

NRRC Stakeholders Guidelines

Kingdom of Saudi Arabia

Application for Authorization of Radiation Dosimetry Calibration

NRRC-SG-008



هيئة الرقابة النووية والإشعاعية
Nuclear and Radiological Regulatory Commission

2023

Stakeholder Guideline

Application for Authorization of Radiation Dosimetry Calibration
2023
NRRC-SG-008



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. 1381 dated 16/07/2023.



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1. Purpose

Nuclear and Radiological Regulatory Commission (NRRC) has developed an effective regulatory framework for the safe and secure authorization of radiation calibration practice throughout its life cycle. Under the regulatory framework, the prime responsibility for safety and security within Calibration by Using Radiation Sources practice lies with the authorized person.

The purpose of this guideline document is to give the applicant and/or the authorized person a clear and specific guidance on the submission for the purpose of radiation calibration authorization.

2. Scope

This guideline is addressed to radiation dosimetry calibration facilities and activities, in particular, will address the management system, radiation protection, safety and security aspects of radiation dosimetry calibration practice, including use, storage and transport. This will include industrial radiography 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

Quality control (QC)

Part of quality management intended to verify that structures, systems and components correspond to predetermined requirements.

Storage container:

A container in which sealed sources are secured and stored.

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
QE	Qualified Expert

Abbreviation	Definition
TLD	A thermoluminescent dosimeter
OSL	Optically stimulated luminescence

5. General and Administrative Information

The applicant should fill and sign the application form.

6. Integrated Management System

6.1. Management structure and responsibilities

The applicant should provide 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 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:

- 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. 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 Control (QC) 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.
- 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 radiation generators

7.1.1. Information on gamma and X-Ray generators

- The applicant should provide the following:
 - Manufacturer of the gamma and X-Ray generators.
 - Address of the manufacturer of the radiation generators
 - Model.
 - ID number.
 - Name and address of a supplier if different for a manufacturer of the gamma and X-Ray generators.

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

- Radionuclide.

- Model.
- Source serial numbers for radioactive sources
- Source activity and reference date.
- Manufacturer of the source.
- Supplier of the source.
- Special form certificate. Attach special form certificate for the radioactive source.
- Design, manufacturing, and testing of the source.
- Leak test.
- Working life of the source given by the manufacturer.

7.2. Description of the facility / facilities

7.2.1. Calibration laboratory(s):

- Layout of the calibration room.
 - Demonstrate that design of the calibration room enables optimization of radiation protection for workers and members of the public. The layout needs to be given using a scale enabling analysis of the radiation room and adjacent areas characteristics (e.g., entrances, maze, doors, roof, floors, and penetrations used for ventilation and electricity), source storage places, rooms for additional equipment if applicable. In par-



ticular, the layout may include details related to the control room, which needs to be located outside the calibration room, and to all other 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 used in the calibration room and process flow diagram. Position(s) of source(s) and equipment is given.
- Specify all adjacent equipment.
- Radioactive source storage.
- Provide copy of the construction schemes, including inserts, brackets and other hardware used to anchor or hold in place such items as the source holder, guide rods or cables moving of the source (or the sample chamber), and various pipes for other services; specify all construction materials, e.g. material, thickness and density; describe and include the radiation safety assessment provide by the producer demonstrating that design of the source container enables optimization of radiation protection for workers.
- Provide demonstrate that doses are below dose limit, dose constraints for workers are established, and doses are optimized to be as low as possible.
- Provide that a QE was involved in the calculations.
- Shielding calculation and assumptions used.
 - Demonstrate that design and shielding as well as assumptions used (e.g., use factor and occupancy factor) took into account radiation fields produced by sources

during calibration. Provide dose and dose rate calculations related to exposure for workers and members of the public. In designs with minimal or no roof, demonstrate that due consideration has been made of the air scattering of radiation (or 'sky shine') and to scattering from objects outside the enclosure, such as higher ceilings or walls in the vicinity of the enclosure, if it is to be constructed inside another building. Demonstrate that leakage radiation is taken into account.

- Specify maximum operating condition of equipment, e.g., maximum activity of radioactive source and directions of the beam. Provide plan of calibration room surroundings. Demonstrate that doses are below dose limit, dose constraints for workers and members of the public are established, and doses are optimized to be as low as possible.
- Demonstrate that a QE was involved in the calculations.
- Safety features.
- Specify position of all technical safety features and warning systems. Describe design and function of safety and warning systems, including independence of safety systems, their redundancy and diversity as well as the emergency power supply system to supply services essential for safety, such as emergency lighting, instrumentation, and control, etc.



- Specify in details the description and procedures to assess all safety systems, e.g.: safety interlock systems for a control of access to the radiation source, back-up access control for personal entry (e.g. photoelectric cell), removable radiation room shield plugs (e.g. roof plugs), fixed radiation monitor with alarms, multipurpose access key attached to a portable survey meter, emergency stop device at the control console, device for disabling the irradiation at the control console for maintenance work, safety delay timer inside the calibration room with alarms, emergency stop device (e.g. emergency cord) in the calibration room, emergency exit, shielding, temperature detection and control system, earthquake detectors, fire detection and fire extinguishing system, electrical power, non-electrical power (e.g. pneumatic power or hydraulic power), product conveyor mechanism, product movement timer, safety interlocks for product entry and exit ports, backup access control for product entry and exit ports (e.g. photoelectric cell), product exit radiation monitor, source status indicators, device for positioning and removing radioactive sources from a source rack, anti-collision system and source guard, emergency source cooling system, source travel timer, emergency access ports, source rack position indicators, ventilation and air control,(including ozone control).

- Specify in detail how safety systems are controlled by using a control console, e.g.: safety systems, including emergency shutdown button (i.e., emergency stop device), device for disabling the irradiation at the control console for maintenance, single control and access key for the radiation generators, light and audible signals showing of the calibration operation, including radiation (source) status, and viewing screen for the product conveyor system.
- Demonstrate that all equipment inside the radiation room of the calibration facility (including wiring, electrical equipment, notices, and lighting) is selected to minimize failure due to prolonged exposure to radiation.
- Demonstrate that good engineering practice is taken into account. Demonstrate that the text of the notices is in a language understandable to the persons likely to be in areas around the calibration room(s).
- Specify how fire protection manages hazard related to the existing radioactive sources. Specify in detail how preparation for irradiation is taking place, e.g., daily checks of safety systems as required by the manufacturer, preparation of products to be exposed, start-up sequence, irradiation process, releasing irradiated products.



- Specify boundaries of controlled and supervised areas.

7.2.2. Technical information of radiation monitoring equipment: The applicant should provide and demonstrate the following equipment:

- Installed radiation monitor(s) in calibration room.
 - Specify technical information related to radiation monitors permanently installed and demonstrate suitability and calibration of the monitor(s).
 - Portable survey meters.
 - Specify technical information related to portable survey meter(s) to be used and demonstrate suitability and calibration of portable survey meters.
 - Specify their use and number, e.g., specify that survey meter(s) used for calibration are suitable, and the applicant has sufficient number of portable meters.
 - Personnel monitoring devices are provided to all workers.
 - Demonstrate that following functions are in place: personal dosimetry (e.g., TLD, OSLD), direct reading, and alarming. Specify all technical information.
 - Safe and secure management and control of radiation sources once it has been decided to take them out of use.

8. Safety Assessment

8.1. The safety assessment consideration

- Expected doses (occupational, public) arising from normal operation of the practice.
- Estimation of the potential doses (occupational, public) 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 features of the practice.
- Description of the severity of the potential consequences for workers and members of the public and 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 con-

sequences associated with each initiating event. Risk may be classified following a prioritization principle to facilitate further decision making.

- Conclusions. Include 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.
 - Demonstrate to the NRRC how the design of the calibration laboratory and the related operational procedures will contribute to the prevention of accidents or to the mitigation of the effects of accidents. This information should be provided in the form of a documented safety assessment describing and evaluating the predicted response of the plant to incidents (including postulated malfunctions or failures of equipment, common cause failures and human errors) and external events that could lead to accident conditions.
- These analyses should include consideration of combinations of such malfunctions, failures, errors, and events. Issues to be examined in the safety assessment include:
- Loss of access control.

- Malfunctions and failures of structures, systems, and components.
- Loss of control over the system for the movement of radioactive sources, including a source rack becoming stuck in the unshielded position.
- Loss of integrity of systems or components, including shielding integrity, encapsulation of sealed sources.
- Electrical distribution faults, from localized faults to complete loss of external energy sources.
- Failures of safety systems caused by fires within the facility.
- Failures of safety systems resulting from external causes such as storms, floods, earthquakes, or explosions.
- Failures of personnel to observe proper, safe procedures (for whatever reasons).
- Breakdown of procedures for preventing access to the facility by unauthorized persons.
- Breakdown of administrative procedures, leading to unsafe practices.
- Detection of contamination.
- High radiation levels in locations where high levels would not be expected.



9. Radiation Protection Program

- The applicant should provide radiation protection program as follow:

9.1. Protection of Workers

9.1.1. Education and training of workers.

- The applicant should specify names, qualification, education, training, and retraining.
- The applicant should describe how staff (including assistants and trainees) are trained and qualified.

9.1.2. Personal dosimetry.

- The applicant should specify and provide the personnel dosimetry service and arrangements related to monitoring of personal doses.
- The applicant should 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.

9.1.3. Workers' health surveillance.

- The applicant should specify programs for health surveillance.

9.1.4. Itinerant workers.

- The applicant should describe the allocation and documentation of the responsibilities of the employer and the applicant for safety and protection of itinerant workers.

9.1.5. Arrangements for the Radiation Protection Program (RPP).

- The applicant should 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.
 - * The applicant should specify designation of controlled and supervised area using safety assessment and measured dose rates at working room(s)/area(s), storages(s).
 - * The applicant should demonstrate appropriate managing of labels, marks, and notices.
 - Practice specific local rules.
 - * The applicant should 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.
 - * The applicant should specify roles and responsibilities as well as demonstrate that supervision of processes is taking place.
 - * The applicant should demonstrate that rules, labels, and marks are in a language understood by those for whom they are intended workplace and area monitoring program.



- * The applicant should 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.
- Personal protective equipment.
 - * The applicant should demonstrate that need to rely on administrative control and personal protective equipment for protection and safety is minimized giving the priority to engineering controls.
 - * The applicant should demonstrate that appropriate personal protective equipment is provided, and arrangements are made for its proper use, testing and maintenance.
- Record and reporting of information.
 - * The applicant should 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.
- Audit and review of the RPP and the Security Plan (SP).
 - * The applicant should 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:

- The applicant should describe the system of protection and safety to protect members of the public.
- The applicant should demonstrate that optimization of radiation protection of public is in place.
- The applicant should 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.
- The applicant should 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.
- The applicant should 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. Emergency Preparedness and Response Plan

10.1. The content of a basic emergency plan

- 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, specific to each type of emergency identified:
 - Initial stage, to contain the situation.
 - Planning stage, to plan and rehearse the recovery stage.
 - Recovery stage, to regain control of the situation.
 - Post-emergency stage, to return the situation to normal.
 - Reporting stage: preparation of a report, including an assessment of doses.
- Referral to medical experts following overexposure, if indicated.
- 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, as well as the relevant telephone numbers, fax numbers and email addresses.

10.2. Reporting

A report of an incident or an emergency should include the following:

- 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.



10.3. Development of Emergency Plans

The applicant should develop the emergency plan and each of which should be addressed by the licensee:

- Identification of potential incidents during nuclear gauge 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.

11. Radioactive Sources Security Plan

11.1. Assignment of radioactive material to category and security levels

- The applicant should identify and explain the basis for the categorization of each radioactive material and its associated security level.

11.2. Site description

- The applicant should 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.

11.3. Operational description

- The applicant should 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.



11.4. Security training and qualification

- The applicant should provide the following information:
 - 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.

11.5. Access authorization

- The applicant should 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.

11.6. Information protection

- The applicant should 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).

11.7. Maintenance program

- The applicant should describe the program for maintaining security equipment to ensure continuous and reliable operation.

11.8. Threat information

- The applicant should describe the types of information on threat provided, and how it is provided.

11.9. Security assessment methodology

- The applicant should describe the process or methodology used to design the security system and assess its vulnerabilities, taking into account the threat information provided.

11.10. Security system design

- The applicant should 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.

11.11. Access control

- The applicant should 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.

11.12. Detection, assessment, and delay measures. For each controlled or secured area, the applicant should 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.

11.13. Procedures for key and lock control

- The applicant should 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.

11.14. Procedures for accounting and inventory

- The applicant should 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.

11.15. Procedures for accounting and inventory

- The applicant should 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.

11.16. Security event reporting

- The applicant should 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.

11.17. Security during emergencies and contingencies

- The applicant should 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.



12. 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.

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King Fahd National Library Cataloging-in-Publication Data

L.D. no. 1445/80

ISBN: 978-603-92072-2-1





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