

GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 8 OF 2024

The Ionising Radiation Protection Act, 2005
(Act No. 16 of 2005)**The Ionising Radiation Protection (Radiotherapy)
Regulations, 2024**

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IN EXERCISE of the powers contained in section 46 of the Ionising Radiation Protection Act, 2005, the following Regulations are made:

PART I

PRELIMINARY PROVISIONS

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| 1. | These Regulations may be cited as the Ionising Radiation Protection (Radiotherapy) Regulations, 2024. | Title |
| 2. | In these Regulations, unless the context otherwise requires— | Interpretation |
| | “accident” means any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible; | |
| | “activity” means an amount of radionuclide in a given energy state at a given time; | |
| | “becquerel” means an activity of a quantity of radioactive material in which one nucleus decays per second; | |
| | “brachytherapy” means a medical procedure performed by placing a radioactive material directly into, or on, the patient; | |
| | “brachytherapy implant” means a radioactive material placed in a patient temporarily or permanently; | |
| | “calibration” means a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by measurement standards; | |
| | “carer” means a person who willingly and voluntarily helps in the care, support and comfort of a patient undergoing radiological procedures for medical diagnosis or medical treatment; | |
| | “compulsory standard” has the meaning assigned to the words in the Compulsory Standards Act, 2017; | Act N.o 3 of 2017 |
| | “contamination” means the unintended or undesirable presence of, or the process giving rise to, radioactive substances on surfaces or within solids, liquids or gases; | |
| | “controlled area” means an area in which specific protection measures and safety provisions are, or can be, required for controlling exposures or preventing the spread of contamination in normal working conditions, and preventing or limiting the extent of potential radiation exposure; | |

“decontamination” means the complete or partial removal of contamination by a deliberate physical, chemical or biological process;

“commissioning” means the process of systems and components of facilities and activities, which having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria;

“diagnostic reference level” means a level used in medical imaging to indicate whether, in routine conditions, the dose to the patient or the amount of radio pharmaceuticals administered in a specified radiological procedure for medical imaging is unusually high or low for that procedure;

“dose” means a measure of the energy deposited by radiation in a target or patient;

“emergency” means a non routine situation or event that necessitates prompt action, primarily to mitigate a hazard or adverse consequences to human life, health, property and the environment;

“external beam radiotherapy” means a radiation therapy that uses a machine to aim high energy rays at the cancer from outside of the body;

“exposure” means the state or condition of being subject to irradiation;

“external exposure” means exposure to radiation from a radioactive material or radiation emitting device outside the body;

Act No. 24
of 2009

“health facility” has the meaning assigned to the words in the Health Professions Act, 2009;

Act No. 24
of 2009

“health practitioner” has the meaning assigned to the words in the Health Professions Act, 2009;

“high dose rate brachytherapy” means high dose rate brachytherapy techniques;

“International Atomic Energy Agency” means an international organisation that seeks to promote the peaceful use of nuclear energy and to inhibit its use for a military purpose which entered into force on 29th July, 1957 and was ratified by Zambia on 8th January, 1969;

“investigation level” means the value of a quantity per unit area or volume at or above which an investigation would be conducted;

“low dose rate brachytherapy” means performing a medical procedure by placing a low dose radioactive material directly into or on the patient;

“maintenance” means the organised activity, both administrative and technical, of keeping structures, systems and components in good operating condition, including both preventive and corrective aspects;

“medical exposure” means exposure incurred by a patient for the purposes of that patient’s own medical treatment or diagnostic examination;

“medical physicist” means a person with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practice independently in one or more of the subfields of medical physics;

“medical radiological equipment” means radiological equipment used in a radiotherapy facility to perform radiotherapy procedures that delivers an exposure to an individual or directly controls or influences the extent of that exposure;

“occupational exposure” means exposure of a worker incurred in the course of duty of that worker;

“operator” means a person in charge of a radiotherapy facility;

“public exposure” means exposure incurred by members of the public due to sources in planned exposure situations, emergency exposure situations and existing exposure situations, excluding any occupational exposure or medical exposure;

“radiation monitoring” means the measurement of dose, dose rate or activity for reasons relating to the assessment or control of exposure to radiation or exposure due to radioactive substances, and the interpretation of the results;

“radiation protection programme” means a program developed by a radiotherapy facility on radiation protection;

“radiation therapy” means a branch of clinical medicine that uses ionising radiation for the treatment of a patient with cancer or other diseases;

“radiation source” means anything that may cause radiation exposure by emitting ionising radiation or releasing radioactive substances or materials;

“radioactive material” means a material designated by the Authority as being subject to regulatory control because of its radioactivity;

“radioactive waste” means a material for which no further use is foreseen that contains, or is contaminated with, radionuclides at activity concentrations greater than clearance levels as determined by the Authority;

“radiological procedure” means a medical imaging procedure or therapeutic procedure that involves ionising radiation delivered by a radiation generator, a device containing a sealed source or an unsealed source or by means of a radiopharmaceutical administered to a patient;

“radiotherapy facility” means a health facility where radiation therapy is performed;

“supervised area” means an area not designated as a controlled area but for which occupational exposure conditions are kept under review, and where specific protection measures or safety provisions are not usually required;

Act No. 6 of
2019

“supporter” has the meaning assigned to the word in the Mental Health Act, 2019;

Cap. 1

“young person” has the meaning assigned to the words in the Constitution;

Act No. 4 of
2017

“Zambia Bureau of Standards” means the Zambia Bureau of Standards established under the Standards Act, 2017; and

Act No. 3 of
2017

“Zambia Compulsory Standards Agency” means the Zambia Compulsory Standards Agency established under the Compulsory Standards Act, 2017.

PART II

RADIATION PROTECTION MANAGEMENT

3. (1) Subject to these Regulations, a radiotherapy facility shall employ an appropriate number of qualified staff for the protection and safety of people using radiation therapy.

Staff at radio
therapy
facility

(2) A radiotherapy facility shall assess the performance of qualified staff referred to under subregulation (1) periodically taking into consideration the workload and the introduction of new techniques and equipment in radiation therapy.

(3) An operator shall ensure that the following staff are provided with specific instructions on radiation protection:

- (a) nurses working in a controlled or supervised area;
- (b) staff who do not belong to radiation therapy practice but need to enter a controlled area; and
- (c) staff who transport radioactive materials within the radiotherapy facility.

(4) A person who carries on work at a radiotherapy facility in an area near a radioactive source shall be informed of the radiation hazard, details of the specific use and the radiation protection programme referred to in regulation 4.

4. (1) A radiotherapy facility shall establish a radiation protection programme relating to all phases of the radiation therapy practice from designing to decommissioning.

Radiation
protection
programme

(2) An operator shall review the radiation protection programme periodically and provide the necessary resources to comply with the radiation protection programme.

(3) A radiation protection programme shall include management's responsibility in the radiotherapy facility for radiation protection and safety through the management structure, policies, procedures and organisational arrangements.

PART III

SAFETY AND SECURITY OF RADIOACTIVE MATERIAL AND RADIOACTIVE
SOURCE

Security of
radioactive
material

5. (1) A radiotherapy facility shall develop procedures for the safe receipt and movement of a radioactive material within the radiotherapy facility and shall establish controls to prevent the—

- (a) theft, loss and unauthorised withdrawal of a radioactive material; or
- (b) entrance of unauthorised personnel into a controlled area.

(2) A radiotherapy facility, shall establish written procedures to check and confirm whether a radioactive material is in its assigned location and is secure.

Calibration
of
radioactive
material and
instrument
for
dosimetry
of patients

6. (1) An operator shall ensure that—

- (a) a radioactive material and an instrument used for dosimetry of a patient in a radiotherapy facility is calibrated; and
- (b) the calibration of a radioactive material and instrument is done by a medical physicist or qualified expert.

(2) An operator shall ensure that the calibration of x ray based radiological medical equipment follows the guidelines specified by the manufacturer and approved by the Authority.

(3) An operator shall ensure that an instrument used for dosimetry of a patient is calibrated periodically as determined by the manufacturer or approved by the Authority.

(4) An operator shall ensure that the calibration of an instrument used in dosimetry is traceable to a standards dosimetry laboratory.

(5) A radiotherapy facility shall keep records of calibration measurements and submit the calibration measurements to the Authority within seven days of the Authority requesting the calibration measurements.

Transportation
of
radioactive
material or
radioactive
source

7. An operator shall ensure that the transportation of a radioactive material or radioactive source from the radiation therapy facility complies with the Authority's regulations on safe and secure transportation of a radioactive material or radioactive source.

PART IV

MEDICAL RADIOLOGICAL EQUIPMENT

8. (1) A radiotherapy facility shall ensure medical radiological equipment meets national and recognised international standards, and is certified by the Zambia Bureau of Standards and the Zambia Compulsory Standards Agency, where applicable.

Medical
radiological
equipment

(2) A radiotherapy facility shall develop procedures, in writing, for the purchase, installation, acceptance, commissioning, use, maintenance, decommissioning and quality control of medical radiological equipment.

9. (1) A radiotherapy facility shall ensure that the design features for operational performance of medical radiological equipment are reproducible, accurate, predictable, safe, secured and meet the requirements for the operational optimisation of patient protection.

General
design
features for
medical
radiological
equipment

(2) A radiotherapy facility shall ensure that the design features specified under subregulation (1) include—

- (a) a fail safe operational design;
- (b) safety operational systems capable of preventing use by unauthorised personnel;
- (c) an operational manual system that allows the radioactive material or radioactive source to be manually taken back in the shielded position in the event of failure by the system to automatically reformat the radioactive material;
- (d) automatic recording and verification of information on systems for the radiological medical equipment; and
- (e) the ability to transfer data on the radiotherapy facility's network.

10. (1) A radiotherapy facility shall ensure that the design features for medical radiological equipment used in external beam radiotherapy, in brachytherapy and in treatment planning systems, meet the appropriate national and recognised international standards, and are certified by the Zambia Bureau of Standards and the Zambia Compulsory Standards Agency, where applicable.

Design
features for
medical
radiological
equipment in
external
beam
radiotherapy
and others

(2) The design features for medical radiological equipment used in external beam radiotherapy under subregulation (1) shall include—

- (a) safety interlocks or other means designed to prevent the clinical use of the medical radiological equipment in conditions other than those selected at the control panel;
- (b) a feature to permit interruption of the treatment from the control panel;
- (c) a fail safe feature despite the radiation beam being on or off;
- (d) a feature that shows that the—
 - (i) radiation field within the treatment area is uniform, in the absence of radiation beam modifiers;
 - (ii) dose rates outside the treatment area due to radiation leakage or scattering is kept as low as reasonably achievable; and
 - (iii) medical radiological equipment for high energy X-ray beams of >10 MV, is not producing potential hazards to patients from neutron activation.

(3) The design features for medical radiological equipment used in brachytherapy under subregulation (1) shall include—

- (a) the applicators that are specifically used for the radioactive material; and
- (b) compatibility of the applicators with the medical radiological equipment.

(4) The design features for medical radiological equipment used in treatment planning systems shall, in addition to subregulation (1), meet the clinical goals.

Simulators

11. (1) A radiotherapy facility shall ensure that the design features for simulators meet the appropriate national and recognised international standards, and are certified by the Zambia Bureau of Standards and the Zambia Compulsory Standards Agency, where applicable.

(2) A radiotherapy facility shall ensure that the design features for computed tomography scanners used as virtual simulators have features that allow patients to be simulated in the treatment position.

12. (1) A radiotherapy facility shall ensure that the following ancillary equipment is available at the radiotherapy facility: Ancillary equipment

- (a) for manual brachytherapy, radiation protection and safety equipment including a radiation detector source, handling equipment source, manipulators and several shielded containers;
- (b) for remote after loading brachytherapy, equipment for source handling a storage container in the treatment room, wire cutters and a suitable radiation monitoring instrument for source localisation;
- (c) radiation monitoring instruments, including area monitors and portable survey metres, ionisation chambers and scintillators; and
- (d) for accelerators producing high energy X-ray beams of >10 MV, a neutron monitoring instrument.

(2) An ancillary equipment referred to under subregulation (1) shall meet the appropriate national or recognised international standards, and be certified by the Zambia Bureau of Standards and the Zambia Compulsory Standards Agency, where applicable.

13. An operator shall ensure that an acceptance test is performed on the installation of medical radiological equipment in order to— Acceptance test

- (a) verify the conformity of the medical radiological equipment to technical specifications given by the manufacturer; and
- (b) ensure compliance with safety requirements set out in appropriate national and recognised international standards.

14. An operator shall, after completion of the acceptance test and before starting operation, ensure that medical radiological equipment is commissioned in accordance with appropriate national and recognised international standards. Commissioning

15. An operator shall ensure that — Operations

- (a) medical radiological equipment is operated in accordance with technical documents; and
- (b) manufacturer's operating manual and any additional procedures for radiological equipment are approved in accordance with appropriate national, and recognised international standards and certified by the Zambia Bureau of Standards and the Zambia Compulsory Standards Agency, where applicable.

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| Maintenance | <p>16. (1) An operator shall ensure that preventative and corrective maintenance on the medical radiological equipment is performed in accordance with appropriate national and recognised international standards.</p> <p>(2) An operator shall ensure that the process of removing or returning the medical radiological equipment for, and from, maintenance includes the following:</p> <ul style="list-style-type: none">(a) a record of the maintenance carried out; and(b) tests and measurements to determine that the medical radiological equipment is operating in a satisfactory manner before that medical radiological equipment is used to treat patients. |
| Quality assurance and decommissioning programme | <p>17. A radiotherapy facility shall establish a programme for quality assurance and decommissioning for medical radiological equipment.</p> |

PART V

OCCUPATIONAL RADIATION PROTECTION

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| Controlled or supervised area | <p>18. (1) A radiotherapy facility shall classify the areas of the radiotherapy facility as a controlled or supervised area in accordance with guidelines issued by the Authority.</p> <p>(2) A radiotherapy facility shall, on classification of an area under subregulation (1), put in place requirements for area delineation, signage, protection and safety measures, control of access, provision of personal protective equipment and provision of individual and area monitoring.</p> <p>(3) An operator shall ensure the following rooms meet the requirements of a controlled area in accordance with subregulations (1) and (2):</p> <ul style="list-style-type: none">(a) treatment rooms for external beam radiotherapy;(b) treatment rooms for remote afterloading brachytherapy;(c) operating theaters used during brachytherapy procedures with radioactive materials;(d) brachytherapy patient rooms;(e) radioactive materials storage and handling areas; and(f) rooms where imaging or simulation procedures are performed. |
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(4) A radiotherapy facility shall include the areas surrounding brachytherapy patient rooms or radioactive materials storage and handling areas as supervised areas.

19. (1) A radiotherapy facility shall establish rules and procedures to ensure the protection and safety of workers in a controlled or supervised area.

Rules and
procedures
in controlled
or
supervised
area

(2) Rules and procedures referred to under subregulation (1) shall include—

- (a) a hierarchy of preventive measures for the protection and safety of workers;
- (b) measures to minimise occupational exposure in the course of duty;
- (c) wearing, handling and storing of personal dosimeters, and specify investigation levels and ensuing follow up actions;
- (d) education and training for an occupational worker in radiation protection and safety; and
- (e) requirements for pregnant workers and a worker that is a young person in accordance with the Employment Code Act, 2019.

Act No. 3 of
2019

20. A radiotherapy facility shall establish rules and procedures for area surveys, interlock checks, leak tests and contingencies for the safe operation of external beam radiotherapy.

Rules and
procedures
for external
beam
radiotherapy

21. (1) A radiotherapy facility shall establish rules and procedures for the safe operation of brachytherapy which include maintenance on inventory of radioactive materials.

Rules and
procedures
for operation
of
brachytherapy

(2) An operator shall provide the name of a radionuclide, location and activity with reference date, serial number and unique identifier of each radionuclide at the radiotherapy facility.

22. (1) A radiotherapy facility shall establish rules and procedures for temporary low dose rate brachytherapy applications, whether manual or remotely controlled, which shall include—

Rules and
procedures
for low dose
rate
brachytherapy

- (a) the identification of a patient;
- (b) the identification of a radioactive material;
- (c) the date and time of insertion and removal of a radioactive material;

(d) the required time for nursing and the allowed distances for nurses and visitors; and

(e) instructions for workers in the event of an unplanned removal of a radioactive material from the body of a patient.

(2) Information referred to under subregulation (1) shall be displayed at the entrance to the treatment room.

Rules and
procedures
for high dose
rate
brachytherapy

23. A radiotherapy facility shall establish rules and procedures for high dose rate brachytherapy which shall include—

(a) routine quality assurance tests for the afterloader device at the beginning of each day of treatment;

(b) emergency safety precautions; and

(c) procedures to be implemented if the source fails to return to safety.

Rules and
procedures
for remote-
afterloading
brachytherapy

24. A radiotherapy facility shall establish rules and procedures for remote afterloading brachytherapy which include information on the shielded container.

Rules and
procedures
for manual
brachytherapy

25. (1) A radiotherapy facility shall establish rules and procedures for manual brachytherapy which shall include—

(a) information about an implant with a radioactive material;

(b) the verification and inspection of a radioactive material;

(c) a unique identifier for a radioactive material;

(d) information relating to the containers used for the transportation of radioactive materials;

(e) records on the movements of a radioactive material;

(f) the assignment of responsibilities for occupational workers;

(g) inspection of a reusable radioactive material visually for possible damage;

(h) availability of safety features; and

(i) precaution measures to be observed during the cutting and handling of a radioactive material.

(2) A licensee or an operator shall provide protective equipment to an occupational worker manually handling a radioactive material for brachytherapy.

26. (1) A radiotherapy facility shall, in accordance with guidelines issued by the Authority, establish a workplace monitoring programme.

Workplace
monitoring
programme

(2) A workplace monitoring programme referred to under subregulation (1) shall include—

- (a) procedures on how to monitor a patient with a radioactive material implant;
- (b) radiation measurements made in the working environment;
- (c) schedules for routine monitoring;
- (d) special monitoring for specific occasions, activities or tasks;
- (e) confirmatory monitoring to check assumptions made about exposure conditions;
- (f) details of the radiation detectors to be used for radiation monitoring; and
- (g) information relating to an occupational worker who works in a controlled area often, or occasionally works in a controlled area, and may receive a significant dose from occupational exposure.

(3) Information referred to under subregulation (2)(g) shall include—

- (a) individual radiation monitoring devices for an occupational worker;
- (b) individual radiation doses for each occupational worker, recorded separately; and
- (c) the radiation monitoring period as specified by the Authority.

(4) A workplace monitoring programme referred to under subregulation (1) shall—

- (a) for an external beam therapy room with a radioactive material and in a high dose rate brachytherapy treatment room, indicate that radiation monitors shall be permanently installed to provide daily radiation measurements; and
- (b) for a treatment room where the possibility of induced activity exists, indicate that neutron detectors shall be made available.

Radiation
dose limits
for
occupational
workers

27. (1) An operator shall ensure that an occupational worker is monitored for the following dose limits:

- (a) the limit for effective dose; and
- (b) the limit for equivalent dose to the lens of the eye and to the skin and extremities.

(2) A dose limit referred to under subregulation (1) shall not exceed the dose limits for occupational workers as prescribed.

Investigation
levels of
radiation
doses for
occupational
worker

28. (1) An operator shall follow the investigation levels of radiation doses for an occupational worker as determined by the Authority.

(2) An operator shall ensure that an investigation is initiated, as soon as possible, following a trigger or event, and a written report on the trigger or event is prepared and submitted to the Authority immediately after an investigation is completed.

(3) A report prepared under subregulation (2) shall include a determination or verification of the dose, corrective or mitigatory actions taken, and instructions or recommendations to avoid recurrence.

Radiation
records for
occupational
worker

29. A radiotherapy facility shall keep records of occupational exposure and ensure the records are available to an occupational worker at any reasonable time.

Health
surveillance
of
occupational
worker

30. An operator shall ensure an occupational worker is under a health surveillance programme established by the radiotherapy facility.

Pregnant
occupational
worker

31. An operator shall adapt the working conditions with respect to occupational exposure for a pregnant occupational worker to ensure that the embryo or fetus of the pregnant occupational worker is protected.

Protection
of
occupational
worker
responding
to incidents
in
radiotherapy
facility

32. An operator shall ensure that the occupational dose limits set by the Authority apply to an occupational worker responding to an incident at the radiotherapy facility.

PART VI

RADIATION PROTECTION OF PERSONS DURING RADIATION THERAPY

33. In this Part, a person undergoing medical exposure during radiation therapy does not include another person in the radiotherapy facility or another person waiting for a radiological examination.

Non-
application
of Part VI

34. (1) A health practitioner shall prescribe a medical examination for a person to undergo medical exposure for radiation therapy.

Referral for
medical
exposure

(2) A person referred to under subregulation (1) shall present the prescription at the radiotherapy facility and, on receipt of the prescription, the radiotherapy facility shall treat the prescription as a request for a professional consultation or opinion and not an instruction or order to perform.

(3) A health practitioner at a radiotherapy facility shall consider the following courses of action prior to determining whether a person undergoes medical exposure:

- (a) whether to treat the person using radiation therapy;
- (b) whether to treat the person using another modality;
- (c) whether to give the person a combined treatment approach;
or
- (d) whether the person should not be treated at all.

(4) A health practitioner referred to under subregulation (3) shall, where the health practitioner determines that a person shall undergo medical exposure, inform the person about the expected benefits, risks and limitations of the proposed medical exposure and the consequences of not undergoing medical exposure.

(5) Where a decision made under subregulation (4) involves a pregnant person —

- (a) paediatric procedures shall be put in place to ascertain the pregnancy status of a patient of reproductive capacity before the performance of a radiological procedure; and
- (b) written information of the risks associated with radiation treatment shall be provided to the pregnant person, the spouse, supporter or any other interested party in the life of the embryo or fetus.

Identification
of person
undergoing
medical
exposure

35. (1) A radiotherapy facility shall put in place an effective system for correct identification of a person undergoing medical exposure, whether the medical exposure is diagnostic or therapeutic in nature.

(2) An operator shall ensure that the identification of a person undergoing medical exposure is verified by two members of staff at the radiotherapy facility.

Optimisation
of protection
and safety of
person
undergoing
medical
exposure

36. A radiotherapy facility shall guarantee the optimisation of protection and safety of a person undergoing medical exposure by ensuring that medical radiological equipment used is designed and manufactured to ensure the exposure of volumes to a patient, except the planning target volume, is kept as low as reasonably achievable, consistent with the delivery of the determined dose to the planning target volume within the required tolerances.

Written
procedures
and
protocols for
delivery of
radiation
therapy

37. (1) An operator shall—

(a) ensure that the planning and delivery of treatment for a person undergoing radiation therapy is optimised by the delivery of the treatment with a correct absorbed dose to the correct volume and within the overall determined time, while keeping the dose to normal tissue and organs at risk within the established tolerances and as low as reasonably achievable;

(b) develop written procedures and protocols for the delivery of radiation therapy in accordance with national standards and recognised international standards; and

(c) cause the review of written procedures and protocols annually for a person undergoing medical exposure by radiation therapy.

(2) A written protocol under subregulation (1) (b) shall be designed taking into consideration protection and safety of the person undergoing medical exposure by radiation therapy.

(3) A health practitioner shall, where a health practitioner deviates from the provisions of the written protocol, record a reason for the deviation from the written protocol.

(4) A person who fails to record a reason for a deviation as specified under subregulation (3) commits an offence.

Dosimetry
standards

38. A radiotherapy facility shall develop dosimetry standards for a person undergoing medical exposure during radiation therapy in accordance with national and recognised international standards, and be certified by the Zambia Bureau of Standards, and the Zambia Compulsory Standards Agency, where applicable.

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| <p>39. (1) A health practitioner at a radiotherapy facility shall perform patient dosimetry and determine typical doses to patients for diagnostic radiological procedures.</p> | <p>Radiation doses for patient receiving radiation therapy</p> |
| <p>40. (1) A radiotherapy facility shall establish a diagnostic reference level for radiation therapy procedures.</p> <p>(2) A diagnostic reference level established under subregulation (1) is for the purpose of reviewing the process of optimisation of protection and safety of a patient.</p> | <p>Diagnostic reference level for patient at radiotherapy facility</p> |
| <p>41. An operator shall ensure that for—</p> <p>(a) external beam radiotherapy, a treatment prescription indicates whether the radiation therapy shall be given alone or in combination, concomitantly or sequentially, with chemotherapy and specify the timing of other local treatments; and</p> <p>(b) brachytherapy, the treatment prescription shall contain the information on the total dose to a reference point and to organs at risk, the size of the reference dose volume, the radionuclide, and the type of brachytherapy.</p> | <p>Treatment prescription for external beam radiotherapy and brachytherapy</p> |
| <p>42. (1) An operator shall ensure that the absorbed doses to organs as a result of medical imaging procedures carried out as part of the radiation therapy process, are considered for the irradiated volume and for the critical organs.</p> <p>(2) An operator shall ensure that the absorbed doses arising from neutrons, while using high energy photon beams more than 10mv, are considered when determining doses to the irradiated volume and to the critical organs.</p> | <p>Consideration of absorbed doses to organ</p> |
| <p>43. A radiotherapy facility shall establish means to verify the doses to selected points independent from the treatment planning system calculations.</p> | <p>Verification of doses to selected points</p> |
| <p>44. (1) A radiotherapy facility shall establish a written protocol for the optimisation of protection and safety for a carer of a low dose rate brachytherapy patient or a patient with a permanent implant.</p> <p>(2) A written protocol referred to under subregulation (1) shall include the—</p> <p>(a) criteria specifying who is acceptable as a carer;</p> <p>(b) methods for ensuring that the carer receives a dose that is as low as reasonably achievable; and</p> <p>(c) values of the dose constraints.</p> | <p>Written protocols for protection and safety of carer</p> |

	(3) An operator shall ensure that a carer is informed, in writing, about radiation protection and the radiation risks.
Release of patients after permanent brachytherapy implants	45. A radiotherapy facility shall, in accordance with guidelines issued by the Authority, establish procedures and guidelines for the release of patients from the radiotherapy facility with a permanent brachytherapy implant.
Quality assurance for medical exposure at radiotherapy facility	46. (1) A radiotherapy facility shall establish a quality assurance programme to minimise the occurrence of unintended and accidental medical exposure and for the optimisation of protection and safety in the radiotherapy facility. (2) A quality assurance programme referred to under subregulation (1) shall include the use of checks to ensure that the radiotherapy facility's protocols and procedures for imaging and therapy include radiation protection and safety. (3) A radiotherapy facility shall review and audit the quality assurance programme annually.
PART VII RADIATION PROTECTION OF THE PUBLIC	
Non-application of Part VII	47. In this Part, the public does not include a person who is in, or around, the radiotherapy facility, or a carer.
Person undergoing medical exposure considered member of public	48. Subject to regulation 47, a person shall ensure that a person who is undergoing medical exposure from radiation therapy shall be treated as a member of the public during the time when the treatment is not taking place.
Protection of public from external exposure	49. (1) A radiotherapy facility shall provide shielding at the radiotherapy facility to protect the public from external exposure. (2) A radiotherapy facility shall establish written rules to ensure that the external exposure and contamination of the public is within the public dose limit of 1m Sv per year. (3) A radiotherapy facility shall establish written rules to ensure that the exposure of the public from a patient who has a permanent or temporal radioactive material implant does not exceed the dose limit referred to under subregulation (2).
Control of access	50. An operator shall control access to an area where radiation is being used to ensure constraints for the public and doses to the public are below the dose limits.

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51. (1) An operator shall, in accordance with guidelines issued by the Authority, transfer or dispose of a radioactive material that is not needed or viable for the radioactive material's medical purpose. Radioactive material not in use or viable
- (2) An operator shall, for a radioactive material for teletherapy equipment —
- (a) notify the Authority of the intention to transfer or decommission the Cobalt 60 teletherapy equipment prior to the transfer or decommissioning and the depleted 268 uranium used as shielding material shall be treated as radioactive waste; and
 - (b) ensure that financial resources for the disposal of the radioactive material at the radiotherapy facility is made available when the teletherapy equipment is to be decommissioned.
52. (1) A radiotherapy facility shall — Monitoring programme of public exposure
- (a) establish and carry out a monitoring programme for public exposure that is sufficient to ensure the requirements for public exposure to a radioactive material of external irradiation is satisfied, and to assess the public exposure; and
 - (b) keep appropriate records of the results of the monitoring programme for public exposure.
- (2) A monitoring programme for public exposure referred to under subregulation (1) shall include a dose assessment of the —
- (a) surroundings of irradiation rooms for external beam therapy;
 - (b) brachytherapy wards;
 - (c) source storage and preparation rooms; and
 - (d) waiting rooms.

PART VIII

POTENTIAL EXPOSURE, MITIGATION AND EMERGENCY PLANS

Safety
assessment
of potential
exposure

53. (1) A radiotherapy facility shall conduct a generic or a specific safety assessment of a radioactive source under the responsibility of that radiotherapy facility.

(2) A safety assessment referred to under subregulation (1) shall be documented and reviewed by an external qualified expert when—

- (a) the radioactive material or the radioactive material's facilities are modified;
- (b) operational experience or information on an accident or error indicates that the safety assessment should be reviewed; and
- (c) techniques are modified in a way that safety may be compromised.

Prevention
of accidents

54. (1) A radiotherapy facility shall incorporate the following safety procedures to prevent accidents that may result in potential exposure to radiation:

- (a) identification of possible areas of risk and events that can lead to radiation exposure;
- (b) define in depth measures to cope with identified events and evaluate the reliability of the safety systems; and
- (c) operationalise experience and lessons learned from accidents and errors into training, treatment, maintenance and quality assurance programmes.

(2) An authorised person in a radiotherapy facility shall, where an accident or error occurs, inform an operator immediately of the accident or error occurring.

(3) An operator shall, on receipt of the information under subregulation (2), inform the Authority within twenty-four hours of the accident or error occurring.

Mitigation
of
consequences
of accidents

55. (1) A radiotherapy facility shall develop mitigatory procedures for an accident or error associated with potential radiation exposure.

(2) A mitigatory procedure developed under subregulation (1) shall include the —

- (a) allocation of responsibilities and resources;
- (b) development and implementation of procedures; and
- (c) provision of training and periodic retraining of the relevant staff in executing the mitigatory procedures.

56. (1) A radiotherapy facility shall establish mitigatory procedures and emergency procedures for a radioactive material that is stuck in radiological medical equipment.

Mitigation of consequences of stuck radioactive material

(2) The procedures referred to under subregulation (1) shall include actions to be taken to recover the radioactive material.

57. (1) A radiotherapy facility shall establish mitigatory procedures and emergency procedures for a stuck radioactive material involving the cobalt 60 teletherapy unit.

Mitigation of consequences of stuck radioactive material in cobalt-60 teletherapy unit

(2) Procedures referred to under subregulation (1) shall include —

- (a) provisions for the protection of a patient from unintended radiation exposure; and
- (b) the actions to be taken in response to mitigating the accident.

58. (1) A radiotherapy facility shall establish mitigatory procedures and emergency procedures for a stuck radioactive material involving remote control brachytherapy units.

Mitigation of consequences of stuck radioactive material involving remote control brachytherapy units

(2) Procedures referred to under subregulation (1) shall include the —

- (a) emergency plan;
- (b) use of the emergency container in the treatment room; and
- (c) use of the emergency kit containing long handled forceps for manipulation of the radioactive material, guide tubes and applicators.

(3) A radiotherapy facility shall train staff in the radiotherapy facility on how to apply the procedures referred to under subregulation (1) and ensure that staff regularly participate in drills and exercises.

Mitigation
of accident
or error
during
source
replacement

59. A radiotherapy facility shall establish procedures to handle an accident or error that may occur during the changing of a radioactive material in external beam radiotherapy or remote control brachytherapy units.

Contaminat-
ion

60. An operator shall ensure that in the event of contamination during an accident or error, the area where the accident or error occurred is closed off from further entry and a person who is or was in the area is surveyed and decontaminated, if necessary.

Lost or
missing
radioactive
material in
radiation
therapy

61. (1) An operator shall ensure that a detailed, up to date inventory of radioactive materials in radiation therapy is kept and maintained for the purposes of immediately determining a lost or missing radioactive material.

(2) An inventory referred to under subregulation (1) shall, where a new radioactive material is received, be updated immediately.

(3) An operator shall, where a radioactive material is lost or missing—

- (a) conduct a local search;
- (b) check and ensure physical security and control of other radioactive sources;
- (c) report the theft or loss to the Authority and appropriate competent authorities, providing a description of the radioactive material and its threat;
- (d) secure all information and the scene as much as possible to allow for forensic investigation;
- (e) conduct response actions in cooperation with local officials and law enforcement authorities;
- (f) identify and investigate routes by which the radioactive material may have been lost;
- (g) brief off site officials on risks and provide measures to protect emergency workers including law enforcement personnel and control their dose;
- (h) recommend that local officials inform nearby health facilities, border crossings and scrap metal dealers to be alert for the radioactive material or for radiation induced injuries;

- (i) provide health facilities, border crossings and scrap metal dealers with a description of the radioactive material and its container and of symptoms of radiation injuries;
 - (j) support local officials in explaining the risk to the local public and the media;
 - (k) cause the Authority to notify potentially affected States and the International Atomic Energy Agency if there are indications that the radioactive material may have crossed into another State; and
 - (l) reconstruct or record the doses received, inform those exposed of the risks and arrange, where appropriate, for long term medical follow-up.
- (4) An operator shall, where a lost or missing radioactive material is found, ensure that the radioactive material is not damaged or leaking.
- (5) An operator shall, where the radioactive material referred to under subregulation (4) is damaged or leaking, notify the Authority and local officials and ensure that the radioactive material is surveyed for contamination.

PART IX

GENERAL PROVISIONS

62. A person who contravenes a provision of these Regulations commits an offence and is liable, on conviction, to a fine not exceeding two thousand five hundred penalty units or to imprisonment for a term not exceeding two years, or to both.

General
penalty

63. Where an offence under these Regulations is committed by a body corporate or unincorporate body, with the knowledge, consent or connivance of a director, manager or shareholder of that body corporate or unincorporate body, that director, manager or shareholder is liable, on conviction, to the penalty specified for that offence.

Offences by
principal
officers of
body
corporate or
unincorporate
body

F. MUTATI,
*Minister of Technology
and Science*

LUSAKA

16th January, 2024

[MOTS.64/9/1]

