NRRC Technical Regulations

Notification on and Authorization of Facilities and Activities with Radiation Sources

NRRC-R-02 Rev. 0.1



هيئة الرقابة النووية والإشعاعية Nuclear and Radiological Regulatory Commission



Notification on and Authorization of Facilities and Activities with Radiation Sources

C Nuclear and Radiological Regulatory Commission, 2024

Commission · Nuclear and Radiological Regulatory NRRC-R-02 Rev. 0.1 Notification on and Authorization of Facilities and Activities with Radiation Sources. / Commission · Nuclear and Radiological Regulatory. - Riyadh, 2024

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L.D. no. 1446/5720 ISBN: 978-603-8492-01-7



Regulation

Notification on and Authorization of Facilities and Activities with Radiation Sources

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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 Ministers' 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 in accordance with the Kingdom's international commitments. This regulation has been presented in "the Public Consultation Platform" for the public review, comments, and feedback.

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

This edition, NRRC-R-02 Rev. 0.1 (2024), of the regulation is revised and takes precedence over the previous publication, NRRC-R-02 (2022). In addition, the changes within this revision are editorial.



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Chapter 1: Objective, Scope, and Definitions

Section 1: Objective

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

Section 2: Scope

- 2. This regulation applies to notification or authorization of the following:
 - a. Activity or practice with a radiation source, nuclear material, and/or ore containing uranium or thorium;
 - 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 a service to an external facility that requires the presence of employees in controlled or supervised areas.
- 3. This regulation does not apply to the following:
 - Activities, practices, or facilities with radiation sources that are viewed as exempt, with the exception of nuclear material for safeguards purposes;
 - b. Authorization related to nuclear fuel cycle activity for nuclear installations;
 - 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 Installation

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 the 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 Safeguards Agreement signed by the Kingdom.



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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 or thorium in quantity and of quality that makes mining and extracting the uranium or 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 and authorization of facilities, activities, and practices through a mechanism specified by the NRRC.

Chapter 2: Notification of 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 specified 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 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 notification submittal, the applicant shall provide the information as specified by the NRRC.
- 7. When the NRRC concludes, following a notification submittal, 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 subject to safeguards requirements, the applicant shall proceed further for authorization.

8. The NRRC shall be notified of any change that may increase the radiation safety or security risk associated with the operation 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 Kingdom's territory for the transit/import/export of radioactive material, nuclear material, and/or ore containing uranium or thorium within the Kingdom shall submit a notification to the NRRC.
- 10. Any person intending to import or export radiation generators to the Kingdom shall submit a notification to the NRRC.
- 11. The NRRC may require 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:



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- i. The radiation 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 radiation safety and security are minimal; and
- iv. The history of issues related to radiation safety and security during operations is insignificant.
- b. License: permission granted for activities and/or facilities with a higher risk of exposure requiring 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 radioactive and nuclear materials as specified by the NRRC.
- c. **Permit:** permission granted for the transaction of authorized activities involving the import, export, or transfer of the ownership of radiation sources, nuclear material, and/or ore containing uranium or thorium.
- d. **Approval:** permission granted for specific activities and facilities associated with the transport of radioactive material or any other activities and facilities subject to an assessment of radiation safety, security, and safeguard as specified by the NRRC.
- 14. In addition to the authorization applied by the applicant based on each individual facility and/or activity, the NRRC has the authority to require different or additional authorization(s) from the applicant in order to carry out the purpose of this regulation.
- 15. Notwithstanding Article 14, the applicant shall follow 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 or thorium without first obtaining 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 specified by the NRRC.
- 18. The applicant shall submit the information prescribed in Article 17 through designated mechanisms specified by the NRRC.
- 19. The submission required by Article 17 shall be in a language that enables an accurate assessment of the applicable radiation 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 issued by the NRRC.
- 21. The applicant shall always ensure completeness and correctness of submission.
- 22. Apart from the applicant satisfying the requirement in Article 21, the applicant shall be responsible for ensuring the validity of the documents submitted to the NRRC.
- 23. As part of the authorization process, the applicant shall provide:
 - a. A proof of payment of the applicable fees, as established by the NRRC;
 - b. Additional information from the applicant as deemed necessary to facilitate the decision-making process;
 - c. An on-site assessment of the applicant's premise, as applicable according to a graded approach.

- 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 cancellation after submission.
- 26. The authorization shall be granted only when radiation safety and security are ensured by the applicant.
- 27. The authorization shall be granted upon the submittal of a satisfactory application to the NRRC by the applicant's legal representative.
- 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 conduct of an activity and the operation of a facility after the expiration of the corresponding authorization are prohibited.
- 31. The NRRC reserves the right to deny an authorization in any one of the following circumstances:
 - a. Unjustified activities;
 - b. Non-compliance with other requirements established by the NRRC;
 - c. Radiation protection and radiation 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 or thorium are not met;
 - f. In the absence of proof of payment of the required fees, as established by regulations made under the Law.

- 32. If the NRRC declines to grant authorization, the applicant may submit a new application for authorization.
- 33. In addition to the requirements established by this section, authorization through licensing of facilities shall cover the following phases of facilities' entire lifetime:
 - a. Pre-operational phase, which includes siting, design, construction, testing, and commissioning;
 - b. Operational phase;
 - 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 preoperational 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 nuclear installation;
 - b. Use of 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 Rev. 0.1);
 - 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 radiation 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 activities not listed in Article 34 (a) to (f), taking into consideration radiation safety and security aspects as deemed necessary.
- 35. When applying for a license related to a facility's pre-operational phase, the applicant shall ensure the submission of documentation as specified by the NRRC for that respective phase.

Chapter 5: Operational Phase for Facilities

Section 10: Authorization of Facility and Activity

- 36. Any person intending to initiate the application of activities and operation of facilities with radiation sources, nuclear materials, and/or ores containing uranium or thorium shall obtain valid authorization for the respective purposes.
- 37. The operation of a facility and/or the execution of an activity with a radiation source, nuclear material, and/or ore containing uranium or thorium is subject to authorization through either registration or licensing.
- 38. When applying for authorization, the applicant shall ensure the submission of documentation as specified by the NRRC based on the following:
 - a. The risks associated with radiation safety and security for the facility and activity;
 - b. The applied regulatory measures that shall reduce risks from the potential impact and/or improve radiation safety and security;



- 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 the submission of documentation as specified by the NRRC based on the following:
 - a. The risks associated with radiation safety and security for the facility and activity;
 - b. The applied regulatory measures that shall reduce risks from the potential impact and/or improve radiation safety and security;
 - c. The nuclear material information that is subject to requirements for safeguards.
- 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 the submission of documentation as prescribed by the NRRC based on the following:
 - a. The risks associated with radiation safety and security for the facility;

- b. The applied regulatory measures that shall reduce risks from the potential impact and/or improve radiation safety and security;
- c. The nuclear material information that is subject to requirements for safeguards.
- 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 stipulated by the authorization documents, accounting for any changes in responsibility that may occur during this stage.

Chapter 7: Permits

Section 13: General Requirements 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 or thorium,
 - b. Transfer of ownership of radiation source, nuclear material, and ore containing uranium or 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 the submission of documentation as specified by the NRRC.

Section 14: Permit for Import and Export

49. A valid permit shall be required for the import and/or export of radioactive material, nuclear material, and/or ore containing uranium or thorium through and into the Kingdom.

50. The requirements for activities with radiation sources apply to the import and export of radioactive materials, nuclear materials, and ores containing uranium or thorium.

Section 15: Permit to Transfer the Ownership

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

Chapter 8: Approvals

Section 16: General Requirements for Approval Application

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



- 55. When applying for approval associated with the transport of radioactive material, nuclear material, and ore containing uranium or thorium, the applicant shall submit to the NRRC the information and supporting documents that are defined in the Regulation on Safe Transport of Radioactive Materials (NRRC-R-15 Rev. 0.1).
- 56. The NRRC may specify any other authorization through approval for activity and facility other than those identified in Article 54, subject to an assessment of radiation safety, security, and safeguard as specified by the NRRC.

Chapter 9: Amendment to Authorization

- 57. An amendment to authorization shall be required for the following:
 - Modifications to the authorized facility and/or activity, including constructional, operational, or organizational modifications, that may have an impact on radiation safety and security of radioactive material and safeguard of nuclear material or ore containing uranium or thorium;
 - b. Changes concerning issues such as personnel, roles and responsibilities, inventory of radiation sources, nuclear material, applied activities, etc.;
 - c. Changes concerning the discharge of radioactive material into the environment;
 - d. Changes concerning the clearance of radioactive material.
- 58. When requesting an amendment to an authorization, the applicant shall ensure that the submission of all documents required by the NRRC is made regarding the related facility and/or activity.
- 59. Upon the evaluation of the application for the amendment of an authorization, the NRRC reserves the right to consider the termination of the existing valid

authorization and requires the 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, security of radioactive material, and safeguard requirements are met and this conclusion has been confirmed through inspection, as applicable.

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

Authorization

Section 17: General Provisions

- 61. The operation of facilities and conduct of activities for which authorization is suspended, revoked, or terminated shall be 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 the 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;
- d. Any additional information required to assess radiation safety and security past performance.
- 65. The application for authorization renewal shall be submitted to the NRRC no later than three (3) months before the end of the authorization's validity period or within the time frame determined by the NRRC.
- 66. The NRRC, after evaluating the information and supporting documents for the renewal of an authorization, may require a submittal of a different type of authorization than the one initially granted to the applicant.
- 67. Authorization renewal is granted after the NRRC concludes that radiation safety and security are ensured, safeguard requirements are fulfilled, and the conclusion has been confirmed by inspection as applicable according to a graded approach.
- 68. The validity period of a renewed authorization:
 - a. May differ from that of the initial authorization granted;
 - b. Is subject to NRRC modification based on the facility's previous performance and the radiation safety and security level achieved.
- 69. If the authorization of a facility and/or activity expires, an application shall be submitted to the NRRC for:
 - a. A new authorization; or
 - b. A termination of the authorization.



Section 19: Suspension of Authorization

70. The NRRC has the authority to suspend authorization wholly or partly if:

- It is deemed that continued activity under the authorization would a. pose an unacceptable risk to the people or the environment;
- b. In the event of the following noncompliance:
 - Failure to satisfy one or more of the conditions of i. authorization.
 - Submission of invalid information. ii.
 - Failure to comply with the Commission Laws. iii.
- 71. If authorizations are granted for several facilities and/or activities, the suspension shall apply to each facility and/or activity separately in accordance with Article 70.
- 72. Upon receiving a notification from the NRRC indicating the intention to suspend the authorization, along with the justification for the suspension, the authorized person shall implement necessary corrective actions in response to the notification.
- 73. The authorized person shall comply with the grace period provided by the NRRC to perform the necessary corrective actions before further decision to suspend the authorization is issued 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 has the authority to extend 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 are deemed to be insufficient.



77. The suspension of authorization shall be lifted if satisfactory corrective measures are implemented by the authorized person, as determined by the NRRC.

Section 20: Revocation of Authorization

- 78. If the authorized person further fails to take the required corrective actions for a period exceeding three (3) months after the suspension of the authorization, the NRRC has the authority to revoke authorization for the facility and/or activity for which the authorization was previously suspended.
- 79. The NRRC has the authority to revoke the authorization of a facility or activity without prior suspension for the following reasons:
 - a. An incident or accident associated with an authorized activity significantly impacts radiation safety;
 - b. Any modifications to authorized facility and/or activity that are associated with a significant radiation risk;
 - Any modifications to authorized facility and/or activity that are associated with a significant nuclear security threat or deficiency in the security measures;
 - d. Any modifications to authorized facility and/or activity that adversely affect compliance with safeguards requirements;
 - e. The authorized person permanently fails to comply with requirements stipulated by the NRRC under the Commission Laws;
 - 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 a facility and/or activity for which authorization was revoked, the former authorized person shall apply to the NRRC for new authorization and

submit the required documentation to fulfill the requirements of the relevant regulations.

Section 21: Termination of Authorized Facilities and Activities

- 82. The authorized person who intends to terminate the operation of an authorized facility and/or activity shall apply and submit the following to the NRRC for termination of the respective authorization:
 - a. A statement specifying 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 shall be deemed as a violation of 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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Commission · Nuclear and Radiological Regulatory NRRC-R-02 Rev. 0.1 Notification on and Authorization of Facilities and Activities with Radiation Sources. / Commission · Nuclear and Radiological Regulatory. - Riyadh, 2024

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L.D. no. 1446/5720 ISBN: 978-603-8492-01-7



