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

ARRANGEMENT OF REGULATIONS

Copies of this Statutory Instrument can be obtained from the Government Printer, P.O. Box 30136, 10101 Lusaka. Price K 56.00 each.

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

Title

1. These Regulations may be cited as the Ionising Radiation Protection (Radiotherapy) Regulations, 2024.

Interpretation

2. In these Regulations, unless the context otherwise requires—

"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;

"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;

PART II

RADIATION PROTECTION MANAGEMENT

Staff at radio therapy facility

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.

(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.

Radiation protection programme

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

(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 IV

MEDICAL RADIOLOGICAL EQUIPMENT

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.

(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.

General design features for medical radiogical 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.

(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.

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

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.

Ancillary equipment

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

(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.

Acceptance test

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

(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.

Commissioning

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.

Operations

15. An operator shall ensure that —

(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.

(4) A radiotherapy facility shall include the areas surrounding brachytherapy patient rooms or radioactive materials storage and handling areas as supervised areas.

Rules and procedures in controlled or supervised area

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

Rules and procedures for external beam radiotherapy

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 operation of brachytherapy

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

(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.

Rules and procedures for low dose rate brachytherapy

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—

(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;

Workplace monitoring programme

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

PART VI

Radiation Protection of Persons During Radiation Therapy

Non-application of Part VI

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.

Referral for medical exposure

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

(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.

Radiation doses for patient receiving radiation therapy

39. (1) A health practitioner at a radiotherapy facility shall perform patient dosimetry and determine typical doses to patients for diagnostic radiological procedures.

Diagnostic reference level for patient at radiotherapy facility

40. (1) A radiotherapy facility shall establish a diagnostic reference level for radiation therapy procedures.

(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.

Treatment prescription for external beam radiotherapy and brachytherapy

41. An operator shall ensure that for—

(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

(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.

Consideration of absorbed doses to organ

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.

(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.

Verification of doses to selected points

43. A radiotherapy facility shall establish means to verify the doses to selected points independent from the treatment planning system calculations.

Written protocols for protection and safety of carer

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.

(2) A written protocol referred to under subregulation (1) shall include the—

(a) criteria specifying who is acceptable as a carer;

(b) methods for ensuring that the carer receives a dose that is as low as reasonably achievable; and

(c) values of the dose constraints.

Radioactive material not in use or viable

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.

(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.

Monitoring programme of public exposure

52. (1) A radiotherapy facility shall —

(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.

(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.

Mitigation of consequences of stuck radioactive material

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

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

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

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

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

58. (1) A radiotherapy facility shall establish mitigatory procedures and emergency procedures for a 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.

(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

General penalty

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.

Offences by principal officers of body corporate or unincorporate body

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.

F. Mutati,
Minister of Technology and Science

Lusaka
16th January, 2024
[MOTS.64/9/1]