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

GENERAL

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

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

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

3.4. During image guided interventional procedures, fluoroscopy (primarily) or CT is used as an imaging tool to facilitate the diagnosis and treatment of vascular and non-vascular diseases. Examples of vascular procedures include coronary angiography or angioplasty, uterine artery embolization, aortic valve

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

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

3.6. Different health professionals can take on the role of the radiologicalmedical practitioner (see para. 2.90) in diagnostic radiology and image guided interventional procedures, depending, inter alia, on national laws and regulations. They typically include radiologists, cardiologists, orthopedic surgeons, neurosurgeons, plastic surgeons, vascular surgeons, gastroenterologists, urologists, respiratory and other specialist physicians and surgeons, dentists, chiropractors, osteopaths and podiatrists.

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

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

SAFETY OF MEDICAL RADIATION FACILITIES AND MEDICAL RADIOLOGICAL EQUIPMENT

Radiology facilities

Fixed facilities: Design of X ray rooms

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

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

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

3.12. At the design stage, the use of both structural and ancillary protective barriers to provide shielding should be considered. In rooms using fluoroscopy with staff working close to the patients, such as rooms for image guided interventional procedures, ceiling mounted protective screens and table mounted leaded curtains should be installed. Such ancillary protective barriers for image

guided interventional procedures should be part of the initial facility plan, and should be designed so as not to interfere with the medical procedure (e.g. sterility requirements). Wall shielding should be at least 2 m high, and any doors and viewing windows in walls or doors should have at least the same lead equivalence as the minimum shielding specifications for the shielded wall or barrier in which they are located. Due consideration should be given to the provision of floor and ceiling shielding when rooms immediately below and above the X ray installation are occupied. All penetrations and joints in shielding should be arranged so that they are equally as effective in shielding radiation. More details with respect to structural shielding are given in paras 3.18–3.24.

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

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

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

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

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

Mobile facilities

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

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

Shielding calculations

3.18. Two widely used methodologies for shielding calculations are givenin Refs [57, 58], but other methodologies are also available and used (e.g. see Refs [55, 59]), as well as specific shielding calculations for the WHIS-RADX ray unit[19] [60]. The nominal design dose in an occupied area is derived bythe process of constrained optimization (i.e. selection of a source related dose constraint), with the condition that each individual dose from all relevant sources is well below the dose limit for a person occupying the area to be shielded. Nominal design doses are levels of air kerma used in the design calculations and evaluation of barriers for the protection of individuals, at a reference point beyond the barrier. Specifications for shielding are calculated on the basis of the attenuation that the shielding needs to provide to ensure that the nominal design doses are met.

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

(a) The dose that would be received without shielding is calculated by using workload values, use factors for a given beam direction (the fraction of the total amount of radiation emitted in that direction) and occupancy factors (the fraction of the total exposure that will actually affect individuals at a place, by virtue of the time spent by an individual in that place). For secondary barriers, the use factor is always unity, since scatter and leakage radiation is propagated in all directions all the time. If tabulated figures are used, care should be taken that they reflect the actual usage in the facility and not generic national scenarios. Potential changes in practice andincreases in workload should be considered as part of the calculations.
(b) Once the dose that would be received without shielding is known, attenuation should be calculated to reduce this dose to a design level that meets national regulations and that can be considered optimized protection; that is, a dose below which additional cost and effort in shielding isnot warranted by the dose being averted. This may require successive calculations to determine where this level lies.

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

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

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

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

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

3.23. Specification of shielding, including calculations, should be performed by a medical physicist or a qualified expert in radiation protection. In some States, there may be a requirement for shielding plans to be submitted to the regulatory body for review or approval prior to any construction (see also para. 2.74).

3.24. The adequacy of the shielding should be verified, preferably during construction, and certainly before the room is placed in clinical use, and similarly after any future structural modifications. Clearly, requirements of the regulatory body should be met (para. 2.74).

Design of display and interpretation (reading) rooms

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

3.26. Viewing rooms with workstations for viewing digital images should be ergonomically designed to facilitate image processing and manipulation so that reporting can be performed accurately. The viewing monitors of the workstations should meet applicable standards (see para. 3.46).

Medical radiological equipment, software and ancillary equipment

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

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

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

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

3.30. Displays, gauges and instructions on operating consoles of medical radiological equipment, and accompanying instruction and safety manuals, might be used by staff who do not understand, or who have a poor understanding of, the manufacturer's original language. In such cases, the accompanying documents should comply with IEC and ISO standards and should be translated into the local language or into a language acceptable to the local staff. The software should be designed so that it can be easily converted into the local language, resulting in displays, symbols and instructions that will be understood by the staff. The translations should be subject to a quality assurance process to ensure proper understanding and to avoid operating errors. The same applies to maintenance and service manuals and instructions for maintenance and service engineers and technicians who do not have an adequate understanding of the original language (see also paras 2.104 and 2.137).

3.31. All medical radiological equipment should be supplied with all appropriate radiation protection tools as a default rather than as optional extras. This applies to both patient radiation protection and occupational radiation protection (see also para. 2.105).

Design features for medical radiological equipment

3.32. The design of medical radiological equipment should be such that its performance is always reproducible, accurate and predictable, and that it has features that facilitate the appropriate personnel in meeting the requirementof para. 3.163(b) of GSR Part 3 [3] for operational optimization of patient protection, namely that it provides "Appropriate techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfil the clinical purpose of the radiological procedure, with account taken of relevant norms of acceptable image quality…." Many design features contribute to the

performance of medical radiological equipment and should be considered when purchasing such equipment (see paras 3.33–3.41). Further details on design features and performance standards of medical radiological equipment usedin diagnostic radiology and image guided interventional procedures are givenin Refs [67–74, 76, 78–83, 98–108] (see also paras 3.232–3.246 on quality assurance and acceptance testing, in particular para. 3.236).

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

(a) Means to detect immediately any malfunction of a single component of the system that may lead to an inadvertent underexposure or overexposure of the patient or exposure of staff so that the risk of any unintended or accidental medical exposure is minimized.
(b) Means to minimize the frequency of human error and its impact on the delivery of unintended or accidental medical exposure.
(c) Hardware and software controls that minimize the likelihood of unintended or accidental medical exposures.
(d) Operating parameters for radiation generators, such as the generating tube potential, filtration, focal spot position and size, source to image receptor distance, field size indication and either tube current and time or their product, that are clearly and accurately shown.
(e) Radiation beam control mechanisms, including devices that indicate clearly (visually and/or audibly) and in a fail-safe manner when the beam is on.
(f) X ray tubes with inherent and added filtration adequate to remove low energy components of the X ray beam which do not provide diagnostic information.
(g) Collimating devices to define the radiation beam; in the case of a light beam diaphragm, the light field should align with the radiation field.
(h) With the exception of mammography, dental X ray and CT equipment, diagnostic and interventional X ray equipment that is fitted with continuously adjustable beam collimating devices. Such devices allow the operator[20] to limit the area being imaged to the size of the selected image receptor or the region of interest, whichever is the smaller.
(i) When preset protocols are provided, technique factors that are readily accessible and modifiable by adequately trained personnel.

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

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

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

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

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

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

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

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

(b) Console display of estimated volume CT air kerma index and CT air kerma–length product for the procedure or image acquisition;
(c) Operator alert if exposure factors are set too high (usually expressed in terms of the volume CT air kerma index and/or the CT air kerma–length product);
(d) Means for dose modulation (rotational and z-axis), and means for selection of noise index or equivalent;
(e) A comprehensive range of beam widths and pitches and other ancillary devices (e.g. dynamic collimation) to ensure 'over ranging' in CT is kept as low as reasonably achievable by facilitating the appropriate choice of beam width and pitch to limit patient dose while maintaining diagnostic image quality;
(f) Reconstruction algorithms that result in dose reduction without compromising image quality, such as iterative reconstruction algorithms;
(g) A range of selectable tube potentials, tube current–exposure time products, and filters to facilitate the optimization of protocols, especially for children.

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

(a) Various anode and filter combinations;
(b) Compression and immobilization capabilities;
(c) Magnification views;
(d) Display on the console of a dose index, for example incident air kerma or mean glandular dose;
(e) An image receptor or image receptors to accommodate all breast sizes.

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

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

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

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

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

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

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

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

3.41. For medical radiological equipment used for performing diagnostic and interventional radiology procedures on children, there should be additional design features that both facilitate successful radiological procedures on patients who may be uncooperative and suit the imaging of very small patients. Such features include the following:

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

Other equipment

3.42. For radiology facilities where film is being used as an image receptor, film processing plays a crucial role in ensuring the medical exposure results in an acceptable diagnostic image. Automatic film processors should meet appropriate standards. Film–screen based mammography should have dedicated film processors with extended processing cycles. If manual processing is being performed, specially designed developer, fixer and washing tanks should beused, with processing times based on the developer temperature. The darkroom for processing should meet relevant international and national standards forlight tightness and should be equipped with an appropriately filtered safe-light,

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

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

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

3.45. View boxes, for viewing films, should have sufficient uniform brightness to facilitate diagnosis, and the color of view boxes should be matched through the complete set of view boxes. Means should be available (masks) to restrictthe illuminated area of the radiograph to avoid dazzling. View boxes used for mammography should have higher luminance. Detailed guidance is given in Refs [109–114] (see paras 3.25 and 3.26 for guidance on display and interpretation rooms).

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

Maintenance

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

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

3.49. In line with the guidance provided in para. 2.113, after any modifications or maintenance, the person responsible for maintenance should immediately inform the licensee of the medical radiation facility before the equipment is returned to clinical use. The person responsible for the use of the equipment, in conjunction with the medical physicist, the medical radiation technologist and other appropriate professionals, should decide whether quality control tests are needed with regard to radiation protection, including image quality, and whether changes to protocols are needed.

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

OCCUPATIONAL RADIATION PROTECTION

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

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

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

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

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

3.55. This subsection contains guidance very specific to diagnostic radiology and image guided interventional procedures. More general and comprehensive guidance on occupational radiation protection is given in GSG-7 [23], including guidance on radiation protection programs, assessment of occupational exposure and providers of dosimetry services, applicable to all areas of radiation use (including non-medical uses).

Arrangements under the radiation protection program

Classification of areas

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

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

3.58. Supervised areas may involve areas surrounding X ray rooms. A typical design of a radiology department includes two basic areas: one for patient circulation, which includes the reception, waiting rooms and corridors from which the X ray rooms can be accessed through the dressing cabinets; and another for staff circulation, which includes dark rooms, film and workstation reading rooms and internal corridors. Most of the staff area may be classified asa supervised area, not primarily because of the exposure level, which can be keptvery low, but rather as a ‘buffer zone’ owing to the potential for other individualsto enter the X ray rooms inadvertently and be exposed.

3.59. The control console may be inside the X ray room, separated by structural shielding, or outside the X ray room in the staff area, with visual control of the X ray room and with patient communication. Access of unauthorized individuals to control console areas should be restricted to avoid the distraction of the operator, which might lead to unnecessary or repeated exposures. Control panel areas are not in the public domain and therefore should be classified as either controlled areas or supervised areas.

Local rules and procedures

3.60. Paragraph 3.93 of GSR Part 3 [3] establishes a hierarchy of preventive measures for protection and safety with engineered controls, including structured and ancillary shielding, being supported by administrative controls and personal protective equipment. To this end, and as established in para. 3.94 of GSR Part 3 [3], local rules and procedures are required to be established in writing in any radiology facility. Their purpose is to ensure protection and safetyfor workers and other persons. Such local rules and procedures should include measures to minimize occupational radiation exposure both for normal work andin unusual events. The local rules and procedures should also cover the wearing, handling and storing of personal dosimeters, and should specify investigation levels and ensuing follow-up actions (see paras 3.104–3.129).

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

3.62. Equipment (both hardware and software) should be operated in a manner that ensures satisfactory performance at all times with respect to both the tasks to be accomplished and radiation protection and safety. The manufacturer's operating manual is an important resource in this respect, but additional procedures are likely to be needed. The final documented set of operational procedures should be subject to approval by the licensee of the radiology facility, and should be incorporated into the facility's management system (see paras 2.138–2.149).

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

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

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

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

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

3.67. Immobilization devices (e.g. a CT head cradle) should be used whenever possible and as appropriate to minimize exposure of the patient, the staff member or the carer or comforter. Immobilization of patients should not be performed by staff and, if possible, not by any person. If immobilization requires the use of a person, then this should be someone such as a relative of the patient who has agreed to be a carer or comforter and is afforded radiation protection accordingly (see paras 3.247–3.251).

3.68. For general radiography:

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

3.69. For mobile radiography:

(a) Operators should wear lead aprons and should maintain as much distance as possible between themselves and the patient (to minimize exposure to scatter radiation), whilst still maintaining good visual supervision of the patient and being able to communicate verbally with him or her.
(b) Other staff (e.g. nursing, medical and ancillary staff) are not considered as occupationally exposed workers and hence should be afforded protection as a member of the public. This is achieved by ensuring such persons are as far away from the patient as possible during the exposure (typically at least3 m) or are behind appropriate barriers.

(c) In situations in which a member of staff needs to be close to the patient, protective aprons should be worn (e.g. an anesthetist with a ventilated patient or a nurse with an unstable patient).
(d) Verbal warning of an imminent exposure should be given.
(e) Consideration should be given to other patients nearby (see also para. 3.276 on public radiation protection).

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

(a) Lead aprons should be worn by staff members who need to be adjacent to the patient being exposed.
(b) The primary beam should be directed away from staff and other patients whenever possible.
(c) Staff should keep as far away as possible from the patient during exposure, whilst still maintaining good visual supervision of the patient.
(d) Where available, mobile shields should be used.
(e) Any pregnant staff member (other than radiology staff) should be asked by the medical radiation technologist to leave the vicinity during exposure.
(f) Verbal warning of imminent exposure should be given.

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

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

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

(a) The staff member performing the procedure should use personal protective equipment (a protective apron, a thyroid shield, protective eyewear and

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

(b) In the case of persons providing medical support (e.g. anesthetists), a protective apron should be worn and the person should position themselves as far from the patient as possible during exposure.

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

(a) The staff member performing the procedure should use personal protective equipment (a protective apron, a thyroid shield, protective eyewear and gloves). In addition, care should be exercised to avoid the placing of hands in the primary beam and immediate notification to the fluoroscopist should be given if this happens.
(b) Only essential staff should remain in the room. All such staff are considered occupationally exposed workers.
(c) In situations in which a member of staff needs to be close to the patient, protective aprons should be worn (e.g. an anesthetist with a ventilated patient or a nurse with an unstable patient). At no time should a pregnant staff member take on this role.

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

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

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

(a) Personal protective equipment is not usually needed. Radiation protection is afforded through the use of distance from the patient. Typically, a distance of at least 2 m is recommended.
(b) The operator should not hold the image receptor during the exposure.
(c) Handheld portable X ray equipment for intraoral radiography should be used only for examinations where it is impractical or not medically acceptable to transfer patients to a fixed unit or to use a mobile unit (e.g. in nursing homes, residential care facilities or homes for persons with

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

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

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

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

Specific local rules and procedures for image guided interventional procedures

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

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

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

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

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

3.83. There are many operational factors that affect patient dose during image guided interventional procedures, and these factors in turn affect staff dose because the dose to the patient determines the amount of scatter radiation being produced. Methods to reduce patient dose are described in paras 3.189–3.195, and should always be used to reduce both patient and staff doses.

3.84. Medical radiological equipment specifically designed for image guided interventional procedures often incorporates protective devices, such as ceiling suspended, lead acrylic viewing screens, and under-table and lateral shielding attachments to the X ray couch, and personal mobile shields. Alternatively,such devices can be purchased separately. These devices can afford individuals significant degree of radiation protection, but they can sometimes be cumbersome to use. However, the appropriate use of these devices will result in a significant reduction in staff doses.

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

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

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

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

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

Personal and in-room protective devices

3.89. Paragraphs 3.93 and 3.95 of GSR Part 3 [3] require that personal protective equipment and in-room protective devices be available and used when structural shielding and administrative controls alone cannot afford the required level of occupational radiation protection. This typically arises when staff are required to be in the room during radiological procedures, such as with image guided interventional procedures and fluoroscopy, and with mobile radiography. The need for this protective equipment should be established by the RPO or the medical physicist at the radiology facility.

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

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

(a) From the neck down to at least 10 cm below the knees;
(b) The entire breast bone (sternum) and shoulders;

(c) The sides of the body from not more than 10 cm below the armpits to at least halfway down the thighs;
(d) The back from the shoulders down to and including the buttocks.

3.92. Protective gloves are useful for protecting the hands near the beam, but can produce the opposite effect during fluoroscopy with ABC or ADRC when the hands enter the area covered by the sensor of the ABC or ADRC, because this would drive the exposure to higher levels for both the staff and the patient and would be ineffective in protecting the hands. Even if the fluoroscopy system operates without ABC or ADRC, leaded gloves can prolong the procedure because they do not afford the necessary tactile sensitivity and thus their value is questionable.

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

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

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

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

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

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

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

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

Workplace monitoring

3.100. Paragraphs 3.96–3.98 of GSR Part 3 [3] establish the requirements and responsibilities for workplace monitoring. Workplace monitoring comprises measurements made in the working environment and the interpretation of the results. Workplace monitoring serves several purposes, including routine monitoring, special monitoring for specific occasions, activities or tasks, and confirmatory monitoring to check assumptions made about exposure conditions. Workplace monitoring can be used to verify the occupational doses of personnel whose work involves exposure to predictable low levels of radiation. It is particularly important for staff members who are not individually monitored. Further general guidance on workplace monitoring is given in GSG-7 [23].

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

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

3.102. Workplace monitoring should be performed and documented as part of the radiology facility's radiation protection program. The radiology facility's RPO or medical physicist should provide specific advice on the workplacemonitoring program, including any investigations that are triggered when investigation levels are exceeded (see paras 3.121 and 3.122).

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

Assessment of occupational exposure and health surveillance for workers

Assessment of occupational exposure

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

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

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

taken to other facilities where that person may also work. For example, if a person is issued with a dosimeter at hospital A, it should be worn only at hospital A and not at any other hospitals or medical centers where he or she also works. Monitoring results can then be interpreted for the person working in a specific radiology facility, and this will allow appropriate review of the effectiveness of the optimization of protection and safety for that individual in that facility. However, national regulatory requirements may differ from this advice, and they would need to be followed in those jurisdictions in which they apply (see also paras 3.123–3.125).

3.107. The monitoring period (period of dosimeter deployment) specified by regulatory bodies in most States is typically in the range of one to three months. A one month monitoring period is usually used for persons performing procedures associated with higher occupational exposure, such as image guided interventional procedures. A longer monitoring period (two or three months) is more typical for personnel exposed to lower doses, as a one month cycle would usually mean that the actual occupational dose is less than the minimum detection level of the dosimeter, resulting in no detectable doses. With a longer cycle, it is more likely that a reading can be obtained. Dosimeters should be sent from the radiological facility to the dosimetry service provider, which should then process the dosimeters and return the dose reports, all in a timely manner. Some regulatory bodies may specify a performance criterion for timely reporting.

3.108. The operational dosimetric quantity used is the personal dose equivalent $H_p(d)$. For weakly penetrating radiation and strongly penetrating radiation, the recommended depths, d, are 0.07 mm and 10 mm, respectively. Radiation used in diagnostic radiology and image guided interventional procedures is usually relatively strongly penetrating, and therefore $d = 10$ mm for dosimeters being used to assess effective dose. $H_p(10)$ is used to provide an estimate of effective dose that avoids both underestimation and excessive overestimation [23].In diagnostic radiology and image guided interventional procedures, the overestimation is somewhat larger because of the lower photon penetration from X ray beams in the kV range [119, 120]. If a protective apron or thyroid shield is being worn, the relationship between $H_p(10)$ and effective dose becomes more complex; additional guidance is given in para. 3.115.

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

3.110. For monitoring the lens of the eye, a depth of 3 mm (d = 3) is recommended, and $H_p(3)$ is used to provide an estimate of equivalent dose to the lens of the eye. In practice, however, the use of $H_p(3)$ has not been widely implemented for routine individual monitoring. In cases where eye doses are a concern, such as in image guided interventional procedures, $H_p(0.07)$, and to a lesser extent $H_p(10)$, can be considered as an acceptable surrogate operational quantity (see Ref. [121] for further information).

3.111. There are three dose limits applicable to workers in diagnostic radiology and image guided interventional procedures: the limit for effective dose, and the limits for equivalent dose to the lens of the eye and to the skin and extremities. The dosimeter being worn will be used to estimate one or more of the quantities used for the dose limits. Depending on the work performed by the personbeing individually monitored, there may be a preferred position for wearingthe dosimeter, and more than one dosimeter may be used. For image guided interventional procedures, two dosimeters should be worn.

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

(a) If the monitored worker never wears a protective apron, the dosimeter should be worn on the front of the torso between the shoulders and the waist.
(b) If the monitored worker sometimes wears a protective apron, the dosimeter should be worn on the front of the torso between the shoulders and the waist, and under the apron when it is being worn.
(c) If the monitored worker always wears a protective apron, the dosimeter should be worn on the front of the torso at shoulder or collar level outside the apron (see also para. 3.113), except if national regulations require the dosimeter to be worn under the apron.
(d) If the working situation is such that the radiation always or predominantly comes from one side of the person, such as in image guided interventional procedures, the dosimeter should be placed on the front of the torso on the side closest to the source of radiation; the guidance in (a) to (c) should also be followed in this case.

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

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

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

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

(a) A single dosimeter placed under the apron, reported in $H_p(10)$, provides a good estimate of the contribution to the effective dose of the parts of the body protected by the apron, but underestimates the contribution of the unprotected parts of the body (the thyroid, the head and neck, and the extremities).
(b) A single dosimeter worn outside the apron, reported in $H_p(10)$, provides a significant overestimate of effective dose and should be corrected for the protection afforded by the apron by using an appropriate algorithm [120, 122, 123].
(c) Where two dosimeters are worn, one under the apron and the other outside the apron, an algorithm should be applied to estimate the effective dose from the two reported values of $H_p(10)$ [120, 122].

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

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

3.118. In some radiology facilities and for some individuals with a low level of occupational exposure (e.g. general dental practitioners), area dosimetry to estimate the level of dose per procedure can be an acceptable alternative to individual monitoring. With knowledge of the typical level of dose per procedure for positions where personnel are placed during exposures and the number of procedures per year, the RPO can estimate personnel doses.

3.119. Similarly, occupational doses can be estimated from the results of workplace monitoring. The effective dose for personnel can be inferred from the measured ambient dose equivalent $H^*(10)$. The ICRP [119] provides conversion coefficients from ambient dose equivalent to effective dose for different types of radiation and energy. The conversion coefficients for photons are close to unity except for very low energy photons, such as photons scattered from a mammography X ray beam.

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

Investigation levels for staff exposure

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

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

Persons who work in more than one place

3.123. Some individuals might work in more than one radiology facility. The facilities may be quite separate entities in terms of ownership and management, or they may have common ownership but separate management, or they may even have common ownership and management but be physically quite separate. Regardless of the ownership and management structure, the occupational radiation protection requirements for the particular radiology facility apply when the person is working in that facility. As described in para. 3.106, a dosimeter issued for individual monitoring should be worn only in the facility for which it is issued, as this facilitates the effective optimization of protection and safety in that facility. This approach is logistically more easily implemented, since each physical site has its own dosimeters, and so there is no need to transport dosimeters between facilities, with the risk of losing or forgetting them. In cases where the facilities are under common ownership, it may be seen as an unnecessary financial burden to provide more than one set of dosimeters for staff that work in more than one of its facilities. However, the radiation protection advantages of having the dosimeter results linked to a person's work in only one radiology facility remain (see also para. 3.125).

3.124. There is, however, an important additional consideration, namely the need to ensure compliance with the occupational dose limits. Any person who works in more than one radiology facility should notify the licensee for each of those facilities. Each licensee, through its RPO, should establish formal contact with the licensees of the other radiology facilities and their RPOs, so that each facility has an arrangement to ensure that a personal dosimeter is available and that there is an ongoing record of the occupational doses for that person in all the facilities where he or she works.

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

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

Records of occupational exposure

3.126. Paragraphs 3.103–3.107 of GSR Part 3 [3] establish the detailed requirements for records of occupational exposure and place obligations on employers, registrants and licensees. In addition to demonstrating compliance with legal requirements, records of occupational exposure should be used within the radiology facility for additional purposes, including assessing the effectiveness of the optimization of protection and safety at the facility and evaluating trends in exposure. National or local regulatory bodies might specify additional requirements for records of occupational exposure and for access to the information contained in those records. Employers are required to provide workers with access to records of their own occupational exposure (para. 3.106(a) of GSR Part 3 [3]). Further general guidance on records of occupational exposure is given in GSG-7 [23].

Health surveillance for workers

3.127. The primary purpose of health surveillance is to assess the initial and continuing fitness of employees for their intended tasks, and requirements are given in paras 3.108 and 3.109 of GSR Part 3 [3].

3.128. No specific health surveillance relating to exposure to ionizing radiation is necessary for staff involved in diagnostic radiology and image guided interventional procedures, with perhaps the possible exception of initial eye assessment and periodic eye assessments for visual acuity and contrast resolution for personnel performing significant numbers of image guided interventional procedures. Only in cases of overexposed workers, at doses much higher than the dose limits (e.g. a few hundred millisieverts or higher), would special investigations involving biological dosimetry and further extended diagnosisand medical treatment be necessary [23]. Under normal working conditions,the occupational doses incurred in diagnostic radiology and image guided interventional procedures are low, and no specific radiation related examinations are required for persons who are occupationally exposed to ionizing radiation, as there are no diagnostic tests that yield information relevant to normal exposure. It is, therefore, rare for considerations of occupational exposure arising from the working environment of a radiology facility to influence significantly the

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

3.129. Counselling should be made available to workers who have or may have been exposed in excess of dose limits, and information, advice and, if indicated, counselling should be made available to workers who are concerned abouttheir radiation exposure. In diagnostic radiology and image guided procedures, the latter group may include women who are or may be pregnant. Counselling should be given by appropriately experienced and qualified practitioners. Further guidance is given in GSG-7 [23].

Information, instruction and training

3.130. All staff involved in diagnostic radiology and image guided interventional procedures should meet the respective training and competence criteria described in paras 2.119–2.137. This will include general education, training, qualification and competence for occupational radiation protection. Radiological medical practitioners, medical radiation technologists and nurses working with hybrid units (such as PET–CT and SPECT–CT) may have trained exclusively in their original specialty. They should undertake radiation protection and safety training relevant to the additional imaging modality.

3.131. Paragraph 3.110 of GSR Part 3 [3] places responsibilities on the employer to provide adequate information, instruction and training for protection and safety as it pertains to the radiology facility. This is not only for new staff but also for all staff as part of their continuing professional development. Specific instruction and training should be provided when new medical radiological procedures, equipment, software and technologies are introduced.

Conditions of service and special arrangements

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

Pregnant workers

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

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

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

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

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

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

Persons under 18

3.136. In many States, there is the possibility of students aged 16 or more, but under 18, commencing their studies and training to become a medical radiation technologist or other health professional that can involve occupational exposure to ionizing radiation. Paragraph 3.116 of GSR Part 3 [3] establishes the requirements for access to controlled areas and the dose limits for such persons are more restrictive (see Box 1 of this Safety Guide and Schedule III of GSR Part 3 [3]).

RADIATION PROTECTION OF INDIVIDUALS UNDERGOING MEDICAL EXPOSURE

3.137. This section covers radiation protection of patients, carers and comforters, and volunteers in biomedical research. The term ‘patient’, when used in the context of medical exposure, means the person undergoing the radiological procedure. Other patients in the radiology facility, including those who may be waiting for their own radiological procedure, are considered members of the public and their radiation protection is covered in paras 3.273–3.282.

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

Justification of medical exposure

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

3.140. The roles of the health authority and professional bodies with respect to a level 2 or generic justification of radiological procedures, justification of health screening programs, and justification of screening intended for the early detection of disease, but not as part of a health screening program, are described in paras 2.55–2.60.

Justification of medical exposure for the individual patient

3.141. GSR Part 3 [3] requires a joint approach to justification at the level of an individual patient, with a shared decision involving both the referring medical practitioner (who initiates the request for a radiological procedure) and the radiological medical practitioner. A referral should be regarded as a request for a professional consultation or opinion rather than an instruction or order to perform. The referring medical practitioner brings the knowledge of the medical context and the patient’s history to the decision process, while the radiological medical practitioner has specialist expertise on the radiological procedure. The efficacy, benefits and risks of alternative methods (both methods involving ionizing radiation and methods not involving ionizing radiation) should be considered. In all cases, the justification is required to take into account national or international referral guidelines (para. 3.158 of GSR Part 3 [3]). For examples of such

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

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

3.143. Justification, which is a principle of radiation protection, is implemented more effectively as part of the medical process of determining the 'appropriateness' of a radiological procedure. The process of determining appropriateness is an evidence based approach to choosing the best test for a given clinical scenario, with account taken of the diagnostic efficacy of the proposed radiological procedure as well as of alternative procedures that do not use ionizing radiation, for example, ultrasound, MRI or endoscopy. Useful tools to support this decision making process include national or international imaging referral guidelines developed by professional societies [127–133]. Imaging referral guidelines can be disseminated or utilized through electronic requesting systems[22] and clinical decision support tools or systems. It should be ensuredthat such systems correctly apply the regulatory requirements for justification, inparticular with respect to roles and responsibilities.

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

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

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

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

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

3.145. For some radiological procedures, primarily 'well established' procedures and low dose procedures, the practical implementation of justification in many States is carried out by the medical radiation technologist, who is effectively representing the radiological medical practitioner with the formal understanding that, if there is uncertainty, the radiological medical practitioner is contacted and the final decision is taken by the radiological medical practitioner in consultation with the referring medical practitioner. Such justification is guided by national or international referral guidelines. It should be noted that,in all cases, the responsibility for justification lies with the radiological medical practitioner and the referring medical practitioner.

3.146. For a small percentage of radiological procedures, primarily because of a combination of complexity, difficult medical context and higher dose, the justification is likely to be led by the radiological medical practitioner, with the referring medical practitioner providing any necessary further clarification on the medical context. Again, the justification should take into account national or international referral guidelines.

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

(a) Owing to the higher radiosensitivity of the embryo or fetus, it should be ascertained whether a female patient is pregnant before an X ray examination for diagnosis or an image guided interventional procedure is performed. Paragraph 3.176 of GSR Part 3 [3] requires that procedures be "in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus". Pregnancy

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

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

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

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

3.150. 'Self-presentation' occurs when a member of the public asks for a radiological procedure without a referral from a health professional. This may have been prompted by media reports or advertising. Examples include 'individual health assessments' which often involves CT procedures in asymptomatic individuals for early detection of cancer (e.g. whole body CT, lung CT or colon CT) and quantification of coronary artery calcification (coronary artery CT). Justification is required, as for all radiological procedures. Relevant professional bodies have an important role in considering evidence for developing guidance when new practices are proposed, as for example in the case of CT [135]. States may choose to incorporate such guidance into legislation [136].

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

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

Justification of medical exposure for biomedical research volunteers

3.152. The role of the ethics committee in the justification of medical exposure of volunteers exposed as part of a program of biomedical research is describedin para. 2.99.

Justification of medical exposure for carers and comforters

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

Optimization of protection and safety

3.154. In medical exposure, optimization of protection and safety has several components, some applicable directly to the radiological procedure about to be performed and others providing the support or framework for the other components. These components of optimization of protection and safety are described in paras 3.155–3.252. Key personnel in the optimization process are the radiological medical practitioner, the medical radiation technologist and the medical physicist.

Design considerations

3.155. The use of appropriate and well designed medical radiological equipment and associated software underpins any radiological procedure in diagnostic radiology or any image guided interventional procedure. X ray generators

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

Operational considerations: General

3.156. Following justification, the diagnostic radiological procedure or image guided interventional procedure is required to be performed in such a way as to optimize patient protection (para. 3.163 of GSR Part 3 [3]). The level of image quality sufficient for diagnosis is determined by the radiological medical practitioner and is based on the clinical question posed and the anatomical structures imaged (e.g. the diagnosis of the pattern of sinusitis on CT requires only a low dose procedure as high contrast structures, namely air and bone, be imaged). With image guided interventional procedures, the level of image qualityshould be sufficient to guide the intervention.

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

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

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

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

3.160. Cooperation of the patient should be ensured to achieve an image of diagnostic quality. This is particularly relevant when imaging children. Good communication helps to achieve this. Verbal interaction between the medical radiological technologist or the medical radiological practitioner and the patient should take place before, during and after the procedure.

3.161. Optimization of protection and safety for a woman undergoing a radiological procedure during pregnancy should take into account the woman and the embryo or fetus. Routine diagnostic CT examinations of the pelvic region with and without contrast injection can lead to a dose of 50 mSv to the uterus, which is assumed to be the same as the dose that would be received by the fetus in early pregnancy. When CT scanning is indicated for a pregnant patient, low dose CT protocols should be used and the scanning area should be reduced to a minimum (see also paras 3.176–3.185).

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

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

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

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

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

Operational considerations: Radiography

3.166. In developing protocols for radiography, many technique factors should be considered, which can influence the image quality and the patient dose for the radiographic projection. Detailed guidance on appropriate choices for those factors is widely available (see Refs [137, 142, 143, 148–153]). Such factors include: the tube potential; current; exposure time; focal spot size; filtration; source to image receptor distance; choice of anti-scatter grids or Bucky device; collimation; image receptor size; positioning, immobilization and compression of the patient; the number of projections needed (e.g. a posterior–anterior chest X ray rather than posterior–anterior and lateral X rays); and organ shielding where appropriate (e.g. testicular shielding for pelvic radiographs in male patients).

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

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

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

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

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

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

Operational considerations: Mammography

3.172. In developing protocols for mammography, consideration of radiographic technique factors should be made as for radiography (see para. 3.166). Additional factors that should be considered include: adequate compression of the breast; tissue composition (e.g. dense glandular breasts identified on previous mammograms); and correct choice of anode and filters. Detailed guidance on appropriate choices for technique factors and additional factors is available (see Refs [111–114, 139, 155, 156]).

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

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

3.175. Viewing conditions are of paramount importance for both digital and film based mammography systems, and the operational performance should be meet the conditions described in paras 3.25, 3.26 and 3.45. Poor viewing conditions not only compromise the reporting of a good quality image, but they may, in a mistaken attempt to compensate for the poor viewing conditions, also lead to changes in technique factors that actually result in suboptimal image quality. For example, the use of low luminance viewing boxes may lead to radiographs being produced that have a low density with insufficient diagnostic content. Although the dose may have been reduced, there might be an unacceptable loss of diagnostic information.

Operational considerations: Computed tomography

3.176. In developing protocols for CT, many technique factors and features should be considered which can influence the image quality and the patient dose for the examination, including: tube potential; tube current; tube current modulation with noise index; pitch; beam width; and total scan length, over ranging and over beaming for the scan. These and other factors may be optimized through the AEC system where available. The choice of protocol will be determined by the clinical question to be answered (e.g. for cardiac CT, a low dose protocol is sufficient for stratifying risk in patients with intermediate probability of coronary artery disease; whereas a higher dose contrast enhanced protocol is necessary for patients with suspected coronary artery disease). Detailed guidance on appropriate choices for these factors and features is available (see Refs [19, 62, 138, 144, 145, 147, 150, 152, 159–163]).

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

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

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

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

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

3.182. Irradiating the lens of the eye within the primary beam should beavoided. This may be achieved in brain scans by using a head cradle or, in some cases, tilting the gantry.

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

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

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

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

tube current–exposure time product; field of view; voxel size; and the number of projections.

Operational considerations: Dentistry

3.187. In developing protocols for conventional intraoral radiography, factors that can influence the image quality and the patient dose include: tube potential; current; exposure time; collimation; focus to skin distance; and, for analogue systems, film speed and processing development time and temperature.Detailed guidance on appropriate choices for those factors is available (seeRefs [166, 167]).

3.188. In developing protocols for panoramic imaging, additional factors that can influence the image quality and the patient dose include: patient positioning (e.g. jaw open or closed); collimation (e.g. for examinations of the temporomandibular joint, only those areas should be included); and foranalogue systems, film speed or screen speed, and processing development time and temperature. Detailed guidance on appropriate choices for those factors is available (see Refs [166, 167]).

Operational considerations: Image guided interventional procedures

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

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

3.191. In developing protocols for fluoroscopically guided interventional procedures, many technique factors and features should be considered, which can influence the image quality and the patient dose for the intervention, including:

tube potential; tube current; use of pulsed fluoroscopy (hence pulse width and rate); dose rate mode (effectively the image intensifier or flat panel detector input air kerma rate); collimation, and collimation tracking with the distance from the focus to the detector; filtration (fixed and variable); use of magnification; total fluoroscopy time for the intervention; image acquisition dose mode (effectively input air kerma per frame for the image intensifier or flat panel detector);image acquisition frame rate; number of frames per run and the total numberof acquisitions. Detailed guidance on appropriate choices for these factors and features is available (see Refs [19, 117, 140, 146, 150, 152, 168–171]).

3.192. Many of the factors in para. 3.191 are automated through an algorithm driven ADRC system. Nevertheless, in setting up the algorithm, scope exists for the optimization of protection and safety through the selection of values for these parameters. For example, the input air kerma rates (for fluoroscopy) and input air kerma per frame (for image acquisition) for the image intensifier or flat panel detector are set during installation and adjusted thereafter during periodic maintenance and servicing. The values actually used for these settings can vary considerably. High rate dose modes in fluoroscopy should be used only during the minimum indispensable time necessary to the procedure. The use of magnification modes should be kept to a minimum consistent with a successful intervention.

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

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

3.195. In developing protocols for CT guided interventional procedures, technique factors that should be considered, which can influence the image quality and the patient dose for the intervention, include: tube potential, tube current and beam width. The number of image acquisitions (tube rotations)should be kept to a minimum consistent with a successful intervention.

Operational considerations: Fluoroscopy

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

Operational considerations: Bone densitometry

3.197. Selection of the appropriate site for densitometry will take into account both the anatomical area of clinical concern as well as the likelihoodof non-representative images and measurements owing to artefacts (e.g. massive vertebral osteophytes may obviate the value of lumbar densitometry). Information on best practices is given in Ref. [172].

Operational considerations: Emergency radiology

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

Calibration: General

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

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

Calibration: Medical radiological equipment

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

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

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

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

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

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

3.205. Measurements of these dosimetric quantities, when being used to calibrate or characterize a given X ray, CT or mammography unit output or performance, should be made for a range of representative technique factors used clinically, and following recognized protocols such as those in Ref. [11].

Calibration: Dosimetry instrumentation

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

3.207. Paragraph 3.167(d) of GSR Part 3 [3] requires that the calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory. Ideally, this would be the national standards dosimetry laboratory (primary or secondary) in the State concerned, with access either directly or through aduly accredited calibration facility. However, it may be necessary for dosimetry instruments to be sent to another State or region if there is no national standards dosimetry laboratory in the State or region where the instruments are used. At present, only some of the secondary standards dosimetry laboratories ofthe IAEA/WHO Network of Secondary Standards Dosimetry Laboratories (SSDL Network) provide calibration services using diagnostic radiology spectra and dose rates representative of clinical practice. However, since dosimetry accuracy is not as critical in diagnostic radiology as in radiationtherapy, calibrations with comparable radiation qualities should be sufficient. Alternatively, the regulatory body might accept instrument manufacturers' calibrations as described in the 'certificate of calibration' issued by the instrumentmanufacturer, provided that the manufacturer operates or uses a calibrationfacility that is itself traceable to a standards dosimetry laboratory and appropriatecalibration conditions have been used. This certificate should state the overall uncertainty of the calibration coefficient.

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

3.209. There is a role for cross-calibration of dosimeters, where the radiology facility's dosimeters that have been officially calibrated are used to check or compare with other dosimeters. This is particularly important for field air kerma–area product meters, which should be calibrated (or cross-calibrated)against a reference air kerma–area product meter or air kerma dosimeter in situin the clinical environment rather than in a standards dosimetry laboratory environment [11]. It might also be done when a radiology facility has many dosimeters, and to calibrate all dosimeters could be too costly. Cross-calibration can also be utilized as a constancy test as part of periodic quality control tests.

Dosimetry of patients: General

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

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

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

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

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

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

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

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

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

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

3.217. Sometimes, patient dosimetry in diagnostic radiology or image guided interventional procedures may be required for specific individual patients, either through measurements or calculations. Reasons might include an unintended or accidental medical exposure, where an estimation of patient doses is required as part of the investigation and report (see para. 3.265), or because there is a need to estimate the dose to an embryo or fetus (see para. 3.161).

3.218. There are several indirect and direct methods to estimate patient dose in diagnostic radiology and image guided interventional procedures. Methodologies for these determinations are explained in detail in Refs [10–12, 171, 173–178] and are summarized in the following:

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

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

Dosimetry of patients: Specific considerations for image guided interventional procedures

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

3.221. The determination of the dose to the most exposed area of skin is not straightforward, since exposure parameters and projection angles change during the procedure and the most exposed area cannot always be anticipated. This makes knowledge of the distribution of the dose over the skin (sometimes called ‘dose mapping’ over the skin) necessary. A comprehensive review of approaches

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

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

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

Diagnostic reference levels

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

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

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

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

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

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

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

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

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

Quality assurance for medical exposures

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

3.233. The purpose of the program of quality assurance for medical exposures is to help to ensure successful optimization of protection and safetyin the radiology facility and to minimize the occurrence of unintended andaccidental medical exposures.

3.234. The complexity of the program of quality assurance for medical exposures will depend on the type of facility. A dental practice with only intraoral radiography will have a simpler program compared with a facility that offers all modalities of diagnostic radiology as well as image guided interventional procedures. Nonetheless, most of the elements of the program are common, andit is more in the degree of application that there are differences. Paragraph 3.171 of GSR Part 3 [3] establishes the common elements of the program.

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

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

3.237. After acceptance and before clinical use on patients, commissioning should be carried out by, or under the supervision of, the medical physicist. Commissioning should include measurements of all parameters and conditions of use that are expected in clinical use, including setting up and validating image acquisition protocols. For most modalities (CT, image guided interventional procedures, tomosynthesis, mammography, radiography and fluoroscopy), the medical physicist should be directly involved in the measurements, calculations and interpretation of data to characterize the equipment’s performance. For the least complex modalities (dental radiography and DXA), the medical physicist should provide documented advice on how the commissioning should be

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

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

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

3.240. Quality control tests should also be performed on other equipmentor devices that have an impact on the successful outcome of the radiological procedure. Such equipment and devices include, but are not limited to: film processors, darkrooms and cassettes for facilities using film based imaging; flat detectors for DR systems; CR imaging plates and CR readers for facilities with CR systems; and view boxes, workstations, and display and interpretation rooms. Many of the references given in para. 3.238 are applicable here.

3.241. The results of the quality control tests should be compared with established tolerance limits. These limits may have been established to ensure compliance with a regulatory requirement for the performance of particular physical parameters or they may be set on the basis of recommended values given in published reports, such as those referenced in para. 3.238. Paragraph 3.171(b) of GSR Part 3 [3] requires the implementation of corrective actions if themeasured values fall outside established tolerance limits. Such corrective actionsare likely to include maintenance or servicing of the equipment, and hence a

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

3.242. The program of quality assurance for medical exposures in the radiology facility should include the use of checks to ensure that the facility's protocols and procedures for imaging and interventional procedures, including radiation protection and safety, are being followed. The periodic review of the protocols and procedures themselves is part of the radiological review at the facility (see paras 3.269–3.271). In addition, a review of imaging procedures mayhave been triggered by a comparison with DRLs (see paras 3.224–3.231).

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

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

3.245. Maintaining records is a crucial aspect of the program of quality assurance for medical exposures. This includes the procedures used in the program and the results of the quality control tests, the dosimetry surveys, theDRL comparisons, the corrective actions, and the investigations of unintended and accidental medical exposures. When planning and developing an effective program of quality assurance, the licensee should recognize that it demands

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

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

Dose constraints: Carers and comforters

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

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

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

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

3.249. The radiation protection afforded the carer or comforter should be optimized, and, as part of this process, dose constraints are required to be applied (para. 3.173 of GSR Part 3 [3]). These are the dose constraints established by

government, as a result of consultation with the health authority, relevant professional bodies and the regulatory body, as required by para. 3.149(a)(i) of GSR Part 3 [3] (see also paras 2.48 and 2.49).

3.250. Written protocols should be drawn up for implementing measures for the optimization of protection and safety for carers and comforters who hold patients during radiological procedures. The measures should utilize the basic methods for radiation protection (i.e. time, distance and shielding). The protocols should include the following:

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

3.251. The licensee should be able to demonstrate that the effective dose to the carer or comforter, by applying the protocols, is unlikely to exceed the dose constraint. It is relatively straightforward to estimate effective doses to carers and comforters from measurements of the ambient dose equivalent rates at the positions where they will be situated. These determinations should be made in advance to ensure that dose constraint is not exceeded. Therefore, individual dose monitoring is normally not necessary.

Dose constraints: Volunteers in biomedical research

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

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

Pregnant patients

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

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

3.255. Neither of the approaches described in para. 3.254 will work if the patient does not know whether she is pregnant. For this reason, para. 3.176 of GSR Part 3 [3] has an additional requirement on facilities to "ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus". Such radiological procedures would include those that involve primary beam irradiation of the abdomen or pelvis area delivering relatively high patient doses directly to the embryo or fetus, or to volumes near the uterus such that significant scatter radiation reaches the embryo or fetus. Cooperation with the referring medical practitioner, through standard requests for pregnancy status for specified procedures, is one approach. The referral form should include a 'tick box'

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

Unintended and accidental medical exposures

Prevention of unintended and accidental medical exposures

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

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

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

3.257. Minimization of the likelihood of unintended or accidental medical exposures in diagnostic radiology and image guided interventional procedures can be brought about by:

(a) The introduction of safety barriers at identified critical points in the process, with specific quality control checks at these points. Quality control should not be confined to physical tests or checks but can include actions such as the correct identification of the patient.
(b) Actively encouraging a culture of always working with awareness and alertness.
(c) Providing detailed protocols and procedures for each process.
(d) Providing sufficient staff who are educated and trained to the appropriate level, and an effective organization, ensuring reasonable patient throughput.
(e) Continuous professional development and practical training and training in applications for all staff involved in providing radiology services.
(f) Clear definitions of the roles, responsibilities and functions of staff in the radiology facility that are understood by all staff.

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

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

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

Investigation of unintended and accidental medical exposures

3.260. The events that constitute unintended or accidental medical exposures are detailed in para. 3.180 of GSR Part 3 [3]. Unintended and accidental medical exposures can occur in all imaging procedures; however, the consequences in CT may be more severe and in image guided interventional procedures may be even more severe [123, 159, 160].

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

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

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

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

3.264. Radiation injuries will continue to occur in image guided interventional procedures. A given procedure performed in accordance with the facility's protocol still has the potential to result in tissue effects because of difficulties with the particular patient. However, most reported cases of severe radiation injuries involving ulceration and necrosis have been associated with unnecessary and extreme exposure conditions, such as: (i) a very short distance between theX ray source and the patient; (ii) the use of a high dose rate mode for much longer than necessary; (iii) a fixed projection exposing the same area of skin; and
(iv) a malfunction of the AEC system. These situations cannot be considered to be normal, their occurrence can be avoided and their severity can be substantially reduced by optimization; they should be considered accidental medical exposures and should be investigated. Facilities at which image guided interventional procedures are performed should have systems in place for identifying patients who may be at risk of late radiation injuries, typically based on estimates of peak skin dose, cumulative reference air kerma or air kerma–area product, which take account of the fact that patients have different sensitivities to radiation. For these patients, information should be added to their medical records so that appropriate observation and follow-up is ensured. For example, it is recommended that patients with estimated skin doses of 3 Gy should be followed up 10–14 days after exposure [123]. Further information on trigger levels for patient follow-up are available on the SAFRAD web site.[23] Any resulting radiation injury should receive appropriate medical attention.

3.265. Paragraph 3.181 of GSR Part 3 [3] establishes what is required during the course of the investigation. This includes calculation or estimation of patient doses, which should be performed by a medical physicist, and notification of the event to the patient's referring medical practitioner. A record of the calculation method and results should also be placed in the patient's file. When required,

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

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

3.266. The investigation of unintended and accidental medical exposures, as required by paras 3.180 and 3.181 of GSR Part 3 [3], has three main purposes. The first is to assess the consequences for the patients affected and to provide remedial and health care actions if necessary. The second is to establish what went wrong and how to prevent or minimize the likelihood of a recurrence inthe radiology facility (i.e. the investigation is for the facility's benefit and the patients' benefit). The third purpose is to provide information to other personsor other radiology facilities. Dissemination of information about unintended and accidental medical exposures and radiation injuries (e.g. see Refs [123,179, 202, 203]) has greatly contributed to increasing awareness and improving methods for minimizing the occurrence of radiation injuries. The regulatory bodyand/or the health authorities could disseminate information on significant events reported to them and on the corrective actions taken, so that other facilities mightlearn from these events. Independently from any legal requirement for reporting to the regulatory body, the implementation of voluntary and anonymous safety reporting and learning systems can significantly contribute to improving safety and safety culture in health care. This includes participation in voluntary international or national databases designed as educative tools. One such databasefor image guided interventional procedures is the SAFRAD reporting system. Facilities performing image guided interventional procedures should participate in SAFRAD or similar databases.

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

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

3.268. Irrespective of whether the event is also reported to the regulatorybody, feedback to staff should be provided in a timely fashion and, wherechanges are recommended, all staff should be involved in bringing about their implementation.

Records and review

Radiological review

3.269. Paragraph 3.182 of GSR Part 3 [3] requires that radiological reviews be performed periodically at the radiology facility. This involves considering both justification and optimization aspects of radiation protection. For the latter, the results of the program of quality assurance for medical exposures, including the periodic independent audit, will be a significant input to the process. As described in paras 2.148 and 2.149, the wider clinical audit could include the radiological review with its assessment of the effective application of the requirements for justification and optimization in the facility for the radiological procedures being performed [48].

3.270. To facilitate compliance with para. 3.182 of GSR Part 3 [3] and to learn from periodic radiological reviews, the methodology used, the original physical, technical and clinical parameters considered and the conclusions reached should be documented and taken into account prior to any new review that may result in an update of the radiology facility's policies and procedures.

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

Records

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

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

RADIATION PROTECTION OF THE PUBLIC

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

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

3.275. Persons who will be undergoing a radiological procedure are also considered members of the public during the time when the radiological procedure is not taking place, for example, while they are sitting in the waiting room. Similarly, for carers and comforters any exposure incurred other than during the radiological procedure in which they are involved will be public exposure.

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

External exposure

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

3.278. Particular consideration should be given to persons in the radiology facility who are not undergoing a radiological procedure, but are in the vicinity when mobile radiography is being performed in their ward or area, or when

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

Control of access

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

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

Monitoring and reporting

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

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

3.282. The program for monitoring public exposure arising from diagnostic radiology and image guided interventional procedures should include dose assessment in the areas in and surrounding the radiology facility that are accessible to the public. Doses can be derived from the shielding calculations in the planning stage, combined with the results from area monitoring at the initial operation of the facility and periodically thereafter. Records of dose assessments should be kept for a period that meets any relevant regulatory requirements. In

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

PREVENTION AND MITIGATION OF ACCIDENTS

Safety assessments of potential exposure

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

3.284. The safety assessment of potential exposure should be systematic, should identify unintended events that can lead to potential exposure, and shouldconsider their likelihood and potential consequences (see Appendix I for a summary of typical causes and contributing factors to accidental exposures in diagnostic radiology and image guided interventional procedures). The safety assessment should cover not only these events, but should also aim at anticipatingother events that have not previously been reported. Clearly, the safety assessmentshould be documented.

3.285. The safety assessment should be revised when:

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

Prevention of accidents

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

3.287. The licensee should incorporate:

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

3.288. Potential exposure of the public from a radiation generator can occurif a person (e.g. a cleaner) enters an interventional or conventional fluoroscopy room in between cases and depresses the exposure foot switch (usually a foot pedal placed on the floor). To prevent such potential exposure, equipment shouldbe provided with a special X ray interlock in the control panel to disconnect the exposure foot switch in between cases, as described in para. 3.38(g).

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

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

Mitigation of the consequences of accidents

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

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