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 centers, 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 ofradiation 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. 3.145of 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 program 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 wouldbe 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 thework, this nurse should be provided with the same level of protection as membersof the public (see para. 3.78 of GSR Part 3 [3]). The term 'carer and comforter' isdefined 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 program 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 program 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 programs of quality assurance. These are described indetail 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 program 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 energyX ray absorptiometry, DXA). At the high risk end is radiation therapy, wherethe 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 program that is as comprehensive as the program 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 toprotection 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.

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[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 protocolsor image post-processing become available. A new national or regional survey will result in a new distribution of facility typical doses, which will reflectthe 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 pediatric 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. 4.205for 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.

[6] See www.eu-alara.net/index.php/surveys-mainmenu-53/36-ean-surveys/156-drls.html
[7] See www.arpansa.gov.au/research-and-expertise/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 pediatric 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 pediatric 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, whowill 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, thisrole 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 exposurearising from a single facility at some fraction of the dose limit. Some Statesuse 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 program 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 program of biomedical research under consideration. Typical patient doses and nationalDRLs 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 whohas 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, authorizationfor 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 notedin 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 authorityand 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 programs;

(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 program.

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 program involves subjecting asymptomatic populations to radiation exposure. The decision to embark upon such a program 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 programs. 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 program, is now increasingly common. Such radiological procedures are not established medical practice, nor are they performed as part of a programof 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, orthopedic 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 releaseof patients after radionuclide therapy, as is described in paras 2.42, 2.47–2.50and 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 program of quality assurance for medical exposure is required. Such programs should be part of the wider management system of the medical radiation facility (see para. 2.140). Nonetheless, there is considerable benefitin making use of resource material and standards established by professional bodies for particular areas of the program of quality assurance. For example, many medical physics professional bodies have developed detailed guidance on performance testing aspects of a program 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, RegulatoryControl 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 SeriesNos 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 registrationmay 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 authorityto carry out medicine practice and health care (see para. 2.52). Meeting radiationsafety 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 describedin 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 andshould 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 guidanceon which events should be reported to them. One of the reasons for reportingto 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 theregulatory 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 exposurein a given specialty. Health professionals that could take on the role of the radiological medical practitioner, depending on the particular use of radiationand on the laws and regulations in a State, include radiologists, nuclear medicinephysicians, radiation oncologists, cardiologists, orthopedic 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 isa 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 andcare 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 practice independently in one or more of the subfields (specialties) of medical physics (e.g. diagnostic radiology, radiationtherapy 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 program 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 requirementsfor 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 program 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 program of biomedical research (para. 3.161 of GSR Part 3 [3]). Thefirst part of this responsibility is to decide whether to approve the program of biomedical research, including the proposed use of radiation. The use of radiation in a program 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 biochemicalprocesses 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 assessedby 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 program.

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 program of biomedical research. Such dose constraints would be guidedby nationally or regionally established dose constraints (see para. 2.50). Dose constraints should be adjusted to the expected benefit of the program 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 programs 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 program 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 program 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 program of biomedical research are justified only if that program 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 isnot 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 inRefs [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 license 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 registrantor 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 license 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 whetheran 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 isneeded, 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 ensuingjustification.

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 outthat 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 mechanismshould assess the education, training and competence of an individual proposed by a licensee to act as a specialized health professional and to decide, on thebasis either of international standards or standards of a State where such a systemexists, 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 numberof 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 protectionand 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 todate 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 authorityand 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 orthopedic surgery and cardiology, havealso 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 criteriaon 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 program of education and training in medical radiationtechnology usually includes significant components of radiation protection (patient protection and occupational protection). On completion of the program, the medical radiation technologist would typically become registered with the national registration board (or a body with a similar function), and hisor her competence in medical radiation technology should include competence inradiation 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 program 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 program of education and training does not necessarily confer competence. For example, the diagnostic radiology program in a State might not cover CT or image guided interventional procedures to the depth needed for competence. Additional education and training should be arrangedto 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 sub specialization 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 Labor 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 competencein medical physics, with academic training in medical physics at a university (typically a postgraduate program), 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 imageguided 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 stilltake 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 isnot 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 givenin 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 program.

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 Labor 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 theirown 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 license may be required to perform servicing and a prerequisite to obtaining such a license 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 programs. In many States, the professional bodies administer such programs, and maintenance of certification of competence in a specialty is dependent on satisfactory participation in the program. Registrants, licensees and the regulatory body can use these programs 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 managementstructure 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 program", in general, and Requirement 24 ofGSR Part 3 [3] establishes arrangements under a "radiation protection program" specifically for occupational exposure. In addition, paras 3.170–3.172 of GSR Part 3 [3] establish requirements for a "comprehensive program ofquality assurance for medical exposures". All three of these programs should be part of the overall management system of the medical radiation facility. Detailed guidance on the radiation protection program for occupational exposure and the program of quality assurance for medical exposures is givenin Sections 3–5.

[15] The medical radiation facility may be a 'stand alone' entity, such as a medical imaging center, 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 ofthe 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 program. 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 ofthe radiation protection program and should report to the radiation safety committee. The licensee should ensure that the RPO is provided with the resources required to oversee the program, as well as the authority to communicate with the committee on a periodic basis. The RPO should be able tocommunicate 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 program of quality assurance for medical exposures within the medical radiation facility. The committee would determine policy and give direction to the program, ensure proper documentation is being maintained and review the effectiveness of the program. The radiation safety committee and the quality assurance committee have some functions in common, especiallywith regard to medical exposure, and the representation of health professionals oneach is likely to be the same. The work of both committees should be harmonizedto 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 havea 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, withits 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 www.dicomstandard.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 isthe 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 careon the outcome and quality of life for the patient. A clinical audit looks beyonda 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 aspectsof 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 investigationand 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 onwhat 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 andthe 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 inGSR Part 7 [7], GSG-2 [8] and GS-G-2.1 [9].