NRRC Stakeholders Guidelines

Kingdom of Saudi Arabia

Application for Authorization of Diagnostic Radiology

NRRC-SG-017

2023

هيئة الرقابة النووية والإشعاعية
Nuclear and Radiological Regulatory Commission

Stakeholder Guideline

Application for Authorization of Diagnostic Radiology

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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. 1415, 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 diagnostic radiology practice throughout its life cycle. Under the regulatory framework, the prime responsibility for safety and security within diagnostic radiology practice lies with the authorized person.

The purpose of this document is to give the applicant and/or the authorized person clear and specific guidance on the submission for the purpose of authorization including Conventional diagnostic radiology, Interventional diagnostic radiology, Computed Tomography Scan (CT), Mobile radiography, Fluoroscopy, Bone densitometry and Mammography.

2. Scope

This guideline is addressed to diagnostic radiology facilities and activities, in particular, will address the management system, radiation protection, safety aspects of diagnostic radiology practice. This will include diagnostic radiology work that uses radiation producing devices, in the authorized facility. 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 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

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 Cobalt-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.

Occupational exposure

Exposure of workers incurred in the course of their work.

Quality assurance (QA)

The function of a management system that provides confidence that specified requirements will be fulfilled.

Radiation protection program (RPP)

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 siting, design, and operation of the facility.

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.

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.
QA	Quality Assurance.
QC	Quality Control.
TLD	Thermoluminescent Dosimeter.
OSL	Optically Simulated Luminescence.
DRD	Direct Reading Dosimeter.

5. Format and content of Diagnostic radiology Application

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

6. Integrated Management System (Administrative Level)

The applicant should provide and perform the following:

6.1 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 RSO in accordance with criteria established

by the NRRC along with duties, responsibilities, and powers of the RSO in writing.

6.2 Responsibilities For Radiation protection and Safety

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

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

- RSO(s),
- All workers in the diagnostic radiology department (e.g., medical physicists, medical practitioners, technologists, nurses).
- Radiation safety committee, if applicable.

6.3 Policy and Procedures/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.

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

iv. **Policy and procedures on Disused Medical Radiological Equipment:** policy and procedures on safe and secure management and control of equipment once it has been decided to take them out of use.

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

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

vii. **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.

7. Technical Information

7.1 Description of the facility:

i. Layout of the diagnostic radiology department, including:

- Layout of the X-ray imaging room(s) and adjacent areas. The layout needs to be given using a scale enabling analysis of the X-ray imaging room and adjacent areas characteristics, e.g. entrances, doors, windows, roof, floors, and penetrations used for ventilation and electricity. Position(s) of equipment is given, Specify all adjacent equipment, imaging X-ray equipment and their control room/s.
- Boundaries of controlled and supervised areas, where controlled areas include all X-ray imaging rooms and console rooms, 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.

i. Safety features. For X-ray imaging room(s), as applicable, specify all technical safety features and warning systems, such as emergency buttons, door interlocks, use of key control, access control measures, barriers, monitors, and warning signals and notices.

ii. Shielding assessment:
    - For new installation, shielding calculation and assumptions used (e.g. workload, wall thickness, main directions of the beam, and leakage radiation) 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.

7.2 Information on medical radiological equipment:

i. the Saudi Food and Drug Authority (SFDA) Approval on:

- the technical and clinical specifications of the medical radiological equipment.

ii. Information on imaging equipment:

- Type of equipment (e.g., mammography, computed tomography, etc.)
- Manufacturer of the equipment.
- Model.
- Serial number.
- Maximum kV and mA/mAs.

7.3 Information on radiation monitoring equipment:

Inventory of all the monitoring equipment within the facility:

i. Portable survey meters:

- Specify technical information (manufacturer, model, serial number, calibration date) related to portable survey meter(s) to be used.
- Specify the purpose of use.
- Specify their quantity.

- Calibration certificates for all survey meters.

ii. Personnel monitoring devices:

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

7.4 Information on radiation measuring equipment:

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

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

8. Safety Assessment

8.1 Safety assessment document:

Taking into account existing shielding, provide calculations of the maximum dose rates expected in all areas outside the imaging 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 accident conditions.

iii. Review of safety assessment.

9. Radiation Protection Program (RPP)

The Radiation Protection Program shall include the following:

9.1 Protection of workers:

i. Qualification of workers. Specify names, education, certificates, Saudi Commission for Health Specialties (SCHS) license, training, and work experience.

ii. Personal dosimetry: Include reading and history of radiation exposure for the past 5 years.

iii. Other elements of RPP:

- Assignment of responsibilities for the RPP.
- Local rules and supervision:

• Describe your local rules and procedures regarding investigation or authorized levels, protective measures and safety provisions, providing adequate supervision, and providing workers information regarding health risks due to occupational exposure in an understood language.

• Describe the facility policies regarding female workers who become pregnant (declaration of pregnancy, and adoption of working conditions to protect fetus/ embryo) and the instructions you will provide to them.

• Personal protective equipment. "As applicable"

• System of record, "provide a template" for the following:

o Personnel exposure:

- Current records
- Prior work history

- o Area surveys:
  - Dose or dose rate
- o Instrument tests and calibrations.
- o Inventory of imaging equipment and accountability.
- o Incident and accident investigation reports.
- o Maintenance and repair work.
- o Facility modifications.
- o Training provided.
- o Transportation.
- o Clinical dosimetry records (patient dosimetry).

9.2 Protection of the public:

i. 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 assessment, control and surveillance of external exposure of public are in place, i.e. use of dose limit for the member of the public. Provide assumptions used to assess external exposure of public.
- Procedures for the control of visitors.
- Procedures for routine periodic measurements of exposure rates in areas adjacent to X-ray imaging rooms.
- Describe the use of signs, labels, marks, and notices to be noticed by members of the public. Confirm that they are in Arabic and English language.

9.3 Protection of Patients:

i. Responsibilities:

- Who can prescribe or approve the prescription imaging procedure? (e.g. medical physician or radiologist) specify elements of the medical exposure prescription.
- Specify how radiological medical practitioners ensure that protection and safety is justified and optimized for each imaging procedure and who is responsible for that, e.g. radiologist.
- Specify who is responsible for the patient's consent, to inform the patient undergoing medical exposure or his/her guardian as appropriate, of the expected benefits and risks.

ii. Justification:

- Specify how imaging procedures are justified by taking into account the benefits and risks of alternate techniques that do not involve medical exposure.
- Procedures for reviewing relevant information on prior to radiological procedures performed on the patient.
- Specify how the referrals from different facility are reviewed and accepted, what is the procedures whether the referral is internal or external?
- How is the patient verified that she is not pregnant?
- Describe a procedure to justify medical exposure for a pregnant or patient.
- Procedure for patient identification: Describe how

each individual is identified to get a justified and optimized medical exposure.

iii. Optimization:

- Describe shortly the most common imaging procedures and how optimization has been ensured.
- Patient records (medical exposures).

9.4 Audit and review of the RPP.

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

9.5 Availability of the RP to radiation workers

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

10. Quality Assurance (QA)

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

10.1 Technical Quality Control (QC):

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

i. For new installation of equipment, provide the acceptance and commissioning 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.

ii. Annual QC report(s) of the physical parameters of medical radiological equipment.

iii. Maintenance report(s).

10.2 Clinical QA:

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

i. Template of the request form of the medical exposure for all modalities within the Diagnostic Radiology.

ii. Template of consent form, as applicable.

11. Emergency Preparedness and Response Plan

11.1 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.

11.2 Special procedures and scenarios to be included in the Emergency Preparedness and Response Plan:

i. Facility's protection strategy for a radiological emergency, including:

- Foreseeable emergencies. An identification of each type of accident, including the following:
  - Tube housing leakage
  - Failure of interlocks.
  - Emergency shutdown buttons failure.
- 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.

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

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