to power a linac or orthovoltage unit and should not be used in this way. An uninterruptible power supply or battery backup systems should be installed to capture the active information at the time of the outage and to shut down all software in a controlled manner. Servers should be programmed to shut down automatically when the power supply is interrupted. Diesel power generators could be used to run systems that are controlled only by timers, such as in the case of ^{60}Co teletherapy units.

5.19. The design of the facility should include an air conditioning system sufficient to maintain the temperature and humidity in the treatment room within the parameters defined by the equipment manufacturers. In addition, a ventilation system with four to six air changes per hour is recommended to remove any ozone generated [285].

5.20. For external beam radiation therapy, lights in the treatment room 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 the lasers off independently for quality control tests.

5.21. In addition to interlocks, as described in para. 5.31, signs and warning lights should be placed at the entrances of controlled areas to prevent inadvertent entry (see also paras 5.290 and 5.291 on control of access). For controlled areas, para. 3.90(c) of GSR Part 3 [3] requires the use of the basic ionizing radiation symbol recommended by ISO [56]. An illuminated warning sign should be displayed at the entrance to the maze or treatment room, and several signs should be displayed 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, stage two will light when the treatment unit is programmed to deliver a radiation beam and stage three will illuminate when the beam or the source is on. Another possibility is that the warning lights flash when the beam is on. Other rooms that are also controlled areas, such as imaging, simulator and source storage rooms, should also have appropriate signs and warning lights.

5.22. 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 after working hours. 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 entrance maze (see para. 5.30) and/or the treatment room, or a door interlock. If these devices indicate the possible 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. [282] (see also para. 5.88).

5.23. 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 given in Ref. [283].

Design of rooms within the radiation therapy facility: Treatment rooms for high energy external beam radiation therapy and HDR afterloading brachytherapy

5.24. External beam radiation therapy and HDR/PDR brachytherapy should be carried out within the radiation therapy facility in treatment rooms designed for that purpose.

5.25. A shielded treatment room should not be shared between HDR/PDR brachytherapy and external beam radiation therapy, as this can negatively influence procedure flow and efficiency. Further guidance is given in Ref. [281].

5.26. The size of the treatment room will depend on many factors, including the treatment equipment and the in-room imaging equipment and the intended techniques of the various treatments to be carried out. 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 may 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 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 patient positioning and immobilization devices, and ease of patient positioning and staff movement during the set-up procedures may be better facilitated in a larger room. Careful placement of accessory equipment within the room can help to minimize the walking distance for each patient set-up. Further guidance is given in Refs [281–283].

5.27. 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 introducing IMRT, changing from ^{60}Co to linac or installing a non-isocentric unit, for instance.

5.28. 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 protection and safety.

5.29. The treatment and imaging room designs should include an open access conduit for the control panel, and monitoring and dosimetry equipment cables. No duct should run orthogonally through a radiation barrier; it could either run

at an angle through the barrier or have one or more bends in it so that the total length of the duct is greater than the thickness of the radiation barrier [282].

5.30. Entrance to the treatment room may be through a shielded door or 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 space. More guidance on mazes and entrances is given in Refs [282, 283, 285].

5.31. 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 other than the patient is inside the room and that the patient set-up 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. 5.71).

5.32. The design should be such that access to the treatment (and imaging) rooms should be visible to the operators at all times. Furthermore, the controls should be installed in such a way that access to the treatment room can be monitored at all times.

5.33. A safety system, such as a 'last person out button', should be in place to ensure that all staff have left the room prior to the commencement of treatment.

5.34. 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. These switches should be positioned to avoid having to cross the primary beam when activating them and to avoid any accidental actuation.

5.35. Adequate systems, audiovisual 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.

5.36. When using sealed sources, a powered fail-safe area radiation monitor (audiovisual) should be visible upon entering the room.

5.37. 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 that manual operation of heavy doors should be possible.

5.38. Enclosed patient changing cubicles should not be located within the treatment room.

Design of rooms within the radiation therapy facility: Storage and preparation rooms for manual and LDR brachytherapy

5.39. Typical radiation protection and safety features for rooms used for the storage and preparation of sealed radioactive sources for manual and LDR brachytherapy include the following:

(a) The room should be provided with a lockable door to control access and to maintain source security (see also paras 5.13 and 5.88).
(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 any exposure of personnel during the handling and transfer of sources.
(c) The safe should have compartments for sources of different 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 work surface for source preparation should be smooth and seamless to avoid losing small sources such as ^{192}Ir wire fragments or small ^{125}I seeds.
(g) 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.

(h) 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.
(i) 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 provided either by an area radiation monitor that is visible on entering the room and during any handling of the unshielded sources, or by a survey meter that is 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.
(l) Space should be available for trolleys for transporting sources.

Design of rooms within the radiation therapy facility: Patient rooms for manual and LDR brachytherapy

5.40. 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, movable shielding for the nurses and potential visitors should be provided whenever possible (see also para. 5.150).

5.41. The treatment room should contain a shielded storage container, large enough to accept the applicators if necessary, and a remote handling tool (forceps) for use in the event of a dislodged source.

5.42. An area radiation 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.

5.43. For remote afterloading LDR units, the door to the room where the treatment is given should be interlocked with the LDR system whenever possible.

Design of rooms within the radiation therapy facility: Imaging and other non-treatment rooms

5.44. Patient preparation and imaging areas where radiation is used, such as simulator rooms (CT, PET–CT and conventional simulators), together with their console areas and patient changing areas, should be designed to ensure that the requirements for occupational protection and protection of the public are met. Details are given in paras 3.9–3.16 and 4.8–4.28, and further guidance is given in Refs [281, 283].

Design of rooms within the radiation therapy facility: Shielding considerations

5.45. Radiation therapy facilities typically require significant shielding, especially for the treatment rooms, to ensure that the requirements for occupational radiation protection and radiation protection of the public are met. The nominal design dose in occupied areas is derived by the process of constrained optimization (i.e. selection of 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. Paragraphs 5.46–5.53 highlight some considerations with respect to shielding design. Methodologies and data for shielding calculations for treatment rooms are presented in Refs [282, 286, 287].

5.46. Care should be taken to avoid multiplication of conservative assumptions, which can lead to unrealistic overestimates of the shielding required. Typical conservative assumptions are: 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 room. Therefore, a balanced decision should be achieved and accumulation of overly conservative measures that may go beyond optimization should be avoided.

5.47. 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.

5.48. The design and specification for the radiation shielding should be performed by a medical physicist or a qualified expert in radiation protection to ensure that the required level of occupational and public radiation protection is achieved. The medical physicist or qualified expert in radiation protection 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 qualified expert in radiation protection should be provided with all relevant information with regard to the proposed medical radiological equipment and its use, the type of building construction, and the occupancy of nearby areas. The shielding assumptions and specifications should be documented, and signed off by the medical physicist or qualified expert in radiation protection and all documentation, including calculations, should be archived for the lifetime of the facility. Depending on the 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.

5.49. The shielding of the radiation treatment room should be constructed so that its integrity 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.

5.50. The door to the treatment room and the design of the maze for high energy machines requires special consideration to ensure adequate radiation protection without sacrificing operational efficiency.

5.51. The medical physicist or qualified expert in radiation protection should undertake site visits during construction to ensure that there has been, from the radiation protection and 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 either that the ducting does not go through the primary shielding or that it is not aligned with the primary beam. It is also advisable to check that the concrete density is adequate.

5.52. A final assessment of the adequacy of the shielding should be performed by the medical physicist or qualified expert in radiation protection after construction and installation of the equipment has been completed prior to clinical use. This may be achieved through a comprehensive radiation survey.

5.53. Shielding considerations for imaging and simulator rooms, depending on the modalities used, are given in paras 3.18–3.24 and 4.32–4.36.

Medical radiological equipment, software and ancillary equipment

5.54. This subsection 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 radiotherapy includes superficial units (including units using Grenz rays or Bucky rays), orthovoltage units, gamma ray teletherapy units, linacs, and proton or heavy ion accelerators. While the radiological equipment used for external beam radiotherapy falls into two main categories — linac based and ^{60}Co based equipment — the techniques used and therefore how the equipment is constructed, its features and configurations vary enormously depending on whether treatment is via conventional external beam radiotherapy, SRS, SBRT, 3-D conformal radiation therapy, IMRT, VMAT or other techniques. There are generally three linac configurations: C-arm units (gantry based), ring based or robotic arm based. Some external beam radiotherapy units incorporate imaging systems, such as radiography, fluoroscopy, CT, kV-CBCT, MV-CBCT or MRI, and can perform IGRT. Brachytherapy may be manual or remote and is classified into 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 [288, 289]. Radiation therapy with unsealed sources is covered in Section 4.

5.55. The requirements for medical radiological equipment and its software are established in paras 3.49 and 3.162 of GSR Part 3 [3]. The IEC has published international standards applicable to medical radiological equipment used in radiation therapy. Current IEC standards relevant to radiation therapy include Refs [285, 290–306] (for those relevant to the X ray based imaging systems used in radiation therapy, see para. 3.28; and for those relevant to radiopharmaceutical based imaging used in radiation therapy, see para. 4.41). It is recommended that the IEC web site be visited to view the most up to date list of standards. ISO publishes international standards applicable to medical radiological equipment used in radiation therapy. Current ISO standards relevant to radiation therapy include Refs [307–309]. It is recommended that the ISO web site be visited to view the most up to date list of standards.

5.56. Guidance on X ray based medical radiological equipment used for imaging as part of pre-treatment simulation, IGRT or for follow-up assessment, as described in paras 5.3 and 5.54, is given in paras 3.27–3.41.

5.57. 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 or equivalent national standards. In some States, there may be an agency with responsibilities for medical devices or a 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.

5.58. Displays, gauges and instructions on operating consoles of medical radiological equipment, and accompanying instruction and safety manuals, might be used by staff who do 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 or into a language acceptable to the local staff. The software, either used in conjunction with medical radiological equipment or as part of treatment planning (see also para. 5.78), 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 should be subject to a quality assurance process to ensure proper understanding and to avoid operating errors. The same should apply to maintenance and service manuals and instructions for maintenance and service engineers and technicians who do not have an adequate understanding of the original language (see also paras 2.104 and 2.137).

5.59. 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 (e.g. medical radiological practitioner, medical radiation technologist, biomedical engineer and IT specialist) and the radiation therapy facility's radiation protection committee and quality assurance committee.

5.60. 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 criteria for remedial action and suspension from service are given in Ref. [184]. A strategy or transition period for replacement based on social and economic factors is helpful (see also paras 5.228–5.247 on programmes of quality assurance for medical exposure).

Design features for medical radiological equipment: General considerations

5.61. 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 meeting the requirements of paras 3.163 and 3.164 of GSR Part 3 [3] for operational optimization of patient protection. Many design features contribute to the performance of medical radiological equipment and should be considered when purchasing such equipment (see paras 5.62–5.81). Further details on design features and performance standards of medical radiological equipment used in radiation therapy are given in Refs [290–296, 298–305] (see also paras 5.228–5.247 on quality assurance and acceptance testing, in particular para. 5.240).

5.62. Medical radiological equipment should include provisions for selection, reliable indication and confirmation (when appropriate and to the extent feasible) of operating 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.

5.63. As noted in para. 5.55, radioactive sources for teletherapy and brachytherapy should meet relevant international standards [307–309].

5.64. 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. The equipment design should include the ability to override the software control, but only by appropriate persons who have been authorized by the radiation therapy facility's licensee. When dynamic treatments are interrupted owing to their being outside defined tolerances, there should be a system or method available to resume and complete the treatment.

5.65. 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.

5.66. Medical radiological equipment used in 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.

5.67. External beam radiotherapy equipment containing radioactive sources and remotely controlled afterloading brachytherapy (HDR/PDR/LDR) 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 using radioactive sources, it should be possible to close the shielding door on the unit manually.

5.68. 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.

5.69. Record and verify systems (RVSs) and their related interfaces with imaging systems, treatment planning systems (TPSs), treatment delivery systems, and image and administrative data storage systems (e.g. operational information systems, PACS and RIS) 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, and should allow 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 should be supervised, by the medical physicist. The system should be subject to periodic quality control because, if these parameters are incorrectly introduced into the RVS, systematic treatment errors will occur. Detailed guidance on RVSs is given in Refs [305, 310].

5.70. The transfer and integrity of data, including patient information, should be maintained throughout the radiation therapy facility's network. Thus, the IT specialist should be familiar with the radiation therapy process and should work in close cooperation with the radiological oncology team (radiological medical practitioner, medical radiation technologist and medical physicist).

Design features for medical radiological equipment: External beam radiotherapy

5.71. Medical radiological equipment used for external beam radiotherapy should meet the specifications given in relevant IEC standards [290–293, 298, 299, 302, 304] and should follow the guidance on design specifications and

performance provided in Refs [281, 311–313], as appropriate. In addition to the recommendations given in paras 5.61–5.70, 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) The design of equipment 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. 5.21).
(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 non-uniformity should be stated by the supplier. The non-uniformity of flattening filter free beams should also be specified by the supplier.
(e) The design of the unit should be such that dose rates outside the treatment area due to radiation leakage or scattering are 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.

5.72. When designing accelerators producing high energy X ray beams (>10 MV), manufacturers should minimize potential hazards from neutron activation of patients and materials in the treatment room (induced radioactivity secondary to radiotherapy) [314].

Design features for medical radiological equipment: Brachytherapy

5.73. Medical radiological equipment used for brachytherapy should meet the specifications given in Ref. [294] and should follow the guidance in Refs [281, 315], as appropriate.

5.74. LDR, PDR and HDR sources should be accompanied by a source certificate specifying:

(a) The source strength in terms of reference air kerma rate in air or equivalent quantity as recommended by the ICRU [316], at a specified distance, for a specified date (see also para. 5.208(b));
(b) The quality control tests applied to the source including leakage and contamination tests.

5.75. Applicators for brachytherapy should be manufactured specifically for the source to be used or should 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.

5.76. Where manual brachytherapy sources incorporating ^{226}Ra or encapsulated ^{137}Cs 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 or applicator rupture due to radiation damage. When not in use, all brachytherapy sources should be stored safely and securely.

5.77. Sources using beta emitters, such as ^{90}Sr and ^{106}Ru 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 for treatment planning systems

5.78. The capabilities of TPSs have evolved in parallel with advances in computers and computing. Depending on the TPS, these capabilities may include complex 3-D or 4-D image manipulation and dose calculations. The design features for the TPS should meet the clinical goals of the radiation therapy facility. TPSs should meet the standards given in Ref. [304], and should follow the guidance on TPSs, including specifications and performance, given in Refs [281, 317–319].

Design features for simulators and imaging equipment

5.79. 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 conventional simulators are used, these should meet the specifications given in

IEC standards [295, 296, 300, 301] and should follow the recommendations of Refs [281, 320, 321]. CT scanners used as virtual simulators should be designed so that patients can be simulated in the treatment position; this should include the positioning lasers, which should be consistent with those of the treatment room. As noted in para. 5.56, 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 paras 3.27–3.41 and 4.45–4.51 (see also paras 5.3, 5.26 and 5.207).

5.80. Guidance applicable to C-arm imaging devices used in brachytherapy is given in paras 3.38 and 3.39.

5.81. Guidance applicable to PET–CT scanners used for radiotherapy planning and follow-up, as well as for range assessment in proton facilities, is given in para. 4.49.

Ancillary equipment

5.82. The radiation therapy facility should have equipment, instruments and test objects for reference and relative dosimetry appropriate for the type of measurement necessary for beam characterization and quality control. This may include ionization chambers (thimble, plane-parallel and well-type ionization chambers), solid-state detectors, detectors for small field dosimetry, electrometers, thermometers, barometers, phantoms, and geometry and mechanical test tools. Further guidance on appropriate equipment, instruments and test objects is given in Refs [281, 297, 306, 313, 322, 323].

5.83. Immobilization devices are now more commonly prepared in the simulation area, and multileaf collimators remove the need for shielding blocks in most cases. For radiation therapy facilities without multileaf collimators, a mould room (also known as a patient preparation area or workshop) should be available that is equipped to prepare beam modifiers, positioning aids and immobilization devices (e.g. blocks, compensators and bolus). 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.

5.84. In addition to laser positioning beams, the radiation therapy facility may need to have other positioning devices, including surface optical scanners, radio frequency systems, body GPS transmitters and ultrasound units.

5.85. For manual brachytherapy, the radiation therapy facility should be equipped with radiation protection and safety equipment, including a radiation detector such as a Geiger–Müller counter, source handling equipment including a magnifying glass, source manipulators (such as forceps, tweezers or tongs), clippers or wire cutters, and several shielded containers.

5.86. For remote 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, wire cutters and a suitable radiation monitoring instrument for source localization.

5.87. The radiation therapy facility should be equipped with radiation monitoring instruments (area monitors and portable survey meters) based on Geiger–Müller detectors, ionization chambers and/or scintillators. For accelerators producing high energy X ray beams (>10 MV), access to a neutron monitoring instrument is recommended.

Security of sources

5.88. 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 of para. 3.53 of GSR Part 3 [3]. Further details on the security of sealed sources can be found in Ref. [232]. In a radiation therapy facility, the sources include sealed sources used in teletherapy and brachytherapy, and sealed sources used for calibration or quality control tests. Situations that are particularly critical with respect to security of sources in a radiation therapy facility include receipt of sources, storage of sources and movement of sources within the facility. The licensee of the radiation therapy facility should develop procedures to ensure the safe receipt and movement of radioactive sources within the institution and should establish controls to prevent the theft, loss and unauthorized withdrawal of radioactive materials or the entrance of unauthorized personnel to controlled areas. An inventory of sources should be maintained, and procedures should be put in place to check and confirm that the sources are in their assigned locations and are secure.

Maintenance

5.89. Paragraphs 3.15(i) and 3.41 of GSR Part 3 [3] establish 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 before initial operation and on an ongoing basis. This can be achieved through a maintenance contract (preventive maintenance and corrective maintenance) with the manufacturer, or by in-house staff or third party contractor only if appropriately trained and authorized (see also para. 2.114).

5.90. Maintenance includes not just maintenance of the medical radiological equipment and its hardware, but also of software, networks, data bases and other supporting systems in the radiation therapy facility (e.g. HIS, PACS and RIS).

5.91. In addition to the guidance in paras 2.112 and 2.113, 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, following breakdown or exchange of sources includes the following:

(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 repairs 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, para. 3.167(b) of GSR Part 3 [3] requires that a radiation therapy medical physicist perform specific tests or measurements to determine that the equipment is operating satisfactorily before it is used to treat patients.

5.92. The electrical safety and mechanical safety aspects of the medical radiological equipment are an important part of the maintenance programme, as these can have direct or indirect effects on radiation protection and safety. This work should be performed by appropriately authorized persons who understand the specifications of the medical radiological equipment (see also paras 2.112–2.114). Electrical and mechanical maintenance should be included in the programme of quality assurance and should be performed, preferably by the manufacturer of the medical radiological equipment or an authorized agent, at a frequency recommended by the manufacturer. Servicing should include a written report describing the findings. These reports and follow-up corrective actions should be archived as part of the programme of quality assurance.

5.93. In radiation therapy radiological procedures, as described in paras 5.1–5.8, occupationally exposed individuals are usually medical radiation technologists, radiological medical practitioners (typically radiation oncologists) and medical physicists. In some radiation therapy facilities, other health professionals, such as nurses, may also be considered occupationally exposed.

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

5.95. Other radiation therapy facility workers such as social workers, dieticians, physiotherapists, patient porters, orderlies, assistants, cleaning and other service support personnel, and workers in the wider medical facility where the nuclear medicine facility is located, for whom radiation sources are not required by, or directly related to, their work, are required to have the same level of protection as members of the public, as established in para. 3.78 of GSR Part 3 [3]. Consequently, the recommendations provided in paras 5.286–5.291 are also applicable in respect of such workers. Rules should be established for these workers, especially with regard to access to controlled areas and supervised areas.

5.96. This subsection contains guidance very specific to radiation therapy. More general and comprehensive guidance on occupational radiation protection is given in GSG-7 [23], 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).

Arrangements under the radiation protection programme

Classification of areas

5.97. Various areas and rooms in a radiation therapy facility should be classified as controlled areas or supervised areas, in line with the requirements established in paras 3.88–3.92 of GSR Part 3 [3]. All other rooms and areas that are not so designated are considered as being in the public domain, and levels of radiation in these areas should be low enough to ensure compliance with the dose limits for public exposure. Paragraphs 5.98–5.101 give general guidance, and it would be expected that final decisions by the licensee for a given medical radiation facility would be based on the expert advice of the medical physicist, a qualified expert in radiation protection or the RPO.

5.98. In a radiation therapy facility, all treatment rooms for external beam radiotherapy 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.

5.99. Supervised areas might include the areas surrounding brachytherapy patients' rooms or around radioactive source storage and handling areas.

5.100. The area around the control panel for all medical radiological equipment used in radiation therapy should be classified as either a controlled area or a supervised area, even though the radiation levels may be very low owing to the shielding design. In either case, this area should have restricted access, inter alia, to avoid distraction of staff, which could lead to accidental medical exposure of patients.

5.101. In order to avoid uncertainties about the extent of controlled areas and supervised areas, the boundaries of such areas should, when possible, be walls and doors, partitions or other physical barriers, clearly marked or identified with suitable warning signs.

Local rules and procedures

5.102. Paragraph 3.93 of GSR Part 3 [3] 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 established in para. 3.94 of GSR Part 3 [3], written local rules and procedures are required in any radiation therapy facility. Their purpose is to ensure protection and safety for workers and other persons. Such local rules and procedures should include measures to minimize occupational radiation exposure both for normal work and in unusual events. The local rules and procedures should also cover the wearing, handling and storing of personal dosimeters, and should specify investigation levels and ensuing follow-up actions (see also paras 5.159–5.178).

5.103. Since all personnel involved in using radiation in radiation therapy need to know and follow the local rules and procedures, the development and review of these local rules and procedures should involve representatives of all health professionals involved in radiation therapy.

5.104. Equipment (both 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 protection and safety. The manufacturer's operating manual is an important resource in this respect, but additional procedures should also be considered. The final documented set of operational procedures should be subject to approval by the licensee of the radiation therapy facility, and should be incorporated into the facility's management system (see paras 2.138–2.149).

5.105. Radiation therapy staff should understand the documented procedures for the operation of the equipment with which they work, including the safety features, and should be trained, with periodic refresher training, in what to do if things go wrong. Additional education and training should be conducted when new devices or techniques are introduced into radiation therapy practice.

5.106. Many local rules and procedures address some or all aspects of occupational radiation protection, patient radiation protection and public radiation protection, either directly or indirectly, as well as providing for a successful application of the treatment. Paragraphs 5.107–5.146 give recommendations that should be incorporated into the radiation therapy facility's local rules and procedures. They are placed in this section on occupational radiation protection because they are to be followed by workers, but they will often also have significance for patient and public radiation protection.

5.107. For external beam radiotherapy, HDR and PDR brachytherapy, no one should be in the treatment room during the delivery of treatment, except the patient being treated. All attending personnel should be in appropriately shielded areas.

5.108. Safety features such as interlocks, the presence of accessories such as the T-bar for manual ^{60}Co source retraction and the functionality of survey meters should be checked daily prior to patient treatment. More detail is given in Ref. [281], and see also para. 5.240 on quality control tests in general.

5.109. Sealed sources should be subject to leak tests prior to their first use and at regular intervals thereafter, in conformity with international standards [308]. These tests should be sufficiently sensitive to be able to detect the presence of very small amounts of removable contamination, for example 0.2 kBq.

5.110. Area surveys should be performed periodically (e.g. every six months) around all treatment units and check sources, including ^{60}Co units, shielded safes and source storage facilities for LDR, PDR and HDR sources.

5.111. Local rules for pregnant workers and persons under the age of 18 should reflect the guidance given in paras 5.182–5.185 and 5.186, respectively.

Specific local rules and procedures for external beam radiotherapy

5.112. The safe operation of external beam radiotherapy units requires procedures for area surveys, interlock checks, leak tests (for sealed sources) and procedures for contingencies such as a source becoming stuck in the on position or partially in the on position. Such procedures require that the necessary equipment be available, calibrated and in working order, including:

(a) A radiation monitor;
(b) Leak test capabilities (for radioactive sources);
(c) Personal alarm dosimeters, especially for unplanned exposures.

5.113. The procedures for the use of radiation monitoring equipment should take into account that some instruments can give erroneous readings in a high radiation field, and that this phenomenon, if it occurs, can be addressed 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).

5.114. 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. 5.100.

5.115. As described in para. 5.109, regular leak tests should be performed for sealed sources. For external beam radiotherapy, the method that should be used is an indirect leak test of the nearest accessible surface.

5.116. Irradiation that involves the extended use 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.

Specific local rules and procedures for brachytherapy

5.117. An inventory of sources 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 identifier or an alphanumeric identifier.

5.118. Sources should never be left on preparation surfaces. They should be either in storage, in transit or in use.

5.119. As described in para. 5.109, regular leak tests should be performed for sealed sources. For long lived LDR brachytherapy sources, the typical method used is a direct moist wipe leak test, while for remote controlled brachytherapy the method to be used is an indirect wipe test of the nearest accessible surface. For an HDR/PDR unit, the leak tests should be carried out only on the afterloading drive assembly and transport containers, since the source itself has too high a dose rate to allow a direct wipe test.

5.120. As stated in para. 5.110, area surveys should be performed periodically around the source storage facilities for LDR, HDR, PDR brachytherapy and sources to be used in permanent implants.

5.121. The source storage facilities should be marked to indicate that they contain radioactive materials, and instructions should be provided on how to contact the RPO, medical physicist or other responsible radiation safety individual in the event of an emergency.

5.122. Source storage rooms should be kept locked at all times, except when access is required to remove or return a source.

5.123. 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. Bed 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.

5.124. Sterilization processes in brachytherapy should be appropriate and should be consistent with manufacturer's recommendations to prevent damage to sources and applicators that could affect safety.

5.125. Among other safety checks, the catheters, couplings and transfer tubes should be checked before and after each treatment, to ensure that there are no obstacles to prevent motion of the source. Further details on safety checks are given in Ref. [324].

Specific local rules and procedures for brachytherapy: Additional for LDR sources

5.126. 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 the use of mobile shielding where available, and concise instructions for the unplanned removal of a source or applicator and for dealing with an emergency, including contact details. A patient with a removable source in or on the body should leave the room only in exceptional circumstances and should be accompanied by an attendant from the radiation therapy facility at all times.

5.127. 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.

5.128. 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.

5.129. Sources should be handled only with long forceps or tongs.

5.130. A mobile shielded container should be available for transporting sources and the shortest route possible should be used. The container should have a long handle and/or a long handled trolley should be used.

5.131. 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, such sources should be inspected before and after every use.

5.132. Work surfaces should be continuous, easy to clean and brightly lit to make it easy to find any sources that have been dropped.

5.133. 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 sewerage system when a source is left in the applicator or a patient removes a source and puts it in the sink. Such situations are preventable by placing a filter in the sink's drain.

Specific local rules and procedures for brachytherapy: Additional for HDR/PDR sources

5.134. The HDR/PDR afterloader should undergo routine quality assurance tests at the beginning of each treatment day [324].

5.135. 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 the patient.

5.136. Manufacturers provide suggested emergency procedures to be implemented 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. The procedures 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 subsequent actions are required. The general sequence is the following:

(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 source retract 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 source retract button on the remote afterloading unit);

(f) Manual retraction of the source (using a hand crank);
(g) Survey of the patient and survey of the afterloader (confirming that the source is in the safe);
(h) Removal of the applicator and placement in the emergency container;
(i) Survey of the patient and survey of the emergency container (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;
(k) Informing of the personnel responsible for the maintenance of the afterloader, the RPO and, depending on national rules, the regulatory body.

Specific local rules and procedures for remote control afterloading brachytherapy

5.137. Remote afterloading equipment requires specific mitigatory procedures, as these are especially critical for HDR/PDR brachytherapy. These procedures are dealt with in paras 5.316–5.319. A shielded container large enough to accommodate the largest applicator set should be kept next to the unit in case the source gets stuck.

Specific local rules and procedures for manual brachytherapy

5.138. For implants with sources of different activities, after verification of the source strength, the source or source holder should be marked with a unique identifier (e.g. a pre-established colour that cannot be compromised by body fluids), to facilitate visual recognition and to prevent the possibility of confusion between different sources or batches. Containers utilized for the transport of radioactive sources should conform with the requirements established in SSR-6 (Rev. 1) [279] (see also paras 5.324–5.326).

5.139. 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 request and of its issuance from, and its return to, the safe, with signatures (see also para. 5.88).

5.140. 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.

5.141. Sources should be handled only with long forceps or tongs, never directly with the fingers.

5.142. A mobile shielded container should be available for transporting sources and the shortest route possible should be used. The container should have a long handle or a long handled trolley should be used.

5.143. 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, chemical attack and mechanical stresses. Therefore, such sources should be inspected after every use.

5.144. Available safety features listed in para. 5.39 should be effectively used.

5.145. 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 and magnifying glasses and good illumination of the work surface are available and used and that, if ^{192}Ir 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 another appropriate licensee or an authorized waste disposal facility (see also paras 5.292 and 5.293);
(c) Surfaces and tools are properly decontaminated.

Specific local rules and procedures for imaging and simulation

5.146. Local rules and procedures for performing imaging procedures as part of pre-planning and simulation should follow the guidance, where appropriate, given in paras 3.60–3.86 and 4.70–4.104. Additional information relevant to local rules specific to using imaging equipment as part of IGRT is given in Ref. [321].

Personal protective equipment and in-room protective devices

5.147. Paragraphs 3.93 and 3.95 of GSR Part 3 [3] require that personal protective equipment and in-room protective devices be available and used when structural shielding and administrative controls alone cannot provide the required level of occupational radiation protection. The need for this protective equipment should be established by the RPO or by the medical physicist at the radiation therapy facility.

5.148. For current procedures in external beam radiotherapy, personal protective equipment is not usually needed. However, during patient preparation, source implantation or manual afterloading techniques in brachytherapy, and in the simulation or pre-planning phase when imaging equipment is in use (e.g. C-arm, CT and PET–CT), the relevant recommendations given in paras 3.89–3.99, 4.110 and 4.111 covering these procedures should be applied.

5.149. In the case of manual handling of sources for brachytherapy, protective equipment such as shielding blocks on the workbench and a lead glass screen should be used, as well as appropriate devices for handling sources (see paras 5.142 and 5.145).

5.150. 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. [325].

5.151. Protective equipment for emergencies in brachytherapy (e.g. a stuck source in HDR) should include an emergency container suitable for applicators and sources (see also paras 5.316–5.319 on procedures for contingencies).

Workplace monitoring

5.152. Paragraphs 3.96–3.98 of GSR Part 3 [3] establish the requirements and responsibilities for workplace monitoring. Workplace monitoring comprises measurements made in the working environment and the interpretation of the 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 GSG-7 [23].

5.153. Workplace monitoring in areas around each item of 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, regardless of 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;

(c) Source replacements have taken place in teletherapy or remote controlled brachytherapy;
(d) New software for the medical radiological equipment is installed or there is a significant upgrade;
(e) New techniques are introduced;
(f) Servicing of the medical radiological equipment has been performed, which could have an impact on the radiation delivered.

5.154. Initial workplace monitoring includes measurements of radiation leakage from the equipment and the radiation levels of the accessible areas around, above and below irradiation rooms using suitable phantoms. This initial monitoring should be performed as part of acceptance tests, prior to clinical use of the equipment.

5.155. In addition, dose rates in teletherapy rooms with radioactive sources and in HDR brachytherapy treatment rooms should be continuously monitored through the use of permanently installed area radiation 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.

5.156. For treatment rooms where the possibility of induced activity exists, for example 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 [314, 326].

5.157. Workplace monitoring should be done in association with brachytherapy procedures. Soon after implantation of the sources, a survey of dose rates in the vicinity of the patient is necessary.

5.158. Survey meters used for workplace monitoring should normally be calibrated in terms of ambient dose equivalent. In radiation therapy procedures, the quantity is the ambient dose equivalent, $H^*(10)$, and the unit is the sievert (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. 5.245).

Assessment of occupational exposure and health surveillance for workers

Assessment of occupational exposure

5.159. The purpose of monitoring and dose assessment is, inter alia, to provide information about the exposure of workers and to confirm good working practices and regulatory compliance. Paragraph 3.100 of GSR Part 3 [3] establishes the requirement of individual monitoring for "any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure". Workers who may require individual monitoring include radiation oncologists, medical physicists, medical radiation technologists, the RPO, biomedical engineers, maintenance and servicing personnel, and any nursing or other staff who need to spend time with patients with implanted radioactive sources.

5.160. Monitoring involves more than just measurement. It includes interpretation, assessment, investigation and reporting, which may lead to corrective measures, if necessary. Individual external doses can be assessed by using individual monitoring devices, which include thermoluminescent dosimeters, optical stimulated luminescent dosimeters, radiophotoluminiscent dosimeters, film badges and electronic dosimeters. Individual monitoring devices should be calibrated and should be traceable to a standards dosimetry laboratory (for more detailed guidance, see GSG-7 [23]).

5.161. With the exception of electronic dosimeters used sequentially by several workers with individual doses recorded separately, each personal dosimeter should be used for monitoring only the person to whom it is issued, for work performed at that radiation therapy facility, and it should not be taken to other facilities where that person may also 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 or she also works. Monitoring results can then be interpreted for the person working in a specific radiation therapy facility, and this will allow appropriate review of the effectiveness of the optimization of protection and safety for that individual in that facility. However, national regulatory requirements may differ from this advice, and they would need to be followed in those jurisdictions in which they apply (see also paras 5.172–5.174).

5.162. The monitoring period (period of dosimeter deployment) specified by regulatory bodies in most States 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 exposure. 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 is less than the minimum detection level of the dosimeter, resulting in no detectable doses. With a longer cycle, it is more likely that a reading can be obtained. Unnecessary delays in the return, reading and reporting of the dose recorded on dosimeters should be avoided. Dosimeters should be sent from the radiation therapy facility to the dosimetry service provider, which 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.

5.163. The operational dosimetric quantity used is the personal dose equivalent $H_p(d)$. For weakly penetrating radiation 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 radiation and therefore $d = 10$ mm, except in the 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 [23].

5.164. 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 of the hands exists, such as in the handling of brachytherapy sources, extremity dosimeters should be worn (if this is compatible with good clinical practice).

5.165. 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 is generally 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 in 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 dose to the lens of the eye may be considered in these or similar cases.

5.166. There are three dose limits applicable to workers in radiation therapy: the limit for effective dose, and the limits for equivalent dose to the lens of the eye and to the 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 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 necessary, the manufacturer's specific wearing instructions should be followed.

5.167. When not in use, individual dosimeters should be kept in a dedicated place and should be protected from damage or from irradiation. If an individual loses his or her dosimeter, the individual should inform the RPO, who should perform a dose assessment, record this evaluation of the dose and add it to the individual's dose record. Where there is a national dose registry, it should be updated with 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 cases where the individual performs non-routine types of work, it may be better to use the doses of co-workers experiencing similar exposure conditions as the basis for the dose estimate.

5.168. In some cases, 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 $H^*(10)$, provided the dose gradient in the workplace is relatively low. The ICRP [119] provides conversion coefficients from ambient dose equivalent to effective dose for different types of radiation and energy. 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 kV.

5.169. Additional direct reading operational dosimeters, such as electronic dosimeters, should be considered for use in a radiation therapy facility, for example in a new facility or with the introduction of new modalities or procedures, as these devices can give the worker an instant indication of both the cumulative dose and the current dose rate and also allow pre-setting of an alarm to alert when a given level has been reached [23]. They will also be helpful in accidents or emergency situations (see paras 5.306–5.323).

Investigation levels for staff exposure

5.170. Investigation levels are different from dose constraints and dose limits; they are a tool used to provide a warning of the need to review procedures and performance, to investigate what is not working as expected and to take timely corrective action. The exceeding of an investigation level should prompt such actions. 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 events should also trigger an investigation. In all cases, the investigation should be carried out with a view to improving the optimization of occupational protection, and the results should be recorded. Investigation levels should also be set for workplace monitoring, with account taken of exposure scenarios and the predetermined values adopted for investigation levels for workers. Details on investigation levels are provided in GSG-7 [23].

5.171. An investigation should be initiated as soon as possible following a trigger or event, and a written report should be prepared concerning the cause, including determination or verification of the dose, corrective or mitigatory actions, and instructions or recommendations to avoid recurrence. Such reports should be reviewed by the quality assurance committee and the radiation safety committee, as appropriate, and the licensee should be informed. It is good practice to submit the report to an international or national safety reporting system. In some cases, the regulatory body may also need to be informed.

Persons who work in more than one place

5.172. Some individuals might 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. Regardless of the ownership and management structure, the occupational radiation protection requirements for the particular radiation therapy facility apply when the person is working in that facility. As described in para. 5.161, a dosimeter issued for individual monitoring should be worn only in the facility for which it is issued, as this facilitates the effective optimization of protection and safety in that facility. This approach is logistically more easily implemented, since each physical site has its own dosimeters, and so there is no need to transport dosimeters between facilities, with the risk of losing 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. 5.174).

5.173. There is, however, an important additional consideration, namely the need to ensure 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 its RPO, should establish 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 ongoing record of the occupational doses for that person in all the facilities where he or she works.

5.174. Some individuals, such as consultant medical physicists or service engineers, might perform work in many radiation therapy facilities and, in addition, in other medical radiation facilities. They can be employed by a company or be self-employed, providing contracted services to the radiation therapy facility and the other facilities. In such cases, it is simpler for the company or the self-employed person to provide the dosimeters for individual monitoring. Therefore, in these cases, a worker uses the same dosimeter for work performed in all radiation therapy facilities (and other medical radiation facilities) in the monitoring period.

Records of occupational exposure

5.175. Paragraphs 3.103–3.107 of GSR Part 3 [3] establish the detailed requirements for records of occupational exposure and place obligations on employers, registrants and licensees. In addition to 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 optimization of protection and safety at the facility and evaluating trends in exposure. Further general guidance on records of occupational exposure is given in GSG-7 [23].

Health surveillance for workers

5.176. 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 paras 3.108 and 3.109 of GSR Part 3 [3].

5.177. No specific health surveillance relating 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, and no specific radiation related examinations are normally required for persons who are occupationally exposed to ionizing radiation, as there are no diagnostic tests that yield information relevant to such normal exposure. It is, therefore, rare for considerations of occupational exposure arising from the working environment of a radiation therapy facility to influence significantly the decision about the fitness of a worker to undertake work with radiation or to influence the general conditions of service [23].

5.178. Counselling should be made 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 made 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, 327].

Information, instruction and training

5.179. All staff involved in radiation therapy should meet the respective training and competence criteria described in paras 2.119–2.137. This will include general 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 they should undertake radiation protection and safety training relevant to the additional imaging modalities in their radiation therapy facility.

5.180. Paragraph 3.110 of GSR Part 3 [3] places responsibilities on the employer to provide, inter alia, adequate information, instruction and training for protection and safety as it pertains to the radiation therapy facility. 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 technologies are introduced.

Conditions of service and special arrangements

5.181. Paragraph 3.111 of GSR Part 3 [3] requires that no special benefits be offered to staff because they are occupationally exposed. It is not acceptable to offer benefits as substitutes for measures for protection and safety.

Pregnant workers

5.182. There is no requirement in GSR Part 3 [3] for a worker to notify the licensee that she is pregnant, but it is necessary that female workers understand the importance of making such notifications so that their working conditions can be modified accordingly. Paragraph 3.113(b) of GSR Part 3 [3] establishes the requirement that employers, in cooperation with registrants and licensees, provide female workers with appropriate information in this regard.

5.183. Paragraph 3.114 of GSR Part 3 [3] establishes the requirement that:

> "The employer of a female worker, who has been notified of her suspected pregnancy…shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or fetus…is afforded the same broad level of protection as is required for members of the public."

The limitation of the dose to the embryo or fetus does not mean that pregnant women should avoid work with radiation, but it does mean 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, might reach the dose limit for members of the public (see Box 1). To prevent this from happening, rigorous time, shielding and distance restrictions should be implemented.

5.184. Other possible solutions include reassignment of a pregnant worker to duties where the likelihood of an accident is lower or to a location that has a lower ambient dose equivalent. Such reassignments should be accompanied by adequate training. A further consideration is the need to avoid having pregnant workers respond to an accident such as those described in paras 5.310–5.320, for example, with a ^{60}Co unit or an HDR brachytherapy unit.

5.185. With regard to the dose limit of 1 mSv for the embryo or fetus, the reading of a dosimeter can overestimate the dose to the embryo or fetus by a factor that depends on the energy and type of the incident radiation (by a factor of 10 for low energy X rays and by a factor of about 2 for ^{60}Co and high energy X rays). The dose to the embryo fetus should be assessed using an appropriately positioned additional dosimeter (see also GSG-7 [23]). Information, advice and, if indicated, counselling for pregnant workers should be made available (see also para. 5.178).

Persons under 18

5.186. In many States, 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 can involve occupational exposure to ionizing radiation. Paragraph 3.116 of GSR Part 3 [3] establishes the requirements for access to controlled areas and the dose limits for such persons are more restrictive (see Box 1 of this Safety Guide and Schedule III of GSR Part 3 [3]).

Protection of workers responding to incidents in a radiation therapy facility

5.187. 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 incidents should be considered in advance in the safety assessment for the facility and mitigatory procedures should be developed accordingly (see the guidance in paras 5.297–5.323 on prevention and mitigation of accidents).

5.188. Occupational exposure of staff responding to such incidents is still subject to the occupational dose limits, and the mitigatory procedures for incidents should include considerations for the optimization of protection and safety for the responding workers. The mitigatory procedures should also include allocation of responsibilities and should provide for the education and training of the relevant staff in executing the mitigatory measures, which should be periodically exercised. Most of these situations, for example the retraction of a stuck ^{60}Co source, can be executed in a planned manner so that doses received can be kept low.

RADIATION PROTECTION OF INDIVIDUALS UNDERGOING MEDICAL EXPOSURE

5.189. This section covers radiation protection of patients, 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 radiation therapy facility or wider medical facility, including those who may be waiting for their own radiological procedure, are considered members of the public and their radiation protection is covered in paras 5.282–5.296.

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

Justification of medical exposure

5.191. The requirements for justification of medical exposure (paras 3.155–3.161 of GSR Part 3 [3]) incorporate the three-level approach to justification (see para. 2.11) [4, 125, 126].

5.192. The roles of the health authority and professional bodies with respect to a level 2 or generic justification of radiological procedures in radiation therapy are described in paras 2.55–2.60.

Justification of medical exposure for the individual patient

5.193. GSR Part 3 [3] requires a joint approach to justification at the level of an individual patient, with a shared decision involving both the referring medical practitioner (who initiates the request for a radiological procedure) 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 on 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 within the team and documented at a 'tumour board' or equivalent multidisciplinary meeting.

5.194. From a 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 should also be justified. This includes consideration of the expected benefits that the imaging brings to improving the treatment outcome, such as PET–CT for improved target delineation or daily IGRT.

5.195. Two particular groups of patients identified in para. 3.157 of GSR Part 3 [3] for special consideration with respect to justification are patients who are pregnant or are paediatric.

(a) Owing to the higher radiosensitivity of the embryo or fetus, it should be ascertained whether a female patient is pregnant. Paragraph 3.176

of GSR Part 3 [3] requires that procedures be "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". Pregnancy would then be a factor in the justification process and might influence the timing of the proposed treatment or a decision as to whether another approach to treatment is more appropriate. Confirmation of pregnancy could occur after the initial justification and before the treatment commences or during treatment, in which case repeat justification is then necessary, with account taken of the additional sensitivity of the pregnant patient and embryo or fetus.

(b) As children are at greater risk of incurring radiation induced stochastic effects, paediatric treatments necessitate special consideration in the justification process.

5.196. The decision of the multidisciplinary oncology team should be conveyed to the patient or the legal guardian of the patient. The patient, or the legal guardian of the patient, 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. Female patients of reproductive capacity should also be made aware of the risks associated with becoming pregnant during treatment. The patient's consent for treatment should be obtained before any further patient management action is initiated.

Justification of medical exposure for biomedical research volunteers

5.197. 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 para. 2.99. Healthy individuals should not take part in a programme of biomedical research involving radiation therapy procedures.

Justification of medical exposure for carers and comforters

5.198. The three-level approach to justification is not applicable for carers and comforters. Instead, para. 3.155 of GSR Part 3 [3] establishes the requirement to ensure that there be some net benefit arising from the exposure, for example the successful performance of a diagnostic procedure on a child. The crucial component in the justification of medical exposure of carers and comforters is their knowledge and understanding about radiation protection and the radiation risks for the procedure being considered. To this end, the radiological medical practitioner or medical radiation technologist involved in the radiological procedure, prior to the performance of the procedure, has the responsibility to

ensure that the carer or comforter is correctly informed about radiation protection and the radiation risks involved, and that the carer or comforter understands this information and consequently agrees to take on the role of carer or comforter.

Optimization of protection and safety

5.199. In medical exposure, optimization of protection and safety has several components, some applicable 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 paras 5.200–5.253. Key personnel in the optimization process are the radiological medical practitioner, the medical radiation technologist and the medical physicist.

Design considerations

5.200. The use of appropriate and well designed medical radiological equipment and associated software underpins any treatment in radiation therapy. Linacs, X ray generators, radioactive source based equipment (teletherapy and brachytherapy) and their associated technologies and accessories (including TPS) 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. Guidance on design considerations is given in the subsection on medical radiological equipment in radiation therapy in paras 5.61–5.81. Guidance on design considerations for imaging systems, such as those used in radiation therapy for simulation, patient preparation, image guidance and follow-up procedures, is given in paras 3.32–3.41 and 4.45–4.51. Ultimately, as established in para. 3.162 of GSR Part 3 [3], it is the responsibility of the licensee of the radiation therapy facility to ensure that the facility uses only medical radiological equipment and software that meets applicable international or national standards.

Operational considerations

5.201. Following justification, the planning and delivery of treatment are required to be performed in such a way as to optimize patient protection (para. 3.164 of GSR Part 3 [3]). 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.

5.202. Written procedures and protocols for the delivery of radiation therapy, consistent with the above goal, should be drawn up. Protocols should be consistent with current best radiation therapy practice, published by the relevant professional bodies, national, regional or international (see Refs [328–333]).

5.203. Advanced radiation therapy techniques (e.g. 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, high quality imaging and delivery equipment and immobilization devices should be utilized.

5.204. The use of advanced technology has led to the delivery of higher doses to the target volume, and complex and unconventional field or source arrangements are frequently used. 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 such techniques.

5.205. Calculation of the dose to the embryo or fetus before the treatment of a pregnant patient should be part of the treatment plan. The distance from the field edge to the embryo or fetus is the most important factor in embryo or fetal dose, together with other factors such as field size, angle and radiation energy [124, 334].

5.206. Specific protocols for the use of imaging equipment (e.g. CT and PET–CT) in the pre-planning stage (simulation) of external beam radiotherapy should be used to ensure appropriate optimization of protection and safety. In addition to the relevant guidance given in paras 3.176–3.185, the following should be considered:

(a) A medical radiation technologist specialized in radiation therapy should always be present when images for the planning of external beam radiotherapy are acquired in a diagnostic imaging facility.
(b) Patients should be in the treatment position for all images acquired for the planning of external beam radiotherapy.
(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 sufficiently large bore that images can be acquired with the patient in the treatment position.
(e) A comparable table top should be used for image acquisition for treatment planning and for treatment delivery, for example using a flat table top or a flat insert.
(f) A reference system consistent with those in the treatment room should be used when acquiring images for the planning of external beam radiotherapy. The TPS reference point and the patient treatment reference point should be correlated.
(g) When a respiratory or motion management and monitoring system is used for CT imaging for 4-D radiotherapy, it should be consistent with that used in the treatment room.
(h) Imaging protocols in radiation therapy should include the specific technical parameters required for the simulation. For example, for CT this would include the CT number for dose computation accuracy, the 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.

5.207. Specific protocols for the use of imaging equipment in IGRT should be used to ensure appropriate optimization of protection and safety. In addition to the relevant guidance given in paras 3.176–3.186, more specific guidance is given in Refs [321, 335].

Calibration: Medical radiological equipment

5.208. Paragraph 3.167(a) of GSR Part 3 [3] establishes the requirements for the 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) Medical radiological equipment for external beam radiotherapy 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 [316, 336]. The calibrations should be performed 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 an equivalent quantity as recommended by the ICRU, at a specified distance, for a specified date [316].

(c) Internationally or nationally accepted calibration protocols should be used. Examples of such protocols include Refs [324, 336–342].
(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 [339–342].
(e) Particular attention should be given to the calibration of sources used for special radiation therapy procedures (e.g. radiosurgery, IORT, SRT, tomotherapy and total body irradiation) which may necessitate adaptation of the existing international codes of practice and may introduce additional uncertainties associated with making measurements in non-reference conditions. A particular consideration is small field dosimetry, and guidance is given in Refs [343, 344].
(f) Imaging devices used in the radiation therapy process, such as conventional simulators, CT scanners, CBCT, fluoroscopy, radiography and hybrid imaging systems (PET–CT and SPECT–CT) should be calibrated following the relevant recommendations in paras 3.201–3.205 and 4.197–4.202. Guidance for MV imaging devices is given in Refs [345, 346].

5.209. Paragraphs 3.154(d) and 3.167 of GSR Part 3 [3] require that the responsibility for calibration in radiation therapy be placed 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 direct presence and involvement of the medical physicist is essential. For the imaging devices used in the radiation therapy process, a medical physicist with competence in diagnostic radiology and image guided interventional procedures, or in nuclear medicine, should be involved as appropriate (see also paras 5.219–5.227 on patient dosimetry and 5.228–5.247 on the programme of quality assurance for medical exposures).

5.210. Paragraph 3.167(b) of GSR Part 3 [3] specifies when such calibrations are required to be carried out. In addition to the initial calibration prior to clinical use and calibration after major maintenance or upgrade, periodic calibrations are required to be carried out. The intervals for these calibrations may differ, depending on the type of source and unit. For example, linacs should be calibrated at least yearly. These intervals will be specified by the regulatory body in each State, under advice from the professional bodies when appropriate. Constancy tests are addressed in paras 5.228–5.247.

5.211. Paragraph 3.167(c) of GSR Part 3 [3] requires independent verification of the calibration of radiation therapy equipment 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 use of a remote dosimetry audit (e.g. IAEA/WHO thermoluminescent dosimetry postal dose audit service), 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.

5.212. The licensee of the radiation therapy facility should ensure that independent verification of the calibration of all radiation therapy equipment is performed through participation in a national, regional or international programme. A period of two years is recommended for the intervals between independent verifications of calibration. One of the simplest mechanisms for independent verifications of external beam calibration or physical dosimetry is participation in an IAEA/WHO thermoluminescent dosimetry postal dose quality audit. The regulatory body should encourage licensees to participate in this or similar programmes.

5.213. Sealed sources used for external beam radiotherapy and brachytherapy will also have a calibration certificate provided by the manufacturer, in accordance with Ref. [307] or its national equivalent standards. While important, this does not replace the calibrations required by para. 3.167 of GSR Part 3 [3] and described in paras 5.208–5.212.

5.214. 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 source 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. [341].

Calibration: Dosimetry instrumentation

5.215. Dosimetry instrumentation used at a radiation therapy facility should be calibrated at appropriate intervals. Detailed guidance is given in Ref. [36]. A period of not more than two years is recommended for the reference instruments.

5.216. Paragraph 3.167(d) of GSR Part 3 [3] requires that the calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory. Ideally, this would be the national standards dosimetry laboratory (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 State or region if there is no national standards dosimetry laboratory in the State or region 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.

5.217. Given the expense 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 carried out with instruments intercompared with the local standard on a periodic basis.

5.218. Records of calibration measurements and associated calculations, including uncertainty determinations (uncertainty budgets), should be maintained as described in para. 5.280.

Dosimetry of patients

5.219. Paragraph 3.168 of GSR Part 3 [3] establishes the requirements for dosimetry of patients in radiation therapy. Dosimetry is required for each patient undergoing external beam radiotherapy 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).

5.220. For external beam radiotherapy, 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); the total dose; the dose per fraction; the fractionation; and the overall treatment period of each course of treatment 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 should specify 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 doses 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 scatter radiation. The treatment prescription is then used as the basis for treatment planning, followed by delivery of the treatment and verification of the dose. The requirements of GSR Part 3 [3] 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.

5.221. There are many different terms, concepts and approaches in use for different aspects of prescribing, recording and reporting of doses in external beam radiotherapy. For example, there are many specifications of volumes, including gross tumour volume, clinical target volume, planning target volume, organ at risk and 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 radiotherapy [347–352]. Further guidance on dosimetry in external beam radiotherapy is given in Refs [33, 335–339, 353–359].

5.222. 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 radionuclide; and the type of brachytherapy (manual, HDR, PDR or LDR). The specification of volumes and the prescribing, recording and reporting of doses should be in accordance with the recommendations of the ICRU [360–362]. Further guidance on dosimetry in brachytherapy is given in Refs [358, 363–370].

5.223. Absorbed doses to organs as a result of imaging procedures carried out as part of the radiation therapy process should be considered both for the irradiated volume and for 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, such absorbed doses as a result of imaging procedures 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. [371].

5.224. 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 (e.g. see Ref. [372]).

5.225. Whenever appropriate, radiobiological considerations should be incorporated into treatment decisions, for example by calculation of biologically

effective doses [373]. Examples are when doses from external beam radiotherapy and brachytherapy are added, when hypofractionation is used, or when the patient has missed some fractions owing to clinical or technical reasons.

5.226. TPSs 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, means should be established to verify the dose to selected points, independent from the TPS calculations, for example manual calculations, independent monitor unit verification software, or case specific quality assurance measurements in a phantom [318, 374, 375].

5.227. The radiation therapy facility medical physicist should perform phantom or in vivo measurements as appropriate. An example is the verification of lung dose distributions for total body irradiation with photons.

Quality assurance for medical exposures

5.228. Paragraph 3.170 of GSR Part 3 [3] requires that radiation therapy facilities have in place a comprehensive programme of quality assurance for medical exposures. General guidance on the management system is given in paras 2.138–2.149, and it is reiterated here that the programme of quality assurance for medical exposures should fit in with, and be part of, the wider management system at the facility.

5.229. When planning and developing an effective programme of quality assurance for medical exposures, the licensee should recognize that it demands strong managerial commitment and support in the form of training and allocation of time, personnel and equipment resources.

5.230. The purpose of the programme of quality assurance for medical exposures is to help to ensure successful optimization of protection and safety in the radiation therapy facility and to minimize the occurrence of unintended and accidental medical exposures. Paragraph 3.171 of GSR Part 3 [3] establishes the elements of the programme.

5.231. 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, the

programme of quality assurance for medical exposures should include the testing of both the hardware and software.

5.232. Measurements on medical radiological equipment used in radiation therapy are an important component of the programme of quality assurance. 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. The acceptance test should be followed immediately by commissioning, and then ongoing periodic quality control tests, including constancy tests. The purpose is to ensure that, at all times, all medical radiological equipment performs correctly, accurately, reproducibly and predictably. Acceptance and commissioning tests should be performed in the same way for equipment and software that has been donated.

5.233. 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 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 [376–378].

5.234. 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 the IEC or other recognized standards [290–305]. Depending on the equipment purchase agreement, acceptance tests can be performed by the manufacturer in the presence of the local medical physicist representing the user, or, if acceptable to the manufacturer and the purchaser, by a medical physicist jointly with the manufacturer. 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.

5.235. Acceptance tests should ensure that equipment and software are compatible with the other equipment with which it will have an interface. The accuracy and integrity of data, including during transfer processes, should be verified.

5.236. After acceptance and before starting clinical use, commissioning of equipment (hardware and software) should be performed (i.e. radiation sources

and radiation beams should be characterized and software should be 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 their 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 [379, 380]. During commissioning, the medical physicist should identify, measure and compile all data required for clinical use. This should be followed by validation of the data [281, 310, 317].

5.237. During commissioning, the quantities and measures including tolerances and action levels should be defined for the periodic quality control tests to set the baseline for subsequent constancy tests (see also para. 5.240).

5.238. 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 quality control 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 [276, 379, 381].

5.239. As noted in para. 5.232, the comprehensive programme of quality assurance, with acceptance, commissioning and ongoing quality control tests should include software, including its installation, upgrade or modification. A particular case is a software upgrade of a TPS 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 quality control tests can take place prior to reintroduction of treatment.

5.240. In addition to the acceptance testing and commissioning, para. 3.171 of GSR Part 3 [3] requires, periodically and after any major maintenance procedure or upgrade, the measurement of physical parameters of medical radiological equipment. There are many published reports from international and national organizations and national and 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 in aspects of, radiation therapy, how they should be performed, tolerances and action levels, and recommended frequencies [184, 281, 310–312,

315, 317–319, 321, 322, 324, 325, 328–331, 335, 339, 345, 374, 375, 382–400]. In addition, many of these organizations and professional bodies publish on their web sites new or updated publications on the topic. The regulatory body may have its own specific requirements for the tests that should be performed, their frequencies and the competence of the specialists involved. Such specific requirements should be established with consultation between the regulatory body and the relevant professional bodies.

5.241. The programme of quality assurance for medical exposures should include testing of sealed sources at regular intervals for leakage, as required by the regulatory body. The programme of quality assurance should also include the regular update of inventories of all radiation sources, at intervals determined by the regulatory body.

5.242. For guidance with respect to imaging medical radiological equipment, see paras 3.238 and 4.227. A diagnostic medical physicist and a radiation therapy medical physicist should be consulted. Specific parameters for radiotherapy that should be considered include, for example, CT number calibration for CT and geometric accuracy.

5.243. 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 those referenced in para. 5.240. Paragraph 3.171(b) of GSR Part 3 [3] requires the implementation of corrective actions if the measured values fall outside established tolerance limits. Such corrective actions are likely to include maintenance or servicing of the equipment, and hence a maintenance programme should be in place at the radiation therapy facility. In some cases, the equipment might be outside the tolerance limits by a significant amount and the equipment should be immediately taken out of clinical use and not returned until servicing has taken place and it has been ascertained by the medical physicist that the equipment now meets the performance requirements for clinical use.

5.244. The programme of quality assurance for medical exposures in radiation therapy should 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 and an independent check of treatment plans and of patient set-up should be carried out by a second

professional. The periodic review of the protocols and procedures themselves is part of the radiological review at the facility (see paras 5.277–5.279).

5.245. Paragraph 3.171(e) of GSR Part 3 [3] specifically requires that the periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment be part of the programme of quality assurance. 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 5.215–5.218), 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. 5.215) and a set of quality control tests on the operation of each instrument to be performed at regular intervals, based on recommendations by professional bodies and international organizations (e.g. see Ref. [336]). Preventive maintenance should be carried out on a regular basis.

5.246. 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 relating to acceptance, commissioning, calibration and dosimetry should be documented, including independent verification. Records should also be kept for the results of the periodic quality control tests and corrective actions. The regulatory body, in its inspections of a radiation therapy facility, should review the records of the programme of quality assurance for medical exposures.

5.247. In line with standard practices for quality management, para. 3.172 of GSR Part 3 [3] requires that "regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks." Such audits should be performed relatively frequently, for example every two years for a radiation therapy facility performing complex radiation therapy treatments, and when new techniques are implemented. Such audits may be external audits or internal audits. Internal audits are usually logistically simpler to conduct, while an external audit generally has the advantage of bringing in an outside perspective. The audit of the programme of quality assurance for medical exposures can be incorporated into more comprehensive audits of the management system performed by the licensee. Furthermore, the results of the audit of the programme of quality assurance for medical exposures will be a major input into the radiological review

performed at the facility (see paras 5.277–5.279). If indicated from the audit, the programme of quality assurance for medical exposures should be updated or modified, accordingly. Furthermore, feedback from operational experience and lessons identified from accidents or near misses (see also para. 5.274) can help to identify potential problems and correct deficiencies, and therefore should be used systematically in improving the programme of quality assurance.

Dose constraints: Carers and comforters

5.248. In radiation therapy, the likelihood of a person having the role of a carer or comforter (as defined in GSR Part 3 [3]) is generally limited, as accompanying a patient during external beam radiotherapy or access to HDR or PDR brachytherapy patients during treatment is not allowed. However, since LDR brachytherapy treatments last two to three days, visits by close relatives could be allowed, provided dose constraints for these carers or comforters are established and applied. 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 GSR Part 3 [3]) and as such is not subject to dose limits. However, paras 3.153 and 3.173 of GSR Part 3 [3] require that such carers and comforters be afforded radiation protection through the application of the requirements for the optimization of protection and safety and, in particular, the use of dose constraints in this process. Such dose constraints are required to be established, as a result of consultation between the health authority, relevant professional bodies and the regulatory body (see para. 3.149(a)(i) of GSR Part 3 [3]). Guidance on setting dose constraints, including considerations for children and pregnant women, is given in paras 2.48 and 2.49.

5.249. Written protocols should be drawn up for implementing measures for the optimization of protection and safety 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. time, distance and shielding). The protocols 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 achievable;
(c) The values of the dose constraints to be applied (see para. 2.49).

5.250. The licensee should be able to demonstrate that the effective dose to the carer or comforter, by applying the protocols, 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 ensure that dose constraint is not exceeded. Therefore, individual dose monitoring is normally not necessary.

5.251. Paragraph 3.153 of GSR Part 3 [3] states that:

> "Registrants and licensees shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure."

The carer or comforter should indicate that he or she is still willing to provide support, care and comfort to the patient. Appropriate written instructions should be available and provided to the carer or comforter.

5.252. Guidance applicable to carers and comforters supporting patients undergoing imaging radiological procedures as part of the treatment process in the radiation therapy facility is given in paras 3.247–3.251.

Dose constraints: Volunteers in biomedical research

5.253. 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 para. 2.99, and this normally includes the setting of applicable dose constraints (para. 2.100).

Pregnant patients

5.254. Patients who are pregnant form a special subgroup of patients that should be given particular consideration with respect to radiation protection. The decision to treat is one that should be made following consultation between the pregnant patient and the medical radiological practitioner. These considerations are described in para. 5.195(a) with respect to justification and para. 5.205 with respect to optimization. None of these considerations can take place if it is not known whether the patient is pregnant. Therefore, it is crucial, as is required in

paras 3.175 and 3.176 of GSR Part 3 [3], for the radiation therapy facility to have in place means for ensuring that the pregnancy status of patients is known.

5.255. The first approach is through the posting of clear signs (possibly including a pictorial representation of pregnancy) in languages easily understood by the people using the radiation therapy facility, posing 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 in waiting rooms and cubicles. The second approach is to ask patients directly whether they are or might be pregnant. This might not always be so easy given social and cultural sensitivities, but it should be done when necessary.

5.256. Neither of the approaches described in para. 5.255 will work if the patient does not know whether she is pregnant. For this reason, para. 3.176 of GSR Part 3 [3] has an additional requirement on facilities to "ensure that there are 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 or scatter radiation reaches the embryo or fetus. Cooperation with the referring medical practitioner, through standard requests for pregnancy status for specified procedures, is one approach. The referral form should include a 'tick box' for pregnancy status. In case of doubt, a pregnancy test or a determination of hormone levels to assess menopausal status can be carried out.

Release of patients after permanent brachytherapy implants

5.257. In accordance with para. 3.178 of GSR Part 3 [3], a radiation therapy facility is required to 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 whom the patient may encounter or with whom the patient may 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 Box 1), while exposure of carers and comforters is not subject to dose limits but is instead controlled through dose constraints (see paras 2.46–2.49 and 5.248–5.252). Furthermore, as stated 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.

5.258. The medical physicist or RPO at the radiation therapy facility should establish prior to the release of a patient that the radioactivity of the implants is such that the doses that could be received by members of the public would not exceed the 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 of estimating 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 suggest that systematic dose monitoring, at least in the case of permanent brachytherapy implanted sources for the treatment of prostate cancer, is not necessary [340, 401].

5.259. As indicated in para. 5.258, the patient or the 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. Individuals of particular concern are children and pregnant partners of patients. The ICRP provides detailed guidance and a sample information sheet for implanted sources for prostate cancer in Ref. [401].

5.260. There is a low probability of an implanted seed being expelled, for example with prostate treatment. The written instructions should cover this possibility and should provide guidance on what to do and what not to do. Detailed advice is provided by the ICRP [401].

5.261. The patient with permanent brachytherapy implants should be informed that, if he or she is to undergo subsequent surgery, 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 [401] (see para. 5.289 on management of a deceased patient with permanent implants).

5.262. Information should also be provided to the patient on radiation risks, including guidance with respect to fertility in the case of implants for prostate cancer [401].

Unintended and accidental medical exposures

Prevention of unintended and accidental medical exposures

5.263. Paragraph 3.179 of GSR Part 3 [3] states that:

> "Registrants and licensees…shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error."

Paragraph 3.180 of GSR Part 3 [3] requires that the registrants and licensees promptly investigate if such exposures occur. General strategies for addressing those problems include the regular maintenance of medical radiological equipment and software, a comprehensive programme of quality assurance, continuing education and training of staff, and the promotion of a safety culture. Lessons identified from events that have occurred should be used for preventing or minimizing unintended and accidental medical exposures, as described in para. 5.273.

5.264. Minimization of the likelihood of unintended or accidental medical exposures in radiation therapy can be brought about by:

(a) The introduction of safety barriers at identified critical points in the process, with specific quality control checks at these points. Quality control should not be 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.
(b) Actively encouraging a culture of always working with awareness and alertness.
(c) Providing detailed protocols and procedures for each process.
(d) Providing sufficient staff who are educated and trained to the appropriate level, and an effective organization, ensuring reasonable patient throughput.
(e) Continuous professional development and practical training and training in applications for all staff involved in the preparation and delivery of radiation therapy.
(f) Clear definitions of the roles, responsibilities and functions of staff in the radiation therapy facility that are understood by all staff.

5.265. 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-outs', where staff take time to review what has been planned, prior to delivering treatment, should be considered.

5.266. As noted in para. 5.264, comprehensive protocols and procedures covering the various steps in the process should exist for the major part of the facility's activities [328–333, 395, 402–408]. Checklists detailing actions, and signed by the responsible parties at each step, are very helpful [409]. 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. When new techniques are introduced, they should also be subject to an audit.

5.267. Preventive measures should include reporting of incidents and near incidents, analysis and feedback, including lessons from international experience [276, 377, 379, 380, 410–413]. Preventive measures should also include checking of the robustness of the safety system of the facility against reported incidents (see Refs [276, 379, 410] for reviews of case histories from an extensive collection of accidental medical exposures).

5.268. Proactive risk assessment should also be carried out to try to pre-empt the occurrence of 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 effects analysis, and risk matrices to assess the probability and likely consequences of such unacceptable events. Detailed guidance on some of these tools and approaches is provided by the ICRP [410] and the European Commission [404].

5.269. Before the introduction of 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 a reporting system such as SAFRON and ROSEIS.

5.270. In addition to the guidance in paras 5.263–5.269, the following three-step strategy (commonly called 'prospective risk management') can help to prevent unintended and accidental exposures in radiation therapy:

(a) Allocation of responsibilities to appropriately qualified health professionals only and ensuring that a management system is in place that includes radiation protection and safety;
(b) Use of the lessons from unintended and accidental medical exposures to test whether the management system, including for radiation protection and safety, is robust enough against these types of event;
(c) Identification of other latent risks by posing the questions 'What else could go wrong?' or 'What other potential hazards might be present?'in a systematic, anticipative manner for all steps in the radiation therapy process, using, for example, the proactive methods briefly described in para. 5.268.

Investigation of unintended and accidental medical exposures

5.271. The events that constitute unintended or accidental medical exposures are detailed in para. 3.180 of GSR Part 3 [3], and for a radiation therapy facility such events include those associated with imaging and with treatment. For imaging, reference should be made to paras 3.260–3.264 (for X ray) and 4.253 and 4.254 (for nuclear medicine). Unintended and accidental medical exposures can occur at any stage in the radiation therapy process. For treatment in radiation therapy, unintended or accidental medical exposures can be either underexposures or overexposures. The events identified in para. 3.180 of GSR Part 3 [3] also include near misses, and these should be considered in the same way as actual events.

5.272. One of the events identified in para. 3.180 of GSR Part 3 [3] is a dose or dose fractionation being delivered that differs substantially from (over or under) the prescribed dose. Guidance on the level of dose that would be considered as substantially different can be found in international and regional recommendations [379, 403]. A system with clear procedures should be put in place 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 will generally be detectable in most cases by the radiation oncologist or relevant health professional, on the basis of an unusually high incidence of adverse patient reactions [379], and the radiation therapy facility's procedures should include such patient monitoring to act as a trigger for further investigation. The clinical identification of situations in which a dose is delivered under the prescribed dose is more difficult, but may become evident through poor tumour control; again, monitoring for such situations should be part of the radiation therapy facility's procedures. In addition to the clinically based approaches to identifying doses delivered that are substantially different from those prescribed,

other approaches should be used in parallel, including the review processes that are part of quality assurance.

5.273. The radiation therapy facility should put in place a system to manage the investigation of unintended and accidental medical exposures, and the ensuing actions and reporting. Paragraph 3.181 of GSR Part 3 [3] establishes what is required during 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's file. When required, counselling of the patient should be undertaken by an individual with appropriate experience and clinical knowledge.

5.274. The investigation of unintended and accidental medical exposures, as required by paras 3.180 and 3.181 of GSR Part 3 [3], has three main purposes. The first is to assess the consequences for the patients affected and to 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 radiation therapy facility (i.e. the investigation is for the facility's benefit and the patients' benefit). The third 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. The regulatory body and/or the health authorities could disseminate information on significant events reported to them and on the corrective actions taken, so that other facilities might learn from these events (see also para. 5.275). 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 ROSEIS reporting systems. Facilities performing radiation therapy should be active participants and users of SAFRON, ROSEIS or similar international databases or equivalent national ones.

5.275. Paragraph 3.181 of GSR Part 3 [3] establishes requirements for the reporting (in writing) of significant events to the regulatory body and, if appropriate, to the relevant health authority. The regulatory body may also specify its own requirements for the reporting of events by registrants and licensees. It is difficult to quantify the term 'significant': specification of a numerical trigger value immediately creates an artificial distinction between values immediately

below that value (and hence would not be reported) and those just above the value (which would 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 exposure, the likelihood of a similar event occurring in other radiation therapy facilities, a large number of patients having been affected, and gross misconduct or negligence by the responsible health professionals. As stated in para. 5.274, one of the roles of the regulatory body for such a reported event is to disseminate information on the event and any lessons identified to all potentially affected parties, typically other radiation therapy facilities and relevant professional bodies, but also in some cases manufacturers, suppliers and maintenance companies.

5.276. 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

5.277. Paragraph 3.182 of GSR Part 3 [3] requires that radiological reviews be performed periodically 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, will be a significant input to the process. As described in paras 2.148 and 2.149, the wider clinical audit could include the radiological review with its assessment of the effective application of the requirements for justification and optimization in the facility for the radiation therapy being performed [50, 414].

5.278. To facilitate compliance with para. 3.182 of GSR Part 3 [3] 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 institutional policies and procedures.

5.279. In radiation therapy, radiological reviews should consider patient outcome (survival, control of disease, acute side effects or late side effects), and

the effect of introducing new technologies or new techniques on efficiency and cost, such as, for example, the effect of the introduction of hypofractionation either for curative or palliative intent. A system for the ongoing collection of relevant data to support such reviews should be in place at the facility.

Records

5.280. Records should be in place to demonstrate ongoing compliance with radiation protection requirements. Paragraphs 3.183–3.185 of GSR Part 3 [3] establish the requirements for maintaining personnel records, records of calibration, dosimetry and quality assurance, and records of medical exposure. These records are required to be kept for the period specified by the regulatory body. In the absence of such a requirement, a suggested period for keeping records is ten years. In the case of children, records should be kept for a longer time.

5.281. In the case of records for a radiation therapy facility, care should also be taken to 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

5.282. Public exposure can arise from the performance of radiation therapy for persons in and around the radiation therapy facility.

5.283. The requirements for public protection established in paras 3.117–3.137 of GSR Part 3 [3] apply to radiation therapy facilities. This subsection contains guidance that is specific to radiation therapy facilities. More general and comprehensive guidance on radiation protection of the public is given in GSG-8 [24].

5.284. Persons who will be undergoing radiation therapy are also considered members of the public during the time when the treatment or other radiological procedure is not taking place, for example, while they are sitting in the waiting room. Similarly for carers and comforters, any exposure incurred other than during the radiological procedure in which they are involved will be public exposure.

5.285. Members of the public also include visitors, such as persons delivering goods or supplies, sales personnel, accompanying persons and other patients in the facility.

External exposure and contamination

5.286. The primary means for protecting the public from external exposure is the shielding in place at the radiation therapy facility (see paras 5.45–5.53), which should be sufficient so that public exposure resulting from being in any immediately adjacent areas, including accessible rooms above and below, is in compliance with the public dose limits, and preferably less than any dose constraint that the regulatory body may have applied (see paras 2.16, 2.17 and 2.46).

5.287. Patients receiving permanent implants might expose members of the public in the radiation therapy facility and upon discharge. Patients receiving temporary implants might 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. 5.258. 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. [415].

5.288. When deciding on the appropriate activity at discharge for a particular patient, the licensee and the 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, which may contain a migrating source. In some cases, such as for elderly patients or paediatric patients, it may be necessary to discuss the precautions to be taken with other family members.

5.289. 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, on the basis of 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 individuals carrying out autopsies or embalming, as contamination and radioactive waste are likely to be generated [401]. 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 indicate that the ashes should be stored until adequate decay has been achieved before they are released to the family, or the cremation should not be carried out, depending on the time of death and the half-life of the radionuclide [416].

Control of access

5.290. Access to areas where radiation is being used should be controlled to ensure doses to visitors are below the dose limits and constraints for the public. Paragraph 3.128 of GSR Part 3 [3] requires that access of visitors to controlled areas or supervised areas be restricted. In exceptional cases, a visitor may be permitted to enter a controlled area, but he or she should be accompanied at all times by a staff member who knows the protection and safety measures for the area. Written procedures should be drawn up specifying when such exceptions can take place and who may accompany the visitor. Particular consideration, in all cases, should be given with respect to women who are or may be pregnant.

5.291. Controlled areas and supervised areas should be clearly identified to help to prevent inadvertent entry to areas where treatment or other radiological procedures are being performed (see also para. 5.21). Further control can be afforded by the use of keys (or passwords) to restrict access to the control panels of medical radiological equipment to authorized persons only.

Radioactive sources no longer in use

5.292. When a radioactive source in the radiation therapy facility is no longer needed or is no longer viable for their medical purpose, the licensee should ensure that the source is either transferred or disposed of appropriately. The licensee retains responsibility for the source until the time of its 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 SSG-45 [277].

5.293. Specifically for radioactive source teletherapy equipment, the licensee:

(a) Should notify the regulatory body of any intention to transfer or decommission ^{60}Co teletherapy equipment prior to doing so. Depleted

uranium used as shielding material should also be treated as radioactive waste. For example, a ^{60}Co teletherapy head might contain depleted uranium and should be managed appropriately.

(b) Should ensure that resources for the disposal of the sources will be made available when the teletherapy equipment is to be decommissioned.

5.294. The regulatory body may require an applicant for a licence to have in place a programme for the 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 for the return of sources is acceptable evidence of such a programme.

Activation products

5.295. When equipment used for radiotherapy purposes is decommissioned, the licensee should ensure that activated materials from the head of the linac are correctly disposed of.

Monitoring and reporting

5.296. The programme for monitoring public exposure arising from radiation therapy should include dose assessment in the areas in and surrounding the radiation therapy facility that are accessible to the public. Doses can be derived from the shielding calculations in the planning stage, combined with the results from area monitoring at the initial operation of the facility and periodically thereafter. Records of dose assessments should be kept for a period that meets any relevant regulatory requirements. In the absence of such requirements, a suggested period for keeping records is seven to ten years.

PREVENTION AND MITIGATION OF ACCIDENTS

Safety assessments of potential exposure

5.297. To comply with the requirements for safety assessments established in paras 3.29–3.36 of GSR Part 3 [3], the registrant or licensee is required to conduct a safety assessment applied to all stages of the design and operation of the radiotherapy facility. Furthermore, para. 3.29 of GSR Part 3 [3] states that: “the responsible person or organization shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body.”

Paragraphs 2.150–2.154 describe general considerations for facilities using ionizing radiation for medical purposes.

5.298. The safety assessment of potential exposure should be systematic, should identify unintended events that can lead to potential exposure, and should consider their likelihood and potential consequences. Information on events, causes and contributing factors identified from reported accidents is available in Refs [276, 377, 379, 380, 404, 405, 410–413] (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 should also aim at anticipating other events that have not previously been reported. Clearly, the safety assessment should be documented.

5.299. 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 changes in workload;
(c) Operational experience or information on accidents or errors indicates that the safety assessment is to be reviewed.

5.300. Safety assessments for radiation therapy facilities performing brachytherapy or teletherapy with sealed sources should include consideration of all the steps associated with sealed sources, including the following:

(a) Ordering, transporting and receiving sealed sources;
(b) Unpacking, storing, preparing and handling sources prior to their use in the treatment of the patient;
(c) Care of patients with high amounts of activity;
(d) Storage and handling of sources after removal and the management of unused radioactive seeds.

5.301. The safety assessment for a radiation therapy facility, as described in para. 5.300, can be complemented by participation in international networks for sharing information, such as SAFRON and ROSEIS or in national networks such as the Radiation Oncology Incident Learning System (RO–ILS) and the National Reporting and Learning Systems (NRLS). 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 the use of systematic techniques, for example fault and event trees and probabilistic

safety assessment technique, such as those described for unintended or accidental medical exposure of patients in para. 5.268.

5.302. For radiation therapy, as described in para. 5.263, 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 in imaging, during patient preparation, simulation in treatment planning and in guidance during treatment.

Prevention of accidents

5.303. Accident prevention is clearly the best means for avoiding potential exposure, and paras 3.39–3.42 of GSR Part 3 [3] establish the requirements for 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 5.10–5.87.

5.304. The licensee should incorporate:

(a) Defence in depth measures to cope with events identified in the safety assessment, and evaluation of the reliability of the safety systems (including administrative and operational procedures, equipment and facility design).
(b) Operational experience and lessons from accidents and errors [276, 379, 410]. This information should be incorporated into the training, maintenance and quality assurance programmes.

5.305. Means for preventing or minimizing unintended and accidental medical exposures in radiation therapy are described in paras 5.263–5.270, and the ensuing investigation and corrective actions are described in paras 5.271–5.276.

Mitigation of the consequences of accidents

5.306. Paragraph 1.20 of GSR Part 3 [3] states that:

> "If an event or a sequence of events that has been considered in the assessment of potential exposure does actually occur, it may be treated either as a planned exposure situation or, if an emergency has been declared, as an emergency exposure situation."

On the basis of events identified in the safety assessment for the radiotherapy facility, mitigatory procedures should be prepared for events associated with potential exposure, including the 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 mitigatory measures.

5.307. Paragraph 3.43 of GSR Part 3 [3] states that:

> "If the safety assessment indicates that there is a reasonable likelihood of an emergency affecting either workers or members of the public, the registrant or licensee shall prepare an emergency plan for the protection of people and the environment."

Emergency arrangements and procedures commensurate with the hazard assessed and the potential consequences are required to be established, as appropriate, in accordance with GSR Part 7 [7], GSG-2 [8] and GS-G-2.1 [9]. As part of the emergency arrangements, responsibilities and resources, emergency procedures, and the provision of training and periodic retraining of the relevant staff in executing the necessary response actions should be established.

5.308. Owing to the fact that very high doses can be received within seconds or minutes, if an emergency occurs in a radiation therapy facility, personnel should act promptly. Thus, emergency procedures should include response time objectives, and they should be regularly tested in exercises.

5.309. The exposure of workers involved in mitigation of the consequences of radiation therapy events or in emergency response should be kept below the dose limits for occupational exposure in planned exposure situations. However, if it is justified that these dose limits are exceeded, emergency workers should be protected in accordance with the requirements and guidance for emergency exposure situations contained in section 4 of GSR Part 3 [3], and GSR Part 7 [7] and GSG-7 [23].

Stuck sources: General

5.310. Mitigatory procedures and emergency 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 to take other lifesaving

actions [417]. Further actions to recover the source, and to repair and test the equipment for returning it to use are not of the same urgency.

5.311. 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 response actions will be the same as source recovery actions, for example the retrieval of remote control brachytherapy sources from the patient and their return to the safe, either manually, electrically or using the manual crank.

Stuck sources: ^{60}Co teletherapy units

5.312. Mitigation procedures and emergency 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 exposure of the personnel involved.

5.313. In the case of such an event, the first step is to note the time, and immediately to 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 the RPO should be notified and should take control of the situation, including deciding when it is safe to re-enter the room. Before resuming the treatment of patients, the medical physicist should check the calibration of the radiation therapy and should verify that it has not changed, particularly in the event of a timer error in ^{60}Co teletherapy units.

5.314. Actions should be performed only by personnel that are knowledgeable and trained in the response actions and have regularly participated in drills and exercises.

5.315. After the necessary response actions have been implemented, 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 should check the machine for re-use after the engineer has completed the inspection and any associated maintenance.
(c) The RPO should assess the doses to personnel involved in response to the event and recovery.

(d) A record should be kept of all actions.
(e) The regulatory body may need to be notified, depending on the State's regulations.
(f) Information should be sent to an international safety learning system such as SAFRON or ROSEIS or a national learning system.
(g) Medical attention, as necessary, should be provided to those involved, commensurate with the doses received [7, 8].

Stuck sources: Remote control brachytherapy units

5.316. The emergency plan should 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 5.135 and 5.137. The emergency container should be placed close to the patient and should be sufficiently large to accept the entire applicator assembly containing the source that has been removed from the patient. Staff should be trained on how to apply such a procedure and should regularly participate in drills and exercises.

5.317. In HDR applications, the short response time (minutes) required for contingency actions 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 emergency procedures and actions.

5.318. Manufacturers usually provide suggested emergency procedures if the source fails to return to the safe. Such procedures 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 stated in para. 5.136.

5.319. After the necessary response actions have been implemented, 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 should check the machine for re-use after the engineer has completed the inspection and any associated maintenance.
(c) The RPO should make an assessment of the dose to personnel involved in response and recovery.

(d) The assessments should be recorded.
(e) The regulatory body may need to be notified, depending on the State's regulations.
(f) Information should be sent to an international safety learning system such as SAFRON or ROSEIS or a national learning system.
(g) Medical attention, as necessary, should be provided to those involved, commensurate with the doses received [7, 8].

Incidents and accidents during source replacement

5.320. Only trained and authorized maintenance or servicing personnel should deal with accidents during a change of a source in external beam radiotherapy or 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

5.321. Although ^{226}Ra has been removed from most radiation therapy facilities, encapsulated ^{137}Cs 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 all individuals who were in the area should be surveyed, and decontaminated if necessary. Windows should be closed and other ventilation systems should be turned off. The RPO should be contacted immediately once the possibility of contamination is suspected. Contact details for the RPO should be posted throughout the radiation therapy facility.

Lost radiation therapy sources

5.322. 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 source is missing, its type and activity, its last known location, and who was last in possession of it. The area where the sources were last known to be should be closed to entry and exit until after a survey has been conducted. This search should be performed with the most sensitive radiation survey meter available.

5.323. If a source cannot be located and it is suspected that it is off the site, the relevant authorities should be notified and immediate actions should be taken in accordance with GSR Part 7 [7] and GS-G-2.1 [9].

SAFETY IN THE TRANSPORT OF RADIOACTIVE MATERIAL

5.324. Paragraph 2.25 of GSR Part 3 [3] establishes the requirements for the transport of radioactive material, invoking in particular SSR-6 (Rev. 1) [279]. SSR-6 (Rev. 1) [279] uses 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.

5.325. The licensee of a radiation therapy facility may be both a consignee and a consignor, and hence may have responsibilities for both the receipt and the shipment of radioactive sources, for example, sources for external beam radiotherapy and brachytherapy.

5.326. 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 established in SSR-6 (Rev. 1) [279]. Emergency arrangements for the transport of radioactive material should be put in place, in line with the requirements of GSR Part 7 [7] and the guidelines of the regulatory body. The licensee and the RPO of the radiation therapy facility should be familiar with these regulations to ensure that the transport of radioactive material for which they are responsible complies with the regulations.

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 the use of radiation in diagnostic radiology and image guided interventional procedures that have been identified from previously reported incidents include the following:

(a) Equipment not meeting IEC or equivalent national standards;
(b) Maintenance errors;
(c) Errors in the identification of patients and examination sites;
(d) Inappropriate examination protocols or a lack of examination protocols.

I.2. Factors that may influence the frequency and severity of accidental exposures include the following:

(a) Insufficient training and expertise of radiological medical practitioners (in particular interventionists), medical physicists or medical radiation technologists, in the following areas:
   — Lack of knowledge about the equipment being used and its features and options;
   — Lack of knowledge about the optimization of protection and safety for patients;
   — Lack of knowledge about the optimization of protection and safety for staff.
(b) No reassessment of staffing requirements after the purchase of new equipment or an increase in workload.
(c) Inadequate quality assurance and lack of defence in depth, as follows:
   — Dose rates for interventional equipment set too high;
   — AEC malfunction.
(d) Lack of a programme for acceptance tests and commissioning of equipment.
(e) Lack of a maintenance programme.
(f) Poor, misunderstood or violated procedures.
(g) Lack of operating documents in a language understandable to users.
(h) Dose display or dose rate display not used during a procedure.
(i) Lack of dose alerts if selected factors seem inappropriate.

(j) Lack of radiation protection tools and devices in the examination room.
(k) Misunderstanding of displays or software messages.
(l) Inattention of staff to the task at hand.
(m) 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 follows:

(a) Lack of commitment of the licensee (administrators and managers of the medical facility and/or the radiology facility);
(b) Staff insufficiently trained;
(c) Insufficient quality assurance.

NUCLEAR MEDICINE

I.4. Problems that lead to accidental exposures associated with the use of radiation in nuclear medicine that have been identified from previously reported incidents include the following:

(a) Communication errors, faulty transmission of information, misunderstanding of prescriptions and protocols, or use of obsolete protocols;
(b) Errors in the identification of the patient;
(c) Use of the wrong source, the wrong radiopharmaceutical or the wrong activity;
(d) Calibration errors;
(e) Maintenance errors.

I.5. Factors that may influence the frequency and severity of accidental exposures include the following:

(a) Insufficient training and expertise of radiological medical practitioners (nuclear medicine physicians), medical physicists or medical radiation technologists (nuclear medicine technologists);
(b) No reassessment of staffing requirements after the purchase of new equipment, the hiring of new medical radiation technologists or an increase in workload;
(c) Inadequate quality assurance and lack of defence in depth;
(d) Lack of a programme for acceptance tests and commissioning of equipment;
(e) Lack of a maintenance programme;
(f) Poor, misunderstood or violated procedures;

(g) Lack of operating documents in a language understandable to users;
(h) Misunderstanding of displays or software messages;
(i) Inattention of staff to the task at hand;
(j) 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 follows:

(a) Lack of commitment of the licensee (administrators and managers of the medical facility and/or the nuclear medicine facility);
(b) Staff insufficiently briefed or trained;
(c) Insufficient quality assurance.

RADIATION THERAPY

I.7. Problems that lead to accidental exposures associated with using radiation in radiation therapy that have been identified from previously reported incidents include the following:

(a) External beam radiotherapy 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 that were still accessible.
(b) External beam radiotherapy:
  — Errors in acceptance tests and commissioning or lack of tests of 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.
(c) Brachytherapy:
  — Use of an incorrect source, incorrect source applicator or incorrect units of source strength;
  — Dislodging of HDR/PDR brachytherapy sources;
  — Mistakes in source handling during brachytherapy treatment;
  — Leakage or rupture of sealed source encapsulation;

— Sources left in patients and loss of radiation sources;
— Movement of the applicator during treatment.

I.8. The following contributing factors allowed these errors to remain undetected until they became accidental medical exposures:

(a) Insufficient education of the radiological medical practitioner (radiation oncologist), medical physicist, medical radiation technologist (radiotherapy technologist), maintenance engineers and brachytherapy nurses;
(b) Overloaded staff when new equipment was purchased or workload increased;
(c) Insufficient quality assurance and lack of independent checks for safety critical activities, such as beam calibration;
(d) Lack of a programme for acceptance testing and commissioning;
(e) Lack of a maintenance programme;
(f) Poor, misunderstood or violated procedures;
(g) Lack of operating documents in a language understandable to the users;
(h) Inattention of staff to the task at hand (work in an environment in which staff were prone to distraction);
(i) Inconsistent use of quantities and units.

I.9. In most accidental exposures, there was a combination of several contributing factors, which can be summarized as follows:

(a) Lack of commitment of the licensee (administrators and managers of the medical facility and/or the radiation therapy facility);
(b) Insufficiently educated or trained staff;
(c) 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 becoming pregnant following radiopharmaceutical therapy with long lived radionuclides are given in Table 2, adapted with modifications from Ref. [238].

TABLE 2. RECOMMENDATIONS FOR AVOIDANCE OF PREGNANCY FOLLOWING RADIOPHARMACEUTICAL THERAPY

Nuclide and form	Disease	All activities up to[a] (MBq)	Avoid pregnancy (months)
^{32}P phosphate	Polycythaemia and related disorders	200	3
^{89}Sr chloride	Bone metastases	150	24
^{90}Y colloid	Arthritic joints	400	0
^{90}Y antibody or ^{90}Y-octreotide	Cancer	4000	1
^{131}I iodide	Benign thyroid disease	800	6–12
^{131}I iodide	Thyroid cancer	6000	6–12
^{131}I MIBG[b]	Malignancy	7500	3
^{153}Sm colloid	Bone metastases	2600	1
^{169}Er colloid	Arthritic joints	400	0

[a] The administration of activities smaller than those indicated in column 3 does not imply that the advisory period specified in column 4 can be reduced.

[b] Metaiodobenzylguanidine.

Appendix III

CESSATION OF BREAST-FEEDING

III.1. Recommendations for cessation of breast-feeding following administration of various radiopharmaceuticals are given in Table 3, adapted from the recommendations of Refs [235, 236, 238, 259]. A conservative approach is applied in cases in which recommendations in literature differ.

III.2. The advice on breast-feeding interruption takes into account both internal exposure from breast milk and external exposure of the infant from the mother. The milk expressed during the interruption period should be discharged.

III.3. For radiopharmaceuticals not included in the Table 3, the period of interruption of breast-feeding should continue until the radiopharmaceutical is no longer secreted in an amount estimated to give an effective dose greater than 1 mSv to the child [259].

TABLE 3. RECOMMENDATIONS FOR CESSATION OF BREAST-FEEDING FOLLOWING ADMINISTRATION OF RADIOPHARMACEUTICALS

Radiopharmaceutical	Most common clinical use	Typical administered activity (MBq)	Feeding interruption time
^{11}C labelled	Tumour, brain or myocardial imaging	Any	No
^{13}N labelled	Myocardial imaging	Any	No
^{15}O labelled	Flow/perfusion measurements	Any	No
^{18}F-FDG	Tumour and infection imaging	400	4 h[a]
^{51}Cr-EDTA	GFR	2	No
^{67}Ga-citrate	Tumour and infection imaging	200	>3 weeks or complete cessation
^{68}Ga-DOTA-conjugated peptides	Tumour imaging	100–200	4 h[a]
^{99m}Tc-DMSA	Renal cortical imaging	80–200	4 h[b]
^{99m}Tc-DTPA	Renal imaging and function (GFR)	40–400	4 h[b]
^{99m}Tc-ECD	Brain perfusion	800	4 h[b]
^{99m}Tc-HMPAO	Brain perfusion	500	4 h[b]
^{99m}Tc-MDP and other phosphate agents (e.g. HDP and DPD)	Bone scan	800	4 h[b]
^{99m}Tc-MIBI	Myocardial perfusion, parathyroid scanning	250–700	4 h[b]
^{99m}Tc-tetrofosmin	Myocardial perfusion	250–700	4 h[b]
^{99m}Tc-SC	Liver scan	200–400	4 h[b]
^{99m}Tc-DTPA aerosol	Lung ventilation imaging and function	50	4 h[b]

TABLE 3. RECOMMENDATIONS FOR CESSATION OF BREAST-FEEDING FOLLOWING ADMINISTRATION OF RADIOPHARMACEUTICALS (cont.)

Radiopharmaceutical	Most common clinical use	Typical administered activity (MBq)	Feeding interruption time
^{99m}Tc labelled carbon (Technegas)	Lung ventilation imaging	40	4 h[b]
^{99m}Tc-MAG3	Imaging and function of kidneys and urinary tract	40–400	4 h[b]
^{99m}Tc-pertechnetate	Thyroid scan, Meckel's diverticulum	100–400	12 h[c]
^{99m}Tc-MAA	Lung perfusion imaging	40–150	12 h
^{99m}Tc-exametazime WBC	Infection imaging	180–400	12 h
^{99m}Tc labelled RBC	Radionuclide ventriculography	800	12 h
^{99m}Tc-mebrofenin/ disofenin and other IDA derivatives	Hepatobiliary imaging and function	300	4 h[b]
^{99m}Tc human albumin nanocolloidal particles	Sentinel nodes Liver scanning	5–120 120–200	4 h[b] 4 h[b]
^{111}In-octreotide	Neuroendocrine tumours (somatostatine receptor scintigraphy)	100–200	60 h (2.5 d)
^{123}I-MIBG	Neuroblastoma imaging	400	>3 weeks or complete cessation[d]
^{123}I-NaI	Thyroid imaging and function	20	>3 weeks or complete cessation[d]
^{123}I-ioflupane (FP-CIT)	Dopaminergic neurotransmission (D1) in movement disorders	150–250	>3 weeks or complete cessation[d]
^{123}I-hippurate	Imaging and function of kidneys and urinary tract	20–40	12 h[e]

TABLE 3. RECOMMENDATIONS FOR CESSATION OF BREAST-FEEDING FOLLOWING ADMINISTRATION OF RADIOPHARMACEUTICALS (cont.)

Radiopharmaceutical	Most common clinical use	Typical administered activity (MBq)	Feeding interruption time
^{131}I-NaI	Diagnostic and therapy of benign and malignant thyroid diseases	Any	Complete cessation[f]
^{131}I-MIBG	Adrenal tumour imaging and therapy	Any	>3 weeks or complete cessation
^{201}Tl-chloride	Myocardial perfusion	100	96 h (4 d)

Note: DMSA — dimercaptosuccinic acid; DPD — dicarboxypropane diphosphonate; DTPA — diethylenetriaminepentaacetic acid; ECD — ethyl cysteinate dimer; EDTA — ethylene diamine tetraacetic acid; FDG — fluorodeoxyglucose; GFR — glomerular filtration rate; HDP — hydroxymethane diphosphonate; HMPAO — hexamethylpropyleneamine oxime; IDA — iminodiacetic acid; MAA — macroaggregate of albumin; MAG3 — mercaptoacetyltriglycine; MDP — methylene diphosphonate; MIBG — metaiodobenzylguanidine; MIBI — methoxyisobutylisonitrile; RBC — red blood cells; SC — sulphur colloid; WBC — white blood cells.

[a] The interruption time of 4 h during which one meal should be discharged takes into account both internal exposure from breast milk and external exposure of the infant from the mother.

[b] The interruption time of 4 h during which one meal should be discharged takes into account both internal exposure from breast milk in those unusual situations when free pertechnetate is not negligible, and external exposure of the infant from the mother.

[c] Activities of ^{99m}Tc-pertechnetate higher than 400 MBq require an interruption time of 24 h.

[d] The recommended interruption time of at least 3 weeks for all substances labelled with ^{123}I (except iodohippurate) is due to the risk of presence of impurities of other iodine isotopes (^{124}I or ^{125}I).

[e] The interruption time of 12 h only concerns patients with normal renal function.

[f] Patients should discontinue breast-feeding 6 weeks before radioiodine administration in order to minimize the radiation dose to the breast.

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ABBREVIATIONS

ABC	automatic brightness control
ADRC	automatic dose rate control
AEC	automatic exposure control
CBCT	cone beam computed tomography
CPOE	computerized physician order entry
CR	computed radiography
CT	computed tomography
DICOM	Digital Imaging and Communication in Medicine
DR	digital radiography
DRL	diagnostic reference level
DXA	dual energy X ray absorptiometry
EPID	electronic portal imaging device
FDG	fluorodeoxyglucose
HDR	high dose rate
HIS	hospital information system
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
IEC	International Electrotechnical Commission
IGRT	image guided radiation therapy
IMRT	intensity modulated radiation therapy
IORT	intraoperative radiotherapy
ISO	International Organization for Standardization
kV	kilovoltage
LDR	low dose rate
linac	linear accelerator
MDR	medium dose rate
MRI	magnetic resonance imaging
MV	megavoltage
PACS	picture archiving and communication system
PDR	pulsed dose rate
PET	positron emission tomography
RIS	radiology information system
ROSEIS	Radiation Oncology Safety Education and Information System
RPO	radiation protection officer
SAFRAD	Safety in Radiological Procedures
SAFRON	Safety in Radiation Oncology

SBRT	stereotactic body radiotherapy
SPECT	single photon emission computed tomography
SRS	stereotactic radiosurgery
SRT	stereotactic radiotherapy
TPS	treatment planning system
VMAT	volumetric modulated arc therapy

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