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

GENERAL

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

4.2. All nuclear medicine procedures involve the administration of a radiopharmaceutical to the patient. For diagnostic nuclear medicine procedures, trace amounts of compounds are labelled with photon or positron emitters, forming what is called a radiopharmaceutical. For photon emitters, the distribution of the radiopharmaceutical in the human body can be imaged with different modalities, such as planar imaging (including whole body imaging) or SPECT. In the case of positron emitters, the detection of annihilation photons allows registering of the 3-D spatial distribution of the radiopharmaceutical using PET. In hybrid imaging, SPECT and PET are combined with an X ray based modality, such as in PET–CT and SPECT–CT, and more recently also with MRI, such as in PET–MRI. In addition, probes may be used for the intraoperative localization of tumors and lymph nodes or leaks, and for uptake measurements in specific organs, such as the thyroid or lungs. In therapeutic nuclear medicine, therapeutic activities of radiopharmaceuticals are administered that are usually labelled with beta and/or gamma emitting radionuclides, more recently also with alpha emitters; therapy with Auger electrons is mostly experimental. The nuclear medicine facility might also perform in vitro studies, although these are not a primary focus of this Safety Guide. Some nuclear medicine facilities might also have an associated cyclotron facility for on-site radionuclide production. Detailed guidance for such cyclotron facilities is beyond the scope of this Safety Guide.

4.3. The generic term ‘medical radiation facility’ is used widely in Section 2 to mean any medical facility where radiological procedures are performed. In Section 4, the narrower term ‘nuclear medicine facility’ is used to cover any medical radiation facility where nuclear medicine procedures are performed. A nuclear medicine facility may be a nuclear medicine department inside a larger hospital or medical Center, or it may be a stand alone facility providing nuclear

medicine services. In some cases, the nuclear medicine facility may be a mobile facility.

4.4. The defined term ‘radiological procedure’ is used in GSR Part 3 [3] to cover all imaging and therapeutic procedures using ionizing radiation. In a nuclear medicine facility, both imaging and therapeutic radiological procedures may occur, and this needs to be borne in mind when reading the guidance in Section 4. In cases where the guidance is specific to one of either imaging or treatment, additional qualifiers, such as ‘imaging’, ‘diagnostic’, ‘therapy’ or ‘treatment’, are used.

4.5. Different health professionals can take on the role of the radiologicalmedical practitioner (see para. 2.90) in nuclear medicine procedures, depending, inter alia, on national laws and regulations. They primarily include nuclear medicine physicians, but they may include other specialists such as radiologists, cardiologists and radiation oncologists.

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

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

SAFETY OF MEDICAL RADIATION FACILITIES AND MEDICAL RADIOLOGICAL EQUIPMENT

Nuclear medicine facilities

4.8. Provisions for the incorporation of radiation protection and safety features should be made at the facility design stage. The siting and layout should take into account workload and patient flow, both within the nuclear medicine facility and, in cases where the nuclear medicine facility is part of a larger hospital or medical Center, within other departments of the facility. The nuclear medicine facility is likely to provide services to both inpatients and outpatients, so the location of

the facility should give easy access to both groups. Consideration should also be given to providing easy exit routes for patients, after the examination or treatment has been performed, that minimize movement through the facility.

4.9. A typical nuclear medicine facility using unsealed sources[24] will have areas for the following: source storage and preparation (radiopharmacy, radioisotope laboratory or 'hot lab'), radiopharmaceutical administration to patients, uptake rooms, imaging (in vivo), sample measurement (in vitro), waiting areas, changing areas and toilets, radioactive waste storage and predisposal processing. Separate waiting areas for patients before and after radiopharmaceutical administration should be considered. For those nuclear medicine facilities at which therapy with radiopharmaceuticals is performed, a dedicated ward for patients undergoing such treatments should be considered. The facility will also have areas where radioactive materials are not expected to be found, such as in offices, reporting areas and staff rooms, including cloakrooms, showers and toilets for staff. Detailed guidance on setting up nuclear medicine facilities, including PET–CT facilities, is given in Refs [62, 204–210].

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

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

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

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

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

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

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

4.16. The design of the nuclear medicine facility should include provision for secure and shielded storage for radioactive sources. Facility design personnel and engineers should be consulted with regard to floor-loading requirements, with account taken of factors such as radiation shielding, imaging and ancillary equipment. Shielding should be appropriate to the type and energy of the emitted radiation. Storage may be provided in a room or a separate space outside the work area or in a locked cupboard, safe, refrigerator or freezer situated in the work area. Separate storage compartments for radiopharmaceuticals and an area for temporary storage of radioactive waste should be provided, with appropriate protective barriers.

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

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

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

Mobile facilities

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

Areas where unsealed radioactive materials are handled

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

(a) Means to prevent access by unauthorized persons;
(b) Adequate storage space for equipment used in the given room or area to be available at all times to minimize the potential for spreading contamination to other areas;
(c) A contained workstation for easy decontamination;
(d) Shielded storage for radioactive sources;
(e) Shielded temporary storage for both solid and liquid radioactive waste, and places designated for the authorized discharge of liquid radioactive effluent;
(f) Shielding to protect workers where significant external exposure might occur;
(g) A wash-up area for contaminated articles, such as glassware;

(h) An entry area where protective clothing can be stored, put on and taken off, and which is provided with a hand washing sink and a contamination monitor;
(i) Taps and soap dispenser that are operable without direct hand contact and disposable towels or a hot air dryer;
(j) An emergency eyewash, installed near the hand washing sink;
(k) An emergency shower for decontamination of persons.

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

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

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

4.23. Drainpipes from sinks in a radiopharmacy or laboratory should go asdirectly as possible to the main building sewer and should not connect withother drains within the building, unless those other drains also carry radioactive material. This is to minimize the possibility of the drainage system ‘backing up’ and contaminating other, non-controlled, areas. The final plans of the drainage system, which should be supplied to maintenance personnel, should clearly identify the drains from radiopharmacies and laboratories. Pipelines through

which radioactive materials flow should be marked to ensure that monitoring precedes any maintenance.

4.24. Some States require that drainpipes from a nuclear medicine facility and especially from radionuclide therapy wards terminate in a delay tank. Requirements on this issue differ very much among States, but each nuclear medicine facility should comply with the State's regulations (see para. 4.280(g)).

4.25. The floors of areas with the potential for contamination should be finished in an impermeable material that is washable and resistant to chemical change, curved to the walls, with all joints sealed and glued to the floor. The walls should be finished in a smooth and washable surface, for example painted with washable, non-porous paint. The surfaces of the room where unsealed radioactive materials are used or stored, such as benches, tables, seats, and door and drawer handles, should be smooth and non-absorbent, so that they can be cleaned and decontaminated easily. Supplies (e.g. gas, electricity and vacuum equipment) should not be mounted on bench tops, but on walls or stands.

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

4.27. Radiopharmacies or laboratories in which radioactive aerosols or gases are produced or handled should have an appropriate ventilation system that includes a fume hood, laminar airflow cabinet or glove box. The fume hood should be constructed of material that is smooth, impervious, washable and resistant to chemicals, and it should exhibit a negative flow rate. The work surface should have a slightly raised lip to contain any spills. The ventilation system should be designed such that the radiopharmacy or laboratory is at negative pressure relative to surrounding areas and should be adequate to the radioisotopes used [210].

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

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

Treatment rooms and wards

4.29. Floors and other surfaces of rooms designated for patients undergoing radiopharmaceutical therapy should be covered with smooth, continuous and non-absorbent materials that can be easily cleaned and decontaminated. Shielding should be designed using appropriate dose constraints for workers and the public. Bins for the temporary storage of linen and waste contaminated with radioactive materials should be located in secure areas. Storage areas should be clearly marked, using the basic ionizing radiation symbol recommended by ISO [56].

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

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

Shielding calculations

4.32. The shielding should be designed to meet the requirements for the optimization of protection and safety and should take into consideration the classification of the areas within the facility, the type of work to be done and the radionuclides (and their activity) intended to be used. Shielding should consider both structural and ancillary protective barriers at the design stage. It is convenient to shield the source, where possible, rather than the room or the person. The need for wall, floor and ceiling shielding should be assessed, for example in the design of therapy facilities and of PET–CT facilities, to reduce occupational and public exposure to acceptable levels. Wall shielding may be needed in the design of rooms housing sensitive instruments (to keep a low background), such as well counters, probes and imaging equipment (gamma cameras and PET scanners). In designing such wall shielding, consideration should be given to the height of the wall to ensure that scatter radiation, such as from a CT scanner, does not pass over the wall into the area being protected.

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

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

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

4.36. The adequacy of the shielding should be verified, preferably during construction, and certainly before the facility, room or area comes into clinical use. Clearly, requirements of the regulatory body should be met (para. 2.74).

Design of display and interpretation (reading) rooms

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

4.38. Viewing rooms with workstations for viewing digital images should be ergonomically designed to facilitate image processing and manipulation so that

reporting can be performed accurately. The viewing monitors of the workstations should meet applicable standards (see para. 3.46).

Radiopharmaceuticals

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

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

Medical radiological equipment, software and ancillary equipment

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

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

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

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

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

Design features for medical radiological equipment

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

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

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

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

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

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

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

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

(a) Detector features:
— Spatial resolution;
— Sensitivity;
— Scatter fraction, count losses and random measurements;
— Energy resolution;
— Image quality and accuracy of attenuation, and scatter correction and quantitation;
— Coincidence timing resolution for time of flight PET accuracy.
(b) Time of flight capability.
(c) Data acquisition features, including 2-D and 3-D whole body imaging, and cardiac and respiratory gating.
(d) Data processing system, including image reconstruction algorithms, image manipulation and image correction.
(e) Emergency stop.

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

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

Ancillary equipment

4.52. All equipment used for digital image display should meet appropriate international or national standards, for example meeting the performance specifications in Ref. [115]. Workstations and image processing and display software should be specifically designed for nuclear medicine, ensuring DICOM conformance and network interconnectivity. Guidance on DICOM image and data management for nuclear medicine is given in Ref. [229] (see paras 4.37and 4.38 for guidance on display and interpretation rooms).

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

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

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

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

Security of sources

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

Maintenance

4.57. Paragraphs 3.15(i) and 3.41 of GSR Part 3 [3] establish requirements for maintenance to ensure that sources meet their design requirements for protection and safety throughout their lifetime and to prevent accidents as far as reasonably practicable. The registrant or licensee is required to ensure that adequate

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

4.58. All maintenance procedures should be included in the program of quality assurance and should be carried out at the frequency recommended bythe manufacturer of the equipment and relevant professional bodies. Servicing should include a report describing the equipment fault, the work done andthe parts replaced and adjustments made, which should be filed as 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 toclinical use.

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

4.60. The electrical safety and mechanical safety aspects of the medical radiological equipment are an important part of the maintenance 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.

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

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

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

4.64. This subsection contains guidance very specific to nuclear medicine. More general and comprehensive guidance on occupational radiation protection isgiven 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

4.65. Various areas and rooms in a nuclear medicine facility should be classified as controlled areas or supervised areas, in line with the requirements established in paras 3.88–3.92 of GSR Part 3 [3]. Once designated, these areas should meet the requirements established in paras 3.89 and 3.90 (for controlled areas) and 3.91 and 3.92 (for supervised areas) of GSR Part 3 [3], including requirements for area delineation, signage, protection and safety measures, control of access, provision of personal protective equipment, provision of individual and area monitoring, provision of equipment for monitoring for contamination, and provision of

personal decontamination facilities. All other rooms and areas that are not so designated are considered as being in the public domain, and levels of radiation in these areas should be low enough to ensure compliance with the dose limits for public exposure. Classification of areas in a nuclear medicine facility should be based on the analysis of the process as a whole, and not only on the location of the equipment and the radiation sources. Paragraphs 4.66–4.69 give general guidance, and it would be expected that final decisions by the licensee for a given medical radiation facility would be based on the expert advice of the medical physicist, a qualified expert in radiation protection or the RPO.

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

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

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

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

Local rules and procedures

4.70. Paragraph 3.93 of GSR Part 3 [3] establishes a hierarchy of preventive measures for protection and safety with engineered controls, including structured and ancillary shielding, specific physical barriers, signs and interlocks, being supported by administrative controls and personal protective equipment. To this end, and as established in para. 3.94 of GSR Part 3 [3], local rules and procedures are required to be established in writing in any nuclear medicine facility. Their purpose is to ensure protection and safety for workers and other persons. Such local rules and procedures should include measures to minimize occupational radiation exposure both for normal work and in unusual events. The local rules and procedures should also cover the wearing, handling and storing of personal dosimeters, and should specify investigation levels and ensuing follow-up actions (see paras 4.118–4.140).

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

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

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

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

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

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

4.76. No food or drink, cosmetic or smoking materials, crockery or cutleryshould be brought into an area where unsealed radioactive materials are used. An exception to this is food that is radiolabeled for patient studies. Food or drink should not be stored in a refrigerator used for unsealed radioactive materials. Personal cell phones and handkerchiefs should not be used in such areas (with respect to the latter, an adequate supply of paper tissues should be provided). Before a person enters an area where radioactive material is handled, any cut or break in the skin should be covered with a waterproof dressing.

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

4.78. Staff leaving a controlled area, classified as such on account of the potential for contamination, should, after removal of their protective clothing, wash their hands and then monitor their hands, clothing and body for residual contamination. Liquid soap should be provided unless aseptic considerations require an alternative cleaner. Non-abrasive nail brushes should only be used if contamination persists after simple washing (see also paras 4.105–4.109 on decontamination of persons).

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

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

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

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

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

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

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

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

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

4.86. All operations involving radioactive gases or aerosols should be carried out in a fume hood or similar ventilated device to prevent airborne contamination. Exhaust vents should be situated well away from air intakes. The administration of aerosols to patients, such as for ventilation studies, should be performed using a mouthpiece and nose clip or mask for the patient. The placing of extracting devices close to the patient could be considered to improve radiation protection.

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

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

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

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

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

Specific local rules and procedures for radiopharmaceutical therapy

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

(a) Shielded syringes should be utilized during the intravenous or intra-arterial administration of radiopharmaceuticals as necessary to ensure extremity doses are maintained below occupational dose constraints. Absorbent materials or pads should be placed underneath an injection or infusion site. The RPO at the facility should be consulted to determine the necessity of

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

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

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

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

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

4.95. As described in para. 4.66, rooms occupied by patients treated with radiopharmaceuticals should be designated as controlled areas, and both the basic ionizing radiation symbol recommended by ISO [56] and a warning sign should be posted. Access should be restricted and a list of relevant contacts (such as nuclear medicine physicians and on-call physicians, medical radiation technologists and the RPO) should be provided. Protective clothing, such as laboratory coats, gloves and shoe covers, should be made available at the entrance to the room. The nursing staff should be familiar with the implications of the procedures for

controlled areas, the time and date the radiopharmaceuticals were administered, and any relevant instructions to carers and comforters.

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

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

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

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

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

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

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

Specific local rules and procedures for PET facilities

4.103. Personnel carrying out PET imaging can receive relatively large annual occupational radiation doses compared to their counterparts in general nuclear medicine. The main contribution to the occupational dose for personnel comes from patient handling. PET radiopharmacists at facilities performing radiopharmaceutical synthesis and unit dose preparations can receive significant hand and body doses, even where heavily shielded 'hot cells' are available to moderate doses. For these reasons, local rules and procedures for PET facilities should emphasize the means described in paras 4.75–4.102 for minimizing the dose to personnel when handling radiopharmaceuticals and patients containing radiopharmaceuticals.

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

Decontamination of persons

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

4.106. The RPO should be consulted when contamination of parts of the body other than the hands is suspected, or when the procedures for decontamination of the hands are ineffective. Special care should be taken in the decontamination of the face to restrict entry of radioactive material into the eyes, nose or mouth.

4.107. If the skin is broken or a wound is sustained under conditions where there is a risk of radioactive contamination, the injury should be flushed with water as soon as appropriate, and care should be taken not to wash contaminationinto the wound. As soon as the first aid measures have been taken, the person

should seek further treatment, including decontamination if necessary. The RPO should be consulted as needed.

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

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

Personal protective equipment and in-room protective devices

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

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

(a) Shields for bench tops, vials, syringes, activity meters and for the preparation of the radiopharmaceuticals (i.e. L-blocks and side blocks) of a material and thickness appropriate to the type and energy of the radiation. Particular considerations for the choice of shield include the following:
   — Alpha emitters may need to be shielded by high atomic number materials because of their characteristic X rays and high energy gamma components.
   — ^{223}Ra does not need a high atomic number shield because the gamma component does not contribute significantly to the dose.
   — Solutions containing pure low energy beta emitters, such as ^{14}C, require a plastic shield to attenuate the beta particles.
   — Solutions containing high energy beta emitters, such as ^{32}P and ^{90}Y, require a plastic shield to attenuate the beta particles followed by a high atomic number material shield for the bremsstrahlung radiation.
   — Solutions containing radionuclides that have both beta radiation and gamma radiation, such as ^{169}Er, ^{177}Lu, ^{186}Re and ^{153}Sm, may need lead shielding to attenuate the high energy gamma photons.

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

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

(c) When lower energy beta emitters are handled, gloves should be thickenough to protect against external beta radiation.

(d) Lead aprons should be worn when entering a room with hybrid imaging (e.g. PET–CT) if the X rays are about to be used and either a carer or comforter or a staff member needs to be in the room with the patient. Lead aprons may also be worn when preparing and administering high activities of ^{99m}Tc, although their use is not recommended, as other protective measures are more effective (see para. 4.83).

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

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

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

Workplace monitoring

4.112. Paragraphs 3.96–3.98 of GSR Part 3 [3] establish the requirements and responsibilities for workplace monitoring. Workplace monitoring comprises measurements made in the working environment and the interpretation of the results. Workplace monitoring serves several purposes, including routine monitoring, special monitoring for specific occasions, activities or tasks, and confirmatory monitoring to check assumptions made about exposure conditions. Workplace monitoring can be used to verify the occupational doses of personnel whose work involves exposure to predictable low levels of radiation. It is

particularly important for staff members who are not individually monitored. In the nuclear medicine facility, workplace monitoring should address both external exposure and contamination. Further general guidance on workplace monitoring is given in GSG-7 [23].

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

(a) All work surfaces (including the interior of enclosures), tools, equipment and devices (including dosimetry systems, computers and peripherals, and stress testing units), the floor and any items removed from these areas;
(b) Workstations, ventilation systems and drains, when any of these needs to be accessed for maintenance purposes;
(c) Protective and personal clothing, and shoes, particularly when the wearer is leaving a controlled area (monitors should be available near the exit);
(d) Clothing, bedding and utensils used by radiopharmaceutical therapy patients.

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

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

4.116. Workplace monitoring should be performed and documented as part of the nuclear medicine facility's radiation protection program. The nuclear medicine facility's RPO or medical physicist should provide specific advice on the workplace monitoring program, including any investigations that are triggered when investigation levels are exceeded (see paras 4.131 and 4.132).

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

Assessment of occupational exposure and health surveillance for workers

Assessment of occupational exposure

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

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

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

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

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

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

4.124. For monitoring the lens of the eye, a depth of 3 mm ($d = 3$) is recommended, and $H_p(3)$ is used to provide an estimate of equivalent dose to the lens of the eye. In practice, however, the use of $H_p(3)$ has not been widely implemented for routine individual monitoring. In nuclear medicine, it is generally expected that the dose to the lens of the eye is not significantly higher than for the rest of the body. A possible exception is in the handling of sources for preparation and administration, but with accepted practices (as described in paras 4.70–4.91) the lens of the eye should be adequately protected. Nonetheless, monitoring of dose to the lens of the eye may need to be considered.

4.125. There are three dose limits applicable to workers in nuclear medicine: the limit for effective dose, and the limits for equivalent dose to the lens of the eye and to the skin and extremities. However, in nuclear medicine, both exposurefrom external radiation and exposure from internal contamination are relevant. The dosimeter being worn will measure external radiation only and will be used to estimate one or more of the quantities used for the dose limits. Depending on the work performed by the person being individually monitored, there may be a preferred position for wearing the dosimeter, and more than one dosimeter may be used. In nuclear medicine, dosimeters are usually worn on the front of the upper torso (and under any protective clothing), as occupational exposure arisingfrom most nuclear medicine procedures results in the whole body being fairly uniformly exposed (see para. 4.123 for guidance on when extremity dosimeters should be worn).

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

(a) A single dosimeter placed under the apron, reported in $H_p(10)$, provides a good estimate of the contribution to the effective dose of the parts of the body protected by the apron, but underestimates the contribution of the unprotected parts of the body (the thyroid, the head and neck, and the extremities).
(b) A single dosimeter worn outside the apron, reported in $H_p(10)$, provides a significant overestimate of effective dose and should be corrected for the protection afforded by the apron by using an appropriate algorithm [120, 122].
(c) Notwithstanding (a) and (b), in nuclear medicine, a single dosimeter under the apron provides an estimate of the effective dose that is sufficient for radiation protection purposes.

4.127. In nuclear medicine, certain workers may be at risk of both surface (skin) contamination and internal contamination by ingestion, inhalation or adsorption of radioactive material. Employers are responsible for identifying those persons and for arranging for appropriate monitoring (para. 3.102 of GSR Part 3 [3]). This requirement is typically met by monitoring the thyroid with an external detector that assesses the iodine uptake for individuals handling radioiodineand by monitoring the hands after the protective gloves have been removed. In some special cases, it may be required to measure the activity of urine samples. The committed effective dose should be calculated as part of the worker's total effective dose [23].

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

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

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

Investigation levels for staff exposure

4.131. Investigation levels are different from dose constraints and dose limits; they are a tool used to provide a warning of the need to review procedures and performance, to investigate what is not working as expected and to take timely corrective action. The exceeding of an investigation level should prompt such actions. In nuclear medicine, one could use predetermined values such as 0.5 mSv per month for effective dose or 15 mSv per month for finger dose. Suitable alternatives can be doses that exceed an appropriate fraction (e.g. 25%), pro rata per monitoring period, of the annual dose limits or a pre-set value above a historical average. Abnormal conditions and events should also trigger an investigation. In all cases, the investigation should be carried out with a view to improving the optimization of occupational protection, and the results should be recorded. Investigation levels should also be set for workplace monitoring, with

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

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

Persons who work in more than one place

4.133. Some individuals might work in more than one nuclear medicine facility. The facilities may be quite separate entities in terms of ownership and management, or they may have common ownership but separate management, or they may even have common ownership and management but be physically quite separate. Regardless of the ownership and management structure, the occupational radiation protection requirements for the particular nuclearmedicine facility apply when the person is working in that facility. As described in para. 4.120, a dosimeter issued for individual monitoring should be worn onlyin the facility for which it is issued, as this facilitates the effective optimizationof 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 setof dosimeters for staff that work in more than one of its facilities. However,the radiation protection advantages of having the dosimeter results linked to a person's work in only one nuclear medicine facility remain (see also para. 4.135).

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

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

Records of occupational exposure

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

Health surveillance for workers

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

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

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

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

Information, instruction and training

4.141. All staff involved in nuclear medicine should meet the respective training and competence criteria described in paras 2.119–2.137. This will includegeneral education, training, qualification and competence for occupational radiation protection in nuclear medicine. Nuclear medicine physicians, medical radiation technologists, medical physicists and nurses may not have been trained with respect to the X ray based component of hybrid imaging systems, suchas PET–CT, and as such they should undertake radiation protection and safety training relevant to the additional imaging modalities in their nuclear medicine facility.

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

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

Conditions of service and special arrangements

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

Pregnant or breast-feeding workers

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

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

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

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

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

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

4.149. With regard to the dose limit of 1 mSv for the embryo or fetus, the dose to the embryo or fetus is not likely to exceed 25% of the personal dosimeter measurement of external exposure. This value depends on the penetration of the radiation (i.e. on the photon energy of the radionuclides in use). Information, advice and, if indicated, counselling for pregnant workers should be made available (see also para. 4.140).

Persons under 18

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

Protection of workers responding to incidents in a nuclear medicine facility

4.151. The practice of nuclear medicine is a planned exposure situation, and when circumstances result in incidents that lead to, or could lead to, unintended or accidental exposures of patients or staff, they are still within the framework of a planned exposure situation. The potential occurrence of such incidents should be considered in advance in the safety assessment for the facility and mitigatory procedures should be developed accordingly (see the guidance in paras 4.283–4.301 on prevention and mitigation of accidents).

4.152. Occupational exposure of staff responding to such incidents is stillsubject to the occupational dose limits, and the mitigatory procedures for incidents should include considerations for the optimization of protection and safety for the responding workers. The mitigatory procedures should also include allocation of responsibilities and should provide for the education and training of the relevant staff in executing the mitigatory measures, which should be periodically exercised. Most of these situations, for example the response to spillage of radioactive materials on work surfaces, can be executed in a planned manner so that doses can be kept low. There may be situations with high doses, for example in medical emergencies involving immediate care of patients in the case of a stroke or cardiac arrest, when large amounts of radioactive material have been incorporated (e.g. 2 GBq of ^{131}I), but in these events the dose is justified because the procedure is lifesaving. However, even in the case of urgentsurgery, rotation of personnel may be utilized if the surgical procedure is lengthy

to help to maintain optimized occupational radiation protection for this situation. The advice of the facility's RPO should be sought for these situations (see the guidance in paras 4.299 and 4.300 for more details).

RADIATION PROTECTION OF INDIVIDUALS UNDERGOING MEDICAL EXPOSURE

4.153. This section covers radiation protection of patients, carers and comforters, and volunteers in biomedical research. The term 'patient', when used in the context of medical exposure, means the person undergoing the radiological procedure. Other patients in the nuclear medicine facility, including those who may be waiting for their own radiological procedure, are considered members of the public and their radiation protection is covered in paras 4.263–4.272.

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

Justification of medical exposure

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

4.156. The roles of the health authority and professional bodies with respect to a level 2 or generic justification of radiological procedures, justification of health screening 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

4.157. GSR Part 3 [3] requires a joint approach to justification at the level of an individual patient, with a shared decision involving both the referring medical practitioner (who initiates the request for a radiological procedure) and the radiological medical practitioner. A referral for a nuclear medicine procedure should be regarded as a request for a professional consultation or opinion rather than an instruction or order to perform. The referring medical practitioner brings the knowledge of the medical context and the patient's history to the decision process, while the radiological medical practitioner has the specialist expertise

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

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

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

4.160. In nuclear medicine imaging, requirements for justification are applied more effectively as part of the medical process of determining the 'appropriateness' of a radiological procedure. The process of determining appropriateness is an evidence based approach to choosing the best test for a given clinical scenario, with account taken of diagnostic efficacy and justificationas well as alternative procedures that do not use ionizing radiation, for example, ultrasound or MRI. Useful tools to support this decision making process include national or international imaging referral guidelines developed by professional societies [127–133, 233]. Imaging referral guidelines can be disseminated or utilized through electronic requesting systems[25] and clinical decision support tools or systems.

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

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

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

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

(b) Is it needed? The anticipated outcome of the proposed radiological procedure (positive or negative) should influence the patient's management.

(c) Is it needed now? The timing of the proposed radiological procedure in relation to the progression of the suspected disease and the possibilities for treatment should all be considered as a whole.

(d) Is this the best investigation to answer the clinical question? Advances in imaging techniques are taking place continually, and the referring medical practitioner may need to discuss with the radiological medical practitioner what is currently available for a given problem.

(e) Has the clinical problem been explained to the radiological medical practitioner? The medical context for the requested radiological procedure is crucial for ensuring the correct technique is performed with the correct focus.

4.162. The three particular groups of patients identified in para. 3.157 ofGSR Part 3 [3] for special consideration with respect to justification in nuclear medicine are patients who are pregnant or breast-feeding 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 a nuclear medicine procedure is performed. Paragraph 3.176 of GSR Part 3 [3] requires that procedures be "in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus". Pregnancy would then be a factor in the justification process and might influence the timing of the proposed radiological procedure or a decision as to whether another approach to treatment is more appropriate. Care should be taken to ascertain that the examination or treatment selected is indeed indicated for a medical condition that requires prompt medical treatment. Confirmation of pregnancy could occur after the initial justification and before the radiological procedure is performed. Repeat justification is then

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

(i) Most diagnostic procedures with ^{99m}Tc do not cause high fetal doses. For radionuclides that do not cross the placenta, the fetal dose is derived from the radioactivity in maternal tissues. Some radiopharmaceuticals, or their breakdown components, that do cross the placenta and concentrate in a specific organ or tissue can pose a significant risk to the fetus. Particular attention should be given to radiopharmaceuticals labelled with iodine isotopes. Radiopharmaceuticals labelled with other radionuclides, in particular positron emitters, need special consideration. In all these instances, the medical physicist should estimate the fetal dose. Detailed information on doses to the embryo or fetus from intakes of radionuclides by the mother is given by the ICRP [234].

(ii) As a rule, a pregnant patient should not be subject to radioiodine therapy unless the application is lifesaving. Otherwise, the therapeutic application should be deferred until after the pregnancy and after any period of breast-feeding [124, 235, 236]. In particular, radioiodine will easily cross the placenta, and the fetal thyroid begins to accumulate iodine at about ten weeks of gestation.

(b) In breast-feeding patients, excretion through the milk and possibly enhanced dose to the breast should be considered in the justification process. Detailed information on doses to infants from the ingestion of radionuclides in breast milk is given by the ICRP [237].

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

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

4.164. ‘Self-presentation’, including ‘individual health assessment’, occurs when a member of the public asks for a radiological procedure without a referral from a health professional. This may have been prompted by media reports or advertising. Self-presentation for nuclear medicine procedures is not widely prevalent, but for any such case justification is required, as for all radiological

procedures. Relevant professional bodies have an important role in considering evidence for developing guidance when new practices are proposed. States may choose to incorporate such guidance into legislation [136].

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

Justification of medical exposure for biomedical research volunteers

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

Justification of medical exposure for carers and comforters

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

Optimization of protection and safety

4.168. In medical exposure, optimization of protection and safety has several components, some applicable directly to the radiological procedure about to be performed and others providing the support or framework for the other components. These components of optimization of protection and safety are

described in paras 4.169–4.240. Key personnel in the optimization process are the radiological medical practitioner, the medical radiation technologist and the medical physicist.

Design considerations

4.169. The use of appropriate and well designed medical radiologicalequipment and associated software underpins any nuclear medicine procedure. Gamma cameras, SPECT–CT and PET–CT scanners and their accessories should be designed and manufactured so as to facilitate the keeping of doses from medical exposure as low as reasonably achievable consistent with obtaining adequate diagnostic information. Guidance on design considerations is given in the subsection on medical radiological equipment in paras 4.45–4.51. Guidance on design considerations applicable for X ray imaging systems as part of hybrid systems is given in paras 3.32–3.41. Ultimately, as established in para. 3.162 of GSR Part 3 [3], it is the responsibility of the licensee of the nuclear medicine facility to ensure that the facility uses only medical radiological equipment and software that meets applicable international or national standards.

Operational considerations: General

4.170. Following justification, the nuclear medicine procedure is required to be performed in such a way as to optimize patient protection (para. 3.163 of GSR Part 3 [3] for diagnostic procedures and para. 3.165 of GSR Part 3 [3] for radiopharmaceutical therapy procedures). The level of image quality sufficient for diagnosis is determined by the radiological medical practitioner and is based on the clinical question posed.

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

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

Operational considerations: Diagnostic imaging

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

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

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

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

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

— Correct hydration.

(c) The storage or retention of radiopharmaceuticals within specific organs can be influenced by drugs such as diuretics or gall bladder stimulants, whenever they do not adversely interfere with the procedure. This method is sometimes used to increase the specificity of the examination, but has also a positive influence on radiation protection, for example the use of a 'diuretic challenge' in renography.

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

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

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

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

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

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

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

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

Operational considerations: Radiopharmaceutical therapy

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

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

(a) Verbal and written information and instructions should be provided to patients about their radiopharmaceutical therapy and about how to minimize exposure of family members and the public, and advice should be provided on pregnancy and contraception after therapy (for detailed guidance, including sample information sheets, see Refs [21, 204, 246–249]).
(b) Special attention should be given to preventing the spread of contamination due to patient vomit and excreta.
(c) A protocol should be drawn up for the release of patients after the administration of therapeutic doses of radiopharmaceuticals (see the guidance in paras 4.246–4.248).
(d) A protocol should be drawn up for the actions to be taken when the dose incurred is above or below the value prescribed by the radiological medical practitioner as required by para. 3.180 of GSR Part 3 [3].

4.182. Paragraph 3.165 of GSR Part 3 [3] establishes the requirement that the type and activity of the therapeutic radiopharmaceuticals that are administered to each patient are appropriate. Although algorithms for determining appropriate activities for a given patient on the basis of radiation doses to critical organs exist, there is no standardized algorithm. Methodologies are described in Refs [250–256]. Ideally, the administered activity should be based on the results of a pre-therapeutic dosimetry. Typically, therapeutic radiopharmaceuticals are administered at standard fixed activities (GBq), standard fixed activities per unit body mass (MBq/kg) or standard fixed activities per unit body surface area

(MBq/m^2), based on the results of toxicity studies and evaluation of side effects in clinical trials.

4.183. For female patients, their pregnancy and breast-feeding status should be evaluated before administration of a therapeutic dose (see also paras 4.241–4.245).

4.184. Immediately prior to administration of a therapeutic radiopharmaceutical, the following information, as applicable, should be verified, preferably by two individuals:

(a) The dose on the radiopharmaceutical label matches the prescription;
(b) The identity of the patient by two independent means;
(c) The identity of the radionuclide;
(d) The identity of the radiopharmaceutical;
(e) The total activity;
(f) The date and time of calibration.

4.185. The administered activity should be verified by means of an activity meter (dose calibrator) or other suitable device to ensure that the total activity does not deviate significantly from the prescribed administered activity (e.g. <5% deviation), and the measured value should be recorded. Corrections should be calculated for residual activity in the syringe, cups, tubing, inline filter or other materials used in the administration.

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

4.187. Both female and male patients should be advised about avoidance of pregnancy after therapeutic administrations. Data on the periods during which conception should be avoided after administration of a radiopharmaceutical to a female patient for therapeutic purposes are given in Appendix II, with further guidance provided in Ref. [238].

4.188. The administration of therapeutic doses of relatively long lived radionuclides in ionic chemical forms to male patients is a possible source of concern because of the presence of larger quantities of these radionuclides in ejaculate and in sperm. It may be prudent to advise sexually active men who have been treated with, for example, ^{32}P (phosphate), ^{89}Sr (chloride), ^{131}I (iodide), ^{223}Ra (chloride) to avoid fathering children for a period of four months after

treatment, and to have protected intercourse for a period of time to be defined by the medical practitioner. The period of four months is suggested, as this is longer than the sperm regeneration cycle [238, 249, 257].

Operational considerations: Pregnant patients

4.189. Administration of radiopharmaceuticals for therapy to patients who are or might be pregnant should be generally avoided. There may be exceptions when the treatment is lifesaving (see also paras 4.162 on justification and 4.241–4.243 on the need to ascertain pregnancy status).

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

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

4.192. In the case of radiopharmaceuticals that are rapidly eliminated by the maternal kidneys, the bladder is the major source of fetal irradiation. After the administration of such radiopharmaceuticals, drinking plenty of fluid and frequently emptying the bladder should be encouraged. Some radiopharmaceuticals, for example radioactive iodides, including those administered for diagnostic purposes, cross the placenta freely and are taken up by fetal tissue, for example the thyroid. Failure to ascertain whether a patient is pregnant when administering ^{131}I for a scan, for example, may lead to a severe accidental exposure of the fetus.

4.193. Of special concern is also the use of CT in PET–CT or SPECT–CT examinations. Routine diagnostic CT examinations of the pelvic region with and without contrast injection can lead to a dose of 50 mSv to the uterus, which is assumed to be equivalent to the fetal dose in early pregnancy. When PET–CT or SPECT–CT scanning is indicated for a pregnant patient, low dose CT protocols should be used and the scanning area should be reduced to a minimum (see also paras 3.176–3.185).

4.194. In the use of fluorodeoxyglucose (FDG) or other radiopharmaceuticals in PET imaging with patients who are or might be pregnant, a lower activity of

FDG should be considered. Protection of the fetus can be optimized by using smaller administered activities and longer imaging times. Further guidance is given in Refs [62, 258].

Operational considerations: Breast-feeding

4.195. Female patients should be advised that breast-feeding is generally contraindicated after administration of some radiopharmaceuticals, due to both the external irradiation of the suckling baby and the potential excretion of radioactivity through the breast milk (see also paras 4.162 on justification and 4.244 and 4.245 on the need to ascertain breast-feeding status).

4.196. Depending on the radiopharmaceutical, breast-feeding may need to be interrupted for a period or even stopped following its administration. The milk expressed during the interruption period should be discarded. More specific advice is given in Appendix III and Refs [235, 236, 238, 259].

Calibration

4.197. Requirements for the calibration of sources and instruments used for dosimetry of patients are given in para. 3.167 of GSR Part 3 [3]. In nuclear medicine, responsibility for calibration is assigned to the nuclear medicine facility's medical physicist. Unsealed sources for nuclear medicine procedures should be calibrated in terms of the activity of the radiopharmaceutical to be administered, with the activity being determined and recorded at the time of administration. Detailed guidance on acceptable protocols for making activity measurements can be found in Refs [230, 260].

4.198. Radionuclides should be checked for radioactive impurities when these are liable to be present. This particularly applies to examining short lived radionuclides for the presence of longer lived impurities that could deliver a significant fraction of the absorbed dose.

4.199. The calibration of X ray based imaging devices that are part of hybrid imaging systems, such as CT in PET–CT or SPECT–CT, should follow the guidance for such modalities in paras 3.201, 3.203 and 3.205.

4.200. In the nuclear medicine facility, instruments used for dosimetry of patients, such as activity meters (dose calibrators), should also be calibrated at appropriate intervals using calibrated reference sources that cover the energy range used in clinical practice. After the initial calibration, the intervals for

periodic calibrations might differ, depending on the availability at the facility of radioactive sources for calibration. A period of not more than two years is recommended.

4.201. Paragraph 3.167(d) of GSR Part 3 [3] requires that the calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory. Ideally, this would be the national standards dosimetry laboratory (primaryor 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.

4.202. Records of calibration measurements and associated calculations, including uncertainty determinations (uncertainty budgets), should be maintained as described in para. 4.262.

Dosimetry of patients: Diagnostic procedures

4.203. Paragraph 3.168 of GSR Part 3 [3] requires that registrants and licensees of nuclear medicine facilities ensure that patient dosimetry be performed and that typical doses to patients for diagnostic radiological procedures be determined. Knowledge of the typical doses at a facility forms the basis for applying methods of dose reduction as part of optimization of protection and safety. It also enables the nuclear medicine facility to use DRLs (see paras 4.213–4.220) as another tool for the optimization of protection and safety. Administered activity (in MBq) is the most widely used surrogate for dose in diagnostic nuclear medicine; however, organ doses and effective doses can be calculated from activity using established methodologies (see para. 4.210).

4.204. Clearly, the more radiological procedures at the nuclear medicine facility for which typical doses are known, the better the basis for optimization of protection and safety. GSR Part 3 [3] requires determination of typical doses for common diagnostic radiological procedures. The procedures that are considered to fall into this category will vary from facility to facility, and State to State, but common examinations generally include thyroid scans, bone scans, myocardial perfusion imaging, FDG–PET/CT in oncology, renal scans and lung scans.

4.205. The term ‘typical dose’, as used in para. 3.168 of GSR Part 3 [3], refers to the median or average dose or activity for a particular size of patients. In nuclear medicine, DRLs are set in activity administered to the patient (MBq) or in activity per unit of body mass (MBq/kg). Patient size has a large influence

on dose, so some selection or grouping of patients is required. Such groupings include ‘standard adult’, often based on an average mass of 70 kg with a range of ±20 kg. Groupings for children have sometimes been based on age, such as newborn (0 years), infant (1 year), small child (5 years), child (10 years) and teenager (15 years), but more recently size specific groupings are being recommended and used, for example by using body mass intervals. Patientsize groupings should be adopted that correspond to the groupings used for the DRLs in the State or region. The sample size used for each patient grouping and radiological procedure should be of sufficient size to assure confidence in the determination of the typical dose. Such sample sizes are typically in the range of 10–20 patients: the larger sample size the lower the statistical uncertainties (see also paras 2.39–2.41 and Refs [14, 242]).

4.206. The dose in the term ‘typical dose’, as used in para. 3.168 of GSR Part 3 [3], means, for the given diagnostic nuclear medicine procedure,the activity administered to the patient (MBq) or the activity per unit of body mass (MBq/kg), or, in the case of X ray imaging, an accepted dosimetric quantity as described in paras 3.202 and 3.203. For combined doses from radiopharmaceuticals and X rays, the dose to the organ concerned should be used.

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

4.208. The results of the surveys used to determine typical doses at the nuclear medicine facility should be used as part of the ongoing review of the optimization of protection and safety at the facility, and should be used for comparison with established DRLs (see paras 4.213–4.220). The results should also be submitted to the organization in the State or region that is responsible for establishing and reviewing national or regional DRLs. With these considerations in mind, the patient surveys of administered activities from which patient doses can be calculated, as required by GSR Part 3 [3], should take place at intervals of no more than five years and preferably no more than three years. Another trigger fora survey would be the introduction of new radiopharmaceuticals, equipment or technology into the nuclear medicine facility or when significant changes have been made to the protocols or the equipment.

4.209. Sometimes, patient dosimetry in diagnostic nuclear medicine procedures may be required for specific individual patients. Reasons might include an unintended or accidental medical exposure where an estimation of patient doses is required as part of the investigation and report (see para. 4.255), or there may be the need to estimate the dose to an embryo or fetus (see para. 4.191).

4.210. There are several indirect and direct methods to estimate patient dose in diagnostic nuclear medicine procedures. In the case of hybrid systems, the contribution from each of X rays and radionuclides should be calculatedand combined. Methodologies and data for the determination of doses from radiopharmaceuticals are given in Refs [238, 259, 261–265] and methodologies for X ray imaging in para. 3.218.

Dosimetry of patients: Radiopharmaceutical therapy procedures

4.211. Paragraph 3.168 of GSR Part 3 [3] requires that nuclear medicine facilities determine typical absorbed doses to patients for their therapeutic radiological procedures. Methodologies for the determination of doses from therapy radiopharmaceuticals are explained in detail in Refs [238, 252, 254–256, 266–272].

4.212. Radiopharmaceutical toxicity in therapeutic nuclear medicine depends on the absorbed dose to critical organs (e.g. to the hematopoietic system), and the efficacy of the treatment depends on the absorbed dose received by target tissues. In current clinical practice, the nuclear medicine therapeutic treatmentis usually delivered on the basis of an administered activity prescription, insome cases with adjustments made for body mass or surface area. Ideally, a pre-treatment calculation of the absorbed doses received by organs at risk and target tissues would allow for an accurate prediction of toxicity and efficacy of the treatment. The dosimetry calculations performed in this context should take into account individual patient pharmacokinetics and anatomy.

Diagnostic reference levels

4.213. Paragraphs 3.168 and 3.169 of GSR Part 3 [3] require that patient dosimetry surveys be performed for the diagnostic procedures at a nuclear medicine facility, as described in paras 4.203–4.210, and that these results be compared with the established DRLs for the State or region. The purpose is to ascertain whether or not the typical dose or activity for the facility for a given diagnostic nuclear medicine procedure compares favorably with the value of the

DRL for that nuclear medicine procedure. Guidance on establishing national or regional DRLs is given in paras 2.34–2.45.

4.214. A review of optimization of protection and safety for that particular nuclear medicine procedure is triggered if the comparison shows that the typical dose or activity for the facility exceeds the DRL, or that the typical dose or activity for the facility is substantially below the DRL and it is evident that the exposures are not producing images of diagnostic usefulness or are not yielding the expected medical benefit to the patient. However, future advances in technology might result in typical doses or activities substantially below the DRLs, and still produce images of diagnostic usefulness.

4.215. Given the uncertainties in determining the typical dose or activity for a facility, questions can arise over whether or not a DRL has really been exceeded. Some States adopt an algorithmic approach, for example where the typical dose or activity for the facility, minus two times its standard error, should be greater than the value of the DRL [16]. A simpler approach, based purely on the typical value for the facility, may be sufficient, as the purpose is to identify the need for a review [14–16].

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

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

4.218. The review of how the given nuclear medicine procedure is being performed and of the optimization of protection and safety, triggered by the DRL comparison, might conclude that there are valid reasons supported bysound clinical judgement why the nuclear medicine facility has a typical dose or activity that exceeds the DRL. These reasons should be documented as part of thefacility's program of quality assurance. On the other hand, the review might identify areas for improvement resulting in revised protocols for that nuclear medicine procedure. The results of the DRL comparison and any ensuing reviewand actions should be documented as part of the facility's program of quality assurance.

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

4.220. The regulatory body in a given State may specify frequencies for performing DRL comparisons. Otherwise, the general guidance for patient dosimetry, described in para. 4.208, would be applicable.

Quality assurance for medical exposures

4.221. Paragraph 3.170 of GSR Part 3 [3] requires that nuclear medicine facilities have in place a comprehensive 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.

4.222. The purpose of the program of quality assurance for medical exposures is to help to ensure successful optimization of protection and safety inthe nuclear medicine facility and to minimize the occurrence of unintended and accidental medical exposures.

4.223. The complexity of the program of quality assurance for medical exposures will depend on the type of nuclear medicine facility. A facility with only limited diagnostic procedures will have a simpler program compared with a facility that offers a comprehensive diagnostic service, including PET–CT imaging, radiopharmaceutical therapy, and that has a radiopharmacy. Nonetheless, most of the elements of the program are common, and it ismore in the degree of application that there are differences. Paragraph 3.171 of GSR Part 3 [3] establishes the common elements of the program.

4.224. Measurements on medical radiological equipment are one of the components of the program of quality assurance. Acceptance tests are required for new or significantly refurbished or repaired equipment, or afterthe installation of new software or modification of existing software that could affect protection and safety. The acceptance test should be followed immediatelyby commissioning, and then ongoing periodic quality control tests, including constancy tests. The purpose is to ensure that, at all times, all medical radiological

equipment performs correctly, accurately, reproducibly and predictably. Acceptance and commissioning tests should be performed in the same way for equipment and software that has been donated.

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

4.226. After acceptance and before clinical use on patients, commissioning should be carried out by, or under the supervision of, the medical physicist. Commissioning should include measurements of all parameters and conditions of use that are expected in clinical use. For most situations, the medical physicist should be directly involved in the measurements, calculations and interpretation of data to characterize the equipment's performance. In some simple situations, it may be sufficient for the medical physicist to provide documented advice on how the commissioning should be performed. During commissioning, the baseline for subsequent constancy tests is established.

4.227. In addition to the acceptance testing and commissioning, para. 3.171 of GSR Part 3 [3] requires, periodically and after any major maintenance procedure or upgrade, the measurement of physical parameters of medical radiological equipment. There are many published reports from international and national organizations and national and regional professional bodies giving detailed guidance on the quality control tests that should be performed in nuclear medicine, including recommended frequencies [183, 184, 187, 200, 201, 204, 205, 215–228, 230, 260, 266, 273–275]. In addition, many of these organizationsand professional bodies publish on their web sites new or updated publications on the topic. The regulatory body may have its own specific requirements forthe tests that should be performed, their frequencies and the competence ofthe specialists involved. Such specific requirements should be established with consultation between the regulatory body and the relevant professional bodies.

4.228. Guidance on the quality control tests for X ray imaging devices used in nuclear medicine is provided in the references listed in para. 3.238.

4.229. In nuclear medicine, there is an additional factor of the radiopharmaceuticals themselves. The program of quality assurance for

medical exposures should ensure that radiopharmaceuticals intended for administration to patients are prepared in a manner that meets clinical needs and that satisfies both radiation protection and safety and pharmaceutical quality requirements [204, 207, 208]. Therefore, in complex nuclear medicine facilities, radiopharmacists and radiochemists, in conjunction with other health professionals as appropriate, should be involved.

4.230. Paragraph 3.171(e) of GSR Part 3 [3] specifically requires that periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment be part of the program of quality assurance. This is to ensure that such instrumentation has a current calibration, typically conducted within the last two years (see para. 4.200), and that it is functioning correctly. The 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 software relating to dosimetry (e.g. software used for calculating specific uptake values from which doses can be estimated).

4.231. The results of the quality control tests should be compared with established tolerance limits. These limits may have been established to ensure compliance with a regulatory requirement for the performance of particular physical parameters or they may be set on the basis of recommended values given in published reports, such as those referenced in para. 4.227. Paragraph 3.171(b) of GSR Part 3 [3] requires the implementation of corrective actions if themeasured values fall outside established tolerance limits. Such corrective actionsare likely to include maintenance or servicing of the equipment, and hence a maintenance program should be put in place at the nuclear medicine facility. Insome cases, the equipment might be outside the tolerance limits by a significant amount and the equipment should be immediately taken out of clinical use and not returned until servicing has taken place and it has been ascertained that the equipment now meets the performance requirements.

4.232. The program of quality assurance for medical exposures in nuclear medicine should include the use of checks to ensure that the facility's protocols and procedures for imaging and therapy, including radiation protectionand safety, are being followed. The periodic review of the protocols and procedures themselves is part of the radiological review at the facility (seeparas 4.259–4.261). In addition, a review of imaging procedures may have been triggered by a comparison with DRLs (see paras 4.213–4.220).

4.233. Maintaining records is a crucial aspect of the program of quality assurance for medical exposures. This includes the procedures used in the program, the results of the quality control tests including trend analysis,the dosimetry surveys, the DRL comparisons, the corrective actions, and the investigations of unintended and accidental medical exposures. When planning and developing an effective 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 nuclear medicine facility, should review the records of the program of quality assurance for medical exposures.

4.234. In line with standard practices for quality management, para. 3.172 of GSR Part 3 [3] requires that "regular and independent audits are made of the 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 4.259–4.261).

Dose constraints: Carers and comforters

4.235. Some diagnostic nuclear medicine procedures, particularly of children, can be better performed with the assistance of a carer or comforter, for example a relative in the case of a pediatric patient, or a relative or friend for a disabled patient or very elderly or very ill patient. In these circumstances, the carer or comforter will be exposed. This is usually to a low dose, such as when caring for a child undergoing a renal examination, but in some cases the dose is not insignificant, for example in the case of staying with a child during a PET examination. Furthermore, in nuclear medicine there is also the additional consideration of exposure of carers and comforters after the diagnostic procedure, or in the case of radiopharmaceutical therapy with radioiodine, their exposure during the course of the treatment. This exposure is defined as medical exposure and as such is not subject to dose limits. However, paras 3.153 and 3.173 of GSR Part 3 [3] require that such carers and comforters be afforded radiation protection through the application of the requirements for the optimization of protection and safety and, in particular, the use of dose constraints in this

process. These are the dose constraints established by government, as a result of consultation with the health authority, relevant professional bodies and the regulatory body, as required by para. 3.149(a)(i) of GSR Part 3 [3]. Guidance on setting dose constraints, including considerations for children and pregnant women, is given in paras 2.48 and 2.49.

4.236. Written protocols should be drawn up for implementing measures for the optimization of protection and safety for carers and comforters of patients during or after nuclear medicine procedures. The measures should utilize the basic methods for radiation protection (i.e. time, distance and shielding, and measures to minimize spread of contamination). The protocols should include thefollowing:

(a) Criteria specifying who would be acceptable for acting as a carer or comforter;
(b) Methods for ensuring that the carer or comforter receives a dose that is as low as reasonably achievable;
(c) The values of the dose constraints to be applied (see para. 2.49).

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

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

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

The carer or comforter should indicate that he or she is still willing to provide support, care and comfort to the patient that is undergoing or has undergone a nuclear medicine procedure. In the case of radiopharmaceutical therapy with iodine, both for patients still in the hospital and for those that have been released (see also para. 4.248), appropriate written instructions should be provided to the

carer or comforter of the patient (including for example, instructions on time spent with the patient and proximity to the patient, minimizing of physical contactand not sharing food or drinks). Further guidance is given in Refs [21, 246].

4.239. Guidance applicable to carers and comforters supporting patients undergoing X ray imaging radiological procedures as part of the nuclear medicine procedure in the nuclear medicine facility is given in paras 3.247–3.251.

Dose constraints: Volunteers in biomedical research

4.240. Some individuals will undergo diagnostic nuclear medicine procedures as part of their voluntary participation in an approved 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 nuclear medicine procedures (see para. 2.100). When the volunteer presents himself or herself at the nuclear medicine facility, he or she is to be afforded the same radiation protection as if he or she were a patient ready to undergo a nuclear medicine procedure, but with the additional restriction that his or her exposure will be subject to a dose constraint, either a nationally established dose constraint or a dose constraint specified by the ethics committee that approved the biomedical research program (see paras 2.50, 2.99 and 2.100).

Pregnant patients

4.241. Patients who are pregnant form a special subgroup of patients that should be given particular consideration with respect to radiation protection. These considerations are described in para. 4.162(a) with respect to justification and paras 4.189–4.194 with respect to optimization. None of these considerationscan 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 nuclearmedicine facility to have in place means for ensuring that the pregnancy status ofpatients is known.

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

4.243. Neither of the approaches described in para. 4.242 will work if the patient does not know whether she is pregnant. For this reason, para. 3.176 of GSR Part 3 [3] has an additional requirement on facilities to "ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus". In nuclear medicine, pregnancy status should be ascertained for all radiopharmaceutical therapy, and it is advisable for all diagnostic procedures, in particular for those radiopharmaceuticals that are known to cross the placental barrier. Cooperation with the referring medical practitioner, through standard requests for pregnancy status for specified procedures, is one approach. The referral form should include a 'tick box' for pregnancy status. In case of doubt, a pregnancy test or a determination of hormone levels to assess menopausal status can be carried out.

Breast-feeding patients

4.244. Breast-feeding patients form a special subgroup of patients that should be given particular consideration with respect to radiation protection in nuclear medicine. These considerations have been described in para. 4.162(b) with respect to justification and paras 4.195 and 4.196 with respect to optimization. None of these considerations can take place if it is not known whether the patientis breast-feeding. Therefore, it is crucial, as is required in paras 3.175 and 3.176 of GSR Part 3 [3], for the nuclear medicine facility to have in place means for ensuring that the breast-feeding status of patients is known.

4.245. The first approach is through the posting of clear signs, in languages able to be understood by the people using the nuclear medicine facility, posing the question 'Are you breast-feeding?' and 'If so, please tell the staff'. Such signs should be posted widely in the facility, including in waiting rooms and cubicles. The second approach is to directly ask patients directly whether they are breast-feeding. This might not always be so easy given social and cultural sensitivities, but it should be done when necessary.

Release of patients after radiopharmaceutical therapy

4.246. Paragraph 3.178 of GSR Part 3 [3] requires that a nuclear medicine facility have arrangements in place to manage the release of patients who have undergone radiopharmaceutical therapy. Once the patient is released, two groups of persons should be afforded appropriate radiation protection: the general public whom the patient may encounter or with whom the patient may interact, and members of the patient's family and close friends, who may be viewed simply

as also being members of the public or as carers and comforters. Exposure of members of the public is subject to the public dose limits (see Box 1), while exposure of carers and comforters is not subject to dose limits but is instead controlled through dose constraints (see paras 4.235–4.239). Furthermore, as stated in para. 2.46, public exposure arising from a single 'source', such as a patient who has undergone radiopharmaceutical therapy, should be subject to dose constraints set at some fraction of the dose limits.

4.247. The medical physicist or RPO at the nuclear medicine facility should establish prior to the release of a patient that the retained radioactivity in the patient is such that the doses that could be received by members of the public would not exceed public dose limits, and would be unlikely to exceed the relevant dose constraints for both members of the public and carers and comforters. An acceptable method of estimating the acceptable retained activity for patients being discharged from hospitals is to calculate the time integral of the ambient dose equivalent rate, considering the activity, energy and effective half-life ofthe radionuclides. When deciding on the discharge for a particular patient, the living conditions of the patient, such as the extent to which he or she can be isolated from other family members, in particular children and pregnant women, should also be considered. Safe management of the patient's contaminated excreta should be addressed. Special consideration should be given to incontinentpatients. In the case of carers and comforters, the assumptions made for the calculations should be consistent with the written instructions that will be given at the time the patient is discharged from the facility. Published data suggest that systematic dose monitoring is not necessary (for detailed guidance on all aspectspertaining to the release of patients, see Refs [21, 246, 247]).

4.248. As indicated in para. 4.247, the patient or the legal guardian of the patient should be provided with written instructions on how to keep doses to members of the public and carers and comforters as low as reasonably achievable. Individuals of particular concern are children and pregnant partners of patients (for detailed guidance, including sample information sheets, see Refs [21, 246, 247]).

Unintended and accidental medical exposures

Prevention of unintended and accidental medical exposures

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

> "Registrants and licensees…shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical

exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error."

Paragraph 3.180 of GSR Part 3 [3] requires that the registrants and licensees promptly investigate if such exposures occur. General strategies for addressing those problems include the regular maintenance of medical radiological equipment and software, a comprehensive 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. 4.251.

4.250. Minimization of the likelihood of unintended or accidental medical exposures in nuclear medicine can be brought about by:

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

4.251. Preventive measures should include reporting of incidents and near incidents, analysis and feedback, including lessons from international experience [276]. Preventive measures should also include checking of the robustness of the safety system of the facility against reported incidents (seeRef. [276] for a review of case histories from an extensive collection of accidental medical exposures, including examples relevant to nuclear medicine).

4.252. In addition to the guidance in paras 4.249–4.251, the following three-step strategy (commonly called 'prospective risk management') can help to prevent unintended and accidental medical exposures in nuclear medicine:

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

Investigation of unintended and accidental medical exposures

4.253. The events that constitute unintended or accidental medical exposures are detailed in para. 3.180 of GSR Part 3 [3], and for a nuclear medicine facility such events include those associated with diagnostic procedures and with radiopharmaceutical therapy. For diagnostic procedures, reference should also be made to paras 3.260–3.264 for aspects relating to X ray imaging. Unintended and accidental medical exposures can occur at any stage in the nuclear medicine process. For radiopharmaceutical therapy, unintended or accidental medical exposures can be either underexposures or overexposures. The events identified in para. 3.180 of GSR Part 3 [3] also include near misses, and these should be considered in the same way as actual events.

4.254. One of the events identified in para. 3.180 of GSR Part 3 [3] is a dose administered in radiopharmaceutical therapy differing substantially from (over or under) the prescribed dose. Consensus recommendations on the level ofactivity difference that would be considered as substantially different appear to be lacking, but a pragmatic approach for use within the nuclear medicine facilitymight be the specification of deviations greater than 10% as being substantially different. A system with clear procedures should be put in place for identifying when this type of event occurs.

4.255. Paragraph 3.181 of GSR Part 3 [3] establishes what is required during the course of the investigation. This includes calculation or estimation of patient doses, which should be performed by a medical physicist. A record of the calculation method and results should also be placed in the patient's file. When required, counselling of the patient should be undertaken by an individual with appropriate experience and clinical knowledge.

4.256. The investigation of unintended and accidental medical exposures, as required by paras 3.180 and 3.181 of GSR Part 3 [3], has three main purposes. The first is to assess the consequences for the patients affected and to provide remedial and health care actions if necessary. The second is to establish what went wrong and how to prevent or minimize the likelihood of a recurrence in thenuclear medicine facility (i.e. the investigation is for the facility's benefit and thepatients' benefit). The third purpose is to provide information to other persons or other nuclear medicine facilities. Dissemination of information about unintendedand accidental medical exposures and radiation injuries has greatly contributedto improving methods for minimizing their occurrence. The regulatory body and/or the health authorities could disseminate information on significant events reported to them and on the corrective actions taken, so that other facilities 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, as is the case for image guided interventional procedures and radiation therapy (see paras 3.266 and 5.274, respectively).

4.257. Paragraph 3.181 of GSR Part 3 [3] establishes requirements forthe reporting (in writing) of significant events to the regulatory body and, if appropriate, to the relevant health authority. The regulatory body may also specify its own requirements for the reporting of events by registrants and licensees. It is difficult to quantify the term 'significant': specification of a numerical trigger value immediately creates an artificial distinction between values immediately below that value (and hence would not be reported) and those just above the value (which would be reported). However, the attributes of significant events can be elaborated, and events with one or more of these attributes should be reported to the regulatory body. Such attributes would include the occurrenceof, or the potential for, serious unintended or unexpected health effects due to radiation exposure (in this case the health authority should also be informed), thelikelihood of a similar event occurring in other nuclear medicine facilities, a largenumber of patients having been affected, and gross misconduct or negligence by the responsible health professionals. As stated in para. 4.256, one of the roles of the regulatory body for such a reported event is to disseminate information on theevent and any lessons identified to all potentially affected parties, typically othernuclear medicine facilities and relevant professional bodies, but also in some cases manufacturers, suppliers and maintenance companies.

4.258. Irrespective of whether the event is also reported to the 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

4.259. Paragraph 3.182 of GSR Part 3 [3] requires that radiological reviews be performed periodically at the nuclear medicine facility. This involves considering both justification and optimization aspects of radiation protection. For the latter, the results of the program of quality assurance for medical exposures, including the periodic independent audit, will be a significant input tothe process. As described in paras 2.148 and 2.149, the wider clinical audit couldinclude the radiological review with its assessment of the effective application of the requirements for justification and optimization in the facility for the nuclear medicine procedures being performed [49].

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

4.261. Radiological reviews should consider changes in patient management that result from the diagnostic nuclear medicine procedures, and the effect of introducing new technologies or radiopharmaceuticals on efficiency and cost. In radiopharmaceutical therapy, radiological reviews should consider patient outcome (survival, acute side effects or late side effects), and the effect of introducing new radiopharmaceuticals on efficiency and cost. A system for the ongoing collection of relevant data to support such reviews should be in place at the facility.

Records

4.262. Records should be in place to demonstrate ongoing compliance with radiation protection requirements. Paragraphs 3.183–3.185 of GSR Part 3 [3] establish the requirements for maintaining personnel records, records of calibration, dosimetry and quality assurance, and records of medical exposure. These records are required to be kept for the period specified by the regulatory

body. In the absence of such a requirement, a suggested period for keeping records is ten years. In the case of children, records should be kept for a longer time.

RADIATION PROTECTION OF THE PUBLIC

4.263. Public exposure can arise from the performance of nuclear medicine for persons in and around the nuclear medicine facility and also in the wider public domain. The latter can occur as a result of the release from the nuclear medicine facility of patients with some remaining radioactivity. Radiation exposure of carers and comforters while performing that role is considered medical exposure and not public exposure and is not covered here (see paras 4.235–4.239 for guidance on carers and comforters). In addition, there is the possibility, albeit low, of public exposure from exposure pathways associated with the managementof radioactive waste.

4.264. The requirements for public protection established in paras 3.117–3.137 of GSR Part 3 [3] apply to nuclear medicine facilities. This subsection contains guidance that is specific to nuclear medicine facilities. More generaland comprehensive guidance on radiation protection of the public is given in GSG-8 [24].

Members of the public in the medical facility

4.265. Persons who will be undergoing a nuclear medicine procedure are also considered members of the public during the time when the treatment or diagnostic procedure is not taking place, for example, while they are sitting in the waiting room before being administered radiopharmaceuticals. Similarly for carers and comforters, any exposure incurred other than that arising from the nuclear medicine procedure in which they are involved will be public exposure.

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

External exposure and contamination

4.267. The primary means for protecting the public from external exposure is the shielding in place at the nuclear medicine facility (see paras 4.32–4.36), which should be sufficient so that public exposure resulting from being in any

immediately adjacent areas, including accessible rooms above and below, is in compliance with the public dose limits, and preferably less than any dose constraint that the regulatory body may have applied (see paras 2.16 and 2.46).

4.268. Patients that have been administered radiopharmaceuticals could expose members of the public in the nuclear medicine facility and upon release (see paras 4.246–4.248). In the nuclear medicine facility, the RPO should establish rules to ensure that the exposure of any member of the public will be less than thepublic dose limit and, preferably, lower than any applicable dose constraint. At the design stage of the nuclear medicine facility, consideration should be given to the respective flow of patients and visitors in the facility so that their contact or proximity is minimized, thereby reducing the potential for both external exposure and spread of contamination.

Control of access

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

4.270. Controlled areas and supervised areas should be clearly identified to help to prevent inadvertent entry. This includes areas such as toilets designated for nuclear medicine patients. Further control can be afforded by the use of keys (or passwords) to restrict access to the control panels of medical radiological equipment to authorized persons only.

Members of the public in the wider public domain

4.271. There are usually no restrictions with respect to public exposure for the release of patients that have undergone diagnostic nuclear medicine procedures. Patients should be advised on measures to enhance elimination of the residual

radioactivity (such as drinking plenty of fluid and frequently emptying the bladder) and to avoid prolonged contact with sensitive members of the public (young children and pregnant women), if appropriate.

4.272. The exposure of other persons, in the wider public domain, by patients who have received radiopharmaceutical therapy can occur through external irradiation of persons close to the patient, such as on public transport, and through internal contamination of persons as a result of excreted or exhaled radionuclides. The RPO of the nuclear medicine facility should establish rules to ensure that the exposure of any member of the public, following the release of a radiopharmaceutical therapy patient, will be less than the public dose limit and, preferably, lower than any applicable dose constraint. As stated in para. 4.248, the patient should be given written instructions that include means for avoiding external and internal exposure of the public. An acceptable method to estimate the acceptable retained activity for patients being discharged is described inpara. 4.247. Results of the calculations should be recorded. When deciding on the appropriate discharge activity for a particular patient, the licensee and the RPO should take into account the transport and the living conditions of the patient, such as the extent to which the patient can be isolated from other family membersand the safe management of the patient's excreta and body fluids (for detailed guidance on the release of radiopharmaceutical therapy patients and radiation protection of the public, see Refs [21, 246, 247]).

Death of a patient who has undergone a nuclear medicine procedure

4.273. Precautions may be required after the death of a patient to whom radiopharmaceuticals have been administered, particularly in the case of radiopharmaceutical therapy. This applies to the immediate handling of thebody, both in the hospital and in the home or other place, but also with respectto autopsy, embalming, burial or cremation. The radiation protection precautions should be determined by the RPO, on the basis of a generic safety assessment of the need for monitoring personnel who carry out these procedures, the need for monitoring the premises and the need for minimizing external radiation exposure and the potential for contamination. In addition to whole body monitoring, finger monitoring may be required for individuals carrying out autopsies or embalming, as contamination and radioactive waste are likely to be generated. The situation for patients injected with bone seeking radiopharmaceuticals such as ^{89}Sr for pain management of skeletal metastases is more of a problem because of the relatively long half-life of this radionuclide (50 days). Storage of the body is impractical. In the case of cremation, depending on the family's intention for the ashes, storage may be needed in order to comply with local regulations (for detailed guidance,

see Refs [21, 246]). Other considerations, such as cultural or ethical concerns, should be taken into account. Regulatory bodies should provide guidance in such situations.

Radioactive waste

4.274. Another potential pathway for public exposure is from radioactive waste; and hence, Requirement 31 and paras 3.131–3.134 of GSR Part 3 [3] require that systems and procedures be put in place to manage radioactive waste and discharges of radioactive material. Detailed guidance on the managementof radioactive waste applicable to nuclear medicine facilities is given in IAEA Safety Standards Series No. SSG-45, Predisposal Management of Radioactive Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education [277].

4.275. Most radioactive waste from nuclear medicine is waste containing short lived radionuclides, and it is feasible to consider such waste as non-radioactive waste, either immediately or after some time to allow for decay. A formal mechanism should be put in place, including rigorous control measures, to demonstrate compliance with regulatory requirements in respect of the release from regulatory control of radioactive material that is no longer are considered radioactive waste. Further guidance is given in SSG-45 [277].

4.276. Since waiting for decay until the radioactive material meets the regulatory criteria for clearance or authorized discharge is an essential method in nuclear medicine, a room for the interim storage of radioactive waste should be made available. The room should be locked, properly marked and ventilated. Records should be kept from which the origin of the waste can be identified. The process requires the grouping (segregation) of the waste in accordance to the expected time for the decay of the radionuclides (initial activity and physical half-life) and the physical form of the waste. Examples of different physical forms include the following:

(a) Vials that might contain residual radioactivity;
(b) Biological waste that will undergo decomposition;
(c) Infectious waste requiring sterilization;
(d) Broken glassware, syringes and needles requiring collection in separate containers to prevent personnel being injured;
(e) Radionuclide generators, bed linen and clothing from hospital wards (therapeutic applications);
(f) Liquid scintillation solutions.

Containers to allow segregation of different types of radioactive waste should be provided in areas where the waste is generated. The containers should be suitable for their purpose (e.g. in terms of volume, shielding and leak tightness).

4.277. In practice, it is mainly ^{131}I and the waste from radiopharmaceutical therapy patients that require special precautions. Appropriate storage of radioactive material to allow for decay will minimize the environmental impact of the release. The majority of diagnostic studies are performed using ^{99m}Tc, which has a physical half-life of 6 hours. Following storage of 2.5 days (10 half-lives, i.e. a decay of a factor of more than 1000), most of this waste can be treated as conventional waste. Technetium generators contain ^{99}Mo with a half-life of 2.75 days; depending on the initial activity of such generators, the time allowed for decay at the nuclear medicine facility should be 1.5–2 months.

4.278. The most commonly used radionuclide in PET is ^{18}F. The short physical half-life of 110 minutes generally allows for discharge of the radioactive material after 24 hours.

4.279. Management of radioactive waste containing longer lived radionuclides should take into account the initial activity and the half-life. The nuclear medicine facility's RPO should give advice in these situations.

4.280. Following the considerations in paras 4.274–4.279, a summary of practical advice for specific situations in nuclear medicine can be given asfollows:

(a) Technetium generators: The two options are (i) returning to the supplier after use, ensuring compliance with regulations for the transport of radioactive material (see paras 4.302–4.304) or (ii) waiting for decay. After 1.5–2 months, the generator can be dismantled and the elution column can be removed, as the material is considered non-radioactive. The generator column should be check for long half-life radionuclide contaminants before disposal. Labels should then be removed.

(b) Used syringes and needles: These can be collected in a shielded container in the rooms used for the preparation and injection of radiopharmaceuticals. When the container is full, it should be sealed and the expected date of release from regulatory control should be marked on it. After this time, the external dose rate can be monitored. The container can be released from regulatory control when the external ambient dose equivalent rate is the same as the background or in line with national or local regulations.

(c) Vials containing residues of ^{99m}Tc, ^{67}Ga, ^{111}In, ^{123}I, ^{131}I, ^{32}P, ^{89}Sr and ^{201}Tl: A similar procedure should be established as for the syringes, but segregation should be based on the physical half-life of the radionuclide. Caution should be exercised in storing waste containing very low levels of longer lived residues such as ^{68}Ge (half-life 271 days), as such residues could accumulate over time to activities at which they need to be considered as radioactive waste and could require prolonged storage before release from regulatory control.

(d) Gloves and cover paper: These should be collected in plastic bags in the rooms used for the preparation and injection of radiopharmaceuticals. When a bag is filled, it should be sealed. After waiting for decay or with appropriate monitoring, these can be released from regulatory control and treated as ordinary, non-radioactive waste.

(e) Sealed sources for calibration: These sources used for calibrating activity meters, for the quality control of gamma cameras and counters, and for the anatomical marking of images should be released from regulatory control as determined by the RPO and in accordance with national regulations and authorization by the regulatory body (clearance).

(f) Carbon and hydrogen isotopes: Small activities of ^{14}C and ^{3}H in organic solutions can usually be treated as non-radioactive waste. In certain instances, because of their potential toxicity, special precautions may apply, and appropriate biohazard precautions need to be taken.

(g) Patients' excreta, such as urine containing ^{131}I: For diagnostic patients, there is no need for the collection of excreta and ordinary toilets can be used. For therapy patients, policies vary for different States, but in principle the approaches used follow the dilution or decay methodologies (e.g. eitherby collecting and storing excreta or by designing facilities with drainpipes terminating in a delay tank). In most situations, it is better to dilute and disperse the waste activity in a continuous sewerage system, rather than to concentrate and store excreta for decay. Some precautions may be required where sewerage systems allow rapid processing of effluent with subsequent mixing with river water or usage for irrigation of land used for growing vegetables (see also Refs [21, 246, 278]).

(h) Waste management at home following the release of patient after radionuclide therapy: Patient should be advised to flush the toilet after use, avoid splashing and clean the toilet after use. The shower and bathtub should be rinsed well after use. Contaminated fabrics such as, clothing and bedding, should be laundered separately (see also Refs [21, 246, 247]).

Monitoring and reporting

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

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

4.282. The program for monitoring public exposure arising from nuclear medicine should include dose assessment in the areas in and surrounding the nuclear medicine facility that are accessible to the public. Doses can be derived from the shielding calculations in the planning stage, combined with the results from area monitoring and contamination monitoring at the initial operation of the facility and periodically thereafter. Records of dose assessments should be kept for a period that meets any relevant regulatory requirements. In the absence of such requirements, a suggested period for keeping records is seven to ten years.

PREVENTION AND MITIGATION OF ACCIDENTS

Safety assessments of potential exposure

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

4.284. The safety assessment of potential exposure should be systematic, should identify unintended events that can lead to potential exposure, and shouldconsider their likelihood and potential consequences (see Appendix I for a summary of typical causes and contributing factors to accidental exposures in

nuclear medicine). The safety assessment should not only cover these events, but should also aim at anticipating other events that have not previously been reported. Clearly, the safety assessment should be documented.

4.285. The safety assessment should be revised when:

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

4.286. Safety assessments in nuclear medicine should include consideration of all the steps in the use of radiopharmaceuticals for diagnosis and treatment in the nuclear medicine facility. The steps include the following:

(a) Ordering, transport and receipt of radiopharmaceuticals, including unpacking and storage;
(b) Preparation and administration of radiopharmaceuticals to patients;
(c) Examination, treatment and care of therapy patients receiving large amounts of radioactive material;
(d) Storage and handling of radioactive waste.

Prevention of accidents

4.287. Accident prevention is clearly the best means for avoiding potential exposure, and paras 3.39–3.42 of GSR Part 3 [3] establish the requirements for good engineering practice, defense in depth and facility based arrangements to achieve this. Design considerations for the nuclear medicine facility, medical radiological equipment and ancillary equipment are described in paras 4.8–4.55.

4.288. Registrants and licensees should incorporate:

(a) 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). For example, theft of sources can be minimized through multiple layers of security including having sources locked up in a safe within a locked room, in an area that has restricted access with camera surveillance and is routinely patrolled.

(b) Operational experience and lessons from accidents and errors. This information should be incorporated into the training, maintenance and quality assurance programs.

4.289. Means for preventing or minimizing unintended and accidental medical exposures in nuclear medicine are described in paras 4.249–4.252, and theensuing investigation and corrective actions are described in paras 4.253–4.258.

Mitigation of the consequences of accidents

4.290. Paragraph 1.20 of GSR Part 3 [3] states that:

> "If an event or a sequence of events that has been considered in the assessment of potential exposure does actually occur, it may be treated either as a planned exposure situation or, if an emergency has been declared, as an emergency exposure situation."

On the basis of events identified in the safety assessment for the nuclear medicine facility, mitigatory procedures should be prepared for events associated with potential exposure, including the allocation of responsibilities and resources, the development and implementation of procedures, and the provision of training and periodic retraining of the relevant staff in executing the mitigatory measures.

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

> "If the safety assessment indicates that there is a reasonable likelihood of an emergency affecting either workers or members of the public, the registrant or licensee shall prepare an emergency plan for the protection of people and the environment."

Emergency arrangements and procedures commensurate with the hazard and the potential consequences are required to be established, as appropriate, in accordance with GSR Part 7 [7], GSG-2 [8] and GS-G-2.1 [9].

4.292. Mitigatory procedures in a nuclear medicine facility should cover, but not be limited to, the following:

(a) Accidents, including those of low probability, and actions to deal with them;
(b) Persons responsible for taking actions in the event of an accident, with full contact details;

(c) Responsibilities of individual personnel in implementing mitigatory procedures and emergency procedures (e.g. nuclear medicine physicians, medical physicists, nuclear medicine technologists and the RPO);
(d) Equipment and tools necessary for carrying out the mitigatory procedures and emergency procedures;
(e) Training and periodic exercises;
(f) Recording and reporting systems;
(g) Immediate measures to avoid unnecessary radiation doses to patients, staff and the public;
(h) Measures to prevent access of persons to the affected area;
(i) Measures to prevent the spread of contamination, including leakage from fume hoods and room ventilation systems.

4.293. Kits should be kept readily available for implementing mitigatory procedures and emergency procedures. These should include the following:

(a) Protective clothing, for example overshoes and gloves;
(b) Decontamination materials for the affected areas, including absorbent materials for wiping up spills;
(c) Decontamination materials for persons;
(d) Warning notices and barrier tape;
(e) Portable monitoring equipment;
(f) Bags for waste, together with tape, labels and pencils.

4.294. The exposure of workers involved in such nuclear medicine events or in emergency response should be kept below the dose limits for occupational exposure in planned exposure situations. However, if it is justified that these dose limits are exceeded, emergency workers should be protected in accordance with the requirements and guidance for emergency exposure situations contained in section 4 of GSR Part 3 [3], and GSR Part 7 [7] and GSG-7 [23].

Lost sources

4.295. An up to date inventory should be maintained (see para. 4.56) so that it can be determined immediately when a source is missing, what its type and activity are, when and where it was last known to be, and who last took possession of it. A proactive attitude is recommended in the case that sources are ordered and not received at the expected time. Confirming that a source has arrived at

the expected time should be part of the procedures. The actions to be part of the emergency plans and procedures in this case should include the following:

(a) Obtain assistance from the RPO when necessary;
(b) Conduct a local search;
(c) Check and ensure security and control of the other sources if a theft in the facility is suspected;
(d) If the source is not found, call the supplier and inform them of the loss so that they can trace the shipment;
(e) If the source is not found, notify the relevant authorities of the loss, consistently with GSR Part 7 [7] and GS-G-2.1 [9].

Damage to radionuclide generators

4.296. Radionuclide generators, such as generators for ^{68}Ga, ^{82}Rb and ^{99m}Tc, contain a relatively large amount of activity. In the event of a radionuclide generator being damaged, the measures to be taken should include the following:

(a) Evacuate the area immediately and implement measures to prevent entry to the area;
(b) Inform the RPO, who should confirm the spillage, define the safety boundaries and supervise the decontamination and monitoring procedures, including when restrictions to enter the area can be lifted;
(c) Record the event and report to the relevant authorities.

Spillage of small amounts of radioactive material

4.297. After a spillage of a small amount of radioactive material, for example low volumes of non-toxic radiopharmaceuticals that can easily be removed, such as up to 10 MBq of ^{18}F or ^{99m}Tc, the following actions should be taken:

(a) Use protective clothing and disposable gloves.
(b) Quickly blot the spill with an absorbent pad to prevent it spreading.
(c) Remove the pad from the spill and dispose of it.
(d) Wipe with a tissue or paper towel from the edge of the contaminated area towards the Center.
(e) Monitor the paper towel for residual activity, for example using a contamination monitor or performing a wipe test.
(f) Continue the cycle of cleaning and monitoring until the measurements indicate that the spill has been removed, and try to keep the volume of contaminated waste as small as possible. In some cases, such as with short

lived radionuclides, it can be simpler to quarantine the area for a sufficient time to allow for decay, for example cover the spill site, such as with a laboratory coat, and prevent access to the area.

(g) Use a plastic bag to hold contaminated items. Suitable bags and paper towels should be readily available.
(h) If the decontamination process is not successful, contact the RPO.
(i) Monitor all people involved in the spill for contamination when leaving the room; in particular, monitor shoes if the spill is on the floor.

Spillage of large amounts of radioactive material

4.298. After a spillage of a large amount of radioactive material, for example if a patient undergoing ^{131}I therapy vomits shortly after administration, the following actions should be taken:

(a) Throw absorbent pads over the spill to prevent further spread of contamination.
(b) Evacuate people not involved in the spill from the area immediately.
(c) Inform the RPO immediately and conduct clean-up under his or her direct supervision.
(d) Monitor all people involved in the spill for contamination when leaving the room.
(e) If necessary, perform a thyroid bioassay of all people involved.
(f) If clothing is contaminated, remove it and place it in a plastic bag labelled 'RADIOACTIVE'.
(g) If contamination of the skin occurs, wash the area immediately.
(h) If contamination of the eye occurs, flush with large quantities of water.
(i) When the contamination is contained, the procedures outlined for cleaning small spills may be followed, with particular care that the contaminated waste bags are appropriately labelled and stored.
(j) Restrict the entry to the contaminated area until decontamination has been completed and the area has been released by the RPO.

Medical emergencies involving patients who have received therapeutic radiopharmaceuticals

4.299. There may be medical emergencies, such as in the case of a stroke or cardiac arrest, involving immediate care of patients who have been administered large amounts of radioactive material (e.g. of the order of several GBq of ^{131}I) for radiopharmaceutical therapy. In these cases, dose rates near the patient are high, and attendant medical personnel may receive significant doses. However, the dose

will be acceptable because the procedure is lifesaving (see GSR Part 3 [3] and GSR Part 7 [7]). Measures should be used to minimize such doses. All members of the medical team should wear impermeable protective gloves. Medical staff should be informed and trained on how to deal with such patients. Exercises of the procedures should be held periodically.

Need for urgent patient attention, including surgery

4.300. Radiation protection considerations should not prevent or delay lifesaving operations in the event that surgery is required on a patient who has been administered radiopharmaceuticals. The following precautions should be observed:

(a) Notify the operating room staff;
(b) Modify operating procedures under the supervision of the RPO to minimize exposure and spread of contamination;
(c) Use protective equipment as long as efficiency and speed are not affected;
(d) Rotate personnel as necessary if the surgical procedure is lengthy;
(e) Determine the doses of the people involved in the procedure.

Fires, earthquakes and other disasters affecting the nuclear medicine facility

4.301. The normal facility drill should be observed, providing for safe evacuation of patients, visitors and staff. When first responders (e.g. fire brigade) attend, they should be informed of the presence of radioactive material. No one other than emergency responders should re-enter the building until it has been checked for contamination by the RPO or by the radiation safety staff of the agency in charge of emergency response (see para. 2.154). Requirements and guidance for the arrangements to deal with such emergencies can be found in GSR Part 7 [7] and GS-G-2.1 [9].

SAFETY IN THE TRANSPORT OF RADIOACTIVE MATERIAL

4.302. Paragraph 2.25 of GSR Part 3 [3] establishes the requirements for the transport of radioactive material, invoking in particular IAEA Safety Standards Series No. SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material, 2018 Edition [279]. SSR-6 (Rev. 1) [279] uses the defined terms ‘consignor’ to mean any person, organization or government that prepares a consignment for transport, and ‘consignee’ to mean any person, organization or government that is entitled to take delivery of a consignment. ‘Consignment’ is

also a defined term, meaning any package or packages, or load of radioactivematerial, presented by a consignor for transport.

4.303. The licensee of a nuclear medicine facility may be both a consigneeand a consignor, and hence may have responsibilities for both the receipt andthe shipment of radioactive material. Receipt of radioactive material will be a regular occurrence for all nuclear medicine facilities. Shipments may take place if the facility has a cyclotron or laboratory that sends radiopharmaceuticals to other sites, or when expired radiation generators, old sealed calibration sources or radioactive liquids (e.g. ^{14}C solutions) need to be returned to the supplier or disposed of off the site, as applicable.

The detailed requirements for the safe transport of radioactive material, including general provisions, activity limits and classification, requirements and controls for transport, requirements for radioactive material and for packaging and packages, test procedures, and approval and administrative requirements, areestablished in SSR-6 (Rev. 1) [279]. Emergency arrangements for the transport of radioactive material should be put in place, in line with the requirements of GSR Part 7 [7] and the guidelines of the regulatory body. The licensee and the RPO of the nuclear medicine facility should be familiar with these regulations toensure that the transport of radioactive material for which they are responsible complies with the regulations.