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REGULATION N°003/R/RS-NRP/RURA/2021 OF 25/02/2021 GOVERNING RADIATION PROTECTION IN RADIOTHERAPY IN RWANDA

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PLEAMBLE

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 in Rwanda;

Pursuant to in General Regulation No 001/R/RS-RP/RURA/2019 of 15/11/2019 governing Radiation Safety in Rwanda

Considering that Radiotherapy is the branch of medicine that uses ionizing radiation, either alone or in combination with other modalities, for the treatment of patients with malignancies or other diseases;

Given that the use of radiotherapy has overall societal benefit, but the high radiation doses involved with therapeutic exposures have the potential to cause harm to those who benefit from the treatment and to health care staff and members of the public if inadvertent radiation exposure occurs;

Based on the recommendations made during consultative meetings held on 03rd December 2020 between RURA and different stakeholders in this sector;

After consideration and deliberation in its session of …….;

Hereby issues the following:

CHAPTER ONE: GENERAL PROVISIONS

Article One: Purpose of this Regulation

The purpose of this regulation is to put in place a Regulatory framework governing radiation protection in radiotherapy in Rwanda.

Article 2: Definitions of Terms

In this regulation, the terms below have the following meanings:

1^0 Authorization: a written permission granted by the Regulatory Authority to a person to carry out an activity or a practice other than operation;

2^0 Ionising radiations facility: any irradiation installations, mining and milling facilities, waste management facilities and any other place where radioactive materials are produced, processed, used, handled, stored or incinerated or where ionising radiations generators are installed on such a scale that consideration of protection and safety is required;

3^0 License: a written permission issued by the Regulatory Authority to a person carrying out activities related to the operation of a radiotherapy facility;

4^0 Licensee: a person to who license has been issued to carry out any activity involving ionising radiations sources;

5^0 Medical exposure: exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly exposed while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure;

6^0 Notification: a document submitted to the regulatory body by a legal person to notify an intention to carry out a practice or other use of a source;

7⁰ Protection and safety: the protection of people against exposure to ionizing radiation or radioactive materials and the safety of radiation sources, including the means for achieving this, and the means for preventing accidents and for mitigating the consequences of accidents should they occur;

8⁰Radiation protection: the protection of people, biodiversity and environment from harmful effects of exposure to ionising radiations, and the means for achieving this;

9⁰Radiation protection officer: an individual technically competent in radiation protection matters relevant for a given type of practice who is designated by the licensee;

10⁰ Radiation sources: means anything that may cause radiation exposure such as by emitting ionizing radiation or by releasing radioactive substances or materials and which can be treated as a single entity for protection and safety purposes;

11⁰ Radioactive material: any material emitting ionising radiations including neutrons as to entail significant risk of disability or disease as a result of exposure;

12⁰ Radiotherapy: is the branch of clinical medicine that uses ionizing radiation, either alone or in combination with other modalities, for the treatment of patients with malignancies or other diseases;

13º Registrant: is an applicant who is granted registration of a practice or source and has recognized rights and duties for such a practice or source, particularly in relation to protection and safety;

14º Risk: is 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;

15º Regulatory Authority: National body to which the government has given the responsibility and powers to perform regulatory functions referred to in this regulation;

16º Sealed Source: is radioactive material that is a) permanently sealed in a capsule or (b) closely bounded and in a solid form. The capsule or material of a sealed source must be strong enough to

maintain leak tightness under the conditions of use and wear for which the source was designed, also under foreseeable mishaps;

17º Safety assessment: is 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;

18^0 Source: anything that may cause radiation exposure, such as by emitting ionizing radiation or by releasing radioactive substances or materials, materials emitting radon are sources in the environment, a sterilization gamma irradiation unit is a source for the practice of radiation preservation of food, an X ray unit may be a source for the practice of radiodiagnosis, and a nuclear power plant is a source for the practice of generating electricity by nuclear power.

Article 3: Objectives

The objectives of this Regulation are:

1. To protect patients, workers and the general public from the risks associated with exposure to ionizing radiation in the course of radiotherapy practice;
2. To assist licensees in meeting radiation safety requirements in radiotherapy practice for the attainment of adequate radiation protection and safety of patients, worker and the public.

Article 4: Scope of this Regulation

This regulation applies to the following:

1. The radiation therapy, the branch of medicine that uses ionizing radiation (teletherapy and brachytherapy), either alone or in combination with other modalities, for the treatment of patients with cancer or other diseases. It includes responsibility for the treatment decision, treatment preparation and planning, treatment delivery, follow-up and supportive care of the patient as an integral part of the multidisciplinary management of patients;

2. The exposure of patients as part of their treatment;

3. The exposure of individuals participating in research programs; the occupational exposure of individuals arising from radiotherapy practice;

4. The exposure of members of the public arising from the use of medical radiation equipment and radioactive sources including:
   a. The exposure of health professionals, other than those occupationally exposed;
   b. The exposure of carers;

5. Potential and emergency exposure situations;
6. To all therapeutic medical exposures, including intended, unintended and accidental exposure.

CHAPTER II: TEHCNICAL REQUIREMENTS FOR RADIOTHERAPY FACILITY

SECTION ONE: RADIOTHERAPY FACILITY DESIGN

Article 5: Reception, Administration and Waiting areas

In setting up reception, administration and waiting areas, the following are considered:

1. The reception and main waiting areas must be located at the main entrance to the facility and act as distribution point for all the different sections in the facility;
2. The waiting area must have separate waiting areas for patients attending clinics and those awaiting treatment;
3. The clinic waiting area should have space for approximately eight patients for each physician and the treatment waiting area should be adjacent to the treatment room, with space for seating of about twelve people for each machine;
4. There must also be an area provided for patients on stretchers, which should be adjacent to the treatment area, but they should preferably be separated from ambulatory patients. The area should be large enough to accommodate three stretchers;
5. Appropriate changing facilities close to the entrance of the treatment room, and shielded from the view of other patients and visitors;
6. The reception stations including consultation rooms must be sufficient to accommodate oncologists and medical officers in place for new and follow-up patients;
7. Sufficient parking closer to the facility must be made available for ambulances, and patients.

Article 6: Imaging and Treatment planning room

In setting up an Imaging and Treatment planning room, the following technical specific criteria are considered:

1. The room with large enough space to accommodate the simulator (7m x 7mx4 Height);

2. means for securely mounting the patient positioning lasers to the wall at points appropriate for projection of lines through the isocentre should be included in the plans;
3. Means for dimming the room lights should be considered in the design of the room;
4. Adequate space for cabinetry to store treatment devices and daily used quality assurance equipment;
5. Cabinet space to store supplies for their fabrication of immobilization devices;
6. A sink;
7. A viewing window for the control room;
8. Light boxes in the control room and simulator room are useful.

In addition to these specific criteria, the Imaging and Treatment planning room must be designed according to the requirements provided in the international master planning and concept design considerations for Radiotherapy facilities.

Article 7: Mould room

Mould room is designed in accordance to the following requirements:

1. Adequate space to fabricate custom designed blocks and compensators;
2. Adequate space for tools, a block cutter and counter-top workspace for pouring and mounting the blocks;
3. Adequate storage space for supplies of Styrofoam, trays and shielding materials;
4. Adequate ventilation if shielding materials are melted in the room;
5. Adequate space for a patient couch if immobilization devices are fabricated in the mould room;
6. Sink with a refuse trap.

Article 8: External beam therapy

External beam therapy must meet the following specific criteria:

1. Adequate space to accommodate the treatment machine, allowing the full range of motion of the treatment table;
2. A door interlock or other suitable means to prevent unauthorized access;
3. Warning signs of the radiation hazard, in accordance with regulatory authority requirements;
4. An area radiation monitor safe against a power failure should be visible on entering the room;
5. Air condition system sufficient to maintain the temperature and humidity in the treatment room;
6. A reliable and stable power supply for or modern equipment and IT systems;
7. Dimming lights available in the treatment room;
8. Radiation warning lights in two stages, one for the power to treatment unit, another when the beam or the source is one;
9. A separate changing room for patient;
10. The treatment room placed above the ground. No any other building should be above or under the treatment room.

In addition to these specific criteria, the Imaging and Treatment planning room has to be designed according to the requirements provided in the international master planning and concept design considerations for Radiotherapy facilities

Article 9: Low dose brachytherapy

Low dose brachytherapy design must meet the following specific criteria:

1. A door interlock or other suitable means to prevent unauthorized access;
2. Warning signs of the radiation hazard, in accordance with international standards
3. An area radiation monitor safe against a power failure should be visible on entering the room.;

4. Air condition system sufficient to maintain the temperature and humidity in the treatment room;
5. A reliable and stable poor supply for or modern equipment and IT systems;
6. Radiation warning lights in two stages, one for the power to treatment unit, another when the beam or the source is one;
7. A separate changing room for patients;
8. A separate source storage and preparation room;
9. The treatment and storage rooms should be adjacent to each other in order to reduce distances over which patients and sources have to be transported;
10. Sterilization facilities for applicators;

In addition to these specific criteria, the low dose brachytherapy room has to be designed according to the requirements provided in the international master planning and concept design considerations for Radiotherapy facilities.

Article 10: High dose rate brachytherapy

High dose rate brachytherapy design should meet the following criteria:

1. Adequate space to accommodate the treatment and simulator machines;
2. A door interlock or other suitable means to prevent unauthorized access;
3. Warning signs of the radiation hazard, in accordance with regulatory authority requirements;
4. An area radiation monitor safe against a power failure should be visible on entering the room;
5. Air condition system sufficient to maintain the temperature and humidity in the treatment room;
6. A reliable and stable poor supply for or modern equipment and IT systems;
7. Dimming lights available in the treatment room;
8. Radiation warning lights in two stages, one for the power to treatment unit, another when the beam or the source is one;
9. A separate changing room for patients;

10. A separate source storage and preparation room;
11. The treatment room placed above the ground. No any other building should be above or under the treatment room;
12. The treatment and storage rooms must be adjacent to each other in order to reduce distances over which patients and sources have to be transported;
13. Sterilization facilities for applicators.

In addition to these specific criteria, the high dose brachytherapy room has to be designed according to the requirements provided in the international master planning and concept design considerations for Radiotherapy facilities.

SECTION 2: STAGES OF RADIOTHERAPY PRACTICES

Article 11: Stages

Any person who intends to utilize radiation sources for radiotherapy purposes must comply with radiation safety requirements for the following stages of the radiotherapy practice:

1. Site assessment and evaluation;
2. Design and construction;
3. Operation (acceptance, commissioning, clinical use, maintenance)
4. Modifications and;
5. Decommissioning (partial or total) and return or disposal of sources.

Article 12: Site assessment and evaluation

The applicant when assessing and evaluating the site, takes into account the following:

1. A geotechnical investigation, including but not limited to surface and subsurface exploration of the site;
2. A complete foundation investigation and analysis must 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;

3. The investigation and analysis has to be performed in compliance with international standards and generally accepted principles of sound engineering practice;
4. The size of the land required must be of a minimum of 3500m2 excluding access roads and parking areas. However, consideration has to be given to future expansion needs;
5. 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 radiotherapy facility's needs and for future expansion of services;
6. The fence of the radiotherapy facility must be at least thirty (30) meters from other medical facilities fences;
7. There must be at least fifty (50) meters distance from residential area.

Article13: Design and construction

The design and Construction of a radiotherapy facility is carried out by a competent professional team that is multidisciplinary.

At a minimum, the team consists of the following:

1. A qualified architect, preferably experienced in the design and construction of radiation oncology facilities;
2. A structural or civil engineer with experience in large concrete structures;
3. A mechanical engineer with experience in hospital design, including cooling, heating and ventilation systems;
4. An electrical engineer experienced in the calculation and design of reticulation and standby electrical systems for hospitals;
5. A cost consultant or quantity surveyor or equivalent;
6. A clinically qualified radiotherapy medical physicist with competency in the planning of new departments in similar environments;
7. A qualified radiation oncologist experienced in setting up and coordinating a radiation oncology facility.

The layout of the facility has to be planned taking into consideration equipment requirements, water and electrical utilities needed, room shielding required (including dosimetry ports) and climate control. Careful attention must be focused on the flow of patients in the treatment facility.

The layout has to be planned in accordance with internationally accepted radiation safety standards and in consultation with the radiation oncologist, physicist and equipment manufacturer.

SECTION 3: STAFFING

Article 14: Personnel required in radiotherapy

For radiotherapy practice, the following individuals must carry responsibilities for protection and safety, by virtue of tasks involving decisions, operation or manipulation of sources or equipment used in radiotherapy:

a) Radiation oncologist;
b) Medical physicists;
c) Radiation therapists;
d) Oncology nurses;
e) Dosimetrists; Radiation safety officer;
f) Biomedical engineers and technicians for maintenance of radiotherapy equipment;
g) Supporting staff.

The minimum required staff per category of service is provided in **annex I** of this regulation

Article 15: Qualifications of practitioners in radiotherapy

For a person to do any radiotherapy related work, must comply with the qualification required by the laws in force and must be registered and licensed members of a competent professional council.

The licensee must ensure that only staff with the relevant practice licenses fill the position he is attached to and that aware of:

1. The conditions and limitations of the license;

2. The institutional radiation safety and protection policies and procedures (including practice recover);
3. Their own individual responsibilities;
4. The use and operation of equipment;
5. The local quality assurance programme and quantity control procedures, which has to be in an accessible manual recover;
6. Review and analysis of incidents and accidents that have occurred in the institution or documented from elsewhere;
7. Instructions provided to patients and caretakers.

Article 16: Training of personnel

The licensee must provide workers with adequate information, instruction and training for protection and safety to ensure that:

1. Workers have adequate information on health risks due to their occupational exposure in normal operation, anticipated operational occurrences and accident conditions;
2. Workers have adequate instruction and regular training in protection and safety;
3. Workers have adequate information on the significance of their actions for protection and safety.

The Licensee must also maintain records of the training provided to individual workers.

SECTION 4: ADMINISTRATIVE REQUIREMENTS

Article 17: Safety Policy statement

Radiotherapy facility management has to be committed to an effective protection and safety policy, particularly at senior level, and by clearly demonstrable support for those persons with direct responsibility for radiation safety.

The commitment is expressed in a written policy statement that clearly assigns prime importance to protection and safety in radiotherapy, whilst recognizing that the prime objective of medical care is the treatment and well-being of the patients.

Article 18: Organization and responsibilities

The principal parties having the main responsibilities for the application of this regulation are the licensees.

The licensee assigns clear responsibilities to personnel including, workers, radiation safety officers, medical practitioners, health professionals, qualified experts, ethical review committees so that adequate radiation protection of patient, workers and the public is ensured.

Article 19: Establishment of Radiation protection programs

The licensee establishes a radiation protection program and provide the necessary resources to comply with this program. The program covers all phases of the practice, from design, through operation to decommissioning. The program reflects management responsibility, procedures and organisational arrangements that are commensurable with the risk.

SECTION 5: QUALITY ASSURANCE AND MAINTENANCE PROGRAMME

Article 20: Quality assurance programme

The licensee must establish a comprehensive quality assurance program for radiation protection and safety to ensure that all necessary procedures are developed and implemented in order to comply with the regulations for radiation safety within the terms and conditions of the license or authorization.

The programme of quality assurance for medical exposures includes:

1. measurements of the physical parameters of medical radiological equipment made by or under the supervision of, a medical physicist;

2. implementation of corrective actions if measured values of the physical parameters mentioned in are outside established tolerance limits.

Any licensee must ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks.

Article 21: Quality Control

The licensee must establish and implement a comprehensive quality control programme for radiation protection and safety to ensure that all necessary procedures are developed and implemented in order to comply with the regulations for radiation safety within the terms and conditions of the license or authorization.
A comprehensive regular list of quality control tests and tolerances is provided in the **annex II** of this regulation

Article 22: Maintenance of radiotherapy equipment

The licensee must ensure that maintenance of radiotherapy equipment is carried out by certified personnel or institution in collaboration with a medical physicist and biomedical engineer of the facility and keep proper record of maintenance activities.

CHAPTER III: SAFETY AND SECURITY OF SOURCES

Article 23: Safety in the design of radiation sources and equipment

In the safety design of radiation sources and equipment, the licensee has to ensure that:

1. Failure of a single component of the system be promptly detectable so that any unplanned medical exposure of patients is minimized; and
2. The incidence of human error in the delivery of unplanned medical exposure be minimized by:
    a. Taking into account information provided by suppliers, identify possible equipment failures and human errors that could result in unplanned medical exposures;
    b. Taking all reasonable measures to prevent failures and errors, including the selection of suitably qualified personnel, the establishment of adequate procedures for the calibration, quality assurance and operation of therapeutic equipment, and the provision to personnel of appropriate training and periodic retraining in the procedures, including protection and safety aspects;
    c. Taking all reasonable measures to minimize the consequences of failures and errors that may occur;
    d. Developing appropriate emergency plans for responding to events that may occur, display plans prominently' and periodically conduct practice drills.

Article 24: Design Requirements

1. The following design requirements are applicable only to external beam therapy equipment:
    a. The primary beam must be only directed towards primary barriers with sufficient shielding. If a primary shielding is incorporated to the equipment, electrical or mechanical interlocks has to be provided to avoid that the beam be directed toward the secondary barriers when the shielding is not intercepting the beam;
    b. External beam tele-therapy equipment has to be stable in any position and it must be possible to fix it in any desired position; and;

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

2. The design of the facility has to provide safety systems or devices to be inherent to the equipment and room, to lower the probability of occurrence of abnormal situations;
3. The shielding has to be calculated using optimization principles and, dose constraints must be developed and used as required by this regulation. The overall design of the facility including these calculations have to be performed by an appropriate qualified expert;
4. The licensee has to consider access control when determining the location of therapy treatment rooms and source storage areas;
5. Radiation monitoring equipment, where appropriate, has to be installed or be available to give warning of an unusual situation in the use of radiation generators and radionuclide therapy equipment;

Article 25: Sealed sources

Radioactive sources for either tele-therapy or brachytherapy has to be so constructed that they conform to the definition of a sealed source. To meet this requirement, sealed sources used for external beam therapy and brachytherapy must comply with ISO 2919 standard or equivalent national standards.

Sealed sources used for external beam and brachytherapy must have a calibration certificate provided by the manufacturer, in accordance with International Standards or equivalent national standards.

Sources used for manual brachytherapy is used either with metallic applicators or with plastic applicators compatible with the sources as stated by the manufacturer.

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

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

<u>Article 26</u>: Radiotherapy Equipment and Sources

The licensee must ensure that radiation sources, radioactive material, equipment and accessories, are purchased only from authorized suppliers. Prior to acquiring any radiation sources, the licensee has to ensure to have written user guidelines including methods for installation, acceptance, commissioning, use, maintenance, quality control and decommissioning of the acquired material as per manufacturer specifications.

Licensees, in co-operation with suppliers, must ensure that:

1. all equipment conform to applicable standards of the International Electro Technical Commission and the International Standards Organization or to equivalent National Standards;
2. performance specifications, operating and maintenance instructions, including protection and safety instructions are in compliance with the relevant International Electro-technical Commission or International Standards Organization with regard to accompanying documents; and are provided in any of the official languages.

Where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in any of the official languages;

Compliance is confirmed for the particular piece of equipment delivered, by including the relevant tests of the International Electro-technical Commission standards in the acceptance protocol. The set of tests to be included in the protocol has to be specified in the purchasing conditions.

Tele-therapy equipment containing radioactive sources must be provided with a device to return sources manually to the shielded position in case of emergency. For gamma knife units, it must be possible to close the shielding door manually; and

The irradiation heads in external beam equipment and source containers in brachytherapy has to be provided with a clear permanent sign indicating the existence of radioactive material. Containers and devices containing radioactive sources, when outside the radiotherapy department, has to be labelled with a warning sign, which is recognized as "DANGER" by any member of the public.

Article 27: Safety associated with acceptance test

Acceptance tests is not being restricted to radiation emitting equipment or sources but also be conducted for any system that has implications on safety, such as treatment planning systems;

After equipment installation, acceptance test is conducted in order to verify that the equipment conforms to technical specifications given by the manufacturer and to verify compliance with safety requirements of International Electro-Technical Commission Standard;

As indicated in paragraph (2), the tests are included in the acceptance protocol must specified in the purchasing conditions and contracts clearly establish responsibility of suppliers for resolving non-conformity identified during acceptance testing.

Article 28: Safety associated with commissioning and operation

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

With regard to operation, equipment is operated in accordance with the technical requirements, ensuring satisfactory operation at all times.

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

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

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

An independent audit of the calibration of the sources is carried out before starting clinical use of the source. The audit must be conducted by a recognised person or institution.

Article 29: Safe operation of external beam therapy

Safe operations of external beam treatment units require procedures for area surveys, interlock checks, wipe tests and procedures for emergencies such as a source which becomes stuck in or partially on position and the necessary equipment for procedures mentioned above must be available, calibrated and in working order.

These include:

(a) A radiation monitor with scales from one mSv and greater;

(b) Equipment for wipe test;

(c) Personal alarm dosimeters, especially for emergency intervention.

Article 30: Safe operation of brachytherapy

The licensee develops an operating procedures manual for Low Dose Rate and High Dose Rate sources taking into consideration source inventories, storage, leak test, area survey and patient monitoring.

The source strength is determined individually, before it is used on a patient and the source documentation has to be checked carefully.

The unit of activity used for source calibration must be the same as the unit of activity used in the treatment planning system.

The following information is posted in the case of Low Dose Rate brachytherapy, both manual as well as remote controlled:

1. identification of the patient and sources;
2. date and time of insertion and removal;
3. nursing required, time 'allowance for nurses and visitors;
4. Concise instructions for unplanned source and applicator removal and for emergency;

Patient with removable source in or upon his body must not leave the room unless accompanied by a hospital attendant.

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

Article 31: Security of sources

The licensee must ensure that sources are kept secured so as to prevent theft or damage and to prevent any unauthorized use by ensuring that:

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

(b) A source is not transferred unless approved by the regulatory authority;

(c) A regular inventory of movable sources is conducted at appropriate intervals to confirm that they are in their assigned locations and are secured.

Specific protection measures are required for avoiding loss of control in the following situations:

(a) Storage of sources before installation;

(b) Temporary or permanent cessation of use;

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

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

The licensee must ensure that the number of sources in a container when removing and when returning the sources is checked and that a physical· inventory of all sealed sources is performed.

The licensee maintains a source movement log with a record indicating the date of removal, the name of the patient and the return of the source.

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

CHAPTER IV: OCCUPATIONAL AND MEDICAL EXPOSURE

SECTION ONE: OCCUPATIONAL EXPOSURE

Article 32: Responsibilities and conditions of service

The licensee is responsible for the protection of workers from occupational exposure by ensuring that workers:

a. Follow any applicable policies and procedures for protection and safety specified by the licensee;
b. Use properly the monitoring devices and the protective equipment and clothing provided;
c. Provide information on their past and current work as is relevant to ensure effective and comprehensive protection and safety for themselves and others.

The licensee develops and implements special policies and procedures for protection of workers during intervention.

Article 33: Pregnant workers

A female worker, on becoming aware that she is pregnant, notifies her employer for assessing her working conditions and adjust them where necessary.

Upon notification, the licensee must adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus is afforded the same broad level of protection as required for members of the public.

Article 34: Classification of areas

Areas in radiotherapy practice are classified as controlled, supervised, and public.

In radiotherapy practice, areas requiring specific protection measures are designated "controlled areas" and these are including, at least, all irradiation rooms for external beam therapy and remote

after loading brachytherapy, operating rooms during brachytherapy procedures using real sources, brachytherapy patient rooms, radioactive source storage and handling areas.

Controlled areas are demarcated by physical boundaries like walls or other physical barriers marked and identified with 'radiation area' signs.

Areas surrounding brachytherapy patient rooms or around radioactive source storage and handling areas shave are designated" supervised" areas.

All areas not designated as controlled nor supervised areas have to be such that persons inside are afforded the same level of protection as members of the public.

Article 35: Personal Protective equipment

Licensees must ensure that workers are provided with suitable and adequate personal protective equipment as provided in the General Regulation governing radiation safety in Rwanda.

Article 36: Individual exposure monitoring

The licensee is responsible for arranging for the assessment of the occupational exposure of workers as provided in General Regulation governing radiation safety in Rwanda. These workers include but not limited to radiation oncologists, qualified experts in radiotherapy physics, Radiation Safety Officer, radiotherapy technologies, source handlers, maintenance staff, nurses or other staff who must spend time in the radiotherapy facility.

Article 37: Health Surveillance

The licensee ensures that medical surveillance for workers is performed at least once a year to assess continuing fitness of employees for their intended tasks.

Upon the results from health surveillance, the licensee avails counselling services to workers in need including accidentally exposed, 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 38: Records

The licensee maintains and preserves exposure records for each worker. The exposure records include information on the general nature of the work involving occupational exposure, information on doses, and the data upon which the dose assessments have been based.

Licensees must provide for access by workers to information in their own exposure records; and give due care and attention to the maintenance or' appropriate confidentiality of records.

The licensee provides quarterly occupational exposure report to the Regulatory Authority for compilation of the national dose records.

SECTION 2: MEDICAL EXPOSURE

Article 39: Responsibilities of the licensee

The licensee must with regard to responsibilities for medical exposure ensure that the requirements of this regulation for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in this regulation are fulfilled by or under the supervision of a medical physicist. By doing so, the following should be taken into consideration:

1. No patient is administrated a therapeutic medical exposure unless exposure is prescribed by a radiation oncologist;
2. Radiation oncologist has to be assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;
3. The radiation therapist has to discharge assigned tasks in the conduct of the therapeutic procedure that the radiation oncologist prescribes;

4. For therapeutic uses of radiation, the calibration, dosimetry and quality assurance, is conducted under the supervision of a qualified expert in radiotherapy physics.

Any person involved in delivery of medical exposure is required to:

1. Follow the applicable rules and procedures for the protection and safety of patients, as specified by the licensee;
2. Be aware that prescription of treatment and treatment plan need to be signed by the radiation oncologist prior to initiation of treatment;
3. The licensee must ensure that the exposure of individuals incurred knowingly while voluntarily helping in the care, support or comfort of patients undergoing medical diagnosis of treatment are constrained as specified in the General Regulations on radiation safety;
4. Radiation oncologist in chief must promptly inform the licensee of any deficiencies or needs regarding compliance with laws and Regulations in force in respect of protection and safety of patients and take such action as may be appropriate to ensure the protection and safety patients.

Licensee of radiotherapy practices ensures that:

a. Exposure of normal tissue during radiotherapy are kept as low as reasonable achievable consistent with delivering the required dose to the planning targeted volume (95-105% of the prescribed dose), and organ shielding has to be used where practicable and appropriate;
b. Radiotherapy procedures causing exposure of the abdomen or pelvis or women who are pregnant or likely to be pregnant has to be avoided unless there are strong clinical indications;
c. Any therapeutic procedure for pregnant women has to be planned to deliver the minimum dose to any embryo or foetus;
d. The patient is informed of possible risks and make a consent before the procedure.

The licensee provides written instructions on actions to be taken to reduce exposure to comforters, caregivers and members of the public from sources in brachytherapy patients with permanent implants. These instructions include minimizing prolonged contact with children and potentially pregnant women, and procedures to follow in the event that a source becomes dislodged.

Article 40: Calibration in Radiotherapy practice

Licensees ensures that:

a. The calibration of sources used for medical exposure are traceable to a Standards dosimetry laboratory;
b. Radiotherapy equipment is calibrated in terms of radiation quality or energy and either absorbed dose or absorbed dose rate at a predefined distance under specified conditions;
c. Sealed sources used for brachytherapy is calibrated in terms of activity, reference air kerma rate in air or absorbed dose rate in a specified medium, at a specified distance, for a specified reference date;
d. The calibration is carried out at the time of commissioning a unit, after any maintenance procedure that may have an effect on the dosimetry and at intervals approved by the Regulatory Authority.

The licensee ensures that tele-therapy equipment outputs are compared at least once every two years in a national, regional or international programme for independent dose verification. The licensee develops, adopts, implements, and follows a protocol for calibration of radiation sources used for radiotherapy.

At least two different qualified experts in radiotherapy physics and preferably using different dosimetry systems has to do calibration of new equipment and new radiation sources independently and the results have to be compared only after the completion of both measurements.

New brachytherapy sources are calibrated and the sources are used for patient's treatment if the difference is greater than 5% until the difference is investigated and resolved. The responsibility for the investigation and for further action remain with the licensee, and the investigation is usually performed by the qualified expert in radiotherapy physics, with or without external help.

Article 41: Clinical dosimetry

Licensee ensures that dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted or nationally accepted protocols to determine the following:

1. Absorbed doses to the planning target volume and absorbed doses to relevant tissues or organs for each patient treated with external beam therapy and/or brachytherapy as determined by the radiation oncologist;
2. For brachytherapy, the process must also begin with the treatment prescription, dated and signed by the radiation oncologist.
3. The treatment prescription must contain at least the following information: 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.

The licensee has to keep electronic records of the clinical dosimetry of patients throughout the lifetime of the facility. After facility decommissioning, those data should be handled to the Competent Authority.

The specification of volumes and the prescribing, recording and reporting of doses shall be in accordance with the updated recommendations of the International Commission on Radiation Units and measurements in radiotherapy dosimetry

Article 42: Discharge of Patients

The licensee must ensure that no patient who has undergone a therapeutic radiological procedure with a sealed source is discharged from a medical radiation facility until it has been established that:

1. The activity of radiation source in the patient is such that doses that could be received by members of the public do not exceed dose limits prescribed in General Regulation Governing Radiation Safety in Rwanda;
2. The patient or the legal guardian of the patient is provided with:

   i. Written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination;

   ii. Information on the radiation risks.

Article 43: Investigation on accidental medical exposure

The licensee must immediately notify the Regulatory Authority and investigate any of the following incidents:

a. any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong treatment plan, or with a dose or dose fractionation differing substantially from the values prescribed by the radiation oncologist or which may lead to undue acute secondary effects;
b. 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 must, with respect to any investigation required by this regulation:

1. Calculate or estimate the doses received and their distribution within the patient;
2. Indicate the corrective measures required to prevent recurrence of such an incident;
3. Implement all the corrective measures that are under their own responsibility;
4. Submit to the regulatory Authority, as soon as possible after the investigation or as otherwise specified by the Regulatory Authority, a comprehensive written report on the cause, consequences and action taken on the incident.

CHAPTER V: PUBLIC EXPOSURE, EMERGENCY PREPAREDNESS AND RESPONSE

SECTION ONE: PUBLIC EXPOSURE

Article 44: Responsibilities of the licensee

The licensee has the following responsibilities with regard to public exposure:

1. Controlling public exposure resulting from a radiotherapy facility and practice;
2. Prevent access by members of the public to areas in and near the radiotherapy facility; has to be considered when designing shielding of storage and use of facilities;
3. Develop and implement measures for use, transport and storage of radiation sources and radioactive materials to ensure the safety and security of radiotherapy sources to control public exposures in accordance with the regulations and requirements in place;
4. Control and maintain constant surveillance of sources that is not in storage and secure stored sources from unauthorized access, removal, or use, and the storage facility has to be locked at all times.

Article 45: Access control for visitors

The licensee makes arrangements to control access of members of the public to the controlled area and provides adequate information and instruction to the visitors before they enter a controlled area so as to ensure appropriate protection of members of the public.

Article 46: Radioactive waste and sources no longer in use

The licensee notifies the Regulatory Authority and submits a plan for transfer or disposal of sources if they are no longer in use.

The licensee is responsible for the sources until the time of their transfer to another appropriate licensee or to an authorized waste disposal facility and ensures that resources for the disposal of the sources are made available.

Article 47: Monitoring of public exposure

The licensee establishes and carries out a monitoring programme sufficient to ensure that the requirements set in General Regulation No 001/R/RS-RP/RURA/2019 governing Radiation Safety in Rwanda regarding public exposure to sources of external irradiation are satisfied.

SECTION 2: EMERGENCY PREPAREDNESS AND RESPONSE

Article 48: Safety assessment of potential exposure events

Licensees prepares a safety assessment applied to al1 stages of design, construction, operation, maintenance and decommissioning of the radiotherapy facility, and submit it to the Regulatory Authority.

The assessment must be systematic and contain information on identification of possible events leading to accidental exposure.

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

The safety assessment is documented and revised by an independent expert where:

1. Modification of the radiation sources or its facilities are made;
2. Operational experience or information on accidents or errors indicates that the safety assessment has to be reviewed;
3. Techniques are modified in such a way that safety may be compromised.

Article 49: Prevention of accidents

The licenses incorporate in the safety procedures:

1. Defence-in-depth measures to cope with identified event, and evaluate the reliability of the safety systems;
2. The operational experience and lessons learned from accidents and errors into training, maintenance and quality assurance programme;

3. Measures to promptly inform the Authority of all patient and public overexposure situations as well as other reportable events;

Article 50: Emergency preparedness and response plans

Based on the events identified by the safety assessment, the licensee elaborates mitigation measures embodied in a set of emergency procedures, the relevant staff is trained in the mitigation measures, which must be periodically rehearsed, and the lessons learned from the rehearsals have to be used to review and update the emergency plans.

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

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

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

The Regulatory Authority reviews and approves all individual emergency preparedness and response plans submitted by the operating facilities prior to authorization.

CHAPTER VI: LICENSING REGIME FOR RADIATION SAFETY IN RADIOTHERAPY

Article 51: Types of licenses and Authorization issued in radiotherapy field

The Regulatory Authority with regard to radiotherapy field issues licences and authorisations.

Authorizations issued in radiotherapy are classified in four types as follow:

1. Authorization for Site Assessment;
2. Authorization for Design and construction of radiotherapy facility;
3. Authorization to import radiotherapy equipment;
4. Authorization for modification and/or Decommissioning.

The Regulatory Authority issues also license to operate a radiotherapy facility.

Article 52: Application for License or Authorisation

Any person who intends to perform any radiotherapy activity falling under the above license/authorization categories must apply to the Regulatory Authority a license or authorization by filling an appropriate form related to the activity to be carried out.

The form as annexed **(Annex III)** to this regulation indicates required documents accompanying the application

Article 53: Criteria for license or authorisation issuance in radiotherapy field

Depending on the nature of activity performed in radiotherapy field, the Regulatory Authority issues licenses or authorizations to applicants who:

1. Fulfil all technical requirements prescribed in this regulation depending on the stage of the Radiotherapy field;
2. Has sufficient economic resources to meet the radiotherapy activity, ability and the professional skills needed with regard to the special nature of the radiotherapy activity,
3. Demonstrate the relevant information necessary to the safety of the practice.

The Regulatory Authority may determine any other substantive criteria needed to fully ensure radiation safety in radiotherapy.

Article 54: Authorization for Site Assessment

The authorization holder has the following obligations:

1. Fulfil all obligations provided in this regulation, especially in article 12;
2. Notify the Regulatory Authority any modification in the Facility land title, layout and plan;
3. Provide to the Regulatory Authority a detailed report of the site assessment;
4. Comply with any other obligation as requested by the Regulatory Authority

Article 55: Authorization for Design and construction of radiotherapy facility

The authorization holder has the following obligations:

1. Fulfil all obligations provided in this regulation, especially in article13;
2. Notify to the Regulatory Authority any modification in the Facility land title, layout and plan;
3. Comply with any other obligation as requested by the Regulatory Authority.

Article 56: Authorization to import a radiotherapy equipment

The authorization holder has the following obligations:

1. Fulfil all obligations provided in this regulation;
2. Notify to the Regulatory Authority the import schedule and the arrival of the equipment on the territory of Rwanda;
3. Provide to the regulatory authority a detailed report of the test performed on the equipment;
4. Comply with any other obligation as requested by the Regulatory Authority.

Article 57: License to operate a radiotherapy facility

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

1. Ensure that all technical Obligations with regard to safety and protection are met as provided in this regulation;

2. Ensure that all obligations related to commissioning, clinical use, and maintenance are met;
3. Ensure compliance of decommissioning obligations;
4. Ensure continuous training of personnel;
5. Reports all incidents and accidents as provided in this regulation.

Article 58: Authorisation 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 59: Validity of licenses/authorisations and related fees

The validity of Authorisations issued in radiotherapy 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 renewable.

Application and license fees per type of activity carried out in radiotherapy field are determined in the table annexed (**Annex IV**) to this regulation.

The annual contributions to the functioning of the Regulatory Authority is paid where applicable by the licensee or authorization holder according to the Regulatory Board decision governing the matter.

Licenses and Authorisation for each type of radiotherapy activity is issued to the applicant upon presentation of proof of payment of the license/authorisation fees.

The Regulatory Authority reserves the right to modify the validity and license or application fees when deemed necessary**.**

Article 60: 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. When applicable, Bank slip of payment of regulatory fees for previous years is required.

The authorisation holder who has not achieved activities within the timeframe of the authorisation may apply for extension to the Regulatory Authority.

The Regulatory Authority reserves the right to grant the renewal or reject the application.

Article 61: License/Authorisation modification

The modification of license/authorisation in radiotherapy is made in the following circumstances:

1. If the Regulatory Authority orders that modification;
2. The licensee requests it due to relevant reasons.

Article 62: License/Authorisation suspension

A license/Authorisation may be immediately suspended in the following circumstances:

1. To protect public health and safety;
2. To preserve the security of the source;
3. In the case of failure by the licensee to comply with any license obligations.
4. Upon request by the licensee in the event he/she intend to stop the licensed activity for a period not exceeding 6 months.

The request for license suspension indicates the reason of such suspension and the duration of suspension.

License suspension takes effect from the date the suspension has been approved by the Regulatory Authority. From that period, the licensee must not operate or provide any service he/she was authorized for and has to return to the Regulatory Authority the granted license/Authorisation.

Article 63: License/Authorisation Revocation

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

a. Abandonment of licensed activities,
b. Liquidation of the licensee/authorisation 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/authorisation holder to comply with any of the terms and conditions of the license.

CHAPTER VII: FAULTS AND RELATED SANCTIONS

Article 64: Failure to notify the Regulatory Authority

Any licensee/authorisation 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 (200.000) Rwandan francs.

Article 65: 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 overexposure to individuals or environment, the licensee is punished in accordance with the law in force governing radiation protection.

Article 66: Modification of radiotherapy 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 67: 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 faults 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 68: 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 VIII: TRANSITIONAL AND FINAL PROVISIONS

Article 69: Transitional period

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

Article 70: Repealing provision

All other prior provisions contrary to this regulation are hereby repealed

Article 71: Commencement

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

Done at Kigali on 25/02/2021

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Dr Ignace GATARE
Chairperson of the Regulatory Board

ANNEXES

ANNEX I: MINIMUM REQUIRED STAFF PER CATEGORY OF SERVICE

CATEGORY	STAFFING
Radiation oncologist-in-chief	One per facility
Staff radiation oncologist	One additional for each 200 patients treated annually. No more than 25–30 patients under treatment by a single physician at any one time.
Radiation physicist	One per centre for up to 300 patients annually. Additional in ratio of 1 per 300 patients treated annually.
Treatment planning staff: Dosimetrist or physics assistant	One per 300 patients treated annually.
Radiation therapy Technologist (RTT): Supervisor RTT	One per centre Two per megavoltage unit up to 25 patients treated daily;
RTT-Sim (teletherapy)	Ten for every 300 patients simulated annually
RTT-Br (Brachytherapy)	2 per 300 patients treated annually
Nurse	One per centre for up to 300 patients treated annually and an additional one per 300 patients treated annually
Social worker	As needed to provide service
Physiotherapist	As needed to provide service
Dietician	As needed to provide service
Maintenance engineer or electronics technician	One per one megavoltage unit and a simulator if equipment serviced ‘in-house’

ANNEX II: QUALITY CONTROL TESTS FOR EXTERNAL BEAM TREATMENT UNITS

Quality Control of Orthovoltage Units

FREQUENCY	PROCEDURE	TOLERANCE
Daily	Output constancy	±5%
	Interlocks and warnings	Functional
	Mechanical fixtures	Functional
	Filter interlock	Functional
Monthly	Output measurement	±3%
	Timer end error	±0.01 min
	Timer accuracy	±2% or ±0.02
	Backup timer	Functional
	Timer response to power failure	Functional
	Filter interlocks	Functional
	Mechanical fixtures	Functional
	Monitor chamber linearity	±2%
	Coincidence of light beam and X ray beam	±5 mm
	HVL constancy	±5%
Annually	Field uniformity	±5%
	Half-value layer	±10%
	Applicator factors	±3%

Quality Control of ^{60}Co Units

FREQUENCY	PROCEDURE	TOLERANCE
Daily	***Safety***	
	Door interlock	Functional
	Radiation room monitor	Functional
	Audio Visual	Functional
	Mechanical	
	Localizing laser	2 mm
	Optical distance indicator (ODI)	2 mm
Weekly	Check of source positioning	3 mm
Monthly	***Dosimetry***	
	Output constancy	2%
	Mechanical checks	
	Coincidence of light and radiation fields size indicator (collimator setting)	3 mm
	Gantry and collimator angle indicator Cross-hair centering	2 mm/1^0 2 mm
	Latching of wedges and trays	Functional
	Safety interlocks	
	Emergency off witches	Functional
	Wedge interlocks	Functional

Annually	***Dosimetry***	
	Output constancy traceable to SSDL	2%
	Field size dependence of output constancy	2%
	Central axis dosimetry parameter constancy (PDD/TAR)	2%
	Transmission factor constancy for all standard accessories	2%
	Wedge transmission factor constancy	2%
	Time linearity and error	1%
	Output constancy versus gantry angle	2%
	Beam uniformity versus gantry angle	3%
	Off-axis point measurements with and without wedges	3%
	Safety interlocks	
	Follow test procedures of manufacture	Functional
	Mechanical checks	
	Collimator rotation isocenter	2 mm diameter
	Gantry rotation isocenter	3 mm diameter
	Couch rotation isocenter	2 mm diameter
	Coincidence of collimator, gantry and couch axes with isocenter	2 mm diameter
	Coincidence of radiation and mechanical isocenter	2 mm diameter
	Table top sag with 80 kg mass evenly distributed	5 mm
	Vertical travel of table	2 mm
	Field intensity of light	Functional

The tolerances listed should be interpreted to mean that if a parameter either exceeds the tabulated value (e.g., the measured isocentre under gantry rotation exceeds 2 mm diameter) or the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term ‘constancy’ for the latter case. Moreover, for constancy, per cent values are plus/minus the deviation of the parameter with respect to its nominal value; distances are referenced to the isocentre or nominal SSD.

Quality Control of Linear Accelerators without Electron Beams

FREQUENCY	PROCEDURE	TOLERANCE
Daily	***DOSIMETRY***	
	Output constancy	3%
	Safety	
	Door interlock	Functional
	Audiovisual monitor	Functional
	MECHANICAL	
	Localizing lasers	2 mm
	Distance Indicator (ODI)	2 mm
Monthly	***DOSIMETRY***	
	Output constancy with field instrument, with appropriate corrections	2%
	Backup monitor constancy	2%
	Central axis dosimetry parameter constancy (e.g. PDD and TAR)	2%
	Beam flatness constancy	3%
	Beam symmetry	3%
	MECHANICAL CHECKS	
	Coincidence of light and radiation fields	2 mm or 1% on a side
	Field size indicator (collimator setting)	2 mm
	Field light intensity	Functional
	Jaw symmetry	2 mm
	Gantry and collimator angle indicator	1^{o}
	Cross-hair centering	2 mm diameter
	Wedge position	2 mm or 2% change in transmission factor
	Tray position	2 mm
	Treatment couch position indicators	2 mm/1^{0}
	Latching of wedges and blocking tray	Functional
	SAFETY INTERLOCKS	
	Emergency off switches	Functional
	Wedge interlocks	Functional

Annually	***DOSIMETRY***	
	Output calibration traceable to SSDL	2%
	Field size dependence of output constancy	2%
	Transmission factor constancy for all standard accessories	2%
	Off-axis factor constancy	2%
	Wedge transmission factor constancy (including depth and field size dependence)	2%
	Monitor chamber linearity	1%
	Output constancy versus gantry angle	2%
	Beam uniformity constancy versus gantry angle	2%
	Arc mode	As specified by the manufacturer
	Off-axis point measurements with and without wedges	3%
	SAFETY INTERLOCKS	
	Follow test procedures of manufacturer	Functional
	MECHANICAL CHECKS	
	Collimator rotation isocentre	2 mm diameter
	Gantry rotation isocentre	2 mm diameter
	Couch rotation isocentre	2 mm diameter
	Coincidence of collimator, gantry and couch axes with isocentre	2 mm diameter
	Coincidence of radiation and mechanical isocentres	2 mm diameter
	Table top sag with 80 kg mass evenly distributed	2 mm
	Vertical travel of table	2 mm

The tolerances listed should be interpreted to mean that if a parameter either exceeds the tabulated value (e.g., the measured isocentre under gantry rotation exceeds 2 mm diameter) or the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term ‘constancy’ for the latter case. Moreover, for constancy, per cent values are plus/minus the deviation of the parameter with respect to its nominal value; distances are referenced to the isocentre or nominal SSD.

Quality Control of Linear Accelerator Electron Beams

FREQUENCY	*PROCEDURE*	*TOLERANCE*
Daily	***DOSIMETRY***	
	Output constancy with constancy meter	±3%
Monthly	***DOSIMETRY***	
	Output constancy with field instrument, with appropriate corrections	2%
	Central axis dosimetry parameter constancy (PDD)	2 mm at therapeutic depth
	Beam flatness constancy	3%
	Beam symmetry	3%
	MECHANICAL CHECKS	
	Applicator position	2 mm
	SAFETY INTERLOCKS	
	Electron cone interlocks	Functional
Annually	Field uniformity	±5%
	Half-value layer	±10%
	Applicator factors	±3%

1. These tests are those that are additional to those given in the previous table, for accelerators equipped with an electron beam.

2. All these procedures should be carried out during commissioning.

3. Appropriate tests should be performed following any repair of the teletherapy unit.

4. The tolerances listed should be interpreted to mean that if a parameter either exceeds the tabulated value (e.g., the measured isocentre under gantry rotation exceeds 2 mm diameter) or the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term ‘constancy’ for the latter case. Moreover, for constancy, per cent values are plus/minus the deviation of the parameter with respect to its nominal value; distances are referenced to the isocentre or nominal SSD.

Quality Control of Simulators

FREQUENCY	*PROCEDURE*	*TOLERANCE*
Daily	Localizing lasers	2 mm
	Distance Indicator (ODI)	2 mm
Monthly	Field size indicator	2 mm
	Gantry/collimator angle indicators	1º
	Cross-hair centering	2 mm
	Focal spot-axis indicator	2 mm
	Fluoroscopic image quality	Baseline
	Emergency/collision avoidance	Functional
	Coincidence of light and radiation fields	2 mm or 1%
	Film processor sensitometry	Baseline
Annually	**MECHANICAL CHECKS**	
	Collimator rotation isocentre	2 mm diameter
	Gantry rotation isocentre	3 mm diameter
	Couch rotation isocentre	2 mm diameter
	Coincidence of collimator, gantry, couch axes and isocentre	2 mm diameter
	Table top sag with 80 kg mass evenly distributed	5 mm
	Vertical travel of couch	2 mm
	RADIOGRAPHIC CHECKS	
	Exposure rate	Baseline
	Table top exposure with fluoroscopy	Baseline
	kVp and mAs calibration	Baseline
	High and low contrast resolutions	Baseline

The tolerances mean that the parameter exceeds the tabulated value (e.g., the measured isocentre under gantry rotation exceeds 2 mm diameter).

Quality Control for Treatment Planning Systems and Treatment Time Calculations

FREQUENCY	***PROCEDURE***	***TOLERANCE***
Commissioning and following software updates	Understand algorithm Single field or source isodose distributions Treatment time calculations including inhomogeneity corrections where appropriate Test cases I/O system	Functional 2%[a] or 2 mm[b] 2% or 5% if including inhomogeneities 2% or 2 mm 1 mm
Daily	I/O devices	1 mm
Monthly	Check sum Subset of reference quality assurance test set (when check sums not available) I/O system	No change 2% or 2 mm[c] 1 mm
Annually	Treatment time calculations Reference quality assurance test set I/O system	2% 2% or 2 mm[d] 1 mm

1. ***Per cent differences between calculations of the computer TPS and measurements (or independent calculations).***
2. ***In the region of high dose gradients, the distance between isodose lines is more appropriate than the percentage difference. In addition, less accuracy may be obtained near the end of single sources.***
3. ***These limits refer to a comparison of dose calculations at commissioning with the same calculations subsequently.***
4. ***These limits refer to a comparison of calculations with measurements in a water tan***

ANNEX III: BRACHYTHERAPY

Quality Control of Remote after Loading Brachytherapy Units

FREQUENCY	***TEST***	***TOLERANCE***
Each treatment day	Room safety door interlocks, lights and alarms	Functional
	Console functions, switches, batteries and printer	Functional
	Visual inspection of source guides	Free of kinks and firmly attached
	Verify accuracy of ribbon preparation	Autoradiograph
Weekly	Accuracy of source and dummy loading (dummies used for spacing and/or simulation/verification)	1 mm
	Source positioning	1 mm
At each source change or quarterly	Calibration[a]	3%
	Timer function	1%
	Check accuracy of source guides and connectors	1 mm
	Mechanical integrity of applicators (by X ray if appropriate)	Functional
Annually	Dose calculation algorithm (at least one standard source configuration for each isotope)	3%, 1 mm
	Simulate emergency conditions	
	Verify source inventory	

NB: When changing a source, calibrate both the new and the old sources to establish and document the reproducibility of the calibration method.

Quality Control Tests for Brachytherapy Sources

TYPE OF SOURCE	*TEST*	*FREQUENCY*	*TOLERANCE*
Long half-life: description	Physical/chemical form Source encapsulation Radionuclide distribution and source uniformity Location of radionuclide in encapsulation	I I I I	D D D D
Long half-life: calibration	Mean of batch Deviation from mean Verification of calibration	I I E	3% 5%, D [a]
Short half-life: description	Physical/chemical form Source encapsulation	I I	D D
Short half-life: calibration	Mean of batch Deviation from mean[b] Radionuclide distribution and source uniformity	E E E	3% 5% V[c]

Key:

I*: initial purchase;*

D*: documented;*

E*: at every use.*

[a]*: Visual check of source colour code or measurement in a calibrator.*

[b]*: For short half-life sources, this may not always be practical.*

V[c]*: visual check, autoradiograph or ionometric check.*

Quality Control Tests for Brachytherapy Applicators

TYPE OF APPLICATOR	***TEST***	***FREQUENCY***	***TOLERANCE***
Intracavitary	Source location Coincidence of dummy and active sources Location of shields	I, yearly I[a] I[b]	D 1mm D
Interstitial	Coincidence of dummy and active sources	I,E	1mm

Key:

I*: initial use or following malfunction and repairs;*

D*: documented and correction applied or noted in report of measurement, when appropriate;*

E*: as a minimum, a visual inspection to verify that the dummy sources fairly represent the active source distribution*

[a]*: To reduce exposure of personnel, the dummy source location may be checked instead of the active source if it is established that the dummy and active source locations are coincident*

[b]*: The location of shields should be verified by radiograph before first use. Before every use, the applicator may be shaken to listen for loose parts.*

Quality Control Tests for Brachytherapy Source Calibrators

INSTRUMENT TYPE	*TEST*	*FREQUENCY*	*TOLERANCE*
Well type ionization chamber	Standards laboratory calibration	I, S[a]	D
	Precision	I,	2%
	Linearity	Every two years	1%
	Collection efficiency	I	1%
	Geometrical/length dependence	I	D
	Energy dependence	I	D
	Source wall dependence	I	D
	Venting	I	D
	Redundancy check	E	2%
	Leakage	E	D
In-air calibration chamber and external source holder	SSDL calibration	I, S[a]	D
	Accuracy of source chamber distance	Annually, S	1%, D
	Redundancy	E	D

***Key**:*

***I**: initial use or following malfunction and repairs*

[a]: instrument or sources have a calibration traceable

***S**: isotope/source specification;*

***D**: documented and correction applied or noted in report of measurement, when appropriate;*

E: at each use (measurement sequence) or ongoing evaluation.

ANNEXE IV: MEASUREMENT EQUIPMENT

Basic Equipment recommended for Dosimetry in External Radiation Therapy

BASIC EQUIPMENT	**^{60}CO**	**LINAC, PHOTONS ONLY**	**LINAC WITH ELECTRONS**
An ionization chamber of farmer type, of 0.6 cm^3 volume approximately, with plastic walls (robust), a Co-60 buildup cap, a 10 m long cable and a 10 m long extension cable with connectors calibrated at a standards laboratory.	×	×	×
An ionization chamber of farmer type, of 0.6cm^3 volume approximately, with graphite walls, a Co-60 buildup cap and a 10 m long cable, calibrated at a standards laboratory in terms of absorbed dose to water.	×	×	×
A cylindrical ionization chamber, of 0.1–0.3 cm^3volume approximately, with a 10 m long cable (maximum electrode diameter: 1 mm)	×	×	×
A radioactive source for checking the stability of the cylindrical ionization chamber	×	×	×
A plane-parallel ionization chamber for electrons (minimum width of guard ring: 4mm).			×
An electrometer compatible with the chambers above and calibrated or compared at a standards laboratory	×	×	×
An additional electrometer with varying voltage bias (V1/V2 ratio equal to or greater than 3), and the possibility to reverse the polarity		×	×
A water phantom for calibration and checks, of volume 20 ×20 × 10 cm^3 approximately, with PMMA walls, including a holder for ionization chambers	×	×	

A water phantom for calibration, of 30 × 40 × 40 cm^3 volume approximately, with PMMA walls, including a holder for ion chambers with manual steps or an automatic system to vary the position of the chamber	×	×	
A plastic slab phantom for verification of field size and coincidence of radiation and light field. Used also for output verification, with holes for the chambers, and preferably TLD	×	×	×
A barometer (minimum scale 1 mbar or hPa, or 0.5 mmHg),preferably of aneroid type or digital, calibrated or compared at a standards laboratory	×	×	×
A thermometer (minimum scale: 0.25°C), calibrated or compared at a standards laboratory	×	×	×
A densitometer to measure the optical density (OD) of X ray films, with an automatic reader and coordinate system. An OD calibration film strip for checking of the instrument OD scale. Requires having access to film development	×	×	×
A radiation field analyser to measure isodose distributions, of 50 × 50 × 40 cm^3 volume approximately, with a water tank, a phantom trolley with vertical movement and a water pump		×	×

Additional equipment may include:

1. A TLD system (both relative dosimetry and in vivo)
2. An array of diodes or ion chambers for daily quality assurance checks
3. A precision water level
4. Calipers and a metal ruler
5. A multimeter (volt, ohm)

Additional Equipment for Low Energy X Ray Dosimetry

EQUIPMENT	**50 KV or LESS**	**50-100KV**
Grenz ray chamber	×	
Ionization chamber		×
Plastic phantom		×

ANNEX V: DOCUMENTS TO BE ENCLOSED WITH THE APPLICATION FORM

	Documents to be enclosed with the application form
Site Assessment	1. Application letter addressed to the Director General 2. Company domestic registration certificate 3. Lay out of the facility 4. Professional registration(s) and license(s) of workers 5. land title certificate
Design and Construction	1. Application letter addressed to the Director General 2. Company domestic registration certificate 3. Lay out of the facility 4. Professional registration(s) and license(s) of workers 5. land title certificate 6. construction permit 7. site assessment report
import radiotherapy equipment	1. Application letter addressed to the Director General 2. Company domestic registration certificate 3. Emergency preparedness and response plan 4. Lay out of the facility 5. Professional registration(s) and license(s) of workers 6. Radiation protection programme 7. License to transport nuclear/radiation sources 8. Copy of machine specifications and manual 9. Copy of contract with the manufacturer to return the source after use
Operation	1. Application letter addressed to the Director General

	2. Company domestic registration certificate 3. Emergency preparedness and response plan 4. Lay out of the facility 5. Occupational dose monitoring 6. Professional registration(s) and license(s) of workers 7. Radiation protection programme 8. Copy of machine specifications and manual
modification and/or Decommissioning	1. Application letter addressed to the Director General 2. Company domestic registration certificate 3. Emergency preparedness and response plan 4. Lay out of the facility 5. Occupational dose monitoring 6. Radiation protection programme 7. Copy of contract with the manufacturer to return the source after use (for decommissioning)

ANNEX VI: CATEGORIES OF PERMISSIONS ISSUED IN RADIOTHERAPY FIELD AND RELATED FEES

TYPE OF PERMISSION	APPLICATION FEES/FRW	LICENSE/AUTHORIZATION FEES/FRW
Authorization for site evaluation	200,000	500,000
Authorization for Design and construction	200,000	1000,000
Authorization for import of radiotherapy equipment	100,000	500,000
License for Operation	500,000	15,000,000
Authorization for modification and Decommissioning	200,000	500,000

Seen to be attached to the **Regulation N° 003/R/RS-NRP/RURA/2021 of 25/02/2021 governing radiation protection in radiotherapy in Rwanda.**

Done at Kigali on 25/02 /2021

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Dr Ignace GATARE

Chairperson of the Regulatory Board