NRRC Technical Regulations

Authorization and Regulatory Control of Nuclear-Related Items

NRRC-R-18 2022



هيئة الرقابة النووية والإشعاعية Nuclear and Radiological Regulatory Commission

NRRC-R-18 -

Regulation

Authorization and Regulatory Control of Nuclear-Related Items

2022 NRRC-R-18

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 Statue 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 : Objective, Scope and Definitions

Section 1: Objective

 This regulation provides the regulatory requirements for control of nuclear related items and the responsibilities of the person conducting related activities, for the purpose of non-proliferation of nuclear weapons.

Section 2: Scope

- 2. This regulation applies to the development, production, import, export, re-export, transfer, transit, trans-shipment of nuclear related items, including technology and software, and any other activities related to non-proliferation of nuclear weapons, as prescribed by the NRRC for the purpose of this regulation.
- 3. This regulation prescribes requirements for notification, authorization and control of activities prescribed in Article 2.
- 4. Authorization of nuclear facilities, nuclear materials and radioactive materials are prescribed in other regulations by the NRRC.

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.

Development

All phases before "production" such as design, design research, design analysis, design concepts, assembly and testing of prototypes, pilot production schemes, design data, process of transforming design data into a product, configuration design, integration design and layouts.

Dual-use materials and components

Any material or component which has a technical use in both nuclear and non-nuclear applications and is subject to certain conditions of supply because such material or equipment could make a major contribution to a nuclear explosive activity.

Internal Compliance Program (ICP)

A set of internal control measures, including processes and procedure, required for monitoring compliance with the provisions of this regulation.

Non-Proliferation

Refers to the effort to eliminate the spread of nuclear weapon and its technology.

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Production

All production phases such as production engineering, manufacture, integration, assembly (mounting), inspection, testing and quality assurance, except construction.

Re-export

The export of nuclear related items, which were originally imported.

Software

A set of instructions, data, or programs used to operate a computer and execute specific tasks.

Submission

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

Technology

Specific information required for the "Development", "Production", or "Use" of any nuclear related item. This information may take the form of "Technical Data", or "Technical Assistance".

Technical Assistance

May take forms such as: instruction, skills, training, working knowledge, consulting services.

Technical Data

May take forms such as blueprints, plans, diagrams, models, formulae,

engineering designs and specifications, manuals and instructions written or recorded on other media or devices such as disk, tape, read-only memories.

Transfer

Any transfer of ownership or control of nuclear related items between authorized persons in the Kingdom.

Transit

Transport of nuclear related items through the territory of the Kingdom where the nuclear related items remain on board the original means of transport (e.g., vessel or aircraft).

Trans-shipment

Transport of nuclear related items through the territory of the Kingdom where the nuclear related items are unloaded from one means of transport and loaded on to another means of transport (e.g., from a vessel to an aircraft).

Chapter 2 : Notification on Activities

Section 4: General Requirements for Notification

- 5. Any person intending to carry out an activity prescribed in Article 2 shall notify the NRRC of such intention as early as possible prior to initiation of the activity.
- 6. For submission of notification, the applicant shall provide the information as specified by the NRRC.

- Related activities dealing with nuclear dual-use materials and components shall be subject to notification requirements under this regulation.
- 8. Any person, upon receiving authorization, shall notify the NRRC for any changes to the activities and its status as prescribed by the NRRC.

Chapter 3 : Activitieszation of Activities

Section 5: General Provisions for Authorization

- 9. At any time, no person shall initiate any activity without holding a valid authorization issued by the NRRC.
- 10. When applying for authorization, the applicant shall submit to the NRRC the information and supporting documents required by this regulation including any other supplementary information as prescribed by the NRRC.
- 11. The applicant shall submit the requirements set forth in Article 9 through the designated mechanism requested by the NRRC.
- 12. The submission as prescribed in Article 9 shall be in a language that enables the NRRC to conduct an adequate evaluation of the activities to be authorized.
- 13. As part of the authorization process, the following shall be provided:
 - a. A proof of payment of the necessary fees, as prescribed by regulations made under the Law;

- b. Additional information from the applicant as deemed necessary to facilitate the decision-making process; and
- c. A meeting with the applicant's legal representatives.
- 14. In case the applicant is not able to comply with the requirements in Article 12, the NRRC has the right to cancel the evaluation process and reject the application for authorization.
- 15. The applicant shall always have the right to request for cancellation after submission.
- 16. The authorization shall be granted upon the applicant's legal representative submitting a satisfactory application to the NRRC in accordance with this regulation.
- 17. At all times, the authorized person shall comply to the requirements and conditions of the authorization granted by the NRRC.
- The NRRC has the right to refuse granting an authorization, in any of the following cases:
 - a. Unjustified activities;
 - b. Non-compliance to the NRRC relevant requirements; or
 - c. In the absence of proof of payment for the necessary fees, as prescribed by regulations made under the Law.
- 19. In case the NRRC refuses to grant an authorization, the applicant may submit a new application in accordance with Article 9.

20. Based on each individual activity for which the applicant intends to apply, the NRRC may request different or additional authorization(s).

Section 6: Amendment to Authorization

- 21. Authorized person may apply to amend its authorization when there is a modification to the authorized activities, subject to the NRRC approval.
- 22. The applicant shall ensure submission as required by the NRRC related to, the concerned activities when requesting an amendment to authorization.
- 23. Upon evaluation of the application for the amendment of an authorization, the NRRC may consider termination of the existing valid authorization and requesting that the applicant apply for a different type of authorization.

Section 7: Renewal of Authorization

- 24. 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.
- 25. The applicant shall submit the information and supporting documents for authorization renewal, and a report summarizing any possible nonconformities and associated corrective actions that have taken place.

- 26. 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.
- 27. Renewal of authorization is granted only after the NRRC concludes that all requirements prescribed under this regulation have been met, and this conclusion has been verified by inspection if required.
- 28. 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 authorized person's previous performance.
- 29. If the authorization of the authorized person and/or activity expires, an application shall be submitted to the NRRC for:
 - a. A new authorization; or
 - b. The termination of the authorization.

Section 8: Suspension of Authorization

- 30. The NRRC may suspend authorization wholly or partially in the event of the following non-compliance:
 - a. Failure to comply with one or more of the conditions of authorization.
 - b. Submission of invalid information.
 - c. Failure to comply with requirements made under this regulation.

- 31. The authorized person shall comply to the period (grace period) provided by the NRRC to take the necessary corrective actions before further decision to suspend the authorization is taken by the NRRC.
- 32. Within the defined grace period, a report shall be submitted to the NRRC that details actions taken in response to the reasons leading to the suspension of the authorization and the associated results.
- 33. The NRRC may prolong the grace period to allow for the completion of the necessary corrective actions.
- 34. The authorization to be suspended if the corrective actions taken by the authorized person are determined by the NRRC to be insufficient.
- 35. The suspension of authorization to be lifted if satisfactory corrective measures are satisfactorily taken by the authorized person.

Section 9: Revocation of Authorization

- 36. 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 activities for which the authorization previously was suspended.
- 37. The NRRC can revoke authorization of activities without prior suspension subject to regulatory judgement of the consequences of the non-compliance action done by the authorized person.
- 38. To resume activities for which authorization was revoked, the person shall apply to the NRRC for a new authorization and submit the authorization requirements.

Section 10: Termination of Authorized Activities

- 39. The authorized person intends to terminate an authorized activity shall apply to the NRRC for termination of the respective authorization and submit to the NRRC a statement specifying the termination date for the activity, the associated reasoning, any possible consequences and associated corrective actions.
- 40. Termination of an authorized activity without prior authorization from the NRRC is a violation of this regulation.

Chapter 4 : Appeals

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

Chapter 5 : Fees

42. The fees for the services provided by the NRRC during the authorization process shall be paid by the applicant as prescribed by the NRRC.

Chapter 6 : Authorized Person obligations

Section 11: General Obligations

43. The authorized person shall be responsible to implement all necessary measures to fulfil the requirements of this regulation, regardless of any delegation of duties to a third party.

- 44. In the implementation of activities, the authorized person shall ensure that the safety and security are not compromised.
- 45. Security measures of nuclear-related items shall be under the responsibility of the authorized person.
- 46. The authorized person is responsible for the correctness and completeness of information submitted to the NRRC, as well as for its timely submission.

Section 12: Internal Compliance Program

- 47. The authorized person shall draw up an internal compliance program (ICP) for activities that details and instructs the authorized person on how to carry out the responsibilities, including, control, reporting and other obligations on the activities.
- 48. The ICP shall be documented in such a way that the NRRC can assess the authorized person's ability to meet the obligations under the authorized person's responsibility.
- 49. The authorized person shall be capable of having up-to-date information on all nuclear related item inventories, and activities associated with them.
- 50. The authorized person shall be able to generate the reports and notifications required by this regulation.
- 51. The authorized person shall keep inventory and operating records for his activities, in which the records shall be retained for the lifetime of the authorized person.

- 52. The ICP shall be kept up to date at all times.
- 53. The authorized person shall appoint a person responsible for the ICP to liaise with the NRRC on the compliance to the requirements made under this regulation.

Section 13: Protection of Confidential Information

54. The authorized person and any other person for the purpose of implementing this regulation shall take every precaution to protect confidential information as prescribed by the Regulation on Information Protection and Cybersecurity (NRRC-R-20).

Section 14: Obligations for Facilitating Regulatory Oversight

- 55. The authorized person shall enable, facilitate, and support the NRRC in carrying out its oversight responsibilities under this regulation, including but not limited to the following:
 - a. Provide access to any facility or place where such activity is being carried out,
 - Facilitate taking samples, use of measurement devices, application of seals and other identifying and tamper indicating devices on the applicant's premises where, according to the application, the activity would be carried out;
 - Provide reports in the format prescribed by the NRRC, as well as other necessary information and notifications as prescribed by the NRRC;

- d. Provide other information, including the plans and contracts and their grounds concerning the fabrication, quality control or processing of nuclear related items;
- e. Facilitate IAEA inspection and surveillance as prescribed by the NRRC; and
- f. Any other activities as prescribed by the NRRC for the purpose of this regulation.
- 56. The seals and devices of the NRRC or installed with the consent of the NRRC shall not be removed, tampered with, exposed to damage and prevented to operate as in-tended by any means, and may only be removed with prior approval from the NRRC.

Chapter 7 : Obligations for Provision of Information

Section 15: Activity Program

- 57. The authorized person shall communicate to the NRRC the activity program as prescribed by the NRRC, which shall include at least the following:
 - The general plans for the activities related to or involving nuclear related items, including the anticipated or exact dates; and
 - Any other necessary information supporting the implementation of the NRRC regulatory control for activities prescribed under this regulation.

58. The authorized person shall inform the NRRC about any changes to the activity Program without delay.

Section 16: Incident Reports

- 59. The authorized person shall submit to the NRRC an incident report in the event of loss of nuclear related item or breach or damage to the seals and devices.
- 60. The authorized person shall notify the NRRC about any other incidents relevant to the implementation of the requirements of this regulation as soon as incident has been noticed, and if the NRRC requires, the authorized person shall submit incident reports, as prescribed by the NRRC.

Section 17: Annual Report

- 61. The annual report shall state the activities during the reporting year and include a list of nuclear related items prescribed by this regulation at the end of the year.
- 62. The annual report shall be accompanied by a report of the internal audit of the authorized person's ICP.

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