FORMAT AND CONTENT OF RADIATION PROTECTION PROGRAM

REGULATORY GUIDE

PAKISTAN NUCLEAR REGULATORY AUTHORITY
For Further Details

Directorate of Policies & Procedures
PAKISTAN NUCLEAR REGULATORY AUTHORITY
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FORMAT AND CONTENT OF RADIATION PROTECTION PROGRAM

ABSTRACT

To comply with the requirements of PNRA Regulations on Radiation Protection - (PAK/904), Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installations - (PAK/908), Regulations for Licensing of Nuclear Installations in Pakistan - (PAK/909) and Regulations for the Safe Transport of Radioactive Material - (PAK/916), the licensees prepare and submit Radiation Protection Program (RPP). This regulatory guide will provide guidance on the format and content of RPP for nuclear installations, and radiation facilities and activities in Pakistan.
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1. INTRODUCTION

Pakistan Nuclear Regulatory Authority (PNRA) has been vested with the responsibility for controlling, regulating and supervising all matters related to nuclear safety and radiation protection in Pakistan. Further, PNRA is empowered to devise, adopt, make and enforce such rules, regulations, orders or codes of practice for nuclear safety and radiation protection as may, in its opinion, be necessary. So far, PNRA has issued various regulations and Regulatory Guides (RGs).

Different types of Nuclear Installations (NIs) like Nuclear Power Plants (NPPs), research reactors, etc. and radiation facilities like diagnostic & interventional radiology, nuclear medicine, radiotherapy, industrial radiography, nuclear gauges, irradiators, well logging facilities, etc. are being operated in Pakistan. These facilities use variety of radiation generators, nuclear material, radioactive material and sources. To ensure that radiation safety is being maintained and radiation protection measures as required by PNRA regulations, are taken effectively, the licensee prepares many documents and submits to PNRA including RPP.

The RPP describes the ways in which management structures, policies, procedures and organizational arrangements are implemented to protect workers, patients, the general public and the environment from unnecessary radiation exposure. It also covers the safe transport, receipt, handling, use and storage of radioactive materials. The licensee submits the radiation protection program to PNRA for review and acceptance to ensure that safe conditions for the proper use of radiation are maintained, radiation exposures are kept As Low As Reasonably Achievable (ALARA), operations and transport of radioactive material are in compliance with the requirement of PNRA regulations. This document provides guidance to the licensees in the preparation of radiation protection program. Annexure I is attached which describes the applicability of different sections of this regulatory guide according to the type of facility.

2. OBJECTIVE

The objective of this RG is to provide guidance to licensees regarding preparation of radiation protection program to meet the requirements of PNRA Regulations on Radiation Protection - (PAK/904) and Regulations for these Safe Transport of Radioactive Material - (PAK/916) according to type of installation/facility and activities.

3. SCOPE

This RG is intended to provide guidance for the following types of installations, facilities and activities:
i. NIs i.e. NPPs, Research Reactors, Nuclear Fuel Cycle Facilities, Molybdenum Production Facility, etc.;
ii. Medical facilities including full fledge medical centers, radiotherapy, nuclear medicine/cardiology;
iii. Industrial facilities including industrial radiography, oil well logging, nuclear gauges with radioactive sources of category 1, 2 & 3, etc.;
iv. Irradiators including industrial irradiators for food and sterilization, agricultural irradiators and blood irradiators;
v. Scanners including vehicle/cargo scanners;
vi. Manufacturers including manufacturers of consumer products, radioactive sources, special form radioactive materials, radiation generators, packages, casks containing radioactive material as component and radio-isotope production facilities. This also includes stockist having bulk storages of consumer products, sealed/unsealed sources;
vii. Research, education and training institutes having radioactive sources of category 1, 2 & 3 and radiation generators;
viii. Calibration and dosimetry service providers having radioactive sources of category 1, 2 & 3;
ix. Importers, exporters and traders of radioactive material/sealed sources and unsealed sources;
x. Any organization or facility involved in transport of radioactive material; and
xi. Any other facility or practice so identified by PNRA.

4. CONTENTS FOR PREPARING RPP

Depending on the type and nature of nuclear installation and radiation facilities or activities, 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;
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 and Accountability of Sources;
xi. Contamination Control/Handling Program;
ix. Radiation Protection Training Program;

x. Quality Assurance;

xi. Health Surveillance;

xii. Radioactive Waste Handling;

xiii. Conditions of Service;

xiv. Program Revision Frequency;

xv. Record Keeping; and

xvi. Definitions and Abbreviations.

4.1. Introduction

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

i. Legal name of the facility and name or designation of the licensee 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.;

ii. 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.

iii. 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

iv. 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.
4.2 Objective and Scope

This section should describe aim and goal intended to be achieved by establishment of the RPP. The objective of RPP should include implementation of the requirements of Regulations PAK/904 and PAK/916 and to keep the radiation doses of workers and public within applicable dose limits and ALARA. This section should also describe all the activities and workers on which the RPP is applicable.

4.3 References for RPP

This section should include all the documents used in the preparation of radiation protection program. Reference documents may be:

i. PNRA Regulations and Regulatory Guides;

ii. Standards and guides of International Atomic Energy Agency (IAEA), International Commission on Radiological Protection (ICRP), National Council on Radiation Protection & Measurements (NCRP), etc.

4.4 Organizational Structure and Responsibilities

4.4.1 Organizational Structure

This section of RPP should describe organizational arrangements and lines of communications that result in an appropriate flow of information on protection and safety at and between the various levels in the entire organization. This section of RPP should describe:

i. Overall organizational chart of the facility showing different sections of the organization and reporting and communication lines for the protection and safety as given in Annexure II (II.A). The organizational chart should reflect the designations of all relevant personnel of the facility such as owner, administrator, medical physicist, station health physicist, Radiation Protection Officer (RPO), technicians, persons responsible for transport of radioactive material, etc.;

ii. Designation of an individual as RPO, station health physicist, radiotherapist, nuclear medicine specialist, nuclear cardiologist, medical physicist, radiologist, medical technologist, radiographer, operator, technician, etc. as per PNRA criteria; and

iii. Hierarchy and composition of any advisory body, oversight group or radiation protection committee as practiced at the facility.
A sample organizational structure is given in Annexure II (II.A) and organizational setup for radiation protection section is indicated in Annexure II (II.B).

4.4.2 Designation of RPO

In this section, the licensee should describe the process for designation of RPO, who is responsible to look after the radiation related matters. The criteria should be in accordance with the criteria mentioned in Regulations PAK/904.

4.4.3 Roles and Responsibilities

This section of RPP should describe 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. These individuals or positions may include:

i. Licensee (owner or management i.e. Chief Executive Officer (CEO), Director, Head, etc.);
ii. Advisors, oversight committees or Radiation Protection Committee (RPC);
iii. Operators/Technicians;
iv. RPOs;
v. Health professionals (radiation oncologist, nuclear medicine specialist, nuclear cardiologist, radiologist, medical physicist, etc.);
vi. Personnel involved in transport of radioactive material; and
vii. 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 licensee, RPO, technicians/workers and RPC are attached as Annexure III.

4.5 Dose Limits and Dose Constraints

This section of RPP should describe the process/mechanism followed by the licensee 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 licensed or/and authorized practices, exceeds any relevant dose limit specified in Annexure IV of Regulations PAK/904.

This section should also describe the process/mechanism followed by the licensee to optimize the radiation safety measures associated with a given practice so that the
resulting doses to the workers of the facility and the general public (in case of any source that can release radioactive substances to the environment) do not exceed dose constraints which are equal to the dose limits specified in Annexure IV of Regulations PAK/904 or any lower values agreed by the Authority. In case of transport of radioactive material, relevant regulatory limits defined in Regulations PAK/916 will be followed. This section should include the dose limits and dose constraints applicable at the facility, their compliance and specific actions if doses exceed the limits/set dose constraints.

4.6 Classification of Areas and Access Control

This section should describe the area classification of the facility i.e. controlled area and supervised area on the basis of dose limits. A layout of the facility showing classification of areas, description of rules & 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.

4.6.1 Controlled Area

Any area of the facility should be designated as 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 relevant dose limit as prescribed in Regulations PAK/904. 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.

This section 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.

4.6.2 Supervised Area

Any area of the facility should be designated as 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 relevant dose limit as prescribed in Regulations PAK/904. 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.

4.6.3 Personal Protective Equipment

This section of 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 the personal protective equipment.

4.7 Radiation Monitoring

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

4.7.1 Individual Dose Monitoring Arrangements

This section of RPP should describe the facility arrangements for the assessment of occupational exposures of workers which should at least include all workers who work in controlled area as per Regulation 30 of Regulations PAK/904 and Regulation 305 of Regulations PAK/916. 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. Thermoluminescent Dosimeter (TLD), Film Badge or Optically Stimulated Luminescence (OSL) dosimeter;
iv. Duration for use of dosimeter as agreed with service provider;
v. Number of dosimeters/badges;
vi. Arrangement for personal alarm monitors in industrial radiography facilities and nuclear installations;
vii. Arrangements made with service providers for dispatch and receipt of dosimeters or badges and results including arrangements for immediate accidental monitoring of workers;
viii. Arrangements for information and access of workers to their dose records;
ix. Assessment of the committed doses, if there is a potential of intake of radioactive substances;
x. 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;
xii. Arrangements for keeping the workers record of the periods of employment with other facilities, if any, and the corresponding doses in each period; and

4.7.2 Workplace Monitoring Arrangements

This section of RPP should describe the facility arrangements for establishing, maintaining and keeping under review the program for monitoring of workplace as per Regulation 31 of Regulations PAK/904 and Regulation 305 of Regulations PAK/916 respectively. This section should describe:

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, action level and intervention 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 equipments/instruments along with calibration frequency of these instruments/equipments from Secondary Standard Dosimetry Laboratory (SSDL).
4.7.3 **Effluent Monitoring Arrangements**

This section of RPP should describe the facility arrangements for establishing, maintaining and keeping under review the program for monitoring of effluents. This section should describe:

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, action level and intervention 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.

4.8 **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 PNRA. Contents of investigation report on radiation overexposure event are attached as Annexure IV.

4.9 **Emergency Preparedness and Response**

Regulation 6 of Regulations PAK/904 requires from the licensee to communicate any breach to the Authority timely (within 24 hours) and immediately whenever an emergency exposure situation has developed or is developing. This section should describe the means of communication for notification to the Authority about any abnormal/emergency situation at the facility. Furthermore, the licensee is also required to describe existing system for emergency preparedness and include the following contact points of (Nuclear and Radiological Emergency Coordination Centre (NRECC), PNRA in case of emergency communications:

**Phone:**
- (i) 051-9262019
- (ii) 051-2289210

**Fax:**
- (i) 051-9260201
- (ii) 051-2289233

**Officer Incharge (NRECC):**
- (i) 0300-8540319
- (ii) 0334-5131978

**Toll Free Number:**
- (i) 0800-77766

**Email:**
- (i) nrecc@pnra.org
4.10 Security and Accountability of Sources

This section of RPP should include the provisions for, maintaining records of source inventory including records of receipt, transfer and disposal of sources and the confirmation that source is not transferred unless the receiver possesses a valid license or authorization from PNRA. 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.

This section should also include the provision for conduct of periodic physical verification of sources and immediate reporting of any security related event to Authority. The sources should be verified according to their category (i.e. quarterly for Category 1 and bi-annually for remaining categories of sources).

4.11 Contamination Control and Handling Arrangements

This section of the RPP should provide description of the mechanism to control the spread of contamination, arrangements to control the contamination of workers and equipments and decontamination facilities to handle the fixed and removable contamination from items and individuals, contamination limits applicable for transport packages & conveyances, their compliance and specific actions if contamination limits exceeds the regulatory limits given in Regulations 508-509 of Regulations PAK/916. In case of spread of contamination during transport activity, arrangements for control of contamination should be described.

4.12 Radiation Protection Training Program

This section of RPP should include facility program to conduct training and re-training (with defined frequency) on radiation safety matters of all individuals either performing or supervising activities using radioactive sources or radiation generators as per Regulation Nos. 25(g), 28(2)(a), (2)(c), 35(c) and 46(2)(c) of Regulations PAK/904 and Regulation Nos. 314 & 315 of Regulations PAK/916.

This section should also provide information on arrangements available at the facility to conduct such trainings including resource persons, training material and facilities and description, if some or all of the trainings are arranged from outside the organization, as the case may be and records of trainings provided. The contents of training program are described in Annexure V.
4.13 Quality Assurance

In this section, licensee 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). This section should describe:

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.

4.14 Health Surveillance

This section of RPP should describe arrangements to conduct health surveillance to assess the initial and continuous fitness of worker(s) designated to work in controlled areas as required by Regulation 33 of Regulations PAK/904. This section should describe:

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 (in line with the requirements of Annexure V of Regulations PAK/904) and tests reports examination 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 situations, for administration of first aid and for carrying out external decontamination of affected persons as applicable.

4.15 Radioactive Waste Handling

The licensee is also bound to maintain radiation protection measures during handling and management of radioactive waste. Necessary radiation protection arrangements for proper handling of radioactive waste generated at the facility should also be described in this section. Some of the examples are: 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

As per Regulation 26 of Regulations PAK/904, this section should describe the licensee's 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, notification of pregnancy by female workers to licensee, 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 age 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 Program Revision Frequency

This section should describe continuous monitoring, review of implementation and effectiveness of RPP at the facility and its revision in the light of operating experience and feedback. The program should be reviewed and revised (if needed) at a frequency of three (3) years. However, it may be revised as and when required (before three years) by the licensee.

4.18 Record Keeping

This section of RPP should describe 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 per Regulation 24 of Regulations PAK/904. These records should at least include, but not limited to following:

i. Record of worker exposure (as per Regulation 32 of Regulations PAK/904);  
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 records;  
vi. Inventory of radiation monitors and protective equipment;  
vii. Radiation protection training records; and  
viii. Documents (plans & procedures) revision record.
4.19 Definitions and Abbreviations

This section should include definitions of technical terminology and abbreviations used in radiation protection program.

5. ADDITIONAL CONTENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

In case, the applicant/licensee is involved in transport of radioactive material, then RPP should additionally contain following sections:

5.1.1 Dose Assessment

The licensee should perform assessment of radiation doses to workers and public due to transport of radioactive material. For the assessment and evaluation of transport related radiation doses, the package type & category, exposure time, dose rate, frequency of operation, transport volume, necessity of in-transit storage and use of different modes of transport or conveyances should be considered. Specific handling procedures (e.g. for small packages or packages that are remotely handled) should also be taken into account.

5.1.2 Segregation Distances

As per Regulation 306 of Regulations PAK/916, licensees are required to ensure sufficient segregation distances of packages/materials from workers and members of the public. External dose rates from packages of radioactive material can be high, but exposures of workers and members of the public can be limited by adequate segregation of such packages from workers and public or by use of other protective measures. This section should include information about those measures.

6. ADDITIONAL CONTENTS FOR MEDICAL RADIATION FACILITIES

Depending on the type and nature of medical radiation facility included in the scope of this RG, 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.

6.1 Medical Exposure Control Responsibilities

Regulation 35 of Regulations PAK/904 requires from the licensee to ensure that
medical 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. This section of RPP should include the responsibilities of individuals designated by licensee who have overall task of medical exposure protection.

6.2 System for Investigation and Reporting of Medical Overexposure

This section of RPP should describe licensees 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 what happened;
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 licensee should notify about an incident, accident, event to PNRA on priority and within 24 hours as per Regulation 44 of Regulations PAK/904 and also submit written report to the Authority, within thirty (30) days after discovery of the incident. The investigation should be undertaken by the facility Head/RPO together with the supervisor of the area in which the incident occurred and the report should describe the occurrence, its cause(s) and effects, the radiation doses received and all necessary corrective and preventive actions. This section should also provide detail about the necessary lines of reporting within the organization and to PNRA.

6.3 Calibration and Clinical Dosimetry

This section of RPP should describe the facility arrangement for calibration of sources used for medical exposure traceable to SSDL as per Regulation 39 of Regulations PAK/904. This section should describe:

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.
6.4 Quality Assurance of Medical Exposure

This section of RPP should describe 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 Regulation 40 of Regulations PAK/904. This frequency should not be more than twelve (12) calendar months after the initial measurement at the time of commissioning.

This section should describe the 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 case of radiotherapy facilities, this section should indicate the facility arrangement, if any, of independent quality audit reviews of the quality assurance program.

6.5 Activity Levels for Patients on Discharge

This section of RPP should describe the 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 Regulations 42 of Regulations PAK/904. This section should 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.

6.6 Guidance Levels for Medical Exposure

This section of the RPP should describe the guidance levels for medical exposure practiced at the facility as per Regulations 41 of Regulations PAK/904. Also specify if guidance levels (with reference of document) other than given in Regulations PAK/904 are followed.

7. ADDITIONAL CONTENTS FOR NUCLEAR INSTALLATIONS

For the preparation of RPP of Nuclear Installations (NIs), the format and contents described in this regulatory guide will be followed. However, depending on the type and nature of NIs included in the scope of this regulatory guide, the radiation protection program should additionally contain facility specific sections regarding radiation work planning, radiation work permits/special work permits, further zoning within radiation controlled/supervised areas, policy for preparation of ALARA Plans, system for pre-job and post job briefings, achievements of Refueling Outage (RFO) targets and goals, categories of radiation workers, modes of training for different categories of radiation workers, etc.
7.1 Radiation Work Planning

This section of RPP should describe the facility arrangement for work planning. The planning stage is an essential period within which plan is made to implement work management actions and optimize radiation protection. Work planning and scheduling should integrate radiation protection criteria and use feedback experience to ensure that most effective approaches are implemented. ALARA plans should be prepared for all hot jobs to keep the radiation doses ALARA with estimated collective dose per job and individual dose per person per day. For development of ALARA plan following may be considered:

i. Plant operation condition;
ii. Expected duration of job;
iii. Number of radiation workers involved;
iv. Requirement of personal protective equipment;
v. Expected dose rate or contamination level;
vi. Temporary shielding;
vii. Equipment required for radiation survey/monitoring;
viii. Requirement of extremity dosimetry;
ix. Preparation of rubber area to avoid spread of contamination;
x. Handling of radioactive waste;
xi. Possibility of mock-up training; and
xii. Estimation of doses during job.

Before start of hot jobs, pre-job briefing should be arranged to make radiation workers aware with the radiological condition of area and the possibility of changes that may occur due to unforeseen problems.

7.2 Radiation Work Permits

This section should describe the arrangements to control the entry of personnel to radiation controlled areas by means of Radiation Work Permits (RWP). The radiation work permit is usually written and approved document establishing all radiation protection measures necessary for safe performance of a specific activity or job considered as "radiation work" and addressing the radioactive waste aspects related to the activity. These permits given to workers by the radiation protection staff prior to starting the job, usually contain information like date and time of job, number of workers, description of job, predictive dose, dose rates, surface and atmospheric contamination levels, protective clothing needed, biological shielding, type of radiation protection monitoring for the job, etc.

The radiation work permits should be issued on the basis of latest radiation and
contamination surveys and they provide guidance regarding the requirement of necessary personnel protective equipment items to be taken during the job. All maintenance jobs involving high radiation hazard should be performed after the issuance of Special Radiation Work Permit (SRWP).

7.3 Radiation Controlled Area Zoning

This section should describe the classification of radiation controlled area on the basis of radiation dose levels. It is common practice to identify "radiation zones" within a NIs. The zone designations are established to reflect the design maximum dose rates that may exist in areas within the NIs where facility personnel must have access to perform required activities/tasks. The radiation controlled area can be further divided into radiation zones to ensure that the annual effective doses of radiation workers remains below the regulatory limit. The radiation zones are divided on the basis of dose rate in the particular area and different color coding may be used for identification/reorganization of radiation zones.

7.4 Monitoring of Internal Radiation Exposure

The personnel working in the NIs should be monitored for internal radiation exposure in addition to external exposure with respect to nature of job. This section of the RPP should have a brief description of arrangement for internal radiation monitoring at the facility e.g. whole body counting, bioassay, etc.
8. REFERENCES

1. Regulations on Radiation Protection (PAK/904), Pakistan Nuclear Regulatory Authority (PNRA), Islamabad (2004).
2. Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s) (PAK/908), Pakistan Nuclear Regulatory Authority (PNRA), Islamabad (2004).
3. Regulations for Licensing of Nuclear Installations in Pakistan (PAK/909), Pakistan Nuclear Regulatory Authority (PNRA), Islamabad (2012).
## ANNEXURE I

### Applicable Sections of Regulatory Guide According to Type of Facility

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Scope</th>
<th>Applicable Sections</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Nuclear Installations i.e. Nuclear Power Plants, Research Reactors, Nuclear Fuel Cycle Facilities, Molybdenum Production Facility etc.</td>
<td>Complete section 4, section 5 &amp; section 7</td>
</tr>
<tr>
<td></td>
<td><strong>Medical Facilities</strong></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>i. Full Fledge Medical Centers</td>
<td>4, 5 &amp; 6</td>
</tr>
<tr>
<td></td>
<td>ii. Nuclear Medicine/Cardiology</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Radiotherapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>i. Full Fledge Medical Centers</td>
<td>4 (except 4.7.3), 5 {if internal transportation (from port to end-users) is responsibility of authorized importer/clearing agent then this section may not be applicable} &amp; 6</td>
</tr>
<tr>
<td></td>
<td>ii. Nuclear Medicine/Cardiology</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>i. Industrial Facilities including industrial radiography, oil well logging, nuclear gauges with radioactive sources of category 1, 2 &amp; 3 etc.</td>
<td>4 (except 4.7.3) &amp; 5</td>
</tr>
<tr>
<td></td>
<td>ii. Scanners including vehicle/cargo scanners (using radioactive sources)</td>
<td></td>
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<tr>
<td></td>
<td>iii. Importers/exporters/traders of radioactive material/sealed radioactive sources and unsealed sources</td>
<td></td>
</tr>
<tr>
<td></td>
<td>iv. Any organization/facility involved in transport of radioactive material</td>
<td></td>
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<tr>
<td>5.</td>
<td>i. Irradiators including industrial irradiators for food and sterilization, agricultural irradiators and blood irradiators</td>
<td>4 (except 4.7.3) &amp; 5 {if internal transportation (from port to end-users) is responsibility of authorized importer/clearing agent then this section may not be applicable}</td>
</tr>
<tr>
<td></td>
<td>ii. Calibration and Dosimetry service provider having radioactive sources of category 1, 2 &amp; 3</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>i. Scanners including vehicle/cargo scanners (using X-rays).</td>
<td>4 (except 4.7.3, 4.10, 4.11, 4.15)</td>
</tr>
<tr>
<td></td>
<td>ii. Manufacturers of radiation generators</td>
<td></td>
</tr>
<tr>
<td></td>
<td>iii. Research, education and training institutes having radiation generators</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Manufacturers including 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</td>
<td>4 &amp; 5</td>
</tr>
<tr>
<td>8.</td>
<td>Research, education and training institutes having radioactive sources of category 1, 2 &amp; 3</td>
<td>4</td>
</tr>
<tr>
<td>9.</td>
<td>Any other facility or practice so identified by PNRA</td>
<td>-</td>
</tr>
</tbody>
</table>
II.A Overall Organizational Chart of the Facility

II.B Organizational Chart of Radiation Protection Section
III.A Responsibilities of the Licensee (Owner or Management)

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

i. Ensure safe use of ionizing radiations at facility premises;
ii. Ensure that for all workers, occupational exposures are limited as specified in Annexure IV of Regulations PAK/904 and promptly report to PNRA if any relevant dose limits are exceeded;
iii. 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;
iv. Ensure that all radiation workers including female workers are aware of hazards associated with their work and their obligations and responsibilities;
v. Ensure compliance and implementation of PNRA regulations, local rules and procedures;
vi. Designate a radiation protection officer as per PNRA defined criteria;
vi. Establish and ensure implementation of policies and procedures to maintain radiation exposures as low as reasonably achievable (ALARA);
vi. Ensure that suitable and adequate facilities for protection and safety are provided to radiation workers including personal protective items and radiation monitoring equipment;
ix. Ensure that requirements related to safety culture are being implemented;
x. Ensure arrangements for initial and continuous health surveillance of radiation workers;
x. Ensure training and retraining of radiation workers;
xii. Record any report received from a worker regarding unsafe conditions or circumstances and take appropriate remedial action;
xiii. 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
xiv. Ensure integration of management system and radiation protection 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:

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

iii. Exposures of individuals incurred knowingly while voluntarily helping in the care, support or comfort (other than in their occupation) are constrained as specified in Annexure IV of Regulations PAK/904;

iv. Medical exposures are justified and optimized as per the requirements of Regulations PAK/904;

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

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

III.B Responsibilities of Radiation Protection Officer (RPO)

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

i. Develop RPP and supervise its implementation at the facility;

ii. Identify deficiencies in implementation of the Radiation Protection Program, reporting these to the management and supervise the corrective actions in this regard;

iii. Ensure that tasks requiring specific training, experience and licensing requirements are only performed by staff fulfilling the requisite criteria;

iv. Identify, develop and implement approved standard operating procedures;

v. Identify that enough and appropriate radiation monitoring instruments are available and that they are calibrated and serviced periodically as required;

vi. Implement a personal and workplace monitoring program at the facility;

vii. Ensure that arrangements are made for proper use of personal protective items and personal monitoring equipment;

viii. Inform all radiation workers of their personal doses and ensure that these are consistent with optimization;

ix. Ensure that appropriate measures are taken to control the exposure of pregnant workers if applicable;

x. Assess potential hazards from foreseeable incidents/accidents and develop radiation emergency plan;

xi. Conduct exercises according to approved radiation emergency plans/procedures;

xii. Ensure that appropriate action is taken when an employee reports a matter which can compromise radiation protection;

xiii. Maintain records of occupational exposures, workplace monitoring and health
surveillance, etc.;

xiv. Maintain a system for using experience feedback;

xv. Communicate to management for any training/course necessary for workers to achieve safety; and

xvi. Shipment of radioactive material is in compliance with regulatory requirements.

III.C Responsibilities of Technicians and other 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:

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

ii. Follow applicable instructions and procedures for protection and safety and comply with all instructions from RPO;

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

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

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

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

III.D Responsibilities of Radiation Protection Committee

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

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

ii. Review of occupational radiation doses and any accident reports prepared by the radiation protection officer;

iii. Making recommendations for improvements in the radiation protection program;

iv. Provision of guidance and direction on the performance of the radiation protection officer's duties; and

v. Preparation and dissemination of regular reports to all staff about relevant radiation safety issues.
Contents of Investigation Report on Radiation Overexposure Event

i. Name/address of institution/facility/consignor;
ii. Registration/license No.;
iii. Type of radiation facility;
iv. Name and CNIC No. of overexposed person;
v. Designation, qualification and job experience of overexposed person;
vi. Dosimeter No./Code;
vii. Period of use of dosimeter;
viii. Dose received from radiation overexposure;
ix. Collective dose of last five years;
x. Circumstances and causes of overexposure;
xii. Findings of investigation;
xiii. Corrective measures to prevent recurrence of event;
xiv. Name and signature of Radiation Protection Officer;
xv. Name and signature of Head of institution/facility.
Contents for Training Program

Training topics may include:

**Fundamental Concepts and Measurements**
- i. Basic radiation concepts (Types of radiation, radioactivity, half life, etc.);
- ii. Radiation quantities and units;
- iii. Radiation detecting instruments;
- iv. Biological effects of radiations.

**Principles of Radiation Protection**
- v. System of radiation protection (justification, optimization and dose limitation);
- vi. Relevant regulatory requirements (Regulations PAK/904, PAK/908, PAK/909, PAK/916, etc.);
- vii. Designation of controlled, supervised areas and access control;
- viii. Dose limits and investigation levels.

**Practical Radiation Protection**
- ix. Effects of time, distance and shielding;
- x. Individual and workplace monitoring;
- xi. Contamination control and handling;
- xii. Working practices to limit doses and maintain them as low as reasonably achievable (ALARA);
- xiii. Storage of radioactive sources;
- xiv. Correct operation and maintenance of radiation equipment;
- xv. Local rules and procedures;
- xvi. Radiation protection program;
- xvii. Emergency plans;
- xviii. Security of radioactive sources;
- xix. Transport of radioactive materials;
- xx. Radioactive waste management program;
- xxi. Management of disused sources;
- xxii. Accidents and other incidents involving radiation sources, their consequences and lesson learned;
GLOSSARY

Accident
Any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection and safety.

Activity
The quantity A for an amount of radionuclide in a given energy state at a given time, defined as:

\[ A(t) = \frac{dN}{dt} \]

where \( dN \) is the expectation value of the number of spontaneous nuclear transformations from the given energy state in the time interval \( dt \). The SI unit for activity is reciprocal second (s\(^{-1}\)), termed the becquerel (Bq).

Action Level
The level of dose rate or activity concentration above which remedial actions or protective actions should be carried out in chronic exposure or emergency exposure situations. An action level can also be expressed in terms of any other measurable quantity as a level above which intervention should be undertaken.

Authority
The Pakistan Nuclear Regulatory Authority established under section 3 of the Ordinance No. III of 2001.

Bioassay
Any procedure used to determine the nature, activity, location or retention of radionuclides in the body by direct (in vivo) measurement or by in vitro analysis of material excreted or otherwise removed from the body.

Contamination
Radioactive substances on surfaces, or within solids, liquids or gases (including the human body), where their presence is unintended or undesirable, or the process giving rise to their presence in such places.

Controlled Area
A defined area in which specific protection measures and safety provisions are or could be required for controlling normal exposures or preventing the spread of contamination during normal working conditions, and preventing or limiting the extent of potential exposures.
Decontamination
The complete or partial removal of contamination by a deliberate physical, chemical or biological process. This definition is intended to include a wide range of processes for removing contamination from people, equipment and buildings, but to exclude the removal of radionuclides from within the human body or the removal of radionuclides by natural weathering or migration processes, which are not considered to be decontamination.

Dose
A measure of the energy deposited by radiation in a target.

Dose Constraint
A prospective restriction on the individual dose delivered by a source, which serves as an upper limit on the dose in optimization of protection and safety for the source.

Dose Limit
The value of the effective dose or the equivalent dose to individuals in planned exposure situations that is not to be exceeded.

Effective Dose, E
The quantity E, defined as a summation of the tissue or organ equivalent doses, each multiplied by the appropriate tissue weighting factor:

\[ E = \sum T W_T H_T \]

where \( H_T \) is the equivalent dose in tissue or organ T and \( W_T \) is the tissue weighting factor for tissue or organ T. From the definition of equivalent dose, it follows that:

\[ E = \sum T W_T \sum R W_R D_{T,R} \]

where \( W_R \) is the radiation weighting factor for radiation type R and \( D_{T,R} \) is the average absorbed dose in the tissue or organ T delivered by radiation type R. The SI unit for effective dose is joule per kilogram (J/kg), termed as sievert (Sv).

Emergency
A non-routine situation that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear or radiological emergencies and conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes. It includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard.
**Exposure**
The act or condition of being subject to irradiation. Exposure can be either external exposure (irradiation by source outside the body) or internal exposure (irradiation by source inside the body). Exposure can be classified as either normal exposure or potential exposure; occupational, medical or public exposure; and, in intervention situations, either emergency exposure or chronic exposure. The term exposure is also used in radiodosimetry to express the amount of ionization produced in air by ionizing radiations.

**Health Professional**
An individual who has been formally recognized through appropriate national procedures to practice a profession related to health (e.g. medicine, dentistry, chiropractic, podiatry, nursing, medical physics, medical radiation technology, radiopharmacy, occupational health).

**Incident**
Any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

**Intake**
The act or process of taking radionuclides into the body by inhalation or ingestion or through the skin.

**Investigation Level**
The value of a quantity such as effective dose, intake or contamination per unit area or volume at or above which an investigation should be conducted.

**Licensee**
The holder of a valid licence.

**Medical Exposure**
Exposure incurred by patients as part of their own medical or dental diagnosis (diagnostic exposure) or treatment (therapeutic exposure); by persons, other than those occupationally exposed, knowingly exposed while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.

**Medical Professional**
An individual who: (a) has been accredited through Pakistan Medical and Dental Council (PMDC) as a registered medical practitioner or registered dental surgeon; and (b) fulfills the requirements of training and experience as approved by the Authority.
**Monitoring**
The measurement of dose or contamination for reasons related to the assessment or control of exposure to radiation or radioactive substances, and the interpretation of the results.

**Occupational Exposure**
All exposure of workers incurred in the course of their work, with the exception of excluded exposures and exposures from exempt practices or exempt sources.

**Optimization**
The process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, “as low as reasonably achievable, economic and social factors being taken into account” (ALARA).

**Potential Exposure**
Exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

**Radiation**
Ionizing radiation i.e. gamma rays, X-rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles.

**Radiation Protection**
The protection of people from harmful effects of exposure to ionizing radiation, and the means for achieving this.

**Radiation Protection Officer (RPO)**
A person technically competent in radiation protection matters relevant for a given type of practice who is designated by the licensee or employer to oversee the application of regulatory requirements.

**Radioactive Source**
A source containing radioactive material that is used as a source of radiation.

**Radioactive Material**
Any substance which contains or consists of radioactive nuclides, naturally occurring or artificially produced, provided that the specific activity of the substance is in accordance with the levels as may be prescribed by the Authority by regulations.

**Radioactive Waste**
Waste that contains, or is contaminated with, radionuclides at activity concentrations greater than clearance levels as established by the Authority.

**Reference Levels**
Action level, intervention level, investigation level or recording level.
**Recording Level**
The level of dose, exposure or intake specified at or above which values of dose, exposure or intake received by workers are to be entered in their individual exposure records.

**Radiation Generator**
A device or an apparatus capable of generating ionizing radiation, such as X rays, neutrons, electrons or other charged particles, which may be used for scientific, medical, industrial or research purposes.

**Sealed Source**
A radioactive source in which the radioactive material is permanently sealed in a capsule, or closely bonded and in a solid form.

**Unsealed Source**
A source that does not meet the definition of a sealed source.

**Worker**
Any individual who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection. (A self-employed person is regarded as having the duties of both an employer and a worker).

**Workplace Monitoring**
Monitoring using measurements made in the working environment.