NRRC Stakeholders Guidelines

Kingdom of Saudi Arabia

Application for Authorization of Nuclear Medicine

NRRC-SG-016

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. 1414w, dated 23/07/2023.

Contents

1. Introduction

1.1 Purpose

The Nuclear and Radiological Regulatory Commission (NRRC) has developed an effective regulatory framework for the safe and secure authorization of Nuclear medicine practice throughout its life cycle. Under the regulatory framework, the prime responsibility for safety and security within nuclear medicine 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 of the authorization application for nuclear medicine practice.

1.2 Scope

This guideline is addressed to nuclear medicine practice. In addition, it includes the required information relating to radiation safety and security in order to verify the adequacy of the safety and security measures as part of the authorization process.

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 authorization of new license, renewal as well as amendment of license.

1.3 Definitions

Annual dose

The dose from external exposure in a year plus the committed dose from intakes of radionuclides in that year.

Assessment

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

Applicant

Any person applying to the NRRC for authorization to undertake specified activities and facilities including practices. Strictly, an applicant would be such from the time at which an application is submitted until the requested authorization is either granted or refused.

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.

Dose limit

The value of a quantity used in certain specified activities or circumstances that must not be exceeded.

Emergency plan

A description of the objectives, policy, and concept of operations for the response to an emergency and of the structure, authorities and responsibilities for a systematic,

coordinated and effective response. The emergency plan serves as the basis for the development of other plans, procedures, and checklists.

Emergency preparedness

The capability to take actions that will effectively mitigate the consequences of an emergency for human health and safety, quality of life, property, and the environment.

Exposure

The state or condition of being subject to irradiation.

Management system

A set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner.

Medical exposure

Exposure incurred by patients for the purposes of medical or dental diagnosis or treatment; by carers and comforters; and by volunteers subject to exposure as part of a program of biomedical research.

Medical radiological equipment

Radiological equipment used in medical radiation facilities to perform radiological procedures that either delivers an exposure of an individual or directly controls or influences the extent of such exposure. The term applies to radiation generators, such as X ray machines or medical linear accelerators; to devices containing sealed sources, such as Co-60 teletherapy units; to devices used in medical imaging to capture images, such as gamma cameras, image intensifiers

or flat panel detectors, and to hybrid systems such as positron emission tomography-computed tomography scanners.

Nuclear Medicine

The branch of clinical medicine in which unsealed radioactive materials are administered to patients for diagnosis or treatment of disease, or for clinical or pre-clinical research. X-ray imaging such as CT can occur in conjunction with a nuclear medicine procedure, like in hybrid imaging. Devices commonly used in Nuclear Medicine

Nuclear Security

Prevention and detection of any theft, sabotage, unauthorized access, illegal transfer (or any other criminal act) involving nuclear, nuclear-related or radioactive materials and associated facilities.

Radiation protection program

Systematic arrangements that are aimed at providing adequate consideration of radiation protection measures.

Safety assessment

Assessment of all aspects of an activity that are relevant to protection and safety; for an authorized facility. This includes sitting, design and operation of the facility.

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.

1.4 Abbreviations

ABBREVIATION	DEFINITION
CEO	Chief Executive Officer of the NRRC.
GM	General Manager.
IG	Internal Guideline.
NRRC	Nuclear and Radiological Regulatory Commission.
RPP	Radiation Protection Program.
RSO	Radiation Safety Officer.
QA	Quality Assurance.
QC	Quality Control.
PPE	Personal protective equipment.
TLD	Thermoluminescent Dosimeter.
OSL	Optically Simulated Luminescence.
DRD	Direct Reading Dosimeter.
TEDA	Triethylene di-amine.

1.5 Format and content of Nuclear Medicine Application

The following sections and subsections describe the content and level of detail that should be included within the Nuclear Medicine application for authorization.

2. Integrated Management System (Administrative Level)

The applicant should provide and perform the following:

2.1 Management Structure

i. License application that is signed by the management representative.

ii. A pledge letter signed by the management representative, assigning the RSO to be responsible for implementing

radiation safety and to have independent authority to stop unsafe operations and that he/she will be given sufficient time to fulfill the radiation safety duties and responsibilities.

iii. Appointment of the RSO in accordance with the criteria established by the NRRC along with defining the duties, responsibilities, and powers of the RSO in writing.

2.2 Responsibilities for Radiation protection and Safety.

i. Qualifications required for each job position in the nuclear medicine department that includes Education, training, and competence.

ii. Description and clear definition of the responsibilities related to radiation safety and security for the following parties as appropriate:

- RSO(s),
- All workers in the nuclear medicine department, (e.g., Nuclear medicine specialists, Medical Physicists, Technologists, Nurses, etc.)
- Radioactive sources security workers if they differ from the nuclear medicine department.
- Radiation safety committee, if applicable.

2.3 Procedures And Programs

i. **Radiation Safety Training Program:** topics addressed, frequency of the training, and audit; clarifying how frequent radiation safety training is conducted, given by whom? Who needs to attend? and how training records are established and

maintained.

ii. **Quality Assurance (QA)Program:**

- Describe the tests, responsibilities to perform the tests and to approve the results, established tolerance limits, implementation of corrective actions if measured values of the physical parameters are outside established tolerance limits.
- Description on how independent dosimetry audit is carried out.
- Reporting and learning systems: Description on how results of investigation of an unintended dose are used to improve the safety and patient protection.
- Responsibility for the regular and independent audit of the QA program. Maintenance of records of relevant procedures and results.

iii. **Program/ procedures for Maintenance:** Describe how adequate maintenance of the medical radiological equipment has been arranged.

iv. **Policy and procedures on Disused Sources:** policy and procedures on safe and secure management and control of sealed sources/ equipment once it has been decided to take them out of use.

v. **Program/ procedures for Import and export** of radioactive sources.

vi. **Program/ procedures for the improvement of the integrated management system** (frequent audits of policies and other related documents).

vii. **Policy and procedures** of occupational exposure monitoring.

viii. **Policy and procedures to carry out the procedure. e.g. presence of the Nuclear medicine specialist, Medical physicist**

ix. **Policy and procedures** for Record keeping: describe policy and procedures on how records are kept and maintained, e.g. QA records, maintenance, patients records, occupational exposures.

3. Technical Information

3.1 Description of Facility

i. Layout of the nuclear medicine department, shall include:

- Layout of the nuclear medicine rooms. The layout needs to be given using a scale enabling analysis of the laboratory and adjacent areas characteristics, e.g. laboratory for preparation of the nuclear medicine dose and dosage, injection room, patient waiting areas, imaging rooms, patient toilets, uptake room, offices and other working areas and areas for the staff, corridors, storages, and inpatient rooms for patients undergoing radionuclide therapy. Position(s) of source(s) and equipment is given. Specify all adjacent equipment, such as medical radiological equipment and their control rooms.
- Radioactive source storage and the radioactive waste storage. Specify which sources and equipment given before will be stored in the storage area. In particular, specify maximum capacity of the storage.
- Boundaries of controlled and supervised areas, where

controlled areas include: hot laboratory/Radiopharmacy, injection room, imaging rooms uptake room or stress rooms if patients are injected in them, radionuclide storage room, and radioactive waste storage, and supervised areas include any 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.

- Safety features. For nuclear medicine rooms, specify position of all technical safety features and warning systems such as emergency button of a device, radiation monitor(s) in case of a discharge, use of key control, warning signs, and notices. For radioactive source storage and the interim radioactive waste storage, specify the position of all technical safety systems, e.g. monitors, sensors, access control measures, barriers. Demonstrate that the text of the notices is in Arabic and English language.

ii. Shielding assessment:

- For new installation of medical radiological equipment, the following shall be performed and provided shielding calculation and assumptions used (e.g. workload, isodose/iso-exposure plot/map, main directions of the beam, occupancy factor) and radiation survey report for the verification of the adequacy of installed shielding Demonstrate that doses are below dose constraints for workers and dose limit for members of the public
- For renewal or amendment of existing application, radiation

survey report, after any change in surrounding occupancy, new penetrations, lead flow, room modifications, equipment modifications, changes, or layouts.

3.2 Information on Radioactive Sources, Medical Radiological Equipment, and medical procedures:

i. The Saudi Food and Drug Authority (SFDA) approval on:

- The technical and clinical specifications of the medical radiological equipment; and
- The technical and clinical specification of radioactive material prior to requesting for its import license to the Kingdom, from the NRRC.

ii. Information on unsealed sources (each radionuclide separately) shall include:

- Radionuclide
- Physical form (e.g. liquid, capsulated, gas).
- Manufacturer of the source.
- Maximum activity to be possessed at time.
- Main purposes for the use (e.g. diagnostic imaging, therapy, calibration, marker) and location.

iii. Information on sealed radioactive sources shall include:

- Radionuclide.
- Manufacturer of the source.
- Model.
- Source serial number.
- Transporter of the source.
- Source activity and reference date.

- Leak test.
- Certificate for sealed radioactive source.
- Recommended working life given by the manufacturer.
- Main purpose of use and location.

iv. Information on medical radiological equipment (e.g. Gamma camera, SPECT, and PET) shall include:

- Type of equipment.
- Manufacturer of the equipment.
- Model of the device.
- Serial number(s) of the device (generator Where applicable).
- Maximum kV and mA/mAs (Where Applicable).

3.3 Information on measuring Instruments shall include:

i. Inventory all measuring instruments used in the Quality Control to include:

- Technical information (manufacturer, model, serial number, calibration date).
- Calibration certificates.

ii. Activity calibrators: The manufacturer of the device, model, and serial number, and Certificate of calibration.

3.4 Information of Radiation Monitoring Equipment shall include

Inventory of all the monitoring equipment within the facility:

- Installed radiation monitor(s) in laboratories in "hot areas" and for discharges as appropriate:
  - Specify technical information related to

radiation monitors permanently installed. (Manufacturer, model and serial number)
- Demonstrate suitability and calibration of the monitor(s).
- Specify their numbers.

- Portable survey meters:
  - Specify technical information related to portable survey meter(s) for monitoring external exposure, air contamination and surface contamination. (manufacturer, model and serial number)
  - Demonstrate suitability and calibration of portable survey meters.
  - Specify the purpose of use.
  - Specify their quantity .
  - Personnel monitoring devices:

    Specify the type of personal monitoring devices in use and their suitability for the activities conducted in the facility (e.g., TLD, DRD, or OSL).

3.5 Specific Requirements for the Hot Lab

- Applicants shall prove the availability of the following:
  - Suitable sinks and washing area. The taps should be operable without direct hand contact and disposable towels or hot air should be available.
  - An emergency eyewash should be installed near the

hand-washing sink and there should be access to an emergency shower in or near the laboratory.

- Floors and other surfaces of the area should be covered with smooth, continuous, non-absorbent, and non-porous surfaces that can be easily cleaned and decontaminated.
- The walls should be finished in a smooth and washable surface.

3.6 Special Requirements for the Isolation Rooms "Treatment with I-131"

i. Applicants shall prove the availability of the following:

- A designated area suitable for isolation of iodine patients including Shielding calculation and assumptions used is provided and clearly identified with satisfactory results.
- Having separate toilet and washing facilities which should be connected toa delay tank.
- Having a Ventilation system
- Floors and other surfaces of the area should be covered with smooth, continuous, non-absorbent, and non-porous surfaces that can be easily cleaned and decontaminated.
- The walls should be finished on a smooth and washable surface.

ii. Procedures for handling waste from isolation room toilets.

4. Safety Assessment

The applicant shall provide a Safety assessment document as

following:

Taking into account existing shielding, provide calculations of the maximum dose rates expected in all areas outside the treatment room(s) which could be occupied. For these calculations, assume any radiation beam is oriented in the position that would result in the highest directional exposures.

i. Expected doses (occupational, public and from medical exposure) arising from normal operation of the practice.
ii. Estimation of the potential doses (occupational, public and from medical exposure) from anticipated accident conditions.
iii. Review of safety assessment.

5. Radiation Protection Program (RPP)

The Radiation Protection Program shall include the following:

5.1 Protection of Workers

i. Qualification of workers. Specify names, education, Saudi Commission for Health Specialties (SCHS) license, training, and work experience.
ii. Personal dosimetry. Include reading and history for the past Five (5) years.
iii. Other elements of RPP:
    - Local rules and supervision:
        - o Describe the local rules and procedures regarding investigation level and dose constraints, protective measures and safety provisions, providing adequate supervision, and providing workers information

regarding health risks due to occupational exposure.

- Describe the policies regarding female workers who become pregnant that include : , declaration of pregnancy and adoption of working conditions to protect fetus/embryo, and the instructions provide to them.

- Local rules and supervision:
  Demonstrate that appropriate personal protective equipment is provided, and arrangements are made for its proper use, testing and maintenance.
- System of record, "provide a template" for the following:
  - Disposal of material.
  - Personnel exposure:
    - Current records
    - Prior work history
  - Area surveys:
    - dose rate survey
    - Contamination survey
  - Instrument tests and calibrations.
  - Leakage tests for radioactive sealed source.
  - Inventory and sources accountability.
  - Incident and accident investigation reports.
  - Training provided.
  - Receipt and Transportation

o receiving of radioactive sources.

5.2 Protection of The Public

i. System of protection and safety to protect member of the public:

- Describe the system of protection and safety to protect members of the public.
- Provide assumptions used to assess external exposure of public and the procedures conducted for routine periodic measurements of exposure rates in areas adjacent to treatment and storage.
- Procedures for the control of visitors.
- Describe the use of signs, labels, marks and notices in controlled and supervised areas to be noticed by members of the public. Confirm that they are in both in Arabic and English language.

5.3 Protection of Patients

i. Responsibilities:

- Specify how radiological medical practitioners ensures that protection and safety is justified and optimized for each medical exposure and who is responsible for that, e.g. chief nuclear medicine physician.

ii. Justification:

- Specify how treatment procedures are justified by taking into account the benefits and risks of alternate

techniques that do not involve medical exposure.

- specify who can prescribe a nuclear medicine procedure. e.g. nuclear medicine consultant.
- Procedures for reviewing relevant information on prior to radiological procedures performed on the patient.
- Specify how the referrals from different facilities are reviewed and accepted, what are the procedures whether the referral is internal or external?
- Describe how the patient is verified that she is not pregnant or breastfeeding? Describe a procedure to justify medical exposure for a pregnant patient.
- Describe procedures to inform the patient on precautions after receiving radionuclides to protect an infant of a breast-feeding patient.
- Procedure for patient identification. Describe how each individual is identified to get a justified and optimized medical exposure.
- Procedure for the release of patient after radionuclide therapy.

iii. Optimization:

- Describe the most common imaging and treatment procedures and how optimization has been ensured. Describe the implementation of diagnostic reference levels.
- Patient records (information of the medical exposure). Describe how patient records are kept and what kind

of information is recorded from medical exposures.

5.4 Audit and review of the RPP.

Description on responsibilities assignment for the RPP audit, and how frequently the RPP is audited/reviewed.

5.5 Availability of the RPP to Radiation Workers.

Describe how the RPP is available to all occupationally exposed to radiation.

6. Quality Assurance

In term of quality assurance, the following shall be performed and provided:

6.1 Technical Quality Control (QC)

Confirm the effective and safe medical radiological equipment performance by providing the following for all medical radiological equipment:

- For new installation of medical radiological equipment, provide the acceptance and commissioning test report of the equipment prior to its clinical use on patients: with description of the tests, responsibilities to perform the tests and to approve the results, criteria for the tests and used standards, e.g. a reference to a standard procedure of acceptance testing.
- Annual QC report(s) of the physical parameters of

medical radiological equipment.

- Maintenance report(s).

6.2 Clinical QA

Confirm the effective and safe clinical performance by submitting the following:

- Provide a written protocols for every type of radiological procedure.
- Provide information on Investigation of Unintended and Accidental Medical radiological exposure.
- A description on how regular and independent audits are performed for the program.
- Treatment procedures (workflow): Procedures carried out from justification to follow-up of the patients after treatments.
- Provide supporting documents to section d above, such as templates and examples of the following (but not limited to):
  - Radiation treatment prescription
  - Referral request
  - Consent form

7. Radioactive Sources Security Plan

The security plan of radioactive materials shall include:

- A description of the radioactive material and the environment for its use and storage.
- A description of the specific security concerns to be addressed.

- A description of the security system implemented and its objectives.
- Administrative aspects, including defining the roles and responsibilities of individuals with security responsibilities, access authorization processes, trustworthiness determination processes, information protection processes, inventories and records, event reporting, and review and revision of the security plan .
- Response actions including cooperation with relevant competent authorities in the location and recovery of radioactive material.

8. Emergency preparedness and response

8.1 General Elements

i. Availability of the Emergency plan for all workers in an understood language.

ii. Frequent audit and an update of the emergency plan

iii. Ensuring the effectiveness of the emergency plan:
Through training, drills and exercises for all members, tests and calibration of the equipment.

iv. Availability of emergency equipment:
- Including a list of the equipment that should be available, its location and the names of people trained to use it.

v. Notification process and details.
- The RSO, emergency plan members, as well as the (NRRC) notification process and details.

vi. Method for reporting Radiological, fires and other emergencies.

vii. Accident/incident records keeping.

8.2 Special Procedures and scenarios to be included in the Emergency Preparedness and Response Plan

i. Procedures for handling radioactive material in emergency scenarios.

ii. Procedures for decontamination in an emergency.

iii. Procedures for management of radioactive waste in an emergency.

iv. Facility's protection strategy for a radiological emergency, should include:

- Foreseeable emergencies. An identification of each type of accident, including the following:
  - Spillage of radioactive material.
  - Loss/theft of radioactive material.
  - Death of a patient administered with therapeutic quantity of radioactivity.
  - Misadministration of radiopharmaceutical.
  - Any other event that may lead to situations of radiological consequence.
- Action plans. A set of procedures to be implemented for each foreseeable emergency and including a brief description of the means to protect workers onsite.

- Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.
- Rescue and medical duties for any workers designated to perform them.
- An evacuation policy and procedure. "Emergency escape procedures and route assignments, such as floor plans, workplace maps, and safe or refuge areas."
- Procedures for employees who remain to perform or shut down critical operations, operate fire extinguishers, or perform other essential services that cannot be shut down for every emergency alarm before evacuating.

9. Radioactive Waste Management Plan

The radioactive waste management plan shall include the following aspects:

i. Inventory list of radioactive waste.
ii. Forms of radioactive waste (e.g. liquid, solid).
iii. Maximum activity.
iv. Procedures for radioactive waste segregation (e.g. Tc-99m sharps, Tc-99m non-sharps, long-lived isotopes sharps, long-lived isotopes non-sharps, non-radioactive waste).
v. Procedures for waste labelling.
vi. Procedures for disposal of radioactive waste (e.g. gaseous, aerosols, liquids, solids), including:

- Disposal of release of delay tank effluents into drainage system if applicable
- Disposal of airborne radioactive waste into the environment

vii. Procedures for disused sealed sources.

viii. Procedures for on-site decay storage.

ix. Procedures for clearance.

x. Record keeping.

10. Related Documents and Files

Document Name	Document Type	Document Number	Relation to This 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
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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