

NRRC Specific Regulations

Radiation Safety for Consumers Products

NRRC-R-01-SR12



هيئة الرقابة النووية والإشعاعية
Nuclear and Radiological Regulatory Commission

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Specific Regulation

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NRRC-R-01-SR12

Preamble

In accordance with the provisions of the Radiation Safety Regulation (NRRC-R-01), approved by the NRRC's Board of Directors in resolution No. (R/1/1/2022), dated 20 April 2022, in chapter (14) section (93), this specific regulation establishes specific criteria to ensure the control of the consumer products to be provided to the public and the requirements for the authorization of such activity in compliance with the Radiation Safety Regulation (NRRC-R-01).

This specific regulation has been prepared on the basis of International Atomic Energy Agency (IAEA) standards, as well as the international best practices and the experiences of similar international regulatory bodies, and in accordance with the Kingdom's international commitments, and it has been approved by the NRRC's CEO resolution No. 1366 dated 9/7/2023.

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Chapter 1: Objective, Scope, and Definitions

Section 1: Objective

1. This specific regulation establishes the criteria for the authorization of manufacturing, importing and providing consumer products to the public and radiation safety requirements of consumer products for free use by the members of the public defined in the Regulation on Radiation Safety (NRRC-R-01), Section 93.

Section 2: Scope

2. This specific regulation applies to:
 - a. All the manufacturers, importers and providers of consumer products; and
 - b. The production, provision, import, distribution, retail, and disposal of consumer products.
3. This specific regulation does not apply to the end-users of consumer products.

Section 3: Definitions

Consumer product

A device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale.

Member of the public

For purposes of protection and safety, in a general sense, any individual in the population except when subject to occupational exposure or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, this is the representative person. In the present document the "end-user" is synonymous to the member of the public.

Provider of consumer product

Designers, manufacturers, producers, constructors, installers, distributors, sellers, and importers and exporters of consumer products.

Provision of consumer product

Activities conducted by the provider that involves the distribution, installation, seal or expost of of consumer products

Importation of consumer product

The activity conducted by the provider leading to the importation of consumer product from outside the Kingdom of Saudi Arabia.

Manufacture of the consumer product

The activity conducted by the provider leading to the production and construction of a consumer product in the Kindom of Saudi Arabia.

Chapter 2: Authorization

4. The person responsible for activity(ies) involving the import, provision, or manufacture of consumer products that could be provided to the public shall apply to the NRRC for an authorization.
5. The applicant for an authorization for the import and provision of consumer products shall provide the NRRC with information on:
 - a. The description of the consumer products;
 - b. The application and proposed end-use of the consumer products;
 - c. The types of radionuclides in the consumer products and their activities;
 - d. The chemical and physical form of the radionuclides in the consumer products;
 - e. A description of the required actions in the event of misuse or accidental damage of consumer products;
6. In addition to the items described in Article 6, the applicant for an authorization for the import of consumer products shall provide the NRRC with:
 - a. The approval of the consumer product issued by the regulatory authority of the country of origin;
 - b. Information on the scope of the activities and operations under the responsibility of the applicant that are associated with the import of the consumer products;



- c. Any related information requested by the NRRC for evaluating safety in the activities and operations with the imported consumer products.
7. In addition to the items described in Article 6, the applicant for an authorization to provide consumer products to the public shall submit to the NRRC:
 - a. Information on the expected end-users and mechanisms to provide the consumer products;
 - b. The authorization for the import or manufacture of the concerned consumer products;
 - c. Information on the scope of the activities and operations under the responsibility of the applicant that are associated with the provision of the consumer products;
 - d. Any related information requested by the NRRC for evaluating safety in the processes associated with the provision of the consumer products.
8. The applicant for an authorization to manufacture consumer products shall provide the NRRC with the relevant information specified in Chapter 4 of this regulation.

Chapter 3: Responsibilities for the manufacture, provision and import of consumer products

Section 4: Responsibilities for manufacture of consumer products

9. The manufacturers for the production, use, possession, storage, transport, import, export or disposal of radioactive materials and their facilities shall comply with the relevant requirements specified in Regulation on Radiation Safety (NRRC-R-01) and other relevant regulations.
10. The manufacturers shall ensure that the products comply with the safety requirements specified in Chapter 4 of this regulation.
11. The manufacturers shall request the NRRC's approval for the design of the consumer products prior to their production.
12. The manufacturers shall ensure that radiation safety is optimized in the design of new consumer products and the choice of the radionuclides included or/and their activities.
13. The manufacturers shall properly apply the following criteria in the design and production of consumer products:
 - a. Selection of the most appropriate radionuclide(s) with respect to their half-life, activity, and emitted radiation type and energy;
 - b. For irradiated gemstones, optimization of radiation protection and safety by planning the irradiation conditions to minimize the production of those radionuclides with longer half-lives and by retaining those gemstones with the highest activity concentrations.

- c. Selection of physical and chemical forms of radionuclide(s) that provide the highest degree of intrinsic safety under both normal and accident conditions and for disposal;
 - d. Proper configuration of the consumer product;
 - e. Prevention of access to the radionuclide(s) without the use of special tools;
 - f. Use of the experience with other consumer products, particularly similar products, that have previously been assessed;
 - g. Implementation of applicable quality assurance provisions.
14. When requesting the approval of the design of a consumer product the manufacturer shall provide the NRRC with:
- a. A description of the consumer product;
 - b. Information on the application and proposed end-use of the consumer product;
 - c. Information on the types of radionuclides in the consumer product and their activity;
 - d. Information on the chemical and physical forms of the radionuclides in the consumer product;
 - e. A safety assessment concerning the use of the consumer product;
 - f. A description of the required actions in the event of misuse or accidental damage of the consumer product;

15. The manufacturers shall:

- a. Ensure that the consumer product is constructed in accordance with other standards specified by the NRRC; and
- b. Be responsible for arranging any type of testing that is specified in the relevant standards.

Section 5: Responsibilities for the provision of consumer products

16. In addition to the responsibilities specified in Regulation on Radiation Safety (NRRC-R-01) Sections 94 and 96 the providers shall ensure:

- a. That the consumer products comply with the safety requirements specified in Chapter 4 of this regulation;
- b. The safety and security of the place of handling and storage of consumer products.
- c. That procedures for handling and providing consumer products are established and regularly updated;
- d. That consumer products are not sold in bulk to member of the public.
- e. That records on distributors of the consumer products are maintained.

17. In addition to the requirements specified in Regulation on Radiation Safety (NRRC-R-01) Section 96 the providers shall ensure that:
- a. The consumer products are accompanied by information in languages that are appropriate for the particular market in which the product is to be sold;
 - b. Instructions are provided with the consumer products including information on proper operation, considerations for safety and procedures to be followed when the products are no longer used;
 - c. In case of consumer products that must be recycled rather than disposed of as waste, information is given on where the disused products shall be taken to or sent for recycling; and
 - d. Where appropriate, instructions accompanying the consumer products shall contain warnings not to dismantle the product where this could result in access being gained to a radioactive source.
18. When required by the NRRC the provider shall develop a safety assessment for the provision of the consumer products according to the criteria specified by the NRRC.
19. The providers shall comply with the requirements and authorization conditions established by the NRRC based on the scope of the operations and activities under their responsibilities.

Section 6: Responsibilities for the import of consumer products

20. The importers shall ensure that the imported consumer products comply with the safety requirements specified in Chapter 4 of this regulation.
21. The importers shall ensure that the consumer products have been approved by the relevant regulatory bodies of the country of their origin and that the concerned approval is provided to NRRC for information purposes.
22. The importers shall ensure that the import of consumer products is carried out only for providers granting a relevant NRRC's authorization.
23. The importers shall comply with the requirements and authorization conditions established by the NRRC with regard to the scope of the activities and operations under their responsibilities.

Chapter 4: Safety requirements for consumer products

24. In addition to the criteria specified in Regulation on Radiation Safety (NRRC-R-01) Sections 93 and 95, the consumer products shall meet the following requirements:
 - a. Irradiated gemstones shall not be provided to the public unless they are exempted.
 - b. The radiation label shall be clearly visible on the container of consumer products including radionuclides with activities higher than the respective exemption levels.



- c. Consumer products containing radionuclides with activities higher than the exemption levels shall be labelled to warn users of the presence of radioactive substances.

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