NRRC Stakeholders Guidelines

Kingdom of Saudi Arabia

Application for Authorization of Radiotherapy

NRRC-SG-015

2023

هيئة الرقابة النووية والإشعاعية
Nuclear and Radiological Regulatory Commission

Stakeholder Guideline

Application for Authorization of Radiotherapy

2023

NRRC-SG-015

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. 1417, 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 Radiotherapy practice throughout its life cycle. Under the regulatory framework, the prime responsibility for safety and security within radiotherapy 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 radiotherapy practice.

2. Scope

This guideline is addressed to radiotherapy practice including Radiotherapy using LINAC, Radiation brachytherapy, Radiotherapy using accelerated ions, Radiotherapy using x-ray, Teletherapy using sealed sources. 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.

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 deliver 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.

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.

Occupational exposure

Exposure of workers incurred in the course of their work.

Quality assurance

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

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 siting, 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.

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
TPS	Treatment Planning system

5. Format and Content of Radiotherapy Application

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

6. Integrated Management System (Administrative Level)

The applicant shall 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 imple-

menting 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 radiotherapy department, (e.g., Radiation Oncologist, Medical Physicists, Medical dosimetrists, Radiation Therapist, Technologists, Nurses)
- Radioactive sources security workers if they differ from radiotherapy department.
- 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, including TPS.

- Description on how independent dosimetry audit is carried out.

- Treatment planning: Describe responsibilities for dose planning, verification and approval.

- 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 therapy and imaging 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 treatment. e.g. presence of the Radiation Oncologists, Medical physicist, or the number of therapist.

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.

7. Technical Information

7.1. Description of Facility

i. Layout of the radiotherapy department, shall include:

- Radiotherapy room(s) and adjacent areas. The layout needs to be given using a scale enabling analysis of the radiotherapy room and adjacent areas characteristics, e.g. entrances, maze, doors, roof, floors, and penetrations used for ventilation and electricity.
- Position(s) of source(s) and equipment is given, including an isocenter point if any.
- Specify all adjacent rooms, such as: Radiotherapy bunkers, and imaging rooms.
- Radioactive storage "as applicable". Specify which sources and equipment given before will be stored in the storage area. Specify maximum capacity of the storage.
- Boundaries of controlled and supervised areas, where controlled areas include: (All treatment rooms, brachytherapy source preparation rooms, and source storage areas), 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 radiotherapy room(s), specify all technical safety features and warning systems, such as emergency buttons, radiation monitor(s) in case of a radioactive source (e.g. dose rate monitor in the room), door interlocks, use of key control, access control measures, barriers, monitors, and warning signals and notices. For radioactive storage, specify positions of all technical safety systems, e.g. monitors, sensors, access control measures, barriers, detectors causing warning signals, and notices.

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, occupancy factor, equipment orientation, 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 the following shall be performed and provided: radiation survey report for the verification of the shielding. Demonstrate that doses are below dose constraints for workers and dose limit for members of the public. Specify the Workload.

7.2. 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 sealed radioactive sources (if applicable) shall include:

- Radionuclide.
- Manufacturer of the source.
- Model.
- Source serial number.
- Maximum, typical and minimum activity for clinical use.
- Source activity and reference date.
- Leak test.
- Certificate for sealed radioactive source.
- Transporter.
- Recommended working life given by the manufacturer.

iii. Information on brachytherapy units (if applicable) shall include.

- Manufacturer of the equipment.
- Model of the equipment.
- Type of loading e.g. manual or remote.
- Dose rate e.g. high or low.
- Maximum activity.
- Number of channels.
- Compatibility of the equipment.
- System interlocks.

iv. Information on gamma-knife units (if applicable) shall include:

- Manufacturer of the equipment.
- Model of the equipment.
- Number of sources installed.
- Maximum design activity.
- Total activity installed.

- Type of source carrier or shutter (exposure mechanism).

- System interlocks.

v. Information on linear accelerator (if applicable) shall include:

- Type of linear accelerator.
- Manufacturer of the linear accelerator.
- Model of the linear accelerator.
- Serial number(s) of the linear accelerator.
- Nominal beam energies: for different beams e.g. photons & electrons.
- Maximum energy.
- Maximum current (mA).
- Maximum dose rate (mu/min).
- Maximum leakage radiation.
- On board imaging (yes/no)
- If yes, type(s), and serial number of x-ray tube.
- System interlocks.

vi. Information on radiotherapy simulator shall include:

- Manufacturer of the simulator.
- Model of the simulator.
- Type of the simulator (e.g. CT simulator, PET-CT simulator, Conventional simulator)
- Serial number(s) of the simulator system and x-ray tube.
- Maximum kVp and mA/mAs.
- System interlocks.

vii. Additional information on imaging device with radiation source for radiotherapy units (if applicable) shall include:

- Manufacturer of the equipment.
- Serial number.
- Model.
- Safety features (e.g. system interlocks).

viii. Information on medical procedures: Describe types of treatments and activities carried out in the facility using linacs.

- IORT
- IMRT
- Arc therapy
- Stereotactic (SRS, SRT, SBRT
- TBI
- Other: explain ……

7.3. Information on Measuring Instruments shall include:

Inventory of all measuring instruments used in Quality Assurance including technical information of the following "as applicable":

i. Ionization chambers for photon beams, electron beams and brachytherapy unit

ii. Electrometer.

iii. Calibration certificates for all ionization chambers and electrometers.

7.4. Information on Radiation Monitoring Equipment shall include:

Inventory of all the monitoring equipment within the facility:

i. Installed radiation monitor(s) in radiotherapy rooms with radioactive source(s):

- Specify technical information (manufacturer, model, serial number, calibration date) related to radiation monitors permanently installed.
- Specify their quantity.
- Calibration certificates for all area monitors.

ii. 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.

iii. 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).

7.5. Information on Technical Patient Protection Systems

Specify technical information for the following systems:

i. Treatment Planning Systems (TPS): Specify (manufacturer, model, version, algorithm)

ii. Image guiding systems and treatment verification systems: Specify (type of imaging verification systems)

iii. Immobilization devices: Specify (different devices for different techniques used within the facility)

iv. Visual and audial communication systems between a control room and a treatment room.

8. 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 accident conditions.

ii. 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 exposure for at least the past 5 years.

ii. Other elements of RPP:

- Local rules and supervision:

  - Describe the 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 occu-

pational exposure in an understood language.

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

- Personal protective equipment. "As applicable"
- 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 "as applicable":

  - Disposal of spent sources.
  - Personnel exposure:
  - Current records
  - Prior work history
  - Area surveys:
  - Dose or dose rate
  - Contamination
  - Instrument tests and calibrations.
  - Leakage test for radioactive sealed source.

- Inventory and sources accountability.
- Incident and accident investigation reports.
- Maintenance and repair work.
- Facility modifications.
- Training provided.
- Receipt and Transportation.
- Patient discharge surveys.
- 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 constraints for the member of the public.
- Provide assumptions used to assess external exposure of public and the procedure 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.

9.3. Protection of Patients:

i. Responsibilities:

- Specify how radiological medical practitioners ensure that protection and safety is justified and optimized for each treatment and who is responsible for that, (e.g. chief oncologist.)
- Specify who is the responsible medical physicist e.g. a chief physicist.
- 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 treatment procedures are justified by taking into account the benefits and risks of alternate techniques that do not involve medical exposure (e.g. tumor board, pathology report, etc.)
- Specify who can prescribe a treatment? (e.g., On-

cologist, gynecologist, or Radiation Oncologist) specify elements of the treatment prescription.

- 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?
- How is the patient verified that she is not pregnant?
- Describe a procedure to justify a treatment for a pregnant patient, and arrangements for appropriate radiation protection for the fetus in pregnant patients.
- Release of patients after permanent brachytherapy implants.

iii. Optimization:

- Procedures for most common treatments. Describe shortly the most common treatment procedures and how optimization has been ensured.
- Patient records (information of the treatment). Describe how patient records are kept and what kind of information is recorded from medical exposure, in incorporating at least the study, date, equipment,

and technical parameters used, including the number of exposures and the duration, allowing retrospective assessment.

- Peer review of patients' treatment process (chart rounds).
- Describe how patient protection has been optimized using technical systems such as:
  - Treatment planning systems (TPS).
  - Image guiding systems and treatment verification systems.
  - Immobilization devices.
  - Visual and audial communication systems between a control room and a treatment room.
- Follow-up of the treatments. Describe how radiological review of treatments are carried out, including an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the treatments that are performed in the medical radiation facility.

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 RPP to Radiation Workers.

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

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 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.

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

iii. Maintenance report(s).

iv. TPS annual QA report(s)

10.2. Clinical QA

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

i. Treatment procedures (workflow): Procedures carried out from justification to follow-up of the patients after treatments.

ii. Provide supporting documents to section i above, such as templates and examples of the following (but not limited to):

- Radiation treatment prescription
- Referral request
- Consent form
- CT simulation request
- Treatment planning (external beam and brachy) verification checklist and approval
- Treatment data transferred to technologists.
- Patients file verification checklist prior to the start of treatment including different techniques.
- Checklist of records kept in patients' treatment.
- Completeness of treatment.

11. Radioactive Sources Security Plan

Describe security system and security management measures for the practice according to NRRC-R-17 to include at least the following:

- Assignment of radioactive material to category and security levels.
- Site Description.
- Operational Description.
- Security Plan
- Vulnerability Assessment
- Training and Qualification
- Security roles and responsibilities.
- Access Authorization.
- Information Security.
- Personal Trustworthiness and Reliability
- Maintenance and testing.
- Procedures for Routine, Off-shift, and Emergency Operations.
- Procedures for Receipt and Transfer of Radioactive Material.
- Inventory control

- Communications
- Security Event Reporting.

12. Emergency Preparedness and Response Plan

12.1. 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

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

iii. 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.

iv. Notification process and details.

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

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

vi. Accident/incident records keeping.

12.2. Special procedures and scenarios to be included in the Emergency Preparedness and Response Plan

Facility's protection strategy for a radiological emergency, shall include:

- Identification of emergency situation including but not limited to "as applicable":
  - Radioactive source failing to return to the safe shielding position.
  - Damage or dislodge/loss/theft of radioactive source at the installation during use, storage, transport, loss of source shielding or natural calamities such as fire, flood, or earthquake.
  - Death of patient, with sources in situ.
  - selection of wrong treatment mode,
  - selection of wrong beam modifiers
  - wrong dose delivery.
  - Selection of wrong plan
  - Collision between machine head and patient.
  - Failure of interlocks.
  - Improper retraction of source to OFF position.
  - Improper measurement of source length.
  - Emergency shutdown buttons failure.

a. 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.

b. Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

c. Procedures for handling radioactive material in emergency scenarios.

d. Rescue and medical duties for any workers designated to perform them.

e. An evacuation policy and procedure. "Emergency escape procedures and route assignments, such as floor plans, workplace maps, and safe or refuge areas."

f. 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.

13. Related Documents and Files

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

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

King Fahd National Library Cataloging-in-Publication Data

L.D. no. 1445/248
ISBN: 978-603-92074-0-5

هيئة الرقابة النووية والإشعاعية

Nuclear and Radiological Regulatory Commission

Kingdom of Saudi Arabia

@saudinrrc

nrrc.gov.sa