Radiation Protection Authority

Zambia

SAFETY GUIDE

RPA SG 11

DIAGNOSTIC

RADIOLOGY AND IMAGE GUIDED

INTERVENTIONAL

PROCEDURES

2023

NOTICE OF APPROVAL

Under the terms of Part II of the Ionising Radiation Protection Act No. 16 of 2005 and Part V of the Statutory Instrument No.98 of 2011, the Radiation Protection Authority (RPA) is authorized to establish or adopt standards of safety for protection of health and minimization of risk to life and the environment, and to provide for the application of these standards.

The Radiation Protection Authority Board (RPAB), has on the 19th December 2024, approved the safety guide on Diagnostic Radiology and Image Guided Interventional procedures

This guide is approved for the purposes of providing practical guidance with respect to the Ionizing Radiation Protection (General) Regulations, SI No. 98 of 2011.

This guide comes into effect on 19th December 2023

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List of Abbreviations

Abbreviation	Definition
ADRC	Automatic dose rate control
ABC	Automatic brightness control
CBCT	Cone-beam computed tomography
CR	Computed radiography
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
DR	Digital radiography
DRL	Diagnostic Reference Level
DXA	Dual-energy X-ray absorptiometry
ECG	Electrocardiogram
ICRU	International Commission on Radiation Units and Measurements
IEC	International Electrotechnical Commission
IGRT	Image-guided radiation therapy
ISO	International Organization for Standardization
MRI	Magnetic resonance imaging
PACS	Picture Archiving and Communications System
PET	Positron Emission Tomography
RIS	Radiology Information System
RPA	Radiation Protection Authority
RPAB	Radiation Protection Authority Board
RPO	Radiation Protection Officer
SG	Safety Guide
SPECT	Single photon emission computed tomography

FOREWORD

Radiation Protection Authority (RPA) was established by the Ionising Radiation Protection Act No. 16 of 2005. It is a national regulatory body which implements the policies of the Zambian government relating to the protection of the public, workers and the environment from harmful effects of ionising radiation.

This guidance is intended for both regulators and users of radiation sources in nuclear medicine. Regulators may use it for reviewing applications for authorisation and during inspection of facilities. Licensees should follow the guidance in order to comply with requirements of the regulations.

Preparation of the Guideline was carried out in line with National and International Standards.

PREFACE

Radiation Protection Authority (RPA) was established by the Ionising Radiation Protection Act No. 16 of 2005. The structure of the implementation of the protection and safety was established to be compatible with the International Basic Safety Standards.

The structure was commensurate with the number and density and complexity of application and anticipated introduction of practices and sources within practices.

The essential element of the structured approach consisted of the following hierarchy:

- **Legislation** which established the Radiation Protection Authority Board and its powers and functions;
- **Radiation Safety Regulations** which prescribed the standards for radiation safety, waste safety and transport safety.
- **Radiation Protection and Safety Guides** which provides guidance for regulators, registrant and licensees and all stakeholders to comply with the regulation as required by the Ionising Radiation (General) Regulations statutory instrument No. 98 of 2011.

1.0 INTRODUCTION

1.1 General

1.1.1 When ionising radiation was discovered more than 100 years ago, its beneficial uses were quickly realised by the medical profession. Over the years, new diagnostic and therapeutic techniques have evolved and the general level of health care worldwide has improved. In Zambia, radiation exposure in medical applications mainly arises from the use of radioactive sources and/or devices such as those used in nuclear medicine, radiotherapy and radiology.

1.1.2 This guideline covers radiographic and fluoroscopic diagnostic procedures, image guided interventional procedures, and imaging studies using X ray radiation that are part of the processes of radiation therapy or nuclear medicine.

1.1.3 This Safety Guide is applicable to all the established uses of ionising radiation sources employed in diagnostic and interventional radiology, to the facilities where the sources are located and used, and to the individuals involved. The Safety Guide covers occupational, public, medical, and potential and emergency exposure situations.

2.0 SAFETY OF MEDICAL RADIATION FACILITIES AND MEDICAL RADIOLOGICAL EQUIPMENT

2.1 Radiology facilities

2.1.1 Fixed facilities: Design of X ray rooms
The facility should ensure that:

2.1.1.1 The provisions for the design incorporate radiation protection and safety features;

2.1.1.2 The siting and layout consider the following:

a. the types of radiological procedures

b. workload and patient flow both within the radiology facility and within other departments of the facility, where the radiology facility is part of a larger hospital or medical centre.

2.1.1.3 the three factors relevant to dose reduction (time, distance and shielding) be combined in the design to optimize occupational radiation protection and public radiation protection.

2.1.1.4 shielding requirements be tailored to meet any national requirements and to suit the practice requirements based on the intended patient workload and the types of examination to be performed.

2.1.1.5 assessments be undertaken when the intended use of a room changes, X ray equipment is upgraded, underlying procedures or patient workload changes, or the surrounding room occupancy is altered.

2.1.1.6 at the design stage, the use of both structural and ancillary protective barriers to provide shielding be considered.

2.1.1.7 The rooms using fluoroscopy with staff working close to the patients, such as rooms for image guided interventional procedures, ceiling mounted protective screens and table mounted leaded curtains should be installed.

2.1.1.8 Ancillary protective barriers for image guided interventional procedures be part of the initial facility plan, and be designed so as not to interfere with the medical procedure.

2.1.1.9 wall shielding be at least 2 m high, and any doors and viewing windows in walls or doors have at least the same lead equivalence as the minimum shielding specifications for the shielded wall or barrier in which they are located.

2.1.1.10 consideration be given to the provision of floor and ceiling shielding when rooms immediately below and above the X ray installation are occupied.

2.1.1.11 all penetrations and joints in shielding be arranged so that they are equally as effective in shielding radiation.

2.1.1.12 general safety features of radiography, mammography, CT and fluoroscopy rooms include the following:

2.1.1.13 A barrier placed at the control console to shield staff to the extent that they do not need to wear protective clothing while at the console.

2.1.1.14 in radiography, all possible intended directions of the X ray beam be taken into consideration in the room design so that the X ray beam cannot be directed at any area that is not shielded and which could lead to potentially unacceptable doses being received in this area.

2.1.1.15 The doors provide protective shielding for secondary radiation and be shut when the X ray beam is on.

2.1.1.16 In radiography, the X ray room be designed so as to avoid the direct incidence of the X ray beam on the access doors.

2.1.1.17 The medical radiation technologist be able to clearly observe and communicate with the patient at all times during an X ray diagnostic procedure.

2.1.1.18 Signs and warning lights be positioned at eye level and at the entrances of controlled and supervised areas to prevent inadvertent entry.

2.1.1.19 Signs and warning lights are in line with basic ionizing radiation symbol recommended by the International Organization for Standardization.

2.1.1.20 The signs be clear and easily understandable.

2.1.1.21 Warning lights, such as illuminated or flashing signs be activated when radiation is being produced inside the controlled area or supervised area.

2.1.1.22 A stable power supply be available.

2.1.1.23 an uninterruptible power supply or battery backup systems be installed to capture the active information at the time of the outage and to shut down all software in a controlled manner.

2.1.1.24 servers be programmed to shut down automatically when the power supply is interrupted.

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

2.1.2 Mobile facilities should ensure that

2.1.2.1 Mammography and CT vans are used in areas where fixed facilities are not available.

2.1.2.2 General safety features of mobile facilities include the following:

a) Mobile facilities be built so that protection is optimized mainly through shielding (in all relevant directions during use), as providing protection through distance is often limited and exposure time is determined by the procedure being performed.

b) An appropriate power supply be available with reliable connections.

c) Entrance to the mobile facility be under the control of the mobile facility personnel.

d) Waiting areas, if they exist, be appropriately shielded to afford levels of protection consistent with public exposure limits.

e) To facilitate the imaging procedure, including patient flow, mobile CT facilities are usually operated adjacent to a hospital or clinic, from where they can draw water and electricity, and where patients can use the toilets, waiting rooms and changing rooms and have access to

physician offices. Similarly, mobile mammography facilities may also utilize hospital or clinic facilities.

2.1.3 Shielding calculations

The facility should ensure that:

2.1.3.1 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.

2.1.3.2 When a shielding methodology is applied to optimize occupational and public radiation protection, decisions will need to be made about many factors that can greatly influence the final results for the shielding specification.

2.1.3.3 To use the following but not limited assumptions that would each lead to conservatism in the shielding specification:

2.1.3.4 For primary barriers, the attenuation by the patient and image receptor is not considered.

2.1.3.5 Workload, use and occupancy factors are overestimated.

2.1.3.6 Staff members are always in the most exposed place of the room.

2.1.3.7 Distances are always the minimum possible.

2.1.3.8 Leakage radiation is the maximum all the time.

2.1.3.9 Field sizes used for the calculation of scatter radiation are overestimated.

2.1.3.10 Attenuation of the materials is usually considered for the maximum beam quality used.

2.1.3.11 The numerical value of calculated air kerma (in mGy) is directly compared with dose limits or dose constraints (in mSv), which are given in terms of effective dose.

2.1.3.12 Particular attention be given to hybrid imaging systems, where the shielding should be calculated for each modality and combined as appropriate.

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

2.1.3.14 Specification of shielding, including calculations, be performed by a medical physicist or a qualified expert in radiation protection.

2.1.3.15 The adequacy of the shielding be verified, preferably during construction, and certainly before the room is placed in clinical use, and similarly after any future structural modifications.

2.1.4 Design of display and interpretation (reading) rooms
The facility should ensure that:

2.1.4.1 To facilitate their interpretation by the radiological medical practitioner, images be displayed in rooms specifically designed for such purposes.

2.1.4.2 Viewing rooms with workstations for viewing digital images be ergonomically designed to facilitate image processing and manipulation so that reporting can be performed accurately.

2.1.4.3 The viewing monitors of the workstations meet applicable National and international standards

2.1.5 Medical radiological equipment, software and ancillary equipment

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

The facility should ensure that:

2.1.5.1 The medical radiological equipment complies with the International Electrotechnical Commission (IEC) and ISO international standards or equivalent national standards.

2.1.5.2 Displays, gauges and instructions on operating consoles of medical radiological equipment, and accompanying instruction and safety manuals 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.

2.1.5.3 The software be designed so that it can be easily converted into the National 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.

2.1.5.4 All medical radiological equipment be supplied with all appropriate radiation protection tools as a default rather than as optional extras.

2.1.6 Design features for medical radiological equipment

The facility should ensure that:

2.1.6.1 The design of medical radiological equipment be such that its performance is always reproducible, accurate and predictable, and that it has features that facilitate the appropriate personnel in meeting the National and International requirements for operational optimization of patient protection.

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

a. Means to detect immediately any malfunction of a single component of the system that may lead to an inadvertent underexposure or overexposure of the patient, or exposure of staff so that the risk of any unintended or accidental exposure is minimized.

b. Means to minimize the frequency of human error and its impact on the delivery of unintended or accidental medical exposure.

c. Hardware and software controls that minimize the likelihood of unintended or accidental medical exposures.

d. Operating parameters for radiation generators, such as the generating tube potential, filtration, focal spot position and size, source to image receptor distance, field size indication and either tube current and time or their product, that are clearly and accurately shown.

e. Radiation beam control mechanisms, including devices that indicate clearly (visually and/or audibly) and in a fail-safe manner when the beam is on.

f. X ray tubes with inherent and added filtration adequate to remove low energy components of the X ray beam which do not provide diagnostic information.

g. Collimating devices to define the radiation beam; in the case of a light beam diaphragm, the light field should align with the radiation field.

h. With the exception of mammography, dental X ray and CT equipment, diagnostic and interventional X ray equipment that is fitted with continuously adjustable beam collimating devices. Such devices allow the operator to limit the area being imaged to the size of the selected image receptor or the region of interest, whichever is smaller. When preset protocols are provided, technique factors that are readily accessible and modifiable by

i. adequately trained personnel.

j. Design of the X ray tube to keep radiation leakage as low as reasonably achievable and not exceeding 1 mGy in an hour measured

at 1 m from the focal spot, and less than maximum levels specified in international standards or National regulations.

2.1.7 Specific design features for medical radiological equipment used in radiography

The facility should ensure that:

2.1.7.1 Specific design features for medical radiological equipment used in radiography include the following:

a. The provision of devices that automatically terminate the irradiation after a preset time, tube current–exposure time product, or dose to the automatic exposure control (AEC) detector, or when the 'dead man switch' is released.

b. The incorporation of AEC systems in radiographic units, where practicable.

c. Indications or displays of the air kerma–area product and/or incident air kerma.

2.1.7.2 Specific design features for medical radiological equipment used for dental radiography include the following:

a. A minimum tube potential of 60 kVp;

b. For intraoral dental systems, an open-ended (preferably rectangular) collimator providing a focus to skin distance of at least 20 cm and a field size at the collimator end of no more than 4 cm × 5 cm if rectangular or 6 cm in diameter if cylindrical, and limitation of field size to the dimensions of the image receptor;

c. For panoramic dental systems, limitation of field size to the area required for diagnosis by means of programmed field size trimming and the 'child imaging mode';

d. For dental CBCT, adjustable X ray tube potential and tube current–exposure time product, and a choice of volume sizes and voxel sizes.

2.1.7.3 Specific design features for medical radiological equipment used for CT include the following:

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

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

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

2.1.7.5 Specific design features for medical radiological equipment used for fluoroscopy include the following:

a. The provision of a device that energizes the X ray tube only when continuously depressed (such as an exposure foot switch or 'dead man' switch);
b. Indications or display (both at the control console and on monitors) of the elapsed time, air kerma–area product, and cumulative reference air kerma;
c. Automatic brightness control (ABC) or automatic dose rate control (ADRC);
d. Pulsed fluoroscopy and pulsed image acquisition modes;
e. The capture and display of the last acquired frame (last image hold);
f. Interlocks that prevent inadvertent energizing of the X ray beam when the image detector is removed from the imaging chain;
g. The capability to deactivate the exposure foot switch between cases; and
h. The provision of a timer and an alarm that sounds at the end of a pre-set interval (typically 5 min).

2.1.7.6 Design features for medical radiological equipment used for image guided interventional procedures should include the following:

a. X ray tubes that have high heat capacities to enable operation at high tube currents and short times.
b. A radiation generator with a capability of at least 80 kW.
c. A radiation generator with a large dynamic range of tube current and tube potential (to minimize the pulse width necessary to accommodate differences in patient attenuation).

2.1.7.7 For paediatric work, the following are put in place:

a. A radiation generator that supports an X ray tube with a minimum of three focal spots;
b. An anti-scatter grid that is removable;

c. An image acquisition frame rate that extends up to at least 60 frames per second for small children.

2.1.7.8 A real time display of air kerma–area product and cumulative reference air kerma.

2.1.7.9 Imaging detectors that allow different fields of view (magnification) to improve spatial resolution.

2.1.7.10 Automatic collimation.

2.1.7.11 Dual-shape collimators incorporating both circular and elliptical shutters to be used to modify the field for collimation along cardiac contours.

2.1.7.12 System specific variable filtration in the X ray beam that is applied according to patient attenuation.

2.1.7.13 Selectable dose per pulse and selectable number of pulses per second.

2.1.7.14 Wedge filters that move automatically into the field of view to attenuate the beam in areas where there is no tissue and thus no need for imaging.

2.1.7.15 Possible means for manipulation of diaphragms while in 'last image hold'.

2.1.7.16 The option of the automatic display of the last acquired image run.

a. Display and recording in a dose report in digital format of the following parameters:
b. Reference air kerma rate;
c. Cumulative reference air kerma;
d. Cumulative air kerma
e. Dose area product
f. Cumulative time of fluoroscopy;
g. Cumulative number of image acquisitions (acquisition runs and frames per run);
h. Integrated reference air kerma;
i. Option for digital subtraction angiography;
j. Road mapping, which is a technique used for navigation of the catheter or wire in endovascular procedures.

2.1.7.17 All digital medical radiological equipment has the following additional features:

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

b. Connectivity to RIS and to PACS.

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

a. Capability of very short exposure times for radiography;

b. Specifically, designed AEC systems;

2.1.7.19 Provision of 'paediatric modes' for the automatic brightness and/or dose rate control systems in fluoroscopy and image guided interventional procedures;

2.1.7.20 Paediatric protocols for CT;

2.1.7.21 Child imaging mode for dental panoramic and CBCT equipment.

2.1.7.22 Automatic film processors meet appropriate standards.

2.1.7.23 Film–screen-based mammography has dedicated film processors with extended processing cycles.

2.1.7.24 If manual processing is being performed, specially designed developer, fixer and washing tanks be used, with processing times based on the developer temperature.

2.1.7.25 The darkroom for processing meets relevant international and national standards for light tightness and be equipped with an appropriately filtered safe-light, compatible with the film being used.

2.1.7.26 The resolution of the printer not be less than the resolution of the detector, so that the image quality of the final image is not limited or compromised.

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

2.1.7.28 View boxes, for viewing films, have sufficient uniform brightness to facilitate diagnosis, and the colour of view boxes be matched through the complete set of view boxes.

2.1.7.29 Means should be available (masks) to restrict the illuminated area of the radiograph to avoid dazzling.

2.1.7.30 View boxes used for mammography should have higher luminance.

2.1.7.31 All equipment used for digital image display meet appropriate international and national standards.

2.1.8 Maintenance

The facility should ensure that:

2.1.8.1 maintenance programmes are established to ensure that sources meet their design requirements for protection and safety throughout their lifetime and to prevent accidents as far as reasonably practicable.

2.1.8.2 adequate maintenance (preventive maintenance and corrective maintenance) is performed as necessary to ensure that medical radiological equipment retains, or improves through appropriate hardware and software upgrades, its design specifications for image quality and radiation protection and safety for its useful life.

2.1.8.3 necessary arrangements are made and coordination with the manufacturer or installer before initial operation and on an ongoing basis.

2.1.8.4 All maintenance procedures be included in the comprehensive programme of quality assurance and be carried out at the frequency recommended by the manufacturer of the equipment.

2.1.8.5 Servicing include a report describing the equipment fault, the work done and the parts replaced and adjustments made, which should be filed as part of the programme of quality assurance.

2.1.8.6 A record of maintenance carried out be kept for each item of equipment. This should include information on any defects found by users (a fault log), remedial actions taken (both interim repairs and subsequent repairs) and the results of testing before equipment is reintroduced to clinical use.

2.1.8.7 after any modifications or maintenance, the person responsible for maintenance immediately inform the medical radiation facility before the equipment is returned to clinical use.

2.1.8.8 The person responsible for the use of the equipment, in conjunction with the medical physicist, the medical radiation technologist and other appropriate professionals, decide whether quality control tests are needed with regard to radiation protection, including image quality, and whether changes to protocols are needed.

2.1.8.9 Electrical and mechanical maintenance be included in the programme of quality assurance and be performed, preferably by the manufacturer of the medical radiological equipment or an authorized agent, at a frequency recommended by the manufacturer.

2.1.8.10 Servicing include a written report describing the findings. These reports and follow-up corrective actions be archived as part of the programme of quality assurance.

3.0 OCCUPATIONAL RADIATION PROTECTION

3.1 Occupationally exposed individuals

3.1.1 Occupationally exposed individuals include but not limited to:

3.1.1.1 medical radiation technologists

3.1.1.2 radiologists

3.1.1.3 medical physicists

3.1.1.4 dentists operating X ray machines

3.1.1.5 The following Health Practitioners who are part of radiological diagnostics and image guided procedures,

a) nurses
b) emergency department physicians
c) anaesthetists
d) Interventional cardiologists,
e) vascular surgeons,
f) orthopaedic surgeons,
g) neurosurgeons,
h) urologists,
i) respiratory physicians and
j) gastroenterologists,
k) technicians

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

3.1.3 Other radiology facility workers, such as ward nurses, imaging staff who work exclusively with imaging modalities without ionizing radiation (ultrasound or magnetic resonance imaging (MRI), patient porters, orderlies, assistants, cleaners and other service support personnel, for whom radiation sources are not required by, or directly related to, their work, are required to have the same level of protection as members of the public.

3.2 Classification of areas

3.2.1 The facility should ensure that:

3.2.1.1 Various areas and rooms in a radiology facility be classified as controlled areas or supervised areas.

3.2.1.2 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 be low enough to ensure compliance with the dose limits for public exposure.

3.2.1.3 All X ray rooms be designated as controlled areas; in addition, areas where mobile X ray units are used can also be categorized as controlled areas during the time in which radiological procedures are being carried out.

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

3.2.1.5 Supervised areas involve areas surrounding X ray rooms.

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

3.2.1.7 The control console be inside the X ray room, separated by structural shielding, or outside the X ray room in the staff area, with visual control of the X ray room and with patient communication.

3.2.1.8 Access of unauthorized individuals to control console areas be restricted to avoid the distraction of the operator, which might lead to unnecessary or repeated exposures.

3.2.1.9 Control panel areas are not in the public domain and therefore be classified as either controlled areas or supervised areas.

3.3 Local rules and procedures

3.3.1 The facility should ensure that:

3.3.1.1 local rules and procedures be established in writing in any radiology facility.

3.3.1.2 local rules and procedures include measures to minimize occupational radiation exposure both for normal work and in unusual events.

3.3.1.3 The local rules and procedures also cover the wearing, handling and storing of personal dosimeters, and specify investigation levels and ensuing follow-up actions.

3.3.1.4 All personnel involved in using radiation in a radiology facility know and follow the local rules and procedures.

3.3.1.5 The development and review of the local rules and procedures involve representatives of all health professionals involved in diagnostic radiology and image guided interventional procedures.

3.3.1.6 Equipment (both hardware and software) be operated in a manner that ensures satisfactory performance at all times with respect to both the tasks to be accomplished and radiation protection and safety.

3.3.1.7 The final documented set of operational procedures be subject to approval by radiology facility, and be incorporated into the facility's management system.

3.3.1.8 Radiology facility staff understand the documented procedures for their work with radiation and for the operation of the equipment with which they work, including the safety features, and be trained, with periodic refresher training, in what to do if things go wrong.

3.3.1.9 Additional training be conducted when new medical radiological equipment is brought into use in the radiology facility.

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

3.3.1.11 In general, there be no need for occupationally exposed staff to hold, or have close contact with patients during a radiological procedure. If such holding or contact is indeed necessary, then the person to be used in

that role be considered a carer or comforter of the patient, and should be afforded the appropriate radiation protection.

3.3.1.12 Immobilization devices (e.g. a CT head cradle and pediatric immobilisation devices) be used whenever possible and as appropriate to minimize exposure of the patient, the staff member or the carer or comforter.

3.3.1.13 Immobilization of patients not be performed by staff and, if possible, not by any person. If immobilization requires the use of a person, then this should be someone such as a relative of the patient who has agreed to be a carer or comforter and is afforded radiation protection accordingly

3.3.1.14 For general radiography the following are done:

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

3.3.1.15 For mobile radiography the following are done:

a) Operators wear lead aprons and should maintain as much distance as possible between themselves and the patient (to minimize exposure to scatter radiation), whilst still maintaining good visual supervision of the patient and being able to communicate verbally with him or her.
b) Other staff (e.g. nursing, medical and ancillary staff) are not considered as occupationally exposed workers and hence be afforded protection as a member of the public. This is achieved by ensuring such persons are as far away from the patient as possible during the exposure (typically at least 3 m) or are behind appropriate barriers.

3.3.1.16 In situations in which a member of staff needs to be close to the patient (e.g. an anesthetist with a ventilated patient or a nurse with an unstable patient), protective aprons should be worn.

3.3.1.17 Verbal warning of an imminent exposure be given.

3.3.1.18 Consideration be given to other patients nearby

3.3.1.19 In many emergency departments, ceiling suspended X ray equipment provides a versatile environment for performing rapid trauma radiography.

3.3.1.20 Appropriate occupational radiation protection can be afforded through the following:

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

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

3.3.1.22 In the case of CT interventions, the interventionist uses appropriate personal protective equipment (a protective apron, a thyroid shield and protective eyewear).

3.3.1.23 In addition, care be exercised to avoid the placing of hands in the primary beam and immediate notification to the interventionist be given if this happens.

3.3.1.24 In the case of persons providing medical support (e.g. anesthetists), a protective apron be worn and the person should position themselves as far from the gantry as possible, whilst still maintaining good visual supervision of the patient.

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

a. The staff member performing the procedure use personal protective equipment (a protective apron, a thyroid shield, protective eyewear and gloves).
b. In addition, care be exercised to avoid the placing of hands in the primary beam and immediate notification to the fluoroscopist should be given if this happens.
c. In the case of persons providing medical support (e.g. anaesthetists), a protective apron be worn and the person should position themselves as far from the patient as possible during exposure.

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

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

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

3.3.1.28 For dental facilities with intraoral and panoramic equipment, the following measures be taken:

a. maintain a distance of at least 2m from the patient.
b. The operator not to hold the image receptor during the exposure.
c. Handheld portable X ray equipment for intraoral radiography be used only for examinations where it is impractical or not medically

acceptable to transfer patients to a fixed unit or to use a mobile unit (e.g. in nursing homes, residential care facilities or homes for persons with disabilities);

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

3.3.1.30 For DXA, the radiation levels around the unit are very low, and there are no specific precautions that be taken with respect to occupational radiation protection.

3.3.1.31 Typically, the operator can be in the room with the patient when the machine is operating. The operator's desk should be positioned at least 1 m away from a pencil beam, and at least 2 m from a fan beam system. In the case of fan beam and cone beam configurations or if the distances above cannot be accommodated, the use of protective screens should be considered.

3.3.1.32 Local rules for pregnant workers and persons under the age of 18 reflect the guidance given in the RPA general regulations.

3.4 Specific local rules and procedures for image guided interventional procedures

3.4.1 The facility should ensure that:

3.4.1.1 Image guided interventional procedures are performed either in fluoroscopy rooms or dedicated interventional rooms.

3.4.1.2 Interventional procedures use designed and dedicated equipment.

3.4.1.3 Automatic contrast media injectors be used when feasible to allow personnel to move away from the patient, ideally behind a shield.

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

3.4.1.5 Consider the many operational factors that affect patient dose during image guided interventional procedures, and these factors in turn affect staff dose because the dose to the patient determines the amount of scatter radiation being produced.

3.4.1.6 Medical radiological equipment specifically designed for image guided interventional procedures often incorporates protective devices, such as ceiling suspended, lead acrylic viewing screens, and under-table and lateral shielding attachments to the X ray couch, and personal mobile shields.

3.4.1.7 Interventionists, and other staff who routinely work close to the patient, always use ceiling mounted screens or protective eyewear.

3.4.1.8 Care be taken in the proper positioning of the imaging displays to ensure optimum benefit is derived from the use of screens and protective eyewear.

3.4.1.9 For image guided interventional procedures involving intracoronary implantation of unsealed and sealed radiation sources guidelines in radiation therapy be implemented.

3.5 Personal and in-room protective devices

3.5.1 The facility should ensure that:

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

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

a. From the neck down to at least 10 cm below the knees;
b. The entire breast bone (sternum) and shoulders;
c. The sides of the body from not more than 10 cm below the armpits to at least halfway down the thighs;
d. The back from the shoulders down to and including the buttocks.

3.5.1.3 Protective gloves be worn appropriately.

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

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

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

3.5.1.7 Personal protective equipment be examined under fluoroscopy or radiography at least bi-annual to confirm its shielding integrity.

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

a) Ceiling suspended protective screens for protecting eyes and the thyroid while keeping visual contact with the patient. Technical advances with such screens include systems that move with the operator.

b) Protective lead curtains or drapes mounted on the patient table.

c) Mobile shields either attached to the table (lateral shields) or mounted on coasters (full body).

d) Disposable protective drapes for the patient.

3.6 Workplace monitoring

3.6.1 The facility should ensure that:

3.6.1.1 Workplace monitoring includes routine monitoring, special monitoring for specific occasions, activities or tasks, and confirmatory monitoring to check assumptions made about exposure conditions.

3.6.1.2 Workplace monitoring be used to verify the occupational doses of personnel whose work involves exposure to predictable low levels of radiation.

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

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

3.6.1.4 Workplace monitoring be performed and documented as part of the radiology facility's radiation protection programme.

3.6.1.5 The survey meters used for radiation monitoring be calibrated in terms of ambient dose equivalent.

3.6.1.6 The calibration be valid and be traceable to a secondary standards dosimetry laboratory.

3.6.1.7 For diagnostic radiology and image guided interventional procedures, the quantity is the ambient dose equivalent, H*(10), and the unit is the sievert (Sv) and its submultiples

3.7 Assessment of occupational exposure and health surveillance for workers

3.7.1 The facility should ensure that:

3.7.1.1 The purpose of monitoring and dose assessment is, among others, to provide information about the exposure of workers and to confirm good working practices and regulatory compliance.

3.7.1.2 establishes the requirement of individual monitoring for any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure.

3.7.1.3 Individual monitored workers include but not limited to: radiographers, radiologists, cardiologists, gastroenterologists, endoscopists, urologists, orthopaedic surgeons, neurosurgeons, respiratory physicians, anaesthetists, medical physicists, biomedical and clinical engineers, medical radiation technologists, nurses and the RPO.

3.7.1.4 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.

3.7.1.5 When electronic dosimeters are used in pulsed X ray fields, care be taken to ensure that they are functioning correctly.

3.7.1.6 Individual monitoring devices be calibrated and be traceable to a secondary standards dosimetry laboratory.

3.7.1.7 Each dosimeter be used for monitoring only the person to whom it is issued, for work performed at that facility, and it not be taken to other facilities where that person may also work.

3.7.1.8 The monitoring period (period of dosimeter deployment) specified by the Authority.

3.7.1.9 A one-month monitoring period for persons performing procedures associated with higher occupational exposure, such as image guided interventional procedures.

3.7.1.10 Two months for personnel exposed to lower doses, as a one-month cycle would usually mean that the actual occupational dose is less than the minimum detection level of the dosimeter, resulting in no detectable doses.

3.7.1.11 Dosimeters be sent from the radiological facility to the dosimetry service provider, which should then process the dosimeters and return the dose reports, all in a timely manner (depending on the cycle).

3.7.1.12 The operational dosimetric quantity used is the personal dose equivalent Hp (d). For weakly penetrating radiation and strongly penetrating radiation, the depths, d, are 0.07 mm and 10 mm, respectively. Hp (10) is used to provide an estimate of effective dose that avoids both underestimation and overestimation. Hp (0.07) is used to provide an estimate of equivalent dose to the skin and extremities.

3.7.1.13 For monitoring the lens of the eye, a depth of 3 mm (d = 3) and Hp (3) is used to provide an estimate of equivalent dose to the lens of the eye.

3.7.1.14 In cases where eye doses are a concern, such as in image guided interventional procedures, Hp (0.07), and to a lesser extent Hp (10), can be considered as an acceptable surrogate operational quantity.

3.7.1.15 three dose limits applicable to workers in diagnostic radiology and image guided interventional procedures which are limits for effective dose, and the limits for equivalent dose to the lens of the eye and to the skin and extremities are considered.

3.7.1.16 The dosimeter being worn be used to estimate one or more of the quantities used for the dose limits.

3.7.1.17 For image guided interventional procedures, two dosimeters should be worn.

3.7.1.18 For individual monitoring with only one dosimeter in diagnostic radiology and image guided interventional procedures the following should be done:

a. If the monitored worker never wears a protective apron, the dosimeter be worn on the front of the torso between the shoulders and the waist.

b. In cases where the monitored worker wears a protective apron, the dosimeter be worn on the front of the torso between the shoulders and the waist, and under the apron when it is being worn.

c. In cases where the monitored worker always wears a protective apron, the dosimeter be worn on the front of the torso at shoulder or collar level outside the apron except if the regulations require the dosimeter to be worn under the apron.

d. If the working situation is such that the radiation always or predominantly comes from one side of the person, such as in image guided interventional procedures, the dosimeter should be placed on the front of the torso on the side closest to the source of radiation

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

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

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

3.7.1.22 When not in use, individual dosimeters be kept in a dedicated place and be protected from damage or from irradiation.

3.7.1.23 If an individual loses his or her dosimeter, the individual informs the RPO, who should perform a dose assessment, record this evaluation of the dose and add it to the individual's dose record.

3.7.1.24 In some radiology facilities and for some individuals with a low level of occupational exposure (e.g. general dental practitioners), area dosimetry to estimate the level of dose per procedure can be an acceptable alternative to individual monitoring.

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

3.8 Investigation levels for staff exposure

3.8.1 The facility should ensure that:

3.8.1.1 Investigation levels be set for workplace monitoring, with account taken of exposure scenarios and the predetermined values adopted for investigation levels for workers as guided by the Authority.

3.8.1.2 An investigation be initiated as soon as possible following a trigger or event, and a written report 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 be submitted to the Authority

3.9 Persons who work in more than one Facility

3.9.1 The facility should ensure that:

3.9.1.1 a dosimeter issued for individual monitoring be worn only in the facility for which it is issued, as this facilitates the effective optimization of protection and safety in that facility.

3.9.1.2 Any person who works in more than one radiology facility notifies the licensee for each of those facilities. Each licensee, through its RPO, should establish formal contact with the licensees of the other radiology facilities and their RPOs, so that each facility has an arrangement to ensure that a personal dosimeter is available and that there is an ongoing record of the occupational doses for that person in all the facilities where he or she works.

3.9.1.3 For Individuals, who perform work in many radiology facilities and other medical radiation such as consultant medical physicist and engineers for such cases, let the company or the self-employed person provide

the dosimeters for individual monitoring. Therefore, a worker uses the same dosimeter for work performed in all radiology facilities (and other medical radiation facilities) in the monitoring period.

3.10Records of occupational exposure

3.10.1 The facility should ensure that:

3.10.1.1 records of occupational exposure be kept and be used for assessing the effectiveness of the optimization of protection and safety at the facility and evaluating trends in exposure.

3.10.1.2 They provide workers with access to records of their own occupational exposure

3.11Health surveillance for workers

The primary purpose of health surveillance is to assess the initial and continuing fitness of employees for their intended tasks.

3.11.1 The facility should ensure that:

3.11.1.1 No specific health surveillance relating to exposure to ionizing radiation is necessary for staff involved in diagnostic radiology and image guided interventional procedures, with perhaps the possible exception of initial eye assessment and periodic eye assessments for visual acuity and contrast resolution for personnel performing significant numbers of image guided interventional procedures.

3.11.1.2 Counselling be made available to workers who have or may have been exposed in excess of dose limits.

3.11.1.3 Information, advice and, if indicated, counselling be made available to workers who are concerned about their radiation exposure.

3.11.1.4 In diagnostic radiology and image guided procedures, the latter group may include women who are or may be pregnant.

3.11.1.5 Counselling be given by appropriately experienced and qualified practitioners.

3.12Information, instruction and training

3.12.1 The facility should ensure that:

3.12.1.1 All staff involved in diagnostic radiology and image guided interventional procedures meet the respective training and competence criteria in line with National and International Standards.

3.12.1.2 The information includes general education, training, qualification and competence for occupational radiation protection.

3.12.1.3 Radiological medical practitioners, medical radiation technologists and nurses working with hybrid units (such as PET–CT and SPECT–CT) have trained exclusively in their original specialty.

3.12.1.4 They undertake radiation protection and safety training relevant to the additional imaging modality.

3.12.1.5 they provide adequate information, instruction and training for protection and safety as it pertains to the radiology facility. This is not only for new staff but also for all staff as part of their continuing professional development.

3.12.1.6 Specific instruction and training be provided when new medical radiological procedures, equipment, software and technologies are introduced.

3.13Pregnant workers

3.13.1 The facility should ensure that:

3.13.1.1 provide female workers with appropriate information in radiation protection.

3.13.1.2 female workers understand the importance of making notifications of their pregnancies t so that their working conditions can be modified accordingly.

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

to radiography or to CT. Such reassignments should be accompanied by adequate training.

3.13.1.4 dose limit of 1 mSv for the embryo or fetus, the reading of a dosimeter can overestimate the dose to the embryo or fetus by a factor of 10. If the reading corresponds to a dosimeter worn outside a lead apron, the overestimation can rise to a factor of 100.

3.13.1.5 The dose to the embryo or fetus be assessed using an appropriately positioned additional dosimeter

3.13.1.6 Information, advice and, if indicated, counselling for pregnant workers should be made available

3.14 Persons under 18

3.14.1 The facility should ensure that:

3.14.1.1 Workers who are under the age of 18 years, will work in the radiation area in line with the provision of the RPA regulations.

4.0 RADIATION PROTECTION OF INDIVIDUALS UNDERGOING MEDICAL EXPOSURE

The term 'patient', when used in the context of medical exposure, means the person undergoing the radiological procedure. Other patients in the radiology facility, including those who may be waiting for their own radiological procedure, are considered members of the public.

4.1 Justification of medical exposure

4.1.1 The facility should ensure that:

4.1.1.1 All medical procedures are justified.

4.2 Justification of medical exposure for the individual patient

4.2.1 The facility should ensure that:

4.2.1.1 A referral be regarded as a request for a professional consultation or opinion rather than an instruction or order to perform.

4.2.1.2 The referring medical practitioner brings the knowledge of the medical context and the patient's history to the decision process, while the

radiological medical practitioner has specialist expertise on the radiological procedure.

4.2.1.3 The efficacy, benefits and risks of alternative methods (both methods involving ionizing radiation and methods not involving ionizing radiation) be considered.

4.2.1.4 The patient 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.

4.2.1.5 Justification, which is a principle of radiation protection, is implemented more effectively as part of the medical process of determining the 'appropriateness' of a radiological procedure.

4.2.1.6 The process of determining appropriateness is an evidence-based approach to choosing the best test for a given clinical scenario, with account taken of the diagnostic efficacy of the proposed radiological procedure as well as of alternative procedures that do not use ionizing radiation, for example, ultrasound, MRI or endoscopy.

4.2.1.7 Useful tools to support the decision-making process include national or international imaging referral guidelines.

4.2.1.8 Imaging referral guidelines be disseminated or utilized through electronic requesting systems and clinical decision support tools or systems.

4.2.1.9 It be ensured that such systems correctly apply the regulatory requirements for justification, in particular with respect to roles and responsibilities.

4.2.1.10 In determining the appropriateness of the radiological procedure for an individual patient, the following questions be asked by the referring medical practitioner.

a. Has it already been done? A radiological procedure that has already been performed within a reasonable time period (depending on the procedure and clinical question) should not be repeated (unless the clinical scenario indicates the appropriateness of repeating the

procedure). The results (images and reports) of previous examinations should be made available, not only at a given radiology facility but also for consultation at different facilities. Digital imaging modalities and electronic networks should facilitate this process. Individual patient exposure records should be used to facilitate the decision-making process if available.

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

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

4.2.1.11 A radiological procedure that has already been performed within a reasonable time period (depending on the procedure and clinical question) not be repeated (unless the clinical scenario indicates the appropriateness of repeating the procedure).

4.2.1.12 The results (images and reports) of previous examinations be made available, not only at a given radiology facility but also for consultation at different facilities.

4.2.1.13 Digital imaging modalities and electronic networks facilitates this process.

4.2.1.14 Individual patient exposure records be used to facilitate the decision-making process if available.

4.2.1.15 The anticipated outcome of the proposed radiological procedure (positive or negative) influences the patient's management.

4.2.1.16 The timing of the proposed radiological procedure in relation to the progression of the suspected disease and the possibilities for treatment all be considered as a whole.

4.2.1.17 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.

4.2.1.18 The medical context for the requested radiological procedure is crucial for ensuring the correct technique is performed with the correct focus.

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

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

4.2.1.21 Two particular groups of patients for special consideration with respect to justification are patients who are pregnant or are paediatric.

4.2.1.22 Owing to the higher radiosensitivity of the embryo or fetus, it be ascertained whether a female patient is pregnant before an X ray

examination for diagnosis or an image guided interventional procedure is performed.

4.2.1.23 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".

4.2.1.24 Confirmation of pregnancy occur after the initial justification and before the radiological procedure is performed.

4.2.1.25 Repeat justification is then necessary, with account taken of the additional sensitivity of the pregnant patient and embryo or fetus.

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

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

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

4.2.1.29 'Self-presentation' occurs when a member of the public asks for a radiological procedure without a referral from a health professional. This may have been prompted by media reports or advertising. Examples include 'individual health assessments' which often involves CT procedures in asymptomatic individuals for early detection of cancer

(e.g. whole-body CT, lung CT or colon CT) and quantification of coronary artery calcification (coronary artery CT). Justification is required, as for all radiological procedures.

4.2.1.30 Means to improve awareness, appropriateness and auditing be developed to support the application of the requirement for justification of medical exposure.

4.2.1.31 Awareness of the need for justification underpins the whole process of justification.

4.2.1.32 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.

4.3 Justification of medical exposure for biomedical research volunteers

4.3.1 The facility should ensure that:

4.3.1.1 The ethics committee provides clearance in the justification of medical exposure of volunteers exposed as part of a programme of biomedical research.

4.4 Justification of medical exposure for carers and comforters

4.4.1 The facility should ensure that:

4.4.1.1 The three-level approach to justification is not applicable for carers and comforters.

4.4.1.2 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 are considered.

4.4.1.3 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.

4.5 Optimization of protection and safety

4.5.1 The facility should ensure that:

4.5.1.1 Optimization of protection and safety to the radiological procedure be ascertained.

4.5.1.2 These components of optimization of protection and safety are adhered to Key personnel in the optimisation process are the radiological medical practitioner, the medical radiation technologist and the medical physicist.

4.6 Design considerations

4.6.1 The facility should ensure that:

4.6.1.1 The use of appropriate and well-designed medical radiological equipment and associated software underpins any radiological procedure in diagnostic radiology or any image guided interventional procedure.

4.6.1.2 X ray generators and their accessories be designed and manufactured so as to facilitate the keeping of doses in medical exposure as low as reasonably achievable consistent with obtaining adequate diagnostic information or guidance for the intervention.

4.6.1.3 it uses only medical radiological equipment and software that meets applicable international or national standards.

4.7 Operational considerations: General

4.7.1 The facility should ensure that:

4.7.1.1 Following justification, the diagnostic radiological procedure or image guided interventional procedure is required to be performed in such a way as to optimize patient protection.

4.7.1.2 The level of image quality sufficient for diagnosis is determined by the radiological medical practitioner and is based on the clinical question posed and the anatomical structures imaged (e.g. the diagnosis of the pattern of sinusitis on CT requires only a low dose procedure as high contrast structures, namely air and bone, be imaged).

4.7.1.3 With image guided interventional procedures, the level of image quality be sufficient to guide the intervention.

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

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

4.7.1.5 The first step in operational considerations of optimization is selection of the appropriate medical radiological equipment.

4.7.1.6 The volume (area) of the patient that is exposed be strictly limited to that of clinical interest.

4.7.1.7 Cooperation of the patient be ensured to achieve an image of diagnostic quality.

4.7.1.8 Optimization of protection and safety for a woman undergoing a radiological procedure during pregnancy consider the woman and the embryo or fetus.

4.7.1.9 When CT scanning is indicated for a pregnant patient, low dose CT protocols be used and the scanning area be reduced to a minimum

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

4.7.1.11 Written protocols that specify the operating parameters to be used for common diagnostic radiological procedures be developed, adopted and applied in each radiology facility.

4.7.1.12 protocol 'technique charts' be posted adjacent to each X ray generator and be specific for each piece of equipment.

4.7.1.13 The protocols consider the anatomical region, as well as patient mass and size.

4.7.1.14 The protocols be developed using guidelines from national or international standards.

4.7.1.15 For modern digital equipment, many of the factors are automated through the menu driven selection of options on the console. Nevertheless, in setting up these options, significant scope exists for the optimization of protection and safety through the appropriate selection of values.

4.7.1.16 Size specific written protocols be developed for children, from neonates to teenagers, and include additional operational considerations, such as the use of additional filtration or the removal of grids when appropriate.

4.7.1.17 All aspects of protection be considered before the approval of the health screening programme and during its implementation, such as the selection of X ray equipment suitable for the particular screening and parameters settings.

4.7.1.18 A dedicated, comprehensive programme of quality assurance be implemented to meet screening objectives and set requirements for the education and training of the medical professionals involved in the health screening programme, for adequate quality management for the whole screening chain and for documentation and evaluation of the results.

4.8 Operational considerations: Radiography

4.8.1 The facility should ensure that:

4.8.1.1 In developing protocols for radiography, many technique factors be considered, which can influence the image quality and the patient dose for the radiographic projection. Such factors include: the tube potential; current; exposure time; focal spot size; filtration; source to image receptor distance; choice of anti-scatter grids or Bucky device;

collimation; image receptor size; positioning, immobilization and compression of the patient; the number of projections needed (e.g. a posterior–anterior chest X ray rather than posterior–anterior and lateral X rays); and organ shielding where appropriate (e.g. testicular shielding for pelvic radiographs in male patients).

4.8.1.2 Suitably calibrated and maintained AEC systems be used when available and appropriate. Particular attention be given in paediatric radiography to ensuring that AEC sensors are within the radiation field.

4.8.1.3 AEC systems are calibrated on the basis of the radiation exposure at the detector required to produce the desired level of optical density for film–screen systems or a predetermined acceptable level of signal to noise ratio, or surrogate, for digital systems.

4.8.1.4 The value for the signal to noise ratio be established as part of setting up the protocols for radiographic projections for each particular X ray unit.

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

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

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

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

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

4.9 Operational considerations: Mammography

4.9.1 The facility should ensure that:

4.9.1.1 In developing protocols for mammography, consideration of radiographic technique factors be made. Additional factors that should be considered include: adequate compression of the breast; tissue composition (e.g. dense glandular breasts identified on previous mammograms); and correct choice of anode and filters. Detailed guidance on appropriate choices for technique factors and additional factors is available.

4.9.1.2 For film based mammographic systems, additional factors include the type of film–screen combination and the film processing condition (e.g. the chemicals used and developing time and temperature).

4.9.1.3 Viewing conditions are of paramount importance for both digital and film-based mammography systems, and the operational performance be met the conditions.

4.10 Operational considerations: Computed tomography

4.10.1 The facility should ensure that:

4.10.1.1 In developing protocols for CT, many technique factors and features be considered which can influence the image quality and the patient dose for the examination, including: tube potential; tube current; tube current modulation with noise index; pitch; beam width; and total scan length, over ranging and over beaming for the scan.

4.1.10.1 Careful consideration be made as to the need for multiple phase studies to answer the clinical question (e.g. in abdominal CT imaging for routine detection of liver metastases, and the use of portal venous phase acquisitions only, rather than triple phase acquisitions, namely arterial, portal venous and delayed phase acquisitions).

4.1.10.2 Protocols for optimized CT procedures for common clinical conditions be agreed, put in place and used.

4.1.10.3 Special attention be given to developing protocols for children adapted to body size and age.The use of adult protocols for scanning children is inappropriate.

4.1.10.4 Care be taken with the introduction of algorithms related to Improved image presentation, reconstruction and post-processing features to reduce image noise to ensure that the radiation protection of the patient is optimized.

4.1.10.5 Proper positioning of the patient and proper setting of the scanned anatomical area of interest be achieved.

4.1.10.6 Immobilizing devices are used where appropriate. Special attention be made for proper immobilisation of paediatric patients by use of straps, swaddling blankets, plastic holders for the head or body, foam pads, sponges, sand bags, pillows or other objects.

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

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

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

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

4.1.10.11 CBCT, also known as flat panel CT, C-arm CT, cone beam volume CT and digital volume tomography, is used in medical applications (diagnostic and interventional radiology, and IGRT) and dental applications and factors that should be considered include: tube potential; tube current–exposure time product; field of view; voxel size; and the number of projections.

4.11 Operational considerations: Dentistry

4.11.1 The facility should ensure that:

4.11.1.1 In developing protocols for conventional intraoral radiography, factors that can influence the image quality and the patient dose include: tube potential; current; exposure time; collimation; focus to skin distance; and, for analogue systems, film speed and processing development time and temperature be considered.

4.11.1.2 In developing protocols for panoramic imaging, additional factors that can influence the image quality and the patient dose include: patient positioning (e.g. jaw open or closed); collimation (e.g. for examinations of the temporomandibular joint, only those areas should be included); and for analogue systems, film speed or screen speed, and processing development time and temperature be considered.

4.12 Operational considerations: Image guided interventional procedures

4.12.1 The facility should ensure that:

4.12.1.1 The choice of imaging modality for guidance of interventional procedures depends on the clinical scenario (e.g. fluoroscopic guidance for percutaneous coronary intervention and CT guidance for biopsy).

4.12.1.2 Patients be briefed about the intervention prior to the commencement of the procedure so that they know what to expect and how to cooperate.

4.12.1.3 In developing protocols for fluoroscopically guided interventional procedures, many technique factors and features be considered, which can influence the image quality and the patient dose for the intervention, including: tube potential; tube current; use of pulsed fluoroscopy (hence

pulse width and rate); dose rate mode (effectively the image intensifier or flat panel detector input air kerma rate); collimation, and collimation tracking with the distance from the focus to the detector; filtration (fixed and variable); use of magnification; total fluoroscopy time for the intervention; image acquisition dose mode (effectively input air kerma per frame for the image intensifier or flat panel detector); image acquisition frame rate; number of frames per run and the total number of acquisitions.

4.12.1.4 High-rate dose modes in fluoroscopy be used only during the minimum indispensable time necessary to the procedure.

4.12.1.5 The use of magnification modes be kept to a minimum consistent with a successful intervention.

4.12.1.6 In the course of the intervention, the tube orientation and position may need to be changed.

4.12.1.7 For long procedures, the area of skin upon which the X ray beam is incident be changed during the procedure to avoid deterministic skin effects.

4.12.1.8 Steep oblique projections be avoided.

4.12.1.9 The distance between the X ray tube and patient always be maximized to reduce patient dose.

4.12.1.10 the image intensifier or flat panel detector be positioned as close to the patient as possible.

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

4.12.1.12 In developing protocols for CT guided interventional procedures, technique factors that must be considered, which can influence the image quality and the patient dose for the intervention, include: tube potential, tube current and beam width.

4.12.1.13 The number of image acquisitions (tube rotations) be kept to a minimum consistent with a successful intervention.

4.13 Operational considerations: Fluoroscopy

4.13.1 The facility should ensure that:

4.13.1.1 Guidelines in 4.1.12 apply to fluoroscopy used in diagnostic radiology

4.14 Operational considerations: Bone densitometry

4.14.1 The facility should ensure that:

4.14.1.1 Selection of the appropriate site for densitometry consider both the anatomical area of clinical concern as well as the likelihood of non-representative images and measurements owing to artefacts (e.g. massive vertebral osteophytes may obviate the value of lumbar densitometry).

4.15 Operational considerations: Emergency radiology

4.15.1 The facility should ensure that:

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

4.16 Calibration: General

4.16.1 The facility should ensure that:

4.16.1.1 In line with National and International Standards the dosimetric quantities and units of the ICRU are to be used for diagnostic radiology and image guided interventional procedures.

4.16.1.2 Calibration requirements for medical radiological equipment and dosimetry equipment are established

4.17 Calibration: Medical radiological equipment

4.17.1 The facility should ensure that:

4.17.1.1 In diagnostic radiology, including the use of medical radiological equipment for simulation of radiation therapy, treatment verification systems and hybrid imaging systems, and for image guided interventional procedures, 'source calibration' is to be interpreted as the

measurement of certain dosimetric quantities that are modality dependent and which be carried out in reference conditions.

4.17.1.2 For diagnostic radiographic and fluoroscopic medical radiological equipment, including conventional radiation therapy simulators, the dosimetric quantities are in line with National and international standards.

4.17.1.3 In mammography, the three dosimetric quantities be used which are incident air kerma, entrance surface air kerma and mean glandular dose, usually in mGy.

4.17.1.4 Measurements of these dosimetric quantities, when being used to calibrate or characterize a given X ray, CT or mammography unit output or performance, be made for a range of representative technique factors used clinically, and following recognized protocols

4.18 Calibration: Dosimetry instrumentation

4.18.1 The facility should ensure that:

4.18.1.1 Dosimetry instrumentation used at a radiology facility be calibrated at appropriate intervals. A period of not more than two years is recommended.

4.18.1.2 Calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory.

4.18.1.3 Records of calibration measurements and associated calculations, including uncertainty determinations (uncertainty budgets), be maintained.

4.19 Dosimetry of patients: General

4.19.1 The facility should ensure that:

4.19.1.1 patient dosimetry be performed in diagnostic radiology and image guided interventional procedures and that typical doses to patients for radiological procedures be determined.

4.19.1.2 determination of typical doses for common radiological procedures in radiology facilities are done.

4.19.1.3 For image guided interventional procedures, typical doses for the broad types of procedure performed at the facility be ascertained.

4.19.1.4 Patient size groupings be adopted that correspond to the groupings used for the DRLs in the Country or region.

4.19.1.5 The sample size used for each patient grouping and radiological procedure be of sufficient size to assure confidence in the determination of the typical dose.

4.19.1.6 Patient dosimetry to determine typical doses be carried out in conjunction with an assessment of the diagnostic image quality.

4.19.1.7 The results of the surveys used to determine typical doses at the radiology facility be used as part of the ongoing review of the optimization of protection and safety at the facility, and be used for comparison with established DRLs.

4.19.1.8 Patient dosimetry surveys, take place at intervals of no more than five years and preferably no more than three years. Another trigger for a survey would be the introduction of new equipment or technology into the radiology facility or when significant changes have been made to the protocols or the equipment.

4.19.1.9 patient dosimetry in diagnostic radiology or image guided interventional procedures be required for specific individual patients, either through measurements or calculations.

4.20 Dosimetry of patients: Specific considerations for image guided interventional procedures

4.20.1 The facility should ensure that:

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

4.20.1.2 The cumulative reference air kerma at the patient entrance reference point, defined as the kerma in air at 15 cm from the isocentre in the

direction of the X ray tube either displayed during the procedure or obtained from the DICOM header, be used as a conservative estimate for peak skin dose.

4.21 Diagnostic reference levels

4.21.1 The facility should ensure that:

4.21.1.1 patient dosimetry surveys be performed for the diagnostic procedures at a radiology facility, and that these results be compared with the established DRLs for the Region or Country.

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

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

4.21.1.4 the comparison not simply determine whether the radiology facility complies with the DRL. 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.

4.21.1.5 The review of how the given radiological procedure is being performed and of the optimization of protection and safety, triggered by the DRL comparison, might conclude that there are valid reasons supported by sound clinical judgement why the radiology facility has a typical dose that exceeds the DRL. These reasons should be documented as part of the facility's programme of quality assurance.

4.21.1.6 Adequateness of image quality always be considered.

4.21.1.7 The results of the DRL comparison and any ensuing review and actions should be documented as part of the facility's programme of quality assurance.

4.22 Quality assurance for medical exposures

4.22.1 The facility should ensure that:

4.22.1.1 a comprehensive programme of quality assurance for medical exposures is put in place.

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

4.22.1.3 The complexity of the programme of quality assurance for medical exposures will depends on the type of facility. A dental practice with only intraoral radiography will have a simpler programme compared with a facility that offers all modalities of diagnostic radiology as well as image guided interventional procedures.

4.22.1.4 Measurements on medical radiological equipment are one of the components of the comprehensive programme of quality assurance.

4.22.1.5 Acceptance tests are done for new or significantly refurbished or repaired equipment, or after the installation of new software or modification of existing software that could affect protection and safety.

4.22.1.6 The acceptance test be followed immediately by commissioning, and then ongoing periodic quality control tests, including constancy tests.

4.22.1.7 Acceptance and commissioning tests be performed in the same way for equipment and software that has been donated.

4.22.1.8 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.

4.22.1.9 The process involves verification of all specifications and features of the equipment.

4.22.1.10 After acceptance and before clinical use on patients, commissioning be carried out by, or under the supervision of, the medical physicist.

4.22.1.11 Commissioning includes measurements of all parameters and conditions of use that are expected in clinical use, including setting up and validating image acquisition protocols.

4.22.1.12 For most modalities (CT, image guided interventional procedures, tomosynthesis, mammography, radiography and fluoroscopy), the medical physicist be directly involved in the measurements, calculations and interpretation of data to characterize the equipment's performance.

4.22.1.13 For the least complex modalities (dental radiography and DXA), the medical physicist provide documented advice on how the commissioning should be performed.

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

4.22.1.15 In addition to the acceptance testing and commissioning, periodically and after any major maintenance procedure or upgrade, the measurement of physical parameters of medical radiological equipment.

4.22.1.16 While traditional approaches to constancy testing are based on measurements of technical parameters for the system or using test objects and phantoms, it is likely that in the future clinically derived data be used in the monitoring of equipment and in ensuring consistency in clinical practice.

4.22.1.17 Quality control tests be performed on other equipment or devices that have an impact on the successful outcome of the radiological procedure. Such equipment and devices include, but are not limited to: film processors, darkrooms and cassettes for facilities using film-based imaging; flat detectors for DR systems; CR imaging plates and CR readers for facilities with CR systems; and view boxes, workstations, and display and interpretation rooms.

4.22.1.18 The results of the quality control tests 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

4.22.1.19 corrective actions include maintenance or servicing of the equipment, and hence a preventive maintenance programme be put in place at the radiology facility.

4.22.1.20 the equipment which might be outside the tolerance limits by a significant amount be immediately taken out of clinical use and not returned until servicing has taken place and it has been ascertained that the equipment meets the performance requirements.

4.22.1.21 The programme of quality assurance for medical exposures in the radiology facility include the use of checks to ensure that the facility's protocols and procedures for imaging and interventional procedures, including radiation protection and safety, are being followed.

4.22.1.22 As part of the programme of quality assurance for medical exposure, 'repeat and reject analysis' be performed on a periodic basis.

4.22.1.23 periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment be part of the programme of quality assurance.

4.22.1.24 programme of quality assurance for medical exposures 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.

4.22.1.25 Phantoms used in quality assurance and dosimetry fulfil the requirements specified in the corresponding international standards.

4.22.1.26 Maintaining records is a crucial aspect of the programme of quality assurance for medical exposures. This includes the procedures used in the programme and the results of the quality control tests, the dosimetry surveys, the DRL comparisons, the corrective actions, and the investigations of unintended and accidental medical exposures.

4.22.1.27 When planning and developing an effective programme of quality assurance, strong managerial commitment and support in the form of

training and allocation of time, personnel and equipment resources be put in place.

4.22.1.28 In line with standard practices for quality management, regular and independent audits are made part of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks. Such audits may be external audits or internal audits. Internal audits are usually logistically simpler to conduct, while an external audit generally has the advantage of bringing in an outside perspective.

4.22.1.29 The audit of the programme of quality assurance for medical exposures can be incorporated into more comprehensive audits of the management system performed.

4.22.1.30 the results of the audit of the programme of quality assurance for medicalexposures be a major input into the radiological review performed at the facility.

4.23 Dose constraints: Carers and comforters

4.23.1 The facility should ensure that:

4.1.23.1 Some diagnostic radiological procedures be better performed with the assistance of a carer or comforter, for example a relative in the case of a paediatric patientor a relative or friend for a disabled or very elderly or very ill patient. In these circumstances, the carer or comforter be exposed to a low dose.

4.1.23.2 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.

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

4.1.23.4 The radiation protection afforded the carer or comforter be optimized, and, as part of this process, dose constraints is applied.

4.1.23.5 Written protocols be drawn up for implementing measures for the optimization of protection and safety for carers and comforters who hold patients during radiological procedures.

4.1.23.6 The measures utilize the basic principles for radiation protection (i.e. time, distance and shielding).

4.1.23.7 The protocols should include the following:

a. Methods to avoid the need for holding patients, for example the administration of sedatives (especially for long procedures such as CT examinations) and the use of infant restraints.
b. Criteria specifying which carers and comforters are allowed to hold patients, for example friends and relatives, provided that they are not pregnant, but not employees of the facility, such as porters and nurses.
c. Methods for positioning and protecting the carer or comforter so that his or her exposure is as low as reasonably achievable, for example by ensuring that the carer or comforter is not in the direct beam of the radiation device and that appropriate personal protective equipment is used, for example a protective apron or ancillary shields of a specified lead equivalence.

4.1.23.8 A would-be carer or comforter for a diagnostic radiological procedure, in cases where this is unavoidable, his or her dose be constrained to less than 1 mSv.

4.1.23.9 It is able to demonstrate that the effective dose to the carer or comforter, by applying the protocols, is unlikely to exceed the dose constraint.

4.1.23.10 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 be situated.

4.1.23.11 These determinations be made in advance to ensure that dose constraint is not exceeded. Therefore, individual dose monitoring is normally not necessary.

4.24 Dose constraints: Volunteers in biomedical research

4.24.1 The facility should ensure that:

4.24.1.1 When volunteer presents himself or herself at the radiology facility, he or she is afforded the same radiation protection as if he or she were a patient ready to undergo a radiological procedure, but with the additional restriction that his or her exposure will be subject to a dose constraint, either a nationally established dose constraint or a dose constraint specified by the ethics committee that approved the biomedical research programme.

4.25 Pregnant patients

4.25.1 The facility should ensure that:

4.25.1.1 Patients who are pregnant be given particular consideration with respect to radiation protection.

4.25.1.2 clear signs (possibly including a pictorial representation of pregnancy) in languages easily understood by the people using the radiology facility, posing the question 'Are you pregnant or possibly pregnant?' and 'If so, please tell the staff' are posted at the facility. Such signs should be posted widely in the facility, including in waiting rooms and cubicles.

4.25.1.3 patients are asked directly whether they are or might be pregnant.

4.25.1.4 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".

4.25.1.5 Such radiological procedures include those that involve primary beam irradiation of the abdomen or pelvis area delivering relatively high patient doses directly to the embryo or fetus, or to volumes near the

uterus such that significant scatter radiation reaches the embryo or fetus.

4.25.1.6 Cooperation with the referring medical practitioner, through standard requests for pregnancy status for specified procedures, is done

4.25.1.7 The referral form includes a 'tick box' for pregnancy status.

4.26 Unintended and accidental medical exposures (Prevention).

4.26.1 The facility should ensure that:

4.26.1.1 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.

4.26.1.2 promptly investigate if such exposures occur.

4.26.1.3 General strategies for addressing the problems include the regular maintenance of medical radiological equipment and software, a comprehensive programme of quality assurance, continuing education and training of staff, and the promotion of a safety culture.

4.26.1.4 Lessons identified from events that have occurred be used for preventing or minimizing unintended and accidental medical exposures.

4.26.1.5 the likelihood of unintended or accidental medical exposures in diagnostic radiology and image guided interventional procedures is minimised. These unintended or accidental medical exposures can be minimised by:

a. The introduction of safety barriers at identified critical points in the process, with specific quality control checks at these points. Quality control should not be confined to physical tests or checks but can include actions such as the correct identification of the patient.
b. Actively encouraging a culture of always working with awareness and alertness.
c. Providing detailed protocols and procedures for each process.

d. Providing sufficient staff who are educated and trained to the appropriate level, and an effective organization, ensuring reasonable patient throughput.
e. Continuous professional development and practical training and training in applications for all staff involved in providing radiology services.
f. Clear definitions of the roles, responsibilities and functions of staff in the radiology facility that are understood by all staff.

4.26.1.6 Preventive measures include reporting of incidents and near incidents, analysis and feedback, including lessons from international experience.

4.26.1.7 Preventive measures also include checking of the robustness of the safety system of the facility against reported incidents for a review of case histories from a collection of unintended and accidental medical exposures in image guided interventional procedures).

4.26.1.8 the following three-step strategy (commonly called 'prospective risk management') is used to prevent unintended and accidental medical exposures in a radiology facility:

4.26.1.9 Allocation of responsibilities to appropriately qualified health professionals only and ensuring that a management system is in place that includes radiation protection and safety;

4.26.1.10 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;

4.26.1.11 Identification of other latent risks by posing the questions 'What else could go wrong?' or 'What other potential hazards might be present?' in a systematic, anticipative manner for all steps in the diagnostic and image guided interventional radiology process.

4.27 Investigation of unintended and accidental medical exposures

4.27.1 The facility should ensure that:

4.27.1.1 Procedures be put in place that consist of several independent methods of patient identification, and verification of requisition of the examination and of the orientation of the patient.

4.27.1.2 Incidents that should be investigated include the inadvertent exposure of the embryo or fetus in the course of a radiological procedure where, at the time of the procedure, it was not known that the woman was pregnant.

4.27.1.3 accidental medical exposures which result in radiation injuries be investigated.

4.27.1.4 patients who may be at risk of late radiation injuries, information be added to their medical records so that appropriate observation and follow-up is ensured. A record of the calculation method and results be placed in the patient's file. counselling of the patient be undertaken by an individual with appropriate experience and clinical knowledge.

4.27.1.5 reporting (in writing) of significant events to the regulatory body and, if appropriate, to the relevant health authority is done.

4.27.1.6 Incidents with one or more of the following attributes be reported to the regulatory body and the health authority;

a. the occurrence of, or the potential for, serious unintended or unexpected health effects due to radiation exposure,
b. the likelihood of a similar incident occurring in other radiology facilities,
c. a large number of patients having been affected,
d. and gross misconduct or negligence by the responsible health professionals.

4.27.1.7 Irrespective of whether the incidence is also reported to the regulatory body, feedback to staff be provided in a timely fashion and, where changes are recommended, all staff be involved in bringing about their implementation.

4.28 Records and review

4.28.1 The facility should ensure that:

4.28.1.1 Radiological review be performed periodically at the radiology facility. This involves considering both justification and optimization aspects of radiation protection.

4.28.1.2 To facilitate compliance and to learn from periodic radiological reviews, the methodology used, the original physical, technical and clinical parameters considered and the conclusions reached be documented and considered prior to any new review that may result in an update of the radiology facility's policies and procedures.

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

4.29 Records

4.29.1 The facility should ensure that:

4.29.1.1 Records be in place to demonstrate ongoing compliance with radiation protection requirements.

4.29.1.2 These records are 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 be kept for a longer time.

5.0 RADIATION PROTECTION OF THE PUBLIC

5.1 Public Exposure

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

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

any exposure incurred other than during the radiological procedure in which they are involved will be public exposure.

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

5.2 External exposure

5.2.1 The facility should ensure that:

5.2.1.1 Shielding is sufficient so that public exposure resulting from being in any immediately adjacent areas, including accessible rooms above and below, follows the public dose limits, and preferably less than any dose constraint that the regulatory body may have applied.

5.2.1.2 Particular consideration be given to persons in the radiology facility who are not undergoing a radiological procedure, but are in the vicinity when mobile radiography is being performed in their ward or area, or when fixed radiography being performed in an open area, such as in an emergency department. In these cases, a combination of distance, placement of mobile shielding and careful control of the X ray beam direction sensure that appropriate public radiation protection is being afforded.

5.3 Control of access

5.3.1 The facility should ensure that:

5.3.1.1 Access to areas where radiation is being used be controlled to ensure doses to visitors are below the dose limits and constraints for the public.

5.3.1.2 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 be accompanied at all times by a staff member who knows the protection and safety measures for the area.

5.3.1.3 Written procedures be drawn up specifying when such exceptions can take place and who may accompany the visitor.

5.3.1.4 Particular consideration, in all cases, be given with respect to women who are or may be pregnant.

5.3.1.5 Controlled areas and supervised areas be clearly identified to help to prevent inadvertent entry to areas where diagnostic radiology or image guided interventional procedures are being performed.

5.3.1.6 Further control be afforded by the use of keys (or passwords) to restrict access to the control panels of medical radiological equipment to authorized persons only.

5.4 Monitoring and reporting

5.4.1 The facility should ensure that:

5.4.1.1 Procedures are to be in place to ensure that:

a. The requirements for public exposure are satisfied and such exposure is assessed;

b. Appropriate records of the results of the monitoring programmes are kept.

5.4.1.2 The programme for monitoring public exposure arising from diagnostic radiology and image guided interventional procedures include dose assessment in the areas in and surrounding the radiology facility that are accessible to the public.

5.4.1.3 Records of dose assessments 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.

6.0 PREVENTION AND MITIGATION OF ACCIDENTS

6.1 Safety assessments of potential exposure

6.1.1 The facility should ensure that:

6.1.1.1 safety assessment is conducted which applies to all stages of the design and operation of the radiology facility.

6.1.1.2 a safety assessment is submitted for review and assessment by the regulatory body.

6.1.1.3 The safety assessment of potential exposure be systematic,

6.1.1.4 identify unintended events that can lead to potential exposure,

6.1.1.5 consider their likelihood and potential consequences.

6.1.1.6 The safety assessment covers not only events, but should also aim at anticipating other events that have not previously been reported.

6.1.1.7 The safety assessment be documented.

6.1.1.8 The safety assessment should be revised when:

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

6.2 Prevention of accidents

6.2.1 The facility should ensure that:

6.2.1.1 Accident prevention is clearly the best means for avoiding potential exposure, and establish the requirements for good engineering practice, defence in depth and facility-based arrangements to achieve this.

6.2.1.2 Design considerations for medical radiological equipment and the radiology facility.

6.2.1.3 The following are incorporate:

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

6.2.1.4 equipment be provided with a special X ray interlock in the control panel to disconnect the exposure foot switch in between cases

6.2.1.5 Inadvertent entry into the room when a patient is undergoing a radiological procedure is prevented

6.3 Mitigation of the consequences of accidents

6.3.1 The facility should ensure that:

6.3.1.1 All relevant staff be adequately trained to be able to recognize when medical radiological equipment is not functioning correctly or, for example, when a programming error in the software is suspected.

6.3.1.2 If there are implications for occupational protection and/or patient protection, and if medical considerations allow it, the radiological procedure be discontinued and the X ray unit turned off.

6.3.1.3 For Some interventional radiology facilities which use sealed or unsealed radioactive sources for implantation or administration as part of the image guided interventional procedure. Loss of a source, rupture of the encapsulation or spillage of radioactivity can lead to contamination relevant guidance are considered.

Definition

"A1 and A2" means quantities of radioactivity, which are used to determine such things as the type of packaging necessary for a particular radioactive material shipment. **A1** applies to special form and **A2** applies to other than special form radioactive material.

"accident" means any unintended event including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety;

"Act" means the Radiation Protection Act No. 16 of 2005,

"Administer ionizing radiation" means an intentional act of subjecting ionizing radiation to persons for the purpose of medical treatment or diagnosis by a qualified medical expert whether it be internal or external.

"**Qualified medical practitioner**" means a medical practitioner responsible for the medical surveillance of workers who are liable to receive a dose greater than three-tenths of the annual maximum permissible dose.

"**apparatus**" means equipment associated with the emission of radiation.

"article" means item or thing, or equipment associated with emission of radiation.

"**Atomic energy**" means ionizing radiation emitted because of electronic or nuclear transitions in an atom.

"authorization" means a permission granted in a document by the Authority to a legal person who has applied to carry out a practice or any other action described in the general obligations for practices under this Act. The authorization can take the form of registration or a license.

"Authorized officer" means an officer appointed or authorized to perform any functions in relation to the enforcement of the provisions of these Regulations. **"Board"** means the Board of the Radiation Protection Authority as provided for in the Schedule to the Act;

"Clearance" means removal of radioactive materials or radioactive objects within authorized practices from any further control by the Authority

"Continuous exposure" means external exposure where the source of radiation subjects the body or any critical organ to prolonged exposure or internal exposure due to continuous intake.

"Critical Group" means a group of members of the public which is reasonably homogeneous with respect to its exposure for a given radiation source and given exposure pathways and its typical of individuals receiving the highest effective dose (as applicable) by the given exposure pathway from the given source.

"**Executive Director**" means the Executive Director of the Radiation Protection Authority

"disease" includes injury and bodily or mental deficiency or abnormality.

"**disposal**" means the emplacement of waste in an approved, specified facility (e.g., near surface or geological repository) without the intention of retrieval. Disposal may also include the approved direct discharge of effluents (e.g. liquid and gaseous wastes) into the environment with subsequent dispersion;

"dose" means a measure of the radiation received or "absorbed" by a target.

"Dose constraint" means a prospective and source related restriction on the individual dose delivered by the source which serves as a bound in the optimization of protection and safety of the source.

"Dose equivalent" means a quantity used by the International Commission on Radiation Units and measurements (ICRU) in defining the operational quantities ambient dose equivalent, directional dose equivalent and personal dose equivalent.

"**Dose limit**" means the value of the effective dose or the equivalent dose to individuals from controlled practices that are not exceeded.

"Effective dose" means a summation of the tissue equivalent doses, each multiplied by the appropriate weighting factor.

"Emergency plan" means a set of procedures to be implemented in the event of a radiation accident.

"Equivalent dose" means the quantity HT, R defined as HT, R = DT, R. WR

where DT, R is the absorbed dose delivered by radiation type R averaged over a tissue or organ T and WR is the radiation weighting factor for radiation type R.

"Ethical review committee" means a committee of independent persons to advise on the conditions of exposure and the dose constraints to be applied to the medical exposure of individuals exposed for biomedical research purposes when there is no direct benefit to the exposed individual

"Exclusive use" means that a single consignor has sole use of the conveyance (or large freight container) such that all loading and unloading is carried out in accordance with the directions of the consignor or consignee.

"exposure" means the act or condition of being subjected to irradiation.

"External exposure" means the act or condition of being subjected to irradiation by a source outside the body.

"**facility"** means any assembly of devices, equipment, structures or natural features whether simple or complex which serves some purpose or performs some function, in the course of which radiation is, or is capable of being emitted;

"Ionizing radiation" means the radiation of gamma rays and x-rays or corpuscular radiation, capable of producing ions directly or indirectly in its passage through matter.

"**Internal exposure"** the act or condition of being subjected to irradiation by a source inside the body.

"license" means an authorization granted by the Authority based on a safety assessment and accompanied by specific requirements and conditions to be complied with by the licensee.

"licensee" means a person holding a license granted under the Act.

"Medical Practitioner" means an individual who: (a) has been accredited through appropriate international and/or national procedures as a health professional; (b) fulfils the international and/or national requirements on training and experience for prescribing procedures involving medical exposure; and (c) is a registrant or licensee, or a worker who has been designated by a registered or licensed employer for the purpose of prescribing procedures involving medical exposure;

"Minister" means the Minister for the time being responsible for matters relating to nuclear technology.

"notification" means a document submitted to the Authority by a legal person to notify requirements in such a manner as provided for in the regulation.

"Nuclear safety' means the condition and ability of a nuclear Installation and its servicing Personnel to prevent the uncontrolled development of a fission chain reaction or an inadmissible release of radioactive substances or ionizing radiation into the environment, and to reduce the consequences of accidents.

"Nuclear installation" means a nuclear fuel fabrication plant, nuclear reactor (including critical and Sub critical assemblies), research reactor, nuclear power plant, spent fuel storage facility, enrichment plant or reprocessing facility;

"Physical protection" means a system of technical and organizational measures preventing unauthorized activities with nuclear Installations, nuclear materials, and selected items.

"plant" means and includes any machinery, facility, or installation, whether affixed to land or not, but does not include any thing comprised or to be comprised in any means of transport, whether by land, water, or air.

"practice" means any human activity that introduces additional sources of exposure pathways or extends exposure to additional people or modifies the network of exposure

pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed;

"premises" means and includes any land, whether built up or not, including any place underground and any land covered by water.

"Qualified expert" means an individual who by virtue of certification by appropriate boards or societies, professional license or academic qualification and experience, is duly recognized by the Authority as having expertise in a relevant field of specialization e.g., medical physics, radiation protection, occupational health, quality assurance or any relevant engineering or safety specialty.

"radiation" means ionizing radiation.

"Radiation device" means an equipment capable of generating ionizing radiation when energized and it does not contain radioactive material.

"Radiation accident" means any occurrence or succession of occurrences having the same origin, which results into the release of radioactive materials, or radiation doses, which exceeds the safety standards prescribed in Regulations;

"Radiation protection" means a system of technical and organizational measures to reduce or limit exposure of people and the environment.

"Radiation Safety" means measures intended to minimize the likelihood of accidents with radiation sources and, should such an accident occur, to mitigate its consequences;

"Radiation Protection Officer" means an individual who is competent in radiation protection matters and relevant for a given type of practice who is designated the Licensee

"Inspector" means any person appointed under section 35 of the Act to perform radiation inspections and any other duties relating to inspections under the Act;

"Radioactive material" means any matter or substance containing one or more radionuclides the activity or concentration of which is sufficiently intense to entail a significant risk or disability or disease to any person or organ on exposure.

"Radioactive waste" means some material that contains or is contaminated with radionuclides at concentrations or activities greater than exemption levels as established by the Authority and for which no use is foreseen;

"Safety culture" means the assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance;

"**Sealed source**" means a source consisting of radioactive material firmly incorporated in a solid of effectively inactive materials, or sealed in an inactive container of a strength sufficient to prevent, under normal conditions of use, any dispersion of radioactive material and any possibility of contamination;

"security" means measures to prevent unauthorized access or damage to, and loss, theft, or unauthorized transfer of radioactive materials.

"**Single exposure**" means external exposure where the source of radiation subjects the body or organ to exposure of short duration, or internal exposure following the intake of radionuclides over a short period.

"**source**" means an apparatus, device, material, or anything capable of emitting radiation.

"Special form radioactive material" means is either an in dispersible solid radioactive material or a sealed capsule containing radioactive material. The material has a very high degree of physical integrity so that if the material were released from the package in an accident, while there might be a high radiation hazard, it is unlikely that there would be any contamination hazard.

"Transport Index (TI)" means a number that is assigned to transport package (or over pack, freight container or conveyance), which is used to provide control over groups of packages for the purposes of minimizing radiation risks.

"**undertaking**" means and includes any trade, practice, business or profession and in relation to a public or local authority, includes any of the powers or duties of that authority, and, in relation to any other body of persons, whether corporate or
incorporate, includes any of the activities of that body;

Unsealed sources (open sources) mean a source that does not meet the definition of a sealed source;

"user" means a person or body of persons or institution authorized under these Regulations or the Act.

"**Using radiation**" means and includes possession, holding, storage, transporting importing, exporting, installing, purchasing, selling, or applying radiation in any activity. **"Worker**" means any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection.

"Exposures" means the exposures to which the requirement of these Regulations apply are any occupational exposure, medical exposure or public exposure due to any relevant practice or source within a practice, including both normal exposures and potential exposures.

"Exclusions" means the following exposures are excluded from the requirements of these Regulations:

(1) (a). exposures from natural radioactivity in the body; and

(b). exposures from cosmic radiation and from unmodified concentrations of natural radionuclides in raw materials.

(2) any other sources that are essentially unamenable to control as may be determined by the Authority.