

- (a) Correct installation, use and maintenance of the consumer product;
- (b) Servicing and repair;
- (c) The radionuclides and their activities at a specified date;
- (d) Dose rates in normal operation and during servicing and repair;
- (e) Required or recommended options for recycling or disposal.

3.144. Providers of consumer products shall provide the consumer product retailers with appropriate information on safety and instructions on their transport and storage.

MEDICAL EXPOSURE

Scope

3.145. The requirements in respect of medical exposure in planned exposure situations (paras 3.146–3.185) apply to all medical exposures³⁹, including intended, unintended and accidental exposures.

3.146. Dose limits do not apply to medical exposures.

Requirement 34: Responsibilities of the government specific to medical exposure

The government shall ensure that relevant parties are authorized to assume their roles and responsibilities, and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established.

3.147. The government, in accordance with paras 2.13–2.28, shall ensure with regard to medical exposures that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the relevant parties identified in paras 2.40 and 2.41 are authorized to assume their roles and responsibilities, and shall ensure that they are notified of their duties in relation to protection and safety for individuals undergoing medical exposures.

³⁹ Requirements on human imaging using radiation for purposes other than medical diagnosis, medical treatment or biomedical research (and, hence, not within the scope of medical exposure) are stated in paras 3.61–3.67.

3.148. The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.169 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.

3.149. The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following are established:

- (a) Dose constraints, to enable the requirements of paras 3.173 and 3.174, respectively, to be fulfilled for:
 - (i) Exposures of carers and comforters⁴⁰;
 - (ii) Exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research.
- (b) Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources.

Requirement 35: Responsibilities of the regulatory body specific to medical exposure

The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they fulfil the requirements for education, training and competence in the relevant specialty.

3.150. The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they:

⁴⁰ The selection of constraints for carers and comforters is a complex process in which a number of factors have to be taken into account, such as the age of the individual and for a woman the possibility of her being pregnant.

- (a) Are specialized⁴¹ in the appropriate area⁴²;
- (b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32;
- (c) Are named in a list maintained up to date by the registrant or licensee.

Requirement 36: Responsibilities of registrants and licensees specific to medical exposure

Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks.

3.151. Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:

- (a) It is a radiological procedure that has been requested by a referring medical practitioner and information on the clinical context has been provided, or it is part of an approved health screening programme;
- (b) The medical exposure has been justified by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or it is part of an approved health screening programme;
- (c) A radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure as specified in para. 3.154(a);
- (d) The patient or the patient's legal authorized representative has been informed as appropriate of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.

3.152. Registrants and licensees shall ensure that no individual incurs a medical exposure as part of a programme of biomedical research unless the exposure

⁴¹ 'Specialized' means specialized as acknowledged by the relevant professional body, health authority or appropriate organization.

⁴² 'The appropriate area' means, in the first instance, diagnostic radiology, image guided interventional procedures, or radiation therapy or nuclear medicine (diagnostic radiological procedures, therapeutic radiological procedures or both). The area of specialization is often likely to be narrower, however, in particular with regard to the radiological medical practitioner. Examples are dental, chiropractic or podiatric specialists in the case of diagnostic radiology, and cardiologists, urologists or neurologists in the case of image guided interventional procedures.

has been approved by an ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority) as required in para. 3.161 and a radiological medical practitioner has assumed responsibility as specified in para. 3.154(a). Registrants and licensees shall ensure that the requirements specified in para. 3.174 are fulfilled for the optimization of protection and safety for persons subject to exposure as part of a programme of biomedical research.

3.153. 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. Registrants and licensees shall ensure that the requirements specified in para. 3.173 are fulfilled for the optimization of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.

3.154. Registrants and licensees shall ensure that:

- (a) The radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for ensuring overall protection and safety for patients in the planning and delivery of the medical exposure, including the justification of the radiological procedure as required in paras 3.155–3.161 and the optimization of protection and safety, in cooperation with the medical physicist and the medical radiation technologist as required in paras 3.162–3.177;
- (b) Radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals with specific duties in relation to protection and safety for patients in a given radiological procedure are specialized in the appropriate area;
- (c) Sufficient medical personnel and paramedical personnel are available as specified by the health authority;
- (d) For therapeutic radiological procedures, the requirements of these Standards for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in paras 3.167, 3.168(c), 3.170 and 3.171, are fulfilled by or under the supervision of a medical physicist;
- (e) For diagnostic radiological procedures and image guided interventional procedures, the requirements of these Standards for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in

- paras 3.167, 3.168(a) and (b), 3.169, 3.170 and 3.171, are fulfilled by or under the oversight of or with the documented advice of a medical physicist, whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks;
- (f) Any delegation of responsibilities by a principal party is documented.

Requirement 37: Justification of medical exposures

Relevant parties shall ensure that medical exposures are justified.

3.155. Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits⁴³ that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure.

3.156. Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments.

3.157. The justification of medical exposure for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or are paediatric, of:

- (a) The appropriateness of the request;
- (b) The urgency of the radiological procedure;
- (c) The characteristics of the medical exposure;
- (d) The characteristics of the individual patient;
- (e) Relevant information from the patient's previous radiological procedures.

3.158. Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure.

⁴³ The diagnostic or therapeutic benefit that medical exposures are expected to yield may not necessarily be to the person exposed. For patients, this is clearly the case, but for exposures in biomedical research the benefit is expected to be for biomedical sciences and for future health care. Similarly, the benefit for carers and comforters might be, for example, the successful performance of a diagnostic procedure on a child.

3.159. Justification for radiological procedures to be performed as part of a health screening programme for asymptomatic populations shall be carried out by the health authority in conjunction with appropriate professional bodies.

3.160. Any radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, but not as part of an approved health screening programme, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, in accordance with the guidelines of relevant professional bodies or the health authority. As part of this process, the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.

3.161. The medical exposure of volunteers as part of a programme of biomedical research is deemed to be not justified unless:

- (a) It is in accordance with the provisions of the Helsinki Declaration [20] and takes into account the guidelines published by the Council for International Organizations of Medical Sciences [21], together with the recommendations of the ICRP [22];
- (b) It is subject to approval by an ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority), subject to any dose constraints that may be specified (as required in paras 3.149(a)(ii) and 3.174), and subject to applicable national regulations and local regulations.

Requirement 38: Optimization of protection and safety

Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure.

Design considerations

3.162. In addition to ensuring that the responsibilities stated in para. 3.49 are discharged, as applicable, registrants and licensees, in cooperation with suppliers, shall ensure that medical radiological equipment and software that could influence the delivery of medical exposure are used only if they conform to the applicable standards of the International Electrotechnical Commission and the International Organization for Standardization or to national standards adopted by the regulatory body.

Operational considerations

3.163. For diagnostic radiological procedures and image guided interventional procedures, the radiological medical practitioner, in cooperation with the medical radiation technologist and the medical physicist, and if appropriate with the radiopharmacist or radiochemist, shall ensure that the following are used:

- (a) Appropriate medical radiological equipment and software, and, for nuclear medicine, appropriate radiopharmaceuticals;
- (b) Appropriate techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfil the clinical purpose of the radiological procedure, with account taken of relevant norms of acceptable image quality established by relevant professional bodies and of relevant diagnostic reference levels established in accordance with paras 3.148 and 3.169.

3.164. For therapeutic radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, shall ensure that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances.

3.165. For therapeutic radiological procedures in which radiopharmaceuticals are administered, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, and if appropriate with the radiopharmacist or radiochemist, shall ensure that for each patient the appropriate radiopharmaceutical with the appropriate activity is selected and administered, so that the radioactivity is primarily localized in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable.

3.166. Registrants and licensees shall ensure that the particular aspects of medical exposures are considered in the optimization process for:

- (a) Paediatric patients subject to medical exposure;
- (b) Individuals subject to medical exposure as part of an approved health screening programme;
- (c) Volunteers subject to medical exposure as part of a programme of biomedical research;

- (d) Relatively high doses⁴⁴ to the patient;
- (e) Exposure of the embryo or fetus, in particular for radiological procedures in which the abdomen or pelvis of the pregnant female patient is exposed to the useful radiation beam or could otherwise receive a significant dose;
- (f) Exposure of a breastfed infant as a result of a female patient having undergone a radiological procedure with radiopharmaceuticals.

Calibration

3.167. In accordance with para. 3.154(d) and (e), the medical physicist shall ensure that:

- (a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;
- (b) Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the regulatory body;
- (c) Calibrations of radiation therapy units are subject to independent verification⁴⁵ prior to clinical use;
- (d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory.

Dosimetry of patients

3.168. Registrants and licensees shall ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted or nationally accepted protocols, including dosimetry to determine the following:

⁴⁴ The term ‘relatively high dose’ is intended to apply in a given context. Clearly, doses from therapeutic radiological procedures are included in ‘relatively high doses’, as are image guided interventional procedures. In medical imaging, ‘relatively high doses’ would include doses from exposures in computed tomography and in radiological procedures in nuclear medicine with higher doses.

⁴⁵ ‘Independent verification’ ideally means verification by a different, independent medical physicist using different dosimetry equipment. However, other options, such as verification by a second medical physicist or verification using a second set of equipment, or even using a form of verification by postal thermoluminescence dosimetry, could be acceptable. In checking for compliance, the regulatory body needs to be aware of the limitations on local resources.

- (a) For diagnostic radiological procedures, typical doses to patients for common procedures;
- (b) For image guided interventional procedures, typical doses to patients;
- (c) For therapeutic radiological procedures, absorbed doses to the planning target volume for each patient treated with external beam therapy and/or brachytherapy and absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner;
- (d) For therapeutic radiological procedures with unsealed sources, typical absorbed doses to patients.

Diagnostic reference levels

3.169. Registrants and licensees shall ensure that:

- (a) Local assessments, on the basis of the measurements required in para. 3.168, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established (para. 3.148).
- (b) A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure:
 - (i) Typical doses or activities exceed the relevant diagnostic reference level; or
 - (ii) Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

Quality assurance for medical exposures

3.170. Registrants and licensees, in applying the requirements of these Standards in respect of management systems, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate. Principles established by the World Health Organization, the Pan American Health Organization and relevant professional bodies shall be taken into account.

3.171. Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility:

- (a) Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist:
 - (i) At the time of acceptance and commissioning of the equipment prior to its clinical use on patients;
 - (ii) Periodically thereafter;
 - (iii) After any major maintenance procedure that could affect protection and safety of patients;
 - (iv) After any installation of new software or modification of existing software that could affect protection and safety of patients.
- (b) Implementation of corrective actions if measured values of the physical parameters mentioned in (a) above are outside established tolerance limits.
- (c) Verification of the appropriate physical and clinical factors used in radiological procedures.
- (d) Maintaining records of relevant procedures and results.
- (e) Periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment.

3.172. Registrants and licensees shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks.

Dose constraints

3.173. Registrants and licensees shall ensure that relevant dose constraints (para. 3.149(a)(i)) are used in the optimization of protection and safety in any radiological procedure in which an individual acts as a carer or comforter.

3.174. Registrants and licensees shall ensure that dose constraints specified or approved by the ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority) on a case by case basis as part of a proposal for biomedical research (para. 3.161) are used in the optimization of protection and safety for persons subject to exposure as part of a programme of biomedical research.

Requirement 39: Pregnant or breast-feeding female patients

Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding.

3.175. Registrants and licensees shall ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places, and that other means of communication are also used as appropriate⁴⁶, to request female patients who are to undergo a radiological procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel in the event that:

- (a) She is or might be pregnant;
- (b) She is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical.

3.176. Registrants and licensees shall 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, so that this information can be considered in the justification for the radiological procedure (paras 3.155 and 3.156) and in the optimization of protection and safety (para. 3.166).

3.177. Registrants and licensees shall ensure that there are arrangements in place for establishing that a female patient is not currently breast-feeding before the performance of any radiological procedure involving the administration of a radiopharmaceutical that could result in a significant dose to a breastfed infant, so that this information can be considered in the justification for the radiological procedure (paras 3.155 and 3.157) and in the optimization of protection and safety (para. 3.166).

Requirement 40: Release of patients after radionuclide therapy

Registrants and licensees shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy.

3.178. The radiological medical practitioner shall ensure that no patient who has undergone a therapeutic radiological procedure with a sealed source or an unsealed source is discharged from a medical radiation facility until it has been established by either a medical physicist or the facility's radiation protection officer that:

⁴⁶ 'Other means of communication' include explicitly asking female patients whether they are or might be pregnant or whether they are breast-feeding.

- (a) The activity of radionuclides in the patient is such that doses that could be received by members of the public and family members would be in compliance with the requirements set by the relevant authorities (para. 3.149(b)); and
- (b) The patient or the legal guardian of the patient is provided with:
 - (i) Written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination;
 - (ii) Information on the radiation risks.

Requirement 41: Unintended and accidental medical exposures

Registrants and licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures. Registrants and licensees shall promptly investigate unintended or accidental medical exposures and, if appropriate, shall implement corrective actions.

3.179. Registrants and licensees, in accordance with the relevant requirements of paras 2.51, 3.41–3.42 and 3.49–3.50, 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.

Investigation of unintended and accidental medical exposures

3.180. Registrants and licensees shall promptly investigate any of the following unintended or accidental medical exposures:

- (a) Any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;
- (b) Any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;
- (c) Any exposure for diagnostic purposes that is substantially greater than was intended;
- (d) Any exposure arising from an image guided interventional procedure that is substantially greater than was intended;

- (e) Any inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure;
- (f) Any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended.

3.181. Registrants and licensees shall, with regard to any unintended or accidental medical exposures investigated as required in para. 3.180:

- (a) Calculate or estimate the doses received and the dose distribution within the patient;
- (b) Indicate the corrective actions required to prevent the recurrence of such an unintended or accidental medical exposure;
- (c) Implement all the corrective actions that are under their own responsibility;
- (d) Produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a)–(c) above, as relevant, and any other information as required by the regulatory body; and for significant unintended or accidental medical exposures or as otherwise required by the regulatory body, submit this written record, as soon as possible, to the regulatory body, and to the relevant health authority if appropriate;
- (e) Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient’s legal authorized representative of the unintended or accidental medical exposure.

Requirement 42: Reviews and records

Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained.

Radiological reviews

3.182. Registrants and licensees shall ensure that radiological reviews are performed periodically by the radiological medical practitioners at the medical radiation facility, in cooperation with the medical radiation technologists and the medical physicists. The radiological review shall include an investigation and critical review of the current practical application of the radiation protection

principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility.

Records

3.183. Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following personnel records:

- (a) Records of any delegation of responsibilities by a principal party (as required in para. 3.154(f));
- (b) Records of training of personnel in radiation protection (as required in para. 3.150(b)).

3.184. Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records of calibration, dosimetry and quality assurance:

- (a) Records of the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatment of patients;
- (b) Records of dosimetry of patients, as required in para. 3.168;
- (c) Records of local assessments and reviews made with regard to diagnostic reference levels, as required in para. 3.169;
- (d) Records associated with the quality assurance programme, as required in para. 3.171(d).

3.185. Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records for medical exposure:

- (a) For diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures;
- (b) For image guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired;
- (c) For nuclear medicine, the types of radiopharmaceutical administered and their activity;
- (d) For external beam radiation therapy or brachytherapy, a description of the planning target volume, the absorbed dose to the centre of the planning target volume, and the maximum and minimum absorbed doses delivered

to the planning target volume, or equivalent alternative information on absorbed doses to the planning target volume, and the absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner; and in addition, for external beam radiation therapy, the dose fractionation and the overall treatment time;

- (e) Exposure records for volunteers subject to medical exposure as part of a programme of biomedical research;
- (f) Reports on investigations of unintended and accidental medical exposures (as required in para. 3.181(d)).

4. EMERGENCY EXPOSURE SITUATIONS

SCOPE

4.1. The requirements for emergency exposure situations established in Section 4 apply to activities undertaken in preparedness for and in response to a nuclear or radiological emergency.

GENERIC REQUIREMENTS

Requirement 43: Emergency management system

The government shall ensure that an integrated and coordinated emergency management system is established and maintained.

4.2. The government shall ensure that an emergency management system is established and maintained on the territories and within the jurisdiction of the State for the purposes of emergency response to protect human life, health and the environment in the event of a nuclear or radiological emergency.

4.3. The emergency management system shall be designed to be commensurate with the results of a hazard assessment [15] and to enable an effective emergency response to reasonably foreseeable events (including very low probability events) in connection with facilities or activities.

4.4. The emergency management system shall be integrated, to the extent practicable, into an all-hazards emergency management system.