NRRC Stakeholders Guidelines

Kingdom of Saudi Arabia

Application for Authorization of Using Radiation Sources in Research and Education Practice

NRRC-SG-010

2023

هيئة الرقابة النووية والإشعاعية
Nuclear and Radiological Regulatory Commission

Stakeholder Guideline

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Preamble

In accordance with the provisions of the NRRC's approved Regulations, this stakeholder guideline describes criteria and/or techniques that are considered appropriate for satisfying the requirements stipulated in the NRRC's regulations.

This stakeholder guideline has been prepared on the basis of International Atomic Energy Agency (IAEA) standards, as well as the and 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. 1410, dated 23/07/2023.

Contents

1.	**Purpose**	**7**
2.	**Scope**	**7**
3.	**Definitions**	**8**
4.	**Abbreviations**	**9**
5.	**General and Administrative Information**	**9**
6.	**Integrated Management System**	**9**
6.1	Management structure and responsibilities	9
6.2	Description of regular assessment of protection, safety and security	10
6.3	Confirmation of the procedures and programs	10
7.	**Technical Information**	**11**
7.1	Information on radiation Sources	11
7.2	Information on radiation generators	12
7.3	Description of the facility / facilities	13
7.4	Technical information of radiation monitoring equipment	13
8.	**Safety Assessment**	**14**
8.1	The safety assessment consideration	14
9.	**Radiation Protection Program**	**15**
9.1	Protection of Workers	15
9.2	Protection of the Public	18

10. Radioactive Sources Security Plan 19

10.1 Assignment of radioactive material to category and security levels 19

10.2 Site description 19

10.3 Operational description 19

10.4 Security training and qualification 20

10.5 Access authorization 20

10.6 Information protection 21

10.7 Maintenance program 22

10.8 Threat information 22

10.9 Security assessment methodology 22

10.10 Security system design 22

10.11 Access control 23

10.12 Detection, assessment, and delay measures. For each controlled or secured area, describe 23

10.13 Procedures for key and lock control 23

10.14 Procedures for accounting and inventory 24

10.15 Procedures for receipt and transfer of radioactive material 24

10.16 Security event reporting 24

10.17 Security during emergencies and contingencies 25

11. Radioactive Waste Management Plan 25

12. Emergency Preparedness and Response Plan 26

12.1 Emergency Plan Basic Content 26

12.2 Reporting 26

12.3 Development of Emergency Plans 27

13. Related documents and files 28

1. Purpose

Nuclear and Radiological Regulatory Commission (NRRC) has developed an effective regulatory framework for the safe and secure authorization of using ionizing radiation in research and education practice throughout its life cycle. Under the regulatory framework, the prime responsibility for safety and security within using ionizing radiation in research and education practice lies with the authorized person.

The purpose of this guideline document is to give the applicant and/or the authorized person clear and specific guidance on the submission for the purpose of using ionizing radiation in research and education practice authorization.

2. Scope

This guideline is addressed to using ionizing radiation in research and education facilities and activities, in particular, will address the management system, radiation protection, safety and security aspects of industrial radiography practice, including use, storage and transport. This will include using ionizing radiation in research and education work that uses radiation sources, both in the authorized facility and outside facilities. However, it is considered appropriate that a graded approach in the application of the requirements will be taken into account and should be adapted to the risks inherent to each facility.

This guideline includes the required information relating to radiation safety and security by the NRRC in order to verify the adequacy of the proposed safety and security measures as part of the

authorization process.

This guideline applies for new authorization (License issuance), renewing the license as well as the license amendment.

3. Definitions

Assessment

The process, and the result, of analyzing systematically and evaluating the hazards associated with sources and practices, and associated protection and safety measures.

Radiation generator

A device capable of generating ionizing radiation, such as X-rays, neutrons, electrons or other charged particles, that may be used for scientific, industrial or medical purposes.

Controlled area

A defined area in which specific protection measures and safety provisions are or could be required for controlling exposures or preventing the spread of contamination in normal working conditions, and preventing or limiting the extent of potential exposures.

Supervised area

A defined area not designated as a controlled area but for which occupational exposure conditions are kept under review, even though specific protection measures or safety provisions are not normally needed.

4. Abbreviations

ABBREVIATION	DEFINITION
NRRC	Nuclear and Radiological Regulatory Commission.
RPP	Radiation Protection Program.
RSO	Radiation Safety Officer.
QS	Quality Control.
SP	Security Plan.

5. General and Administrative Information

- Fill and sign the application form. On all non-exempt radiation sources.
- Whether a program of biomedical research that includes medical exposure of volunteers is considered justified by the authorized person responsible for such a program, this authorized person should apply for a specific authorization before starting its implementation.

6. Integrated Management System

6.1 Management structure and responsibilities

- Describe overall organizational system and integrated management system assuring that protection and safety and security are effectively incorporated into the overall management system of the applicant.
- Describe and clearly define responsibilities for radiation safety and security for the following parties as appropriate: RSO(s), person responsible for security, workers, itinerant workers, radiation safety committee and clients including responsibilities for cooperation and consultation.

- Provide security roles and responsibilities.
- Document the assignment of all roles and responsibilities with respect to the security of radioactive material, including the roles and responsibilities of the following:

1. Site leadership, management, and supervisors.
2. Positions directly responsible for the security of radioactive material.
3. Positions with responsibility for regulatory matters, including any positions such as the licensee, radiation safety officer, security personnel, advisers, guards, and other security related positions specifically required by regulation. Provide an organization chart showing the staffing structure with lines of authority and supervision to demonstrate how the security organization and responsibilities fit within the overall site organization.

6.2 Description of regular assessment of protection, safety and security

The applicant should verify the compliance by Providing description of regular assessment of protection and safety and security such as Quality Assurance (QA) program and plans for regular reviews.

6.3 Confirmation of the procedures and programs

The applicant should Confirm by affirmation by the applicant and/or submittal of the following procedures and programs to the NRRC:

- Radiation source inventory, supply of sources, prior assessment of the radioactive sources and radiation generators and inventory of disused sources.
- Education, training and competence of the staff and their training, retraining, and informing.
- Investigation of incidents and accidents.
- Emergency preparedness and response.
- Control of modification(s) of facilities, equipment, and activity.
- Management of disused sources and depleted uranium if applicable.
- Safe transport.
- Import and export of radioactive sources.
- Control of visitors.
- Program for the improvement of the integrated management system.

7. Technical Information

7.1 Information on the radioactive sources Provide Information on the radioactive sources (on all non-exempt sources, including sources for checking equipment, calibration sources): (if applicable)

- Radionuclide.
- Type (sealed/unsealed)
- Manufacturer of the source.
- Model.

- Source serial number.
- Source activity and reference date.
- Design, manufacturing and testing of the source.
- Leak test.
- Working life of the source.
- Certificate for sealed/unsealed radioactive source.

7.2 Information on radiation generators Provide Information on radiation generators as following:

- Type of the radiation generators different beams e.g. X-ray generator, electron accelerator, neutron generator or charged particle accelerator.
- Manufacturer of the radiation generators.
- Model.
- Serial number(s) of the radiation generators.
- ID number.
- Usage method: portable, mobile or stationary.
- Type of shielding: removable or not removable.
- Maximum energy.
- Maximum current (mA).
- Maximum dose rate.
- Maximum leakage radiation.
- Beam alignment: required or not required.
- Beam interlocks: whether present or absent.
- Name and address of a supplier if different for a manufacturer of the radiation generator irradiator.

7.3 Description of the facility / facilities

Radioactive source storage:

- Provide a layout by using a scale enabling analysis of storage characteristics, e.g., entrances, doors, windows, roof, floors, penetrations, and adjacent offices or buildings. In particular, all construction materials may be specified e.g., material, thickness and density. Specify which sources and equipment given before will be stored in the storage area and the maximum capacity of the storage.
- Demonstrate that assumptions used (e.g., shielding design, workload, and occupancy factor) took into account radiation fields produced by all sources to be stored. Demonstrate that doses are below dose limits, dose constraints for workers and member of the public are established, and doses are optimized.
- Specify position within facility layout of all technical safety systems, e.g., monitors, sensors, access control measures, barriers, detectors causing warning signals and notices.
- Describe design and function of safety and warning systems.
- Specify the boundaries of controlled and supervised areas.

7.4 Technical information of radiation monitoring equipment

7.4.1 Portable survey meters

- Demonstrate suitability and calibration of portable survey meters.
- Specify their use and number, e.g., specify that survey meter(s) used for practice are suitable and the applicant has sufficient number of portable meters.

7.4.2 Personnel monitoring devices are provided to all workers

- Demonstrate that following functions are in place: personal dosimetry, direct reading, and alarming. Specify all technical information.

8. Safety Assessment

8.1 The safety assessment consideration

- Consideration of the dose rates from both shielded and unshielded radioactive sources.
- radioactive sources; Potential exposures of researchers, other workers and the public, for a range of scenarios representing normal use and reasonably foreseeable incidents.
- Limits and technical conditions for operation of sources.
- Ways in which structures, systems, and components, as well as procedures relating to protection and safety, might fail or might otherwise lead to potential exposures, and the consequences of such failures.
- Ways in which external factors could affect protection and safety.

- Ways in which operating errors and human factors could affect protection and safety.
- Evaluation of the implications of any proposed modifications for protection and safety.

9. Radiation Protection Program

The applicant should provide radiation protection program as follow:

9.1 Protection of Workers

9.1.1 Personal dosimetry

- Specify and provide the personnel dosimetry service and arrangements related to monitoring of personal doses.
- Provide the results of the review on past occupational doses. Provide workers' (including itinerant) records of past occupational exposure if not already recorded in the registry of occupational doses.
- Specify and provide information on the monitoring of radioactive aerosol inhalation, and the assessment of committed effective dose.

9.1.2 Workers' health surveillance

- The applicant should specify programs for health surveillance.

9.1.3 Education and training of workers

- Specify names, qualification, education, training, and retraining.
- Describe how staff (including assistants and trainees) are trained and qualified.

9.1.4 Outside researchers

- Describe the allocation and documentation of the responsibilities of the employer and the applicant for safety and protection of itinerant workers.
- Ensure that the particular aspects of volunteer medical exposures are considered in the optimization process.
- Arrangements for the Radiation Protection Program (RPP).
- Assignment of responsibilities for the RPP.
- Specify designation of controlled and supervised area using safety assessment and measured dose rates at working room(s)/area(s), storages(s).
- Demonstrate appropriate managing of labels, marks, and notices.
- Demonstrate that local rules applicable for researchers are prepared for all processes of the applicant and that an adequate number of researchers is involved in the practice.
- Specify roles and responsibilities as well as demonstrate that supervision of processes is

taking place.

- Demonstrate that rules, labels, and marks are in a language understood by those for whom they are intended Workplace and area monitoring program.
- Demonstrate that the necessary amount of radiation monitoring equipment is available and specify their technical specification, selection, calibration, maintenance, testing and use of radiation monitoring equipment. Demonstrate that monitoring program takes into account all processes of the applicant, e.g., use and maintenance of radiation equipment, accepting packages with new radioactive sources and preparing packages for transport.
- Demonstrate that need to rely on administrative control and personal protective equipment for protection and safety is minimized giving the priority to engineering controls.
- Demonstrate that appropriate personal protective equipment is provided, and arrangements are made for its proper use, testing and maintenance.
- Describe the system for recording and reporting all information related to exposure control, decisions regarding measures for occupational radiation protection and safety as well as

individual radiation monitoring.

- Specify the methods for periodic auditing and review of implementation of the RPP and SP.

9.2 Protection of the Public

9.2.1 Procedures of protection and safety to protect members of the public:

- Describe the system of protection and safety to protect members of the public.
- Demonstrate that optimization of radiation protection of public is in place.
- Demonstrate that assessment, control, and surveillance of external and internal exposure of public are in place, i.e., use of dose constraints for the member of the public. Provide assumptions used to assess external exposure of public.
- Establish dose constraints for the volunteers participating in medical or biomedical research.
- Describe training of personnel having functions relevant to protection and safety of members of the public. Demonstrate that monitoring program and management of records are in place.
- Describe the use of signs, labels, marks, and notices to be noticed by members of the public. Confirm that they are in a language to be understood by members of the public.

10. Radioactive Sources Security Plan

10.1 Assignment of radioactive material to category and security levels

- Identify and explain the basis for the categorization of each radioactive material and its associated security level.

10.2 Site description

Describe the physical features of the site on which the practice is conducted and its surrounding environment, including diagrams and scale floor and building drawings and photographs. This information must include:

- The location and layout of the site, particularly indicating areas accessible to the public, roads and parking areas, nearest public thoroughfares, central security office, building and site perimeter, access points, and physical barriers.
- The site's surrounding environment such as industrial, commercial, residential, or other uses; indication of distances to nearest police stations and other response services; proximity to other buildings and roads; and other features of security or operational interest such as other facilities with hazardous materials.

10.3 Operational description

Describe site operations in relation to the practice, including working and non-working hours; the number and type of staff involved in the site's operations; and the typical number,

type, and frequency of other people, such as visitors, public, customers, service personnel or contractors, who may be at the site during scheduled operations or at any other time.

10.4 Security training and qualification

- Requirements for qualification of staff with security responsibilities.
- Training to be provided to each individual, including the required initial, specialized, advanced, or refresher training for each position with security responsibilities; security awareness training for all staff; and other relevant, specific, on-the-job training such as procedures and work instructions.
- Provider(s) of the identified training and how frequently each part of training must be conducted.
- How training records that document satisfactory completion of all security related training are established and maintained.

10.5 Access authorization

Describe the process used for authorizing personnel who need unescorted access to radioactive source locations, secured areas, and/or security sensitive information in order to perform their duties (which may or may not be directly related to security), including how the following functions are performed:

- Identify the positions requiring unescorted access.
- Verify individuals holding the identified positions are trustworthy.

- Verify individuals holding the identified positions have the necessary training.
- Perform timely withdrawal of access for individuals who no longer require it.
- Conduct periodic review and re-evaluation for circumstances, such as withdrawing access authorization when personnel or positions no longer have need for unescorted access, transfer of job responsibilities, or termination of employment.
- Maintain up to date records of personnel authorized for unescorted access.

10.6 Information protection

Describe the measures for protecting information whose unauthorized disclosure could compromise security of radioactive material, including the following:

- The information that needs protection.
- How the protected information is identified, such as the use of markings or other designators that will ensure all users of this information recognize it as requiring protection
- The forms of protected information such as paper documents, electronic media, or video recordings.
- Where the protected information is stored and who has custody of it.
- Who has access to sensitive information and how is that access determined.

- The protection measures in place to prevent unauthorized access when the information is being used or is being stored (for example physical protection, encryption).

10.7 Maintenance program

Describe the program for maintaining security equipment to ensure continuous and reliable operation.

10.8 Threat information

Describe the types of information on threat provided, and how it is provided.

10.9 Security assessment methodology

Describe the process or methodology used to design the security system and assess its vulnerabilities, taking into account the threat information provided.

10.10 Security system design

Describe how the security system has been designed to provide the level of protection required, taking into account the graded approach and principles of defence in depth and balanced protection. Indicate how each secured area and associated radioactive material are protected by detection, delay, and response measures in an integrated and balanced way. Identify the types of equipment and systems installed and their location.

10.11 Access control

Describe the physical measures for controlling access, including:

- How personnel are physically controlled at each control point to limit access only to authorized persons according to the access authorization procedure and to prevent unauthorized access.
- Specific media used to authenticate the identity of authorized persons such as key card, personal identification number, biometric device, or a combination.
- Procedures to be followed by authorized persons to access a secured area, including application of the two-person rule, where relevant.

10.12 Detection, assessment, and delay measures. For each controlled or secured area, describe:

- Means of detection, including intrusion detection systems and observation by site personnel.
- Method of assessment, including people and equipment supporting the assessment.
- Delay measures used to increase adversary task time relative to response time.

10.13 Procedures for key and lock control

Describe the procedures used for control of all keys, locks,

combinations, passwords, and related measures used to control access to secured areas and security systems. Identify who is responsible for changing access control measures and the specific conditions that require them to be changed, such as the compromise of a combination or password, loss of a security key, or termination of a staff member's access.

10.14 Procedures for accounting and inventory

- Verification method used, such as a physical check, remote video monitoring, examination of seals or other tamper indicating devices, or radiation measurements.
- Records generated indicating results of each verification, when, by whom, and by what method.
- Requirements for corrective actions and reporting if the presence of radioactive material cannot be verified. Also describe how the site establishes and maintains an inventory of its radioactive material.

10.15 Procedures for receipt and transfer of radioactive material

Describe the procedures for ensuring that security and control of a radioactive source is maintained when it is being received from outside the site and when it is transferred to another authorized person.

10.16 Security event reporting

Describe how security events are reported to the operator's security organization. Describe how events are documented,

who is responsible to document the event, and subsequent external reporting requirements.

10.17 Security during emergencies and contingencies

Summarize arrangements and actions to be taken during non-security emergencies or other contingency situations to ensure the protection of the radioactive material is maintained.

11. Radioactive Waste Management Plan

Radioactive waste is generated at various points in research and education. Hence, provide radioactive waste management programme as follows:

- Characterization of radioactive waste
- waste minimization plan
- handling and processing of radioactive waste
    1. clearance of materials after processing
    2. on site storage for decay
    3. reuse and recycling of material
- Water and drainage system
- Release of contaminated water and air to the environment
- Radioactive waste inventory
- A handling system for liquid waste with a decay tank for liquid radioactive waste.
- A containment and storage room for radioactive waste.
- Measures for control of the generation of gaseous waste.

12. Emergency Preparedness and Response Plan

12.1 Emergency Plan Basic Content

Ensure the content of a basic emergency plan includes the following:

- Advice on when to implement the emergency plan.
- Prior training as necessary for workers who will be implementing the procedures.
- Description of, and information on, the availability of emergency response equipment.
- Technical data and data relevant to radiological protection for each situation.
- Procedures to be followed at various stages, Identification of persons authorized to implement the various stages of the plan.
- Identification of all persons and organizations who should be contacted as necessary at the various stages of the plan.

12.2 Reporting

- A description of the incident or emergency, with as much detail as possible of the specific equipment involved. The details should include model numbers and serial numbers wherever possible.
- Environmental conditions at the time of the incident or emergency, with particular reference to whether or not these conditions played any significant part in causing the

emergency or incident or affecting the outcome.

- The specific cause of the incident or emergency.
- Details of actions taken to regain control of the situation and to restore conditions to normal, with special reference to any actions that were notably beneficial or detrimental.
- The training and experience of the personnel involved.
- An assessment and summary of the doses received by all affected persons.
- Recommendations made with the aim of preventing similar incidents and emergencies in the future and mitigating the consequences if a similar or related incident or emergency were to occur.

12.3 Development of Emergency Plans

- Identification of potential incidents during research work, followed by an evaluation of the associated risks.
- Development of emergency plans and procedures for dealing with the risks identified.
- Specification and acquisition of emergency equipment.
- Training in implementing the emergency plan and procedures, including training as necessary in the use of emergency equipment.
- Exercises at appropriate intervals to test and evaluate the implementation of the emergency plan.
- Periodic reviews and updates of emergency plans.
- Reports and notifications of incidents and emergencies.

13. Related documents and files

Document Name	Document Type	Document Number	Relation to the guideline
Radiation Safety	Technical Regulation	NRRC-R-01	This Regulation set out the general safety requirements in ensuring protection of people and the environment against the harmful effects of ionizing radiation and for the safety of radiation sources. in addition, this regulation harmonize the requirements applicable in the Kingdom with the international best practices in order to achieve the highest standards of safety in activities and facilities that give rise to radiation risks
Notification on and Authorization of Facilities and Activities with Radiation Sources	Technical Regulation	NRRC-R-02	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

Safe Transport of Radioactive Materials	Technical Regulation	NRRC-R-15	This regulation is to prescribe requirements that shall be fulfilled to ensure safety, security and to protect persons, property, and the environment from any harmful effects of radiation on the transport of radioactive materials or nuclear material.
Management of Radioactive Waste	Technical Regulation	NRRC-R-16	This regulation sets out the safety objectives, criteria and requirements for the protection of human health and the environment that shall be applied to the activities and the requirements that shall be met to ensure the safety of such activities and facilities.
Security of Radioactive Material	Technical Regulation	NRRC-R-17	This regulation that addressed security of radioactive material, associated activity, and associated facility against unauthorized removal of radioactive material and sabotage performed with the intent to cause harmful radiological consequences

King Fahd National Library Cataloging-in-Publication Data

L.D. no. 1445/85
ISBN:978-603-92072-5-2

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