

***REGULATIONS FOR RADIATION
SAFETY IN DIAGNOSTIC AND
INTERVENTIONAL RADIOLOGY***

RADIATION PROTECTION ACT [CHAPTER 15:15]

REGULATIONS FOR RADIATION SAFETY IN DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY

ARRANGEMENT OF REGULATIONS

Part I: General

Regulation

1. Interpretation
2. Objective
3. Scope

Part II: Principal Requirements

4. Authorization of Practices
8. Renewal of Authorization
9. Non Compliance and Suspension or Withdrawal of Authorization
12. Personnel Accreditation
16. Authorization of other Practices related to Radiology
17. Inspection
18. Radiation Protection Requirements
19. Managerial Commitment and Policy Statement
20. Organization and Responsibilities
26. Quality Assurance
28. Human Factor
29. Staffing
30. Education and Training

Part III: Safety of Sources, Equipment and Facilities

35. Defence in Depth
36. Design
38. X-Ray Systems (Tube, Generator and Ancillary Equipment)
45. Facilities (X-Ray Design)
52. Maintenance
53. Electrical and Mechanical Safety
54. Acceptance

55. Commissioning

Part IV: Occupational Exposure

- 56. Classification of Areas
- 57. Local Rules and Supervision
- 58. Protective Equipment and Tools
- 60. Individual Monitoring and Exposure Assessment
- 61. Pregnant Worker
- 62. Monitoring the Workplace
- 63. Investigation Levels
- 66. Health Surveillance
- 67. Records

Part V: Medical Exposure

- 68. Responsibility
- 72. Justification
- 77. Optimisation for Medical Exposures in Radiology
- 78. General Considerations
- 79. Radiography
- 80. Fluoroscopy
- 81. Interventional Radiology
- 82. Computed Tomography
- 83. Mammography
- 84. Paediatric Radiology
- 85. Dental Radiology
- 86. Calibration of Equipment used in Patient Dosimetry and Quality Control
- 87. Clinical Patient Dosimetry
- 88. Quality Assurance for Medical Exposures in Radiology
- 89. Use of Guidance levels
- 90. Dose Constraints
- 91. Investigation of Accidental Medical Exposure in Radiology
- 92. Records

Part VI: Public Exposure

- 93. Responsibilities
- 95. Control Access of Visitors
- 96. Monitoring of Public Exposure

Part VII: Potential Exposure and Emergency

- 97. Safety Assessment
- 98. Prevention of Accidental Exposure and Mitigation of their Consequences
- 99. Emergency Plans

Part VIII Offences, Penalties and Appeals

- 105. Appeal
- 106. Citation

REGULATIONS FOR RADIATION SAFETY IN DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY

PART I: GENERAL

Interpretation

1. In these regulations, unless the context otherwise requires

“**absorbed dose**” means the fundamental dosimetric quantity D , defined as:

$$D = \frac{d\varepsilon}{dm}$$

Where $d\varepsilon$ is the mean energy imparted by ionizing radiation to matter in a volume element and dm is the mass of matter in the volume element. The energy can be averaged over any defined volume, the average dose being equal to the total energy imparted in the volume divided by the mass in the volume. The SI unit of absorbed dose is the joule per kilogram ($\text{J}\cdot\text{kg}^{-1}$), termed the gray (Gy).

“**air kerma area product**” means the integral of the air kerma over the area of the x-ray beam in a plane perpendicular to the beam axis thus

$$P_{KA} = \int_A K(x, y) dx dy$$

Unit: $\text{J}\cdot\text{kg}^{-1}\cdot\text{m}^2$. The special unit of air kerma-area product is $\text{Gy}\cdot\text{m}^2$.

“**air kerma entrance dose**” means the entrance surface air kerma, K_e , is the kerma to air measured on the central beam axis on the patient or phantom entrance surface. Therefore, both the radiation incident on the patient or phantom and the backscattered radiation are included.

“**air kerma length product**” means the air kerma-length product, P_{KL} , is the integral of the air kerma over a line, L , parallel to the axis of rotation of a computed tomography scanner, thus

$$P_{KL} = \int_L K(z) dz$$

Unit: $\text{J}\cdot\text{kg}^{-1}\cdot\text{m}$. The special unit of air kerma-length product is $\text{Gy}\cdot\text{m}$.

“**ambient dose equivalent**” means the quantity $H^*(d)$ at a point in a radiation field, defined as the dose equivalent that would be produced by the corresponding aligned and expanded field in the International Commission for Radiation Units sphere at a depth d on the radius opposing the direction

of the aligned field. A depth $d = 10$ mm is recommended for strongly penetrating radiation.

“**approved**” means approved by Authority.

“**authority**” means the Radiation Protection Authority of Zimbabwe

“**authorization**” means the granting by Authority of written permission to perform specified activities.

“**authorized**” means granted an authorization by Authority

“**Chronic Exposure**” means exposure persisting in time.

“**Computed Tomography Kerma Index**” means the Computed Tomography Kerma Index, C_{100} , for a single axial scan is the quotient of the integral of the air kerma along a line parallel to the axis of rotation of a CT scanner over a length of 100 mm and the product of the number of acquired tomographic sections N and the nominal section thickness T . The integration range is positioned symmetrically about the volume scanned, thus

$$C_{100} = \frac{1}{NT} \int_{-50}^{+50} K(z) dz$$

Unit: Jkg^{-1} . The special unit for Computed Tomography Kerma Index is gray (Gy).

“**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,

(a) For occupational exposures, dose constraint is a source related value of individual dose used to limit the range of options considered in the process of optimization.

(b) For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source. The exposure to which the dose constraint applies is the annual dose to any critical group, summed over all exposure pathways, arising from the predicted operation of the controlled source. The dose constraint for each source is intended to ensure that the sum of doses to the critical group from all controlled sources remains within the dose limit.

(c) For medical exposure the dose constraint levels should be interpreted as guidance levels, except when used in optimizing the protection of persons exposed for medical research purposes or of persons, other than workers, who assist in the care, support or comfort of exposed patients.

“**effective dose**” means the quantity E , defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_T w_T H_T$$

where H_T is the equivalent dose in tissue T and w_T is the tissue weighting factor for tissue T . From the definition of equivalent dose, it follows that:

$$E = \sum_T w_T \sum_R w_R D_{T,R}$$

where w_R is the radiation weighting factor for radiation R and $D_{T,R}$ the average absorbed dose in the organ or tissue T. The unit of effective dose is $J.kg^{-1}$, special name sievert (Sv).

“employer” means a legal person with recognized responsibility, commitment and duties towards a worker in his or her employment by virtue of a mutually agreed relationship. (A self-employed person is regarded as being both an employer and a worker.)

“excluded” means outside the scope of the Radiation Protection Safety and Security Regulations

“health professional” means an individual who has been accredited through appropriate national procedures to practice a profession related to health (e.g., medicine, dentistry, chiropractic, paediatrics, nursing, medical physics, radiation and nuclear medical technology, radiopharmacy, occupational health).

“health surveillance” means medical supervision intended to ensure the initial and continuous fitness of workers for their intended task.

“kerma” means the quantity K defined as:

$$K = \frac{dE_{tr}}{dm}$$

where dE_{tr} is the sum of the initial kinetic energies of all charged ionizing particles liberated by uncharged ionizing particles in a material of mass dm . The SI unit of kerma is the joule per kilogram ($J.kg^{-1}$), termed gray (Gy).

“legal person” means any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action having implications on protection and safety.

“licence” means a legal document issued by the Authority granting authorization to perform specified activities related to a facility or activity

“licensee” means the holder of a current licence.

“**medical exposure**” means exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.

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

“member of the public” means in a general sense, any individual in the population except, for the purposes of the Radiation Protection Safety and Security Regulations

, when subject to occupational or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, the representative individual in the relevant critical group.

“**normal exposure**” means an exposure which is expected to occur under normal operating conditions of a facility or activity, including possible minor mishaps that can be kept under control, i.e. during normal operation and anticipated operation occurrences.

“**notification**” means a document submitted to Authority by a legal person to notify an intention to carry out a practice or other use of a source.

“**occupational exposure**” means all exposures of workers incurred in the course of their work with the exception of exposures excluded from the Radiation Protection Safety and Security Regulations and exposures from practices or sources exempted by the Radiation Protection Safety and Security Regulations.

“**personal dose equivalent**”, $H_p(d)$ means the dose equivalent in soft tissue below a specified point on the body at the appropriate depth. (The relevant depths for the purposes of the Radiation Protection Safety and Security Regulations are generally $d = 10$ mm for strongly penetrating radiation and $d = 0.07$ mm for weakly penetrating radiation).

“**potential exposure**” means exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

“**practice**” means any human activity that introduces additional sources of exposure or 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.

“protection and safety” means the protection of people against exposure to ionizing radiation or radioactive materials and the safety of radiation sources, including the means for achieving this, and the means for preventing accidents and for mitigating the consequences of accidents should they occur.

“protective action” means an intervention intended to avoid or reduce doses to members of the public in chronic or emergency exposure situations.

“public exposure” means exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure and the normal local natural background radiation but including exposure from authorized sources and practices and from intervention situations.

“qualified expert in diagnostic radiology physics” means an individual who, by virtue of certification by appropriate boards or societies, professional licenses or academic qualifications and experience, is duly recognized as having expertise in radiology physics. The Authority requires that for diagnostic uses of radiation (in this case radiology) the imaging and quality assurance requirements of the Radiation Protection Safety and Security Regulations be fulfilled with the advice of a qualified expert in radiology physics. In high-complexity services, the qualified expert is indispensable; in services of low and medium complexity, at the least, a medical physicist should be available to provide periodic advisory services.

“radiation safety officer” means an individual technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant or licensee to oversee the application of the requirements of the Radiation Protection Safety and Security Regulations.

“registrant” means an applicant who is granted registration of a practice or source and has recognized rights and duties for such a practice or source, particularly in relation to protection and safety.

“registration” means a form of authorization for practices of low or moderate risks whereby the legal person responsible for the practice has, as appropriate, prepared and submitted a safety assessment of the facilities and equipment to the regulatory body. The practice or use is authorized with conditions or limitations as appropriate. The requirements for safety assessment and the conditions or limitations applied to the practice should be less severe than those for licensing.

“risk” means a multi attribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with actual or potential exposures. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences.

“safety assessment” means a review of the aspects of design and operation of a source which are relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection

established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations.

“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.

“source” means anything that may cause radiation exposure, such as by emitting ionizing radiation or releasing radioactive substances or materials. For example, materials emitting radon are sources in the environment, a sterilization gamma irradiation unit is a source for the practice of radiation preservation of food, an X-ray unit may be a source for the practice of radio-diagnosis, and a nuclear power plant is a source for the practice of generating electricity by nuclear power. A complex or multiple installations situated at one location or site may as appropriate be considered a single source for the purposes of application of the Radiation Protection Safety and Security Regulations.

“standards dosimetry laboratory” means a laboratory designated by the relevant national authority for the purpose of developing, maintaining or improving primary or secondary standards for radiation dosimetry.

“supplier” means any legal person to whom a registrant or Licensee delegates duties, totally or partially, in relation to the design, manufacture, production or construction of a source. (An importer of a source is considered a supplier of the source.)

“weighted computed tomography air kerma index” means the Computed Tomography Kerma Index is measured both free-in-air along the axis of rotation of the scanner and in acrylic (or polymethyl methacrylate) phantoms. The notations, $C_{100,a}$ and $C_{100,PMMA}$ are used.

The weighted Computed Tomography Kerma Index, C_w , is defined as

$$C_w = \frac{1}{3} (C_{100,PMMA,c} + 2C_{100,PMMA,p})$$

The quantity $C_{100,PMMA,c}$ is the value of the CTKI measured at the centre of a CT phantom (160 or 320 mm diameter by 100 mm thick) and $C_{100,PMMA,p}$ is the average of values of the Computed Tomography Kerma Index measured at four positions around the periphery of the same phantom

“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. (a self-employed person is regarded as having the duties of both an employer and a worker).

Objective

2. To protect patients, workers and the general public from the risks associated with exposure to ionizing radiation in the course of Radiotherapy practice in Zimbabwe and to assist licensees in meeting radiation safety requirements in radiotherapy practice for the attainment of adequate radiation protection and safety of patients, workers and the public.

Scope

3. These regulations are applicable to all established uses of ionizing radiation sources employed in the practice of interventional and diagnostic radiology, to the facilities where the sources are located and to the individuals involved. The regulations cover occupational, public, medical, potential and emergency exposure situations.

PART II: PRINCIPAL REQUIREMENTS

Administrative Requirements

Authorization of Practices

4. (1) Any legal person who intends to utilize radiation sources in radiology shall notify his intention to the Authority and shall apply for authorization in the form of a licence.

(2) The person applying for an authorization shall refrain from carrying out any of the actions of the practice until licence has been granted to him.

(3) The person shall include in the application for authorization:

- a) the qualifications in radiation protection of the medical and dental practitioners who are to be so designated by name in the licence; or
- b) a statement that only medical practitioners with the qualifications in radiation protection specified in these regulations or to be specified in the licence will be permitted to prescribe medical exposure by means of the authorized radiation source.

5. The licensee shall comply with radiation safety requirements for the following stages of the radiology practice:

- a) design and construction;
- b) operation (acceptance, commissioning, clinical use, maintenance);
- c) modifications; and
- d) decommissioning (partial or total) and return or disposal of radiation emitting equipment.

6. Modification with possible implications for radiation safety, of the radiology and of procedures, or cessation of the practice, shall require an amendment to the licence.

7. Application for authorization shall be made on the form issued by the Authority.

Renewal of authorization

8. The authorization shall be renewed annually for diagnostics and bi-

annually for dental.

Non-compliance and suspension or withdrawal of authorization

9. In the event of a breach of any licence condition as per section 4,5 and 6, the licensee shall, as appropriate:

- a) investigate the breach and its causes, circumstances and consequences;
- b) take appropriate action to remedy the circumstances that led to the breach and to prevent a recurrence of similar breaches;
- c) communicate to the Authority, and to any other relevant organizations when applicable, on the cause of the breach and on the corrective or preventive actions taken or to be taken; and
- d) take whatever other actions are necessary as required by the Authority.

10. Failure to take corrective or preventive actions within a specified time shall be a ground for modifying, suspending or withdrawing any authorization that had been granted by the Authority.

11. The Authority will suspend or revoke an authorization when a licensee is in serious breach of the conditions of the licence, the Radiation Protection Safety and Security Regulations or specific requirements of these regulations. In order to be able to resume operation, the licensee shall reapply for authorization in the case of revocation, or apply for reconsideration in case of suspension.

Personnel Accreditation

12. All personnel on whom protection and safety depend shall be appropriately trained and qualified to be able to understand their responsibilities and perform their duties with appropriate judgement according to laid down procedures.

13. Individuals with key positions, i.e. responsibilities for protection and safety and those who could substantially affect protection and safety by virtue of tasks involving manipulation of sources or operation of equipment shall have certificate(s) of education and training in radiology. These individuals are:

- a) medical practitioners working in radiology (radiologists, interventional specialists, cardiologists, dentists, chiropractors);
- b) qualified experts in radiology physics (medical physicists);
- c) radiographers and x-ray operators ;
- d) radiation safety officer; and
- e) staff performing special tasks (e.g. type testing of equipment,

quality control tests).

14. To obtain personal accreditation, the staff listed in these regulations shall meet the following requirements as applicable:

- a) university degree or academic qualification from accredited institutions.
- b) accreditation to exercise the profession granted by the relevant competent authorities or other professional or academic bodies recognized by the Authority;
- c) attendance and passing of required examinations on a course on radiation protection for which the contents, the methodology and the teaching institution are accredited by the Authority or by other professional bodies recognized by the Authority. This course may be integrated in the curricula of the professional education under (a) and (b), and;
- d) on-the-job training supervised by professionals with accreditation by the Authority or other appropriate authorities.

15. Equipment servicing personnel shall have documentary evidence for the individual to perform maintenance of radiology equipment. This documentary evidence should consist of the following:

- a) certification, ideally by the manufacturer, of having completed a training programme on the type of authorized equipment;
- b) course on radiation protection for which the contents, the methodology and the teaching institution are approved by the Authority.

Authorization of other practices related to radiology

16. Since the activities listed below also require authorization:

- a) import, distribution, sale, decommissioning or transfer of X-ray systems;
- b) personal monitoring;
- c) installation and maintenance of radiology equipment.
- d) All service providers to be accredited.

A licensee of radiology practice shall contract any of these services only to enterprises authorized by the Authority.

Inspection

17. A licensee shall permit the Authority to inspect his facilities and records as required by Section 18 of the Act.

Radiation protection requirements

18. The radiation protection requirements on justification of the practice, dose limitation and optimization of protection and dose constraints as provided in the Act and Radiation Protection Safety and Security Regulations shall be applied to radiology. The dose limits for occupational and public exposure are reproduced in Schedule I.

Managerial Requirements

Managerial commitment and policy statement

19 (1) A safety culture shall be fostered and maintained to encourage a questioning and learning attitude to protection and safety and to discourage complacency. To comply with this requirement, the employer shall be committed to an effective protection and safety policy, particularly at management level and by clear demonstrable support for those persons with direct responsibility for radiation protection.

(2) This commitment shall be expressed in a written policy statement that clearly assigns prime importance to protection and safety in the radiology services, while recognizing that the prime objective is the medical care of the patients. Appropriate resources shall be made available to support this commitment. This action should be followed by establishing a radiation safety and quality assurance programmes and fostering a safety culture within the organization.

Organization and Responsibilities

20 (1) The principal parties having the main responsibilities for the application of the Radiation Protection Safety and Security Regulations and these regulations shall be licensees and employers.

(2) Other parties shall have subsidiary responsibilities. These parties include, as appropriate, suppliers, workers, radiation protection officers, medical practitioners, other (non-medical) health professionals, qualified experts, ethical review committees and any other party to whom a principal party has delegated specific responsibilities.

21 (1) A licensee shall establish a Radiation Safety Programme and shall provide the necessary resources to comply with the programme. This programme shall relate to all phases of the practice, from design through operation to decommissioning.

(2) The radiation safety and quality assurance programmes shall reflect the management responsibility for radiation protection and safety through the adoption of management structures, policies, procedures and organizational arrangement that are commensurate with the nature and extent of the risks.

22 (1) A licensee shall assign clear responsibilities to a personnel (e.g. medical practitioner, radiology physicist, radiographers, radiation safety

officer and other health professionals) to ensure adequate radiation protection of patients, workers, and the public.

(2) The need for qualified experts shall be determined by their responsibilities and suitable persons appointed on a full-time or part-time basis as required.

23. (1) A licensee shall appoint a Radiation Safety Officer

(2) The Radiation Safety Officer shall have sufficient authority and management standing to communicate with and direct personnel regarding regulations and licence provisions.

24. The licensee shall ensure that, for diagnostic uses, the imaging and Quality Assurance (including quality control) and optimization of protection, which shall involve patient dosimetry, be carried out with the advice of a medical physics qualified expert, as appropriate.

25. (1) A radiation Safety Committee shall be formed according to the size of institution and complexity of procedures.

(2) (a) The Radiation Safety Committee shall review and audit the entire Radiation Safety Programme systematically to determine whether the activities are conducted in a safe manner and in accordance with the regulations and terms of the authorization.

(b) The committee shall meet at least once a year.

Quality Assurance

26. (1) A licensee shall establish a comprehensive Quality Assurance Programme for radiation protection, safety and image quality to ensure that all necessary procedures are developed and implemented to comply with the regulations for radiation protection within the terms and conditions of the authorization(s) of the facility.

(2) The programme shall cover the entire process from the initial decision to adopt a particular procedure through the interpretation and recording of results and shall include ongoing auditing, both internal and external, as a systematic control methodology.

27. Quality assurance shall cover, as a minimum:

- a) selection of the correct procedure for the patient;
- b) appointment and patient information;
- c) clinical dosimetry;
- d) optimization of examination protocol;
- e) record keeping and report writing;
- f) acceptance and commissioning;
- g) Quality Control of equipment and software;
- h) waste management procedures;
- i) training and continuing education of staff;

- j) clinical audit; and
- k) general outcome of radiology service.

Human factors

28. A licensee shall make provision for reducing as far as practicable the contribution of human error to accidents and other events that could give rise to exposures.

Staffing

29 (1) A licensee shall appoint a number of professionals, each possessing a recognized form of accreditation, sufficient to ensure that all activities relevant to Quality Assurance, radiation protection and safety are undertaken in accordance with these regulations and the Radiation Protection Safety and Security Regulations.

(2) Human resource requirements shall be reviewed as workload increases or as new techniques and new equipment are incorporated into the facility.

Education and training

30. All staff working with X-ray systems in radiology practice, as specified in these regulations shall have appropriate academic qualifications and relevant practical training, as may be required by the relevant professional regulatory bodies.

31. A licensee shall ensure that his staff are aware of:

- a) the conditions of the licence;
- b) use and operation of the equipment;
- c) instructions that should be provided to patients and patient helpers;
- d) institutional radiation protection policies and procedures (including emergency practice drills);
- e) the local Quality Assurance programme and Quality Control procedures;
- f) results of review and analysis of incidents and accidents that have occurred in the institution or elsewhere.

32. (1) This training shall be completed before commencement of duties.

(2) The training of personnel shall be required whenever significant changes occur in duties, regulations, and the terms of the licence or radiation safety procedures.

(3) The training shall be updated as required.

33. A licensee shall establish a policy that encourages and provides continuing education and a programme of professional development.

34. A licensee shall prepare and keep records of the initial and periodic

instruction of personnel. These records should be kept for at least five years after the expiration of the corresponding authorization.

PART III: SAFETY OF SOURCES, EQUIPMENT AND FACILITIES

Defence-In-Depth

35. A multilayer (defence in depth) system of provisions for protection and safety commensurate with the magnitude and likelihood of the potential exposures involved shall be applied to sources such that a failure at one layer is compensated for or corrected by subsequent layers, for the purposes of:

- a) preventing accidents that may cause exposure;
- b) mitigating the consequences of any such accident that does occur; and
- c) restoring sources to safe conditions after any such accident.

Design

36. Radiology equipment used in medical exposure shall be so designed that:

- a) failure of a single component of the system be promptly detectable so that any unplanned exposure of patients or staff be minimized; and
- b) the incidence of human error in the delivery of unplanned medical exposure be minimized.

37. A licensee shall:

- a) take into account information provided by suppliers, identify possible equipment failures and human errors that could result in unplanned medical exposures;
- b) take all reasonable measures to prevent failures and errors, including the selection of suitably qualified personnel, the establishment of adequate procedures for the calibration, Quality Assurance and operation of equipment, and the provision of appropriate training and periodic retraining to personnel in the procedures, including protection and safety aspects;
- c) take all reasonable measures to minimize the consequences of failures and errors that may occur; and
- d) develop appropriate emergency plans for responding to events that may occur, display plans prominently, and periodically conduct practice drills.

X-ray systems (tube, generator and ancillary equipment)

38. A licensee shall only use x-ray equipment in which:

- a) radiation generators and their accessories are designed and manufactured so as to facilitate the keeping of medical exposures as low as reasonably achievable in consistence with obtaining adequate diagnostic information;
- b) operational parameters for radiation generators, such as generating tube potential, filtration, focal spot position, source-image receptor distance, field size indication and either tube current and time or their product, are clearly and accurately indicated;
- c) radiographic equipment are provided with devices that automatically terminate the irradiation after a preset time, tube current-time product or dose (automatic exposure control); and
- d) fluoroscopic equipment are provided with a device that energises the X-ray tube only when continuously depressed (such as a 'dead man's switch') and equipped with indicators of the elapsed time .

39. (1) X-ray systems and accessories shall only be purchased from authorised suppliers and be certified in conformity with the standard of International Electrotechnical Commission or its Zimbabwean equivalent; Standard Association of Zimbabwe.

(2) Compliance with International Electrotechnical Commission or its Zimbabwean equivalent Standard Association of Zimbabwe shall be demonstrated and supported by written evidence.

(3) Compliance shall be confirmed for the particular piece of equipment delivered, by including the relevant tests of the International Electrotechnical Commission standards in the acceptance protocol.

(4) The set of tests to be included in the protocol shall be specified in the purchasing conditions

40. A licensee shall ensure that operator's manual(s) are made available in English Language which is widely understood by users.

41. (1) X-ray systems shall be purpose built for the intended imaging tasks. The X-ray systems shall indicate at the control panel all the important technical parameters relevant to image quality and patient dose. The tube voltage (kV), tube current (mA) and exposure time (or mAs) are the minimum parameters to be displayed during radiographic exposure.

(2) Additional information about the selection of an automatic exposure device as well as the sensor area selected to terminate the exposure, radiation field size and focus skin distance, shall be available to the operator at the console.

(3) The X-ray systems shall always have a collimator to restrict the radiation field size to the area of interest and this shall be in the form of adjustable diaphragms or for specific examinations such as mammography and dental radiography in the form of fixed collimator.

(4) For radiographic equipment (except for dental) there shall be a light

beam to indicate the position and extent of the radiation beam, visible during normal lighting conditions.

(5) All fluoroscopy units shall use an image intensifier (or its equivalent in technology).

(6) (a) Instantaneous values of tube voltage (kV), tube current (mA) and accumulated fluoroscopy time shall be available at the control console.

(b) The degree of magnification (active area of the image intensifier) and the different fluoroscopy modes (low, normal and high) if they exist shall be clearly visible to the operator.

(7) Manual collimation shall be possible in addition to automatic collimation adjusted to (but never greater than) the effective size of the image intensifier.

42 (1) If the fluoroscopy unit is capable of high dose-rate operation, a separate visual or audible warning shall be made available to the operator.

(2) Fluoroscopy systems shall incorporate a “last image hold” mode, where the last acquired image is displayed as long as required.

(3) Fluoroscopy units used in interventional radiology (where the accumulated patient dose may be high) shall incorporate a continuous indication of patient dose such as a dose-area product meter.

43. The licensee should ensure that Quality Control phantoms are available with Computed Tomography and Mammography equipment in the facility where they are installed.

44. Written procedures shall be developed as part of the quality assurance programme for purchasing, installation, acceptance, commissioning, use, maintenance and quality control.

Facilities (X-ray room design)

45. The design of the facility (X-ray room) shall include adequate provisions for radiation safety to reduce the probability of occurrence of accidental exposures.

46. (1) The facility shall be designed in such a way that provisions for safety systems or devices are inherent to the equipment or the room.

(2) The design of the facility shall take into consideration the classification of the areas within it, the type of work to be done and the X-ray systems intended to be used, and as far as possible, all X-ray procedures shall be performed in an appropriate room designed for that purpose

47. (1) Shielding shall be calculated according to principles of optimization of protection. Dose constraints shall be developed and used whilst considering that sometimes other X-ray systems will be mounted in the same room and that the working load could be higher in the future.

(2) (a) The structure of the room shall provide adequate shielding for members of the staff involved in the x-ray procedure and persons in adjacent areas (staff, members of the public, patients or visitors).

(b) If the existing structures do not provide sufficient shielding, then additional shielding shall be installed to create an intrinsically safe working environment.

(3) A protective barrier shall be placed at the control console to shield staff.

48. (1) The design of the room shall be such that the x-ray beam cannot be directed at any area which is not shielded for that purpose. (2) The X-ray room shall be designed so as to avoid the direct incidence of the X-ray beam on the access doors.

(3) The doors shall act as a protective shield for scattered radiation and be shut when the X-ray beam is on.

49. There shall be a means installed to allow the operator to clearly observe the patient at all times during an x-ray procedure. This can be a shielded viewing window, a TV system, or an appropriately placed mirror.

50. (1) A radiation (ISO 361) sign and also a danger warning sign shall be posted on each entrance to an x-ray room both in English and local languages to indicate that the room is a controlled area.

(2) In addition, a warning light shall be placed at the entrance to any room where fluoroscopy or Computed Tomography equipment is in use.

(3) The light shall be illuminated when the x-ray beam is energized.

51. The overall design of the facility including these calculations shall be performed by a qualified expert in radiation protection

Maintenance

52. (1) The licensee shall ensure that adequate maintenance (preventive and corrective) and inspections are performed as necessary to ensure that X-ray systems retain their design specification for image quality, radiation protection and safety for their useful lives.

(2) The licensee shall therefore establish the necessary arrangements and co-ordination with the manufacturer's representative or installer before purchase and initial operation.

(3) All maintenance procedures shall be included in the Quality Assurance Programme at a frequency recommended by the manufacturer of the equipment and the relevant professional body and servicing shall include a report describing the findings, which shall be archived as part of the Quality Assurance Programme.

(4) A qualified expert in radiological physics shall ensure that the equipment is in safe condition for clinical use after maintenance.

Electrical and mechanical safety

53. (1) The electrical and mechanical safety aspects of the X-ray systems are an important part of the maintenance programme, and can have direct or indirect effects on radiation safety.

(2) This work shall be performed by authorized persons who are aware of the specification of the X-ray systems.

(3) Electrical and mechanical maintenance shall be included in the quality assurance programme at a frequency recommended by the manufacturer of the X-ray system and servicing shall include a written report describing the findings. These reports shall be archived as part of the Quality Assurance Programme.

Acceptance

54. (1) After the equipment has been installed, acceptance testing shall be conducted in order to verify that the equipment conforms with technical specifications given by the manufacturer and to verify compliance with the standard safety requirements of International Electrotechnical Commission or its Zimbabwean equivalent; Standard Association of Zimbabwe.

(2) The tests to be included in the acceptance protocol shall be specified in the purchasing conditions and contracts shall clearly establish responsibility of suppliers for resolving non-conformity identified during acceptance testing

Commissioning

55. After acceptance and before starting operation, commissioning shall be performed. During commissioning, the qualified expert in radiological physics shall measure all data required for clinical use.

PART IV: OCCUPATIONAL EXPOSURE

Classification Of Areas

56. (1). In a radiology facility, all X-ray rooms and areas in the facility where mobile X-ray units are used shall be controlled areas. All other areas outside x-ray rooms shall be designated as supervised areas.

(2) Each room of the facility shall be used for its specified work.

Local rules and supervision

57 (1) Employers and licensees shall, in consultation with workers, through their representatives, if appropriate:

- a) establish written local rules and procedures necessary to ensure adequate levels of protection and safety for workers and other persons;
- b) include in the local rules and procedures the values of any relevant investigation level or authorized level, and the procedure to be followed in the event that any such value is exceeded;

- c) make the local rules and procedures, the protective measures and safety provisions known to those workers to whom they apply and to other persons who may be affected by them; and
- d) ensure that any work involving occupational exposure are adequately supervised and take all reasonable steps to ensure that the rules, procedures, protective measures and safety provisions be observed.

(2) These local rules shall include: procedures for wearing, handling, and storing personal dosimeters; actions to minimize radiation exposure during unusual events.

Protective Equipment and Tools

58. (1) A licensee shall ensure that workers are provided with suitable and adequate personal protective equipment, which meets any relevant regulations or standards; protective equipment includes but not limited to lead rubber aprons, thyroid protectors, protective eye-wear , gloves, etc

(2) The need for these protective devices shall be established by the Radiation Safety Officer.

59. Additional protective devices to be made available in fluoroscopy and interventional radiology rooms include but not limited to:

- a) Ceiling suspended protective screens.
- b) Protective lead rubber curtains and rubber curtains mounted on the patient table.
- c) Protective lead rubber curtains for the operator if the X-ray tube is placed in an over couch geometry and if the radiologist must stand near the patient.

Individual monitoring and exposure assessment

60. (1) Individual dose monitoring shall be undertaken for workers who are normally exposed to radiation in controlled areas.

(2) (a) Individual dose monitoring shall be undertaken for workers who are normally exposed to radiation in controlled areas, as indicated in these regulations. These workers include radiologists, medical physicists, the Radiation Safety Officer, radiographers ,nurses and x-ray operators

(b) Other frequent users of x-ray systems such as endoscopists, anaesthetists, cardiologists, surgeons etc., as well as ancillary workers who frequently work in controlled areas, may also be monitored.

(3) Individual external doses may be determined by using individual monitoring devices approved by the Authority, such as thermoluminescent dosimeters and film badges. Each monitor shall be used only by the person to whom it is issued.

(4) (a) The monitoring device shall be worn on the front of the upper torso of the body, between the shoulders and the waist.

- (b) The monitoring period shall be for one month, and shall not exceed three months.
- (c) The exchange of dosimeters and receipt of the dose reports shall be within an interval of 1 month.
- (5) If an individual's dosimeter is lost, the Radiation Safety Officer shall perform a dose assessment and record this evaluation of the dose and add it to the worker's dose record.
- (6) Individual monitoring devices shall be calibrated and this calibration shall be traceable to a standards dosimetry laboratory.

Pregnant Worker

- 61.** (1) A female worker shall, on becoming aware that she is pregnant, notify the employer and licensee in order that her working conditions may be modified if necessary.
- (2) The notification of pregnancy shall not be considered a reason to exclude a female worker from work; however, the employer of a female worker who has notified pregnancy shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus is afforded the same broad level of protection as required for members of the public
- (3) Counselling shall be provided for pregnant woman.

Monitoring the Workplace

- 62.** (1) A licensee shall develop programmes for monitoring of the workplace.
- (2) All survey meters used for workplace monitoring shall be calibrated and this calibration shall be traceable to a standards dosimetry laboratory.
- (3) Initial monitoring shall be conducted immediately after new radiology equipment has been installed and shall include measurements of radiation leakage from equipment, and area monitoring of useable space around radiology rooms.
- (4) Annual area surveys shall be performed
- (5) All radiation monitors shall be calibrated, and their warning devices and operability shall be checked prior to each day of use.

Investigation Levels

- 63.** Employers and licensees shall, in consultation with workers or through their representatives, include in the local rules and procedures the values of any relevant investigation level or authorized level, and the procedure to be followed in the event of any such value being exceeded.
- 64.** A licensee shall conduct formal investigations, as required by the Authority whenever:

- a) an individual effective dose exceeds set investigation levels;
- b) any of the operational parameters related to protection or safety are out of the normal range established for operational conditions;
- c) any equipment failure, severe accident or error takes place, which causes, or has the potential to cause, a dose in excess of annual dose limits; and
- d) any other event or unusual circumstance that causes, or has the potential to cause a dose in excess of the annual dose limits or the operational restrictions imposed on the installation (e.g., the significant change in workload or operating conditions of radiology equipment).

65. (1) The investigation shall be initiated immediately following discovery of the event, and a written report shall be prepared concerning its cause, including determination or verification of any doses received, corrective actions, and instructions or recommendations to avoid recurrence.

(2) The report shall be submitted to the Authority and other concerned bodies as required, within ten working days

Health Surveillance

66. (1) A licensee shall make arrangements to provide health surveillance to workers as specified by the Radiation Protection Safety and Security Regulations.

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

(3) Counselling shall be provided for workers requiring counselling.

Records

67. (1) A licensee shall maintain exposure and medical surveillance records for each worker and the records shall be kept according to the requirements of the Authority.

(2) Employers and licensees shall provide access for workers to information on their own exposure records; and give due care and attention to the maintenance of appropriate confidentiality of records.

PART V: MEDICAL EXPOSURE

Responsibilities

68. With regard to responsibilities for medical exposure, a licensee shall ensure that:

- a) no patient be administered a diagnostic medical exposure unless

the exposure is prescribed by a medical practitioner;

- b) medical practitioners be assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;
- c) medical and paramedical personnel are available as needed, and either be health professionals or have appropriate training adequately to discharge assigned tasks in the conduct of the diagnostic procedure that the medical practitioner prescribes;
- d) the exposure of individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment is constrained (in accordance with the ALARA principle) .

69. A licensee shall ensure that for diagnostic uses of radiation, the imaging and quality assurance requirements are fulfilled with the advice of a qualified expert in radiology physics (medical physicist).

70. Medical practitioners shall promptly inform the licensee of any deficiencies or needs regarding compliance with the Radiation Protection Safety and Security Regulations and these regulations with respect to protection and safety of patients and shall take such actions as may be appropriate to ensure the protection and safety of patients.

71. A licensee shall ensure that workers (including medical practitioner, medical physicist, radiographers):

- a) follow any applicable rules and procedures for the protection and safety of patients, as established by the licensee;
- b) are competent in the operation and use of the equipment used in radiology, of the equipment for radiation detection and measurement, and of the safety systems and devices, commensurate with the significance of the workers' functions and responsibilities; and
- c) know their expected response in the case of patient emergencies

Justification

72. (1) Medical exposures shall be justified by weighing the diagnostic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

(2) The medical practitioner shall consider the efficacy, benefits and risks of alternative diagnostic modalities, e.g. Ultrasound or Magnetic Resonance Imaging.

(3) In justifying each type of diagnostic examination by radiography or fluoroscopy, relevant guidelines will be taken into account, such as those established by the World Health Organization.

(4) Any radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is

deemed to be not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.

73. (1) Mass screening of population groups involving medical exposure is deemed to be unjustified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.

(2) Accounts shall be taken in justification of the potential of the screening procedure for detecting disease, the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease.

74. The exposure of humans for medical research is deemed to be unjustified unless it is:

- a) in accordance with the provisions of the Helsinki Declaration and follows the guidelines for its application prepared by Council for International Organizations of Medical Sciences and World Health Organization.
- b) subject to the advice of an ethical review committee (or any other institutional body assigned with similar functions by the Ministry of Health and Child Welfare) and to applicable Radiation Protection Safety and Security Regulations and these regulations.

75. As children are at greater risk of incurring stochastic effects, paediatric examinations shall require special consideration in the justification process and the benefit of some high dose examinations (e.g. Computed Tomography, Intravenervous Urography, etc.) shall be carefully weighed against the increased risk.

76. (1). The justification of examinations in pregnant women shall require special consideration and due to the higher radio-sensitivity of the foetus, the risk may be substantial, so the licensee shall ascertain whether the female patient is pregnant before performing X-ray examination for diagnosis.

(2) In particular, in a case where the foetus is in or near the primary beam (e.g. abdominal examinations and certain complex interventional procedures), the advice of a medical physics expert shall be required and a foetal dose and nominal foetal and patient risks estimation performed before deciding whether the examination is justified.

Optimisation for Medical Exposures in Radiology

77. A licensee shall ensure for radiology that:

(1) a medical practitioner who prescribes or conducts radiological diagnostic examinations shall:

- a) ensure that the appropriate equipment be used;

- b) ensure that the exposure of patients be the minimum necessary to achieve the required diagnostic objective, taking into account norms of acceptable image quality established by appropriate professional bodies and relevant guidance levels for medical exposure; and
- c) take into account relevant information from previous examinations in order to avoid unnecessary additional examinations;

(2) a medical practitioner, technologist or other imaging staff select the following parameters, as relevant, such that their combination produce the minimum patient exposure consistent with acceptable image quality and the clinical purpose of the examination, paying particular attention to this selection for paediatric radiology and interventional radiology:

- a) the area to be examined, the number and size of views per examination (e.g. number of films or computed tomography slices) or the time per examination (e.g. fluoroscopic time);
- b) the type of image receptor (e.g. high versus low speed screens);
- c) the use of antiscatter grids;
- d) proper collimation of the primary X-ray beam to minimise the volume of patient tissue being irradiated and to improve image quality;
- e) appropriate values of operational parameters (e.g. tube generating potential, current and time or their product);
- f) appropriate image storage techniques in dynamic imaging (e.g. number of images per second); and
- g) adequate image processing factors (e.g. developer temperature and image reconstruction algorithms);

(3) portable and mobile radiological equipment are used only for examinations where it is impractical or not medically acceptable to transfer patients to a stationary radiological installation and only after proper attention has been given to the radiation protection measures required in its use;

(4) radiological examinations causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant be avoided unless there are strong clinical reasons for such examinations;

(5) any diagnostic examination of the abdomen or pelvis of women of reproductive capacity are planned to deliver the minimum dose to any embryo or foetus that might be present; and

(6) whenever feasible, shielding of radiosensitive organs such as the gonads, lens of the eye, breast and thyroid are provided as appropriate.

Optimisation in Specific Radiology Procedures

General Considerations

- 78.** (1) Each type of x-ray equipment shall be operated only by appropriately trained staff, and images interpreted only by medical practitioners trained in those techniques.
- (2) The doors to the room shall be closed during X-ray procedures.
- (3) All individuals in the room not standing behind the control console shall wear a lead protective apron or rubber protective aprons.
- (4) Where the scatter doses are expected to be high, such as in interventional radiology procedures, specific protection for the eyes and thyroid shall be provided.
- (5) With the possible exception of intra-oral films, the x-ray beam size shall not be larger than the size of the image receptor
- (6) A minimum distance from the focus to the skin of the patient shall be required.
- (7) Image receptor combinations used shall be as sensitive as possible, without compromising image quality.
- (8) The total filtration shall be sufficient to ensure that the half value layer of the primary beam for a given x-ray tube and collimator is not less than the recommended values of International Electrotechnical Commission standards
- (9) Film shall be processed according to the manufacturer's instructions. Optimised film processing will reduce patient doses and improve image quality.

Radiography

- 79.** (1) Appropriate clinical and radiographic protocols for all examinations shall be prepared and used.
- (2) In radiographic installations there shall be a comprehensive quality control of the generator and imaging system
- (3) Optical photofluorography shall not be used.
- (4) In radiographic rooms the operator shall always stand behind a protective barrier against scattered radiation. The barrier shall incorporate a means of observing the patient at all times during the examination.
- (5) Any viewing window shall be lead glass or lead plastic.
- (6) The patient shall be fully instructed as to their actions during a particular procedure, for example to avoid movement during the exposure.
- (7) Automatic exposure control shall be incorporated in radiographic equipment, and shall be used
- (8) If automatic Exposure Control is not used, technique charts for each x-ray unit including tube voltage (kVp), radiographic exposure (mAs), focus to skin distance, dimensions of the patient shall be used.

(9) Protocols shall take into account the image receptor being used (for example film-screen sensitivity), use of a grid or air gap, automatic Exposure Control chamber, appropriate collimation and protection of radiosensitive organs.

(10) No exposure shall be repeated unless the diagnostic value of the examination is compromised as assessed, where practicable, by the relevant medical practitioner.

(11) No one other than the patient shall be inside the X-ray room. If a helper is needed, he or she shall be informed on the best position to stand (i.e. where scattered radiation levels are lowest) and shall wear protective clothing.

Fluoroscopy

80. (1) Direct (i.e. unintensified) fluoroscopy shall not be performed.

(2) In fluoroscopy installations there shall be a comprehensive quality control of the generator and imaging system

(3) Fluoroscopy shall not be used as a substitute for radiography.

(4) Whenever possible, automatic exposure control shall be selected. If protection of radiosensitive organs is used, and if the protective shield obscures part of the image, the automatic exposure control should be disabled to avoid high dose rates.

(5) The source (x-ray target) to skin distance shall not be less than 45 cm.

(6) The image intensifier shall always be placed as close as possible to the exit surface of the patient as this reduces patient dose and improves image quality.

(7) Magnification and high dose modes shall only be used when necessary as they can greatly increase the patient dose.

(8) Television monitors shall be placed at suitable locations in the room and be visible at ambient light levels.

(9) If the radiologist or other health professionals are required to be inside the X-ray room during the procedure, they shall be protected with protective aprons or other shields as appropriate and shall stand as far as possible from the patient (who is the main source of scattered radiation).

(10) An alarm shall alert the operator that a certain fluoroscopy time has elapsed. This is useful in minimising the use of fluoroscopy, and hence in minimising patient dose.

Interventional Radiology

81. In addition to the requirements for fluoroscopy in these regulations, the following also apply:

- a) Interventional radiology shall only be performed with x-ray equipment and facilities designed for that purpose.

- b) Users of such equipment (interventional radiologists, cardiologists, urologists etc.) shall have specific training in radiation protection on the safe use of interventional radiography equipment.
- c) Strict dose control procedures shall be included in the quality assurance programme as the risk of deterministic effects (in both patients and medical staff) can be significant.
- d) Real time dose measurement and display shall be used in all interventional radiology procedures, and the total dose for the procedure recorded.
- e) Facilities using interventional radiology shall have protocols for dealing with cases of suspected high doses to patients.

Computed Tomography

82. (1) In Computed Tomography installations there shall be a comprehensive quality control of the generator and imaging system

- (2) Warm up procedures shall not be performed with anyone in the room.
- (3) Anyone who is required to be in the room during a Computed Tomography examination shall wear protective clothing and be instructed as to where they are to stand to minimise scattered radiation dose.
- (4) The examination parameters such as scanned region, number of slices, slice thickness, slice spacing (or scan pitch), tube voltage (kVp) and tube current (mAs) should be optimised and established in clinical protocols.

Mammography

83. (1) In mammography installations there shall be a comprehensive quality control of the generator and imaging system

- (2) A film processor designed for and dedicated to mammography processing shall be used.
- (3) Special viewing boxes (with high brightness and collimation) installed in a low ambient light level environment should be used.
- (4) Dedicated high sensitivity, high resolution mammography film-screen combinations or equivalent digital imaging systems shall be used to produce the image quality required at a low dose.
- (5) Tungsten target/aluminum filter combinations shall not be used.
- (6) The operating factors of the equipment (eg. target/filter combination, kVp, automatic exposure control detector position) shall be chosen for the breast thickness and composition being examined.
- (7) Breast compression shall be used to maximize image quality and minimize mean glandular dose.
- (8) Automatic exposure control shall be used.
- (9) A grid shall be used except where a thin compressed breast thickness is

being examined.

Paediatric Radiology

84. (1) In paediatric radiology installations there shall be a comprehensive quality control of the generator and imaging system

(2) Wherever possible, dedicated paediatric x-ray systems shall be used for babies and small children because they have special features such as special grids, higher beam quality (special filtration) and they also have the ability to use very short exposure times and thus to avoid a degradation of the image quality by patient movement,.

(3) If conventional (adult) x-ray equipment is to be used for babies and small children, the grid shall be removed where possible.

(4) The automatic exposure control for non-dedicated paediatric equipment shall be able to accommodate the different size and stature of children of a range of ages.

(5) Radiographers shall undergo some specific training in managing paediatric patients, in the appropriate radiographic techniques, and use of the immobilization devices.

(6) In paediatric radiology a film shall not be repeated unless a radiologist considers that the obtained image is not of sufficient diagnostic quality.

(7) Use of additional filtration shall be considered for dedicated paediatric equipment, as this can reduce dose.

Dental Radiology

85. (1) In dental radiology installations, there shall be a comprehensive quality control of the generator and imaging system

(2) Intra-oral dental radiology shall be performed on dedicated equipment operating at tube potentials above 50 kVp, preferably 70 kVp.

(3) The collimator shall provide a focus to skin distance of at least 20 cm and a field size no more than 6 cm in diameter at the collimator end, and preferably limited to the image receptor dimensions.

(4) Only open-ended collimators shall be used.

(5).With the exception periapical radiograph, film holders should be used for intra-oral radiographs

(6) E-speed or faster film shall be used and the film shall be processed according to the manufacturer's instructions.

(8) Cephalometry shall be performed at a focus skin distance of at least 1m.

86. A licensee shall ensure that:

- a) equipment used for patient dosimetry in radiology are calibrated and traceable to a standards dosimetry laboratory.

- b) measuring instruments used in quality control testing are calibrated and traceable to a standards laboratory.
- c) records of calibration measurements and associated calculations shall be maintained in accordance with the requirements of the Authority.

Clinical (Patient) Dosimetry

87. A licensee shall ensure that in radiological examinations, representative values for typical sized adult patients of entrance surface doses, dose-area products, dose rates and exposure times, or organ doses shall be determined and documented.

Quality assurance for medical exposures in radiology

88 (1) A licensee shall establish a comprehensive quality assurance programme for medical exposures with the participation of appropriate qualified experts in radiology physics, taking into account the internationally recognised principles.

(2) Quality assurance programmes for medical exposures shall include:

- a) measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter;
- b) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;
- c) written records of relevant procedures and results;
- d) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment.
- e) corrective actions based on the results of the above mentioned components

(3) A licensee shall, as far as possible, include regular and independent quality audit reviews of the quality assurance programme for radiology.

Use of Guidance Levels

89 (1) A licensee shall measure typical patient doses and take into consideration relevant guidance levels established by the Authority, for use by medical practitioners in order that:

- a) corrective actions are taken as necessary if doses fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients;
- b) reviews are considered if doses exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice

(2) The guidance levels established by the Authority shall be revised as technology improves.

Dose Constraints

90 (1) An ethical review committee or other institutional body assigned with similar functions on the subject by the Ministry of Health and Child Welfare shall specify dose constraints to be applied on a case by case basis in the optimization of protection for persons exposed for medical research purposes if such medical exposure does not produce direct benefit to the exposed individual.

(2) A licensee shall constrain any dose to individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis, to a level not exceeding that specified in the Radiation Protection Safety and Security Regulations.

Investigation of Accidental Medical Exposure in Radiology

91 (1) A licensee shall promptly investigate:

- a) any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels;
- b) any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

(2) A licensee shall, with respect to any investigation of the above:

- a) calculate or estimate the doses received and their distribution within the patient;
- b) indicate the corrective measures required to prevent recurrence of such an incident;
- c) implement all the corrective measures that are under their own responsibility;
- d) submit to the Authority, as soon as possible after the investigation or as otherwise specified by the Authority, a written report which states the cause of the incident and includes the information specified in (a) to (c), as relevant, and any other information required by the Authority; and
- e) inform the patient and his or her doctor about the incident.

Records

92. A licensee shall keep for a period of 5 years and make available, as required, necessary information to allow retrospective dose assessment, including: the number of radiographic exposures, the duration of fluoroscopic examinations, and exposure of volunteers in medical

research.

PART VI: PUBLIC EXPOSURE

Responsibilities

93. A licensee shall be responsible for controlling public exposure resulting from a radiology practice.

94. In order to control public exposures, a licensee shall be responsible, with respect to the sources under his responsibility, for the establishment, implementation and maintenance of:

- a) protection and safety policies, procedures and organizational arrangements for the use of radiology sources to ensure their safety and security in accordance with the requirements of the Authority;
- b) measures for ensuring the optimization of the protection of members of the public;
- c) measures for ensuring the safety of such sources, in order that the likelihood of public exposures be controlled;
- d) appropriate protection and safety training to the personnel having functions relevant to the protection of the public, as well as periodic retraining and updating as required, in order to ensure the necessary level of competence;
- e) appropriate monitoring equipment and surveillance programmes to assess public exposure;
- f) adequate records of the surveillance and monitoring as required by the Authority;
- g) emergency plans and procedures, commensurate with the nature and magnitude of the risk involved, and kept ready to actuate in accordance with the requirements of the Authority.

Control Access of Visitors

95 (1). There shall be no visitors to radiology equipment rooms while in use.

(2) A licensee shall :

- a) ensure that visitors be accompanied in any controlled area by a person knowledgeable about the protection and safety measures for that area;
- b) provide adequate information and instruction to visitors before they enter a controlled area so as to ensure appropriate protection of the visitors and of other individuals who could be affected by their actions.

Monitoring of Public Exposure

96. (1) A licensee shall, as appropriate:

- a) establish and carry out a monitoring programme sufficient to ensure that the requirements of the Authority regarding public exposure to radiation sources are satisfied and to assess such exposure and;
- b) keep appropriate records of the results of the monitoring programmes

(2) The programme for monitoring public exposure from radiology shall include dose assessment in the areas surrounding radiology facilities that are accessible to the public.

PART VII: POTENTIAL EXPOSURE AND EMERGENCY

97. A licensee shall ensure that all reasonable steps are taken to reduce the probability and the magnitude of accidental or unintended doses to patients from radiological practices, economic and social factors being taken into account.

Safety Assessment

98. (1) A licensee shall conduct a safety assessment applied to all stages of the design and operation of the radiology facility, and present the report to the Authority if required.

(2) The safety assessment shall include, as appropriate, a systematic critical review of identification of possible events leading to accidental exposure.

(3) The safety assessment shall be documented and, if appropriate, independently reviewed by an expert, within the Quality Assurance programme. Additional reviews shall be performed as necessary whenever:

- a) safety may be compromised as a result of modifications of the facilities or of the procedures;
- b) operational experience or information on accidents or errors indicates that a review is necessary; or
- c) any significant changes to relevant guidelines or standards are envisaged or have been made.
- d) Any consequential modifications shall be made cautiously and only after a favourable assessment of all the implications for protection and safety.

Prevention of accidental exposure and mitigation of their consequences

99. (1) A licensee shall incorporate within the Radiation Protection Programmes:

- a) defence in depth measures to cope with identified events, and an evaluation of the reliability of the safety systems (including administrative and operational procedures, and equipment and facility design); and
- b) operational experience and lessons learned from accidents and errors. This information shall be incorporated into the training, maintenance and Quality Assurance Programmes.

(2) The licensee shall promptly inform the Authority of all reportable events, and make suitable arrangements to limit the consequences of any accident or incident that does occur

Emergency Plans

100. (1) On the basis of events identified by the safety assessment, the registrant and licensee shall prepare emergency procedures.

(2) The procedures shall be clear, concise and unambiguous and shall be posted visibly in places where their need is anticipated.

(3) An emergency plan shall, as a minimum, list and describe:

- a) predictable incidents and accidents and measures to deal with them;
- b) the persons responsible for taking actions, with full contact details;
- c) the responsibilities of individual personnel in emergency procedures (radiologists, medical physicists, radiographers, etc.);
- d) equipment and tools necessary to carry out the emergency procedures;
- e) training and periodic rehearsal;
- f) recording and reporting system;
- g) immediate measures to avoid unnecessary radiation doses to patients, staff and public.

PART VIII: OFFENCES, PENALTIES AND APPEALS

101. Any person who contravenes any of the provisions of these regulations commits an offence

102 Any person who commits an offence under these regulations shall be liable to the penalties as established in the enforcement policy issued by the Authority

103 The Authority shall impose penalties such as suspension or revocation of authorization, imposing administrative fine or closure of facility or any combination of these

104 Any person or body corporate who, being a holder of authorisation under these regulations, who commits an offence shall be liable to prosecution in the court of law and upon conviction be liable to pay fines not exceeding level fourteen or imprisonment for a period not exceeding ten years or both.

Appeal

105. Any person may appeal to the Board of the Authority against a decision made against him pursuant to these regulations.

Citation

106 These regulations may be cited as the “Regulations for Radiation Safety in Diagnostic and Interventional Radiology” and come into effect on**2011**

SCHEDULE I

DOSE LIMITS FOR OCCUPATIONAL AND PUBLIC EXPOSURE

OCCUPATIONAL EXPOSURE

Dose limits

(1). The occupational exposure of any worker shall be so controlled that the following limits be not exceeded:

- (a) an effective dose of 20 mSv per year averaged over five consecutive years
- (b) an effective dose of 50 mSv in any single year;
- (c) an equivalent dose to the lens of the eye of 150 mSv in a year; and
- (d) an equivalent dose to the extremities (hands and feet) or the skin of 500 mSv in a year.

(2). For apprentices of 16 to 18 years of age who are training for employment involving exposure to radiation and for students of age 16 to 18 who are required to use sources in the course of their studies, the occupational exposure shall be so controlled that the following limits be not exceeded:

- (a) an effective dose of 6 mSv in a year;

- (b) an equivalent dose to the lens of the eye of 50 mSv in a year; and
- (c) an equivalent dose to the extremities or the skin of 150 mSv in a year.

Special circumstances

(3). When, in special circumstances, a temporary change in the dose limitation requirements is approved pursuant to Radiation Protection Safety and Security Regulations:

- (a) the dose averaging period mentioned in Para. 1.(1)(a) may exceptionally be up to 10 consecutive years as specified by the Authority, and the effective dose for any worker shall not exceed 20 mSv per year averaged over this period and shall not exceed 50 mSv in any single year, and the circumstances shall be reviewed when the dose accumulated by any worker since the start of the extended averaging period reaches 100 mSv; or
- (b) the temporary change in the dose limitation shall be as specified by the Regulatory Authority but shall not exceed 50 mSv in any year and the period of the temporary change shall not exceed 5 years.

PUBLIC EXPOSURE

Dose limits

(4). The estimated average doses to the relevant critical groups of members of the public that are attributable to practices shall not exceed the following limits:

- (a) an effective dose of 1 mSv in a year;
- (b) in special circumstances, an effective dose of up to 5 mSv in a single year provided that the average dose over five consecutive years does not exceed 1 mSv per year;
- (c) an equivalent dose to the lens of the eye of 15 mSv in a year; and
- (d) an equivalent dose to the skin of 50 mSv in a year.

Dose limitation for comforters and visitors of patients

(5). The dose limits set out in this part shall not apply to comforters of patients, i.e., to individuals knowingly exposed while voluntarily helping (other than in their employment or occupation) in the care, support and comfort of patients undergoing medical diagnosis or treatment, or to visitors of such patients. However, the dose of any such comforter or visitor of patients shall be constrained so that it is unlikely that his or her dose will exceed 5 mSv during the period of a patient's diagnostic examination or treatment. The dose to children visiting patients who have ingested radioactive materials should be similarly constrained to less than 1 mSv.