
REGULATION

Regulation on Technical Services Related to Radiation Safety (FANR-REG-30)

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Federal Authority for Nuclear Regulation (FANR)
P.O. Box 112021, Abu Dhabi, United Arab Emirates
regulation@fanr.gov.ae

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Preamble

This regulation is issued by the Federal Authority for Nuclear Regulation pursuant to the powers conferred to its Board of Management in Article 11(4) and Article 38(1) of the

Federal Law by Decree No. 6 of 2009 Concerning the Peaceful Uses of Nuclear Energy (the Law).

Definitions

Article (1)

For purposes of this regulation, the following terms shall have the meanings ascribed to them in Article 1 of the Law, unless the context requires otherwise: Authority, Commissioning, Decommissioning, Dose, Facility, Ionising Radiation, Licence, Licensee, Radiation Protection, Radiation Source, Radioactive Material, Regulated Activities and State.

In addition, the following term shall have the meaning set forth below.

Worker(s)	Any person who works full-time, part-time or on a temporary basis for a Licensee, and who has rights and duties in relation to occupational Radiation Protection.
Registrant	Any juridical person that is exempted by the Authority from the licensing requirements of this regulation.

Objectives

Article (2)

1. Pursuant to Article 25(15) of the Law, the provision of technical services relating to radiation safety, as listed in Article 4 of this regulation, shall be designated as a Regulated Activity.
2. This regulation establishes the requirements and criteria for a registration or a Licence from the Authority authorising the provision of technical services relating to radiation safety as well as the requirements applicable to the provision of technical services relating to radiation safety, including any modification or termination thereof.

Scope

Article (3)

1. This regulation shall apply to any juridical person, whether in the public or private sector, which is approved by the competent authorities in the State, planning to provide technical services relating to radiation safety in the State, including its free zones and/or special zones, as well as to any Registrant or Licensee providing technical services relating to radiation safety.

2. This regulation applies to the technical services related to radiation safety listed in the table under Article 4 below. The list of the Registrants or Licensees authorised to provide such technical services along with the list of the technical services related to radiation safety they are authorised to provide will be published by the Authority on its website and will be updated on a regular basis.

List of the Technical Services Related to Radiation Safety

Article (4)

Any of the following services shall be deemed a technical service related to radiation safety:

Category	Technical service(s) related to radiation safety
1. Radiation safety consultancy	a) Planning and modification of the conduct of a Regulated Activity b) Commissioning and Decommissioning of a Facility c) Performance audit of a protection and safety programme
2. Maintenance services	a) Verification of Radiation Sources fitness for use b) Preventative and corrective maintenance of Radiation Sources c) Installation and repair of a Radiation Source
3. Measurement and evaluation of Dose to a Worker or member of the public	a) External individual dosimetry service b) Internal individual dosimetry service
4. Calibration and testing	Calibration and testing of radiation measurement devices
5. Remediation services	Decontamination and conditioning of Radioactive Material and equipment
6. Medical physics services	Performance audit of a medical exposure programme
7. Radiation measurement services	Measurement of Ionising Radiation in the environment and commodities

8. Other	Any other technical services related to radiation safety as determined by the Authority.
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Application for a Registration or Licence

Article (5)

1. Any juridical person, whether in the public or private sector, which is approved by the competent authorities in the State, intending to provide any of the technical services relating to radiation safety listed in Article 4 of this regulation shall be registered with the Authority or shall obtain a Licence from the Authority to do so.
2. A juridical person providing any of the technical services relating to radiation safety specified in the Article 4 of this regulation may be exempted by the Authority from the licensing requirements of this regulations if the said judicial person demonstrates compliance with the criteria set forth in:
 - a) Article 5(1) of the Authority's Regulation on the Basic Safety Standards for Facilities and Activities involving Ionising Radiation other than in Nuclear Facilities(FANR-REG-24), as revised, or
 - b) Article 6 or Article 7(1) of the Authority's Regulation on the Registration and Licensing of Radiation Sources (FANR-REG-29).
3. The applicant for a registration shall demonstrate to the Authority its compliance with Article 5(2) of this regulation. The Authority may request the applicant to submit to the Authority any information specified in Article 5(4) of this regulation in support of its application for registration. Upon evaluation of the application for registration, the Authority shall determine whether the applicant shall apply for a Licence under this regulation.
4. An applicant for a Licence authorizing provision of technical services relating to radiation safety shall submit an application to the Authority in the format specified by the Authority and shall provide, *inter alia*, the following:
 - a) list of the technical services relating to radiation safety, as set forth in Article 4 of this regulation, for authorisation of the conduct of which a Licence application is being submitted,
 - b) list of appointed experts recognised by the relevant standards of professional qualifications applicable in the State, as the case may be, demonstrating the

required professional qualifications and experience in conducting the technical services relating to radiation safety for authorisation of the conduct of which a Licence application is being submitted,

c) methodology and protocols, including quality management arrangements encompassing quality assurance programs and quality control protocols as appropriate, for provision of the technical services relating to radiation safety for authorisation of the conduct of which a Licence application is being submitted,

d) copy of a valid accreditation as per the applicable version of ISO/IEC 17025 standard on "General Requirements for the Competence of Testing and Calibration Laboratories", including the International System of Units (SI) for measurement of radioactivity and Dose evaluation methods as per Article 5(4)(a) of this regulation showing, as applicable, the type of Ionising Radiation, radiation energy range (keV), range of Dose (mSv) and/or Dose rate (mSv/h) and radioactivity (Bq) and activity concentration (Bq/g, Bq/l, Bq/cm²),

e) an undertaking relating to the impartiality in the provision of technical services relating to radiation safety,

f) in case a provider of a technical service relating to radiation safety is located in an entity receiving the said technical service related to radiation safety from the same provider, the applicant for a Licence to authorise conduct of such services at the entity shall demonstrate and the Licensee shall ensure that appropriate arrangements are in place to effectively ensure separation of the technical services relating to radiation safety from other activities conducted at the entity.

Requirements Applicable to a Registrant or Licensee

Article (6)

1. A Registrant shall notify the Authority within three (3) working days of any change to any of the information previously provided to the Authority under the provisions of Article 5(2) and Article 5(3) of this regulation or requested by the Authority. Upon evaluation of the notification the Authority shall determine the appropriate action.
2. A Licensee shall apply to the Authority for an amendment to a Licence and shall be granted by the Authority an amended Licence to be authorised to implement any change the Licensee plans to apply to any of the information previously provided to the Authority under the provisions of Article 5(4)(a)-(e) of this regulation.

3. In case of unplanned changes made by the Registrant or Licensee to any of the information previously provided to the Authority under the provisions of Article 5(4)(a)-(e), or in case of unforeseen circumstances preventing the provision by the Registrant or the Licensee of technical services relating to radiation safety in accordance with the registration with the Authority or with the Licence, the Registrant or the Licensee shall immediately suspend the provision of such services and notify the Authority in writing within three (3) working days of the date of the suspension of provision of such services.
4. To renew a Licence, the Licensee shall submit an application to the Authority at least thirty (30) calendar days before the Licence expiry date.
5. A Licensee shall provide the Authority with evidence of a valid accreditation according to Article 5(4)(d) of this regulation, and shall provide the Authority with the renewed accreditation within five (5) working days of the date of issuance of the renewed accreditation. Failure to submit the valid accreditation shall result (a) in an automatic suspension of the Licence on the due date of the failed submission and (b) in immediate concurrent suspension by the Licensee of provision of the technical services relating to radiation safety the conduct of which is authorised by the said Licence.
6. A Licensee intending to terminate the provision of technical services relating to radiation safety whether through surrendering the Licence or upon the expiry thereof, shall notify the Authority three (3) months before the intended termination of provision of the said services. The Licensee shall also provide evidence that the clients to whom the technical services relating to radiation safety are provided have been notified well in advance about the intended termination of such services to allow them appropriate time to identify alternative licensed providers.
7. A Registrant or Licensee shall retain for a period of at least five (5) years records of the data, information and reports obtained during, or as a result of, the provision of technical services relating to radiation safety.
8. A Registrant or Licensee shall protect all the records of the data, information and reports obtained or collected during, or as a result of, the provision of technical services relating to radiation safety, including results from processing of the collected data, information and reports, and shall restrict access of third persons thereto, in accordance with applicable legislation in the State.
9. A Registrant or Licensee shall provide to the client(s) and the Authority the deliverables of the technical services related to radiation safety in accordance with the Authority's relevant guidelines.

10. A Registrant or Licensee shall reasonably ensure that the clients are not in a position to influence the provision of technical services relating to radiation safety nor modify the deliverables resulting from the provision of such services.
11. A Licensee shall include into the State Dose register maintained by the Authority reports on the measurement and evaluation of the occupational Doses resulting from the conduct of technical services relating to radiation safety in the State.
12. While providing technical services relating to radiation safety, a Registrant or Licensee shall remain impartial by not engaging in any activities that may undermine trust in the Registrant's and Licensee's independence.
13. The provision of technical services relating to radiation safety shall not diminish the prime responsibility of any third party licensed by the Authority for the conduct of any given Regulated Activity.
14. The Registrant or Licensee's management and Workers shall comply with the methodology and protocols, including quality management arrangements encompassing quality assurance programs and quality control protocols, for provision of the technical services relating to radiation safety described in the application for registration or in the Licence application, as the case may be.

Entry into Force

Article (7)

1. 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.
2. Any juridical person, whether in the public or private sector, which is approved by the competent authorities in the State, providing any of the services listed in Article 4 of this regulation at the time of its publication in the Official Gazette shall notify the Authority within six (6) months from the date of entry of this regulation into force about the provision of such services and ensure full compliance with the requirements of this regulation within eighteen (18) months from its entry into force.