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**REGULATION N°.../.../RURA/2023 OF.../.../2023 GOVERNING
LICENSING OF NUCLEAR INSTALLATIONS**

CHAPTER I: GENERAL PROVISIONS

Article one: Purpose

The purpose of this Regulation is to put in place a licensing framework for nuclear installations with the goal to protect people and the environment.

Article 2: Definition of terms

For the purpose of this regulation, the terms below have the following meaning:

“**applicant**”: any (legal or natural) person who wished to undertake specified activities of nuclear installations under these Regulations;

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

"**construction**" : a process of manufacturing and assembling the components of a facility, the carrying out of civil works, the installation of components and equipment and the performance of associated tests;

“**construction activities**”: a performance of civil works such as the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations, in-place assembly, erection, fabrication and testing for systems, structures, components and equipment important to safety;

“**Construction Licence**”: a legal document issued by the Regulatory Authority which allows the holder to undertake nuclear installations activities ;

“**decommissioning Licence**”: an authorization issued by the Regulatory Authority which allows the licensee to start the activities and processes directed at reaching the decommissioning end state of the nuclear installation, whether partial or full decontamination or dismantlement, with or without restrictions on further use, as specified in the approved Final Decommissioning Plan;

"**design**": a process and the result of developing a concept, detailed plans, supporting calculations and specifications for nuclear installation(s) and its parts;

"**design life**": a minimal value of lifetimes of all the non-replaceable structures, systems and components of a nuclear installation;

"**fundamental safety functions**": a control of reactivity, cooling of the nuclear fuel and confinement of radioactive material, shielding against radiation and control of planned radioactive releases, as well as limitation of accidental radioactive releases;

“**incident**”: any unintended event, including operating error, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection and safety;

"inspection": an examination, observation, measurement or test undertaken to assess structures, systems, components and materials, as well as operational activities, technical and organizational processes, procedures and personnel competence;

"limit": a value of quantity used in certain specified activities or circumstances, prescribed or notified by or acceptable to the Regulatory Authority, that must not be exceeded;

"management system": a set of interrelated or interacting elements for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner;

"nuclear installation": a nuclear fuel fabrication plant, research reactor (including subcritical and critical assemblies), nuclear power plant, spent fuel storage facility, enrichment plant or reprocessing facility;

"nuclear material": plutonium except that with isotopic concentration exceeding 80% in plutonium-238; uranium-233; uranium enriched in the isotope 235 or 233; uranium containing the mixture of isotopes as occurring in nature other than in the form of ore or ore residue; any material containing one or more of the foregoing;

"nuclear safety": an achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards;

"Operation Licence": a legal document issued by the Regulatory Authority for the operation of a nuclear installation;

"operation": all activities performed to achieve the purpose for which a nuclear installation is constructed and includes maintenance, refuelling, in-service inspection and other associated activities;

"Periodic Safety Review (PSR)": a systematic reassessment of the safety of an operational nuclear installation carried out at regular intervals to deal with the cumulative effects of ageing, modifications, operating experience, technical developments, and siting aspects, and aimed at ensuring a high level of safety throughout the operating lifetime of the nuclear installation;

"Probabilistic Safety Assessment (PSA)" means a comprehensive, structured approach to identifying failure scenarios, constituting a conceptual and mathematical tool for deriving numerical estimates of risk;

"quality assurance" means all the planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy all the given requirements for safety and quality, including, for example, those specified in the licence;

"release from regulatory control": removal of the site of a nuclear installation from any further regulatory control by the Regulatory Authority;

"site": a geographical area containing the nuclear installation, and within which the management of the installation may directly initiate emergency actions;

"siting": a process of selecting a suitable site for nuclear installation(s), including appropriate assessment and definition of the related design bases;

“Site Licence”: an authorization issued by the Regulatory Authority to an applicant to allow preparation of site for the construction of a nuclear facility;

"testing": a determination or verification of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental or operational conditions;

“Law”: The Law N°59/2017 OF 24/1/2018 Governing Radiation Protection in Rwanda

Article 3: Scope of application

This regulation applies to nuclear installations and the authorization of activities directly related to nuclear installations.

Article 4: Objective

Objective of this regulation is to:

1. establish the requirements to be fulfilled by the applicant for the whole lifetime of Nuclear installations
2. ensure the protection of human health and the environment from the hazards associated with Nuclear Installations

CHAPTER II: RESPONSIBILITIES TO OPERATE NUCLEAR INSTALLATIONS

Article 5: General Requirements for license application

Any person intending to operate a nuclear installation shall apply for a license throughout the phases of a nuclear installation that include:

- (a) A Site Licence;
- (b) A Construction Licence;
- (c) An Authorisation for commissioning;
- (d) Authorisation to introduce nuclear material into the nuclear installation;

- (e) An Operation Licence;
- (f) An authorisation to Operate beyond design life;
- (g) A Decommissioning Licence;
- (h) Release from regulatory control.

Any applicant to operate a nuclear installation shall be responsible for the safety of facilities or activities.

The Applicant has to ensure an adequate level of protection and safety by various means, including:

- a) Demonstration of safety by means of the safety case;
- b) Derivation of operational limits, conditions and controls,
- c) Preparation and implementation of appropriate operating procedures, including monitoring;
- d) Ensuring that staff are trained, qualified and competent, and, where applicable, licensed by the Regulatory Authority;
- e) Establishment and implementation of a management system;
- f) Maintenance of records and reporting as required by the regulatory authority, including those records and reports necessary to guarantee the accountability for and traceability of nuclear materials throughout the different processes of nuclear installation;
- g) Establishment and maintenance of a mechanism to provide and ensure adequate financial resources to discharge its responsibilities;
- h) Development of an emergency preparedness and response plan;
- i) Ensure the effective management of radioactive waste and spent fuel;
- j) Consideration of non-radiological hazards and conventional health and safety issues.

Article 6: Administrative requirements for site license

Any person wishing to carry out a site assessment for a nuclear installation shall apply for a license to the Regulatory Authority along with the following documents:

- (a) evidence that the applicant is the owner of the site or has an agreement with the owner of the site to carry on the activities to be licensed;
- (b) a description of the site evaluation process and of the investigations and preparatory work that have been and will be done on the site and in the surrounding area, together with the Quality Assurance Program applied to these activities;
- (c) the name, form, characteristics and quantity of any hazardous substances that may be on the site while the activity to be licensed is carried on;
- (d) Initial Safety Analysis Report (ISAR);
- (e) Radiological Impact Assessment Report for the nuclear installation;
- (f) the program for the pre-operational environmental monitoring, to determine the environmental baseline characteristics of the site and the surrounding area;
- (g) the proposed program to inform persons living in the vicinity of the site of the general nature and characteristics of the anticipated effects on the environment and the health and safety of persons that may result from the activities to be licensed;
- (h) the proposed Quality Assurance Program for the design of the nuclear installation.

Upon review of the documentation submitted in accordance with item (1), the Regulatory Authority shall make a decision on issuing the Site Licence.

The issuance of the Site Licence shall allow for the preparation of the site for construction of the nuclear installation.

Article 7: Validity and revalidation of a site licence

The Site Licence shall be valid for a period of 10 years or as specified in the Site Licence, with the observance of the terms and conditions specified in the licence.

After the expiry of Site Licence, the site preparation activities may only continue or commence after the revalidation of the Site Licence.

If a Construction Licence has been granted, a revalidation of the Site Licence is no longer necessary for the nuclear installations for which the construction has been licensed.

If a new nuclear installation is proposed for construction on an existing nuclear site, which was not included in the initial Site Licence, a new Site Licence shall be applied for and obtained for the respective nuclear installation.

Article 8: Requirements for a Construction license

After receiving the Site Licence, the holder shall establish design and safety criteria in accordance with the nuclear safety standards specified in these regulations and submit them for approval to the Regulatory Authority.

After completion of the design, the licensee shall submit the following documents to the Regulatory Authority, in support of an application for obtaining a Construction Licence:

(a) Preliminary Safety Analysis Report (PSAR);

(b) Physical protection plan

(3) Upon review of the documents required in item (2), the Regulatory Authority shall make a decision on the issuance of the Construction Licence.

(4) The licensee shall not commence the construction activities on the site until a Construction Licence has been issued by the Regulatory Authority.

Article 9: Validity of a construction license and re-application

The Construction Licence shall be valid for a period of 10 years or as specified in the Construction Licence, with the observance of the terms and conditions specified in the licence.

In case the licensee is unable to commence construction of the nuclear installation within a period of 5 years after issuance of the Construction Licence, the Construction Licence shall be deemed to have been cancelled, and the licensee shall have to re-submit the application for the Construction Licence.

After the expiry or cancelation of the Construction Licence, the construction activities may only continue or commence after revalidation of the Construction Licence.

The licensee shall submit a request to the Regulatory Authority for revalidation of the Construction Licence along with the following documents:

- (a) updates of all the documents and reports submitted for the issuance of a Construction Licence;
- (b) reasons for the delay along with justification for continuing or commencing the construction;
- (c) an evaluation of the safety impact of changes such as changes in the design, nuclear safety standards, industrial standards, and experience feedback from international nuclear practice.

Article 10: Requirements for commissioning license

The licensee shall, at least six months before the proposed starting date of commissioning of the nuclear installation, submit a request for Permission for commissioning along with the Commissioning Program and Quality Assurance Program for the commissioning phase.

The Regulatory Authority may, upon approval of the Commissioning Program, Authorise the commissioning without introducing nuclear material into the system of the nuclear installation.

The licensee shall submit commissioning reports up to introduction of nuclear materials into the system of the nuclear installation to the Regulatory Authority for information, reference and record, as specified in the Commissioning Program.

Article 11: Requirements for Authorisation to introduce nuclear material into the system of the nuclear installation

The licensee shall, after the completion of the detailed design and the safety analysis, apply for an Authorisation to introduce nuclear material into the system of the nuclear installation, where applicable, together with the following documents within the time frame as agreed with the Regulatory Authority.

- (a) Pre-Operational Safety Analysis Report (POSAR);
- (b) Probabilistic Safety Analysis (PSA);
- (c) Security Plan and Safeguards Arrangements;
- (d) Emergency Preparedness and Response Program and procedures;
- (e) Radiation Protection Program;
- (f) Environmental Monitoring Program;
- (g) Radioactive Waste Management Program;
- (h) Core Management and Nuclear Fuel Handling Program;
- (i) Programs for maintenance, testing, surveillance and inspection of structures, systems and components important to safety;
- (j) Ageing Management Program;
- (k) Fire Protection Program;

- (l) Operational Experience Feedback Program;
- (m) Quality Assurance Program for Operation;
- (n) Training and Qualification Program for Staff with Jobs Important to Safety;
- (o) Fitness for Duty Program, including medical surveillance of workers;
- (p) the proposed measures, policies, methods and procedures for operating and maintaining the nuclear installation;
- (q) Emergency Operating Procedures and Severe Accident Management Guidelines;
- (r) the proposed procedures for handling, storing, loading and transporting nuclear material and hazardous substances;
- (s) the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical and radiological characteristics;
- (t) the proposed measures to prevent or mitigate the effects of accidental releases of radioactive and hazardous substances on the environment, the health and safety of persons and the maintenance of security;
- (u) the results that have been achieved in implementing the program for recruiting, training and qualifying workers for the operation and maintenance of the nuclear facility.

Article 12: requirements for an operation license

The licensee shall, within six months after completion of the commissioning, apply to the Regulatory Authority an Operation Licence and shall submit the following documents:

- (a) All the commissioning reports including results of the first start-up, criticality, low power tests, power ascension tests and full power tests;
- (b) Final Safety Analysis Report (FSAR);
- (c) updates of all documents submitted for permission to introduce nuclear material in the installation, to reflect the current status of the installation and of the operating organization;

The Regulatory Authority shall, upon review of the reports, results and documents required in item (1), make a decision on granting the Operation Licence.

The validity of the Operation Licence shall be determined by the design life of the nuclear installation and the fulfilment of the terms and conditions prescribed by the Regulatory Authority.

CHAPTER III: RESPONSIBILITIES OF THE LICENSEE FOR A PERIODIC SAFETY REVIEW, OPERATE BEYOND DESIGN LIFE AND DECOMMISSIONING

Article 13: Periodic safety Review

The licensee shall, during the design life of the nuclear installation, perform Periodic Safety Reviews, at least every ten years, with the first Periodic Safety Review completed within 10 years of the issuance of the Operation Licence.

The objective of a Periodic Safety Review shall be to determine, by means of a comprehensive assessment:

- (a) the extent to which the licensing basis remains valid;

- (b) the extent to which the installation conforms to current international safety standards and practices;
- (c) the adequacy of the arrangements that are in place to maintain plant safety until the next Periodic Safety Review or the end of design lifetime;
- (d) and the safety improvements to be implemented to resolve the safety issues that have been identified.

The results of the Periodic Safety Review, documented in a report submitted for review to the Regulatory Authority, together with the updates of the documents submitted in support of the Operation Licence, shall be the basis for continuous operation.

The Regulatory Authority may revise the terms and conditions specified in the Operation Licence.

Article 14: Operation beyond Design life

In case the licensee wishes to operate the nuclear installation beyond its design life he/she shall apply for a license to the Regulatory Authority at least 3 years before the end of design life together with the following documents:

- (a) preconditions, including the current licensing basis, safety upgrading and verification, and operational programmes;
- (b) categorisation of structures, systems and components with regard to degradation and ageing processes;
- (c) revalidation of safety analyses made on the basis of time limited assumptions;
- (d) a justification for operation beyond design life, supported by the results of a specific safety assessment that demonstrates, with due consideration of the ageing of structures, systems and components important to safety, that sufficient safety margins will be maintained;

(e) latest Periodic Safety Review report;

(f) updates of all documents submitted in support of the Operation Licence.

(2) The Regulatory Authority shall, upon review of the documents required under item (1), make a decision on issuing a licence to operate the nuclear installation beyond its design life, for the duration requested in the application or as determined by the Regulatory Authority.

Article 15: Decommissioning Licence

In case the licensee wishes to permanently shut down the nuclear installation, he/she shall apply to the Regulatory Authority for a Decommissioning Licence at least three years before terminating the operation of the nuclear installation.

The application shall be accompanied by the following documents:

(a) Final Decommissioning Plan;

(b) Technical Specifications during decommissioning;

(c) Quality Assurance Program for decommissioning;

(d) Emergency Preparedness Plan;

(e) Security Plan and Safeguards Arrangements;

(f) Radiation Protection Program;

(g) Radioactive Waste Management Program;

(h) Environmental Monitoring Program.

The Regulatory Authority shall, upon review of the documents provided in item (2), make a decision to terminate the Operation Licence and to issue the Decommissioning Licence.

After the completion of all decommissioning activities and restoring the site to condition such that the site can be used for any other purposes, the licensee shall apply for release of the nuclear installation from regulatory control.

The application shall be accompanied by a Decommissioning Completion Report including a Final Radiological Survey Report to prove that all responsibilities and liabilities have been discharged.

The Regulatory Authority may, upon review of the documents in item (2) and satisfied that no potential for radiation hazard exists for using the site for any other purposes, release the site from regulatory control.

CHAPTER IV: REQUIREMENTS FOR SAFETY AND SECURITY

Article 16: Applicable nuclear safety and security standards

The licensee shall ensure that all nuclear installations, for the purposes of siting, design, construction, commissioning, operation and decommissioning, comply with the provisions of the Regulatory Authority 's regulations in force.

The Regulatory Authority may request the licensee to abide to internationally recognized nuclear safety and security standards in circumstances where nuclear safety and security standards are not prescribed by national legislation.

In case the nuclear safety and security standards of another country are proposed to be followed, the applicant or authorization holder shall demonstrate to the satisfaction of the Regulatory Authority that the standards proposed to be followed offer the same or better standards of safety, security, quality and reliability than would have been offered by the nuclear safety and security standards mentioned in items (1) and (2).

Article 17: Inspections

(1) The Licensee shall submit to the Regulatory Authority, A detailed program for the inspection of various activities during siting, manufacturing, construction, commissioning, operation and decommissioning of its nuclear installation prior to commencing those activities.

Article 18: License/Authorization modification

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

- 1° respond to significant changes in a new law or Regulation or Court decision that directly affect the license terms and conditions;
- 2° the request of the licensee due to relevant reasons;
- 3° if it is for the purpose of correction of errors indicated during regulatory review for safety and security in nuclear installations

Article 19: Transfer of the license

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

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

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

Article 20: License/Authorization suspension

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

- 1° failure to comply with license terms and conditions;
- 2° failure to cooperate with the Regulatory Authority's inspection and audits;
- 3° failure to provide the Regulatory Authority with monitoring and reporting data required;
- 4° failure to pay the regulatory fee and such fee remains unpaid six (6) months after it has become due and the Regulatory Authority has given to the Licensee a notice in writing that such payment is overdue and the Licensee has not paid;

Article 21: License/Authorization Revocation

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

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

CHAPTER VI: FAULTS AND AMINISTRATIVE SANCTIONS

Article 22: Failure to notify the Regulatory Authority of any incident

Any licensee/authorization holder who fails to notify the Regulatory Authority on any incident needed to be notified as provided in this regulation commits a fault, and is liable to an administrative fine equivalent between two hundred thousand (200,000) Rwandan francs to five hundred thousand (500.000) Rwandan francs.

Article 23: Unauthorized modification of the nuclear installation

A licensee/authorization holder who modifies a nuclear installation design without an authorization from the Regulatory Authority commits a fault and is liable to an administrative fine of fifty million (20.000.000) Rwandan francs. In the case the modification has caused any injury or death to people, the license will be suspended and the licensee is subject to penalties in accordance with relevant laws and regulations

Article 24: failure to conduct occupational and area exposure monitoring

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

1. Five million Rwandan francs (5,000,000Frw) in the event they are no occupational or area exposure monitoring tools in place;
2. Two million Rwandan francs (2,000,000Frw) in case they are no regular monitoring reports.

Article 25: Failure to perform calibration of detection equipment

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

**ANNEX I: TYPES OF LICENSES AND AUTHORIZATION ISSUED FOR NUCLEAR
INSTALLATIONS AND RELATED FEES**

No:	Installation, facility and activity	Application Fees (Rwf)	License and Authorization Fee (Rwf)
1.	Nuclear power plant		
	Site Licence	1 million	20 million
	Licence for Construction (NPP)	2 million	2 billion
	Authorisation for commissioning	1 million	5 million
	Authorisation to introduce nuclear material into the nuclear installation	1million	10 million
	Licence to Operate nuclear power plant	5 million	10 billion
	Authorisation to Operate beyond design life	2 million	1 million
	Licence Decommission	1 million	150 million
	Authorisation to release from regulatory control	1 million	5 million
2	Nuclear Research Reactor ≤ 1 MW_{th} Installed Capacity		
	Site Licence	100 thousand	1 million
	Licence for Construction	100 thousand	2 million
	Licence to Operate a research reactor	200 thousand	10 million
	Licence Decommission	100 thousand	2 million
3	Nuclear Research Reactor >1 MW_{th} Installed Capacity		
	Site Licence	200 thousand	2 million
	Licence for Construction	200 thousand	50 million
	Licence to Operate a research reactor	500 thousand	100 million
	Licence Decommission	200 thousand	10 million