REGULATIONS FOR RADIATION SAFETY IN RADIOTHERAPY

Arrangement of Regulations

PART I – GENERAL

PART II – PRINCIPAL REQUIREMENTS

PART III SAFETY OF SOURCES

PART IV- OCCUPATIONAL EXPOSURE

RADIATION PROTECTION ACT
REGULATIONS FOR RADIATION SAFETY IN RADIOTHERAPY

Part I – General

Interpretation

These regulations, unless the context otherwise requires:

"Absorbed dose" means The fundamental dosimetric quantity D, defined as:

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

where dε "means" 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 (J/kg), termed the gray (Gy).

"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 Radiation Protection Act [Chapter 15:15]

"Afterloading" means a technique by which applicators or guides are placed on the patient prior to placement of the radioactive material permitting verification of correct positioning as well as prompt loading and unloading of radioactive material.

"Applicant" means any legal person who applies to the Authority for authorization

"Approved" means approved by the Authority.

"Authority" means Radiation Protection Authority of Zimbabwe

"Authorization" means permission granted in a document by Authority to a legal person who has submitted an application to carry out a practice or any other action described in the Act. The authorization can take the form of a registration or a licence.

"Authorized" means granted an authorization by Authority.

" Caregiver" means an individual such as a relative or guardian who assists the patient during the treatment period.

"Controlled area" means any area in which specific protection measures and safety provisions are or could be required for:

(a) controlling normal exposures or preventing the spread of contamination during normal working conditions; and

(b) preventing or limiting the extent of potential exposures.

"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. 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. 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. 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.

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

"Effective dose" means the quantity E, defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_T w_T \cdot H_T$$

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:

$$E = \sum_T w_T \cdot \sum_R w_{R\cdot} D_{T\cdot R}$$

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

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

"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).

"Equipment for remote afterloading" means equipment by which treatment is delivered using remote loading devices.

"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.

"Exclusion" means any exposure whose magnitude or likelihood is essentially unamenable to control through the requirements of these regulations is deemed to be excluded from the regulations

"Health professional" means an individual who has been accredited through appropriate national procedures to practice a profession related to health (for example medicine, dentistry, chiropractic, pediatric, 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.

"High energy radiotherapy equipment" means X-ray equipment and other types of radiation generators capable of operating at generating potentials above 300 kV, and radionuclide teletherapy equipment

"Imaging devices" means electronic equipment used for imaging in diagnostic radiology and Nuclear medicine (e.g., image convertors, gamma cameras).

"Interstitial application" means a radiotherapeutic technique in which the radioactive material is implanted in the tumour.

"Intervention" means any action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of an accident.

"Intracavitary application" means a radiotherapeutic technique in which the radioactive material is placed within natural cavities

"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 taken under the Act.

"Licence" means an authorization granted by the Authority on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by the Licensee.

"Licensee" means the holder of a current licence granted for a practice or source who has recognized rights and duties for the practice or source, particularly in relation to protection, safety and security.

"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.

"Member of the public" means in a general sense, any individual in the population except, for the purposes of the Act and other 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.

"Monitoring" means the measurement of dose or contamination for reasons related to the assessment or control of exposure to radiation or radioactive substances, and the interpretation of the results.

"Normal exposure" means an exposure, which is expected to be received under normal operating conditions of an installation or a source, including possible minor mishaps that can be kept under control.

"Notification" means a document submitted to the Authority by a legal person to notify an intention to carry out a practice or any other action described by the Authority.

"Occupational exposure" means all exposures of workers incurred in the course of their work with the exception of exposures excluded from the Act and exposures from practices or sources exempted by the Act.

"Planning target volume" means a geometrical concept used in radiotherapy for planning treatment with consideration of the net effect of movements of the patient and of the tissues to be irradiated, variations in size and shape of the tissue, and variations in beam geometry such as beam size and beam direction.

"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.

"Preparation table" means working plane surface located within the storage room of a design adequate for safe handling of radioactive sources.

"Protection and safety" means the protection of people against exposure to ionizing radiation or radioactive substances and the safety of radiation sources, including the means for achieving such protection and safety, such as the various procedures and devices for keeping people's doses and risks as low as can reasonably be achieved and below prescribed dose constraints, as well as 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 Radiotherapy Physics (medical physicist)" 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 radiotherapy medicine physics.

"Quality Assurance" means all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

"Radiation Safety Officer" means an individual technically competent in radiation safety and protection matters relevant for a given type of practice who is designated by the registrant or licensee to oversee the implementation of the Act.

"Radiotherapy" means a treatment technique in which the radioactive material is placed within or very close to the tissue volume to be treated.

"Radiotherapy Physician (Radiotherapist)" means specialist in radiation oncology,

accredited for consulting, prescribing and supervising radiation treatment, and evaluating and summarizing the results.

"Radiotherapy technician" means technician in radiation physics, responsible for precise delivery of the treatment prescribed by the radiotherapist, who is capable of detecting changes in patient conditions that may affect treatment.

"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.

"Reference air kerma rate" means the reference air kerma rate of a source is the kerma rate to air, in air, at a reference distance of one metre, corrected for air attenuation and scattering. This quantity is expressed in $mGy.h^{-1}$ at 1 m.

"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.

"Sealed Source" means radioactive material that is (a) permanently sealed in a capsule or (b) closely bounded and in a solid form. The capsule or material of a sealed source shall be strong enough to maintain leak tightness under the conditions of use and wear for which the source was designed, also under foreseeable mishaps.

"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.

"Supervised Area" means any area not designated as a controlled area but for which occupational exposure conditions are kept under review even though protective measures and safety provisions are not normally needed.

"Unsealed Source" means a source that does not meet the definition of a sealed source.

"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 diagnostic radiology.

"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.

"Storage Room" means Facility designated for lodging, preparation, control and sterilization of radioactive sources.

"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.)

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

Objective

2. These regulations specify the minimum requirements for protection of the people against exposure to ionizing radiation and for the safety of radiation sources. They do not relieve an authorized legal person from the duty to take any additional actions as maybe appropriate and necessary to protect the health and safety of people.

Scope

3 (1) These regulations shall apply to all established uses of ionizing radiation sources employed in the practice of radiotherapy, to the facilities where the sources are located and to the individuals involved.

(2) These regulations shall cover occupational, public, medical, potential and emergency exposure situations.

(3) Emerging new techniques utilizing radiation sources (e.g., prevention of restenosis, and stereotactic radiotherapy are not specifically covered by these regulations, although the general principles of protection and safety discussed are applicable).

(4) These regulations do not cover the use of unsealed sources in radiotherapy, which are covered in the Radiation Safety Regulations in Nuclear Medicine

Part II- Principal Requirements

Authorization of the practice

4 (1) Any person who intends to utilize radiation sources for radiotherapy purposes shall notify the Authority of his/her intention and shall apply for an authorization.

(2) Any person applying for an authorization shall provide the Authority with the information necessary to demonstrate the safety of the practice.

(3) Considering the complexity of a radiotherapy practice, the risks involved and the fact that its safety depends on human performance, demonstration of safety requires a detailed safety assessment and therefore its authorization shall take the form of multi-stage licences.

(4) The licensee shall comply with radiation safety requirements for the following stages of the radiotherapy 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 sources.

(5) Modification, with possible implications for radiation safety, of the radiotherapy facilities, of the type and activity of radioactive substances and of procedures, or cessation of the practice, shall require an amendment to the licence.

(6) Application for authorization shall be made on prescribed Authority forms.

Renewal of authorization

5. Authorizations shall be renewable periodically at a frequency determined by Authority. Application for Renewal of authorizations shall be submitted Three (3) months before its expiry. Renewal of authorizations shall be based on documented evidence of compliance with the regulations and the Act.

Personal accreditation for radiation protection and safety

6(1) All personnel on whom protection and safety depend shall be appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgment and according to defined procedures.

(2) In radiotherapy practice, the following individuals carry responsibility for protection and safety, by virtue of tasks involving decisions, operation or manipulation of sources or equipment used in radiotherapy:

(a) medical practitioners working in radiotherapy (radiotherapists, radiation oncologists, oncology nurses);

(b) qualified experts in radiotherapy physics (medical physicists) and dosimetrists or physics assistants;

(c) other health professionals operating radiotherapy equipment or handling radioactive sources (radiotherapy technologists);

(d) Radiation Safety Officer;

(e) Staff for maintenance of radiotherapy equipment; and

(f) Staff performing special tasks (type tests, long term stability checks, etc.)

(g) Oncology nurses

(3) These individuals shall provide evidence of education qualification and training relevant to their duties related to the use of radiation sources.

4(1) For radiotherapists, radiation oncologists, medical physicists, dosimetrists, radiotherapy technologists and radiation safety officers, typical documentary evidence indicated above, i.e., qualification credentials, shall as applicable, consist of:

(a) university degree or academic qualification relevant to the profession, 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 at 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 competent authorities

(2) The documentary evidence for an individual to perform maintenance of radiotherapy equipment shall consist of:

(a) certification by the manufacturer of his or her having completed a training programme on the type of authorized equipment (the certification should indicate the type of equipment and the parts of the equipment that the engineer or technician has been trained to repair or adjust, or the scope of the maintenance he/she is able to perform); and

(b) a course on radiation protection for which contents, methodology and teaching institution are approved by the Authority or other appropriate Authorities.

Authorization of other practices related to radiotherapy

7. Considering that, according to the Act, the activities listed below also require authorization, licensees shall contract any of the following services only to enterprises authorized by the Authority:

(a) import, distribution, sale or transfer of radioactive sources;

(b) installation, maintenance of radiotherapy equipment, including source change, and decommissioning;

(c) disposal of radioactive sources.

Revocation of authorization

8. In the event of a breach of any licence condition, 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 relevant organizations when applicable, on the causes of the breach and on the corrective or preventive actions taken or to be taken; and

(d) take any other actions necessary as required by the Authority.

Withdrawal of Authorization

9(1) Failure to take corrective or preventive actions within a specified period of time shall be grounds for modifying, suspending or withdrawing any authorization that had been granted by the Authority.

(2) The Authority will suspend or revoke an authorization when licensees are in breach of the conditions of the authorization, the Act or specific requirements of these regulations.

(3) In order to be able to resume operation, the licensee shall reapply for authorization in case of revocation, or apply for reconsideration in case of suspension (of the Act)

Inspection

10. The Licensee shall permit inspection by the Authority of the facilities and records at least two times per year.

Radiation safety and protection requirements

11. The radiation safety and protection requirements of justification of the practice, dose limitation and optimization of protection set out in the Act shall be applied to radiotherapy. The dose limits for occupational and public exposure are as contained in Schedule I.

MANAGERIAL REQUIREMENTS

Managerial commitment and policy statement

12(1) A safety culture shall be fostered and maintained to encourage a questioning and learning attitude to protection and safety and to discourage complacency.

(2) To comply with this requirement, hospital management shall be committed to an effective protection and safety policy, particularly at senior level, and by clearly demonstrable support for those persons with direct responsibility for radiation safety, ie Radiation Safety Officer.

(3) The commitment shall be expressed in a written policy statement that clearly assigns prime importance to protection and safety in radiotherapy, whilst recognizing that the prime objective of medical care is the treatment and well-being of the patients. This action shall be followed by establishing a Radiation Safety Programme.

(4) Appropriate resources shall be made available to support the commitment stated in sub-paragraph 3 above.

Organization and responsibilities

13(1) The principal parties having the main responsibilities for the application of

the Zimbabwe Radiation Protection (Safety and security of radioactive sources) Regulations, 2010 and these regulations shall be licensees and employers.

(2) Other parties shall have subsidiary responsibilities for the application of the Act. These parties may include, as appropriate: suppliers, workers, radiation safety officers, medical practitioners, health professionals, qualified experts, ethical review committees and any other party to whom a principal party has delegated specific responsibilities.

(3) The licensee shall assign clear responsibilities to personnel (e.g., medical practitioners, qualified experts in radiotherapy physics, radiotherapy technologists, radiation safety officers and other health professionals) so that adequate radiation protection of patients, workers, and the public is ensured.

(4) The need for qualified experts should be determined; their responsibilities defined and suitable persons shall be appointed either on full-time or part-time basis.

Establishment of radiation protection programmes

14(1) The licensee shall establish a radiation safety programme and provide the necessary resources to comply with this programme. The programme shall relate to all phases of the practice, from design through operation to decommissioning. The programme shall reflect management responsibility for radiation protection and safety through management structure, policies, procedures and organizational arrangements that are commensurate with the risks.

(2) The licensee shall appoint a Radiation Safety Officer. The Radiation Safety Officer should have sufficient authority to communicate with management regarding compliance with regulations and licence provisions.

(3) A Radiation Safety Committee shall be formed in all radiotherapy institutions that handle Category 1 and 2 sources. The committees shall co-ordinate and review the radiation safety and protection programme and the quality assurance procedures. The scope of the committee shall also cover other practices using ionizing radiation in the hospital.

Quality Assurance

15. The licensee shall establish a comprehensive Quality Assurance Programme for radiation protection and safety to ensure that all necessary procedures are developed and implemented in order to comply with the regulations for radiation safety within the terms and conditions of the authorization.

Human factors: Staffing

16. The licensee shall appoint a number of professionals, with personal accreditation for the tasks described in these regulations, sufficient to ensure that all activities relevant to protection and safety are carried out in accordance with these regulations, and the number of persons shall be kept under review, especially

as workload increases, or new techniques and new equipment are incorporated.

Educational qualification and training

17(1) All staff working with radiation sources or treating patients shall have an adequate educational background with relevant practical training, relevant to their duties.

(2) The licensee shall ensure that only staff with the credentials specified in these regulations shall fill these positions and that they are aware of :

(a) the conditions and limitations of the licence;

(b) the institutional radiation safety and protection policies and procedures (including practice recover);

(c) their own individual responsibilities

(d) the use and operation of equipment;

(e) the local quality assurance programme and quality control procedures,;

(f) review and analysis of incidents and accidents that have occurred in the institution or documented from elsewhere; and

(g) instructions provided to patients and caregivers.

(3) The professional education and the training mentioned above shall be completed before commencement of duties and continued subsequently as part of the professional development and as required by the Authority. Furthermore, the instruction of personnel is required whenever significant changes occur in duties, regulations, the terms of the licence or radiation safety procedures.

(4) The licensee shall ensure that the following staff are provided with specific instructions on radiation safety and protection:

(a) oncology nurses;

(b) staff who do not belong to radiotherapy practice but need to enter controlled areas; and

(c) staff who transport radioactive materials within the institution.

(5) The licensee shall establish a policy that encourages and provides continuing professional development programme, with the aim of improving staff skills, maintain familiarity with current practices and foster a safety culture throughout the institution.

(6). Personnel with duties in the vicinity of radioactive sources used in radiotherapy shall be informed of the radiation hazard, details of the specific uses, and the radiation safety programme.

(7). The licensee shall keep a record of the initial and periodic instruction of personnel as part of the records of the Radiation Safety Committee.

Part III- Safety of Sources

Prevention and mitigation of accidents

18. 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 exposure that may cause accidents;

(b) mitigating the consequences of any such accident that does occur; and

(c) restoring sources to safe conditions after any such accident.

Safety in the Design of Radiation Sources and Equipment

19(1) The requirements for the safety of sources specified in Radiation Protection Safety and Security of Sources Regulations in general shall also apply to sources used in radiotherapy, where relevant, and, in particular, equipment used in radiotherapy shall be so designed that:-

(a) failure of a single component of the system be promptly detectable so that any unplanned medical exposure of patients is minimized; and

(b) the incidence of human error in the delivery of unplanned medical exposure be minimized.

(2) Licensees shall:

(a) taking 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 therapeutic equipment, and the provision to personnel of appropriate training and periodic retraining 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 and periodically conduct practice drills.

(e) The licensee should document all radiation incidences and notify the Authority.

Sealed sources

20(1) Radioactive sources for either teletherapy or brachytherapy shall be so constructed that they conform to the definition of a sealed source.

(2) To meet this requirement, sealed sources used for external beam therapy and brachytherapy shall comply with International Standard Organization (ISO) 2919 or the Standards Association Of Zimbabwe equivalent standard.

(3) Sealed sources used for external beam therapy and brachytherapy shall have a calibration certificate provided by the manufacturer, in accordance with International Standard Organization and Standards Association of Zimbabwe.

(4) The use of older teletherapy units containing ^{137}Cs and brachytherapy sources incorporating ^{226}Ra or old ^{137}Cs [1] in preloaded applicators is no longer justified and shall no longer be used.

(5) Sources used for manual brachytherapy shall be used either with metallic applicators or with plastic applicators compatible with the sources as stated by the manufacturer.

(6) In brachytherapy, when applicators are employed, they shall be those manufactured specifically for the source or those, which are compatible. Licensees shall not use radioactive sources after their manufacturer-recommended working life.

(7) Sources using beta emitters shall be provided with shielding of low atomic number to minimize bremsstrahlung, while in storage and preparation for use.

Equipment

21(1) As established by these regulations, radiation sources including radioactive material, equipment and accessories, shall be purchased only from authorized suppliers and shall have a valid type test. Written methods for the purchase, installation, acceptance, commissioning, use, maintenance and quality control of such material shall be developed with the involvement of the responsible staff or the Radiation Safety Committee.

(2) Licensees, in specific co-operation with suppliers, shall ensure that, with regard to equipment consisting of radiation generators and that containing sealed sources used for medical exposures:

(a) whether imported into or manufactured in the country where it is used, the equipment conform to applicable standards of the International Electrotechnical Commission and the International Standards Organization or to Standards Association of Zimbabwe.

(b) performance specifications and operating and maintenance instructions, including protection and safety instructions, shall be provided in English and in compliance with the relevant International Electrotechnical Commision (IEC) or International Standards Organization standards with

[1] Caesium-137 sources with the radionuclide in powder form.

regard to ‘accompanying documents’;

(c) where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in English.

(3) Compliance with International Electrotechnical Commission and Standard Association of Zimbabwe standards shall be demonstrated and supported by written evidence.

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

(5) The Requirements for radiation generators and irradiation installations for radiotherapy shall be, in pertinent part:

(a) radiation beam control mechanisms be provided, including devices that indicate clearly and in a fail-safe manner whether the beam is `on' or `off';

(b) as nearly as practicable, the exposure be limited to the area being examined or treated by using collimating devices aligned with the radiation beam;

(c) the radiation field within the examination or treatment area without any radiation beam modifiers (such as wedges) be as uniform as practicable and the non-uniformity be stated by the supplier; and exposure rates outside the examination or treatment area due to radiation leakage or scattering be kept as low as reasonably achievable.

(6) Licensees, in specific co-operation with suppliers, shall ensure that:

(a) radiation generators and irradiation installations include provisions for selection, reliable indication and confirmation (when appropriate and to the extent feasible) of operational parameters such as type of radiation, indication of energy, beam modifiers such as filters, treatment distance, field size, beam orientation and either treatment time or preset dose;

(b) irradiation installations using radioactive sources be fail-safe in the sense that the source will be automatically shielded in the event of an interruption of power and will remain shielded until the beam control mechanism is reactivated from the control panel;

(c) High energy radiotherapy equipment:

(i) have at least two independent `fail to safety' systems for terminating the irradiation; and

(ii) be provided with safety interlocks or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel;

(iii) the design of safety interlocks be such that operation of the installation during maintenance procedures, if interlocks are bypassed, could be performed only under direct control of the maintenance personnel

using appropriate devices, codes or keys.

(7) (a) It shall be possible to interrupt the irradiation from the control panel. Resuming irradiation shall only be possible from the control panel.

(b) Teletherapy equipment containing radioactive sources shall be provided with a device to return sources manually to the shielded position in case of emergency. For gamma knife units, it shall be possible to close the shielding door manually.

(c) The irradiation heads in external beam equipment and source containers in brachytherapy shall be provided with a clear permanent sign indicating the existence of radioactive material (i.e., ISO 361 symbol). Containers and devices containing radioactive sources, when outside the radiotherapy department, shall be labeled with a warning signal, which is recognized as "DANGER" by any member of the public.

Design Requirements

22 (1) The following design requirements are applicable only to external beam therapy equipment:

(a) The primary beam shall be only directed towards primary barriers with sufficient shielding. If a primary shielding is incorporated to the equipment, electrical or mechanical interlocks shall be provided to avoid that the beam be directed toward the secondary barriers when the shielding is not intercepting the beam.

(b) External beam teletherapy equipment shall be stable in any position and it shall be possible to fix it in any desired position.

(c) Couch and table top movements (vertical, longitudinal, lateral, angular) shall facilitate patient positioning and set-up and shall be fixed by adequate brakes.

Facilities and Ancillary Equipment

23 (1)The design of the facility shall make provisions for safety systems or devices to be inherent to the equipment and room, to lower the probability of occurrence of abnormal situations.

(2) The shielding should be calculated using optimization principles and dose constraints should be developed and used as required by these regulations. The overall design of the facility including these calculations should be performed by an appropriate qualified expert.

(3) The licensee shall consider access control when determining the location of therapy treatment rooms and source storage areas.

(4) Radiation monitoring equipment, where appropriate, shall be installed or be available to give warning of any unusual situation in the use of radiation generators and radionuclide therapy equipment.

Manual Brachytherapy

24 (1) The following rooms shall be available for manual brachytherapy:-

(a) source storage and preparation laboratory

(b) an operating room

(c) a treatment planning room

(2) Access to nursing, i.e., a nursing station next to the wards, shall be available as it has an impact on safety.

(3) The source storage and preparation laboratory shall have a sink for cleansing of sources, provide a filter or trap suitable for preventing loss of sources through the sewerage.

(4) The storage and preparation of radioactive sealed sources for manual brachytherapy shall meet the following requirements:

(a) the room shall only be used for source storage and preparation by designated and trained personnel;

(b) the room shall be provided with a lockable door to control access and maintain source security.

(c) a radiation sign (trefoil) and danger warning notice shall be posted on the entrance;

(d) there shall be a shielded storage safe for all sources. The outer surface of the storage shall be made of fire-proof material. The safe should be located near the preparation workbench to reduce the exposure of personnel during transfer of sources.

(e) the safe shall have compartments for different source activities. Each compartment shall be marked so as to permit immediate and easy identification of its contents from the outside.

(f) the workbench shall be provided with an L-block shielding with a lead glass viewing window.

(g) the source handling area shall be well illuminated and a magnifying glass in a fixed mounting shall be available.

(h) devices for handling sources, typically forceps, shall be available. They shall be as long as practicable, compatible with the effective manipulations. A device shall be provided for threading sources expeditiously with the fingers protected by distance.

(i) sources shall be readily identifiable by sight and where radioactive sources of the same appearance but of different activities are used, they shall be distinguishable, e.g., by different coloured threads or beads.

(j) hand carried transport containers shall be provided with long handles and the lid of the container should be securely fastened to prevent spillage of sources during transportation and containers shall bear the radiation symbol as well as a danger warning sign.

(k) There shall be a clear indication of the radiation level and shall be achieved either by an area radiation monitor which should be visible on entering the room and during any handling of the unshielded sources, or a survey meter should be available and in use during source handling;

(l) space shall be available for source transportation trolleys with source containers;

(m) space shall be available for secure storage to enable decay of short half-life sources, such as ^{192}Ir;

(n) working surface for source preparation shall be smooth and seamless to avoid losing small sources such as ^{192}Ir wire fragments.

5 (1) Treatment rooms shall be located in areas of low personnel flow and access shall be restricted. It is preferable that patient rooms be for single patients. If there is more than one patient room, they shall be adjacent and an area monitor shall be placed at the entrance so as to detect when a source or patient with a source is leaving the room or controlled area.

(2) Shielding shall be provided for nurses and visitors of brachytherapy patients, for which movable shields may be used within patient rooms, especially in manual brachytherapy.

(3) Prior to each treatment, movable shields shall be placed close to the patient's bed in a way that exposure to the nurses caring for the patient is minimized.

(4) The treatment room shall contain a shielded container and a remote handling tool in the event of a dislodged source.

(5) In order to ensure that no source remains within the patient, clothes or bed linen or in the area after treatment shall be monitored.

25 (1) External beam therapy and high dose rate brachytherapy shall be carried out in a treatment room designated for that purpose.

Remote Control Brachytherapy and External Beam Therapy

(2) Entry to the irradiation room while the source is exposed shall be avoided with an interlock system capable of stopping the irradiation when the door is opened or unlocked.

(3) Activation of the interlock system shall automatically interrupt the treatment and the mechanism and procedures shall be capable of maintaining irradiation interruption until the door is closed and locked, and verification has been made that no other person but the patient is inside the room.

(4) After an interruption, provided no operating parameters are changed or reselected, it shall be possible to restart irradiation, but only from the equipment control panel.

(5) An installed radiation monitor and/or a portable survey instrument shall be used to confirm the safe condition of the source.

(6) One or more emergency 'off' switches shall be conveniently placed inside the treatment room to allow interruption of the irradiation from inside the room.

(7) Before start of operation, licensees shall ensure proper operation of door interlocks and other physical parameters necessary for the protection of workers and the public and for delivery of the dose to the patient.

(8) Access to the irradiation room shall be furnished with a visible signal

indicating radiation source ‘on’ or ‘off’ and the same signals for radionuclide therapy machines shall be located on the treatment head or in close vicinity.

(9) (1) Gamma-ray therapy treatment rooms shall be provided with a stationary radiation monitor, visible on entering the room and close to a control panel with warning signal and the monitor shall be power-fail-safe in case of power interruptions or failures.

(10) The control panel shall be installed in such a way that the operator will have total overview of the access to the irradiation room at all times.

(11) Adequate systems, devices, or other means shall be provided to allow the operator to have a clear and full view of the patient and the systems for patient observation shall be redundant and independent.

(12) Oral communication shall be possible within the treatment rooms and patients, by using an intercom or other communication system.

(13) Fire fighting equipment shall be available in order to preserve source integrity in the event of fire.

Safety Associated with Acceptance Test, Commissioning and Operation

26 (1) Acceptance tests and commissioning shall not be restricted to radiation emitting equipment or sources but shall also be conducted for any system that has implications on safety, such as treatment planning systems.

Acceptance

(2) After equipment installation, acceptance testing shall be conducted in order to verify that the equipment conforms to technical specifications given by the manufacturer and to verify compliance with safety requirements of International Electrotechnical Commission Standard.

(3) As indicated in Part III, 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

27. After acceptance and before starting operation, calibration of radiation sources and radiation beams and commissioning shall be performed and during commissioning, the qualified expert in radiotherapy physics shall measure all data required for clinical use.

Operation

28 (1) Equipment shall be operated in accordance with the technical documents, ensuring satisfactory operation at all times, in respect of both the tasks to be accomplished and radiation safety and in particular, the manufacturer’s operating manual, and any additional procedures shall be approved in accordance with the

quality assurance system.

(2) Sealed sources shall be subject to leak tests, prior to the first use and at regular intervals thereafter, in conformity with International Standard Organisation (ISO) and Leak tests shall be capable of detecting the presence of 0.2 kBq of removable contamination of the sealed source.

(3) For manual brachytherapy sources the typical method is the direct wet wipe test, while for external beam therapy and remote control brachytherapy the method to be used is the indirect wipe test of the nearest accessible surface and the sterilization process in brachytherapy shall be appropriate for preventing damage of sources and applicators that could affect safety.

(4) Quality controls need to be carried out following formally established quality control protocols, periodically, after the source has been installed or replaced, or after repairs or maintenance work that has the potential to alter the radiation output.

(5) An independent audit of the calibration of the sources shall be carried out before starting clinical use of the source, e.g., the International Atomic Energy Agency(IAEA) andWorld Health Organisation(WHO) postal quality audit for dosimetry and the requirements on quality assurance for medical exposure are also provided in these regulations.

Maintenance

(6) The licensee shall ensure that adequate maintenance and inspection is performed as necessary to ensure that radiation sources retain their design requirements for radiation protection and safety for their useful lives and this requires that the licensee establish the necessary arrangements and co-ordination with the manufacturer's representative before initial operation.

(7) The licensee shall ensure that removal from and return to clinical service of radiotherapy equipment for maintenance or source exchange:

(a) is documented and a record kept; and

(b) where maintenance of the therapy equipment or treatment planning equipment may affect the accuracy of the physical or clinical dosimetry or the safe operation of the equipment, a qualified expert in radiotherapy physics shall assess whether any specific tests or measurements are to be made and whether that equipment is operating satisfactorily before it is used to treat patients.

(8) If the licensee needs to implement an emergency plan where equipment is out of service for maintenance or source change, usually performed by another company, the licencee shall provide the radiotherapy staff with written procedures containing the scope and a description of responsibilities for these actions.

Safe Operation of External Beam Therapy

29. Safe operations of external beam treatment units require procedures for area surveys, interlock checks, wipe tests and procedures for emergencies such as a

source which becomes stuck in or partially on position and the necessary equipment for procedures mentioned above shall be available, calibrated and in working order. These include:

(a) a radiation monitor with scales from μSv and greater

wipe test capabilities

(b) personal alarm dosimeters, especially for emergency intervention.

Safe Operation of Brachytherapy

30 (1). The source strength shall be determined individually, before it is used on a patient and the source documentation shall be checked carefully.

(2) The unit of activity used for source calibration shall be the same as the unit of activity used in the treatment planning system.

(3) Low Dose Rate and High Dose Rate sources have certain operating procedures for their safe use in common:

(a) Source inventories shall be maintained which show the location and current activity of each source at the facility as well as its unique identifier and this may be either a color-coded or letter/number identifier;

(b) Sources shall never be left on preparation surfaces and they shall be in storage, in transit, or in use.

(c) leak tests shall be performed and documented on a periodic basis; the tests should have sufficient sensitivity to detect the presence of 0.2 kBq of removable contamination of the sealed source:

(d) for the High Dose Rate unit, the wipe tests shall only be performed on the afterloading drive assembly and transport containers since the source itself has too high a dose rate to allow this sort of test.

(e) area surveys shall be performed periodically around the source storage facilities for Low Dose Rate and High Dose Rate sources:

(f) the storage facilities shall be marked to indicate that they contain radioactive materials and how to contact the responsible radiation safety individual in the event of an emergency.

(g) the storage facilities shall be kept locked at all times and

(h) after every brachytherapy treatment, the patient shall be monitored with a radiation survey meter so as to ensure that no activity remains in the patient unintentionally.

(4) The following information shall be posted in the case of Low Dose Rate brachytherapy, both manual as well as remote controlled and identification of the patient, sources, date and time of insertion and removal, nursing required, time allowance for nurses and visitors, and concise instructions for unplanned source and applicator removal and for emergency and a patient with removable source in or upon his body shall not leave the room unless accompanied by a hospital attendant.

(5) The licensee shall ensure that all brachytherapy sources are removed from the patient, except in the case of permanent implants and the patient shall be monitored with a portable detector to ensure that no source remains in or on the

patient.

(6) Linen, dressings, clothing, and equipment shall be kept within the room where the removal of sources takes place until all sources are accounted for and be monitored with a radiation detector as well as rubbish bins, soiled dressing bins and laundry baskets.

(7) Mobile containers and portable equipment containing radioactive sources shall be moved to a store or to a secure place when not in use.

Safe Operation of Manual Brachytherapy

31 (1) After verification of the source strength, the source or source holder shall be marked with unique identifiers (for example, a pre-established colour), to facilitate visual recognition and to prevent the possibility of confusion between different sources.

(2) Containers utilized for transport of radioactive sources shall conform with the requirements established in the Transport of Radioactive Materials Regulations and International Atomic Energy Agency's Regulations for the Safe Transport of Radioactive Material.

(3) The movements of the sources from the time they leave the safe until their return shall be documented and signed by the person responsible for the move.

(4) A person shall be assigned to be in charge of accountability for the sources. The person shall keep record of source order, issuance from and return to the safe with signatures.

(5) The sources shall be inspected visually for possible damage after each use by means of magnifying viewers and a leaded viewing window in a shielded work area.

6 (a) there shall be a diagram at the source storage safe, which has to show exact locations of each source within the safe, aids in reducing the time it takes to locate and identify a source.

(b) sources shall only be handled with long forceps or tongs, never directly with the fingers;

(c) when transporting the sources a mobile, shielded container shall be available and the shortest route possible should be used.

(d) sources, which come into direct contact with body tissues, require cleaning and possible sterilization after each use, which can subject the sources to possible damage from heat, abrasion, chemical attack, and mechanical stresses and these sources shall be inspected after every use.

(e) the work surfaces shall be easily cleaned and brightly lit to make it easy to find any sources that are dropped.

(f) as indicated in these regulations, a filter or a trap shall be used in the drain to prevent loss of sources to the sewerage during cleaning.

(7) Specific precaution to be observed during the cutting and handling of ^{192}Ir wires shall include ensuring that:

(a) appropriate tools and equipment, such as forceps, cutting devices,

magnifying glasses and good illumination of the work surface are available and used; if ^{192}Ir wires are cut-off for immediate use, a container to hold cut lengths shall be provided and labeled:

(b) radioactive waste is collected and stored in adequate containers; and

(c) surfaces and tools are properly decontaminated.

Safe Operation of Remote Control Afterloading Brachytherapy

32 (1) The quality control of the afterloader shall include tests to be performed at the beginning of each treatment day.

(2) The couplings and transfer tubes shall be checked for High Dose Rate and it has to be done before each treatment to ensure that there is nothing to prevent the source from moving as required.

Security of Sources

33 (1) Sources shall be kept secured so as to prevent theft or damage and to prevent any unauthorized use by ensuring that:

(a) control of a source shall not be relinquished without compliance with all relevant requirements specified in the licence and without immediate communication to the Authority, of information regarding any decontrolled, lost, stolen or missing source;

(b) a source shall not be transferred unless the receiver possesses a valid authorization; and

(c) a periodic inventory of movable sources shall be conducted at appropriate intervals to confirm that they are in their assigned locations and are secured.

(2) Specific provisions are required for avoiding loss of control in the

following situations:

(a) storage of sources before installation;

(b) temporary or permanent cessation of use;

(c) Storage after decommissioning whilst awaiting decision on source return or disposal;

(d) brachytherapy sources remaining in the patient, clothes, bed linen or treatment area.

(3) To comply with this requirement, the licensee shall develop procedures to ensure the safe transfer and movement of radioactive sources within the institution, and establish controls to prevent theft, loss, unauthorized withdrawal or damage of sources, or entrance of unauthorized personnel to the controlled areas.

(4) The licensee shall also ensure that the number of sources in a container when removing and when returning the sources is checked and that a physical inventory of all sealed sources is performed to confirm that they are present and secure in

their assigned locations.

(5) The licensee shall maintain a source movement log with a record indicating the date of removal, the name of the patient and the return of the source.

(6) Radiotherapy equipment shall be provided with safety systems capable of preventing their use by unauthorized personnel and a key should be required to energize the system, access to which shall be restricted to authorized staff only.

(7) (1) Any loss of source shall be reported immediately to the Radiation Safety Officer who shall report it to the Radiation Safety Committee and to the Radiation Protection Authority of Zimbabwe.

(2) All linen, dressing, clothing, equipment, and trash container shall be kept within the brachytherapy patient's room, until checks have been performed and documented that sources are not attached to them.

Part IV-Occupational Exposure

Responsibilities and Conditions of Service

34 (1) Licensees and employers of workers who are engaged in activities involving normal exposures or potential exposure shall be responsible for:

(a) the protection of workers from occupational exposure; and

(b) compliance with any other relevant requirements of the Act and any other regulations made thereunder.

(2) Employers who are also licensees shall have the responsibilities of both employers and licensees.

(3) Workers shall:

(a) follow any applicable rules and procedures for protection and safety specified by the employer or licensee:

(b) use properly the monitoring devices and the protective equipment and clothing provided:

(c) co-operate with the employer or licensee with respect to protection and safety and the operation of radiological health surveillance and dose assessment programmes:

(d) provide for the employer or licensee such information on their past and current work as is relevant to ensure effective and comprehensive protection and safety for themselves and others;

(e) abstain from any willful action that could put themselves or others in situations that contravene the requirements of the Act and

(f) accept such information, instruction and training concerning protection and safety as will enable them to conduct their work in accordance with the requirements of the Act and workers can by their own actions contribute to the protection and safety of themselves and others at work.

4 (1) If for any reason a worker is able to identify circumstances that could adversely affect compliance with the Act, the workers shall as soon as practicable report such circumstances to the employer or licensee.

(2) The management shall record any report received from a worker that identifies circumstances which could affect compliance with the Act, and shall take appropriate action.

(3) If workers are engaged in work that involves or could involve a source that is not under the control of their employer, the licensee responsible for the source and the employer shall co-operate by the exchange of information and otherwise as necessary to facilitate proper protective measures and safety provisions.

The Use of Dose Constraints in Radiotherapy

35. Dose constraints shall be used for optimizing protection in the planning stage for each radiation source and anticipated individual doses shall be compared with the appropriate dose constraints and only protective measures that predict doses below dose constraints shall be chosen.

Investigation Levels in Radiotherapy

36 (1) 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 that any such value is exceeded.

(2) The licensee shall conduct formal investigations, as required by the Authority:

(a) an individual effective dose exceeds 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 occurs that causes, or has the potential to cause, a dose in excess of regulatory limits; and

(d) any other event or unusual circumstance occurs that causes, or has the potential to cause, a dose in excess of the regulatory limits or the operational restrictions imposed on the installation e.g. the significant change in workload or operating conditions of radiotherapy equipment.

(3) The investigation shall be initiated as soon as possible following the event, and a report written concerning its cause, including determination or verification of any doses received, corrective actions, and instructions or recommendations to avoid recurrence.

(4)(1) The report shall be submitted to Authority and other concerned bodies as required, as soon as possible after the investigation, or as otherwise specified and kept for a specified period.

(2) In radiotherapy, a suitable quantity shall be used as investigation level e.g. the monthly effective dose or the dose to the hands for staff in manual brachytherapy

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Pregnant Workers

37 (1) A female worker shall, on becoming aware that she is pregnant, notify the employer in order that her working conditions may be modified where 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.

Classification of Areas

38 (1) Areas in a radiotherapy practice shall be classified as controlled or supervised or public.

(2) In radiotherapy practice, areas requiring specific protection measures shall be designated "controlled areas" and these shall include, at least, all irradiation rooms for external beam therapy and remote afterloading brachytherapy, operating rooms during brachytherapy procedures using real sources, brachytherapy patient rooms, radioactive source storage and handling areas.

(3) Controlled areas shall be demarcated by physical boundaries like walls or other physical barriers marked and identified with 'radiation area' signs.

(4)Areas surrounding brachytherapy patients rooms or around radioactive source storage and handling areas shall be designated " *supervised"* areas.

(5) All areas not designated as controlled nor supervised areas shall be such that persons inside are afforded the same level of protection as members of the public

Local Rules and Supervision

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

(a) establish in writing such local rules and procedures as are 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 and the protective measures and safety provisions known to those workers to whom they apply and to other persons who may be affected by them;

(d) ensure that any work involving occupational exposure be adequately supervised and take all reasonable steps to ensure that the rules, procedures, protective measures and safety provisions be observed; and

(e) where the Authority requires, designate a radiation safety officer.

(2) Employers, in co-operation with licensees, shall:

(a) provide to all workers adequate information on the health risks due to their

occupational exposure, whether normal exposure or potential exposure, adequate instruction and training on protection and safety, and adequate information on the significance for protection and safety of their actions;

(b) provide to female workers who are liable to enter controlled areas or supervised areas appropriate information on:

(i) the risk to the embryo or foetus due to exposure of a pregnant woman;

(ii) the importance for a female worker of notifying her employer as soon as she suspects that she is pregnant:

(c) provide to those workers who could be affected by an emergency plan appropriate information, instruction and training; and

(d) keep records of the training provided to individual workers.

Protective Equipment and Tools

40. Licensees shall ensure that workers are provided with suitable and adequate personal protective equipment, which meets any relevant regulations or standards and details of suitable equipment such as shielded L-block, lead glass, handling devices.

Individual Exposure Monitoring

41 (1). The employer of any worker, as well as self-employed individuals, and licensees shall be responsible for arranging for the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that adequate arrangements are made with appropriate dosimetry service provider accredited by the Authority under an adequate quality assurance programme.

(2) For any worker who is normally employed in a controlled area, or who occasionally works in a controlled area and may receive significant occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and practicable. In cases where individual monitoring is inappropriate, inadequate or not feasible, the occupational exposure of the worker shall be assessed on the basis of the results of monitoring of the workplace and on information on the locations and durations of exposure of the worker.

(3) (1) These workers shall include radiation oncologists, qualified experts in radiotherapy physics, Radiation Safety Officer, radiotherapy technologists, source handlers, maintenance staff and any nursing or other staff who must spend time with patients who contain sources.

(2) For any worker who is regularly employed in a supervised area or who enters a controlled area only occasionally, individual monitoring shall not be required but the occupational exposure of the worker shall be assessed and this assessment shall be on the basis of the results of monitoring of the workplace or individual monitoring.

(3) The exchange of dosimeters in a radiotherapy department and receipt of the dose reports shall not exceed a period of one month.

(4) If an individual’s dosimeter is lost, the licensee shall perform and document an

evaluation of the dose the individual received and add it to the worker's dose record.

(5) Individual monitoring devices shall be calibrated and this calibration shall be traceable to a standards dosimetry laboratory.

Investigation and Follow-up

42 (1). The licensee shall conduct formal investigations, as required by the Authority, whenever:

(a) the individual annual effective dose exceeds investigation levels:

(b) any of the operational parameters subject to periodic quality control are out of the normal range established for operational conditions:

(c) any equipment failure, or error takes place, which causes, or has the potential to cause an accident, and

(d) any other change or unusual circumstance that may cause an increase in dose, exceeding dose limits or the operational restrictions imposed on the installation.

(2) (a) The investigation shall be initiated as soon as possible following the event, and a written report shall be prepared concerning its cause, including determination or verification of any doses received, corrective or mitigating actions, and instructions or recommendations to avoid recurrence.

(c) The report shall be submitted to the Authority and other concerned bodies as soon as possible.

Monitoring The Workplace

43 (1) Licensees shall develop programmes for monitoring the workplace.

(2) The nature and frequency of monitoring of workplaces shall be sufficient:

(a) be sufficient to enable:

(i) evaluation of the radiological conditions in all workplaces:

(ii) exposure assessment in controlled areas and supervised areas; and

(iii) review of the classification of controlled and supervised areas; and

(b) depend on the levels of ambient dose equivalent and activity concentration, including their expected fluctuations and the likelihood and magnitude of potential exposures.

(3) (1) The programmes for monitoring of the workplace shall specify:

(a) the quantities to be measured:

(b) when and where the measurements are to be made and at what frequency:

(c) the most appropriate measurement methods and procedures; and

(d) reference levels and the actions to be taken if they are exceeded.

(2) Initial monitoring shall be conducted immediately after the installation of new radiotherapy equipment and after the replacement of teletherapy sources and

remote-controlled brachytherapy sources and shall initial monitoring shall include measurements of radiation leakage from equipment within acceptance tests and area monitoring of occupable space around irradiation rooms.

(3) Initial monitoring of packages containing radioactive sources, upon receipt by the licensee, shall be performed and shall include both surveys for removable contamination and external radiation levels.

(4) Periodic monitoring shall be conducted in association with brachytherapy procedures and as soon as practicable after implantation of the sources, a survey shall be made of exposure rates in the vicinity of the patient and the transport container shall be surveyed before and after brachytherapy procedures.

(5). After removal of brachytherapy sources from a patient, a survey shall be performed to confirm removal from the patient and return to shielding of all sources and periodic monitoring of the source storage and handling area shall be conducted with a survey meter immediately following the removal from or return to storage of brachytherapy sources.

6 (1) Continuous monitoring of exposure levels shall be conducted through the use of area monitors in teletherapy and high dose-rate treatment rooms and continuous monitoring with an area monitor shall be conducted in source storage and handling areas.

(2) All survey meters used for workplace monitoring shall be calibrated and this calibration shall be traceable to a standards dosimetry laboratory.

Protection of Workers in Intervention

44. Although dose limits for practices do not apply to interventions, the exposure of workers in interventions shall not be considered an unexpected exposure but rather it is deliberate and controlled and the dose limits for workers shall apply unless there is an overriding reason not to apply them, such as the need to save life after an accident or to prevent catastrophic conditions.

Health Surveillance

45 (1). The licensee shall make arrangements to provide medical surveillance for workers as specified by the Authority to assess the initial and continuing fitness of employees for their intended tasks and health surveillance programmes shall be based on the general principles of occupational health.

(2)The Licensee shall make arrangements for counseling of workers who have or may have been exposed substantially in excess of dose limits, and workers who may be worried about their radiation exposure.

Records

46 (1) Employers and licensees shall maintain and preserve exposure records for each worker and the exposure records shall include information on the general nature of the work involving occupational exposure; information on doses, and the data upon which the dose assessments have been based.

(2) Where a worker is or has been occupationally exposed while in the

employment of more than one employer, information on the dates of employment with each employer and the doses, exposures and intakes in each such employment; and records of any doses due to emergency interventions or accidents, shall be distinguished from doses, during normal work.

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

Part V-Medical Exposure

Responsibilities

47 (1) The licensees shall with regard to responsibilities for medical exposure ensure that:

(a) no patient be administered a therapeutic medical exposure unless the exposure is prescribe d by a medical practitioner;

(b) medical practitioners shall 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 shall be available as needed and shall either be health professionals or have appropriate training adequately to discharge assigned tasks in the conduct of the therapeutic procedure that the medical practitioner prescribes; and

(d) for therapeutic uses of radiation the calibration, dosimetry and quality assurance requirements of the Act be conducted by or under the supervision of a qualified expert in radiotherapy physics.

(2) All persons involved in delivery of medical exposure shall:

(a) follow the applicable rules and procedures for the protection and safety of patients, as specified by the licensee; and

(b) be aware that prescription of treatment and treatment plan need to be authorized by the medical practitioner prior to initiation of treatment.

(3) The licensee shall ensure that:

(a) the exposure of individuals incurred knowingly while voluntarily helping in the care, support or comfort of patients undergoing medical diagnosis or treatment be constrained as specified ;

(b) the training criteria shall be specified or be subject to approval, as appropriate by the Authority in consultation with relevant professional bodies.

(4). Medical practitioners shall promptly inform the licensee of any deficiencies or needs regarding compliance with the Act and these regulations in respect of protection and safety of patients and shall take such actions as may be appropriate to ensure the protection and safety of patients.

Justification

48 (1) Medical exposures shall be justified by weighting the therapeutic 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 licensee shall ensure that medical practitioners follow a justification procedure that is documented and signed and the medical practitioner shall consider the efficacy, benefits and risks of alternative treatment modalities, e.g., surgery and chemotherapy, either alone or in combination with radiation therapy.

(3). In respect of medical research, the exposure of humans for medical research is deemed not justified 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 Organisation; and

(b) subject to the advice of an Ethical Review Committee or any other institutional body assigned similar functions by the Ministry of Health and to applicable national and local regulations.

(4). Exposure to comforters shall be in accordance with the dose constraints formalized in the Regulations and they shall be provided with instruction on actions to take to limit their exposure while visiting or caring for a patient who has received a brachytherapy implant.

Optimization

49 (1). Licensees of radiotherapy practices shall ensure that:

(a) exposure of normal tissue during radiotherapy be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume, and organ shielding be used where practicable and appropriate.

(b) radiotherapy procedures causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant shall be avoided unless there are strong clinical indications:

(c) any therapeutic procedure for pregnant women shall be planned to deliver the minimum dose to any embryo or foetus; and

(d) the patient shall be informed of possible risks and shall sign a consent form.

(2). The licensee shall provide written instructions on actions to take to reduce exposure to comforters, caregivers and members of the public from sources in brachytherapy patients with permanent implants and these instructions shall include minimizing prolonged contact with children and potentially pregnant women, and procedures to follow in the event that a source becomes dislodged.

Calibration

50 (1). Licensees shall ensure that:

(a) the calibration of sources used for medical exposure shall be traceable to a Standards dosimetry laboratory;

(b) radiotherapy equipment shall be calibrated in terms of radiation quality or

energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions, e.g. following the recommendations given in relevant International Atomic Energy Agency (IAEA) Technical Reports Series:

(c) sealed sources used for brachytherapy shall be calibrated in terms of activity, reference air kerma rate in air or absorbed dose rate in a specified medium, at a specified distance, for a specified reference date; and

(d) the calibrations shall be carried out at the time of commissioning a unit, after any maintenance procedure that may have an effect on the dosimetry and at intervals approved by the Authority.

(2). The licensee shall ensure that all teletherapy equipment outputs are compared at least once every two years in a national, regional or international programme for independent dose verification, such as the Thermo Luminescence Dosimetry (TLD) postal service established by the International Atomic Energy Agency/ World Health Organisation.

(3) (a)The licensee shall develop or adopt, implement, and follow a protocol for calibration of radiation sources used for radiotherapy.

(b) Calibration of new equipment and new radiation sources shall be done independently by at least two different qualified experts in radiotherapy physics and preferably using different dosimetry systems and the results shall be compared only after the completion of both measurements.

(4) New brachytherapy sources shall be calibrated and an investigation shall be conducted where the measurement varies by more than 5% from the manufacturer's certified activity or kerma rate and the sources shall not be used for patient's treatment if the difference is greater than 10% until the difference is investigated and resolved.

(5) The responsibility for the investigation and for further action remains with the licensee, and the investigation is usually performed by the qualified expert in radiotherapy physics, with or without external help.

Clinical Dosimetry

51. Licencees shall ensure that the following items be determined and documented:

(a) for each patient treated with external beam radiotherapy equipment, the maximum and minimum absorbed doses to the planning target volume together with the absorbed dose to a relevant point such as the centre of the planning target volume, plus the dose to other relevant points selected by the medical practitioner prescribing the treatment:

(b) in brachytherapeutic treatments performed with sealed sources, the absorbed doses at selected relevant points in each patient; and

(c) in all radiotherapeutic treatment, the absorbed doses to relevant organs.

Quality Assurance for Medical Exposures

52(1). Licensees, in addition to applying the relevant requirements for quality assurance specified in the Act, shall establish a comprehensive quality assurance

programme for medical exposures with the participation of appropriate qualified experts in the relevant fields, such as radiophysics or radiopharmacy, taking into account the principles established by the World Health Organisation and the Pan American Health Organisation.

(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; and

(e) as far as possible, regular and independent quality audit reviews of the quality assurance programme for radiotherapy procedures.

(3) Following the acceptance of new radiotherapy equipment, sufficient data shall be measured at the commissioning to be used for clinical dosimetry in treatment planning and this data shall be clearly documented in the work book and before being issued for use in treatment planning, the documentation shall be independently verified, signed and dated.

(4) All dosimetry calibrations, clinical dosimetry data and methods of calculation for therapy equipment shall be reconfirmed at regular intervals and the measurements and checks carried out for this purpose shall be sufficiently comprehensive to detect any significant variations from the data in use.

(5) For imaging modalities used for anatomical information and for quantitative purposes in treatment planning computer systems, measurements shall be made by the qualified expert in radiotherapy physics or to determine the required physical data and the size of errors due to instrument distortions and corrections shall be made for significant errors.

(6). Verification of the treatment through “in vivo” dosimetry shall be performed and total dose to the tumor shall be estimated and compared with prescribed dose.

Discharge of Patients

53 (1). In order to restrict the exposure of any members of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and members of the public, such a patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below the level specified in the third schedule of the Zimbabwe Radiation Protection (Safety and Security of radioactive sources) Regulations.

(2) Written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection and safety shall be provided where necessary.

Investigation of Accidental Medical Exposure

54 (1). Licensees shall promptly investigate any of the following incidents:

(a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects; and

(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) Licencees shall, with respect to any investigation required by these regulations:

(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 (regulation 54 (2) paragraph a-c, as relevant, and any other information required by the Authority; and

(e) inform the patient and his or her doctor about the incident.

Part VI-Public Exposure

Responsibilities

55 (1). The location of radiotherapy centers shall be sited in a way so as to ensure public protection;

(a) Radiotherapy centers requiring the use of sealed or unsealed sources shall not be located in residential areas.

(2).The licensee is responsible for controlling public exposure resulting from a radiotherapy practice.

(3) Access by members of the public to areas in and near the radiotherapy department shall be considered when designing shielding of storage and use of facilities.

(4). The licensee shall:

(a) develop and implement use, transport and storage measures for ensuring the safety and security of radiotherapy sources to control public exposures in accordance with the requirements of the Authority; and

(b) control and maintain constant surveillance of sources that is not in storage and secure stored sources from unauthorized access, removal, or use, and the storage facility shall be locked at all times.

Access Control for Visitors

56. The licensee shall make arrangements to control access of members of the public to radiotherapy irradiation rooms, and provide adequate information and instruction to the public before they enter a controlled area so as to ensure appropriate protection (of members of the public and shall be accompanied).

Radioactive Waste and Sources no Longer in Use

57 (1) The licensee shall notify the Authority and submit a plan for transfer or disposal of sources if they are no longer in use.

(2) The licensee shall be responsible for the sources until the time of their transfer to another appropriate licensee or to an authorized waste disposal facility and in particular, the licensee shall:

(a) notify the Authority of any intention to transfer or decommission ^{60}Co teletherapy equipment prior to initiating any action and depleted uranium used as shielding material shall also be treated as radioactive waste. e g , a ^{60}Co teletherapy head may contain depleted uranium and shall be disposed of appropriately; and

(c) ensure that resources for the disposal of the sources are made available where the teletherapy equipment is to be decommissioned.

Monitoring of Public Exposure

58 (1) The licensee shall, as appropriate :

(a) establish and carry out a monitoring programme sufficient to ensure that the requirements of the Act and any other regulations regarding public exposure to sources of external irradiation be 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 radiotherapy shall include dose assessment in and the surrounding of irradiation rooms for external beam therapy, of brachytherapy wards and source storage, preparation room and waiting rooms.

Part VII- Potential Exposure, Mitigation and Emergency Plans

Potential Exposure: Safety Assessment

59 (1) Licensees shall prepare a safety assessment applied to all stages of design, construction, operation, maintenance and decommissioning of the radiotherapy facility, and submit it to the Authority.

(2) The assessment shall be systematic and contain information on identification of

possible events leading to accidental exposure.

(3) The safety assessment shall not only cover these events, but also aim at anticipating other events that have not previously been reported.

(4) The safety assessment shall be documented and revised by an independent expert where:

(a) modification of the radiation sources or its facilities are made

(b) operational experience or information on accidents or errors indicates that the safety assessment shall be reviewed; and

(c) techniques are modified in such a way that safety may be compromised.

Accident Prevention

60 (1) The licensees in safety procedures shall incorporate:

(a) defence-in-depth measures to cope with identified events, and evaluate the reliability of the safety systems.

(b) the operational experience and lessons learned from accidents and errors into training, maintenance and quality assurance programmes.

(2) the licensee shall promptly inform the Authority of all reportable events.

Mitigation: Emergency Plans

61 (1) Based on the events identified by the safety assessment, the licensee shall elaborate mitigation measures embodied in a set of emergency procedures and the relevant staff shall be trained in the mitigation measures, which shall be periodically rehearsed and the lessons learned from the rehearsals shall be used to review and update the emergency plans.

(2) The procedures shall identify the responsibilities of individuals and shall be concise, unambiguous and posted visibly in places where they could be needed.

(3) In cases where the beam control mechanism has failed to terminate the exposure at the end of the pre-set time, the procedure shall include the removal of the patient while avoiding exposure to the direct beam.

(4). A medical practitioner and medical physicist or competent staff specifically trained to remove the catheters and carry out the emergency procedures without delay shall be permanently present during High Dose Rate procedures and emergency equipment to retract the source to a fully shielded position shall also be available.

(5). Emergencies during source change shall be carried out only by maintenance staff trained and authorized for the tasks and if participation of the radiotherapy staff is necessary for any of these actions, the scope of this participation shall be restricted to the operation of the control panel and the responsibilities shall be clearly defined.

Part VIII- Safety in the Transport of Radioactive Materials

Safety Transportation of Radioactive Materials

62 (1) The licensee shall comply with the requirements of the Act, Regulations for the Transportation of Radioactive Sources and the International Atomic Energy Agency TS-R-1 for all activities involving transport of radioactive sources and that of.

(2) In the case of radiotherapy, the requirements apply to external beam radioactive sources and to Brachytherapy sources.

Receipt of Radioactive Materials

63 (1). Prior to each shipment of radioactive material to be dispatched, the licensee or the person responsible for the transport shall make the necessary arrangements with the source supplier, to receive the relevant information and the information shall include the following for each package or container:

(a) the nuclide, number and activity of sources:

(b) A description of the source construction and performance tests, including leakage tests:

(c) special form approval certificate where necessary.

(d) a description of the package:

(e) approval certificate for Type A or B packages, or statement of compliance with IAEA TS-R–1 for other packages.

(f) details of any special arrangements required, including multilateral approvals, where necessary; and

(g) a copy of the transport documents to be sent to the licensee by fax or e-mail before dispatch where necessary.

(2). The licensee shall not agree to the dispatch of the consignment by the supplier unless all the requirements of these regulations are satisfied and the supplier and licensee shall agree on the transport route and responsibility for each stage of the journey.

(3). Arrangements shall also be made for the following where necessary:

(a) the need for special handling equipment for external beam sources, e.g., cranes, forklift trucks etc. during transfer from one mode of transport to another, or between vehicles.

(b) checking of radiation dose rates from the package or container.

(c) checking the correct transport labels as attached to the package or container, and replacing any that are damaged or illegible:

(d) ensuring that the package or container is securely attached to the vehicle and that the vehicle is correctly labeled:

(e) dealing with border controls; and

(f) security of the consignment during transport, particularly during delays or

overnight stops.

Dispatch of Radioactive Materials

64. The licensee shall return packages or containers to the source supplier after receipt of a consignment of radioactive material.

Empty Packages

65. The licenses shall with regard to returning of empty packages;

(a) carry out dose rate and contamination monitoring of both the inside and outside of the package or container to ensure that there is no residual radioactive material present and it can therefore be treated as an empty package or container:

(b) remove or cover all transport labels relating to the sources contained in the package or container when received:

(c) examine the package or container to ensure that it is in good condition, and then close it securely, referring to any procedures provided by the source supplier:

(d) attach a label to the outside of the package or container stating "UN 2908 RADIOACTIVE MATERIAL EXCEPTED PACKAGE — EMPTY PACKAGING":

(e) complete a transport document:

(f) contact the source supplier and agree the transport route and responsibility for each stage of the journey and inform the source supplier of the proposed date of dispatch.

Return of Disused Sources

66 (1). The licenses shall with regard to returning disused sources provide the following information to the consignee for each package or container:

(a) the nuclide, number and activity of sources:

(b) a description of the source construction including leakage tests:

(c) special form approval certificate where necessary.

(d) a description of the packaging in which the source is to be transported:

(e) approval certificate for Type B package, or statement of compliance with International Atomic Energy Agency TS-R–1 for other packages where necessary.

(f) details of any special arrangements required, including multilateral approvals, where necessary; and

(g) a copy of the transport documents to be sent to the consignee by fax or e-mail before dispatch where necessary.

(2). The licensee shall not dispatch the consignment unless they have received

confirmation from the consignee that they are prepared to accept the consignment.

(3). The licensee and consignee shall agree on the transport route and responsibility for each stage of the journey and the Licensee will normally be responsible for dispatch until the consignment reaches the consignee's premises.

(4) Other arrangements are satisfactory provided they are agreed in advance by both parties and are also acceptable to the Authority and other regulatory authorities involved.

(5) The licensee shall in order to prepare the consignment for dispatch:

(a) load the sources into the package, verifying the details to be provided to the consignee e.g., serial numbers and comparable information to be entered on the transport document:

(b) close it securely and then examine the package or container to ensure that it is in good condition, referring to any procedures provided by the source supplier:

(d) carry out contamination monitoring of the outside of the package or container to ensure that there is no residual radioactive material present and it is therefore suitable for transport:

(e) carry out dose rate monitoring of the package or container and attach appropriate transport labels.

(f) refrain from using the transport labels relating to the sources contained in the package or container when received.

(g) complete transport document.

(h) arrangements shall also be made for the following where necessary:

(i) specify the need for special handling equipment e.g., cranes, forklift trucks etc. during transfer from one mode of transport to another, or between vehicles:

(ii) ensure that the package is securely attached to the vehicle and that the vehicle is correctly labelled.:

(iii) deal with border controls; and

(iv) provide security of the consignment during transport, particularly during delays or overnight stops.

Part IX- Offences, Penalties and Appeals

Offences

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

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

69. The Authority shall impose penalties such as suspension, revocation of authorization, imposing administrative fine or closure of facility or any

combination of these.

70. Any person or body corporate who, being a holder of authorization 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 14 for an individual and not exceeding Level 14 for a corporate body or be given a jail term not exceeding ten years or both.

Appeal

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

SCHEDULE I: DOSE LIMITS FOR OCCUPATIONAL AND PUBLIC EXPOSURE

OCCUPATIONAL EXPOSURE

Dose limits

I-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.

I-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

I-3. When, in special circumstances, a temporary change in the dose limitation requirements is approved pursuant to Act:

(a) the dose averaging period mentioned in para. (I.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

I-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

I-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.