
Draft Regulation

Regulation on the Registration and Licensing of Radiation Sources (FANR-REG-29)

Version 0

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DRAFT

Preamble

This regulation is issued by the Authority pursuant to the powers conferred to its Board of Management in accordance with Articles (11) 4 and (26) 2 of the Law.

Definitions

Article (1)

For the purpose of this regulation, the following terms shall have the meaning set forth below. Other capitalised terms used but not defined herein shall have the meaning ascribed to them in Article 1 of the Federal Law by Decree No. 6 of 2009, Concerning the Peaceful Uses of Nuclear Energy (the Law):

Activity Concentration

The radioactivity per unit mass of a material in which the radionuclides are essentially uniformly distributed.

Protection and Safety

The protection of people against exposure to Ionising Radiation or exposure due to Radioactive Material and the Safety of sources including the means of achieving this, and the means of preventing Accidents and mitigating the consequences of Accidents if they do occur.

Radiation Generator

A device capable of generating Ionising Radiation such as X-rays, neutrons, electrons or other charged particles that may be used for scientific, industrial or medical purposes.

Objective and Scope

Article (2)

This regulation applies to the planning, conduct, modification and termination of Regulated Activities in Facilities using Radiation Sources. The regulation aims to establish the licensing requirements to be applied following a graded approach to the abovementioned Regulated Activities including the Exemption criteria and the corresponding requirements applicable to Regulated Material exempted from all or part of Regulatory Control.

General Requirement

Article (3)

1. No Person shall possess, use, manufacture, handle, store, import or export, transport or dispose of any Regulated Material within the scope of this regulation unless the requirements of this regulation are met.
2. Any Person in possession of Regulated Material is required to immediately notify the Authority.

EXEMPTION

Bulk and Moderate Amounts of Radioactive Material exempted from Regulatory Control

Article (4)

1. Bulk and moderate amounts of Radioactive Material are exempted from the obligation to obtain a Licence or to make a registration provided that such amounts of Radioactive Material comply with the criteria set forth in paragraphs (1) and (2) of this article:
 - a) For moderate amounts (not more than one tonne) of Radioactive Material present at a location at any time, which are intended to be used to carry out Regulated Activities covered by this regulation: $\sum_{i,j} \frac{A_{i,j}}{X_{i,j}} < 1$ and $\sum_{i,j} \frac{A_{ki,j}}{X_{ki,j}} < 1$ where $X_{i,j}$ is Activity (Bq) and $X_{ki,j}$ is Activity Concentration (Bq/g) values per radionuclide i in Schedule I Table I-1 of FANR-REG-24 as amended for Radioactive Material j ; or
 - b) For bulk amounts of Radioactive Material present at a location at any time, which are intended to be used to carry out Regulated Activities covered by the this regulation: $\sum_{i,j} \frac{A_{i,j}}{X_{i,j}} < 1$ or $\sum_{i,j} \frac{A_{ki,j}}{X_{ki,j}} < 1$ where $X_{i,j}$ is Activity (Bq) and $X_{ki,j}$ is Activity Concentration (Bq/g) values per radionuclide i from Schedule I Table I-2 for Radioactive Material j of FANR-REG-24 as amended.
2. In the cases stated under paragraph (1) in this article, $A_{i,j}$ is Activity (Bq) and $A_{ki,j}$ is Activity Concentration (Bq/g) of Radioactive Material j per radionuclide i present at a location at any time.
3. A Person shall be able to demonstrate compliance with the criteria set forth in paragraph (1) of Article (3) as may be required by the Authority based on a certificate issued by either the manufacturer of Radioactive Material or a recognised Radiation Safety service provider.
4. Such provisions do not relieve a Person from complying with the requirements specified in FANR-REG-09 or FANR-REG-10.

Radiation Generators exempted from Regulatory Control

Article (5)

1. Radiation Generators with a maximum output of 5 keV are exempted from the obligation to obtain a Licence or to apply for registration. Such provision does not relieve a Person from complying with the requirements specified in FANR-REG-09.
2. A Person shall demonstrate compliance with the requirements set in paragraph (1) of this article as may be required by the Authority based on the certificate issued by either the manufacturer of the Radiation Generator or a recognised Radiation Safety service provider.

Registration of Radioactive Sources

Article (6)

1. A Person shall register with the Authority any Radioactive Source for which it can be demonstrated that the fraction for the radionuclide is higher than 1 and less than 10, as follows:
$$10 > \sum_{i,j} \left(\frac{A_{i,j}}{X_{i,j}} \right) > 1$$
 where $X_{i,j}$ (Bq) is the Activity value per radionuclide i from Table I-1 of Schedule 1 in FANR-REG-24 as amended for Radioactive Source j , and $A_{i,j}$ is the Activity (Bq) of Radioactive Source j per radionuclide i , present at a location at any time where Regulated Activities covered by this regulation are carried out.
2. A Person shall register with the Authority any Radioactive Source satisfying the condition under paragraph (1) of this article before importing or coming into possession of the Radioactive Source. The certificate issued by either the manufacturer or a recognised Radiation Safety service provider demonstrating compliance with conditions set in paragraph (1) of this article shall be provided for the registration.
3. A Person shall register with the Authority any Radioactive Material that does not meet the conditions set in paragraph (1) of this article if a Safety Assessment performed by a recognised Radiation Safety service provider demonstrates that radiological risks associated with the Radioactive Source comply with the requirements stipulated in paragraph (1) of Article (5) of FANR-REG-24 as amended.
4. Notwithstanding paragraphs (1), (2) and (3) of this article, the requirements as set forth in FANR-REG-09 and/ or FANR-REG-10 remain applicable.

Registration of Radiation Generators

Article (7)

1. A Person may be exempted from the requirements of a Licence from the Authority if the Radiation Generator involved in the conduct of Regulated Activities covered in this regulation has an output between 5 keV and 100 keV, or if the Person demonstrates compliance with paragraph (1) of Article (5) of FANR-REG-24 as amended.
2. A Person shall apply for registration with the Authority before importing or coming into possession of any Radiation Generator satisfying the conditions under paragraph (1) of this article. The certificate issued by the manufacturer or a Safety Assessment performed by a recognised Radiation Safety service provider demonstrating compliance with conditions set forth in paragraph (1) of this article shall be provided to the Authority for the registration.
3. Upon evaluation of the application for registration, the Authority shall determine whether a Licence is required.
4. Notwithstanding paragraphs (1), (2) and (3) of this article, the requirements as set forth in FANR-REG-09 remain applicable.

Request for Additional Information for Registration

Article (8)

1. As per Articles (6) and (7) of this regulation, the registration applicant shall provide additional information as requested by the Authority within five (5) working days from the date of issuance of the request for additional information by the Authority unless otherwise specified in the request itself.
2. In exceptional circumstances, the Authority may extend the time to respond to the Authority's request for additional information.
3. Failure by the applicant to respond to the Authority's request for additional information within the time limits set forth in paragraphs (1) and (2) of this article may result in the cancellation of the application for registration.
4. The Authority may terminate the review of the application for registration if the applicant fails to demonstrate compliance with the requirements of this regulation and of Article (5) of FANR-REG-24, as amended, within 30 working days from the date of the submission to the Authority of the registration application.

GRANTING A LICENCE

Safety Assessment

Article (9)

1. A Person shall apply for a Licence if he or she intends to conduct a Regulated Activity involving Regulated Material that is not exempted from Regulatory Control or subject to registration as specified in Articles (4), (5), (6) and (7) of this regulation.
2. As described in paragraph (4) of this article, the Licence application for Regulated Activities involving a Radiation Source shall include, inter alia, a detailed Safety Assessment performed by a recognised Radiation Safety service provider for the planned Facility and Regulated Activity.
3. The detailed Safety Assessment shall demonstrate that the objectives of Radiation Protection and Safety are met.
4. The Safety Assessment shall include, *inter alia*:
 - a) Dose Constraints used as Safety Assessment target for the workers and members of the public as per Articles (8) and (9) of FANR-REG-24 as amended.
 - b) The Facility's floor layouts depicting controlled and supervised areas as per Article (21) of FANR-REG-24 as amended.
 - c) Local rules, monitoring and survey instruments, and personal protective equipment as per Article (22) of FANR-REG-24 as amended.
 - d) A description of the Protection and Safety arrangements as detailed in paragraph (5) of this article.
 - e) Identified occupancy factors for workers and members of the public in line with the guidance of Article (10) of FANR-RG-007 as amended.
 - f) Identified inventory and location of Radiation Sources as per paragraph (3) of Article (18) of FANR-REG-24 as amended.
 - g) A conservative estimate of the expected use of the Radiation Sources as per Article (20) of FANR-REG-24 as amended.
 - h) Identified scenarios relating to regular and abnormal Operation conditions as per paragraph (2) of Article (21) of FANR-REG-24 as amended.
5. Where relevant, Protection and Safety arrangements in accordance with Article (12) of FANR-REG-24 as amended shall include topics relating to the following:

- a) Occupational Radiation Protection
 - b) Individual and workplace monitoring
 - c) Patient exposure protection
 - d) Public protection
 - e) Employee training
 - f) The Facility's management structure
 - g) Roles and responsibility of the Radiation Protection Officer and Qualified Expert
 - h) Operating Procedures
 - i) Incident reporting and investigation
 - j) Emergency Plan
 - k) Maintenance and calibration of Radiation Sources
 - l) Import and export arrangements
 - m) Arrangements for the transportation of Radioactive Material as required by FANR-REG-13
 - n) Management of Radioactive Material at the end of its life
 - o) Quality Assurance of the Protection and Safety programme
 - p) Relevant additional information to support the Licence application
6. For the use, design or manufacture of Type B or Type C packaging, and packaging designed to contain fissile material as stipulated in FANR-REG-13, the Safety Assessment shall include details of structural design, thermal evaluation, shielding evaluation, containment of the nuclear substance in the package, the use of the package, the Maintenance programme to be followed and the applicable Quality Assurance programme.
 7. The Safety Assessment shall be the basis to identify the appropriate pre-Disposal arrangement to manage Radioactive Waste as required by FANR-REG-26 and the Decommissioning plan as required by FANR-REG-21.
 8. The Licensee shall seek the approval of the Authority prior to making any significant change to the Safety Assessment. Such change may require an amendment to the Licence in accordance with Article (14) of this regulation.

Requirements relating to Construction

Article (10)

1. In situations where the Regulated Activities intended to be licensed require the Construction of a specific Facility, the Person shall have the Safety Assessment approved by the Authority prior to Construction as described in Article (9) of this regulation.
2. During Construction, the Authority shall be notified of significant changes to the approved Safety Assessment, which are important to Radiation Protection and Safety, prior to their implementation.
3. Based on the notification of changes, the Authority shall determine whether an approval of such changes is required.
4. The Person shall submit to the Authority a written statement within five (5) working days from the completion of Construction to confirm that Construction has been completed in accordance with the Safety Assessment approved by the Authority. The Person shall enclose a copy of the final Construction report as issued by the construction company, and a provisional time schedule for the installation of Radiation Sources, testing of Radiation Sources, and the Facility's Commissioning for Operation where relevant once the Licence has been obtained from the Authority.

Licensing Requirements

Article (11)

1. A Person may be granted a Licence on the basis of an application and a Safety Assessment as set forth in Article (9) of this regulation, and the submission of the following:
 - a) The final report on Construction issued by the construction company in accordance with Article (10) of this regulation.
 - b) Evidence of a contract with a recognised Radiation Safety service provider.
 - c) Full name, qualifications, training, experience and contact details of the person nominated to be the Operator's Radiation Protection Officer, and copies of relevant qualifications and training certificates.
 - d) Demonstration of sufficient financial resources to ensure the safe conduct of the Regulated Activity for which the Licence is to be granted including the safe Decommissioning of the Facility in which the Regulated Activity is to be

conducted, and the management of the Radiation Sources not intended for further use , and Radioactive Waste resulting from the Regulated Activity.

- e) Demonstration that the Protection and Safety programme for the Facility has adopted Quality Assurance principles and Radiation Protection and Safety features as required in the Safety Assessment as per Article (9) of this regulation including the required staffing as per FANR-REG-24 as amended.
- f) Evidence that the proposed Regulated Activity complies with the requirements established in FANR-REG-09, FANR-REG-10, FANR-REG-24 and FANR-REG-23, where applicable.
- g) Any other supporting document as may be requested by the Authority.

Article (12)

1. In addition to the requirements set forth in Article (11) of this regulation where the Safety Assessment as per Article (9) of this regulation demonstrates that the exposure of either workers or members of the public in abnormal situations has the potential to exceed the respective Dose limits as specified in Articles (10) and (11) of FANR-REG-24 as amended, the applicant for the Licence shall provide the Authority with the following documentation:
 - a) The final report on the installation of the equipment including the Radiation Sources issued by the installation company, where applicable.
 - b) The report on acceptance testing and Commissioning for Operation prepared by an independent third-party recognised Radiation Safety service provider submitted to the Authority within five (5) working days from the day of completion of acceptance testing and Commissioning activities.
 - c) Evidence that the Protection and Safety arrangements are in place, and that the required staff members as per Article (27) of FANR-REG-24 as amended have appropriate knowledge of the arrangements as per the Protection and Safety programme adopting Quality Assurance principles.
 - d) A report (where relevant) on the successful testing on specimens or scale test models for transport packaging issued by a company operated under adequate Quality Assurance programmes.

Request for Additional Information for a Licence Application

Article (13)

1. A Licence applicant for a Regulated Activity within the scope of this regulation shall provide additional information as requested by the Authority within ten (10) working days from the date of the issuance by the Authority of the request for additional information unless otherwise specified in the request.
2. In exceptional circumstances, the Authority may extend the time to respond to its request for additional information.
3. Failure by the applicant to adequately respond to the Authority's request for additional information within the time limits set by paragraphs (1) and (2) of this article may result in the Licence application being rejected.
4. The Authority may stop the review of the application for a Licence if the applicant fails to satisfy the regulatory requirements as set forth in this regulation and in other relevant regulations of the Authority within 60 working days from the date of the submission of the Licence application.
5. When the Authority terminates the licensing process in accordance with paragraph (4) of this article, the Authority shall accept for evaluation a new Licence application from the same applicant after 60 working days from the date of terminating the licensing process.

Amendment to Licensed Regulated Activities

Article (14)

1. Without prejudice to the requirements set forth in FANR-REG-09, FANR-REG-10 and FANR-REG-23, the Licensee shall apply for an amendment of the Licence and provide the Authority with a revised and updated Safety Assessment prior to making the planned modifications, as follows:
 - a) Changing the scope of a licensed Regulated Activity.
 - b) Increasing Dose Constraints for workers or members of the public.
 - c) Modifying Protection and Safety arrangements.
 - d) Modifying the scope of the Facility or its Operation as licensed by the Authority.
 - e) Changing the location of the conduct of the licensed Regulated Activity or the Licensee's name or legal form.

- f) Modifying the inventory specified in the Licence.
2. The Licensee shall obtain an amendment of the Licence before handling a Radiation Source if the integrity of its shielding has been compromised.
3. The Licensee shall notify the Authority of any modification to the Operation of a Facility that needs to be urgently implemented to render the conduct of Regulated Activities safe and secure in accordance with the requirements set forth in other relevant regulations of the Authority. Such modification may require an amendment to the Licence.

IMPORT AND EXPORT

Import and Export of exempted or Registered Radiation Sources

Article (15)

1. Without prejudice to the requirements set forth in FANR-REG-09, FANR-REG-10 and FANR-REG-23, the import and export of Radiation Sources subject to Exemption or registration in accordance with Articles (4), (5), (6) and (7) of this regulation do not require a Licence from the Authority.
2. Evidence of the registration of Radiation Sources with the Authority shall be shared with the relevant national and foreign authorities for the purpose of the import and/ or export of such Radiation Sources.

Import and Export of Regulated Material Subject to a Licence

Article (16)

1. The import and export of any Regulated Material subject to this regulation and not subject to Exemption or registration in accordance with Articles (4), (5), (6) and (7) is a Regulated Activity for which a Licence is required.
2. Without prejudice to the requirements in FANR-REG-09, FANR-REG-10 and FANR-REG-23, the Licensee shall apply to the Authority for approval of the import or export of Regulated Material at least five (5) working days before the expected date of import or export.
3. The import or export of the Regulated Material approved by the Authority pursuant to paragraph (2) of this article shall take place within 60 calendar days from the date of issuance of the approval. The validity of the approval may be extended under special circumstances by the Authority upon request of the Licensee.

4. The Licensee shall notify the Authority of any update in the inventory items' status immediately after and no later than five (5) working days from the date of import or export.

LICENCE RENEWAL AND SURRENDERING

Licence Renewal

Article (17)

1. The Licensee shall submit to the Authority an application for renewal at least 90 days before the expiry date of the Licence.
2. Any proposed modification to the licensed Regulated Activity should be dealt with in accordance with Article (14) of this regulation.

Surrendering or Transferring a Licence

Article (18)

1. A Licensee who intends to surrender a Licence shall provide the Authority with the corresponding application at least 30 days in advance, which shall include, inter alia, the following evidence:
 - a) Demonstration that Decommissioning of the Facility has been completed pursuant to the requirements as set forth in FANR-REG-21, where applicable.
 - b) Demonstration that the Licensee is no longer in possession of Regulated Materials for which the Licence was granted.
 - c) Demonstration that the Licensee has fulfilled all the obligations as set out in the Licence conditions.
2. The Authority may impose additional conditions to be fulfilled before accepting the surrender of the Licence by the Licensee.
3. A Licence, any part hereof, or any right hereunder shall not be transferred or assigned either voluntarily or involuntarily, directly or indirectly.

Updating Information on Licensed Regulated Activities

Article (19)

1. The Licensee shall update the Authority within five (5) working days of any change in information relating to:
 - a) The Facility's location.
 - b) The Facility's contact information.
 - c) The Licensee's contact person.
 - d) Occupationally exposed workers.
 - e) Person(s) responsible for Radiation Safety, Nuclear Security and safeguards, as appropriate.

Collecting a Licence

Article (20)

1. The Authority shall notify the applicant that the Licence is ready for issuance, and shall request that the corresponding Licence fees be paid and the Licence collected within ten (10) working days from the date of notification by the Authority. A Licence will only be issued after the full payment of the abovementioned fees.
2. The applicant shall receive either an electronic copy or a paper copy of the Licence.
3. Failure to pay the fees or to collect the Licence may result in cancellation of the Licence issuing process.
4. The collection of the fees is subject to the Federal Law by Decree No. (15) of 2018 on the Collection of Revenue and Public Funds, and amendments thereto, and the procedures established by the Ministry of Finance.

Entry into Force

Article (21)

This regulation shall be published in the Official Gazette and shall enter into force one (1) month following the date of its publication in the Official Gazette.