Radiation Protection Authority

Zambia

SAFETY GUIDE

RPA SG 10

Radiation Therapy

2024

NOTICE OF APPROVAL

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

The Radiation Protection Authority Board (RPAB), has on the 29./.07./2024

approved the safety guide on Radiotherapy.

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

This guide comes into effect on 29./..07./2024

Mrs. Christabel Ngongola Reinke

.....

BOARD CHAIRPERSON

Radiation Protection Authority Board

Dr. Boster Dearson Siwila, PhD

.....

EXECUTIVE DIRECTOR

Radiation Protection Authority

TABLE OF CONTENT

FOREWORD

The safety guide is intended for both regulators and users of radiation sources in Radiotherapy. Regulators may use it for reviewing applications for authorisation and during the inspection of facilities. Licensees should follow the guidance to comply with requirements of the regulations in radiation therapy.

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

PREFACE

Radiation Protection Authority (RPA) was established by the Ionising Radiation Protection Act No. 16 of 2005 and the statutory instrument No. 98 of 2011(The Ionising Radiation (General) Regulations, 2011). The structure of the implementation of the protection and safety was established to be compatible with the International Basic Safety Standards.

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

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

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

Abbreviation	Definition
CIOMS	Council for International Organizations of Medical Sciences
CT	Computed Tomography
HDR	High Dose Rate
HIS	Hospital Information System
HT	The equivalent dose in tissue T
IAEA	International Atomic Energy Agency
ICRU	International Commission on Radiation Units and Measurements
IEC	International Electrotechnical Commission
IGRT	Image Guided Radiation Therapy
IMRT	Intensity Modulated Radiation Therapy
IORT	Intraoperative Radiotherapy
ISO	International Organization for Standardization
IT	Information and Technology
LDR	Low Dose Rate
LINAC	Linear Accelerator
MRI	Magnetic Resonance Imaging
MV	Megavoltage
PACS	Picture Archiving and Communication System
PDR	Pulsed Dose Rate
PET	Positron Emission Tomography
QA	Quality Assurance
RIS	Radiology Information System
ROSEIS	Radiation Oncology Safety Education and Information System
RPA	Radiation Protection Authority
RPAB	Radiation Protection Authority Board
RPO	Radiation Protection Officer
SAFRON	Safety in Radiation Oncology
SBRT	Stereotactic Body Radiotherapy
SG	Safety Guide
SRS	SRS stereotactic radiosurgery
SRT	Stereotactic Radiotherapy
TPS	Treatment Planning System
WHO	World health Organization
WR	The radiation weighting factor for radiation type R
WT	The tissue weighting factor for tissue T

1.0 INTRODUCTION

1.1 General

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

Radiation exposure to patients, staff members, public and the environment in Radiation Therapy (also known as Radiotherapy) practice may occur during administration of radiotherapy for therapeutic and research procedures. Radiotherapy is described as a mode of treatment that uses high doses of radiation to kill cancer cells and shrink tumours.

However, stochastic, or deterministic effects may result from such exposure as well as the failure to safely use ionizing radiation. Therefore, there is need for a comprehensive legal and operational framework for the control of the widespread use of ionizing radiation and radiation sources leading to radiation exposures while allowing their benefits.

This Safety Guide is applicable to all the established uses of ionising radiation sources employed in the practice of radiotherapy to the facilities where the sources are located and used, and to the individuals involved. The Safety Guide covers occupational, public, medical, potential, and emergency exposure situations.
This Safety Guide can also be used to set an appropriate Radiation Protection Program for Radiation oncology in accordance with the requirements of the Act.

1.2 Objective

The objective of this Safety Guide is to provide guidance on the appropriate and consistent application of requirements in Radiation Therapy facility, by legal persons responsible for the Radiotherapy practice.

2.0 RADIATION PROTECTION AND MANAGEMENT

2.1 Organization and Responsibilities

The facility should ensure to:

2.1.1. Assign clear subsidiary responsibilities to personnel such as medical practitioners, Clinically Qualified medical physicist, radiotherapy technologists, radiotherapist, radiation protection officers and other health professionals so that adequate radiation protection of patients, workers, and the public is ensured.

2.1.2 Determine the need for qualified experts, their responsibilities defined, and suitable people appointed on either a full-time or part-time basis.

2.1.3 Establish a radiation protection and safety program and provide the necessary resources to comply with this program.

2.1.4 The radiation protection program should:

2.1.4.1 Relate to all phases of the practice, from design through operation to decommissioning.

2.1.4.2 Reflect management responsibility for radiation protection and safety through management structure, policies, procedures, and organizational arrangements that are commensurate with the risks.

2.1.5 Appoint a Radiation Protection Officer (RPO) who should have sufficient authority to stop any unsafe practice and to communicate with management regarding compliance with regulations.

2.1.6 A radiation protection committee comprising Radiation oncologists, Medical Physicists, Radiation protection officer and Radiation therapists should be formed to:

2.1.6.1 Co-ordinate and review the radiation protection program and quality assurance procedures: or

2.1.6.2 Cover other practices using ionizing radiation in the hospital.

2.2 Quality Assurance

The facility should ensure that:

2.2.1 A comprehensive quality assurance (QA) programme for radiation protection and safety to ensure that all necessary procedures

are developed and implemented to comply with the regulations for radiation protection within the terms and conditions of the licence(s).

2.3 Human Factors

2.3.1 The facility should make provisions for reducing as far as practicable the contribution of human error to accidents and other events that could give rise to exposures.

2.4 Staffing

The facility should ensure to

2.4.1 Appoint sufficient core radiotherapy professionals, with appropriate accreditation for the tasks to ensure that all activities relevant to protection and safety are carried out in accordance with regulations and this regulatory guidance.

2.4.2 The number of persons should be kept under review, especially as workload increases, or new techniques and new equipment are incorporated.

3.0 SAFETY OF MEDICAL RADIATION FACILITIES, MEDICAL IMAGING AND RADIOTHERAPY EQUIPMENT

3.1 Location and Site

The facility should ensure that:

3.1.1 Location is on a site that gives ready access for inpatients and outpatients, and that at the same time makes fulfilling radiation protection requirements.

3.1.2 They consider the following when locating a new radiation therapy facility, Operational efficiency, initial cost, as well as provision for future

expansion, the need for replacement of units with higher energy units and future increases in workload.

3.1.3 The site, the surrounding environment be considered. This includes the presence of, and implications for, adjacent residential or industrial areas, and the level of public access to, and use of, the area.

3.1.4 When considering expansion of an existing facility, consideration be given to the areas besides, above and below the proposed expansion site.

3.1.5 For physical security purposes, radioactive sources should be in areas where access by members of the public is restricted.

3.1.6 Guidance on the location and site of radiation therapy facilities given in international and national standards is followed.

3.2 Design of Rooms Within the Radiation Therapy Facility

3.2.1 General Considerations

The facility should ensure that:

3.2.1.1 They have the following basic functional areas which include:

a. reception area,
b. clinical consulting areas,
c. treatment planning,
d. external beam radiation therapy and or brachytherapy areas,
e. imaging for Brachytherapy
f. treatment simulation for external beam
g. treatment control
h. Patient waiting area.
i. Patient changing cubicles.

3.2.1.2 The functional areas can include but not limited to the following rooms/areas.

a. mould preparation
b. patient examination,
c. public waiting rooms,
d. operating theatres,
e. source storage
f. preparation rooms.
g. Radiotherapy workshop

h. 3.2.1.18 dosimetry store

i. 3.2.1.19 server room

3.2.1.3 Provision for the incorporation of radiation protection and safety features into these areas and rooms be made at the facility design stage.

3.2.1.4 The layout considers workload and staff and patient flow, both within the radiation therapy facility and, in cases where the radiation therapy facility is part of a larger hospital or medical centre, within other departments of the facility.

3.2.1.5 Wherever possible, treatment rooms be surrounded with rooms that have low or controlled occupancy.

3.2.1.6 Physical signage give information on where different areas are located and should designate hazardous areas; such signs should be preferably in both word and picture format. Colour coding of different areas is also very helpful.

3.2.1.7 The three factors relevant to dose reduction for workers and the public (time, distance and shielding) be combined in the design to optimise occupational exposure and public exposure.

3.2.1.8 Access to the radiation therapy facility and its treatment, imaging, consultation, and patient preparation rooms be considered. This includes provision for the delivery of equipment and for ease of access for patients undergoing clinical assessment and daily treatment. Patients may arrive in wheelchairs or on trolleys or beds.

3.2.1.9 make provision for safety systems or devices associated with the equipment and rooms. This includes ventilation systems, electrical wiring relating to emergency off switches, and standby lighting, safety interlocks and warning signs and signals.

3.2.1.10 A reliable and stable power supply be available for all equipment and IT systems.

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

3.2.1.12 Servers be programmed to shut down automatically when the power supply is interrupted. Diesel power generators could be used to run

systems that are controlled only by timers, such as in the case of 60Co teletherapy units.

3.2.1.13 The design of the facility includes an air conditioning system sufficient to maintain the temperature in the treatment room within the parameters defined by the equipment manufacturers. In addition, a ventilation system with four to six air changes per hour is recommended to remove any ozone generated.

3.2.1.14 For external beam radiation therapy, lights in the treatment room be dimmable so that the alignment lasers and the field defining lights can be seen easily to facilitate patient set-up.

3.2.1.15 The laser switching be controlled from a control panel or remote in the controlled area, but it is also useful to be able to switch the lasers off independently for quality control tests.

3.2.1.16 signs and warning lights be placed at the entrances of controlled areas to prevent inadvertent entry.

3.2.1.17 The warning light/sign be displayed at the entrance to the maze or treatment room.

3.2.1.18 The warning light/sign should be visible from any position outside These signs should be interlocked with the treatment unit control.

3.2.1.19 The illuminated radiation warning lights/sign may have two or three stages.

3.2.1.20 For a two-stage sign, the first stage will be illuminated when there is power to the treatment unit, and the second stage will illuminate when the beam or the source is on.

3.2.1.21 For a three-stage sign, stage one will be illuminated when there is power to the treatment unit, stage two will light when the treatment unit is programmed to deliver a radiation beam and stage three will illuminate when the beam or the source is on.

3.2.1.22 The warning lights flash when the beam is on. Other rooms that are also controlled areas, such as imaging, simulator, and source

storage rooms, should also have appropriate signs and/or warning lights.

3.2.1.23 Implement technical measures so that unauthorised access to sources can be detected in a timely fashion, including after working hours.

3.2.1.24 Technical measures be independent of any interlocks that terminate the radiation beam during normal operation. Such measures could include a video camera that provides continuous remote surveillance and recording of the device, a photoelectric beam or motion detector system installed in the entrance maze and/or the treatment room, or a door interlock.

3.2.1.25 If these devices indicate the possible presence of an unauthorised person, an alarm should indicate this locally and remotely so that personnel can respond in a timely fashion.

3.2.1.26 Firefighting equipment should be available in all areas.

3.2.2 Treatment Rooms for High Energy External Beam Radiation Therapy and High Dose Rate (HDR) After Loading Brachytherapy.

The facility should ensure that:

3.2.2.1 External beam radiation therapy and brachytherapy be carried out within the facility in treatment rooms designed for that purpose.

3.2.2.2 A shielded treatment room is not shared between brachytherapy and external beam radiation therapy, as this can negatively influence procedure flow and efficiency.

3.2.2.3 The room be large enough to allow full extension and rotation of the couch in any direction, with sufficient space for staff to walk around it.

3.2.2.4 The design takes account of the need for larger treatment rooms to allow for specific procedures. For example, total body irradiation may require a larger treatment distance to one wall;

IORT procedures require additional support staff and equipment, and the room may need to be larger.

3.2.2.5 Care be taken when a new machine or unit is to be introduced into an existing treatment room or bunker. The room size and shielding specification should meet the minimum requirement for the equipment in the room. For instance, when introducing IMRT, changing from ^{60}Co to linac or installing a non-isocentric unit.

3.2.2.6 Some current or future equipment integrations, such as cobalt MRI/linear accelerator (LINAC), may have very particular requirements that should be considered in the room design to ensure both efficient and effective operation and radiation protection and safety.

3.2.2.7 The treatment and imaging room designs include an open access conduit for the control panel, monitoring, and dosimetry equipment cables. No conduit should run orthogonally through a radiation barrier; it could either run at an angle through the barrier or have one or more bends in it so that the total length of the duct is greater than the thickness of the radiation barrier.

3.2.2.8 Entrance to the treatment room is through a shielded door or a maze or a combination of both. A maze reduces the need for a heavy shielded door and provides a route for ventilation ducts and electrical conduits without compromising the shielding.

3.2.2.9 Access to the treatment room is furnished with a visible signal indicating whether the radiation source is on or off. An interlock barrier to prevent unauthorised access should be provided. This could include a light beam or a physical barrier such as a gate or door.

3.2.2.10 The design be such that access to the treatment (and imaging) rooms should be always visible to the operators. Furthermore, the

controls should be installed in such a way that access to the treatment room is always monitored.

3.2.2.11 A safety system, such as a 'last person out button', be in place to ensure that all staff have left the room prior to the commencement of treatment.

3.2.2.12 Emergency off switches be conveniently placed inside the treatment room, in addition to those on the control panel and the equipment itself, to allow interruption of the irradiation from inside the treatment room. These switches should be positioned to avoid having to cross the primary beam when activating them and to avoid any accidental actuation.

3.2.2.13 Adequate systems, audio visual devices or other means be provided to allow staff to have communication with, and a clear and full view of, the patient. Oral communication from the control panel should be possible with the patient in the treatment (and imaging) room using an intercom or other communication system.

3.2.2.14 A powered fail-safe radiation monitor (audio visual) be visible upon entering the room.

3.2.2.15 Provision be made in each treatment room to enable the safe removal of the patient in the event of a power outage (e.g., availability of flashlights or torches). This also means that manual operation of heavy doors should be possible.

3.2.2.16 Enclosed patient changing cubicles should not be located within the treatment room or directly in front of the maze.

3.2.3 Storage and Preparation Rooms for Manual and Low Dose Rate (LDR) Brachytherapy

The Facility should ensure that:

3.2.3.1 The room has a lockable door to control access and to maintain source security.

3.2.3.2 There is a shielded storage (e.g., a safe) for all sources, the outer surface of which should be made of fireproof materials. The safe should be located near the preparation workbench to reduce any

exposure of personnel during the handling and transfer of sources.

3.2.3.3 The safe has compartments for sources of different activities. Each compartment should be marked to permit immediate and easy identification of its contents from the outside with a minimum of exposure.

3.2.3.4 Sources be readily identifiable by sight. When radioactive sources of the same appearance but of different activities or activity distribution are used, they should be distinguishable (e.g., by different coloured threads or beads).

3.2.3.5 The workbench should be provided with L-block shielding, and with a lead glass viewing window and a magnifying glass.

3.2.3.6 The work surface for source preparation should be smooth and seamless to avoid losing small sources such as 192-Ir wire fragments or small 125-I seeds.

3.2.3.7 The source handling area should be well illuminated and a magnifying glass in a fixed mounting should be available for viewing to handle sources efficiently and with a minimum of radiation exposure.

3.2.3.8 Devices for handling sources, typically forceps, should be available. They should be as long as practicable, compatible with efficient source handling. A device should be provided for threading sources expeditiously with the fingers protected by distance.

3.2.3.9 The source storage and preparation laboratory should have a sink with a filter or trap to prevent sources being lost into the sewerage system.

3.2.3.10 There is a clear indication of the radiation level in terms of ambient dose equivalent. This be provided either by a radiation monitor that is visible on entering the room and during any

handling of the unshielded sources, or by a survey meter that is available and in use during source handling.

3.2.3.11 Hand carried transport containers be provided with long handles. The lid of the container should be securely fastened to prevent tipping and dropping of sources during transport. Containers should bear the radiation symbol as well as a warning sign.

3.2.3.12 Space is available for trolleys for transporting sources.

3.2.4 Patient Rooms for Manual and LDR Brachytherapy

The facility should ensure that:

3.2.4.1 Where possible patients' rooms be single and adjacent to one another. Where this is not possible, appropriate shielding between patients is necessary to minimize to the external exposure from other patients in the room. Within patients' rooms, movable shielding for the nurses and potential visitors should be provided whenever possible.

3.2.4.2 The treatment room contains a shielded storage container, large enough to accept the applicators if necessary, and a remote handling tool (forceps) for use in the event of a dislodged source.

3.2.4.3 An area radiation monitor is placed at the entrance to detect when a source or a patient with a source is leaving the room or the controlled area.

3.2.4.4 After the treatment no source remains within the patient, clothes, or bed linen, or anywhere in the area, a portable monitor should be available for monitoring these items.

3.2.5 Imaging and Other Non-Treatment Rooms

The facility should ensure that:

3.2.5.1 Patient preparation and imaging areas where radiation is used, such as simulator rooms (i.e., CT, PET–CT and conventional simulators), together with their console areas and patient changing areas, should be designed to ensure that the requirements for occupational protection and protection of the public are met as guided in the international (NCRP147, IAEA).

Refer to the Nuclear Medicine, Diagnostic and Interventional Radiology Safety Guide.

3.2.6 Shielding Considerations

The facility should ensure that:

3.2.6.1 The nominal design dose in occupied areas is derived by the process of constrained optimization (i.e., selection of a source related dose constraint), with the condition that the individual doses from all relevant sources be well below the dose limits for the persons occupying the area to be shielded.

3.2.6.2 An annual effective dose limit of 20 millisieverts (mSv) averaged over five consecutive years, with no single year exceeding 50 mSv is considered for occupational exposed worker and at 1 mSv for the public dose limit.

3.2.6.3 Care should be taken to avoid unrealistic estimations of the shielding required. A balanced decision should be achieved and accumulation of overly conservative measures that may go beyond optimization should be avoided.

3.2.6.4 It is also advisable that the design includes consideration of possible future needs for new equipment and changes in practice or use, increased workloads, and changes in the occupancy of adjacent, above and below spaces.

3.2.6.5 The design and specification for the radiation shielding should be performed by a medical physicist or a qualified expert in radiation protection to ensure that the required level of occupational and public radiation protection is achieved.

3.2.6.6 The medical physicist or qualified expert in radiation protection should be involved from the very beginning because shielding requirements may influence decisions on where to site treatment and imaging rooms, and the type of building construction.

3.2.6.7 The medical physicist or qualified expert in radiation protection should be provided with all relevant information about the proposed medical Imaging and radiotherapy equipment and its

use, the type of building construction, and the occupancy of nearby areas.

3.2.6.8 The shielding assumptions and specifications should be documented and signed off by the medical physicist or qualified expert in radiation protection and all documentation, including calculations, should be archived for the lifetime of the facility.

3.2.6.9 It is a requirement to submit the final shielding specifications to the radiation protection authority for review prior to construction.

3.2.6.10 The shielding of the radiation treatment room is constructed in such a way that its integrity is not compromised by joints, by openings for ducts, pipes or other objects passing through the barriers, or by conduits, service boxes, or other structural elements embedded in the barriers.

3.2.6.11 The door to the treatment room and the design of the maze for high energy machines has adequate radiation protection without sacrificing operational efficiency.

3.2.6.12 The medical physicist or qualified expert in radiation protection should undertake site visits during construction to ensure that there has been, from the radiation protection and safety perspective, the correct positioning of the joins in the structure and to ensure that the concrete has been poured to avoid gaps or cracks in the shielding and either that the ducting does not go through the primary shielding or that it is not aligned with the primary beam. It is also advisable to check that the concrete density is adequate.

3.2.6.13 A final assessment of the adequacy of the shielding should be performed by the medical physicist or qualified expert in radiation protection after construction and installation of the equipment has been completed prior to clinical use. This may be achieved through a comprehensive radiation survey.

3.3 Medical Imaging and Radiotherapy Equipment, Software, And Ancillary Equipment

The facility should ensure that:

3.3.1 Specifications for procurement of Imaging and radiotherapy equipment, software and ancillary equipment should meet relevant international standards of the IEC 60601, IEC 61304 and ISO or equivalent national standards (if any).

3.3.2 Displays, gauges and instructions on operating consoles of medical Imaging and radiotherapy equipment and accompanying instruction and safety manuals should comply with IEC 60601, IEC 61304 and ISO standards and should be translated into the English language.

3.3.3 The software, either used in conjunction with medical Imaging and radiotherapy equipment or as part of treatment planning, should be designed so that it can be easily converted into the English language.

3.3.4 Procedures for procurement, installation, acceptance, commissioning, use, maintenance, Decommissioning and quality control of all equipment (hardware and software) should be developed with the involvement of a medical physicist, together with other radiation therapy professionals as appropriate (e.g. biomedical engineer and IT specialist) and the radiation protection committee and quality assurance committee.

3.4 Design Features for Medical Imaging and Radiotherapy Equipment

3.4.1 General Considerations

The facility should ensure that:

3.4.1.1 Medical Imaging and radiotherapy equipment used for external beam radiotherapy should meet the specifications given in relevant IEC 60601, IEC 61304 standards and should follow the guidance on design specifications and performance provided by relevant international and national regulatory bodies.

3.4.2 External Beam Radiotherapy

The Facility Should Ensure That:

3.4.2.1 External beam radiotherapy equipment should meet the specifications given in IEC 60601, IEC 61304 standards and should follow the guidance on design specifications.

3.4.2.2 In addition, the following considerations should also be included:

a. Safety interlocks or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel should be provided.

b. The design of equipment should permit interruption of the treatment from the control panel; after the interruption, resumption of treatment should be possible only from the control panel.

c. Radiation beam control mechanisms should be provided, including devices that indicate clearly and in a fail-safe manner whether the beam is on or off.

d. The radiation field within the treatment area in the absence of any radiation beam modifiers (such as wedges or multileaf collimators) should be as uniform as practicable and the non-uniformity should be stated by the supplier. The non-uniformity of flattening filter free beams should also be specified by the supplier.

e. The design of the unit should be such that dose rates outside the treatment area due to radiation leakage or scattering are kept as low as reasonably achievable.

f. If primary shielding is incorporated into the equipment, electrical or mechanical interlocks should be provided to avoid the beam being directed towards secondary barriers if the primary shielding is not intercepting the beam.

3.4.2.3 The presence of other staff around the control panel should be kept to the minimum necessary to avoid distraction to the operator.

3.4.2.4 For accelerators producing high energy X ray beams (>10 MV), access to a neutron monitoring instrument is recommended.

3.4.3 Brachytherapy

The facility should ensure that:

3.4.3.1 LDR, PDR and HDR sources are accompanied by a source certificate specifying:

a. The source strength in terms of reference air kerma rate($\mu Gy/m^2.hr$) in air or equivalent quantity as recommended by the ICRU at a specified distance, for a specified date.

b. The quality control tests applied to the source including leakage and contamination tests.

3.4.3.2 Applicators for brachytherapy should be manufactured specifically for the source to be used or should be compatible with it.

3.4.3.3 Use of reusable LDR radioactive sources after the working lifetime recommended by the manufacturer should be continued only after leak testing by the medical physicist or RPO and approval by the Regulatory Authority.

3.4.3.4 Where manual brachytherapy sources incorporating ^{226}Ra or encapsulated ^{137}Cs are still in use, efforts should be made to replace them as soon as practicable with modern afterloading systems. In no case should sources be left in applicators (pre-loaded applicators) in between clinical procedures, to avoid encapsulation or applicator rupture due to radiation damage.

3.4.3.5 When not in use, all brachytherapy sources should be stored safely and securely. The storage facilities are to be kept always locked.

3.4.3.6 Sources using beta emitters, such as ^{90}Sr and ^{106}Ru in ophthalmic applicators, should be provided with low atomic

number shielding to minimize bremsstrahlung while they are in storage and in preparation for use.

3.4.4 Treatment Planning Systems (TPSS)

The facility should ensure that:

3.4.4.1 The design features for the TPS should meet the clinical goals of the radiation therapy facility.

3.4.4.2 TPSs should meet the standards and should follow the guidance on TPSs, including specifications and performance, given in international standards (IEC 60601, IEC 61304) and national standards (if any).

3.4.5 Computed Tomography/Conventional Simulators

The facility should ensure that:

3.4.5.1 Where conventional simulators are used, these should meet the specifications given in IEC 60601, IEC 61304 standards.

3.4.5.2 CT scanners used as virtual simulators should be designed so that patients can be simulated in the treatment position; this should include the positioning lasers, which should be consistent with those of the treatment room.

3.4.6 Ancillary Equipment

The facility should ensure that:

3.4.6.1 The radiation therapy facility should have equipment, instruments and test objects for reference and relative dosimetry appropriate

or the type of measurement necessary for beam characterization and quality control. This may include but not limited to:

a ionization chambers (thimble, plane-parallel and well-type ionization chambers),

b solid-state detectors,

c detectors for small field dosimetry,

d electrometers,

e thermometers,

f barometers,

g phantoms, and geometry mechanical test tools

3.4.6.2 For radiation therapy facilities without multileaf collimators, a mould room is available that is equipped to prepare beam modifiers, positioning aids and immobilization devices (e.g. blocks, compensators, and bolus). Where blocks are still prepared, electronic transfer of data from the TPS to the automatic cutting and milling machines would represent an advantage in terms of accuracy.

3.4.6.3 In addition to laser positioning beams, they may consider including other positioning devices, such as surface optical scanners, radio frequency systems, body GPS transmitters and ultrasound units.

3.4.6.4 For manual brachytherapy, the facility should be equipped with radiation protection and safety equipment, including a radiation detector such as a Geiger–Müller counter, source handling equipment including a magnifying glass, source manipulators (such as forceps, tweezers, or tongs), clippers or wire cutters, and several shielded containers.

3.4.6.5 For remote afterloading brachytherapy, the facility is equipped for source handling in the case of a failure of the afterloading unit, including a shielded storage container present in the treatment room to serve as an emergency source container in case of failure of the afterloader in retracting the source, a remote manipulator,

wire cutters and a suitable radiation monitoring instrument for source localization.

3.4.6.6 It is equipped with radiation monitoring instruments (area monitors and portable survey meters) based on Geiger–Müller detectors, ionization chambers and/or scintillators.

3.4.7 Security of Sources

The facility should ensure that:

3.4.7.1 Procedures to ensure the safe receipt and movement of radioactive sources within the institution are developed.

3.4.7.2 Establish controls to prevent the theft, loss and unauthorized withdrawal of radioactive materials or the entrance of unauthorized personnel to controlled areas.

3.4.7.3 An inventory of sources should be maintained, and procedures should be put in place to check and confirm that the sources are in their assigned locations and are secure.

3.4.8 Maintenance

The facility should ensure that:

3.4.8.1 Establish the necessary arrangements and coordination with the manufacturer before initial operation and on an ongoing basis. This can be achieved through a maintenance contract (preventive maintenance and corrective maintenance) with the manufacturer, or by in-house staff or third-party contractor only if appropriately trained and authorized.

3.4.8.2 Maintenance also includes software, networks, databases and other supporting systems in the radiation therapy facility (e.g. HIS, PACS, OIS and RIS).

3.4.8.3 Include Esses of removal from, and return to, clinical service of radiation therapy medical Imaging and radiotherapy equipment for maintenance, following breakdown or exchange of sources includes the following:

a. A record of maintenance carried out should be kept for each item of equipment. This should include information on any defects found by users (a fault log), remedial actions taken (both interim

repairs and subsequent repairs) and the results of testing before equipment is reintroduced to clinical use.

b. Where maintenance of the therapy and imaging equipment or treatment planning equipment may affect the accuracy of the physical or clinical dosimetry or the safe operation of the equipment, it is recommended that a medical physicist performs specific tests or measurements to determine that the equipment is operating satisfactorily before it is used to treat patients.

3.4.8.4 The electrical safety and mechanical safety aspects of the medical Imaging and radiotherapy equipment should be performed by appropriately authorized persons who understand the specifications of the medical Imaging and radiotherapy equipment.

3.4.8.5 Electrical and mechanical maintenance is included in the programme of quality assurance and should be performed, preferably by the manufacturer of the medical Imaging and radiotherapy equipment or an authorized person, at a frequency recommended.

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

4.0 OCCUPATIONAL RADIATION PROTECTION

4.1 Arrangements Under the Radiation Protection Programme

The facility should ensure that:

4.1.1 Rules are established for occupationally exposed workers (example; radiation oncologists, medical physicists) and workers that are required to have the same level of protection as members of the public (example; social workers, dieticians, physiotherapists), especially regarding access to controlled areas and supervised areas.

4.1.2 Classification of Areas

The facility should ensure that:

4.1.2.1 An area is designated as a controlled area is an area in which specific measures for protection and safety are or could be required for:

a. Controlling exposures or preventing the spread of contamination in normal operation.

b. Preventing or limiting the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions.

4.1.2.2 To consider the magnitude of the exposures expected in normal operation, the likelihood and magnitude of exposures in anticipated operational occurrences and in accident conditions, and the type and extent of the procedures required for protection and safety.

4.1.2.3 All treatment rooms for external beam radiotherapy and remote afterloading brachytherapy, operating theatres used during brachytherapy procedures with radioactive sources, brachytherapy patient rooms, radioactive source storage and handling areas, and rooms where imaging or simulation procedures are performed meet the criteria for controlled areas and should be so designated.

4.1.2.4 Supervised areas might include the areas surrounding brachytherapy patients' rooms or around radioactive source storage and handling areas.

4.1.2.5 The area around the control panel for all medical Imaging and radiotherapy equipment used in radiation therapy should be classified as either a controlled area or a supervised area, even though the radiation levels may be very low owing to the shielding design. In either case, this area should have restricted access, inter alia, to avoid distraction of staff, which could lead to accidental medical exposure of patients.

4.1.2.6 To avoid uncertainties about the extent of controlled areas and supervised areas, the boundaries of such areas should, when

possible, be walls and doors, partitions, or other physical barriers, clearly marked or identified with suitable warning signs.

4.1.3 Local Rules and Procedures

The Facility Should Ensure That:

4.1.3.1 local rules and procedures are established to ensure protection and safety for workers and the public.

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

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

4.1.3.4 The development and review of local rules and procedures should involve representatives of all health professionals involved in radiation therapy.

4.1.3.5 Besides the manufacturer's operating manual, additional procedures should be considered. The final documented set of operational procedures should be subject to approval and should be incorporated into the facility's management system.

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

4.1.3.7 Additional education and training should be conducted when new devices or techniques are introduced into radiation therapy practice.

4.1.3.8 For external beam radiotherapy, HDR and PDR brachytherapy, no one should be in the treatment room during the delivery of treatment, except the patient being treated.

4.1.3.9 All attending personnel should be in appropriately shielded areas.

4.1.3.10 Safety features such as interlocks, the presence of accessories such as the T-bar for manual 60Co source retraction and the

functionality of survey meters should be checked daily prior to patient treatment.

4.1.3.11 Sealed sources should be subject to leak tests prior to their first use and at regular intervals thereafter, in conformity with international standards. These tests should be sufficiently sensitive to be able to detect the presence of very small amounts of removable contamination, for example 0.2 kBq.

4.1.3.12 Area surveys are performed periodically (e.g. every six months) around all treatment units and check sources, including 60Co units, shielded safes and source storage facilities for LDR, PDR and HDR sources.

4.1.3.13 Local rules for pregnant workers and persons under the age of 18 should reflect the guidance given in the safety guide for Nuclear Medicine and Radiology and Image Guided Interventional, respectively.

4.2 Specific Local Rules and Procedures

4.2.1 External Beam Radiotherapy

The facility should ensure that:

4.2.1.1 For external beam radiotherapy unit's safe operation requires procedures for area surveys, interlock checks, leak tests (for sealed sources) and procedures for contingencies such as a source becoming stuck in the on position or partially in the on position. Such procedures require that the necessary equipment be available, calibrated and in working order, including:

a. A radiation monitors.
b. Leak test capabilities (for radioactive sources)
c. Personal alarm dosimeters, especially for unplanned exposures.

4.2.1.2 The presence of other staff around the control panel should be kept to the minimum necessary to avoid distraction to the medical radiation technologist.

4.2.1.3 Regular leak tests should be performed for sealed sources. For external beam radiotherapy, the method that could be used is an indirect leak test of the nearest accessible surface.

4.2.1.4 Irradiation that involves the extended use of high energy X rays, such as beam calibration, dosimetry, and quality control measurements, should be scheduled to take place at the end of

the day's clinical roster so that neutron activated radionuclides (especially the longer-lived ones) can decay significantly overnight.

4.2.2 Brachytherapy

The facility should ensure that:

4.2.2.1 An inventory of sources is maintained, giving the radionuclide, location, and activity with reference date of each source at the facility as well as its serial or batch number, and a unique identifier. The unique identifier may be either a colour coded identifier or an alphanumeric identifier.

4.2.2.2 Sources should never be left on preparation surfaces. They should be either in storage, in transit or in use.

4.2.2.3 Regular leak tests are performed for sealed sources. For long lived LDR brachytherapy sources, the typical method used is a direct moist wipe leak test, while for remote controlled brachytherapy the method to be used is an indirect wipe test of the nearest accessible surface.

4.2.2.4 For an HDR/PDR unit, the leak tests should be carried out only on the afterloading drive assembly and transport containers, since the source itself has too high a dose rate to allow a direct wipe test.

4.2.2.5 Area surveys are performed periodically around the source storage facilities for LDR, HDR, PDR brachytherapy and sources to be used in permanent implants.

4.2.2.6 The source storage facilities should be marked to indicate that they contain radioactive materials, and instructions should be provided on how to contact the RPO, medical physicist or other responsible radiation safety individual in the event of an emergency.

4.2.2.7 Source storage rooms should be kept always locked, except when access is required to remove or return a source.

4.2.2.8 After every brachytherapy treatment, all brachytherapy sources should be removed from the patient, except in the case of

permanent implants. The patient should be monitored with a radiation survey meter to ensure that no radioactive source remains in or on the patient.

4.2.2.9 Bed linen, dressings, clothing, waste, and equipment should be kept within the room where the removal of sources takes place until all sources are accounted for and should be monitored with a radiation detector.

4.2.2.10 Mobile containers and portable equipment containing radioactive sources should be removed to storage or to a secure place when not in use.

4.2.2.11 Sterilization processes in brachytherapy should be appropriate and should be consistent with manufacturer's recommendations to prevent damage to sources and applicators that could affect safety.

4.2.2.12 Among other safety checks, the catheters, couplings, and transfer tubes should be checked before and after each treatment, to ensure that there are no obstacles to prevent motion of the source.

4.2.2.1 Additional for LDR Sources

The facility should ensure that:

a. In the case of temporary LDR brachytherapy applications, both manual as well as remotely controlled, the following information should be displayed at the entrance to the treatment room:
b. identification of the patient,
c. sources,
d. date and time of insertion and removal,
e. nursing required,
f. time/distance allowance for nurses and visitors and the use of mobile shielding where available
g. concise instructions for the unplanned removal of a source or applicator and for dealing with an emergency, including contact details.
h. A patient with a removable source in or on the body should leave the room only in exceptional circumstances and should be always accompanied by an attendant from the radiation therapy facility.

i. Reusable sources should be inspected visually for possible damage after each use, by means of magnifying viewers and a leaded viewing window in a shielded work area.

j. There is a diagram at the source storage safe that shows the exact location of each source within the safe, thus reducing the time taken to locate and identify a source.

k. Sources are handled only with long forceps or tongs.

l. A mobile shielded container should be available for transporting sources and the shortest route possible should be used.

m. The container should have a long handle and/or a long-handled trolley should be used.

n. Reusable sources that come into direct contact with body tissues are cleaned and sterilized after each use. such sources should be inspected before and after every use.

o. Work surfaces should be continuous, easy to clean and brightly lit to make it easy to find any sources that have been dropped.

p. If the source storage and preparation room is also the applicator loading room, there should be a sink (a filter in the sink's drain) for cleaning the applicators.

4.2.2.2 Additional for HDR/PDR Sources

The facility should ensure that:

a. The HDR/PDR afterloader should undergo routine quality assurance tests at the beginning of each treatment day.

b. For emergency safety precautions there is availability of an emergency container in the treatment room, as well as an emergency kit containing surgical clamps and long handled forceps for manipulation of the source guide tubes and applicators if the source fails to return to the safe, or for other source retrieval actions.

c. The emergency container should be placed close to the patient and should be sufficiently large that it can accept the entire applicator assembly containing the source removed from the patient.

d. Emergency procedures to be implemented if the source fails to return to the safe is posted in an appropriate place. The general sequence involved in the emergency procedure is the following:

e. Observation at the console of an error message and emergency indicators (audible and visible alarms)
f. Recovery at the console (e.g. pressing an emergency source retract button)
g. Entry into the room with a portable radiation survey meter (opening the door activates the interlock that retracts the source)
h. Observation of radiation levels in the room (by mounted monitors or portable survey meters)
i. Recovery at the afterloading unit (pressing an emergency source retract button on the remote afterloading unit)
j. Manual retraction of the source (using a hand crank)
k. Survey of the patient and survey of the afterloader (confirming that the source is in the safe)
l. Removal of the applicator and placement in the emergency container
m. Survey of the patient and survey of the emergency container (to confirm that the source is not in the patient and that it is in the emergency container)
n. Removal of the patient from the vault with subsequent redundant survey monitoring
o. Informing of the personnel responsible for the maintenance of the afterloader, and the RPO.

4.2.3 Remote Control Afterloading Brachytherapy

The facility should ensure that:

4.2.3.1 A shielded container large enough to accommodate the largest applicator set should be kept next to the unit in case the source gets stuck. Further information is stated under the section on *Stuck sources: Remote control brachytherapy units.*

4.2.4 Manual Brachytherapy

The facility should ensure that:

4.2.4.1 For implants with sources of different activities, after verification of the source strength, the source or source holder should be marked with a unique identifier (e.g. a pre-established colour that cannot be compromised by body fluids), to facilitate visual

recognition and to prevent the possibility of confusion between different sources or batches.

4.2.4.2 Containers utilized for the transport of radioactive sources should conform with the requirements established in international and national standards.

4.2.4.3 The movements of the sources from the time they leave the safe until their return (if applicable) should be recorded, with the signature of the person responsible for the move (using forms or a logbook). A person should be assigned to oversee accountability for the sources. This person should keep a record of the source request and of its issuance from, and its return to, the safe, with signatures.

4.2.4.4 Reusable sources are inspected visually for possible damage after each use by means of magnifying viewers and a leaded viewing window in a shielded work area.

4.2.4.5 Sources are handled only with long forceps or tongs, never directly with the fingers.

4.2.4.6 A mobile shielded container be available for transporting sources and the shortest route possible should be used. The container should have a long handle, or a long-handled trolley should be used.

4.2.4.7 Reusable sources that come into direct contact with body tissues will require cleaning and sterilization after each use. This can subject the sources to possible damage from heat, abrasion, chemical attack, and mechanical stresses. Therefore, such sources should be inspected after every use.

4.2.4.8 Precautions be observed during the cutting and handling of 192Ir wires to ensure that:

a. Appropriate tools and equipment such as forceps, cutting devices and magnifying glasses and good illumination of the work surface are available and used and that, if 192Ir wires are cut off for immediate use, a container to hold cut lengths is provided and labelled.

b. Surfaces and tools are properly decontaminated.

4.2.5 Specific Local Rules and Procedures for Imaging and Simulation

The facility should ensure that:

4.2.5.1 Local rules and procedures for performing imaging procedures as part of pre-planning and simulation are established. Refer to the safety guide on Radiology and Image Guided Interventional.

4.2.6 PERSONAL PROTECTIVE EQUIPMENT AND IN-ROOM PROTECTIVE DEVICES

The facility should ensure that:

a. Personal Protective Equipment and in-room protective devices be available and used when structural shielding and administrative controls alone cannot provide the required level of occupational radiation protection.
b. The need for this protective equipment should be established by the RPO or by the medical physicist at the radiation therapy facility.
c. In the case of manual handling of sources for brachytherapy, protective equipment such as shielding blocks on the workbench and a lead glass screen should be used, as well as appropriate devices for handling sources.
d. For nursing of brachytherapy patients with either temporary (137Cs or 192Ir) or permanent implants (125I seeds), consideration should be given to the use of movable shielding in the ward.
e. Protective equipment for emergencies in brachytherapy (e.g. a stuck source in HDR) should include an emergency container suitable for applicators and sources.

4.2.5.6 Workplace Monitoring

The facility should ensure that:

a. Establish the requirements and responsibilities for workplace monitoring. Workplace monitoring serves several purposes, including routine monitoring, special monitoring for specific occasions, activities or tasks, and confirmatory monitoring to check assumptions made about exposure conditions.
b. Workplace monitoring in areas around each item of medical Imaging and radiotherapy equipment (therapy and imaging) in the radiation therapy facility, when it is being operated, is carried out when:

c. The room and shielding construction have been completed, regardless of whether it is a new construction or a renovation, and before the room is first used clinically.
d. New or substantially refurbished equipment is commissioned.
e. Source replacements have taken place in teletherapy or remote-controlled brachytherapy.
f. New software for the medical Imaging and radiotherapy equipment is installed or there is a significant upgrade.
g. New techniques are introduced.
h. Servicing of the medical Imaging and radiotherapy equipment has been performed, which could have an impact on the radiation delivered.
i. Initial monitoring is performed as part of acceptance tests, prior to clinical use of the equipment.
j. Dose rates in teletherapy rooms with radioactive sources and in HDR brachytherapy treatment rooms should be continuously monitored using permanently installed area radiation monitors.
k. The source storage and handling area is monitored with a survey meter immediately following the removal from, or return to, storage of brachytherapy sources.
l. For treatment rooms where the possibility of induced activity exists, for example with protons, heavy ions and high energy X ray beams (>10 MV), consideration should be given to the use of appropriate area monitors to detect the presence of neutrons and other radiation being from emitted from induced radionuclides in the treatment room.
m. Workplace monitoring is done in association with brachytherapy procedures. a survey of dose rates in the vicinity of the patient is necessary in case of implantation of source.
n. Survey meters used for workplace monitoring should normally be calibrated in terms of ambient dose equivalent. The calibration should be traceable to a standards dosimetry laboratory. The meters should be subject to regular quality control tests.

4.3 Assessment of Occupational Exposure and Health Surveillance for Workers

4.3.1 Assessment of Occupational Exposure

The facility should ensure that:

4.3.1.1 Individual external doses of occupationally exposed workers be assessed by using individual monitoring devices, these devices should be calibrated and should be traceable to a standards dosimetry laboratory.

4.3.1.2 Each personal dosimeter should be used for monitoring only the person to whom it is issued, for work performed at that radiation therapy facility, and it should not be taken to other facilities where that person may also work. For example, if a person is issued with a dosimeter at hospital A, it should be worn only at hospital A and not at any other hospitals or medical centres where he or she also works.

4.3.1.3 The monitoring period (period of dosimeter deployment) specified by regulatory body is typically every after two months.

4.3.1.4 Dosimeters should be sent to the dosimetry service provider, which should then process the dosimeters and return the dose reports, all in a timely manner.

4.3.1.5 Dosimeters are worn on the front of the upper torso, as occupational exposure arising from most radiation therapy procedures results in the whole body being uniformly exposed.

4.3.1.6 For specialized dosimeters, such as ring dosimeters for monitoring finger doses, the manufacturer's specific wearing instructions should be followed.

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

4.3.1.8 If an individual loses his or her dosimeter, the individual should inform the RPO.

4.3.1.9 Additional direct reading operational dosimeters, such as electronic dosimeters, should be considered for use in a radiation therapy facility, for example in a new facility or with the introduction of new modalities or procedures, as these devices can give the worker an instant indication of both the cumulative

dose and the current dose rate and also allow pre-setting of an alarm to alert when a given level has been reached. They will also be helpful in accidents or emergency situations.

4.3.2 Investigation Levels for Staff Exposure

The facility should ensure that:

4.3.2.1 Any values higher than 1.2 mSv/m (for the dosimeter worn on the torso) should be investigated.

4.3.2.2 Abnormal conditions and events should also trigger an investigation.

4.3.2.3 Investigation levels should also be set for workplace monitoring, with account taken of exposure scenarios and the predetermined values adopted for investigation levels for workers.

4.3.2.4 An investigation should be initiated as soon as possible following a trigger or event, and a written report should be prepared concerning the cause, including determination or verification of the dose, corrective or mitigatory actions, and instructions or recommendations to avoid recurrence.

4.3.2.5 Such reports are to be reviewed by the quality assurance committee and the radiation safety committee (if any), as appropriate. The regulatory body may also need to be informed depending on the level of the event.

4.3.3 Persons Who Work in More Than One Place.

The facility should ensure that:

4.3.3.1 For individuals who might work in more than one radiation therapy facility regardless of the ownership and management structure, the occupational radiation protection requirements for

the radiation therapy facility apply when the person is working in that facility.

4.3.3.2 A dosimeter issued for individual monitoring should be worn only in the facility for which it is issued.

4.3.3.3 Any person who works in more than one radiation therapy facility should notify the licensee for each of those facilities. The RPOs of each facility are to ensure that a personal dosimeter is available and that there is an ongoing record of the occupational doses for that person.

4.3.3.4 For consultant medical physicists or service engineers, working in many radiation therapy facilities and, in other medical radiation facilities. They can be employed by a company or be self-employed, providing contracted services to the radiation therapy facility and the other facilities. In such cases, the company, or the self-employed person to provide the dosimeters for individual monitoring. Therefore, in these cases, a worker uses the same dosimeter for work performed in all radiation therapy facilities (and other medical radiation facilities) in the monitoring period.

4.3.4 Records of Occupational Exposure

The facility should ensure that:

4.3.4.1 They maintain and preserve exposure records for each worker accordingly.

4.3.4.2 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.

4.3.4.3 In additional to compliance with legal requirements, records of occupational exposure should be used within the radiation therapy facility for additional purposes, including assessing the

effectiveness of the optimization of protection and safety at the facility and evaluating trends in exposure.

4.3.4.4 Exposure records should be retained until the age of 75 years.

4.3.5 Health Surveillance for Workers

The facility should ensure that:

4.3.5.1 There is an agreement to provide medical surveillance for workers to assess the initial and continuing fitness of employees for their intended tasks.

4.3.5.2 Only in cases of overexposed workers, at doses much higher than the dose limits (e.g. a few hundred millisieverts or higher), would special investigations involving biological dosimetry and further extended diagnosis and medical treatment be necessary.

4.3.5.3 Counselling should be made available to workers who have or may have been exposed substantially more than dose limits, and information, advice and, if indicated, counselling should be made available to workers who are concerned about their radiation exposure.

4.3.5.4 Counselling should be given by appropriately experienced and qualified practitioners.

4.4 Information, Instruction, And Training

The facility should ensure that:

4.4.1 All staff involved in radiation therapy should have an adequate educational background with relevant practical training, relevant to their duties.

4.4.2 Nurses may not have been trained with respect to imaging or pre-planning systems, such as CT, PET–CT, and as such they should undertake radiation protection and safety training relevant to the additional imaging modalities in their radiation therapy facility.

4.4.3 Establish a policy that encourages and provides continuing professional development programs, with the aim of improving staff skills, maintaining familiarity with current practices, and fostering a safety culture

throughout the institution. Such training and development schemes can be accomplished through informal meetings of the radiotherapy department, seminars, accredited continuing education programs or other means.

4.4.4 Personnel with duties in the vicinity of radioactive sources used in radiotherapy should be informed of the radiation hazard, details of the specific uses, and the radiation protection program.

4.4.5 Specific instruction and training should be provided when new medical Imaging and radiotherapy equipment, software and technologies are introduced.

4.5 Conditions of Service and Special Arrangements

4.5.1 Pregnant Workers

The facility should ensure that:

4.5.1.1 Female worker should, on becoming aware that she is pregnant, notify the employer in order that her working conditions may be modified if necessary.

4.5.1.2 The notification of pregnancy should not be considered a reason to exclude a female worker from work; however, the employer who has been notified should adapt the working conditions in respect of occupational exposure to ensure that the embryo or foetus is afforded the same broad level of protection as required for members of the public.

4.5.1.3 The dose to the embryo foetus should be assessed using an appropriately positioned additional dosimeter.

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

4.6 Protection of Workers Responding to Incidents in A Radiation Therapy Facility

The facility should ensure that:

4.6.1 The potential occurrence of incidents is considered in advance in the safety assessment for the facility and mitigatory procedures should be developed accordingly.

4.6.2 The mitigatory procedures for incidents should include considerations for the optimization of protection and safety for the responding workers.

4.6.3 The mitigatory procedures should also include allocation of responsibilities and should provide for the education and training of the relevant staff in executing the mitigatory measures, which should be periodically exercised.

5.0 RADIATION PROTECTION OF INDIVIDUALS UNDERGOING MEDICAL EXPOSURE

5.1 Justification of Medical Exposure

The facility should ensure that:

5.1.1 Medical exposures should be justified by weighting the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, considering the benefits and risks of available alternative techniques that do not involve medical exposure.

5.1.2 The authorized person should ensure that medical practitioners follow a justification procedure that is documented and signed.

5.1.3 The Radiation oncologist should consider the efficacy, benefits, and risks of alternative treatment modalities, e.g., surgery and chemotherapy, either alone or in combination with radiation therapy.

5.1.4 No patient be administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by Radiation Oncologist.

5.1.5 Health practitioners be assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure.

5.1.6 Health practitioners be available as needed, to discharge assigned tasks in the conduct of the diagnostic or therapeutic procedure that the medical practitioner prescribes.

5.1.7 For therapeutic uses of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and quality assurance

requirements of the regulations be conducted by or under the supervision of a qualified medical physicists.

5.1.8 The exposure of individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment be constrained.

5.1.9 All persons involved in delivery of medical exposure should:

5.1.9.1 Follow the applicable rules and procedures for the protection and safety of patients, as specified.

5.1.9.2 Be aware that prescription of treatment and treatment plan need to be signed by the medical practitioner prior to initiation of treatment.

5.1.9.3 Health practitioners should promptly inform the RPO of any deficiencies or needs regarding compliance with the Standards in respect of protection and safety of patients and should take such actions as may be appropriate to ensure the protection and safety of patients.

5.1.1 Justification of Medical Exposure for The Individual Patient

The facility should ensure that:

5.1.1.1 Every treatment decision should be discussed within the team and documented at a 'tumour board' or equivalent multidisciplinary meeting.

5.1.1.2 Not only the radiation therapy treatment should be justified, but all the imaging and radiotherapy procedures prior to, during and after the treatment should also be justified. Two groups of patients identified in para. 3.157 of GSR Part 3 for special consideration with respect to justification are patients who are pregnant or are paediatric.

5.1.1.3 Procedures be in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any Imaging and radiotherapy procedure that could result in a significant dose to the embryo or foetus.

5.1.1.4 The decision of the multidisciplinary oncology team should be conveyed to the patient or the legal guardian of the patient. The

patient, or the legal guardian of the patient, also should be informed about the expected benefits, risks and limitations of the proposed treatment, as well as the consequences of not undergoing the treatment.

5.1.1.5 Female patients of reproductive capacity should also be made aware of the risks associated with becoming pregnant during treatment.

5.1.1.6 The patient's consent for treatment should be obtained before any further patient management action is initiated.

5.1.2 Justification of Medical Exposure for Biomedical Research Volunteers

The facility should ensure that:

5.1.2.1 Healthy individuals should not take part in a programme of biomedical research involving radiation therapy procedures. The exposure of humans for medical research is deemed to be 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 (CIOMS) and WHO; and
b. Subject to the advice of National Health Research Authority, Tropical disease research centre (TDRC), UNZA Research an Ethical Review Committee (or any other institutional body assigned similar functions by national authorities) and to applicable national and local regulations."

5.1.3 Justification of Medical Exposure for Caregivers

The facility should ensure that:

5.1.3 In the case of implants the carer giver is correctly informed about radiation protection and the radiation risks involved, and that the carer

understands this information and consequently agrees to take on the role of a carer giver.

5.1.3.1 No amount of exposure to care givers should be administered.

5.1.3.2 The authorized person should provide instructions to care givers on actions to take to limit their exposure within 1mSv while visiting or caring for a patient who has received an implant.

5.2 Optimization of Protection and Safety

The facility should ensure that:

5.2.1 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 when feasible and appropriate.

5.2.2 Radiotherapy procedures causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant be avoided unless there are strong clinical indications.

5.2.3 Any therapeutic procedure for pregnant women shall be conducted only.

a After delivery

b After termination of the pregnancy.

5.2.4 The patient be informed of possible risks.

5.2.5 They provide written instructions to the patient on actions to take to reduce exposure to comforters, caregivers, and members of the public from sources in brachytherapy with permanent implants.

5.2.6 Instructions include minimizing prolonged contact with children and potentially pregnant women, and procedures to follow if a source becomes dislodged.

5.2.1 Operational Considerations

The facility should ensure that:

5.2.1.1 The planning and delivery of treatment are required to be performed in such a way as to optimize patient protection.

5.2.1.2 The treatment goal is to deliver the correct absorbed dose to the correct volume within the overall prescribed time while keeping

the dose to normal tissue and organs at risk within the established tolerances and as low as reasonably achievable.

5.2.1.3 Written procedures and protocols for the delivery of radiation therapy, consistent with the above goal, should be drawn up.

5.2.1.4 Protocols should be consistent with current best radiation therapy practice, published by the relevant professional bodies, national, regional, or international.

5.2.1.5 Quality imaging, Radiotherapy equipment and immobilization devices should be utilized.

5.2.1.6 They have all the necessary expertise and resources available before implementing more complex modes of delivery.

5.2.1.7 Specific protocols for the use of imaging equipment (e.g. CT and PET–CT) in the pre-planning stage (simulation) of external beam radiotherapy should be used to ensure appropriate optimization of protection and safety.

5.2.1.8 The following should also be considered:

a. A medical radiation therapist/ radiation technologist specialized in radiation therapy should always be present when images for the planning of external beam radiotherapy are acquired.
b. Patients should be in the treatment position for all images acquired for the planning of external beam radiotherapy.
c. The geometry of the imaging modality should be sufficiently accurate to minimize errors in dose calculation and target delineation.
d. When used as a virtual simulator, a CT scanner should have a minimum bore of 80cm to allow images to be acquired with the patient in the treatment position.
e. A comparable table top should be used for image acquisition for treatment planning and for treatment delivery, for example using a flat table top or a flat insert.
f. A reference system consistent with those in the treatment room should be used when acquiring images for the planning of

external beam radiotherapy. The TPS reference point and the patient treatment reference point should be correlated.

g. when a respiratory or motion management and monitoring system is used for imaging in 4-D radiotherapy, should be consistent with that used in the treatment room.

h. Imaging protocols in radiation therapy should include the specific technical parameters required for the simulation. For example, for CT this would include the CT number for dose computation accuracy, the slice thickness for optimum planning, the scan length necessary to encompass the potential volume and other parameters that may influence the image quality for radiation therapy planning.

i. Specific protocols for the use of imaging equipment in IGRT should be used to ensure appropriate optimization of protection and safety.

5.2.2 Calibration: Medical Imaging and Radiotherapy Equipment

The facility should ensure that:

5.2.2.1 For all external beam medical Imaging and radiotherapy equipment and brachytherapy sources used in the radiation therapy facility should be calibrated, as follows:

a. In terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions; the recommended quantity is absorbed dose to water. The calibrations should be performed for at least the clinically used energies and qualities.

b. Sealed sources used for brachytherapy should be calibrated in terms of reference air kerma rate ($\mu Gy/m^2.hr$) in air or an equivalent quantity as recommended by the ICRU, at a specified distance, for a specified date.

c. Internationally or nationally accepted calibration protocols should be used.

d. For brachytherapy, a distinction can be made between removable and permanent implants. For removable implants, each source should be calibrated individually. For permanent implants when

many sources are being used, a representative sample may be assessed, for example 10% of the sources.

e. Particular attention should be given to the calibration of sources used for special radiation therapy procedures (e.g. radiosurgery, IORT, SRT, Tomotherapy and total body irradiation) which may necessitate adaptation of the existing international codes of practice and may introduce additional uncertainties associated with making measurements in non-reference conditions.

f. Imaging devices used in the radiation therapy process, should be calibrated.

5.2.2.2 The responsibility for calibration in radiation therapy be placed on the medical physicist, with either direct fulfilment or by supervision.

5.2.2.3 For the imaging devices used in the radiation therapy process, a medical physicist with competence in diagnostic radiology and image guided interventional procedures, or in nuclear medicine, should be involved as appropriate.

5.2.2.4 In addition to the initial calibration prior to clinical use and calibration after major maintenance or upgrade, periodic calibrations are required to be carried out. The intervals for these calibrations may differ, depending on the type of source and unit. For example, linacs should be calibrated at least yearly.

5.2.2.5 Ensure that independent verification of the calibration of all radiation therapy equipment is performed through participation in a national, regional, or international programme. A period of two years is recommended for the intervals between independent verifications of calibration.

5.2.2.6 Sealed sources used for external beam radiotherapy and brachytherapy will also have a calibration certificate provided by the manufacturer, while important, this does not replace the calibrations.

5.2.2.7 New brachytherapy sources should be calibrated and differences of more than 5% from the manufacturer's certified reference air

kerma rate should be investigated. The source should not be used for patient treatment until such differences have been investigated and resolved.

5.2.3 Calibration: Dosimetry Instrumentation

The facility should ensure that:

5.2.3.1 The calibration of dosimetry instrumentation be traceable to a standards dosimetry laboratory.

5.2.3.2 The calibrated dosimeter should be checked for consistency periodically in the facility against a reference check source.

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

5.2.4 Treatment Intent and Dosimetry of Patients

The facility should ensure that:

5.2.4.1 The process begins with the treatment prescription, dated, and signed by the radiation oncologist.

5.2.4.2 The treatment prescription should indicate whether the radiation therapy will be given alone or in combination, either concomitantly or sequentially, with chemotherapy and should specify the timing of other local treatments such as surgery.

5.2.4.3 The normal tissues or organs that may receive significant radiation should be identified and the maximum doses to, and, if

possible and necessary, the volumetric distribution of doses in, these organs or tissues at risk should be stated.

5.2.4.4 The treatment prescription is used as the basis for treatment planning, followed by delivery of the treatment and verification of the dose.

5.2.4.5 The specification of volumes and the prescribing, recording, and reporting of doses should be in accordance with the recommendations of the ICRU.

5.2.4.6 Absorbed doses to organs should be considered both for the irradiated volume and for the critical organs.

5.2.4.7 Established means to verify the dose to selected points, independent from the TPS calculations, for example manual calculations, independent monitor unit verification software, or case specific quality assurance measurements in a phantom. The medical physicist should perform phantom or in vivo measurements as appropriate and perform real-time imaging, verification of patient positioning, dosimetric verification, and adapt treatment plans based on changes in patient anatomy.

5.2.5 Quality Assurance for Radiotherapy Equipment and Exposures

The facility should ensure that:

5.2.5.1 There is a comprehensive programme of quality assurance for medical exposure that should fit in with, and be part of, the wider management system at the facility.

5.2.5.2 The programme of quality assurance should encompass the entire radiation therapy process, including the treatment decision, tumour localization, patient positioning and immobilization, image acquisition for treatment planning, treatment planning, treatment

delivery, treatment verification and follow-up. It should include the testing of both the hardware and software.

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

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

5.2.5.5 Acceptance tests and commissioning should not be restricted to radiation emitting equipment or sources but should also be conducted for any system that has implications for safety, such as TPSs and other software integral to or supporting any stage of the radiation therapy process.

5.2.5.6 Depending on the equipment purchase agreement, acceptance tests can be performed by the manufacturer in the presence of the local medical physicist representing the user, or, if acceptable to the manufacturer and the purchaser, by a medical physicist jointly with the manufacturer.

5.2.5.7 Acceptance tests should ensure that equipment and software are compatible with the other equipment with which it will have an interface.

5.2.5.8 During commissioning, the medical physicist should identify, measure, and compile all data required for clinical use.

5.2.5.9 During commissioning, the quantities and measures including tolerances and action levels should be defined for the periodic quality control tests to set the baseline for subsequent constancy.

5.2.5.10 If there has been a major repair or modification or a source replacement that may affect the radiation protection and safety of patients, no treatment can take place until the necessary quality control tests have been completed and checked by the medical physicist.

5.2.5.11 Where remote software modifications are possible, a protocol should be in place that ensures the medical physicist is informed prior to any modifications being carried out so that appropriate

quality control tests can take place prior to reintroduction of treatment.

5.2.5.12 Testing of sealed sources during source exchange for leakage is done.

5.2.5.13 A maintenance programme should be in place.

5.2.5.14 There are periodic review of the protocols and procedures.

5.2.5.15 Maintaining records is a crucial aspect of the programme of quality assurance for medical exposure.

5.2.6 Dose Constraints: Caregivers

The facility should ensure that:

5.2.6.1 Written protocols are drawn up for implementing measures for the optimization of protection and safety for caregivers of LDR brachytherapy patients or patients with permanent implants. The measures should utilize the basic methods for radiation protection (i.e. time, distance and shielding). The protocols should include the following:

a. Criteria specifying who would be acceptable for acting as a carer or comforter.

b. Methods for ensuring that the caregivers receive a dose that is as low as reasonably achievable.

c. The values of the dose constraints to be applied.

5.2.6.2 No individual incurs a medical exposure as a caregiver unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing an Imaging procedure.

5.2.6.3 The caregivers should indicate that he or she is still willing to provide support, care, and comfort to the patient.

5.2.6.4 Appropriate written instructions should be available and provided to the carer or comforter.

5.2.6.5 The doses of any comforter or visitor of patients should be constrained so that it is unlikely that his or her dose will exceed

the recommended limit during the period of a patient's diagnostic examination or treatment.

5.3 Pregnant Patients

The facility to ensure that:

5.3.1 There are means for ensuring that the pregnancy status of patients is known. These may include:

5.3.2 Posting of clear signs (possibly including a pictorial representation of pregnancy) in languages easily understood by the people.

5.3.3 To ask patients directly whether they are or might be pregnant.

5.3.4 Cooperation with the referring medical practitioner, through standard requests for pregnancy status for specified procedures, is one approach.

5.3.5 The referral form should include a 'tick box' for pregnancy status. In case of doubt, a pregnancy test, or a determination of hormone levels to assess menopausal status can be carried out.

5.4 Release of Patients After Permanent Brachytherapy Implants

The Facility Should Ensure That:

5.4.1 Arrangements are in place to manage the release of patients who have permanent brachytherapy implants.

5.4.2 Exposure of any members of the household of a patient who has undergone a therapeutic procedure with sealed radionuclides and members of the public is avoided. Such a patient should not be discharged from hospital before the activity of radioactive substances in the body falls below the specified level.

5.4.3 The medical physicist or RPO at the radiation therapy facility should establish prior to the release of a patient that the radioactivity of the implants is such that the doses that could be received by members of the public would not exceed the dose limits and would be unlikely to exceed the relevant dose constraints for both members of the public and caregivers.

5.4.4 The patient or the legal guardian of the patient should be provided with written instructions on how to keep doses to

members of the public and Caregivers as low as reasonably achievable the instructions should provide guidance on what to do and what not to do.

5.4.5 The patient with permanent brachytherapy implants should be informed of the presence of the implants.

5.4.6 Information is provided to the patient on radiation risks, including guidance with respect to fertility in the case of implants for prostate cancer.

5.4.7 Patients should be insured with an identification card with essential information about the implanted devices.

5.5 Unintended and Accidental Medical Exposures

5.5.1 Prevention of Unintended and Accidental Medical Exposures

The facility should ensure that:

5.5.1.1 All practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical Imaging and radiotherapy equipment, from failures of and errors in software, or because of human error." Conduct promptly investigate if such exposures occur.

a. The likelihood of unintended or accidental medical exposures in radiation therapy is minimized. This can be achieved by:

b. The introduction of safety barriers at identified critical points in the process, with specific quality control checks at these points. Quality control should not be confined to Imaging and radiotherapy equipment physical tests or checks and can include actions such as checks of the treatment plan or dose prescription by independent professionals.

c. Actively encouraging a culture of always working with awareness and alertness.

d. Providing detailed protocols and procedures for each process.

e. Providing sufficient staff who are educated and trained to the appropriate level, and an effective organization, ensuring reasonable patient throughput.

f. Continuous professional development and practical training and training in applications for all staff involved in the preparation and delivery of radiation therapy.

g. Clear definitions of the roles, responsibilities, and functions of staff in the radiation therapy facility that are understood by all staff.

5.5.1.2 Unusual and complex treatments should always trigger an extra warning, and each staff member should be aware and alert in these situations. The use of 'time-outs', where staff take time to review what has been planned, prior to delivering treatment, should be considered.

5.5.1.3 Comprehensive protocols and procedures covering the various steps in the process should exist for a major part of the facility's activities.

5.5.1.4 Checklists detailing actions, and signed by the responsible parties at each step, are established.

5.5.1.5 For critical steps, such as commissioning and calibration of equipment, there should always be a review, either internally or preferably through an external, independent audit.

5.5.1.6 When new techniques are introduced, they should also be subject to an audit.

5.5.1.7 Preventive measures should include reporting of incidents and near incidents, analysis, and feedback, including lessons from international experience. Proactive risk assessment be carried out to try to pre-empt the occurrence of incidents. the following three-step strategy (commonly called 'prospective risk management') can help to prevent unintended and accidental exposures in radiation therapy:

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

b. Use of the lessons from unintended and accidental medical exposures to test whether the management system, including for

radiation protection and safety, is robust enough against these types of events.

c. Identification of other latent risks by posing the questions 'What else could go wrong?' or 'What other potential hazards might be present? 'In a systematic, anticipative manner for all steps in the radiation therapy process, using, for example, the proactive methods.

5.5.2 Investigation of Unintended and Accidental Radiation Medical Exposures

The facility should ensure that:

5.5.2.1 Promptly investigate on any of the following incidents:

a. any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or wrong treatment modality or with a dose or dose fractionation differing from the values prescribed by the Radiation Oncologist 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.

5.5.2.2 A system with clear procedures should be put in place for identifying when unintended and accidental medical exposure event occurs. For example, unintended or accidental medical exposures involving a total dose 10% or more over that prescribed will generally be detectable in most cases by the radiation oncologist or relevant health professional, based on an unusually high incidence of adverse patient reactions.

5.5.2.3 In addition to the clinically based approaches to identifying doses delivered that are substantially different from those prescribed,

other approaches should be used in parallel, including the review processes that are part of quality assurance.

5.5.2.4 To put in place a system to manage the investigation of unintended and accidental medical exposures, and the ensuing actions and reporting.

5.5.2.5 A record of the calculation method and results should also be placed in the patient's file.

5.5.2.6 When required, counselling of the patient should be undertaken by an individual with appropriate experience and clinical knowledge.

5.5.2.7 significant events are reported to Radiation Protection Authority and/or the health authorities and on the corrective actions taken, so that other facilities might learn from these events.

5.5.2.8 Feedback to staff be provided in a timely fashion and, where changes are recommended, all staff should be involved in bringing about their implementation.

5.5.2.9 They are active participants and users of SAFRON, ROSEIS or similar international databases or equivalent national ones.

5.6 Records and Review

5.6.1 Imaging and Radiotherapy Review and Records

The facility should ensure that:

5.6.1.1 Imaging and radiotherapy reviews are performed periodically.

5.6.1.2 A system for the ongoing collection of relevant data to support such reviews should be in place at the facility.

5.6.1.3 Records should be in place.

5.6.1.4 Care be taken to retain the records of the imaging and radiotherapy procedures performed while preparing, planning, treating, and verifying the treatment.

5.6.1.5 The records may be retained at least for about 10 ten years.

6.0 RADIATION PROTECTION OF THE PUBLIC

6.1 External Radiation Medical Exposure and Contamination

The facility should ensure that:

6.1.1 Public exposure is controlled by ensuring that radiation sources are properly shielded and secured (e.g., located in a locked area) interlocks

are functional, keys to the control panel are secured, to prevent unauthorized access or use.

6.1.2 Access by members of the public to areas in and near the radiotherapy department should be considered when designing shielding of storage and use facilities.

6.1.3 The RPO should establish rules to ensure that the exposure of any member of the public will be less than the public dose limit and, preferably, lower than any applicable dose constraint.

6.1.4 When deciding on the appropriate activity at discharge for a particular patient, the licensee and the RPO should consider the transport and the living conditions of the patient.

6.1.5 The RPO determines the radiation protection precautions required after the death of a patient with permanent implants, for autopsy, embalming, burial, or cremation.

6.2 Access Control

The facility should ensure that:

6.2.1 Access of members of the public to radiotherapy irradiation rooms is limited.

6.2.2 Adequate information and instruction are provided to persons before they enter a controlled area.

6.2.3 Those appropriate signs and information be posted these areas.

6.3 Accidental Radiation Medical Exposures to Members of The Public

6.3.1 Radioactive Waste and Sources No Longer in Use

The facility should ensure that:

6.3.1.1 The licensee or the radiation protection officer notifies the regulatory authority and submits a plan for transfer or disposal of sources if they are no longer in use.

6.3.1.2 The licensee should maintain responsibility for the sources until approval is granted by the Authority for transfer to another authorized radiation therapy facility or waste disposal facility.

6.3.1.3 The regulatory authority is notified of any intention to transfer or decommission ^{60}Co teletherapy equipment prior to initiating any action.

6.3.1.4 Notify the regulatory body of any intention to transfer or decommission 60Co teletherapy equipment prior to doing so. Depleted uranium used as shielding material should also be treated as radioactive waste. For

example, a 60Co teletherapy head might contain depleted uranium and should be managed appropriately.

6.3.1.5 Resources for the disposal of the sources will be made available when the radiotherapy equipment is to be decommissioned.

6.3.1.6 have in place a programme for the safe disposal or return of the radioactive sources when their use is discontinued before authorization for the import or purchase of equipment or radiation sources is given. A contract with the manufacturer for the return of sources is acceptable evidence of such a programme.

6.4 Activation Products

6.4.1 The facility should ensure that Activated materials from the head of the linac are correctly disposed off.

6.5 Monitoring and Reporting

The facility should ensure that:

6.5.1 Establish and carry out a monitoring programme sufficient to ensure that the requirements of the standards regarding public exposure to sources of external irradiation be satisfied and to assess such exposure.

6.5.2 Keep appropriate records of the results of the monitoring programmes.

6.5.3 The program for monitoring public exposure from radiotherapy should include dose assessment in the surrounding irradiation rooms for external beam therapy, such as brachytherapy wards and source storage and preparation room and waiting rooms.

7.0 PREVENTION AND MITIGATION OF ACCIDENTS

7.1 Safety Assessments of Potential Exposure

The facility should ensure that.

7.1.1 A safety assessment applied to all stages of the design and operation of the radiotherapy facility is conducted.

7.1.2 The safety assessment should be revised when:

7.1.1.1 New or modified radiation sources are introduced, including equipment and new or renovated facilities.

7.1.1.2 Operational changes occur, including changes in workload.

7.1.1.3 Operational experience or information on accidents or errors indicates that the safety assessment is to be reviewed.

7.1.1.4 Safety assessments to include consideration of all the steps associated with sealed sources, including the following:

7.1.1.5 Ordering, transporting, and receiving sealed sources.

7.1.1.6 Unpacking, storing, preparing, and handling sources prior to their use in the treatment of the patient.

7.1.1.7 Care of patients with high amounts of activity.

7.1.1.8 Storage and handling of sources after removal and the management of unused radioactive seeds.

7.1.3 The safety assessment should be documented and revised by an independent expert when:

7.1.3.1 The radiation sources or their facilities are modified.

7.1.3.2 Operational experience or information on accidents or errors indicates that the safety assessment should be reviewed.

7.1.3.3 Techniques are modified in such a way that safety may be compromised.

7.2 Prevention of Accidents

The facility should ensure that:

7.2.1 They incorporate the following in safety procedures:

7.2.1.1 Defense-in-depth measures to cope with identified events, and evaluate the reliability of the safety systems, (including administrative and operational procedures, and equipment and facility design).

7.2.1.2 The operational experience and lessons learned from accidents and errors into training, maintenance, and quality assurance programs.

7.2.2 To promptly inform the regulatory authority of all reportable incidents or accidents with severe/extreme consequences.

7.3 Mitigation of The Consequences of Accidents

The facility should ensure that:

7.3.1 Based on the events identified by the safety assessment, the facility should elaborate mitigation measures embodied in a set of emergencies procedures

7.3.2 The relevant staff be trained in the mitigation measures, which should be periodically rehearsed.

7.3.3 The lessons learned from the rehearsals are used to review and update emergency plans.

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

7.3.5 In cases where the beam control mechanism has failed to terminate the exposure at the end of the pre-set time, such as a stuck teletherapy

source) the procedure should include the removal of the patient while avoiding exposure to the direct beam.

7.3.6 A Health practitioner trained to remove the catheters and conduct the emergency procedures without delay should be permanently present during HDR procedures.

7.3.7 Emergency equipment to retract the source to a fully shielded position should be readily available.

7.3.8 Emergencies during source change should be conducted only by service engineers authorized for these tasks.

7.3.9 If participation of the radiotherapy staff is necessary for any of these actions, the scope of this participation should be restricted to the operation of the control panel and the responsibilities should be clearly defined.

7.3.1 Stuck Sources:

The facility should ensure that:

7.3.1.1 Mitigatory procedures and emergency procedures be short, concise, unambiguous and, if necessary, illustrated with drawings without explanatory text. They should be able to be read at 'first sight' and followed. It should be made clear that the first sight procedures refer to actions to be taken immediately to prevent or limit serious overexposures, or to take other lifesaving actions.

7.3.2 Stuck Sources: 60co Teletherapy Units

The facility should ensure:

7.3.2.1 Mitigation procedures and emergency procedures be posted at the treatment unit. These procedures should ensure that:

a. The patient is removed from the primary beam as quickly and efficiently as possible whilst minimizing exposure of the personnel involved.
b. To note the time, and immediately to use the source driving mechanism to return the source to the shielded position.

c. If there is a patient on the treatment couch, the patient should be removed from the area and the area should be secured from further entry.
d. The medical physicist or the RPO should be notified and should take control of the situation, including deciding when it is safe to re-enter the room.
e. The medical physicist should check the calibration of the radiation source and should verify that it has not changed, particularly in the event of a timer error in 60Co teletherapy units.

7.3.2.2 Actions should be performed only by personnel that are knowledgeable and trained in the response actions and have regularly participated in drills and exercises. After the necessary response actions have been implemented, the following should be done:

a. The maintenance or service engineer should be contacted to perform an inspection of the machine.

b. The medical physicist should assess the patient doses and should check the machine for re-use after the engineer has completed the inspection and any associated maintenance.

c. The RPO should assess the doses to personnel involved in response to the event and recovery if involved (i.e. in a case where the stuck source cannot be pushed back into its shielded position or members of the public is found in the restricted area during the incident).

d. Put in place a local Incident Reporting System and Incident Learning Programme unique to their environment and types of incidents.

e. A record should be kept of all actions.

f. The regulatory body may to be notified, when necessary

g. Information should be sent to an international safety learning system such as SAFRON or ROSEIS or a national learning system.

h. Medical attention, as necessary, should be provided to those involved, commensurate with the doses received.

7.3.3 Stuck Sources: Remote Control Brachytherapy Units

The facility should ensure that:

7.3.3.1 To establish emergency plan which should include having:

a. An emergency container available in the treatment room

b. An emergency kit containing long handled forceps for manipulation of the source guide tubes.

c. Applicators if the source fails to return to the safe.

7.3.3.2 Staff should be trained on how to apply such a procedure and should regularly participate in drills and exercises. After the necessary response actions have been implemented, the following should be done:

a. Observation at the console of an error message and emergency indicators (audible and visible alarms).

b. Recovery from the console (e.g., pressing an emergency off button).

c. Entry into the room with a portable radiation survey meter (opening the door activates the interlock that retracts the source).

d. Monitoring the radiation levels in the room.

e. Recovery from the after loading unit (by pressing an emergency off button on the remote after loading unit).

f. Manual retraction of the source (using a hand crank).

g. Patient survey and after loading survey (confirming that the source is in the safe).

h. Applicator removal and placement in the emergency container.

i. Patient survey and emergency container survey (to confirm that the source is not in the patient and is in the emergency container).

j. Removal of the patient from the vault (with subsequent survey monitoring).

7.3.3.3 After the emergency the following should be done:

a. The maintenance engineer should be contacted to perform an inspection and, if necessary, repair the machine.

b. The medical physicist should assess the patient doses and clear the use of the machine after maintenance.

c. The radiation protection officer should assess the dose to the staff in the emergency and recovery operation.

d. The assessments should be recorded.

7.3.4 Incidents and Accidents During Source Replacement

The facility should ensure that:

7.3.4.1 Only trained and authorized maintenance or servicing personnel should deal with accidents during a change of a source in external.

7.3.5 Lost Radiation Therapy Sources

The facility should ensure that:

7.3.6.1 A detailed, up to date inventory of all sources be maintained by the RPO of the

7.3.6.2 The area where the sources were last known should be closed to entry and exit until after a survey has been conducted.

7.3.6.3 This search should be performed with the most sensitive radiation survey meter available.

7.3.6.4 If a source cannot be located and it is suspected that it is off the site, the relevant authorities should be notified, and immediate actions should be taken. some actions may include:

a. Obtain assistance from the radiation protection officer.

b. Conduct a local search.

c. Check and ensure physical security and control of other sources.

d. Report the theft or loss to the appropriate competent authorities, providing a description of the device and its threat.

e. Secure all information and the scene as much as possible to allow for forensic investigation.

f. Conduct response actions in cooperation with local officials and law enforcement authorities.

g. Identify and investigate routes by which the source may have been lost such as waste, patient.

h. Brief off-site officials on risks and provide measures to protect emergency workers including law enforcement personnel and control their dose.

i. Recommend that local officials inform nearby medical facilities, border crossings and scrap metal dealers to be alert for the source or for radiation induced injuries; provide them with a description of the source and its container and of symptoms of radiation injuries (e.g., burns with no apparent cause).

j. Support local officials in explaining the risk to the local public and the media.

k. Have the national regulatory body notify potentially affected States and the IAEA if there are indications that the source may have crossed into another State.

l. If the source is found, ensure it is not damaged or leaking — if it is damaged or leaking, notify officials and ensure that it is surveyed for contamination.

m. Evaluate and record the doses received and inform those exposed of the risks; arrange, where appropriate, for long term medical follow-up.

8. 0 SAFETY IN THE TRANSPORT OF RADIOACTIVE MATERIALS

8.1 Receipt Of Radioactive Materials

The facility should ensure that:

8.1.1 Prior to each shipment of radioactive material to be dispatched, the radiation therapy facility responsible for the transport should make the necessary arrangements with the source suppliers to receive the relevant information.

8.1.2 This information should include the following for each package or container:

8.1.2.1 The nuclide, number, and activity of sources.

8.1.2.2 A description of the source construction and performance tests, including leakage tests.

8.1.2.3 Special form approval certificate (where appropriate).

8.1.2.4 A description of the package.

8.1.3 Approval certificate for Type A or B packages, or statement of compliance with IAEA ST–1 for other packages.

8.1.4 Details of any special arrangements required, including multilateral approvals, were necessary.

8.1.5 A copy of the transport documents (to be sent to the radiation therapy facility by fax or e-mail before dispatch if possible).

8.1.6 The radiation therapy facility should not agree to the dispatch of the consignment by the supplier unless all the above items are satisfactory.

8.1.7 The supplier and radiation therapy facility should agree the transport route and responsibility for each stage of the journey.

8.1.8 Arrangements should also be made for the following where necessary:

8.1.8.1 The need for special handling equipment for external beam sources, e.g., cranes, forklift trucks. during transfer from one mode of transport to another, or between vehicles.

8.1.8.2 Checking of radiation dose rates from the package or container.

8.1.8.3 Checking that the correct transport labels are attached to the package or container, and replacing any that are damaged or illegible.

8.1.8.4 Ensuring that the package or container is securely attached to the vehicle and that the vehicle is correctly labelled.

8.1.8.5 Dealing with border controls.

8.1.8.6 Security of the consignment during transport, particularly during delays or overnight stops.

8.2 Dispatch of Radioactive Materials

The facility should ensure:

8.2.1 To return packages or containers to the source supplier after receipt of a consignment of radioactive material.

8.3 Empty Packages

The facility should:

8.2.1 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.

8.2.2 radioactive material present, and it can be therefore treated as an empty package /container.

8.2.3 Remove or cover all transport labels relating to the sources contained in the package or container when received.

8.2.4 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.

8.2.5 Attach a label to the outside of the package or container stating, "UN for example 2905 RADIOACTIVE MATERIAL EXCEPTED PACKAGE — EMPTY PACKAGING".

8.2.6 Complete a transport document.

8.2.7 Contact the source supplier and agree the transport route and responsibility for each stage of the journey. Inform the source supplier of the proposed date of dispatch.

8.3 Return of Disused Sources

The facility should provide.

8.3.1 the following information to the consignee for each package or container:

8.3.1.1 The nuclide, number, and activity of sources.

8.3.1.2 A description of the source construction including leakage tests.

8.3.1.3 Special form approval certificate (where appropriate).

8.3.1.4 A description of the packaging in which the source is to be transported.

8.3.1.5 Approval certificate for Type B package, or statement of compliance with IAEA ST–1 for other packages (as appropriate).

8.3.1.6 Details of any special arrangements required, including multilateral approvals, where necessary.

8.3.1.7 A copy of the transport documents (to be sent to the consignee by fax or e-mail before dispatch if possible).

8.3.2 The radiation therapy facility should not dispatch the consignment unless they have received confirmation from the consignee that they are prepared to accept it.

8.3.3 The radiation therapy facility and consignee should agree on the transport route (as needed) and responsibility for each stage of the journey.

8.3.4 To prepare the consignment for dispatch, Radiotherapy facility should ensure that the:

8.3.4.1 Sources are loaded 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.

8.3.4.2 Package or container is closed securely and then examine to ensure that it is in good condition, referring to any procedures provided by the source supplier.

8.3.4.3 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.

8.3.4.4 Carry out dose rate monitoring of the package or container and attach appropriate transport labels.

8.3.4.5 Refrain from using the transport labels relating to the sources contained in the package or container when received.

8.3.4.6 Complete a transport document.

Definitions

In these Regulations, unless the context otherwise requires-

"**Controlled area**" means any area in which specific protection measures and safety provisions are or may 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.

"**Critical group**" means a group of members of the public which is reasonably homogeneous with respect to its exposure for a given radiation source and given exposure pathway and is typical of individuals receiving the highest effective dose or equivalent dose by the given exposure pathway from the given source.

"**Defence in depth**" means the application of more than a single protective measure for a given safety objective such that the objective is achieved even if one of the protective measures fails.

"**Disposal**" means- (a) the emplacement of waste in an approved, specified facility without the intervention of retrieval; or (b) the approved direct discharge of airborne or liquid effluents into the environment with subsequent dispersion.

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

"***Employer***" means a legal person with recognised responsibility, commitment, and duties towards a worker in his or her employment by virtue of a mutually agreed relationship.

"***Effective dose***" means the radiation dose that the total body can receive uniformly and that can give the same cancer risk when exposing individual organs to different doses, expressed as quantity E, which is the summation (Σ) of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor- where HT is the equivalent dose in tissue T and WT is the tissue weighting factor for tissue T.

"**Equivalent dose**" means the quantity HT, R, defined as: where DT, R is the absorbed dose delivered by radiation type R averaged over a tissue or organ T and WR is the radiation weighting factor for radiation type R. When the radiation field is composed of different radiation types with different values of WR, the equivalent dose is- The unit of equivalent dose is J.kg-1 termed the Sievert (Sv).

"**Fixed contamination**" means contamination other than non-fixed contamination.

"**Guidance level**" means a level of a specified quantity above which appropriate actions should be considered.

"**Health professional**" means a medical practitioner, a dentist or a pharmacist or an allied health professional registered under the Zambia Health Professions Act.

"Health surveillance" means medical supervision intended to ensure the initial and continuous fitness of workers in their intended task.

"**Intervening organisation**" means an organisation designated or otherwise recognised by the Government of Zambia as being responsible for managing or implementing any aspect of an intervention.

"**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 because of an accident.

"**Legal person**" means any organisation, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with any law, who or which has responsibility and authority for actions taken under these Regulations.

"**Licence**" means an authorisation granted by the Board based on a safety assessment and accompanied by specific requirements and conditions to be complied with by the authorised persons.

"**Authorised persons**" means the holder of a current licence granted for a practice or source.

"**Limit**" means the value of a quantity used in certain specified activities or circumstances that must not be exceeded.

"**Medical exposure**" means exposure incurred-

(a) by patients as part of their own medical diagnosis or treatment.

(b) by persons other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients; and

(c) by volunteers in a programme of biomedical research involving their exposure.

"**Medical practitioner**" means a person- (a) registered as a medical practitioner under the Zambia Health Professions Act; (b) who fulfils the national requirements on training and experience for prescribing procedures involving medical exposure; and (c) is an authorised person, or a worker who has been designated by a licensed employer for the purpose of prescribing procedures involving medical exposure.

"**Member of the public**" means- (a) any individual in the population except, for the purposes of these Regulations, when subject to occupational or medical exposure;

and (b) 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.

"**Non-fixed contamination**" means contamination that can be removed from a surface during routine conditions of transport.

"**Normal exposure**" means 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 in the general obligations for practices.

"**Occupational exposure**" means exposure of workers incurred in the course of their work, except for exposures excluded from these Regulations and exposures from practices or sources exempted by these Regulations.

"**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, to increase the exposure or the likelihood of exposure of people or the number of people exposed.

"**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 authorised sources and practices and from intervention situations.

"**Qualified expert**" means an individual who, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, is duly recognised as having expertise in a relevant field of specialisation.

"**Quality assurance**" means all those planned and systematic actions necessary to provide adequate confidence that an item, process, or service will satisfy given requirements for quality.

"**Radiation Safety Officer**" means an individual technically competent in radiation protection matters relevant for a given type of practice who is designated by the radiation therapy facility to oversee the application of the requirements of these Regulations.

"**Radioactive discharges**" means radioactive substances arising from a source within a practice which are discharged as gases, aerosols, liquids, or solids to the environment, generally with the purpose of dilution and dispersion.

"**Radioactive waste**" means material, whatever its physical form, remaining from practices or interventions and for which no further use is foreseen, that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for exemption or clearance from regulatory requirements, and exposure to which is not excluded from these Regulations.

"**Reference level**" means action level, intervention level, investigation level or recording level which may be established for any of the quantities determined in the practice of radiation protection.

"**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 provision 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 organisations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

"**Sealed source**" means a radiation source consisting of a radioactive substance enclosed in enclosures or arranged in such a way that there is no risk of the substance being liberated or becoming accessible to direct contact during normal use.

"**Source**" means anything that may cause radiation or releasing radioactive substances or materials.

"**Storage**" means the placement of radioactive waste in a suitable facility where isolation, environmental protection and human control are provided with the intent that

the waste will be retrieved for clearance or treatment and conditioning, or disposal later.

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

"**Supplier**" means any legal person to whom a radiation therapy facility delegates duties, totally or partially, in relation to the design, manufacture, production or construction of a source.

"**Treatment**" means operations intended to benefit safety or the economy by changing the characteristics of the waste.

"**Unsealed source**" means radioactive material that is- (a) not permanently sealed in a capsule; (b) not closely bounded and is not in a solid form.

"**Waste inventory**" means a detailed, itemised record maintained by the operator or Authority in accordance with these Regulations, which may contain data on the physical quantity, the activity of the waste, the radionuclide content, and other characteristics.

"**Waste management**" means all activities, administrative and operational, including decommissioning activities that are involved in the handling, pre-treatment, conditioning, storage, and disposal of waste from a facility.

"**Waste package**" means the product of conditioning that includes the waste form and any container and internal barriers, as prepared in accordance with requirements for handling, transportation, storage, and disposal.

"**Worker**" means any person who works, whether full time, part time or temporarily for an employer and who has recognised rights and duties in relation to occupational radiation protection.