RWANDA UTILITIES REGULATORY AUTHORITY
P.O BOX 7289 KIGALI, Tel: +250 252584562, Fax: +250 252584563
Email: info@rura.rw
Web-site: www.rura.rw

REGULATION/R/NS-NRP/RURA/2023 OF…. /2023 ON RADIATION PROTECTION AND SAFETY OF X-RAY GENERATORS AND OTHER RADIATION SOURCES USED FOR INSPECTION PURPOSES

February 2023

PREAMBLE

The Regulatory Board;

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

Pursuant to Law n°59/2017 of 24/1/2018 governing radiation protection;

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

Hereby issues the following:

REGULATION ON RADIATION PROTECTION AND SAFETY OF X-RAY GENERATORS AND OTHER RADIATION SOURCES USED FOR INSPECTION PURPOSES

TABLE OF CONTENTS

PREAMBLE 2

CHAPTER I. GENERAL PROVISION **6**

Article 1: Purpose 6

Article 2: Scope 6

Article 3: Exclusion from the scope 6

Article 4: Definition of terms 6

CHAPTER II. LICENSING REGIME **7**

Article 5: Authorisation of using inspection devices 7

Article 6: License application 7

Article 7: License criteria 7

Article 8: Form, content and validity of authorizations 8

Article 9: Authorisation fees 8

Article 10: Suspension, modification, renewal, revocation and relinquishment of authorizations/license 8

Article 11: Authorization for installation, maintenance and servicing of inspection devices 8

Article 12: Authorisation of imports 9

Article 14: Enforcement 9

CHAPTER III. RESPONSIBILITIES **9**

Article 15: Prime responsibility for safety 9

Article 16: Specific responsibilities for radiation protection and safety 9

Article 17: Management system 10

Article 18: Radiation Protection and Safety Programme 10

Article 19: Records 11

Article 20: Responsibilities of suppliers 11

Article 21: Control of radioactive sources 12

Article22: Management of disused radioactive sources 12

Article 23: Transport of inspection devices containing radioactive sources 12

Article 24: Security measures 13

Article 25: Investigation of events 13

CHAPTER IV. APPLICATION OF RADIATION PROTECTION PRINCIPLES **13**

Article 26: Justification of practices involving the use of inspection devices 13

Article 27: Optimisation of protection and safety 14

CHAPTER V. CONTROL OF OCCUPATIONAL EXPOSURE AND OF PUBLIC EXPOSURE **14**

Article 28: Management structure and policies 14
Article 29: Control of access to and operation of inspection devices 14
Article 30: Training 15
Article 31: Classification of areas 15
Article 33: Protection of drivers for vehicles undergoing inspection 16
Article 34: Control of external exposure of members of the public 16
Article 35: Control of public access 16
Article 36: Protection of members of the public inadvertently exposed during inspection 17
CHAPTER VI. SAFETY OF INSPECTION DEVICES AND LOCATION 17
Article 37: Safety Assessment 17
Article 38: Prevention of accidents 17
Article 39: Emergency preparedness and response 18
Article 40: Design of inspection facilities 18
Article 41: Installation of inspection devices 19
Article 42: Acceptance testing of inspection devices 19
Article 43: Commissioning of inspection devices 19
Article 44: Post-installation testing of inspection devices 20
Article 45: Operation of inspection devices 20
Article 46: Maintenance of inspection devices 20
Article 47: Quality Assurance Programme 21
CHAPTER XI: FAULTS AND ADMINISTRATIVE SANCTIONS 21
Article 48: Operating without a license 21
Article 49: Importation or operate x- ray generators used for inspection purposes without 21
a license 21
Article 50: Assembling or changing vehicle or baggage scanner facility without approval 22
Article 51: Absence of warning signs at any general access point to a vehicle or baggage scanner facility 22
Article 52: Lack of mandatory safety devices 22
Article 53: Failure to keep records of monitoring and verification of compliance 22
Article 54: Not reporting incident occurred to the Regulatory Authority 22
CHAPTER VII: TRANSITIONAL AND FINAL PROVISIONS 22
Article 55: Transitional period for existing operators 22
Article 56: Repealing provision 22
Article 57: Commencement 22
ANNEX I: CONTENT OF AUTHORISATION APPLICATION 23

ANNEX II: AUTHORISATIONS' VALIDITIES AND RELATED FEES 25

CHAPTER I. GENERAL PROVISION

Article 1: Purpose

This regulation establishes the specific radiation protection and safety measures on the use of X-ray generators and other types of radiation sources for inspection purposes.

Article 2: Scope

This Regulation shall be applied to the use of X-ray generators and other radiation sources for the purpose of inspecting objects

Article 3: Exclusion from the scope

This Regulation shall not apply to X-ray generators and other types of radiation sources that are used exclusively for forensic examinations, or for non-medical human imaging.

Article 4: Definition of terms

1) The technical terms used in these Regulations shall have the following meaning:
    a) **Acceptance testing:** the initial inspection performed on a piece of medical equipment prior to it being put in place when the device first arrives in the healthcare facility, to ensure it that matches the purchase order, it is functioning as specified, the training for users has been arranged and it is installed correctly;
    b) **Commissioning:** the process by means of which systems and components of facilities, having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria;
    c) **Inspection devices:** all devices that are used for inspection purposes, including imaging devices specifically designed for imaging cargo conveyances for the purpose of detecting concealed objects within cargo or a vehicle, as well as devices using radiation sources as part of a process to identify or detect material or residues on or within objects such as bottles, baggage, cargo and vehicles;
    d) **Investigation level:** the value of the effective dose, committed dose or contamination per unit area or volume at or above which an investigation has to be conducted;
    e) **Maintenance:** the organized activity, both administrative and technical, of keeping structures, systems and components in good operating condition, including both preventive and corrective (or repair) aspects;
    f) **Potential exposure**: a prospectively considered exposure that is not expected to be delivered with certainty but that may result from an anticipated operational occurrence or accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors;
    g) **Quality assurance:** the function of a management system that provides confidence that specified requirements will be fulfilled;
    h) **Qualified Expert:** an individual who, by virtue of certification by appropriate boards or societies, professional licence or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, e.g. radiation protection;
    i) **Radiation Protection Officer:** a person technically competent in radiation protection matters relevant for a given type of practice who is designated by the authorisation holder to oversee the application of regulatory requirements;
    j) **Radioactive source:** a source containing radioactive material that is used as a source of radiation.
    k) **Safety assessment:** assessment of all aspects of a practice that are relevant to protection and safety; for an authorized facility, this includes siting, design and operation of the facility.

2) All other technical terms shall have the same meaning as defined in the General Regulation Governing Radiation Safety.

CHAPTER II. LICENSING REGIME

Article 5: Authorisation of using inspection devices

1) Any person having the intention to use or operate an inspection device shall apply to the Regulatory Authority for authorisation the following activities shall be subject to licensing:
   a) the use of inspection devices for cargo screening and vehicle screening that have a potential for inadvertent exposure of the drivers;
   b) the use of inspection devices consisting in linear accelerators or incorporating neutron sources and gamma sources of category 1, 2 or 3, as defined in art. 45 of the General Regulation Governing Radiation Safety;
   c) the use of hand‑held and portable inspection devices.
2) The use of other inspection devices than the ones listed in paragraph 2) shall be subject to authorisation, unless otherwise decided by the Regulatory Authority following the review of the authorisation application and the onsite verification.
3) Only practices that are justified in accordance with article 28 shall be authorised.

Article 6: License application

1) Any person applying for license shall:
   a) submit to the Regulatory Authority the relevant information necessary to support the application;
   b) assess the nature, likelihood and magnitude of the expected exposures due to the use of the inspection device;
   c) take all necessary measures for radiation protection and safety and document those into a radiation protection programme;
   d) for activities subject to licensing, conduct a safety assessment;
   e) designate the key personnel with responsibilities for radiation protection and safety, as prescribed and ensure they have the necessary competence to fulfil their roles.
2) The content of the authorisation application shall be as prescribed in Annex 1 to this Regulation.
3) The authorisation application shall be submitted either online, on the Regulatory Authority website, or any other means communicated by the Regulatory Authority.

Article 7: License criteria

1) In order to obtain the license, the applicant shall demonstrate to the Regulatory Authority that it has the organizational capability, the organizational structure, adequate resources, adequate competence of managers and staff, and appropriate management arrangements to comply with all the requirements of this Regulation and all other applicable regulations related to this Regulation.
2) In order to issue licensee, the Regulatory Authority shall review and assess the authorisation application and shall verify on site that all operational aspects of radiation protection, as described in the application for authorisation, can be achieved.

3) The intended use of an inspection device shall be authorized only when the Regulatory Authority has confirmed, by review and assessment of the submitted documentation and by verification on site, that the inspection device is going to be used and the inspection activity is going to be conducted in a manner that does not pose an unacceptable radiation risk to people or the environment.

Article 8: Form, content and validity of authorizations

1) licensee shall be granted or denied by means of a decision of the Regulatory Authority, against which an appeal may be filed by the applicant. A license may include, as appropriate, specific conditions and references to specific requirements in the Law and other applicable regulations, as well as impose appropriate restrictions in terms of operational limits and conditions.
2) The authorisations for using inspection devices shall be limited in time.
3) The validity period of the authorisation/license is provided in the annexe of this regulation an authorization shall cease to be valid when any time limit established by the Regulatory Authority or condition of the authorization has expired.

Article 9: Authorisation fees

1) The authorisation fees for using inspection devices are provided in Annex II of this Regulation.
2) The authorisation fees shall only be paid upon notification from the Regulatory Authority.

Article 10: Suspension, modification, renewal, and revocation of authorizations/license

1) Any authorization/license issued pursuant to this Regulation may be suspended, modified or revoked by the Regulatory Authority:
   a) in the event of a violation of the Law Governing Radiation Protection, this Regulation, other applicable regulations or its terms and conditions;
   b) when the conditions under which it was issued are no longer met; or
   c) in any circumstance where the Regulatory Authority determines that continued activity under the authorization/license would pose an unacceptable risk to people or the environment.
2) An authorization/license may be modified on the request of the authorisation holder.
3) An authorization shall not be transferred unless approved by the Regulatory authority.
4) An authorization/licensee may be relinquished by the authorisation holder upon notice to the Regulatory Authority and upon a determination by the Regulatory Authority that relinquishment will not jeopardize the protection of people or the environment.

Article 11: Authorization for installation, maintenance and servicing of inspection devices

1) Any applicant who install, maintain or service inspection devices shall apply for authorisation to the Regulatory Authority to provide such services, the personnel who install, maintain or service inspection devices shall be appropriately trained in radiation protection and safety.

Article 12: Authorisation of imports

Any person intending to import an inspection device shall apply for an authorization to the Regulatory Authority in accordance with the relevant provisions of relevant laws and regulations

Article 14: Enforcement

1) When an authorisation holder/licensee is found to be in non-compliance with this Regulation or the terms and conditions of the authorization/license the Regulatory Authority shall take the necessary enforcement actions commensurate with the safety significance of the non-compliance.
2) In any of such cases as specified in paragraph 1), the Regulatory Authority will issue a warning in writing to the authorisation holder/licensee determining the period of time during which remedial action(s) must be taken.
3) The authorisation holder/licensee shall take the necessary measures to remedy the non-compliance as soon as possible, as required by the Regulatory Authority, and take the necessary measures to prevent a recurrence.
4) In case following the receipt of the warning from the Regulatory Authority, the authorisation holder /licensee does not correct the non-compliance and/or does not sufficiently justify its reasons, the Regulatory Authority may proceed for further penalties that may consist of administrative penalties, including suspension, modification or revocation of the authorization, or monetary penalties (civil fines).

CHAPTER III. RESPONSIBILITIES

Article 15: Prime responsibility for safety

The prime responsibility for safety shall rest with the authorisation holders/licensees using inspection devices, as prescribed in article 16 of the General Regulation Governing Radiation Safety in Rwanda.

Article 16: Specific responsibilities for radiation protection and safety

1) The authorisation holders/licensees shall assign specific responsibilities for radiation protection and safety to:
    a) A senior manager, for overseeing radiation protection and safety and for verifying that the practice is carried out in accordance with all regulatory requirements and the authorisation conditions;
    b) A Radiation Protection Officer, for overseeing the day to day application of the radiation protection arrangements and safety measures and provision of general radiation protection advice;
    c) A Qualified Expert in Radiation Protection, for provision of expert advice on particular aspects of radiation protection and safety and performing various radiation protection measurements;
    d) The workers operating inspection devices, for applying the radiation protection measures and observing the safety measures.
2) The specific responsibilities for radiation protection and safety referred to in paragraph 1) shall be assigned to cover the entire lifetime of the inspection devices at the facility, from ordering and receipt, use and storage, to their end‑of‑life.

3) All the specific responsibilities for radiation protection and safety shall be documented.
4) The managers in charge with radiation protection and safety shall ensure that procedures are in place for the protection of workers and the public, and for ensuring that radiation protection and safety are optimized.
5) All policies and procedures shall be documented and made available to the staff and to the Regulatory Authority, as appropriate.
6) In case the authorisation holder/licensee has more than one location of operations, he/she shall appoint one Radiation Protection Officer for each location.

Article 17 : Management system

1) The authorisation holders/licensee shall develop, apply and continuously improve a management system that integrates its elements, including safety, health, environmental, security, quality, human and organizational factors, societal and economic elements, so that safety is not compromised, in accordance with article 28 of the General Regulation Governing Radiation Safety.
2) The management system referred to in paragraph 1) shall be applied to achieve goals safely, to enhance safety and to foster a strong safety culture, as prescribed in article 29 of the General Regulation Governing Radiation Safety.

Article 18: Radiation Protection and Safety Programme

1) The authorization holders/licensees shall develop, implement and maintain a Radiation Protection and Safety Programme, documenting the radiation protection arrangements, the safety measures, and the mechanism for the review and updating these, as prescribed in article 6 of the General Regulation Governing Radiation Safety.
2) The Radiation Protection and Safety Programme referred to in paragraph 1) shall include the following:
   a) management structure, commitment and policies;
   b) assignment of specific responsibilities for radiation protection and safety;
   c) education and training in radiation protection;
   d) designation of controlled areas and supervised areas;
   e) arrangements for protection of occupationally exposed workers, including local rules and procedures, monitoring of the workplace, assessment of occupational exposure, and workers' health surveillance;
   f) arrangements for protection of workers driving vehicles undergoing inspection;
   g) arrangements for protection of the public, including members of the public who are inadvertently exposed;
   h) safety of facilities and inspection devices, including safety assessments, accident prevention, design considerations, commissioning and maintenance, and quality assurance programmes;
   i) periodic reviews and audits of the performance of the radiation protection and safety programme;
   j) a system for document control and records.
3) The Radiation Protection and Safety Programme and its implementation shall be reviewed on a regular basis, as an integral part of the authorisation holder management system.
4) The periodic review of the Radiation Protection and Safety Programme shall have as objectives:
   a) verifying that the management system is fit for purpose;
   b) identifying any problems that need to be addressed and any modifications that could improve the effectiveness of the Radiation Protection and Safety Programme;

c) assess the effectiveness of corrective actions taken.

5) The periodic review of the Radiation Protection and Safety Programme shall consist in a routine series of audits conducted by independent staff, who has not been involved in the development of the program.

Article 19: Records

1) In order to demonstrate compliance with the requirements of this Regulation, the authorisation holders/licensees shall keep records of:
   a) upgrades, modifications, maintenance and repair of each inspection device;
   b) all aspects of the Quality Assurance Programme, including acceptance tests, quality control tests and preventive maintenance programme;
   c) all training provided to the staff, including the date of training, an outline of the training and the names of the trainees;
   d) individual monitoring and workplace monitoring, and reports of any investigations and public dose assessment;
   e) of any near misses or events, including the corrective actions taken.
2) The records referring to inspection devices, as specified in points a) and b) of paragraph 1), shall be maintained for the entire period of using the respective inspection devices.
3) The training records and occupational dose records, as specified in points c) and d) of paragraph 1), shall be maintained as prescribed in article 62 of the General Regulation Governing Radiation Safety.
4) The public dose records and the investigations reports, as specified in points d) and e) of paragraph 1), shall be maintained for the entire period of validity of the authorisation/license to use an inspection device.

Article 20: Responsibilities of suppliers

1) The suppliers of inspection devices shall ensure that the persons to whom they are supplying such devices hold the necessary authorization/licensee for the use of the devices.
2) Both manufacturers and suppliers of inspection devices, whether the devices are manufactured in, or imported into Rwanda, shall ensure that the inspection devices:
   a) conform to any applicable standards of the International Electrotechnical Commission and the International Organization for Standardization approved by the Standards Board for use in Rwanda;
   b) conform with the general requirements prescribed in article 44 of the General Regulation No 001/RJRS-RP/RURA/2019 of 15th November, 2019 Governing Radiation Safety in Rwanda;
   c) have safety features that include:
      i. radiation beam collimation;
      ii. a visual indication, clearly visible from all possible positions of the operator, of when the radiation beam is on;
      iii. safety systems, as appropriate, to prevent inadvertent exposures;
      iv. shielding incorporated into the device to ensure that occupational exposure and public exposure requirements in areas immediately adjacent to the device are met;
      v. preset operating settings for each mode of operation;
      vi. a key operated and/or password protected control panel;
      vii. suitable warning labels or signs incorporating the basic ionizing radiation symbol recommended by the International Organization for Standardization;

viii. one or more emergency stop buttons, as applicable.

3) The suppliers of inspection devices shall provide training to relevant staff of the users on the operation and maintenance of the inspection device and the associated inspection system and software.

Article 21: Control of radioactive sources

1) The authorisation holders using inspection devices containing radioactive sources shall ensure that they obtain radioactive sources from authorized suppliers only and that disused sources are returned to the original supplier or transferred to another authorized person. The import and export of radioactive sources shall be consistent with the relevant laws and regulation.
2) The authorisation holders/licensee using inspection devices containing radioactive sources shall ensure that sources are kept under proper control from the time the sources are first acquired until they are finally returned to their original supplier or safely dealt with at the end of their lifetime. The authorisation holders/licensee shall keep an inventory of all inspection devices that they use and shall maintain this inventory updated in order to confirm that the devices are in their assigned locations.
3) Inspection devices containing radioactive sources shall be removed from a storage room or moved to another location only by authorized and trained workers. The name of the worker who removed the inspection device shall be recorded, together with the date and time, and the exact new location(s) to which the device is being moved.
4) The records referred to in paragraph 5) shall be audited by the Radiation Protection Officer at least annually.
5) Any suspected loss of control over a inspection devices containing radioactive sources shall be promptly investigated by the authorisation holders. in accordance w and shall be notified to the Regulatory Authority within 24 hours.

Article22: Management of disused radioactive sources

1) The authorisation holders/licensee using inspection devices containing radioactive sources shall review their inventory of radioactive sources at least annually, in order to identify any sources that are not in use anymore.
2) The authorisation holders/licensees using inspection devices containing radioactive sources shall seek an agreement with the supplier of the devices at the time of purchase that disused sources can be returned to the supplier. If such an agreement does not exist, the authorisation holders shall transfer the sources to a licensed operator of adequate facilities for the conditioning, storage and disposal of the disused radioactive sources as radioactive waste.
3) Until the transfer of disused sources as prescribed in paragraph 2), the authorisation holder/licensee shall ensure the continuity of control over the sources in the same manner as when the sources were in use, in accordance with article 21.
4) Licensee shall ensure that disused sealed radioactive sources is not removed from their original shielding containers, nor shall the container be physically modified. Peripheral components not directly associated with the source may be removed, monitored and disposed of appropriately.

Article 23: Transport of inspection devices containing radioactive sources

The authorisation holders using inspection devices containing radioactive sources shall ensure the transport of such devices outside their premises in accordance with the relevant laws and regulations.

Article 24: Security measures

1) The authorisation holders/licensees using inspection devices containing radioactive sources shall implement appropriate security measures to prevent the unauthorized access of individuals and the unauthorized removal of the radioactive sources, in accordance relevant laws and regulations
2) The level of security shall be commensurate with the level of radiological hazard associated with the radioactive sources, as prescribed in the regulations referred to in paragraph 1).
3) The authorisation holders/licensee shall assess and manage the interfaces between safety and security in such a manner so as to ensure that they do not adversely affect one another and that, to the extent possible, they are mutually supportive.

Article 25: Investigation of events

1) The licensee shall ensure that all workers operating inspection devices shall be adequately trained to be able to recognize when an inspection device may not be functioning correctly, either due to hardware or software problems.
2) The authorisation holder/licensee shall investigate whenever:
   a) an individual effective dose exceeds the established investigation level;
   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, which causes, or has the potential to cause, a dose in excess of annual dose limits;
   d) any other event or unusual circumstance that causes, or has the potential to cause a dose in excess of the annual dose limits or the operational restrictions imposed on the installation.
3) The authorisation holder/licensee shall initiate the investigation immediately after the discovery of the event and shall conduct the investigation in such a manner so as to:
   a) determine the root cause of the event;
   b) estimate the doses received by the exposed persons, either workers or members of the public, as the case may be;
   c) ensure that any exposed persons are informed about the accidental exposure;
   d) identify and implement any corrective actions necessary to prevent the recurrence of such an event.
4) The authorisation holder/licensee shall record the results of the investigation in a written report that shall be submitted to the Regulatory Authority and other concerned bodies as required in maximum 5 working days after the end of the investigation.

CHAPTER IV. APPLICATION OF RADIATION PROTECTION PRINCIPLES

Article 26: Justification of practices involving the use of inspection devices

1) any person having the intention to import or in any other way acquire an inspection device, the intended use of which is likely to be a new class or type of practice, shall submit to the Regulatory Authority an application containing the following information:
   a) the applicant's name and contact details;
   b) a description of the type of practice, with drawings and diagrams, as appropriate;

c) a complete description of the radiation sources that will be used and the measures that will be taken to ensure radiation protection and safety as required by this Regulation;
d) an appraisal of the benefits and detriments of the practice, including radiation detriments, as well as economic, social, health and safety, waste management, recycling, radiological environmental impact and decommissioning aspects;
e) an indication of the expected extent of use of the type of practice.

2) On the basis of an assessment of the justification application, the Regulatory Authority will decide whether the intended use of the inspection device(s) is justified if the use of inspection device(s) that is not justified shall be prohibited.

3) The use of inspection device(s) that is justified shall be subject to authorisation in accordance with article 5.

Article 27: Optimisation of protection and safety

1) The authorisation holders/licensee shall ensure that the likelihood and magnitude of exposures and the number of individuals exposed are as low as reasonably achievable, with economic, societal and environmental factors considered.

2) the authorization holders/licensees shall ensure that optimization of protection and safety is conducted within a set of boundary conditions, which shall include individual source related values of dose constraints for occupational exposure and for public exposure.

3) The authorisation holders/licensee shall ensure that Occupational dose constraint are established and , are well below the occupational dose limits.

CHAPTER V. CONTROL OF OCCUPATIONAL EXPOSURE AND OF PUBLIC EXPOSURE

Article 28: Management structure and policies

1) The Radiation Protection and Safety Programme referred to in article 20 shall include:
   a) the authorisation holder policy on radiation protection and safety, including a commitment by the management to keep the radiation doses as low as reasonably achievable and to promote a strong safety culture;
   b) a description of the management structure as it relates to radiation protection and safety.
2) The management structure referred to in point b) of paragraph 1) shall show:
   a) the names of the senior managers responsible for radiation protection and safety and the names of the Radiation Protection Officer(s);
   b) the line of reporting, from the workers operating inspection devices through to the senior manager responsible for radiation protection and safety.
3) In case the authorisation holder/Licensee has more than one location of operations, the management structure shall specify the responsible persons at each location.

Article 29: Control of access to and operation of inspection devices

1) The authorisation holder/licensee shall establish procedures to control the access to, and operation of, an inspection device.

2) The authorisation holder/licensee shall authorise appropriate personnel to operate an inspection device.

3) Control panel keys and/or user password protection shall be used to prevent unauthorized operation of inspection devices.

Article 30: Training

1) The authorisation holder/Licensee shall provide information and training in radiation protection to its staff, as prescribed in article 66 of the General Regulation Governing Radiation Safety.
2) The Radiation Protection and Safety Programme shall describe the training programme in radiation protection and safety for all staff involved in the management and operation of inspection devices.
3) The scope and extent of the training shall be commensurate with the role and responsibility of the individuals involved, as follows:
   a) Facility staff, including the workers who do not operate inspection devices, security guards and administrative staff, as well as the drivers of vehicles that frequently undergo inspection, shall be provided with a basic training in radiation protection;
   b) The workers operating inspection devices, the Radiation Protection Officers and the managers responsible for radiation protection and safety shall be provided with an initial training and refresher training that shall include at least the following:
      i. the type and properties of the radiation source and the radiation emitted;
      ii. the typical radiation exposures from the normal use of the inspection device and from incidents;
      iii. the radiation risk for workers and the public;
      iv. the use of design features, time, distance and shielding to reduce exposures;
      v. the lessons identified from operating experience and from incidents;
      vi. safe working procedures, including procedures for emergency preparedness and response;
      vii. security aspects of the use of radioactive sources, as appropriate.
   c) The workers operating inspections devices shall be provided in addition with specific training that shall include at least the following:
      i. instruction on pre‑operational checks and functional tests;
      ii. safety features;
      iii. operation of the system;
      iv. object positioning;
      v. interpretation of images;
      vi. procedures to be followed if the system is damaged or malfunctions;
      vii. practical operating experience.
4) The authorisation holder shall also provide specific instruction and training when new inspection devices and associated equipment and software are introduced.

Article 31: Classification of areas

1) The Radiation Protection and Safety Programme shall describe where and how controlled areas and supervised areas are to be designated for the use of inspection devices.,
2) In case the controlled area cannot be contained within the enclosure of the inspection device, the licensee shall ensure that delineation of the controlled area is achieved through the use of physical barriers, markings on the floor and walls, and suitable warning signs.

3) For large inspection devices, the delineation of controlled areas shall be incorporated into the building structure.

Article 33: Protection of drivers for vehicles undergoing inspection

1) The licensee shall ensure that drivers for vehicles undergoing inspection shall justified by competent authority.
2) The licensee shall ensure that in circumstances in which drivers for the vehicles are allowed to occupy vehicles during inspection, all possible measures are taken to eliminate or reduce the exposures through the use of interlocks and other safety systems to prevent exposure.
3) The licensee shall ensure that in order to justify the exposure of workers driving vehicles during the inspection, a dose assessment is performed, which shall consider the following:
   a) exposure from scattered radiation;
   b) the possibility of failure of the interlocks or other safety systems intended to prevent exposure;
   c) the possibility that workers driving vehicles may pass through inspection systems several times per day.
4) The licensee shall ensure that in case the exposure for drivers for vehicles undergoing inspection is specifically justified and is authorized to occur, such exposure is controlled as an occupational exposure, in accordance with all relevant provisions of the General Regulation Governing Radiation Safety.
5) The licensee shall ensure that for the optimisation of protection of the workers driving vehicles undergoing inspection, a dose constraint is set at a level such that the public dose limit is not expected to be exceeded.

Article 34: Control of external exposure of members of the public

The authorisation holders/licensee shall ensure that the shielding integral to the inspection devices, and any structural shielding of the premises housing the devices, as well as any other shielding used when the devices are operated, is sufficient to ensure that the exposure of members of the public, including the facility personnel for whom radiation sources are not directly related to their work, from being in any accessible adjacent area, including rooms above and below, is in compliance with the public dose limits established in section 2 of Annex I of the General Regulation Governing Radiation Safety and below any dose constraint that may have established by the Regulatory Authority during the authorisation process.

Article 35: Control of public access

1) The authorisation holders/licensee shall ensure that access by members of the public and by facility personnel for whom radiation sources are not directly related to their work to controlled areas and supervised areas is restricted.
2) The authorisation holders/licensee shall ensure that there are a limited number of ways to enter a controlled area, and that access is controlled either by engineered controls or by facility personnel.
3) The licensee shall ensure that suitable warning signs are placed at the entry points clearly stating who is permitted to enter that area.
4) The licensee shall ensure that the access of visitors in security facilities during the operation of inspection devices is forbidden.

Article 36: Protection of members of the public inadvertently exposed during inspection

1) The licensee shall ensure that in case the exposure of drivers and passengers of vehicles undergoing inspection is specifically justified and authorized to occur, such exposures are controlled as a public exposure, in accordance with all relevant provisions of the General Regulation Governing Radiation Safety, and in particular the observance of the public dose limits and public dose constraint.
2) The licensee shall ensure that the inspection system of cargo containers or vehicles is designed and operated so as to ensure that the likelihood of inadvertent exposure of concealed or hiding persons is as low as reasonably achievable and that, if such exposures were to occur, the individual dose to such persons would be unlikely to exceed the public dose limit.
3) The licensee shall ensure that the condition prescribed in paragraph 3) is demonstrated in the safety assessment submitted as part of the justification process and as part of an application for authorization.

CHAPTER VI. SAFETY OF INSPECTION DEVICES AND LOCATION

Article 37: Safety Assessment

1) Any applicant for a license to use an inspection device shall conduct a safety assessment, before starting to use the inspection device and submit it to the Regulatory Authority.
2) The licensee shall ensure that the safety assessment referred to in paragraph 1) is considered in addition to the occupational exposure and public exposure, the exposure of persons who may be inadvertently exposed during the inspection procedures, such as drivers, passengers and concealed individuals, and the possibility of accidental exposures, as appropriate.
3) The licensee shall ensure that the results of the safety assessment are used for establishing the following:
   a) The engineered control measures that are required for safety;
   b) The development of local rules and procedures to be followed by workers operating inspection devices;
   c) Requirements and procedures for designating controlled areas and supervised areas;
   d) Any requirements for protection of persons inside the cargo container or vehicles;
   e) Any requirements for protection of workers and the public;
   f) The measures required to minimize the likelihood of incidents occurring;
   g) Emergency plans, including the actions to be taken to restrict exposure of persons and for protection of the environment.
4) The safety assessment shall be documented into the Radiation Protection and Safety Programme that shall be approved, together with all its revisions, by the Regulatory Authority, during the authorisation process.
5) The safety assessment shall be either performed by a Qualified Expert, either reviewed and endorsed by a Qualified Expert, before being submitted to the Regulatory Authority.
6) The authorisation holders shall review the safety assessment before any major change in operation, as prescribed in article 35 of the General Regulation No. 001/RJRS-RP/RURA/2019 of 15th November, 2019 Governing Radiation Safety in Rwanda.

Article 38: Prevention of accidents

1) The authorisation holders/licensee shall apply good engineering practice and shall take all practicable measures to prevent accidents as prescribed in relevance laws and regulations.

2) The authorisation holders/licensee shall establish procedures for the workers to follow in the event of a malfunction of, or damage to, an inspection device, which shall also specify the actions or testing necessary before the inspection device is returned into use following repairs or adjustments.

3) The licensee shall ensure that damaged inspection devices, or devices not functioning properly, are removed from operational use until appropriate maintenance or service engineers have corrected the problem and, if necessary, a qualified expert has performed a radiation survey.

Article 39: Emergency preparedness and response

1) The authorisation holders shall put in place arrangements for emergency preparedness and response, including emergency response plans and procedures, as prescribed by relative laws and regulations

2) The licensee shall ensure that the arrangements for emergency preparedness and response are established, implemented and maintained on the basis of the hazards associated with the radiation source used in the inspection device.

3) The licensee shall ensure that the emergency response plans covers all reasonably foreseeable scenarios, including those of very low probability, as identified by the safety assessment.

4) The licensee shall ensure that the emergency response is detailed in emergency response procedures that shall be clear, concise, and unambiguous and are posted visibly in those places where their need is anticipated.

5) The licensee shall ensure that all workers operating inspection devices are aware of the indicators of a potential radiological emergency and be adequately trained to take appropriate actions, as established in the emergency response plan.

6) After the emergency situation has been brought under control and the necessary actions have been implemented, the authorisation holder/licensee shall investigate the circumstances under which the emergency occurred and analyse the emergency response.

7) The investigation referred to in paragraph 6) shall be used to:

   a) determine the root cause of the emergency;
   b) estimate the doses received by the exposed persons, either workers, emergency workers or members of the public, as applicable;
   c) identify and implement any corrective actions necessary to prevent the recurrence of such an emergency;
   d) assess the efficiency of the emergency response actions taken;
   e) identify necessary improvements to the emergency arrangements.

8) The authorisation holder/licensee shall record the results of the investigation in a written report that shall be submitted to the Regulatory Authority and other concerned bodies as required, in maximum 5 working days after the end of the investigation.

Article 40: Design of inspection facilities

1) When choosing a location and designing a facility for using inspection devices, The licensee shall ensure that the following factors are considered:

   a) the occupancy of adjacent areas;
   b) the dose rates and doses per scan;
   c) the workload;
   d) the system orientation (i.e. beam direction);
   e) the flow of people;

f) the flow of vehicles, if relevant.

2) Where practicable, the design of the inspection device the licensee shall ensure that it is incorporated all the necessary shielding to ensure that occupational exposure and public exposure arising from its use in normal operation are well below the relevant dose limits and meets the applicable dose constraints.

3) The licensee shall ensure that inspection devices that produce high dose rates, such as accelerators, high-energy X-ray generators, gamma sources of category 1, 2 or 3, and neutron generators are provided with additional structural shielding.

4) The licensee shall ensure that the design of the inspection device and/or facility are provided with a suitable means for exit, so that any person inadvertently remaining in a room or enclosure containing an X-ray generator, accelerator or radioactive source can make a prompt exit.

5) The licensee shall ensure that the basic ionizing symbol are positioned at entrance points and at appropriate locations within the controlled area, at the eye level. All signs shall be clear and easily understandable in all official languages.

6) The licensee shall ensure that warning signals, such as illuminated or flashing lights or signs, are be positioned at the entrances of controlled areas, at eye level, and shall be activated when radiation is being produced.

Article 41: Installation of inspection devices

1) The licensee shall ensure that inspection devices are installed in accordance with the manufacturer's instructions and in compliance with all relevant regulatory requirements and authorization conditions.

2) The licensee shall ensure that installation of inspection devices is conducted only by properly trained personnel of authorisation holders for provision of installation services.

3) The licensee shall ensure that during installation, the designation of any controlled and supervised areas is confirmed and documented.

Article 42: Acceptance testing of inspection devices

1) The licensee shall ensure that acceptance tests are performed for any new or modified or repaired inspection device, or after the installation of new software or the modification of existing software that could affect radiation protection and safety.

2) The licensee shall ensure that the acceptance tests are conducted by the manufacturer's representative in the presence of the Radiation Protection Officer or the Qualified Expert. The licensee shall ensure that acceptance testing involves the verification of all specifications and features of the inspection device that are relevant to radiation protection and safety.

3) The tests to be included in the acceptance protocol shall be specified in the purchasing contract, which shall also establish the responsibility of suppliers for resolving any non-conformity identified during the acceptance testing.

Article 43: Commissioning of inspection devices

1) The licensee shall ensure that after satisfactory completion of the acceptance tests and before the inspection device is put into use, commissioning tests are carried out by, or under the supervision of, the Radiation Protection Officer or the Qualified Expert.

2) The licensee shall ensure that commissioning of inspection devices a include measurements of all parameters and conditions of use that are expected in operation aiming to demonstrate that the performance of the inspection device meets regulatory requirements and any conditions of the authorization.
3) The licensee shall ensure that as part of the commissioning, the baseline for subsequent constancy tests of the inspection devices are established.
4) The licensee shall ensure that during the commissioning, the Qualified Expert performs a radiation survey of the inspection device and, if applicable, the inspection facility, in order to verify that the radiation protection and safety are optimized.

Article 44: Post-installation testing of inspection devices

1) The licensee shall ensure that after installation of inspection devices or software, the supplier conducts a formal handover, which shall include:
   a) testing to verify that the inspection device and software are performing to the required standards, and
   b) specific training in the use of the device and software for the workers involved in operating the device.
2) The licensee shall produce a written report detailing the post-installation performance results and shall provide this report to the authorisation holder before the device is put into use.

Article 45: Operation of inspection devices

1) The licensee shall ensure that inspection devices, including both hardware and software, are operated in a manner that ensures satisfactory performance at all times with respect to the purpose of the inspection and to radiation protection and safety, in accordance with the authorisation.
2) The licensee shall ensure that Pre-operational checks, functional tests and the operation of the inspection devices are described in operating procedures and performed as instructed by the manufacturer of the devices.
3) The authorisation holder/licensee shall establish which checks need to be performed, who will perform them and how the results are to be recorded and interpreted, in accordance with the manufacturer's recommendations.
4) The licensee shall ensure that the operating procedures consider the operating instructions provided by the manufacturer.
5) The operating procedures shall be approved by the authorisation holder/licensee and shall be documented and incorporated into its management system.

Article 46: Maintenance of inspection devices

1) The authorisation holder/licensee shall ensure that adequate maintenance, both preventive and corrective, is performed as necessary, to ensure that inspection devices retain, or improve through appropriate hardware and/or software upgrades, their design specification for radiation protection and safety for their entire lifetime.
2) The authorisation holder shall establish the necessary maintenance arrangements and coordination with the manufacturer's representative and/or installation company before initial operation and on an ongoing basis thereafter.

3) The licensee shall ensure that maintenance procedures are carried out at the frequency recommended by the manufacturer of the device.
4) The authorisation holder/share shall keep maintenance records for each inspection device.
5) The licensee shall ensure that the maintenance records include information on:
    a) any defects found by the users (a fault log),
    b) all remedial actions taken (both interim and subsequent repairs), and
    c) the results of testing before the device is reintroduced into use.

Article 47: Quality Assurance Programme

1) The authorisation holders/licensee shall establish, implement and maintain a Quality Assurance Programme, designed to ensure that all equipment and safety systems are regularly subjected to quality control tests, and that any faults or deficiencies are brought to the attention of the management and are promptly remedied.
2) The licensee shall ensure that quality control tests are conducted in order to ensure that, at all times, all inspection devices are performing correctly, accurately, reproducibly and predictably.
3) The Quality Assurance Programme provided in article paragraph 1 shall include provisions for:
    a) documentation,
    b) radiation monitoring,
    c) quality control tests,
    d) training,
    e) records,
    f) a preventive maintenance programme,
    g) a review of local rules and procedures.
4) The licensee shall ensure that records of the Quality Assurance Programme are available to the Regulatory Authority for review during inspections.

CHAPTER XI: FAULTS AND ADMINISTRATIVE SANCTIONS

Article 48: Operating without a license

Any person who practice operate x- ray generators and other radiation sources used for inspection purposes and for non-medical human imaging facility without a license commits a fault and is liable to an administrative fine of eight hundred thousand Rwanda francs (800,000FRW) and cessation of practices until all requirements are met and a license is granted.

Article 49: Importation or operate x- ray generators used for inspection purposes without a license

Any person who imports operate x- ray generators and other radiation sources used for inspection purposes and for non-medical human imaging facility equipment without approval of the Regulatory Authority commits a fault and is liable to an administrative fine of four hundred thousand Rwanda francs (400,000FRW).

Article 50: Assembling or changing vehicle or baggage scanner facility without approval

Any person who assembles, change security scanning without approval of the Regulatory Authority commits a fault and is liable to an administrative fine of two million Rwanda francs (2,000,000FRW) and cessation of activity until all requirements are met and approval is granted.

Article 51: Absence of warning signs at any general access point to a vehicle or baggage scanner facility

Any licensee who doesn't put appropriate warning signs at any general access point to a room used for security scanning equipment that produces ionising radiation as provided in this regulation commits a fault and is liable to an administrative fine of Two hundred thousand Rwandan francs (200,000FRW).

Article 52: Lack of mandatory safety devices

Any licensee who operates without mandatory devices provided in this regulation commits fault and is liable to an administrative fine of two hundred thousand Rwandan francs (200,000FRW).

Article 53: Failure to keep records of monitoring and verification of compliance

Any licensee who does not keep records as provided in this regulation for verification by the Regulatory Authority commits fault and is liable to an administrative fine of one million Rwanda francs (1,000,000FRW).

Article 54: Not reporting incident occurred to the Regulatory Authority

Any licensee who does not report an incident arising out of operation of x- ray generators and other radiation sources used for inspection purposes and for non-medical human imaging facility commits a fault and is liable to an administrative fine of two hundred Rwanda francs (200,000FRW).

CHAPTER VII: TRANSITIONAL AND FINAL PROVISIONS

Article 55: Transitional period for existing operators

Any existing entity that is already operating an x- ray generator or and other radiation sources used for inspection purposes is given a Six (6) months period from the date of commencement of this Regulation to align its activities concerning specifically the requirement of the design of security scanning facility with the provisions of this Regulation.

Article 56: Repealing provision

All prior provisions contrary to this Regulation are hereby repealed.

Article 57: Commencement.

This Regulation shall come into force on the date of its signature by the Chairperson of the Regulatory Board.

ANNEX I: CONTENT OF AUTHORISATION APPLICATION

1) Legal information:
   a) Name and address of the applicant and any additional contact information, such as the name of the individual(s) representing the applicant;
   b) Details of any relevant existing authorizations;
   c) Information on whether the facility or activity is fully or partly owned or controlled by a person from another State or by a foreign corporation, and, if so, details of the ownership structure.
2) Information on organizational matters:
   a) The applicant's organizational structure;
   b) Evidence that the applicant has and will continue to maintain adequate financial resources to cover the necessary costs associated with safety, such as regulatory fees, liability insurance and funding for management of disused sources, as applicable;
   c) Evidence that the applicant has adequate human resources to ensure that regulatory requirements and safety standards are met and will continue to be met throughout the lifetime of the facility or activity.
3) Description of the facility where the inspection devices will be used and of the inspection activity:
   a) The nature of the facility or activity that is subject to authorisation;
   b) A description of the relevant premises, including the layout of the facility, buildings and equipment;
   c) A general description of the site where the facility is located or the inspection devices intended to be used.
4) Staff qualification and training:
   a) The names and qualification of the designated manager for supervision of radiation protection and safety, of the designated Radiation Protection Officer and of the contracted Qualified Expert;
   b) Copies of the training records or qualification certificates of the responsible staff (listed in point a);
   c) Identification of the necessary qualifications and training of the staff who will operate the inspection devices;
   d) Details of qualifications and training in radiation protection of the workers will operate the inspection devices;
   e) Evidence of trustworthiness of the responsible staff (listed in point a).
5) The management system:
   a) The operating procedures and maintenance procedures that will be followed;
   b) A description of the system for identification, traceability and preservation of documents and for control of records;
   c) The system for the development of procedures;
   d) A description of the arrangements for establishing and sustaining leadership and management on the part of organizations and managers responsible for radiation protection and safety;
   e) A procedure or description of the process for dealing with modifications of the facility or activity that are subject to approval by the Regulatory Authority;
   f) A description of the quality control arrangements established to ensure that the inspection devices are installed, tested, operated, maintained and replaced in compliance with the relevant safety requirements;
   g) Quality assurance arrangements, including internal and external audits.
6) Radiation protection arrangements and safety measures:
   a) The applicable safety regulations, guides and industrial standards;

b) Safety assessments for exposures in normal operation and for potential exposures, for activities subject to licensing;
c) The occupational radiation protection programme, including arrangements for designation of areas, local rules and procedures, monitoring of workers and the workplace, the health surveillance programme, and provision and maintenance of personal protective equipment;
d) Safety assessments and other design related documents that address the optimization of protection and safety, the design criteria and the design features relating to the assessment of exposure and potential exposure of members of the public, including the persons who may be inadvertently exposed;
e) For new practices, a demonstration that the principle of justification is fulfilled;
f) Arrangements for ensuring safety, which will be maintained for all stages of the lifetime of the facility or the duration of the activity;
g) The safety concepts and criteria used in the design of the facility or for carrying out the activity, including the application of the concept of defence in depth;
h) A description of the items important to safety for operating the facility or conducting the activity (e.g. the facility's structures, systems and components, including their design criteria, the processes involved in their design, and the modes of operation and testing);
i) Arrangements for the management of disused sources, and information on the financial arrangements for such activities;
j) The results of a safety analysis to demonstrate how the design and related operational procedures of the facility or activity will contribute to the prevention of accidents and to the mitigation of the consequences of accidents if they do occur. The analysis should describe and evaluate the predicted response to events, both internal and external, which could lead to anticipated operational occurrences and accident conditions. The analysis should include relevant combinations of such disturbances, malfunctions, failures, errors and events.
k) Information on other plans and programmes established by the applicant in support of its safety activities, such as fire protection.

7) Emergency arrangements, including an emergency response plan and the related financial arrangements, that address the general, functional and infrastructural requirements established in the Regulation No. 006/R/RS-NRP/RURA/2021of 16/11/2021 on Radiological and Nuclear Emergency Preparedness and Response.

8) Interface with nuclear security: a description of the security measures taken to prevent the unauthorized access of individuals and the unauthorized removal of the radioactive sources, their potential influence on the safety measures, and how it was assured that safety measures and security measures do not compromise each other.

ANNEX II: AUTHORISATIONS' VALIDITIES AND RELATED FEES

	Activity	License/Authorization fees / Equipment (FRW)	Application fees (FRW)	Validity
1	Authorisation of X-ray inspection devices to detect explosives and narcotics in bottles containing liquid	150,000	40,000	5 years
2	Authorisation of inspection devices with Ni-63 sources for trace quantities of explosives and narcotics	150,000		5years
3	Registration of post-room X-ray scanners and baggage inspection systems	150,000		5years
4	License to use portable X-ray radiography inspection imaging devices for on-site examination of suspicious objects for security purposes	300,000		3years
5	License to operate hand-held backscatter inspection imaging devices for security and other inspection purposes	300,000		5 years
6	License to operate inspection imaging devices for scanning vehicles	500,000		3years
7	License to operate mobile cargo scanning devices	500,000		3 years
8	License to operate relocatable cargo scanning devices	750,000		3 years
	License to operate baggage x-ray scanner	200,000		3 years
9	License to operate fixed cargo scanning devices	1,000,000		3years
	Importation license for Baggage scanners	100,000		3 months
	Importation license for vehicle cargo scanner	200,000		3 months