NRRC Stakeholders Guidelines

Kingdom of Saudi Arabia

Application for Authorization of Radioisotope Production Using Accelerators Practice

NRRC-SG-007

2023

هيئة الرقابة النووية والإشعاعية
Nuclear and Radiological Regulatory Commission

Stakeholder Guideline

Application for Authorization of Radioisotope Production Using Accelerators Practice

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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. 1408 dated 23/07/2023.

Contents

1. Purpose

Nuclear and Radiological Regulatory Commission (NRRC) has developed an effective regulatory framework for the safe and secure authorization of radioisotopes production in a cyclotron practice throughout its life cycle. Under the regulatory framework, the prime responsibility for safety and security within industrial radiography 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 authorization of radioisotopes production in a cyclotron.

2. Scope

This guideline addresses facilities and activities who practice radioisotopes production in a cyclotron, in particular, will address the management system, radiation protection, safety, including storage and transport. 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 includes the required information relating to authorization of new license, renewal as well as amendment of license.

3. Definitions

Site

A geographical area that contains an authorized facility, authorized activity or source, and within which the management of the authorized facility or authorized activity or first responders may directly initiate emergency response actions.

Commissioning

The process by means of which systems and components of facilities and activities, having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria.

Construction

The process of manufacturing and assembling the components of a facility, the carrying out of civil works, the installation of components and equipment, and the performance of associated tests.

Design

The process and the result of developing a concept, detailed plans, supporting calculations and specifications for a facility and its parts.

Operation

All activities performed to achieve the purpose for which an authorized facility was constructed.

Decommissioning

Administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility.

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.
QC	Quality Control
SP	Security Plan

5. Authorization Stages

5.1. Stage 1: Site authorization

5.1.1. Project Details

- Description of the facility
  - Nature of the planned activities; purpose of operation
  - Type of accelerator to be installed.

- Particles to be accelerated.
- Beam specifications (Max beam current and energy)
- Type of radioactive materials that will be produced.
- Site specific requirements for the facility

- Description of the infrastructure supporting the facility, proposed vendor company and technical and scientific expertise that will support the development and operation.
- Information on the financial assurance for establishing, operating, and decommissioning of the facility.

5.1.2. Proposed location of the facility, site specific information

- Location of the facility
- Site characteristics (site geography, seismology, meteorology, hydrogeology,).
- Surrounded area (Road map, adjacent facilities, public and nearby residential localities, and ground water)
- Environmental radioactivity analysis report (Background radiation on site).
- Layout and civil engineering drawings.

5.1.3. During the process of site selection, particular consideration should be given to potential hazards that cannot be addressed by means of engineered measures. The hazard analysis should also consider nearby chemical or other industrial installations that could constitute potential external hazards.

5.2. Stage 2: Design, Construction, and installation of the accelerator and other equipment

5.2.1. Engineering design and layout

- Clear layout of the facility
- Zoning and Ventilation (air flow, (Heating, ventilation, and air conditioning (HVAC)) design scheme)
- Auxiliary facilities (power, cooling system)
- Physical security measures
- Fire protection
- Locate and specify the supervised and controlled areas.

5.2.2. Safety assessment

The safety assessment plan should cover the following parameters:

- Dose map analysis:
  - Hot cell and source operation scenarios.
  - Maintenance and surveillance scenarios.
  - Scenarios concerning public members.

- Shielding calculation, including Monte Carlo Simulation results.
- Layout of the facility and storage
  - The layout needs to be given using a scale enabling analysis, 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 considered radiation fields produced.
  - Demonstrate that doses are below dose limits, dose constraints for workers and member of the public are established, and doses are optimized.

5.2.3. Safety features.

- Specify position of all technical safety features and warning systems such as emergency cord or button, radiation monitor(s) door interlocks, use of key control, sensors, access control measures, barriers, monitors, and warning signals (i.e. audible and visible) and notices.
- Describe design and function of safety and warning systems, including independence of safety systems, their redundancy and diversity.

- Specify how fire protection manages hazard related to the existing radioactive sources.
- Demonstrate that good engineering practice is taken into account.

5.2.4. Importing the equipment

- The applicant must provide full technical information, testing reports and certification from the country of its origin for accelerator equipment prior rigging and installation.
- The applicant must get all necessary permission to import the accelerator and its components and accessories.

5.2.5. Installation

- Rigging procedures

5.3. Stage 3: Testing and commission

5.3.1. Safety Interlock tests

- Accelerator safety system.
- Targtry Safety system.

5.3.2. Accelerator operating procedures

5.3.3. Beam testing procedures

5.3.4. Cold tests of transfer lines

5.3.5. HVAC testing:

- Verifications of Negative pressure existence in pre-defined area
- Verifications of Positive pressures existence in pre-defined area

5.4. Stage 4: Operation

5.4.1. Acceptance test results for the equipment:

The program should address the following acceptance tests:

- Beam energies
- Beam Current
- Acceleration efficiency
- Beam line transmission (if applicable)
- Production yield (mCi/μA.hr)
- Transfer of activity (Cold tests of transfer lines)

5.4.2. Acceptance tests results for the building:

- Building interlock system
- Access control
- Emergencies stop and “last person out” buttons.
- Signage. Room status, radiation warning light, beam-on light, imaging in progress status, and similar function features, warning signs.

5.4.3. Radiation survey and safety measures.

The following radiation safety measurements should address:

- Radiation survey during first beam on of the unit.
- Comprehensive facility room shielding survey (validation of facility shielding design).
- Verification of cooling system (radioactivity)

5.4.4. Operation and maintenance schedule and scheme

- Safe handling tools and devices required for operation and maintenance of the accelerator and auxiliary equipment.

5.4.5. Quality Assurance program.

5.5. Stage 5: Decommissioning

When the accelerator is no longer to be used, the permission for decommissioning should be obtained from the NRRC and decommissioning should be carried out in accordance with an approved procedure laid down by the NRRC. The induced radioactivity in the accelerator components and the structures should be considered during decommissioning/disposal as a radioactive waste. The licensee should submit a report on the completion of decommissioning, which includes, safe disposal of sources and personnel exposures received during decommissioning. For more information, please see the application guide for authorization of decommissioning.

6. Relevant information in Support of the Authorization Process

6.1. General and Administrative Information

The applicant should fill the licensing application form at the NRRC's Website.

6.2. Integrated Management System (Applicable for Stage 2 and 4).

6.2.1. Provide management structure and responsibilities, including the following:

- 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 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:

- Site leadership, management, and supervisors.

- Positions directly responsible for the security of radioactive material.

- 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.

6.2.2. Provide description of regular assessment of protection and safety and security such as Quality Control (QC) program and plans for regular reviews.

6.2.3. Provide 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.

- Safe transport.
- Import and export of radioactive sources.
- Control of visitors.
- Program for the improvement of the integrated management system.

6.3. Technical information (Applicable for Stage 2, 3 and 4).

6.3.1. Equipment

The applicant should provide detailed description of the following equipment:

- Description of the Cyclotrons (technical and operational characteristics, shielding, access points, under pressure, alarms, flow velocity, indication of flow, finishing of surfaces and materials).
- Description of the hot cells, laminar fume hoods.
- Description of the synthesis and dispensing modules to be used, model, manufacturer, capabilities.
- Compressed air and gas systems;
- Special drains system for liquid radioactive effluents and decay or delay systems;
- Back-up or emergency electrical system: should supply services essential for safety such as: emergency lighting, safety systems, radiation protection systems, etc.;
- Radiation monitoring system: identification and description of equipment, location;

- Fire detection and extinguishing system;
- Air conditioning;

6.3.2. Design of the facility

The applicant should provide detailed information about the following facility's components:

- Layout: showing the location of the facility relative to its neighbourhood and surroundings.
- Axial and transverse sections showing premises adjacent to the facility, indicating materials, wall thicknesses, service penetrations in shielding (electrical and ventilation ducts, transfer, cooling and gas lines, etc.);
- Plan of the facility: distribution and function of, and operations to be performed in the facility's premises and adjacent premises, plus an estimate of occupation factors, including delimitation of the controlled and supervised area and adjoining areas;
- Communication routes between premises and equipment, including their relative pressure levels;
- Location of the cyclotron and radiopharmacy laboratory, including the hot cells (synthesis and dispensing), transfer lines and control room;
- Location of the quality control laboratories, dispatch area for radioactive packages (if one exists), staff decontamination area, component maintenance area, waste storage area and technical access area to the cells. Relat-

ed technical areas should be included such as the filter room, stack, gas area, areas containing cooling systems, electronic modules, etc.;

- Location of signs, emergency shutdown systems and monitors;
- Flow of radioactive material and persons;
- Location of access monitoring systems for persons and materials;

6.3.3. Transfer of radioactive material

The applicant should provide detailed information about transfer lines which carry the product from the target to the hot cell.

6.3.4. Ventilation systems

The applicant should provide description about ventilation system, as follow:

- differential pressure values within the radioisotope production facility.
- Types and location of the High efficiency particulate air (HEPA)

6.4. Safety Assessment (Applicable for Stage 2 and 4).

The applicant should provide detailed information about the following elements:

- Expected doses (occupational and from public exposure) arising from normal operation of the practice.

- Estimation of the potential doses (occupational and from public exposure) from anticipated operational occurrences and accident conditions (failures or internal or external events have occurred that challenge the safety of the facility or activity).
- Identification of postulated accident initiating events, commensurate with the particular features of the practice.
- Description of the severity of the potential consequences for workers, members of the public associated with each of the accident initiating events. Provide the evaluation of the consequences for workers and members of the public based on the potential effect which each accident initiating event could have without taking into account the safety measures or barriers envisaged.
- Description, for each accident initiating event, of the existing safety barriers to prevent or mitigate accidents.
- The risks associated with each accident initiating event. Risk needs to be expressed as a function of the frequency with which the initiating event occurs, the robustness of the safety barriers and the severity of the potential consequences associated with each initiating event. Risk may be classified following a prioritization principle to facilitate further decision making.
- A program of safety measures to be carried out for higher risk initiating events to ensure the optimization

of protection to the highest reasonably achievable safety level.

- Independent verification. Attach the results of independent verification of the safety assessment.
- Review of safety assessment. Demonstrate that regular and documented reviewing of safety assessment is in place.

6.5. Radiation Protection Programme (Applicable for Stage 2, 3 and 4).

The applicant should provide radiation protection programme as follow:

6.5.1. Protection of Workers

- Education and training of workers.
- Personal dosimetry records.
- Workers' health surveillance.
- Arrangements for the Radiation Protection Program (RPP).

Demonstrate that all elements of the RPP are in place, e.g., provide a copy of a RPP:

- Assignment of responsibilities for the RPP.
- Designation of controlled areas or supervised areas.
- Specify designation of controlled and supervised area us-

ing safety assessment and measured dose rates at working room(s)/area(s), storages(s). Demonstrate appropriate managing of labels, marks, and notices.

- Practice specific local rules.
- Demonstrate that local rules applicable for workers are prepared for all processes of the applicant and that an adequate number of workers 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.
- Area and stack monitoring program.
- Demonstrate that the necessary amount of radiation monitoring equipment is available, including stack equipment for monitoring external environment. Specify their technical specification, selection, calibration, maintenance, testing and use of radiation monitoring equipment.
- Personal protective equipment.
- Demonstrate that appropriate personal protective equipment is provided, and arrangements are made for its proper use, testing and maintenance.
- Record and reporting of information.
- Describe the system for recording and reporting all infor-

mation related to exposure control, decisions regarding measures for occupational radiation protection and safety as well as individual radiation monitoring.

- Audit and review of the RPP and the Security Program (SP).
- Specify the methods for periodic auditing and review of implementation of the RPP and SP.

6.5.2. Protection of Public

- System 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 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.
    - 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.

6.6. Radioactive Waste Management Plan (Applicable for Stage 2, 3 and 4).

The applicant should provide radioactive waste management plan as follow:

- Characterization of radioactive waste
- Waste minimization plan
- Handling and processing of radioactive waste
    - clearance of materials after processing
    - storage for decay
    - reuse and recycling of material
- Water and drainage system
- Release of activated water and air to the environment
- Radioactive waste inventory
- On site decay storage

6.7. Emergency Preparedness and Response Plan (Applicable for Stage 2, 3 and 4).

Provide Emergency Preparedness and Response Plan including the following:

- Emergency Plans and Procedures

- Training and Exercises

  Training should cover the following:

  - Procedures for notification of an emergency and activation of an emergency response, including provisions for obtaining assistance from off-site emergency services.
  - Implementation of necessary on-site mitigatory actions and protective actions, including provision of immediate first aid, and procedures for evacuation of non-essential personnel from facility.
  - Assessment of the situation.
  - Use of emergency response tools and equipment including firefighting equipment.
  - Use of personal protective equipment.
  - Use of workplace monitoring equipment.
  - Implementation of recovery actions, including decontamination.
  - Measures to be followed for the protection of personnel who will participate in implementing the emergency plans.

- Reporting

  The report should include the following:

- A detailed description of the emergency, including specifics of the equipment and source(s) involved.
- Environmental and working conditions at the time of the emergency, with reference to whether or not these conditions played any significant part in causing the emergency or affecting the outcome.
- The root causes of the emergency.
- A detailed description of the emergency response taken.
- The personnel involved, the work they performed, and their skills and qualifications.
- An assessment and summary of the doses received by all affected individuals.
- Corrective actions identified with the aim of preventing similar emergencies in the future and necessary for improving overall radiation safety, security, and emergency arrangements.
- Proposed means and time frames for implementation of the corrective actions identified and responsible staff.

6.8. Testing and Maintenance of Equipment (Applicable for Stage 3 and 4).

Provide procedures for maintenance which includes the following:

- The ventilation system (buildings, hot cells, fume hoods) at least annually.
- The heating and cooling systems, generators, radiation monitoring equipment, interlocks, freezers, building monitoring system, HEPA filters in clean rooms and dose calibrators.
- All equipment used in measuring radiation levels and weights, as well as other equipment as required by the NRRC, should tested, calibrated, and maintained on a regular basis.
- Check, in accordance with the manufacturer's instructions, that access to the facility is prevented when the radiation monitor alarm sounds.
- The emergency exit procedure by ensuring that the personnel access door can be opened from the inside and that other means of exit in an emergency are functioning properly.
- Check all visual warning signals and alarms for correct operation. Check all control indicator lights to ensure that they illuminate.
- Verify that the uninterruptible power supply is functioning within specification. It is a good practice to use an uninterruptible power supply as a backup power supply for the linear accelerator control system, as power failure can affect the

operation of control units.

- Verify that the heat detectors and smoke detectors are functioning properly.
- Verify all safety interlocks on removable shield plugs (or self-shield) in the accelerator room.
- Verify that posted notices are in place and that all the details are correct.

6.9. Security of Radioactive Sources Plan (Applicable for Stage 2, 3 and 4).

Provide security of radioactive sources plan as follow:

6.9.1. 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.

6.9.2. 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, patients, customers, service personnel or contractors, who may be at the site during scheduled operations or at any other time.

6.9.3. 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 particular 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.

6.9.4. 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.

6.9.5. 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.

6.9.6. Procedures for accounting and inventory.

Describe how the site performs periodic accounting for radioactive material, including:

- 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.

6.9.7. Procedures for receipt and transfer of radioactive material.

6.9.8. Security event reporting.

6.10. Transport of radioactive material (Applicable for Stage 2, 3 and 4).

The applicant should provide plan for the movement of radioactive sources as follow:

- Responsibilities in the transport of radioactive.
- Movement plan of radioactive material within the site.
- Transport plan of radioactive material to another site.

6.11. Decommissioning Plan (Applicable for Stage 2 and 5).

The operating organization is required to prepare a decommissioning plan for the facility that considers the ultimate disposal of all resultant waste and contaminated and/or activated equipment and materials, including an estimation of cost, identification of the provision of financial resources and assurances to cover the cost associated with decommissioning. This decommissioning plan is required to

be periodically reviewed and updated as necessary in the light of operating experience gained, new or revised safety requirements, lessons learned from the decommissioning of similar facilities, and technological developments relevant to decommissioning.

6.11.1. Decommissioning plan should include:

- Justification and description (techniques and time-frame) of the decommissioning method,
- Expected occupational exposures and measures for their restriction,
- Assessment of the final condition of the area in terms of radiological safety and description of its future use, if applicable,
- Arrangements and commitments, including the required financial resources for the management and possible transport of radioactive sources and materials and/or radioactive waste that are expected to be produced, where applicable.
- Responsibilities for decommissioning
- Final destination of radiation sources

The operating organization should provide the NRRC with a list of anticipated waste streams and sources to be generated at the facility, including waste forms (e.g. solid, liquid, gaseous), estimates of waste volumes, waste categories and plans for storage and disposal.

For more information about decommissioning, please see the application guideline for authorization of decommissioning.

7. 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

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