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REGULATION Nº007/R/RS-NRP/RURA/2023 OF 12/05/2023 ON RADIATION PROTECTION IN NUCLEAR MEDICINE

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The Regulatory Board,

Pursuant to Law n° 09/2013 of 01/03/2013 establishing the Rwanda Utilities Regulatory Authority;

Pursuant to Law n°59/2017 of 24/1/2018 Governing Radiation Protection;

Considering deliberations from the consultative meeting held on February 9, 2023 with different stakeholders;

Upon due consideration and deliberation in its meeting of 12th May 2023;

HEREBY issues the following:

CHAPTER I – GENERAL PROVISIONS

Article one: Purpose

The purpose of this regulation is to establish the regulatory framework for radiation protection in nuclear medicine.

Article 2: Objective

The objective of this regulation is to protect patient, worker, public and the environment from the risks associated with exposure to ionizing radiation in the course of nuclear medicine practice in Rwanda.

Article 3: Scope

This regulation applies to all established uses of ionizing radiation sources employed in the practice of nuclear medicine, to the facilities where the sources are located and to the individuals involved.

This regulation covers occupational, public, medical, potential and emergency exposure situations.

Article 4: Definition of terms

For the purpose of this Regulation, the terms below have the following meanings:

1. **Accreditation:** the action or process of officially recognizing professionals as having a particular status or being qualified to perform a particular activity according to various professional categories.
2. **"Medical event"**: any un-intended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety;
3. **"Applicant":** any legal person who applies to the Regulatory Authority for authorization to undertake any of the activities described in this Regulation
4. **"Authorization":** permission granted in a document by the Regulatory Authority to a legal person who has submitted an application to carry out a practice or any other action described in the law.
5. **"Controlled area":** any area in which specific protection measures and safety provisions are or could be required for:
    a. Controlling normal exposures or preventing the spread of contamination during normal working conditions; and
    b. Preventing or limiting the extent of potential exposures;

6. **"Dose constraint":** a prospective and source related restriction on the individual dose delivered by the source which serves as a bound in the optimization of protection and safety of the source.

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

8. **"Effective dose":** the addition of equivalent doses to all organs, each adjusted to account for the sensitivity of the organ to radiation.

9. **"Emergency plan":** a set of procedures to be implemented in the event of an accident;

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

11. **"Ethics review committee":** a committee of independent persons to advise on the conditions of exposure and the dose constraints to be applied to the medical exposure of individuals exposed for biomedical research purposes when there is no direct benefit to the exposed individual;
12. **"Guidance Reference level for medical exposure":** a value of dose, dose rate or activity selected by professional bodies in consultation with the Regulatory Authority to indicate a level above which there should be a review by medical practitioners in order to determine whether or not the value is excessive, considering the particular circumstances and applying sound clinical judgment;

13. **"Health professional":** an individual who has been accredited through appropriate national procedures to practice a profession related to health:

14. **"Health surveillance":** medical supervision intended to ensure the initial and continuous fitness of workers for their intended task;

15. **"Imaging devices":** electronic equipment used for imaging in Nuclear medicine;

16. **"Intervention":** any action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part of a controlled practice or which are out of control as a consequence of a medical event;

17. **"Legal person":** any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation;

18. **"License":** an authorization granted by the Regulatory Authority on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by the Licensee;

19. **"Licensee":** the holder of a license granted for a practice or source who has recognized rights and duties for the practice or source, particularly in relation to protection and safety;

20. **"Medical exposure":** exposure incurred by patients as part of their own medical diagnosis or treatment; by persons, other than those occupationally exposed, knowingly

while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure;

21. **"Member of the public":** in a general sense, any individual in the population except, for the purposes of the Law, when subject to occupational or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, the representative individual in the relevant critical group;

22. **"Monitoring":** 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;

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

24. **"Notification":** a document submitted to the Regulatory Authority by a legal person to notify an intention to carry out a practice or any other action described by the Authority;

25. **"Occupational exposure":** all exposures of workers incurred in the course of their work with the exception of exposures excluded from the General Regulation of Radiation safety in Rwanda and exposures from practices or sources exempted by General Regulation of Radiation safety in Rwanda;

26. **"Potential exposure":** 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;

27. **"Practice":** any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed;

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

29. **"Protection and safety":** the protection of people against exposure to ionizing radiation or radioactive substances and the safety of radiation sources, including the means for achieving such protection and safety, such as the various procedures and devices for keeping peoples' doses and risks as low as can reasonably be achieved and below prescribed dose constraints, as well as the means for preventing accidents and for mitigating the consequences of accidents should they occur;

30. **"Protective action":** an intervention intended to avoid or reduce doses to members of the public in chronic or emergency exposure situations;

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

32. **“Qualified expert in nuclear medicine physics (medical physicist)”:** an individual who, by virtue of certification by appropriate boards or societies, professional licenses or academic qualifications and experience, is duly recognized as having expertise in nuclear medicine physics;

33. **“Quality assurance”:** all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality;
34. **“Radiation Protection Officer”:** an individual technically competent in safety and radiation protection matters relevant for a given type of practice who is designated by the licensee to oversee the General Regulation of Radiation safety in Rwanda;

35. **“Radioactive waste”:** material, in any physical form, remaining from practices or interventions and for which no further use is foreseen (I) that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for clearance from regulatory requirements, and (ii) exposure to which is not excluded from General Regulation of Radiation safety in Rwanda;

36. **“Reference air karma rate”:** the reference air karma rate of a source is the karma rate to air, in air, at a reference distance of one meter, corrected for air attenuation and scattering.

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

“Sealed source”: radioactive material that is permanently sealed in a capsule or Closely bounded and in a solid form. The capsule or material of a sealed source shall be strong enough to maintain leak tightness under the conditions of use and wear for which the source was designed, also under foreseeable mishaps;

38. **“Safety assessment”:** a review of the aspects of design and operation of a source which are relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations;

39. **“Safety culture”:** the assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance;

40. **“Supervised area”:** any area not designated as a controlled area but for which occupational exposure conditions are kept under review even though protective measures and safety provisions are not normally needed;

41. **“Unsealed source”:** a source that does not meet the definition of a sealed source;

42. **“Source”:** anything that may cause radiation exposure, such as by emitting ionizing radiation or releasing radioactive substances or materials. For example, materials emitting radon are sources in the environment;
43. **“Standards dosimetry laboratory”:** a laboratory designated by the relevant

national Regulatory authority for the purpose of developing, maintaining or improving primary or secondary standards for radiation dosimetry;

44. **“Storage room”:** facility designated for lodging, preparation, control and sterilization of radioactive sources;

45. **“Supplier”:** any legal person to whom a licensee delegates duty, totally or partially, in relation to the design, manufacture, production or construction of a source. (An importer of a source is considered a supplier of the source.);

46. **“Worker”:** any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection;

CHAPTER II: GENERAL REQUIREMENTS

Article 5: Administrative requirements

The applicant applying for an authorization or license shall refrain from carrying out any of the actions of the practice until the Authorization or license, as appropriate, has been granted.

The applicant shall include in the application for authorization or license the qualifications in radiation safety and protection of the medical practitioners who are to be so designated by name in the Authorization or license;

The licensee shall comply with radiation safety requirements for the following stages of the nuclear medicine practice:

(a) Site assessment,

(b) Design and construction,

(c) Operation (acceptance, commissioning, clinical use, maintenance), and

(d) Decommissioning (partial or total) and return or disposal of sources.

The licensee shall apply for the amendment of Authorization or license in case of any modification with possible implications for radiation safety of the nuclear medicine facilities.

Article 6: Staffing

The licensee shall ensure that all personnel on whom protection and safety depends are appropriately trained and qualified so as to understand their responsibilities and perform their duties with appropriate judgment in accordance with the laid down procedures.

Individuals with sole responsibilities for protection and safety and those who could substantially affect protection and safety by virtue of tasks involving manipulation of sources or operation of equipment shall have documented evidence of educational qualification and training in nuclear medicine, these individuals include:

(a) Medical practitioners working with radionuclides

(b) Medical physicists in nuclear medicine (qualified experts in nuclear medicine physics);

(c) Other health professionals involved in the clinical use of radionuclides

(d) Radiation protection officer; and

(e) Staff performing special tasks,

The licensee shall submit a list of staffs in nuclear medicine with their following documents, as applicable:

(a) University degree or academic qualification relevant to the profession, issued by universities, colleges of health technology, polytechnics and colleges of technology and other accredited institutions;

(b) Accreditation to practice the profession granted by the relevant competent authorities or other professional or academic bodies recognized by the Authority;

In addition to the staff needing formal credentials, the following staff shall be provided with specific continuous training on radiation safety and protection:

(a) Nurses attending patients under therapy;

(b) Staff who do not belong to the nuclear medicine practice but need to enter controlled areas; and

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

These training records shall be kept for at **least five years** after the expiry of the corresponding authorization.

The Regulatory Authority shall authorize equipment-servicing personnel.

Article 7: Organizational requirements

The licensee has the primary responsibilities for the application of this regulation.

The following parties shall have subsidiary responsibilities. These parties include but not limited to: suppliers, workers; radiation protection officers; medical practitioners; other (non-medical) health professionals; qualified experts; ethical review committees; and any other party to whom a principal party has delegated specific responsibilities.

The licensee shall establish a radiation protection programme and shall provide the necessary resources to comply with the programme.

The radiation protection programme shall relate to all phases of the practice, from site assessment through operation to decommissioning.

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

The licensee shall assign clear responsibilities for personnel to ensure adequate radiation protection of patients, workers, and the public.
The need for qualified experts shall be determined, their responsibilities defined and suitable persons appointed on a full-time or part-time basis as required.
The licensee shall appoint a Qualified Radiation Protection Officer.
The Radiation Protection Officer shall have sufficient authority and management standing to communicate with and direct personnel regarding the regulations and license provisions.

A Radiation Safety Committee shall be formed that is appropriate to the size of institution and complexity of procedures.

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

The Committee shall meet at least twice a year.

Article 8: Requirements for Quality Assurance

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

The Quality Assurance programme shall be an integral part of the Radiation Safety Program and involve a review and assessment of the overall effectiveness of the protection and safety measures.

The programme shall cover the entire process from the initial decision to adopt a particular procedure through the interpretation and recording of results and shall include ongoing auditing (both internal and external) as a systematic control methodology.
Quality assurance shall include the following but not limited to:

(a) Selection of the correct procedure for the patient;

(b) Appointment and patient information;

(c) Clinical dosimetry;

(d) Optimization of examination protocol;

(e) Record keeping and report writing;

(f) Quality control of radiopharmaceuticals and radionuclide generators;

(g) Acceptance and commissioning;

(h) Quality control of equipment and software;

(i) Waste management procedures;

(j) Training and continuing education of staff;

(k) Clinical audit; and

(l) General outcome of nuclear medicine service.

CHAPTER III: SAFETY OF SOURCES, EQUIPMENT AND FACILITIES

Article 9: Defense in Depth

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

(a) Preventing accidents that may cause exposure;

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

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

Article 10: Equipment Design

The licensee shall ensure that Requirements for the safety of sources used in nuclear medicine, equipment are designed in accordance with the considerations stated in the general Regulation No 001/R/RS-RP/RURA/2019 of 15th November 2019 governing radiation safety in Rwanda

In addition to the provision of the paragraph above the licensee shall:

(a) Consider information provided by suppliers, identify possible equipment failures and human errors that could result in unplanned medical exposures;

(b) Take all reasonable measures to prevent failures and errors, including the selection of suitably qualified personnel, the establishment of adequate procedures for the calibration, Quality Assurance and operation of equipment, the provision of appropriate training and periodic retraining to personnel in the procedures, including protection and safety aspects;

(c) Take all reasonable measures to minimize the consequences of failures and errors that may occur.

Article 11: Facilities and ancillary equipment

The licensee shall ensure that:

(a) A safety assessment is performed at each stage of activities performed in nuclear medicine.

(b) The design of the facility takes into consideration the classification of the areas within it; the type of work to be done and the radionuclides (and their activity) intended to be used.

(c) The floors of controlled areas are finished in an impermeable material, which is washable and resistant to chemical change.

Article 12: Requirements for site assessment

The Licensee when assessing and evaluating the site, shall consider the following:

(a) A geotechnical investigation, including but not limited to surface and subsurface exploration of the site;

(b) A complete foundation investigation and analysis that include but not limited to, in situ tests, field sampling, laboratory testing, and engineering analysis and evaluation, with the results and recommendations presented in a report form;

(c) The investigation and analysis have to be performed in compliance with international standards and generally accepted principles of sound engineering practice;

(d) The size of the land required must be of a minimum of 1000m^2 excluding access roads and parking areas. However, consideration has to be given to future expansion needs;

(e) The availability of reliable three-phase power electrical services. The electrical capacity has to be carefully calculated to have sufficient power supply for the whole nuclear medicine facility's needs and for future expansion of services;

(f) There must be adequate distance from public occupied areas with special consideration of potential risk from public exposure.

Article 13: Requirements for design and construction

The licensee shall ensure that the design and construction of a nuclear medicine facility is carried out by a competent professional team that is multidisciplinary. At a minimum, the team consists of the following:

(a) A qualified architect, preferably experienced in the design and construction of nuclear medicine facilities;

(b) A structural or civil engineer with experience in large concrete structures;

(c) A mechanical engineer with experience in hospital design, including cooling, heating and ventilation systems;

(d) An electrical engineer experienced in the calculation and design of reticulation and standby electrical systems for hospitals;

(e) A cost consultant or quantity surveyor or equivalent;

(f) A clinically qualified nuclear medical physicist with competency in the planning of new departments in similar environments;

(g) A qualified nuclear medicine specialist experienced in setting up and coordinating a nuclear medicine facility.

Areas where radioactive substances are handled, such as the source preparation area, have:

(a) Means to prevent access by unauthorized persons;

(b) The scanning room space of 30 to 35 m^2 with an additional 10 to 15 m^2 for the control room/console area

(c) Adequate storage space for equipment used in the laboratory to be kept at all

times and minimize the potential for spreading contamination to other areas;

(d) Contained workstation for easy decontamination;

(e) Shielded storage for radioactive substances;

(f) Shielded temporary storage for solid radioactive waste and places designated for the disposal of liquid radioactive waste, directly connected to the main sewer;

(g) Shielding to protect the worker where significant external exposure may occur;

(h) A wash-up area for contaminated articles such as glassware;

(i) An entry area where protective clothing can be put on, taken off and kept when not in use and where washing and contamination monitoring can be done.

A source storage area and an area for temporary storage of radioactive waste shall be provided with appropriate protection.

Access control when determining source storage areas and rooms for hospitalized patients undergoing radionuclide therapy.

The facility is designed in such a way that provisions for safety systems or devices are inherent to the equipment or the room in order to lower the probability of occurrence of accidental radiation exposure.

A radiation (ISO 361) sign and a danger warning sign in all official languages is posted to indicate that a room is a controlled area.

The shielding is designed using the principles of optimization of protection. The materials generally shall include lead, iron and low or normal density concrete (1.84 and 2.35 g/cm3, respectively).
Shielding for the CT component of the PET/CT systems shall be the same as that of an independent CT system. The workload for shielding calculations shall be at least 50 patients/ week.

As established in these regulations relevant equipment is purchased from authorized suppliers.

Written methods are developed with the involvement of the responsible staff or the Radiation Protection Officer, for purchasing, installation, acceptance, commissioning, use, maintenance and quality control.

Equipment used in nuclear medicine that influence outcome of diagnosis and therapy meets the relevant IEC standards and any other national equivalent standards, such equipment includes:

(a) Activity meters;

(b) Generators for diagnostic and therapy nuclides;

(c) Gamma cameras;

(d) Uptake probes; and

(e) Radionuclide activity calibrator for assaying doses to be administered to the patient.

Additional equipment must be available to prevent and clean up contamination.
All radiation workers shall participate in workplace monitoring.

The calibration of these instruments is traceable to a certified standards laboratory, and shall be maintained by a regular quality control programme.

Activity meters used to measure the amount of activity of a radiopharmaceutical to be administered to the patient, both for a diagnostic test and for therapeutic purposes, is designed so as to exhibit the performance required for that purpose, and that the effect of background radiation on the instruments be minimized.

Equipment for continuous monitoring of external exposure is considered in rooms assigned for preparation of radiopharmaceuticals.

The manufacturer's operating manual is available in one of the official languages.

Fume hoods is installed for use, as appropriate, for volatile radioactive substances.

The exhaust of the fume hood does not exceed the regulatory limit of release.

Article 14: Maintenance

(1) The licensee shall ensure that adequate maintenance (preventive and corrective) and inspection are performed as necessary to ensure that equipment used in nuclear medicine retains its design specifications for image quality, radiation protection and safety for its useful life.

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

(3) All maintenance procedures shall be included in the Quality Assurance programme at a frequency recommended by the manufacturer of the equipment and the relevant professional body.

(4) Servicing shall include a report describing the findings, which shall be archived as part of the Quality Assurance programme.

(5) A nuclear medicine physicist shall ensure that the equipment is in safe condition for clinical use.

(6) This work shall be authorized by the facility management and performed by persons who are qualified to work on the equipment.

Article 15: Acceptance test

After equipment installation, the licensee shall conduct acceptance testing in order to verify that the equipment conforms to technical specifications given by the manufacturer and to verify compliance with safety requirements from IEC standards and equivalent standards of the Standards Organization of Rwanda.
As indicated in this regulation, the tests to be included in the acceptance protocol shall be specified in the purchasing conditions and contracts and shall clearly establish responsibility of suppliers for resolving non-conformity identified during acceptance testing.

Article 16: Commissioning

The licensee shall ensure that after acceptance and before starting operation, commissioning is performed and qualified expert in nuclear medicine physics measures all data required for clinical use during commissioning

Article 17: Security of sources

The licensee shall maintain an updated inventory of sources and ensure accountability of the source security.

The licensee shall ensure that sources storage is secure so as to prevent theft or damage and to prevent any unauthorized use.

The licensee shall establish security systems to prevent theft, loss, unauthorized use, or damage to sources, or entrance of unauthorized personnel to the controlled areas.

CHAPTER IV - OCCUPATIONAL EXPOSURE

Article 18 : Classification of areas

The licensee shall ensure that:

(a) Areas in a nuclear medicine department are classified as *controlled* or *supervised*.

(b) The rooms for preparation, storage and injection of the radiopharmaceuticals are controlled areas.

(c) The area housing a patient to who therapeutic amounts of activity have been given are also controlled area.

(d) The room for temporary storage of radioactive waste is a controlled area.

(e) The imaging rooms, (gamma camera room) and waiting areas are supervised areas due to the potential risk of contamination.

(f) Each room of the facility is only used for its specified work.

Article 19: Local rules and supervision

The licensee shall:

(a) Establish written local rules and procedures necessary to ensure adequate levels of protection and safety for workers and other persons;

(b) Include in the local rules and procedures the values of any relevant investigation level or authorized level, and the procedure to be followed in the event that any such value is exceeded;

(c) Make the local rules and procedures, the protective measures and safety provisions known to those workers to whom they apply and to other persons who may be affected by them; and

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

For practices performing positron emission tomography studies, the licensee shall ensure that:

(a) When handling radionuclides from the cyclotron room and the radiopharmacy, the dose to the operator is minimized;

(b) Where ever possible, heavy shielding is used, because of the energy of 511KeV due to the annihilation radiation in positron emission tomography energy;

(c) When this shielding is inappropriate, reducing the time of exposure, increasing the

distance from the source by using robotics and handlers to achieve the reduction of exposure of staff. In addition, the Over pack or additional shielding of high-density material shall be considered.

Article 20: Protective equipment and tools

The Licensee shall ensure that workers are provided with suitable and adequate personal protective equipment.
Protective equipment includes but not limited to:

(a) Movable shields, bench top shields and shields for syringes and vials to be used when handling unsealed sources;

(b) Protective clothing, gloves and tools for handling of sources to be used during the work with unsealed sources; and

(c) Fume hoods, shielded containers for temporary segregation and storage of radioactive waste.

Containers utilized for the transfer and transport of radioactive sources outside the institution shall conform to the requirements established in the national regulations.

Surfaces where radioactive material is used and stored should be impervious material to reduce contamination and improve cleanup of spills.

Article 21: Individual monitoring and exposure assessment

The licensee shall ensure that:

(1) Individual dose monitoring is undertaken for workers who are normally exposed to radiation in controlled areas through authorized dosimetry service providers.

(2) The workers who shall be monitored include but not limited to nuclear medicine physicians, nuclear medicine physicists, nuclear medicine technologists, nuclear medicine nurses and radiopharmacists.

(3) The users of radioisotope sources, such as clinical specialists, research staff and ancillary workers who frequently work in controlled areas, are also individually monitored.

(4) Individual external doses are determined by using individual monitoring devices approved by the Authority.

(5) When there is a possibility of high exposure to the hands, such as in the preparation and administration of radiopharmaceuticals, extremity dosimeters are worn (if compatible with good clinical practice).

(6) The exchange of dosimeters and receipt of the dose reports are within an interval of three months.
(7) Individual monitoring devices are calibrated and this calibration is traceable to a standards dosimetry laboratory.

(8) Internal exposure monitoring system is in place.

(9) The licensees shall maintain records for equipment calibration and assays of patient doses.

Article 22: Pregnant Worker

A female worker shall notify the licensee if she is pregnant as soon as she knows of her condition, or if she is breast-feeding, so that radiation protection requirements for fetus and baby can be met with respectively.

The notification of pregnancy shall not be considered a reason to exclude a female worker from work.

The employer of a female worker who has notified pregnancy shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or fetus is afforded the same broad level of protection as required for members of the public.

Article 23: Monitoring the workplace

With regards to monitoring the workplace the licensee shall:

(a) Develop programmes of monitoring.
(b) Perform daily monitoring with a survey meter and contamination monitor or by wipe tests for controlled and supervised areas.
(c) Ensure continuous monitoring for source storage and handling areas.
(d) Ensure laboratories and other areas in which work with unsealed are undertaken are monitored, both for external radiation and for surface contamination, on a systematic basis.

Contamination monitoring shall be required as follows:

(a) All working surfaces (including the interior of enclosures), tools, equipment, the floor and any items removed from this area.

(b) Monitoring shall also be required during maintenance of contained workstations, ventilation systems and drains.

(c) Protective and personal clothing, shoes, particularly when leaving an area that is controlled due to the risk of contamination;

(d) Clothing and bedding for therapy patients.

The licensee shall ensure all radiation monitors including all survey meters used for workplace monitoring are calibrated and this calibration is traceable to a standards dosimetry laboratory.
The radiation monitors operability and those of their warning devices shall be checked prior to each day of use and the facility shall not provide services if not operational,

Article 24: Investigation levels

The licensee shall include in the local rules and procedures the values of any relevant investigation level or authorized level, and the procedure to be followed in the event that any such value is exceeded.

The licensee shall conduct formal investigations as required by the Regulatory Authority in case:

(a) An individual effective dose exceeds investigation levels;

(b) Any of the operational parameters related to protection or safety are out of the normal range established for operational conditions;

(c) Any equipment failure, severe accident or error occurs that causes, or has the potential to cause, a dose in excess of the limits established by the Authority; and

(d) Any other event or unusual circumstance occurs that causes, or has the potential to cause, a dose in excess of the limits established by the Regulatory Authority or the operational restrictions imposed on the installation, that is, the significant change in workload or operating conditions of nuclear medicine equipment.

The licensee shall initiate the investigation as soon as possible following the event and write a report concerning its cause, including determination or verification of any doses received, corrective actions, and instructions or recommendations to avoid recurrence.

The licensee shall ensure report is submitted to the Regulatory Authority and other concerned bodies as required as soon as possible after the investigation or as otherwise specified and kept for a specified period.

Article 25: Health surveillance

The licensee shall plan to provide health surveillance in accordance with the provisions of General Regulation of Radiation Safety in Rwanda to assess the initial and continuing fitness of employees for their intended tasks.
Health surveillance programmes shall be based on the general principles of occupational health.

Counselling shall be available to workers such as women who are or may be pregnant, individual workers who have or may have been exposed substantially in excess of dose limits and workers who may be worried about their radiation exposure.

Article 26: Records

The licensee shall maintain exposure and medical surveillance records for each worker and the records shall be kept according to the requirements of the Authority.

The licensee shall provide for access by workers to information in their own exposure records and give due care and attention to the maintenance of appropriate confidentiality of records.

CHAPTER V - MEDICAL EXPOSURE

Article 27: Licensees' Responsibilities

With regard to responsibilities for medical exposure, the licensee shall ensure that:

(a) No patient is administered a diagnostic or therapeutic medical exposure unless the exposure is justified by a medical practitioner;

(b) Medical practitioners are assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of medical exposure;

(c) Medical and paramedical personnel are available as needed, and are either health professionals or have appropriate training to discharge their assigned tasks in the conduct of the diagnostic or therapeutic procedure that the medical practitioner prescribes;

(d) For therapeutic use of radiation, the calibration, dosimetry and quality assurance requirements are conducted by or under the supervision of a qualified expert in nuclear medicine physics;

(e) 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 as specified in General Regulation of Radiation Safety in Rwanda; and

(f) Training criteria are specified or subject to approval, as appropriate, by the Regulatory Authority in consultation with relevant professional bodies.

Licensee shall ensure that for diagnostic uses of radiation, the imaging and quality assurance requirements are fulfilled with the advice of a qualified expert in nuclear medicine physics.

Medical practitioners shall promptly inform the licensee of any deficiencies or needs regarding compliance with the national regulations concerning protection and safety of patients and shall take such actions as may be appropriate to ensure the protection and safety of patients.

The licensee shall ensure that workers (medical practitioner, medical physicist, technologist):

(a) Follow any applicable rules and procedures for the protection and safety of patients, as established by the licensee;

(b) Are competent in the operation and use of the equipment and sources employed in nuclear medicine, of the equipment for radiation detection and measurement, and of the safety systems and devices, commensurate with the significance of the workers' functions and responsibilities; and

(c) Know their expected response in the case of patient emergencies.

Article 28: Justification

The licensee shall ensure that:

Medical exposures are justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

Any nuclear medicine examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is deemed to be unjustified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.

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

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

The exposure of humans for medical research shall be unjustified unless it is:

(a) In accordance with the provisions of the Helsinki Declaration and follows the guidelines for its application prepared by Council for International Organizations of Medical Sciences and the World Health Organization;

(b) Subject to the advice of an ethical review committee (or any other institutional body assigned similar functions by the Ministry of Health) and to applicable Nuclear and Radiation Protection regulations in Rwanda and these regulations.

Children are at greater risk of incurring stochastic effects; as such paediatric examinations require special consideration in the justification process.

The benefit of some high dose examinations shall be carefully weighed against the increased risk.

The justification of examinations in pregnant women requires special consideration.

In order to avoid any substantial risk, the licensee shall ascertain whether the female patient is pregnant before considering use of a radionuclide for diagnosis or for therapy.

The advice of a medical physics expert shall be required and a foetal dose and nominal foetal and patient risks estimation performed before deciding whether the examination shall be undertaken.

A pregnant woman shall not be treated with a radioactive source unless the application is lifesaving.

The therapeutic application shall be deferred until after the pregnancy and after any period

of breastfeeding.

<u>Article 29</u>: Optimization for medical exposures in nuclear medicine:

The licensee shall ensure that:

Medical practitioners who prescribe or conduct diagnostic applications of radionuclides ensure that:

(a) The exposure of patients is the minimum required to achieve the intended diagnostic objective;

(b) They consider relevant information from previous examinations in order to avoid unnecessary additional examinations; and

(c) They consider the relevant guidance levels established by the regulatory Authority for medical exposure.

(d) The medical practitioner, the technologist, as appropriate, endeavor to achieve the minimum patient exposure consistent with acceptable image quality criteria by:

1) Appropriate selection of the best available radiopharmaceutical and its activity, noting the special requirements for children and for patients with impairment of organ function;

2) Use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable; and

3) Appropriate image acquisition and processing.

The licensee shall ensure that administration of radionuclides for diagnostic or therapeutic procedures to women who are pregnant or likely to be pregnant is avoided unless there are strong clinical indications.

The licensee shall also ensure discontinuation of nursing until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable effective dose to the infant of lactating mothers;

In regards to administration of radionuclides to children for diagnostic procedures, the licensee shall ensure that it is carried out only if there is strong clinical indication, and the amount of activity administered is reduced according to body weight, body surface area or other appropriate criteria.

The licensee shall inform the patient, as appropriate, of possible risks associated with the procedure and obtain a signed consent form from the patient.

In the same vein of optimization, the licensee shall also ensure that:

(a) Equipment is operated within the limits and conditions established in the technical specifications and in the license requirements, ensuring that it will operate satisfactorily at all times, in terms of both the tasks to be accomplished and radiation safety.

(b) The manufacturer's operating manual, and the institutions procedural manual are followed strictly for equipment operation.
(c) Written as well as verbal instructions are provided to patients who have received radionuclide therapy on actions to take to limit exposure to comforters, caregivers and members of the public when leaving the hospital.

(d) The instructions include minimizing prolonged contact with the spouse, other family members, minors and potentially pregnant women.

Article 30: Diagnostic procedures

The licensee shall ensure that:
(a) An effective system is established for correct identification of patients.

(b) Each diagnostic procedure follows a written protocol, designed to maximize the clinical information to be obtained from the study, taking into consideration the appropriate guidance level for the procedure.

(c) The data acquisition conditions are chosen such that the image quality is optimum.

(d) The choice of collimator, energy window, matrix size, acquisition time, and angulation of collimator, Single Photon Emission Computed Tomography or Positron Emission Tomography parameters, and zoom factor shall be such as to obtain optimum quality image.

(e) For dynamic studies, the number of frames, time interval and other parameters are chosen to obtain optimum quality of image sequence.

(f) Care is taken to ensure that there is no contamination on the collimator surface or elsewhere as this may impair the quality of the result.

Article 31: Therapeutic application of radionuclides

The licensee shall ensure that
(a) An effective system is established for correct identification of patients.

(b) Verbal and written instructions on safety are provided to the patient to minimize exposure to family members and the public.

(c) Special attention is given to prevent spread of contamination due to patient vomit and excreta.

(d) National regulations on release of patients after administration of therapeutic doses of radiopharmaceuticals are absolutely followed, as describe in the general Regulation No. 001/R/RS-RP/RURA/2019 of 15th November 2019 governing radiation safety in Rwanda.

Article 32: Conception after therapeutic dose

The licensee shall ensure that following treatment with a therapeutic radionuclide, a female patient is advised to avoid pregnancy until the radiopharmaceutical is no longer released in an amount estimated to give an unacceptable effective dose to the fetus as determined by the qualified medical practitioner.

Article 33: Calibration of equipment and radiation sources

The licensee shall ensure that:

(a) The calibration of radionuclide activity calibrators and other equipment and sources utilized for the practice of nuclear medicine is traceable to a standards dosimetry laboratory;

(b) Radionuclides for nuclear medicine procedures are calibrated in terms of activity of the radiopharmaceutical to be administered;

(c) Records of calibration measurements and associated calculations are maintained in accordance with the requirements of the Regulatory Authority; a regular quality control programme assures the calibration of the instruments.

Article 34: Clinical (patient) Dosimetry

Licensee shall ensure that:

(a) The activity to be administered is determined and recorded at the time of administration;

(b) For diagnostic procedures, representative absorbed doses to the organs and the effective dose to the patient are determined and documented for the amount of activity normally administered according to their standard clinical protocol;

(c) For therapeutic treatments, absorbed doses to relevant organs is evaluated; and

(d) Individual dose calculations for therapeutic procedures are performed with the advice of a qualified expert and each therapeutic dose is recorded.

Article 35: Quality assurance for medical exposures

As established in this regulation, the licensee shall establish a comprehensive Quality Assurance programme for medical exposures with the participation of appropriate qualified experts in the relevant fields, such as nuclear medicine physics and radio-pharmacy.

Quality Assurance programmes for medical exposures shall include:

(a) Measurements of the physical parameters of the imaging devices at the time of commissioning and periodically thereafter;

(b) Verification of the appropriate physical factors such as activity and

radiopharmaceutical used in patient diagnosis or treatment;

(c) Review of the procedures, considering the clinical factors that may influence the results;

(d) Written records of relevant procedures and results;

(e) Verification of the appropriate calibration and conditions of operation of radionuclide activity calibrator; and

(f) Verification of the quality of the prepared radiopharmaceutical.

Article 36: Guidance levels

The Licensee shall ensure that guidance levels for medical exposure are determined as specified in the Nuclear and Radiation Protection Regulations in Rwanda revised as technology improves and used as guidance by medical practitioners, in order that:

(a) Corrective actions can be taken as necessary if doses or activities fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients;

(b) Reviews can be considered if activities exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice; and

(c) The guidance levels can be derived from the data from wide scale quality surveys, which include activities of radiopharmaceuticals administered to patients for the most frequent examinations in nuclear medicine.

Article 37: Dose constraints

The Licensee shall constrain any dose incurred knowingly by those voluntarily helping other than in their occupation in the care, support or comfort of patients undergoing medical diagnosis or treatment, voluntarily participating in research and to visitors to patients who have received therapeutic amounts of radionuclides, to a level not exceeding that specified in the Nuclear and Radiation Protection regulations in Rwanda.

Article 38: Maximum activity for patients in therapy on discharge from Hospital

The licensee shall ensure that:

(a) A patient who has undergone a therapeutic procedure with unsealed radionuclides is not discharged from hospital before the activity of radioactive substances in the body falls below the recommended guidance levels established by the regulatory Authority.

(b) Written and spoken instructions to the patient concerning contact with other persons and relevant precautions for radiation protection is provided as necessary.

(c) Patients under bone pain palliation therapies are discharged based on local rules, which consider the external exposure rate, the risk of contamination and the patient's condition as required in the general Regulation No 001/R/RS-RP/RURA/2019 of 15th November 2019 governing radiation safety in Rwanda

(d) Special consideration is given to the case of patients with urinary incontinence patients.

Article 39: Investigation of accidental medical exposure in nuclear medicine

The licensee shall promptly investigate:

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

(2) Any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels established by the Regulatory Authority.

(3) Any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended

The Licensee shall with regard to any investigation made under this regulation:

(a) Calculate the doses received and their distribution within the patient;

(b) Indicate the corrective measures required to prevent recurrence of such an incident;

(c) Implement all the corrective measures that are under their own responsibility;

(d) Contact to the Regulatory Authority, within maximum 24 hours of identifying a medical incident by phone or email and complete an investigation Report or as otherwise specified by the Regulatory Authority within 15 days. The written report to be submitted shall provide information about the incident, the cause of the incident and includes the information specified in sub paragraphs (a) to (c) as relevant and any other information required by the Regulatory Authority;

(e) The corrective actions to prevent the reoccurrence of the incident; and

(f) Inform the patient and his or her doctor about the incident.

Article 40: Medical Records

The licensee shall keep medical records for a period of 5 years and make available, as required, types of radiopharmaceuticals administered to patients and their activities and exposure of volunteers in medical research.

CHAPTER VI: PUBLIC EXPOSURE

Article 41: Licensees' Responsibilities

The licensee shall be responsible for controlling public exposure resulting from a nuclear medicine practice.

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

(a) Protection and safety policies, procedures and organizational arrangements for the usage, transport, storage and disposal of nuclear medicine sources to ensure their safety and security in accordance with the requirements of the Regulatory Authority;

(b) Measures for ensuring the optimization of the protection of members of the public;

(c) Measures for ensuring the safety of such sources, in order that the likelihood of public exposures are controlled;

(d) Appropriate protection and safety training to the personnel having functions relevant to the protection of the public, as well as periodic retraining and updating as required, in order to ensure the necessary level of competence;

(e) Appropriate monitoring equipment and surveillance programmes to assess public exposure;

(f) Adequate records of the surveillance and monitoring as required by the Regulatory Authority;

(g) Emergency plans and procedures, commensurate with the nature and magnitude of the risk involved, and activate such plans and procedures in accordance with the requirements of the Regulatory Authority.

The Licensee shall develop and implement measures for use, storage and transport to ensure the safety and security of radiopharmaceuticals to control public exposures in accordance with the requirements of the Regulatory Authority; and control and maintain constant surveillance of radioactive sources that are not in storage and secure stored radioactive sources from unauthorized access, removal, or use.

The licensee shall be responsible for ensuring that the optimization process for measures to control the discharge of radioactive substances from a source to the environment is subject to dose constraints established or approved by the Regulatory Authority.

Article 42: Control of access of visitors

The licensee shall:

a) Ensure that visitors are accompanied in any controlled area by a qualified radiation worker about the protection and safety measures for that area;

b) Provide adequate information and instruction to visitors before they enter a controlled area so as to ensure appropriate protection of the visitors and of other individuals who could be affected by their actions;

c) Put in place a system to control access of visitors to patients undergoing radionuclide therapy and provide adequate information and instruction to these visitors before they enter the patient´s room so as to ensure appropriate protection; and

d) Ensure that adequate control over entry of visitors to a supervised area is maintained and that appropriate signs are posted in such areas.

Article 43: Radioactive contamination

The licensee shall ensure that for sources for which they are responsible, measures optimized in accordance with the requirements of the Regulatory Authority are taken, as appropriate, for restricting public exposure to contamination in areas accessible to the public.

Article 44: Radioactive waste

The licensee shall:

(a) Develop and implement a programme for safe and secure disposal of radioactive waste or return of sources when their use is discontinued, as required by the Regulatory Authority;

(b) Ensure that the activity and volume of any radioactive waste resulting from the sources for which they are responsible are kept to the minimum practicable, and that the waste is managed in accordance with the requirements of the Regulatory Authority for Radioactive Waste Management;

(c) Ensure that the discharge of radioactive wastes to the public waste treatment system and to the sewage system is within the limits specified by the Regulatory Authority and

(d) Maintain responsibility for all other radioactive sources until provisions have been made to transfer the radioactive sources to an appropriate licensee or to an authorized waste disposal facility at the end of use.

Article 45: Monitoring of public exposure

The licensee shall:

(a) Establish and carry out a monitoring programme sufficient to ensure that the requirements of the Regulatory Authority regarding public exposure to radioactive sources are satisfied and to assess such exposure;

(b) Establish and carry out a monitoring programme sufficient to ensure that the requirements that the Regulatory Authority for discharges of radioactive substances to the environment are satisfied; and

(c) Keep records of the results of the monitoring programmes.

CHAPTER VII – POTENTIAL EXPOSURE AND EMERGENCY PLANS

Article 46: Safety assessment

The licensee shall conduct a safety assessment applied to all stages of the design and operation of the nuclear medicine facility, and include it in the emergency preparedness and response plan that is submitted to the Regulatory Authority.

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

The safety assessment shall be documented and, if appropriate, independently reviewed. Additional reviews shall be performed as necessary whenever:

(a) Safety may be compromised as a result of modifications of the facilities or of the procedures;

(b) Operational experience or information on accidents or errors indicates that a review is necessary; or

(c) Any significant changes to relevant guidelines or standards are envisaged or have been made.

Article 47: Prevention of accidents and mitigation of their consequences

The licensee shall incorporate within the Emergency Preparedness and Response plan:

(a) Defense in depth measures to cope with identified events, and an evaluation of the reliability of the safety systems (including administrative and operational procedures, and equipment and facility design);

(b) Operational experience and lessons learned from accidents and errors;

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

Article 48: Emergency plans

On the basis of events identified by the safety assessment, the licensee shall prepare emergency procedures.

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

An emergency plan shall as a minimum list or describe:

(a) Predictable incidents and accidents and measures to deal with them;

(b) The persons responsible for taking actions, with full contact details;

(c) The responsibilities of individual personnel in emergency procedures (nuclear medicine physicians, medical physicists, nuclear medicine technologists, etc.);

(d) Equipment and tools necessary to carry out the emergency procedures;

(e) Training and periodic rehearsal;

(f) Recording and reporting system;

(g) Immediate measures to avoid unnecessary radiation doses to patients, staff and public;

(h) Measures to prevent access of persons to the affected area; and

(i) Measures to prevent spread of contamination.

CHAPTER VIII: LICENSING REGIME FOR RADIATION PROTECTION IN NUCLEAR MEDICINE

Article 49: Types of licenses and Authorization issued in Nuclear medicine field

In Nuclear medicine, the Regulatory Authority issues authorization classified in five types as follow:

1. Authorization for site assessment;
2. Authorization for design and construction of nuclear medicine facility;
3. Authorization to import nuclear medicine equipment;
4. Authorization for medical use;
5. Authorization for modification and/or decommissioning.

The Regulatory Authority issues also license to operate a Nuclear medicine facility.

Article 50: Application for License or Authorization

Any person who intends to perform any nuclear medicine activity applies for a license or authorization to the Regulatory Authority.

Article 51: Criteria for license or authorization issuance in Nuclear medicine field

The Regulatory Authority based on the nature of activity performed in nuclear medicine field, issues licenses or authorizations to applicants who:

(a) Fulfils all technical, administrative, operational, safety criteria and other conditions in accordance with applicable laws, regulations and standards;

(b) Has an approved radiation risk assessment by the Regulatory Authority;

(c) Comply with health and safety applicable laws and regulations.

(d) Has paid all applicable fees as provided for in Annex II

Article 52: Authorization for Site Assessment

The authorization holder has the following obligations:

(a) Meet obligations related to site assessment,
(b) Notify the Regulatory Authority any modification in the facility land title, layout and plan;
(c) Provide to the Regulatory Authority a detailed report of the site assessment including safety assessment;
(d) Comply with any other obligation as requested by the Regulatory Authority.

Article 53: Authorization for design and construction of Nuclear medicine facility

The authorization holder has the following obligations:

(a) Meet obligations related to design and construction considering safety assessment recommendations;
(b) Notify to the Regulatory Authority any modification in the facility land title, layout and plan;
(c) Comply with any other obligation as requested by the Regulatory Authority.

Article 54: Authorization to import Nuclear medicine equipment

The applicant has the following obligations:

(a) Meet obligations related to import a nuclear medicine equipment;
(b) Notify to the Regulatory Authority the import schedule and the arrival of the equipment on the territory of Rwanda;
(c) Provide to the regulatory authority a detailed report of the test performed on the equipment;
(d) Comply with any other obligation as requested by the Regulatory Authority.

Article 55: License to operate a Nuclear medicine facility

The person licensed to operate a nuclear medicine facility have the following obligations:

(a) Ensure that all technical obligations with regard to safety and protection are met as provided in this regulation;
(b) Ensure that all obligations related to commissioning, clinical use, and maintenance are met;
(c) Submit a decommissioning plan to the Regulatory Authority;
(d) Ensure continuous training of personnel;
(e) Reports all incidents and medical events as provided in this regulation.

Article 56: Authorization for modification and/or decommissioning

The license holder fulfils all obligations related to modification and decommissioning as provided in this regulation and provides to the Regulatory Authority a detailed report of the modifications.

Article 57: Validity of license/authorization

The validity of Authorization issued in nuclear medicine field other than operational license is determined upon evaluation of the activity to be carried out. For operational license, the validity is five (5) years.

Article 58: License renewal

Application for renewal of license is submitted three (3) months before expiration of the current license and is granted subject to documented evidence of due compliance with laws, regulations and license obligations after payment of required fees.

Article 59: License/Authorization modification

A license modification proceeding may be initiated by the Regulatory Authority or by the request of the licensee. The Regulatory Authority may modify a license before its expiration term when it determines that a modification of the license is needed in order to:

(a) Respond to significant changes in a new law or Regulation or Court decision that directly affect the license terms and conditions;
(b) The request of the licensee due to relevant reasons;
(c) Adjust to the changes necessitated by existing market conditions;
(d) Respond to the requirements of any technological developments or changes;
(e) If it is for the purpose of correction of errors indicated during licensing review for radiation safety in nuclear medicine

Article 60: Transfer of the license

The transfer of license or other transfer of assets or activities subject to a license to a different individual or institution is subject to a prior written approval of the Regulatory Authority.

Such approval is granted after consideration of the matter and if the proposed transferee meets all the conditions to be granted the relevant license.

After the license transfer, the duration of the license and the license terms and conditions remain the same.

Article 61: License/Authorization suspension

The Regulatory Authority may suspend the license to operate a nuclear medicine facility upon determination of the following:

(a) Failure to comply with license terms and conditions;
(b) Failure to cooperate with the Regulatory Authority's inspection and audits;
(c) Failure to provide the Regulatory Authority with monitoring and reporting data required;
(d) Failure to pay the regulatory fee and such fee remains unpaid six (6) months after it has become due and the Regulatory Authority has given to the Licensee a notice in writing that such payment is overdue and the Licensee has not paid;

Article 62: License/Authorization Revocation

The Regulatory Authority may revoke the license/Authorization before its expiration when it determines that the revocation is needed to respond to:

(a) Abandonment of licensed activities,
(b) Liquidation of the licensee/authorization holder;
(c) Submittal of deliberately misleading data or information to the Regulatory Authority in response to its request or in response to its inspection;
(d) Repetitive failure by the licensee/authorization holder to comply with any of the terms and conditions of the license.
(e) Any other severe mistake as judged by the Regulator Authority as a reason of revocation.

CHAPTER IX- FAULTS AND ADMINISTRATION FINES

Article 63: Failure to notify the Regulatory Authority

Any licensee/authorization holder who fails to notify the Regulatory Authority on any matters needed to be notified as provided in this regulation commits a fault, and is liable to an administrative fine equivalent to two hundred thousand (200.000) Rwandan francs.

Article 64: Failure to conduct periodical Quality control tests and maintenance

A licensee who fails to conduct a quality control test and maintenance as prescribed in this regulation commits a fault and is liable to administrative fines as follows:

1. Five hundred thousand Rwandan francs (500,000 Frw) for daily and weekly tests;

2. One million Rwandan francs (1,000,000 Frw) for monthly and quarterly tests;

3. Three million Rwandan francs (3,000,000 Frw) for annually tests.

In the event the failure to conduct quality control tests has led to an injury or over exposure to individuals or environment, the licensee is punished in accordance with the law in force governing radiation protection.

Article 65: Modification of Nuclear medicine facility design

A licensee/authorization holder who modifies a radiation facility design without a prior approval of the Regulatory Authority commits a fault and is liable to an administrative fine of ten million (10.000.000) Rwandan francs.

Article 66: failure to conduct occupational and area exposure monitoring

A licensee who fails to conduct a regular individual and area exposure monitoring as specified under this regulation commits a fault and is liable upon conviction to an administrative fine as follows:

1. Five million Rwandan francs (5,000,000Frw) in the event they are no occupational or area exposure monitoring tools in place;

2. Two million Rwandan francs (2,000,000Frw) in case they are no regular monitoring reports.

Article 67: Failure to perform calibration of equipment

Any licensee operating with a non-calibrated source or equipment commits a fault and is sanctioned by a suspension of a license until the calibration is made and related certificate issued.

CHAPTER XI: TRANSITIONAL AND FINAL PROVISIONS

Article 68: Transitional period

All operators in nuclear medicine field are given six (6) months to comply with this regulation from the date of its signature.

Article 69: Repealing provision

All other prior provisions contrary to this regulation are hereby repealed

Article 70: Commencement

This regulation of radiation safety comes into force on the date of its signature by the Chairperson of Regulatory Board

Kigali, on 26th May 2023

(Sé)

Dr Omar GATERA
Chairperson of the Regulatory Board

ANNEX I. DOSE LIMITS FOR OCCUPATIONAL AND PUBLIC EXPOSURE

Occupational Exposure Dose limits

1. The occupational exposure of any worker shall be so controlled that the following limits be not exceeded an–

a. Effective dose of 20mSv per year averaged over five consecutive years

b. Effective dose of 50mSv in any single year;

c. Equivalent dose to the lens of the eye of 50mSv in a year; and

d. Equivalent dose to the extremities (hands and feet) or the skin of 500mSv in a year.

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

(a) An effective dose of 6mSv in a year;

(b) An equivalent dose to the lens of the eye of 50mSv in a year; and

(c) An equivalent dose to the extremities or the skin of 150mSv in a year.

Special circumstances

When in special circumstances, a temporary change in the dose limitation requirements is approved pursuant to Rwandan Basic Ionising Radiation Regulations:

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

(b) The temporary change in the dose limitation shall be as specified by the Regulatory Authority but shall not exceed 50mSv in any year and the period of the temporary change shall not exceed 5years.

Public Exposure Dose limits

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

(a) An effective dose of 1mSv in a year;

(b) In special circumstances, an effective dose of up to 5mSv in a single year provided that the average dose over five consecutive years does not exceed 1mSv per year;

(c) An equivalent dose to the lens of the eye of 15mSv in a year; and

(d) An equivalent dose to the skin of 50mSv in a year.

Dose limitation for comforters and visitors of patients

The dose limits set out in this part shall not apply to comforters of patients, i.e., to individuals knowingly exposed while voluntarily helping (other than in their employment or occupation) in the care, support and comfort of patients undergoing medical diagnosis or treatment, or to visitors of such patients.

The dose of any such comforter or visitor of patients shall be constrained so that it is unlikely that his or her dose will exceed 5mSv during the period of a patient's diagnostic examination or treatment.

The dose to children visiting patients who have ingested radioactive materials should be similarly constrained to less than 1mSv.

SEEN TO BE ATTACHED TO THE REGULATION No. 007/R/RS-NRP/RURA/2023 OF 12/05/2023 GOVERNING RADIATION PROTECTION IN NUCLEAR MEDICINE

Done at Kigali, on 26/05/2023

(Sé)
Dr Omar GATERA
Chairperson of the Regulatory Board

ANNEX II: CATEGORIES OF PERMISSIONS ISSUED IN NUCLEAR MEDICINE FIELD AND RELATED FEES

TYPE OF PERMISSION	APPLICATION FEES/FRW	LICENSE/ AUTHORIZATION FEES/FRW
Authorization for site evaluation	100,000	300,000
Authorization for Design and construction	100,000	1000,000
Authorization for import of nuclear medicine equipment	100,000	500,000
License for Operation	500,000	15,000,000
Authorization for modification and Decommissioning	NA	500,000

SEEN TO BE ATTACHED TO THE REGULATION Nº 007/R/RS-NRP/RURA/2023 OF 12/05/2023 GOVERNING RADIATION PROTECTION IN NUCLEAR MEDICINE

Done at Kigali on 26/05/2023

(Sé)
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Chairperson of the Regulatory Board