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NRRC Technical Regulations

Notification on and Authorization of Facilities and Activities with Radiation Sources

**NRRC-R-02
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هيئة الرقابة النووية والإشعاعية
Nuclear and Radiological Regulatory Commission

Regulation

Notification on and Authorization of Facilities
and Activities with Radiation Sources

2022

NRRC-R-02

Preamble

In accordance with the provisions of the Law of Nuclear and Radiological Control issued by Royal Decree No. (M/82) dated 25/7/1439 AH, and NRRC's Statute issued by the Minsters' Cabinet Resolution No. (334) dated 25 /6/1439 AH, the NRRC prepared regulations that ensure control over radiological activities and practices as well as nuclear and radiological facilities.

This regulation has been prepared on the basis of International Atomic Energy Agency (IAEA) standards, international best practices and the experiences of similar international regulatory bodies, and in accordance with the Kingdom's international commitments. This Regulation has been presented in "the Public Consultation Platform" for the public review, comments, feedback.

This regulation has been approved by the NRRC's Board of Directors in resolution No. (R/1/1/2022), dated 20/04/2022.



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Chapter 1: Objectives, Scope and Definitions

Section 1: Objectives

1. This regulation prescribes the general requirements for notification on and authorization of activities, facilities and practices with radiation source, nuclear material and/or ore containing uranium and thorium in the Kingdom.

Section 2: Scope

2. This regulation applies to notification on or authorization of any:
 - a. Activity or practice with radiation source, nuclear material and/or ore containing uranium and thorium.
 - b. Facility in the Kingdom, with activity or practice in Article 2(a) above, regardless of whether they are fully or partly owned or controlled by a person from another country or by a foreign corporation,
 - c. Provision of services to external facility that require the presence of employees in controlled or supervised areas.
3. This regulation does not apply to:
 - a. Activities, practices, or facilities, with radiation source that are viewed as exempt except nuclear material for safeguards purposes.
 - b. Authorization related to nuclear fuel cycle activity for nuclear installation facility.

- c. Authorization of activity and facility for nuclear related items.

Section 3: Definitions

Applicant

Any person applying to the NRRC for authorization to undertake specified activities. Strictly, an applicant would be such from the time at which an application is submitted until the requested authorization is either granted or refused.

Authorization

A written permission granted by the NRRC for a person to conduct specified activities.

Authorized person

Person granted authorization under this regulation and/or the relevant NRRC Laws.

Nuclear fuel cycle

All operations associated with the production of nuclear energy.

Nuclear intallation

Any nuclear facility subject to authorization that is part of the nuclear fuel cycle, except facilities for the mining or processing of uranium ores or thorium ores and disposal facilities for radioactive waste.

Nuclear Material

Plutonium, Uranium-233, or enriched Uranium in either of the two isotopes

(Uranium-233 or Uranium-235), Uranium containing an admixture of its naturally occurring isotopes, but which is not ore or ore residue, or any other material NRRC classifies as nuclear material. For purposes of the application of nuclear safeguards, nuclear materials shall mean any source material or fissionable material as defined in the relevant the Kingdom signed Safeguards Agreement.

Nuclear-Related Item

Any nuclear or radiological-related substance, commodity, technology, software or data, as well as nuclear and non-nuclear dual-use materials and components that are subject, when used, to specific restrictions, as they are susceptible to be misused.

Ore (mineral)

A mineral or chemical aggregate containing uranium in a quantity and of a quality that makes mining and extracting the uranium and thorium economically viable.

Radioactive Material

Any material from which ionizing radiation is emitted, whether spontaneously or within other equipment, and which is designated as subject to the control of the NRRC, including naturally occurring radioactive material.

Submission

The process of submitting any document related to notification on and authorization of facilities, activities and practices through a mechanism specified by NRRC.

Chapter 2: Notification on Facilities and Activities

Section 4: Notification Prior to Authorization Requirements

4. Any person intending to establish a facility or carry out any activity or practice as prescribed in Article 2 of this regulation shall notify the NRRC of such intention as early as possible to initiate the authorization process.
5. In case that the person from the beginning applies to the NRRC to be granted authorization, the application shall be considered as a notification.
6. For the purpose of submission of notification, the applicant shall provide the information as specified by the NRRC.
7. When the NRRC concludes, following a notification, that the risk associated with the activity or practice with a radiation source cannot be neglected in terms of radiation safety or security of radioactive material or is a subject to safeguards requirements, the applicant shall proceed further for authorization.
8. The NRRC shall be notified of any change that may increase the safety or security risk associated with the practices or the possession of radiation sources or changes to safeguards information prescribed by the NRRC for which a notification confirmation under Article 6 has been issued.



Section 5: Other Notification Requirements

9. Any person intending to use the territory of the Kingdom for transit of radioactive material, nuclear material and/or ore containing uranium and thorium within the Kingdom shall submit a notification to the NRRC.
10. The authorized person intending to import or export radiation generators to the Kingdom shall submit a notification to the NRRC.
11. The NRRC may prescribe the submission of any other notifications necessary to carry out the provisions of this regulation.

Chapter 3: Authorization of Facilities and Activities

Section 6: Pre-authorization Engagement

12. The applicant shall be subject to the pre-authorization engagement process as part of the authorization process, depending on the complexity of the activity or facility.

Section 7: Types of Authorization

13. The types of authorization that the NRRC grants are:
 - a. Registration: permission granted for activities and/or facilities with low or moderate risk of exposure and for which operations do not vary significantly provided that:
 - i. Safety and security can largely be ensured by the design of the facilities and equipment;

- ii. The operating procedures are simple to follow;
 - iii. The training requirements for safety and security are minimal; and
 - iv. There is an insignificant history of problems relating to safety and security during operations.
- b. License: permission granted for activities and/or facilities with a higher risk of exposure necessitating more complex operations and consequently a detailed assessment of the nature magnitude and likelihood of potential exposures, and any concern related to peaceful uses of nuclear material specified by the NRRC.
 - c. Permit: permission granted for the transaction of authorized activities involving import, export, or transfer of the ownership of radiation sources, nuclear material, and/or ore containing uranium and thorium.
 - d. Approval: permission granted for specific activities associated with the transport of radioactive material.
14. In addition to the authorization applied by the applicant based on each individual facility and/or activity, the NRRC may require an application for a different or additional authorization(s) in order to carry out the purposes of this regulation.
15. Notwithstanding Article 14, the applicant shall follow the NRRC instructions about the associated authorization process and the required information and supporting documents to be submitted.



Section 8: General Provisions for Authorization

16. At any time, no person shall initiate any activity at any facility that contains a radiation source, nuclear material or ore containing uranium and thorium without first obtaining a valid authorization from the NRRC.
17. When submitting an application for authorization, the applicant shall provide the NRRC with the information and supporting documents required by this regulation, as well as any additional information as prescribed by the NRRC.
18. The applicant shall submit the requirements prescribed in Article 17 through the designated mechanism requested by the NRRC.
19. The submission required by Article 17 shall be in a language that enables an accurate assessment of the applicable safety, security, and safeguard provisions applicable to the facilities and activities to be authorized by the NRRC.
20. Upon submission, the applicant is subject to the requirements as specified in the proof of submission issues by the NRRC.
21. The applicant shall ensure completeness and correctness of submission at all times.
22. Regardless of whether the applicant satisfies the requirement in Article 21, the applicant is responsible for ensuring the validity of the documents submitted.

23. As part of the authorization process, the authorized person shall provide:
- a. A proof of payment of the necessary fees, as prescribed by NRRC;
 - b. Additional information from the applicant as deemed necessary to facilitate the decision-making process; and
 - c. An on-site inspection of the applicant's premise, if so, required by the NRRC.
24. If the applicant is unable to comply with the requirements of Article 23, the NRRC reserves the right to halt the evaluation process and reject the application for authorization.
25. At any time, the applicant shall have the right to request for cancellation aftersubmission.
26. The authorization shall be granted only when safety and security are ensured by the applicant.
27. The authorization shall be granted upon the applicant's legal representative submitting a satisfactory application to the NRRC.
28. At all times, the authorized person shall adhere to the NRRC's requirements and conditions for authorization.
29. The authorized person shall adhere to the validity period of the authorization granted by the NRRC.



30. The operation of facilities and the application of activities after the expiration of corresponding authorization are prohibited.
31. The NRRC reserves the right to deny an authorization in the following circumstances:
 - a. Unjustified activities;
 - b. Non-compliance to other requirements established by NRRC;
 - c. Radiation protection and radiological safety are not ensured;
 - d. Security of nuclear and radioactive material is not ensured;
 - e. Safeguard requirements related to nuclear material and/or ore containing uranium and thorium are not being met; and
 - f. In the absence of proof of payment of the required fees, as prescribed by regulations made under the law.
32. If the NRRC declines to grant an authorization, the applicant may submit a new application for an authorization.
33. In addition to the requirements prescribed in this section, authorization through licensing of facilities shall cover the following phases of facilities' entire lifetime:
 - a. Preoperational phase, which includes siting, design, construction, testing, and commissioning;
 - b. Operational phase; and

- c. Closure phase, which includes decommissioning, closure (for waste disposal facilities), and final clearance of the activities and/or facilities.

Chapter 4: Pre-operational Phase for Facilities

Section 9: Licensing during Pre-operational Phase

34. Any person intending to conduct the following activities during the pre-operational phase shall apply for a specific license for site preparation, construction, testing or commissioning of the associated facility:
 - a. Activity and facility related to nuclear material other than for nuclear installation;
 - b. X-ray generators and particle or ion accelerators within specification as prescribed by the NRRC;
 - c. Use of radioactive sources category 1 and category 2 as defined in the Regulation on Radiation Safety (NRRC-R-01);
 - d. Radionuclides production using particle accelerators and accelerators using energy sources within the specification as prescribed by the NRRC;
 - e. Where the implemented practices are novel, complex, or associated with increased risks in terms of radiological safety for the population or the environment;



- f. Operating more than one facility and/or executing more than one activity in the same site, with each of them being likely to impact the level of radiation safety or security of the others;
 - g. Any other facilities not listed in Article 34 (a) to (f) taking into consideration of safety and security aspects as deemed necessary.
35. When applying for a license during the pre-operational phase of a facility, the applicant shall ensure submission as specified by the NRRC for that respective phase.

Chapter 5: Operational Phase for Facilities

Section 10: Authorization of Facilities and Activities

36. Any person intending to initiate the application of activities and operation of facilities with radiation source, nuclear material and/or ore containing uranium and thorium shall obtain a valid authorization for the respective purposes.
37. The operation of facilities and/or the execution of activities with radiation source, nuclear material and/or ore containing uranium and thorium are subject to authorization through either registration or licensing.
38. When applying for an authorization, the applicant shall ensure submission as prescribed by the NRRC based on:
- a. The risks associated with radiation safety and security for the facilities and activities;

- b. The regulatory measures apply that shall reduce risks from the potential impact and/or improving radiation safety and security; and
 - c. The applicable safeguard requirements.
39. The authorized person shall adhere to the conditions in the authorization document issued by the NRRC.

Chapter 6: Closure Phase for Facilities

Section 11: License for Decommissioning of Facilities

40. The authorized person intending to initiate the decommissioning of a facility with radiation sources shall obtain a valid license for the respective purposes.
41. When applying for a license, the applicant shall ensure submission as prescribed by the NRRC based on:
- a. The risks associated with radiation safety and security for the facilities and activities;
 - b. The regulatory measures apply that shall reduce risks from the potential impact and/or improving radiation safety and security; and
 - c. The nuclear material information that are subject to safeguards requirements.



42. The authorized person shall adhere to the conditions in the license document issued by the NRRC.

Section 12: License for Closure of Facilities

43. The authorized person intending to close a waste disposal facility with radiation sources shall obtain a valid license for the respective purposes.
44. When applying for a license, the applicant shall ensure that submission is done as prescribed by the NRRC based on:
- a. The risks associated with radiation safety and security for the facilities;
 - b. The regulatory measures apply that shall reduce risks from the potential impact and/or improving radiation safety and security;
 - c. The nuclear material information that are subject to safeguards requirements; and
 - d. The activities planned for the period after closure.
45. The authorized person shall ensure that the disposal facility will be closed in accordance with the conditions set in the authorization, with consideration given to any changes in responsibility that may occur at this stage.

Chapter 7: Permits

Section 13: General Requirement for Permit Application

46. Any person intending to conduct the following activities shall obtain a valid permit from the NRRC regardless of any other possession of valid authorizations:
- a. Import or export of radioactive material, nuclear material and ore containing uranium and thorium,
 - b. Transfer the ownership of radiation source, nuclear material and ore containing uranium and thorium.
47. Authorization through permit for activities other than those listed in Article 46 shall be determined by the NRRC on a case-by-case basis.
48. When applying for a permit, the applicant shall ensure submission as prescribed by the NRRC.

Section 14: Permit for Import and Export

49. A valid permit shall be required to import and/or export radioactive material, nuclear material and/or ore containing uranium and thorium through and into the Kingdom.
50. The requirements for activities with radiation sources apply to import and export of radioactive material, nuclear material and ore containing uranium and thorium.

Section 15: Permit to Transfer the Ownership

51. A valid permit shall be required to transfer the ownership of radiation source, nuclear material and/or ore containing uranium and thorium.
52. The authorized person intending to transfer the ownership of radiation source, nuclear material and/or ore containing uranium and thorium under his possession shall apply for a permit from the NRRC.
53. The authorized person intending to transfer ownership of radiation source, nuclear material and/or ore containing uranium and thorium shall only transfer to another authorized person by the NRRC.

Chapter 8: Approvals

Section 16: General Requirement for Approval Application

54. Any person intending to conduct the following activities related to transport of radioactive material shall request the approval from the NRRC:
 - a. Approval of special-form radioactive material.
 - b. Approval of low dispersible radioactive material.
 - c. Approval of material excepted from fissile classification.
 - d. Approval of package designs.
 - e. Approval of alternative activity limits for an exempt consignment of instruments or articles.
 - f. Approval of Shipments under special arrangement.

55. When applying for an approval associated to transport of radioactive material, nuclear material and ore containing uranium and thorium, the applicant shall submit to the NRRC the information and supporting documents which are defined in the transport regulation prescribed by the NRRC.
56. The NRRC may prescribe any other authorization through approval for activities and facilities other than those prescribed in Article 54, subject to assessment of safety, security and safeguard prescribed by the NRRC.

Chapter 9: Amendment to Authorization

57. An amendment to authorization shall be required for:
- a. Modifications to the authorized facilities and/or activities (constructional, operational, or organizational) that may have an impact on radiation safety and security of radioactive material and safeguard of nuclear material or ore containing uranium and thorium;
 - b. Changes concerning issues such as personnel, roles and responsibilities, inventory of radiation sources, applied activities, etc.;
 - c. Changes concerning the discharge of radioactive material into the environment; and
 - d. Changes concerning the clearance of radioactive material.



58. When requesting an amendment to an authorization, the applicant shall ensure that all submissions required by the NRRC are made regarding the affected facilities and/or activities.
59. Upon evaluation of the application for the amendment of an authorization, the NRRC may consider termination of the existing valid authorization and request applicant to apply for a different type of authorization.
60. The NRRC may grant an amendment to an authorization only after concluding that radiation safety, radioactive material security, and safeguard requirements are met, and this conclusion has been verified through inspection, as necessary.

Chapter 10: Renewal, Suspension, Revocation, and Termination of Authorization

Section 17: General Provisions

61. The operation of facilities and application of activities for which authorization is suspended or revoked are prohibited.
62. The suspension or revocation of authorization:
 - a. Does not exempt the authorized person from the requirement to comply with the conditions outlined in the authorization.
 - b. Is independent of any additional enforcement actions or other legal implications imposed by the Law.

Section 18: Renewal of Authorization

63. The updated versions of the documents used to support the initial request for authorization, shall be submitted during application for authorization renewal, as applicable.
64. In addition to the information and supporting documents submitted for authorization renewal, the applicant shall submit the following to the NRRC:
- a. A report summarizing possible nonconformities and associated corrective actions that have taken place;
 - b. Adopted optimization measures;
 - c. An evaluation of individual and workplace monitoring results; and
 - d. Any additional information required to assess radiation safety and security past performance.
65. The application for renewal of authorization shall be submitted to the NRRC no later than three (3) months before the end of the authorization's validity period or at the time frame determined by the NRRC.
66. The NRRC, after evaluating the information and supporting documents for the renewal of an authorization may request a different type of authorization than that initially granted to the applicant.



67. Renewal to authorization is granted after the NRRC concludes that safety and security are ensured, safeguard requirements are complied, and the conclusion has been verified by inspection if required.
68. The validity period of a renewed authorization:
- a. May differ from that of the initial authorization granted; and
 - b. Is subject to NRRC modification based on the facility's previous performance and the radiological safety and security level achieved.
69. If the authorization of a facility and/or activity expires, the application shall be submitted to the NRRC for:
- a. A new authorization; or
 - b. The termination of the authorization.

Section 19: Suspension of Authorization

70. The NRRC may suspend authorization wholly or partly if:
- a. It is deemed that continued activity under the authorization would pose an unacceptable risk to people or the environment;
 - b. In the event of the following noncompliance:
 - i. Failure to satisfy to one or more of the conditions of authorization.
 - ii. Submission of invalid information.

- iii. Failure to comply with legal and regulatory obligations.
71. If authorizations are granted for several facilities and/or activities, the suspension shall apply to each facility and/or activity in accordance with Article 70 (a) and (b).
72. Upon notification from NRRC on the intention to suspend the authorization, along with the rationale for the suspension, the authorized person shall implement necessary corrective actions in response to the notification.
73. The authorized person shall comply to the grace period provided by the NRRC to take the necessary corrective actions before further decision to suspend the authorization is taken by the NRRC.
74. Within the defined grace period, a report shall be submitted to the NRRC that includes actions taken in response to the reasons leading to the suspension of the authorization and the associated results.
75. The NRRC may prolong the grace period to allow for the completion of the necessary corrective actions.
76. The authorization shall be suspended if the corrective actions taken in response to the notification in Article 72 deems to be insufficient.
77. The suspension of authorization shall be lifted if satisfactory corrective measures are completely taken by the authorized person.

Section 20: Revocation of Authorization

78. If the authorized person further fails to take sufficient corrective actions for a period exceeding three (3) months after the suspension of the authorization, the NRRC may revoke authorization for the facility and/or activities for which the authorization previously was suspended.
79. The authorization of facilities or activities may be revoked without prior suspension for the following reasons:
- a. An incident or accident associated with authorized activities significantly impacts radiological safety.
 - b. Any modifications to authorized facilities and/or activities which are associated with a significant radiological risk.
 - c. Any modifications to authorized facilities and/or activities which are associated with a significant nuclear security threat or deficiency in the security measures.
 - d. Any modifications to authorized facilities and/or activities which affecting compliance with safeguards requirements.
 - e. The authorized person permanently fails to comply with all legal and regulatory obligations.
 - f. The authorized person permanently fails to satisfy one or more of the conditions for granting the authorization.
80. The NRRC can revoke authorization if it presents associated reasoning.

81. To restart facilities and/or activities for which authorization was revoked, the person shall apply to the NRRC for a new authorization and submission of authorization requirement.

Section 21: Termination of Authorized Facilities and Activities

82. The authorized person intends to terminate operation of an authorized facility and/or an authorized activity shall apply and submit the following to the NRRC for termination of the respective authorization:
- a. A statement that specifies the termination date for the facility and/or activity, and the associated reasoning.
 - b. A decommissioning report, if applicable.
83. Termination of an authorized facility and/or activity without prior authorization from the NRRC constitutes a violation to this regulation.

Chapter 11: Appeals

84. Any applicant or authorized person against whom a decision has been issued by the NRRC may appeal against such decision as prescribed by the NRRC.

Chapter 12: Fees

85. The fees for the authorization shall be paid as prescribed by the NRRC.

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