NRRC Stakeholders Guidelines

Kingdom of Saudi Arabia

Development of Radiation Protection Program

NRRC-SG-020

2023

هيئة الرقابة النووية والإشعاعية
Nuclear and Radiological Regulatory Commission

Stakeholder Guideline

Development of Radiation Protection Program

2023

NRRC-SG-020

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. 1384 dated 16/07/2023.

Contents

1. Purpose

Nuclear and Radiological Regulatory Commission (NRRC) has developed an effective regulatory framework for the safety and security of nuclear and radioactive material throughout their life cycle against unauthorized removal and sabotage. Under the regulatory framework, the prime responsibility for safety and security of nuclear and radioactive material lies with the authorized person.

Section 25 of the Regulation on Radiation Safety (NRRC-R-01) establishes specific requirements for the development, content, revision, and approval of the documented Radiation Protection Program (RPP) by the authorized person as part of the authorization and continuous compliance requirements. To ensure the health and safety of persons in proximity at the authorized activity and/or facility, a radiation protection program for the activity and/or facility is mandatory requirement to be submitted for approval and implemented in accordance with the Regulation on Radiation Safety (NRRC-R-01) for minimizing radiation exposure to workers and to members of the public.

This guideline provides guidance for the applicant and/or the authorized person for the preparation of RPP with the goal of protecting workers, patients, the public and the environment from unnecessary radiation exposure.

2. Scope

This guideline is applicable for the preparation of RPP for radiation activities and facilities that shall be complied as prescribed in Article 74 and 75, of the Regulation on Radiation Safety (NRRC-R-01), that shall be submitted by the applicant for assessment and approval by the NRRC, as part of the documentation required for authorization

process; and shall be documented, reviewed and updated in a way that reflect the actual state of the implemented measures, arrangements and processes for the activity and or at the facility during NRRC inspection. This guideline provides guidance to the authorized person in the preparation of RPP.

3. Abbreviations

Abbreviation	Definition
ALARA	As Low as Reasonably Achievable
CT	Computed Tomography
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
kVp	Kilovoltage peak
mA	milliampere
OSL	Optically Stimulated Luminescence
PET	Positron Emission Tomography
PPE	Personal Protective Equipment
QAP	Quality Assurance Program
RPP	Radiation Protection Program.
RSO	Radiation Safety Officer
RPC	Radiation Protection Committee
SPECT	Single Photon Emission Computed Tomography
SSDL	Secondary Standard Dosimetry Laboratory (SSDL)
TLD	Thermoluminescent Dosimeter

4. Preparation of Radiation Protection Program (RPP)

To ensure that radiation safety is being maintained and radiation protection measures as required by the Commission laws, particularly requirements prescribed in (NRRC-0R-01), are taken effectively, the applicant or the authorized person is required to submit RPP as part of authorization requirement as well as compliance assurance. The RPP describes the ways in which management structures, policies, procedures, and organizational arrangements are implemented to protect workers, patients, the members of public and the environment from undue radiation exposure. It also covers the safe transport, receipt, handling, use and storage of radioactive materials. The licensee submits the RPP for review and assessment by the NRRC to ensure that safe conditions for the proper use of radiation are maintained, radiation exposures are kept ALARA, operations and transport of radioactive material are in compliance with the requirement of the Commission laws.

The objectives of the RPP are as follows:

- Ensure the effective monitoring and control of internal and external radiation doses for onsite personnel and the public;
- Ensure the effective monitoring and control of releases of radioactive material to the environment; and
- Keep radiation exposure as low as is reasonably achievable (ALARA).

4.1. Content of Radiation Protection Program

The RPP considers radiation protection in both normal and abnormal modes of operation and is based on sound engineering

principles and proven practices. The RPP ensures that over the lifetime of the activity and/or facility, any exposure to personnel or individual members of the public will be within the limits established in (NRRC-R-01).

Depending on the type and nature of radiation activities or facilities, the basic structure of the RPP should contain, but not limited to, the following sections with an appropriate level of outlines as indicated in preceding paragraphs:

i. Introduction- Description of Facility;

ii. Objective and Scope;

iii. Basis of the RPP;

iv. Organizational Structure and Responsibilities;

v. Dose Limits and Dose Constraints;

vi. Classification of Areas and Access Control;

vii. Radiation Monitoring;

viii. System for Investigation and Reporting of Overexposure.

ix. Emergency preparedness and Response;

x. Security of Radioactive Material;

xi. Contamination Control/Handling Program;

xii. Radiation Protection Training Program;

xiii. Health Surveillance;

xiv. Radioactive Waste Handling;

xv. Conditions of Service;

xvi. Program Revision Frequency;

xvii. Record Keeping; and

xviii. Quality Assurance;

xix. Definitions and Abbreviations

4.2. Introduction- Description of Facility

The RPP should describe an introduction and a general description of the facility to enable the reviewer to obtain a basic understanding of the overall activities and facility. Following details should at least be described:

i. Description of activity and types of authorization applied to NRRC;

ii. Legal name of the facility and name or designation of the authorized person with clear description that if the facility is a standalone entity or it is part of a larger set-up i.e., organization/hospital, etc.;

iii. All sources of radiation exposure at the installation and facility which includes:

a. Available radiation generators (e.g., superficial, and deep X-ray therapy, linear accelerators, Computed Tomography (CT) alone or combined with Single

Photon Emission Computed Tomography (SPECT) or Positron Emission Tomography (PET), etc.) with complete specifications including peak tube potential (kVp), current (mA), manufacturer, model, serial number, date of installation, etc. and in case of neutron generators, the neutron flux and mean energy, etc.;

b. Available sealed radiation sources, their purpose and complete specification including source ID or serial number, physical form, type of radiation emitted from sources with energy, activity with specified units, reference date and location;

c. Unsealed radioactive material, their purpose, radioisotopes, type of radiation emitted from sources with energy, maximum expected activity to be held/ acquired by the facility in a certain period of time.

iv. Available exposure devices serving the purpose of transport container (portable, fix), transport packages, source changers, storage containers and ancillary equipment along with valid design certificate, design specifications, manufacturer, model, serial number, authorized contents, shielding, etc.; and

v. For transport of radioactive material outside the facility, information related to type, nature, and number of packages to be shipped annually, mode of transport, conveyance type, shipping documents, etc.

4.3. Objective and Scope of the RPP

The RPP should describe the aim and goal intended to be achieved to meet the overall radiation protection goal. The objective of RPP should include implementation of the requirements of the Commission Laws and to keep the radiation doses of workers and public within applicable dose limits and ALARA. There should also be a description of all activities and workers which the RPP is applicable to.

4.4. References for RPP

All the documents used in the preparation of RPP should be documented and properly quoted. Reference documents that commonly refers to may be:

i. Provision of the Commission laws.

ii. Standards and guides of IAEA.

iii. ICRP.

4.5. Organizational Structure and Responsibilities

4.5.1. Organizational Structure

The RPP should describe organizational arrangements and lines of communication that result in an appropriate flow of information on protection and safety at and between the various levels in the entire organization. For this purpose, the RPP should describe:

i. Overall organizational chart based on hierarchy of the facility showing different sections of the organization and reporting and communication lines for the protection and safety as given in Annex II (A).

ii. The organizational chart should reflect the designations of all relevant personnel of the facility such as owner, administrator, RSO, any qualified personnel, radiation worker, technician, persons responsible for transport of radioactive material etc. as required by NRRC; and

iii. Composition of any advisory body, oversight group or radiation protection committee as practiced at the facility.

4.5.2. Roles and Responsibilities

The RPP should provide description of all proposed functions, responsibilities, and authorities of each of the individuals or positions identified in organization structure with respect to radiation protection and safety in management, operation, maintenance, emergency response, record keeping, etc. at the facility and transport of radioactive material outside the facility, including the interface with security. These individuals or positions may include:

i. Authorized person (owner or management i.e., Chief Executive Officer (CEO), Director, Head, etc.);

ii. Advisors, oversight committees or Radiation Protection Committee (RPC);

iii. RSOs;

iv. Qualified personnel;

v. Radiological medical practitioner;

vi. Radiation workers;

vii. Other workers;

viii. Personnel involved in transport of radioactive material; and

ix. Any other person who is involved in performing, supervising, over-sighting, handling or operating radiation equipment or sources at the facility.

The sample responsibilities of authorized person, RSO, radiation workers and RPC are attached as in Annex III.

4.6. Dose Limits and Dose Constraints

This RPP should include description of process/mechanism performed by the authorized person to restrict normal exposure of individuals so that neither the total effective dose nor the total equivalent dose to relevant organs or tissues, caused by the possible combination of exposures from authorized practices, exceeds any relevant dose limit specified in the Commission laws.

There should be description of process/mechanism implemented by the authorized person to optimize the radiation safety measures associated with a given practice so that the resulting doses to the workers of the facility and the public (in case of any source

that can release radioactive substances to the environment) do not exceed dose constraints specified in Commission laws or any lower values agreed by the NRRC. In the case of transport of radioactive material, relevant regulatory limits defined in the Regulation on Safe Transport of Radioactive Materials (NRRC-R-15) and Regulation on Packaging and Transport of Radioactive Materials (NRRC-R-15-SR01) shall apply.

The dose limits and dose constraints applicable at the facility, their compliance, and specific actions if doses exceed the limits/ set dose constraints shall also be included.

4.7. Classification of Areas, and local rules.

This RPP should describe the classification area of the facility i.e., controlled area and supervised area based on the dose limits. A layout of the facility showing classification of areas, description of rules and procedures and necessary arrangements required by the facility to work in respective areas including access control, removal of tools/items, use of protective items and monitoring equipment, etc. should be provided. The arrangements made for demarcation of the areas within the facility or during field work should be described. The area for preparation of packages/shipment within the facility should also be classified based on dose assessment.

4.7.1. Controlled Area

Any area of the facility should be designated as a controlled area where there is a likelihood of receiving an effective

dose greater than 6 mSv in a year or an equivalent dose greater than three tenths of the relevant dose limit as prescribed in Regulation on Radiation Safety (NRRC-R-01). In this area, specific protective measures or safety provisions are (or could be) required for:

i. Controlling normal exposures or preventing the spread of contamination; and

ii. Preventing or limiting the extent of potential exposures.

Information on controlled area should include the following:

i. Arrangements for delineation of controlled areas by physical means;

ii. Display of warning signs and instructions at access points and other appropriate locations within controlled area; and

iii. Description of local rules, procedures applied by the facility for entering, working, and leaving controlled areas and supervision of work with radiation sources.

For example, in case of nuclear medicine, the following areas may be designated as controlled areas:

i. Rooms for preparation, storage, and injection of the radiopharmaceuticals;

ii. Imaging rooms and injected patient waiting areas;

iii. Isolation rooms for therapeutic patients; and

iv. Rooms for temporary storage of radioactive waste.

In radiotherapy, the treatment and simulator rooms are designated as controlled areas. The control panel area and other areas adjacent to the treatment room might also be designated as controlled areas.

4.7.2. Supervised Area

Any area of the facility should be designated as a supervised area where there is a likelihood of receiving an effective dose greater than 1 mSv in a year or an equivalent dose greater than one tenth of the relevant dose limit as prescribed in Regulation on Radiation Safety (NRRC-R-01). There is a need to keep the occupational exposure conditions under review even though specific protection measures and safety provisions are not normally needed. The description of each supervised area and facility arrangements to delineate and identify the supervised areas should be included in this section.

4.7.3. Personal Protective Equipment

The RPP should describe:

i. Type, nature, and specification of personal protective equipment/items available;

ii. The conditions or circumstances when these are to be used;

iii. List of protective equipment or items available at the facility (e.g., protective clothing, lead aprons, gloves, organ shields, protective respiratory equipment, etc.); and

iv. Arrangements for regular testing and maintenance of personal protective equipment.

4.8. Radiation Monitoring

RPP should describe the radiation monitoring arrangements for assessment of radiation exposure to workers at the facility.

4.8.1. Individual Dose Monitoring Arrangements

The RPP shall provide a description of the facility arrangements for the assessment of occupational exposures of workers which shall at least include all workers who work in controlled area prescribed in Regulation on Radiation Safety (NRRC-R-01). This section should describe:

i. Name of Dosimetry Service Provider;

ii. Nature of the dosimetry services e.g., beta, gamma, neutron doses;

iii. Type of dosimeters to be used e.g., TLD, Film Badge or OSL dosimeter;

iv. Frequency of individual monitoring;

v. Duration for use of dosimeter as agreed with service provider;

vi. Number of dosimeters/badges;

vii. Arrangement for personal alarm monitors in industrial radiography facilities

viii. Description and evaluation of dosimetry service providers used by the authorized persons;

ix. Arrangements made with service providers for dispatch and receipt of dosimeters or badges and results including arrangements for immediate accidental monitoring of workers;

x. Description of the alternative methods applied to assess occupational exposure when individual monitoring is not used;

xi. Arrangements for information and access of workers to their dose records;

xii. Assessment of the committed doses if there is a potential of intake of radioactive substances;

xiii. Arrangements to retain the exposure records at least until the worker attains or would have attained the age of seventy-five (75) years and not less than thirty (30) years after the termination of work involving occupational exposure;

xiv. Arrangements for keeping the workers record of the periods of employment with other facilities, if any, and the corresponding doses in each period; and

xv. Recording level, investigation level and action level; as prescribed in Article 296 of Regulation on Radiation Safety (NRRC-R-01), established by the facility with respect to individual radiation dose and corresponding actions to be taken if these are exceeded.

xvi. Arrangements to ensure the submission of relevant individual occupational exposure data to the centralized national database established by the NRRC.

4.8.2. Workplace Monitoring Arrangements

The RPP shall describe the facility arrangements for establishing, maintaining, and keeping under review the program for monitoring of workplace as prescribed in Section 51 of Regulation on Radiation Safety (NRRC-R-01). Information on workplace monitoring may include the following:

i. Nature of monitoring (area monitoring and surface monitoring);

ii. Where and when the measurements are to be made and at what frequency;

iii. Quantities (units) to be measured at the facility;

iv. Reference levels (i.e., recording level, investigation level and, action level) established by the facility with respect to workplace monitoring results and corresponding actions to be taken if these are exceeded;

v. Reference to measurement methods and procedures; and

vi. Type and specifications of the monitoring equipment/instruments of the facility and list of available equipment/instruments along with calibration frequency of these instruments/equipment from SSDL.

4.8.3. Effluent Monitoring Arrangements

The RPP should describe the facility arrangements for establishing, maintaining, and keeping under review the program for monitoring of effluents. The following information may be prepared to provide effluent monitoring arrangement at the facility:

i. Nature of monitoring (liquid effluent and air borne effluent);

ii. Where and when the measurements are to be made and at what frequency;

iii. Quantities (units) to be measured at facility;

iv. Reference levels (i.e., recording level, investigation level and, action level) established by the facility with respect to workplace monitoring results and corresponding actions to be taken if these are exceeded;

v. Reference to measurement methods and procedures; and

vi. Type and specifications of the measurement equipment or

instruments of the facility and list of available equipment or instruments along with calibration frequency of these instruments or equipment from SSDL.

4.9. System for Investigation and Reporting of Overexposure

This section of RPP should describe the mechanism for notification of an incident/accident/event of overexposure, detail of internal system for investigation and subsequent reporting of accidental occupational exposure to the NRRC. Contents of investigation report on radiation overexposure event are attached as Annex IV.

4.10. Emergency Preparedness and Response

NRRC is ensuring safety and security of radiation sources that address the emergency and preparedness for any potential radiological situation through provision of requirement for an emergency plan and regulatory oversight to the authorized person. Article 107 of Regulation on Radiation Safety (NRRC-R-01) make provision that "The authorized person shall prepare an Emergency Plan for the protection of people and the environment reflecting findings from the safety assessment taking into consideration the likelihood of an emergency affecting either workers or members of the public as part of emergency preparedness and response" with the goal to protect people and the environment from any potential harmful effect of radiation. There should be a description on the arrangement of emergency preparedness and response at the facility including measures and means of communication for notification to the NRRC about any abnormal/emergency at

the facility. Furthermore, the authorized person is also required to describe the existing system for emergency preparedness and include the contact points from NRRC in case of emergency communications. For activities and/or facilities with radioactive material of category 1, 2 and 3. A specific Emergency Plan as defined in Stakeholder Guideline Preparation of Radiation Emergency Plan for Radiation Activities/Facilities shall be dedicatedly prepared for NRRC approval.

4.11. Security of Radioactive Material

The of RPP should include the provisions for, maintaining records of source inventory including, for instance, records of receipt, use and transfer of sources and the confirmation that source is not transferred unless the receiver possesses a valid license or authorization from NRRC. Records of sources should be maintained including the following details:

i. Radioisotopes;

ii. Model No.;

iii. Identification No.;

iv. Activity of sources (Reference activity);

v. Location of sources; and

vi. Date of import.

There should also be included in the provision for conducting of periodic physical verification of sources and immediate reporting of any security related event to the NRRC. For activities and/or

facilities with radioactive material of category 1, 2 and 3. A specific Security Plan as defined in Stakeholder Guideline in Development of Security Plan for Radioactive Material shall be dedicatedly prepared for NRRC approval.

4.12. Contamination Control and Handling Arrangements

The RPP should provide description of the mechanism to control the spread of contamination, arrangements to control the contamination of workers and equipment, and decontamination of facilities, to handle the fixed and removable contamination from items and individuals, contamination limits applicable for transport packages and conveyances, their compliance, and specific actions if contamination limits exceed the regulatory limits given in Regulation on Management of Radioactive Waste (NRRC-R-16) and other relevant NRRC's regulations. In case of spread of contamination during transport activity, arrangements for control of contamination should be described.

4.13. Radiation Protection Training Program

The RPP should include facility program to conduct training and retraining (with defined frequency) on radiation safety matters of all individuals either performing or supervising activities using radioactive sources or radiation generators as prescribed in section 57 of Regulation on Radiation Safety (NRRC-R-01).

There should also be provided with information on arrangements available at the facility to conduct such trainings including re-

source persons, training material and facilities and description, if some or all the trainings are arranged from outside the organization, as the case may be and records of trainings provided. The contents of the training program are described in Annex V.

4.14. Health Surveillance

The RPP should provide information on arrangements to conduct health surveillance that assess the initial and continuous fitness of worker(s) designated to work in controlled areas as required in Section 55 of Regulation on Radiation Safety (NRRC-R-01). Information related to health surveillance that should be included are:

i. Medical examination of worker(s) at the time of recruitment;

ii. Periodic medical examination with defined frequency for health surveillance based on general principles of occupational health;

iii. Tests or examinations to be conducted and tests reports examination of the health screening program performed by a qualified medical practitioner;

iv. Policy or arrangement of the facility regarding the provision of adequate information on health risks due to their occupational exposure to the radiation worker including female workers; and

v. Facility arrangements, in case of radiation accident situa-

tions, for administration of first aid and for carrying out external decontamination of affected persons as applicable.

4.15. Radioactive Waste management

The authorized person shall maintain radiation protection measures during the management of radioactive waste. Necessary radiation protection arrangements for proper handling of radioactive waste generated at the facility should also be described. Some of the examples are such as, providing radiation dose monitoring devices, remote handling tools and personal protective clothing/ equipment to workers involved in handling of radioactive waste and working in the radioactive waste management areas, classification of waste management area, segregation/classification of waste with proper marking of waste containers, casks, drums, etc.

4.16. Conditions of Service

The RPP should described policy regarding employment of radiation worker's which includes refrain from providing any benefits to workers as a substitute of proper protection and safety measures as prescribed in Article 172 of Regulation on Radiation Safety (NRRC-R-01), notification of pregnancy by female workers to authorized person, change in workers assigned jobs due to worker's health problems to avoid occupational radiation exposure and prohibition of individual to work as occupational worker under the age of eighteen (18) years. No individual between the ages of 16-18 years should be allowed to work in a controlled area unless supervised and then only for the purpose of the training.

4.17. Record Keeping

The type and nature of records which will be maintained at the facility along with period of time for which these records will be maintained/retained as prescribed in Section 86 of Regulation on Radiation Safety (NRRC-R-01). These records should at least include, but not limited to following:

i. Records for radiation exposure to the worker

- Personal dosimetry in routine operation: effective dose (monthly) and period covered;
- Effective dose resulting from specific exposures (incidents, accidents, or emergencies), and the date of these exposures;
- Committed effective dose from internal exposures.

ii. Health surveillance records;

iii. Radiation survey/workplace monitoring records;

iv. Inventory of radiation sources (sealed radioactive sources and radiation generators);

v. Instrument or equipment calibration/maintenance records;

vi. Inventory of radiation monitors and protective equipment;

vii. Radiation protection training (and retraining) records; and

viii. Documents (plan and procedures) revision record.

ix. Recruitment, termination, or exchange of radiation workers.

x. Import/export records.

xi. Radiation incidents and accidents.

xii. Transfer of ownership of radiation source.

xiii. NRRC inspection visits (including enforcement action).

xiv. Handling/transportation of radioactive materials.

xv. Emergency and security plan testing records.

xvi. Movement of radiation source from/to the storage location.

xvii. Other information required by NRRC from time to time.

4.18. Quality Assurance

The applicant and/or authorized person should describe quality control mechanisms and procedures to review and assess the effectiveness of radiation protection and safety measures within the facility and for transport of radioactive material (if applicable). The following information should be provided in supporting the QA requirements and compliance:

i. Appropriate organizational structure;

ii. Availability of qualified & trained personnel;

iii. Availability of appropriate equipment and their periodic tests/checks;

iv. Development, review, and implementation of plans/procedures;

v. Mechanisms for surveillance/monitoring of workers;

vi. Self-assessment;

vii. Internal and external audits;

viii. Exercises and drills; and

ix. Maintaining records of various activities.

4.19. Definitions and Abbreviations

The RPP shall be systematic and organized that facilitates reference and understanding of all relevant parties. The RPP should include definitions of technical terminology and abbreviations used in radiation protection programs.

5. Additional Contents for Medical Radiation Facilities

Depending on the type and nature of medical radiation facility, the RPP should additionally contain following sections:

i. Medical Exposure Control Responsibilities;

ii. System for Investigation and Reporting of Medical Accidental Exposure;

iii. Calibration and Clinical Dosimetry;

iv. Quality Assurance of Medical Exposure;

v. Activity of Patients on Discharge; and

vi. Guidance Levels for Medical Exposure.

5.1. Medical Exposure Control Responsibilities

The authorized person shall ensure that health professionals are assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure in line with provision of Article 206 of Regulation on Radiation Safety (NRRC-R-01). This RPP should include the responsibilities of individuals designated by authorized person who have overall task of medical exposure protection.

5.2. System for Investigation and Reporting of Medical Overexposure

This authorized person should describe a mechanism to investigate unintended medical exposure to minimize the likelihood of repetition of such incidents. The investigation of accidental, abnormal, or unplanned medical exposures should be aimed at:

i. Establishing the cause of event;

ii. Identifying the failure;

iii. Deciding on remedial action to minimize the chance of a similar failure; and

iv. Estimating the expected radiation doses received by the patient.

The authorized person shall notify about an incident, accident, event to NRRC on priority and within 24 hours as prescribed in article 238 and also submit written report to the NRRC, within thirty (30) days after discovery of the incident. The investigation should be undertaken by the RSO, and the report should describe the occurrence, its cause(s) and effects, the radiation doses received and all necessary corrective and preventive actions. Detail om the necessary lines of reporting within the organization and to NRRC should also be clearly described.

5.3. Calibration and Clinical Dosimetry

The RPP should describe the facility arrangement for calibration of sources used for medical exposure traceable to SSDL as prescribed in Article 216 of Regulation on Radiation Safety (NRRC-R-01), with the following details:

i. In case of radiotherapy facility, the arrangement and frequency of calibration in terms of the relevant dosimetric quantities and irradiation conditions;

ii. In case of nuclear medicine facility, the arrangement and frequency of calibration of the equipment used for activity measurement of unsealed sources to be administered;

iii. Calibration of all dosimeters used for dosimetry of patients; and

iv. Facility policy to calibrate the equipment at time of commissioning, after any maintenance affecting calibration

and frequency set by facility for calibration at regular intervals.

5.4. Quality Assurance of Medical Exposure

The frequency set by the facility for periodical measurement of the physical parameters of the radiation generators including therapeutic and diagnostic equipment as required by Article 255 of Regulation on Radiation Safety (NRRC-R-01). This frequency should not be more than twelve (12) calendar months after the initial measurement at the time of commissioning.

This should also be supported by description on facility mechanism for verification of appropriate physical and clinical factors used in diagnosis and treatment along with mechanism and identification of written records of relevant procedures and results to be retained. In the case of radiotherapy facilities, it should also indicate the facility arrangement, if any, of independent quality audit reviews of the quality assurance program.

5.5. Activity Levels for Patients on Discharge

The authorized person should provide facility policy about maximum activity level to permit the discharge of a patient who has undergone a procedure with sealed or unsealed sources as specified in Article 230 of Regulation on Radiation Safety (NRRC-R-01). There should be information that specify the maximum activity levels for patient discharge from hospital with written instructions/precautions provided to patient on discharge and also describe the facility mechanism to document the justification

and authorization if a patient discharged from hospital is to be permitted before the activity level falls below the specified levels.

5.6. Guidance Levels for Medical Exposure

This section of the RPP should describe the guidance levels for medical exposure practiced at the facility, including specifying if guidance levels (with reference to document) other than prescribed by NRRC are used by the authorized person.

6. Review and Revision of Radiation Protection Program

The RPP of the activity or facility should be reviewed/revised at least once in five years or whenever necessary in the light of:

- Change in application or location of radiation sources, or facility;
- Lessons learned from emergency exercises/drills;
- National and international experience feedback;
- Revision in the reference documents and day to day activities;
- Changes in the regulatory requirements.

The revised RPP should be submitted to NRRC for review and approval.

7. Related documents and files

Document Name	Document Type	Document Number	Relation to the procedure
Radiation Safety	Regulation	NRRC-R-01	Sets out the general safety requirements in ensuring the protection of people and the environment against the harmful effects of ionizing radiation and for the safety of radiation sources.
Safe Transport of Radioactive Materials	Regulation	NRRC-R-15	Sets out the safety requirements in ensuring the protection of people and the environment against the harmful effects of ionizing radiation and for the safety of radiation sources during transport.
Management of Radioactive Waste	Regulation	NRRC-R-16	Presents the requirements for the management of radioactive waste.

Document Name	Document Type	Document Number	Relation to the procedure
Security of Radioactive Materials	Regulation	NRRC-R-17	Presents the requirements for the security of radioactive materials throughout their life cycle against unauthorized removal of the radioactive material and sabotage.
Packaging and Transport of radioactive Material	Regulation	NRRC-R-15-SR01	Present detail technical requirements to support the implementation of NRRC-R-15
Development of Emergency Plan for Radiological Facilities	Stakeholder Guideline	NRRC-SG-018	Present detail technical requirement and recommendation to support the submission of Emergency Plan as part of authorization compliance requirements
Development of Nuclear Security Plan	Stakeholder Guideline	NRRC-SG-001	Present detail technical requirement and recommendation to support the submission of Security Plan as part of authorization compliance requirements

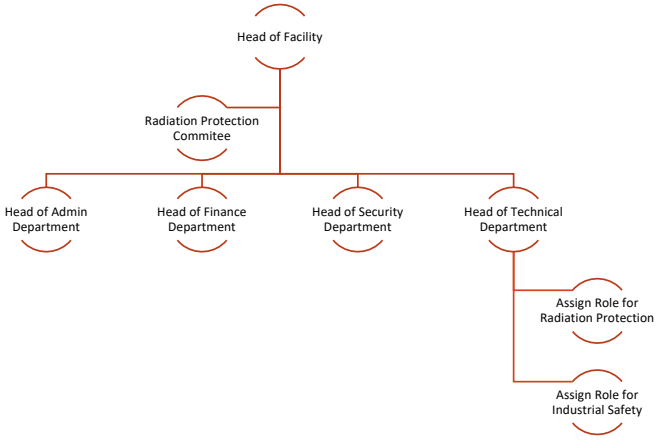
Annex-I: Applicable Sections of Regulatory Guide According to Type of Facility

Num	Scope of Guidance	Applicable Content (Para)
1	Medical Facilities	
	i. Complex Medical Centers ii. Nuclear Medicine/Cardiology	4, 5 and 6
	Radiotherapy	4 (except 4 (except 4.2.8.3), 5 (if internal transportation (from port to end-users) is responsibility of authorized importer/ clearing agent then this section may not be applicable} & 6), 5 {if internal transportation (from port to end-users) is responsibility of authorized importer/ clearing agent then this para may not be applicable} and 6
2	i. Industrial Facilities including industrial radiography, oil well logging, nuclear gauges with radioactive sources of category 1, 2 and 3 etc. ii. Scanners including vehicle/cargo scanners (using radioactive sources) iii. Importers/exporters/traders of radioactive material/sealed radioactive sources and unsealed sources. iv. Any organization/facility involved in transport of radioactive material	4 (except 4.2.8.3) and 5

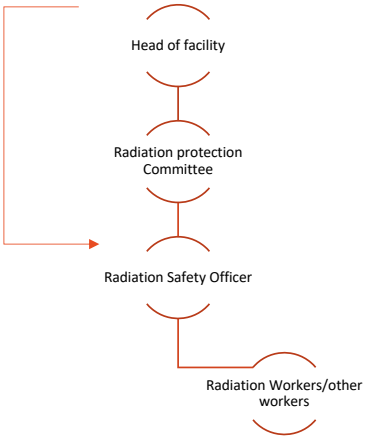
Num	Scope of Guidance	Applicable Content (Para)
3	i. Irradiators including industrial irradiators for food and sterilization, agricultural irradiators, and blood irradiators. ii. Calibration and Dosimetry service provider having radioactive sources of category 1, 2 and 3	4 (except 4.2.8.3) and 5 {if internal transportation (from port to end-users) is responsibility of authorized importer/ clearing agent then this para may not be applicable}
4	i. Scanners including vehicle/cargo scanners (using X-rays). i. Manufacturers of radiation generators i. Research, education, and training institutes having radiation generators	4 (except 4.2.8.3, 4.2.11, 4.2.12, 4.2.15)
5	Manufacturers include manufacturers of consumer products, radioactive sources/special form radioactive materials, packages/casks containing radioactive material as component and radioisotope production facilities. This also includes stockiest having bulk storage of consumer products, sealed/unsealed sources	4 and 5
6	Research, education, and training institutes having radioactive sources of category 1, 2 and 3	4
7	Any other facility or practice so identified by NRRC	To be prescribed based on identified facility

Annex-II: Example of Organizational Chart of the Facility

A. Example of Overall Organizational Chart of the Facility



B. Example of Organizational Chart for Functional Role for Radiation Protection



Annex-III: Typical Assignment of Roles and Responsibilities

1. Responsibilities of the Authorized Person

The responsibilities of the authorized person (Owner, Decision Makers, or Senior Management i.e., Chief Executive Officer (CEO), Director, Head, etc.) should include following:

a. Ensure safe use of ionizing radiations at facility premises;

b. Ensure that for all workers, occupational exposures are limited as specified by the NRRC and promptly report to NRRC if any relevant dose limits are exceeded;

c. Ensure that only workers who are designated in application by name and qualification credentials, as having key assignments related to protection and safety, operation or transport/handling are permitted to undertake and fulfill such required assignments and tasks;

d. Ensure that all radiation workers including female workers are aware of hazards associated with their work and their obligations and responsibilities;

e. Ensure that, under normal operational conditions, the dose limits for persons under 18 years of age are complied with.

f. Ensure compliance and implementation of the Commission laws, local rules, and procedures;

g. Designate a RSO and facilitate the functional role as defined by NRRC;

h. Establish and ensure implementation of policies and procedures to maintain radiation exposures ALARA;

i. Ensure that suitable and adequate facilities for protection and safety are provided to radiation workers including personal protective items and radiation monitoring equipment;

j. Ensure that requirements related to safety culture are being implemented;

k. Ensure arrangements for initial and continuous health surveillance of radiation workers;

l. Ensure training and retraining of radiation workers;

m. Ensure that necessary arrangements for the consultation of and co-operation with workers to ensure the effective implementation of the regulatory requirements for protection and safety are in place;

n. Ensure that necessary arrangements related to the control of outside workers are in place;

o. Record any report received from a worker regarding unsafe conditions or circumstances and take appropriate remedial action;

p. Devise a mechanism to refrain the workers from any willful action that could put themselves/others in situations that are harmful and contravene the regulatory requirements; and

q. Ensure integration of management system and radiation pro-

tection program so that safety may not be compromised due to equipment/packages malfunction.

In addition to the above, following responsibilities related to medical exposure protection should be included to ensure:

a. No patient is administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical professional;

b. Medical or health professionals are available at the facility as needed and have appropriate training to adequately discharge assigned tasks in the conduct of diagnostic or therapeutic procedures;

c. Exposures of individuals incurred knowingly while voluntarily helping in the care, support, or comfort (other than in their occupation) are constrained as specified in Section 82 of Regulation on Radiation Safety (NRRC-R-01).

d. Medical exposures are justified and optimized as per the requirements of Regulation on Radiation Safety (NRRC-R-01);

e. Representative values of clinical dosimetry parameters are determined and documented; and

f. Calibration, dosimetry, and quality assurance are performed under the supervision of a qualified medical physicist.

2. Responsibilities of Radiation Safety Officer (RSO)

Responsibilities of RSO (in-charge of radiation protection and safety) should include the following:

a. Prepare and update the radiation protection program when necessary or requested by NRRC.

b. Prepare emergency planning and preparedness programs i.e., emergency plan, reporting of any radiological emergency to NRRC and incident investigation.

c. Identify and analyze radiological hazards in the work area and environment.

d. Implement radiation equipment maintenance program annually.

e. Implement a program to store radiation sources, calibration and maintenance of radiation equipment and plan for appropriate radioactive waste disposal methods.

f. Organize an annual medical surveillance program for radiation workers.

g. Identify the type and level of radiation protection training for radiation workers.

h. Classify work areas in accordance with the Regulation on Radiation Safety (NRRC-R-01) requirements.

i. Prepare and implement dose monitoring program for radiation worker, area, and environment.

j. Ensure radiation protection equipment is used by radiation workers and remains in good condition.

k. Ensure the recruitment, termination and retirement of radiation workers comply with the procedures set by NRRC.

l. Assess personal background of new radiation workers prior to the hiring.

m. Assess the level of trustworthiness and reliability of radiation workers.

n. Ensuring that any change of location of the radiation equipment receives prior permission from NRRC in advance.

o. Supervise the following works;

   i. High risk work such as planned exposure.

   ii. Maintenance work done on radiation equipment.

   iii. Control and rescue operations during emergencies.

   iv. Transport of radioactive materials.

   v. Prepare a Security Plan with radioactive sources of Category 1, 2 and 3.

   vi. Testing the effectiveness of the Securities Plan.

p. Prepare, record, update and manage records provided in para 4.17 of this guideline.

q. Ensure security of radioactive materials facilities to time to prevent from any risk of loss, sabotage, or theft.

r. Comply with the security measures set by the authorized person.

s. Report any unforeseen event that threatens the security element within 24 hours from the time of the occurrence of the related event.

t. Implement and fully test the Securities Plan approved by the AELB Department and document the implementation report.

u. Stop work operation when violation to the Commission laws is identified.

3. Responsibilities Radiations Workers

Responsibilities of technicians and other workers of the facility designated as occupational radiation workers or assistants/trainees should include at-least the following:

a. Be familiar with ionizing radiation and protect themselves and others from any potential hazard associated with their work;

b. Follow applicable instructions and procedures for protection and safety and comply with all instructions from RSO;

c. Wear assigned radiation dosimeter during work in radiation area for personnel monitoring and its safe keeping in radiation free area during off working hours;

d. Properly use the monitoring devices and protective items provided;

e. Abstain from any willful action that could put themselves or others in situations that are harmful and contravene the regulatory and administrative requirements; and

f. Promptly report to the management/RSO any abnormal occurrence or any circumstances that could adversely affect safety conditions.

4. Responsibilities of Radiation Protection Committee

The responsibilities of the radiation protection committee should include, but not be limited to:

a. Regular review of all aspects of the radiation protection program;

b. Review of occupational radiation doses and any accident reports prepared by the RSO;

c. Making recommendations for improvements in the RPP;

d. Provision of guidance and direction on the performance of the RSO's duties; and

e. Preparation and dissemination of regular reports to all staff about relevant radiation safety issues.

Annex-IV: Contents of Investigation Report on Radiation Overexposure Event

1. **Name/address of institution/facility/consignor;**
2. Authorization Reference No.;
3. Type of radiation facility;
4. Name and identification Number of overexposed person;
5. Designation, qualification, and job experience of overexposed person;
6. Dosimeter No./Code;
7. Period of use of dosimeter;
8. Dose received from radiation overexposure;
9. Collective dose of last five (5) years;
10. Circumstances and causes of overexposure;
11. Findings of investigation;
12. Corrective measures to prevent recurrence of event;
13. Name and signature of Radiation Safety Officer;
14. Name and signature of Authorized Person.

Annex-V: Contents for Training Program

Training topics may include:

1. **Introduction and compliance requirements to the Commission Laws**
2. Responsibilities of a radiation worker.
3. Health risks and precautionary requirements as a radiation worker.
4. Radiological incident preventive measures.
5. Methods and safety measures working/using radiation source devices including with a dose limitation system.
6. Description of the safety measures on the specific radiation source device use at workplace
7. Classification of control, supervise and clean areas.
8. Normal operating plans and procedures.
9. Plans and procedures in the event of a radiation incident/accident.
10. Recovery measures after a radiation incident/accident.
11. Radiological emergency training.
12. Maintenance training on the authorized radiation source device used during activity or at facility.
13. Safety and Security culture training.
14. Security of radioactive material (facility with radioactive source)

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