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FORMAT AND CONTENT OF RADIATION PROTECTION PROGRAMME

REGULATORY GUIDE

PAKISTAN NUCLEAR REGULATORY AUTHORITY

For Further Details

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PAKISTAN NUCLEAR REGULATORY AUTHORITY
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FORMAT AND CONTENT OF RADIATION PROTECTION PROGRAMME

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1 INTRODUCTION

Pakistan Nuclear Regulatory Authority (PNRA) has been vested with the responsibility for 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.

Different types of nuclear installations like nuclear power plants (NPPs), research reactors, etc. and radiation facilities like diagnostic and interventional radiology, nuclear medicine, radiotherapy, industrial radiography, nuclear gauges, irradiators, well logging facilities, etc. are being operated in Pakistan. These facilities use a variety of radiation sources and nuclear or radioactive material. To ensure that radiation safety is being maintained and radiation protection measures are being taken effectively, as required by the relevant PNRA regulations, the licensee prepares various documents and submits to PNRA including radiation protection programme (RPP).

The RPP describes the ways in which management structures, policies, procedures and organisational 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 RPP to PNRA for review and approval to ensure radiation protection during use, operation, maintenance, storage, transport, etc. of radiation sources and nuclear or radioactive material in compliance with the requirement of the applicable PNRA regulations. This document aims to offer guidance on contents and other relevant information in order to assist in preparation of RPP.

2 OBJECTIVE

The objective of this regulatory guide is to provide guidance to licensees regarding preparation of radiation protection programme to meet the requirements of the relevant PNRA regulations according to types of installations, facilities and activities.

3 SCOPE

This regulatory guide is intended to provide guidance for the following types of installations, facilities and activities:

i. Nuclear installations, i.e., NPPs, research reactors, nuclear fuel cycle facilities, radioactive waste predisposal or disposal facilities, molybdenum production facilities, etc.;

ii. Medical facilities including full fledge medical centers, radiotherapy, nuclear medicine or cardiology, etc.;

iii. Industrial facilities including industrial radiography, oil well logging, and those using nuclear gauges with radioactive sources of category 1,2 or 3, etc.;

iv. Irradiators including industrial irradiators for food and sterilization, agricultural irradiators and blood irradiators;

v. Scanners including vehicle or cargo scanners;

vi. Manufacturers including manufacturers of consumer products, radioactive sources and radiation generators, and radioisotope production facilities. This also includes stockist having bulk storages of consumer products, or sealed or unsealed sources;

vii. Research, education or training institutes having radioactive sources of category 1,2 or 3 or radiation generators like particle accelerators, irradiators, etc.;

viii. Calibration or dosimetry service providers having radioactive sources of category 1, 2 or 3;

ix. Importers, exporters or traders of radioactive material or sealed sources or unsealed sources;

x. Any organisation or facility involved in transport of radioactive material; and

xi. Any other facility or practice so identified by PNRA.

4 Format and Content of Radiation Protection Programme

This section outlines the necessary information that an RPP should include. For systematic development, ease of utility and effective implementation of an RPP, it is important that the programme is structured in a harmonised format with relevant content. The following sections provide guidance in that regard in accordance with the level of radiation risk associated with the facility, utilizing a graded approach. Annexure I of this guide describes the applicability of different sections of this regulatory guide according to the type of facility.

4.1 General Instructions for Preparation of Radiation Protection Programme

The applicant or licensee should consider the following instructions while formatting RPP:

i. The information provided should be clear, concise, accurate, and up-to-date;

ii. Comprehensive table of contents that includes sections, figures, tables, annexures, etc., along with their respective page numbers should be provided;

iii. Consistency in definitions and abbreviations throughout the document should be maintained;

iv. Duplication of information should be avoided. If necessary, reference of relevant section should be made;

v. Legible drawings, diagrams, maps, annexures and tables should be added wherever necessary with proper reference; and

vi. The document should be signed by an authorised individual with date.

5 Content of Radiation Protection Programme

The following sections and subsections describe the content and level of detail that should be included within the RPP:

5.1 Introduction

This section of RPP should include an introductory and general description of the overall facility and activities. The following details should at least be described:

i. Name of the facility along with a clear description indicating whether the facility operates as a standalone entity or is a part of a larger organisation or a hospital setup;

ii. A brief description of categorization of radiation sources to be used in or by the facility; and

iii. In case of facilities involved in or carrying out transport of radioactive material or sources; a brief description of material or sources to be transported, as well as the transport packages and containers, mode of transport, etc.;

5.2 Objective and Scope

This section is intended to describe the purpose and objectives of the RPP. The aim of the RPP should encompass the implementation of radiation protection measures in compliance with the regulatory requirements. The primary goal is to maintain radiation doses for workers and the public within the applicable dose limits and ALARA. Additionally, this section should provide a comprehensive description of all the facilities and activities to which the RPP applies.

5.3 Designation of Radiation Protection Officer and Professionals

This section of RPP should describe details about the designation of radiation protection officer (RPO) and professionals. Such details should include full name, title, position within the organisation, relevant qualifications, trainings and experience. The qualification criteria for RPO should be in accordance with the following, depending on the type of facility:

i. For radiation facilities: Regulation 10 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)";

ii. In case of NPPs: Regulation 44 of the "Regulations on the Safety of Nuclear Power Plants Operation - (PAK/913) (Rev.2)"; and

iii. For research reactors: Appendix-II of the "Regulations on the Safety of Nuclear Research Reactor(s) Operation –(PAK/923)".

In case of radiation facilities, the professionals should be designated in accordance with the criteria specified in Regulation 11 of "Regulations on Radiation Protection - (PAK/904) (Rev.1)".

5.4 Organisational Structure and Responsibilities

This section of RPP should describe organisational arrangements and lines of communication that result in smooth flow of information regarding protection and safety across different levels within the organisation. This section of RPP should describe:

i. Overall organisational chart of the facility showing different sections of the organisation and reporting or communication lines for the protection and safety. The organisational chart should reflect the designations of all relevant personnel of the facility such as the licensee, administrator, medical physicist, station health physicist or RPO, technicians, persons responsible for transport of radioactive material, etc.;

ii. Hierarchy and composition of any advisory body, oversight group or radiation protection or safety committee as practiced at the facility.

A sample organisational structure and setup for the radiation protection section are outlined in Annexure II.

This section of RPP should also describe the intended functions, responsibilities and authorities of each of the individuals or positions identified in organisation structure with respect to radiation protection and safety in management, operation, maintenance, record keeping, etc. at the facility and during the 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 or safety committee;

iii. Operators or technicians;

iv. RPO(s);

v. Health professionals (radiation oncologist, nuclear medicine specialist, nuclear cardiologist, radiologist, medical physicist, etc.);

vi. Personnel involved in the 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.

A specimen description of responsibilities of licensee, RPO, technicians or workers, and radiation protection or safety committee is given in Annexure III.

5.5 Training of Workers

This section of RPP should describe the facility's programme for training and re-training of individuals involved in the use of radioactive materials or sources, or radiation generators. The frequency of training sessions should be clearly defined. Additionally, this section should provide details about the arrangements made within the facility to conduct these trainings, including the availability of resource persons, training materials, and facilities. If some or all of the trainings are outsourced to external organisations or institutions, it should be described accordingly. Records of the trainings

provided should also be documented. Sample contents of training programme are given in Annexure IV.

5.6 Dose Limits and Dose Constraints

This section of RPP should describe the process or mechanism followed by the licensee to restrict 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 authorised practices, exceeds any relevant dose limit specified in Regulation 18 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)".

This section of RPP should also describe the process or mechanism implemented to optimise radiation safety measures for a specific practice. This includes minimizing the doses received by both the facility workers and the general public. The description should include the dose limits as well as the measures taken to ensure compliance and address specific actions where doses exceed the set limits.

For occupational exposure dose constraints should be described with the aim of optimizing protection and safety. Similarly, for public exposure involving the release of radioactive substances into the environment, the dose constraints should be described that are approved by the Authority. Also specify the actions where dose constraint exceeds the limit. Dose Constraints are not the dose limits and should be selected based on good practice at some fraction of the dose limit and on what can reasonably be achievable.

5.7 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 the classification of areas, description of rules or procedures and necessary arrangements to work in respective areas including access control, removal of tools or 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 also be described. The regular review of the radiological conditions should be carried out to revise the protection measures or safety provisions, including the boundaries of controlled and supervised areas.

5.7.1 Controlled Area

Any area of the facility should be designated as controlled area where, there is a possibility of receiving an effective dose greater than 6 mSv in a year or an equivalent dose greater than three tenths (3/10) of relevant dose limit as prescribed in Schedule VI of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)". 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;

ii. Preventing or limiting the extent of potential exposures.

This section should include the information regarding designation of controlled areas in the facility and arrangements to meet the requirements mentioned in section 26(1)(c) of the "Regulations on Radiation Protection-(PAK/904) (Rev.1)" such as delineation of controlled areas, display of internationally recognised warning symbols, physical measures to control the spread of contamination, individual monitoring, etc.

For example, in case of nuclear medicine centre, 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.

At radiotherapy centre, 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.

5.7.2 Supervised Area

Any area of the facility should be designated as a supervised area where there is a possibility of receiving an effective dose greater than 1 mSv in a year or an equivalent dose greater than one-tenth (1/10) of the relevant dose limit as prescribed in Schedule VI of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)". There is a need to keep the occupational exposure conditions under review even though specific protection measures and safety provisions are not normally needed.

For example, in nuclear medicine centre, patient waiting area, nuclear physician room, reception, etc. might also be designated as supervised areas.

5.7.3 Access Control

This section of RPP should describe access control measures for the restriction of access to controlled area such as administrative measure, physical barriers involving locks and interlocks etc.

5.8 Personal Protective Equipment

This section of RPP should describe the following information:

i. Type, nature and specification of personal protective equipment or 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 proper use, regular cleaning, inspection, testing and maintenance of the personal protective equipment.

Additionally, this should also describe the arrangement made for medical fitness to sustain possible extra physical effort while using the protective equipment (where applicable).

5.9 Assessment of Occupational Exposure

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 29 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)" or involve in handling of radioactive materials. This section should describe:

i. Arrangements for availing the appropriate dosimetry service from an authorised 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. Arrangements for extremity dosimetry and eye dosimetry where applicable

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

vi. Arrangement for personal alarm monitors such as in industrial radiography facilities and nuclear installations;

vii. Arrangement for monitoring of internal contamination and the committed doses of workers who could be exposed due to intake of radioactive substances.;

viii. Investigation level, may be established by the facility with respect to individual radiation dose in consideration of ALARA and corresponding actions to be taken if these are exceeded.

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

x. Arrangements to retain the exposure records at least until the worker attains or would have attained the age of 75 years and not less than 30 years after the termination of work involving occupational exposure;

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

xii. Describe pertinent actions to be taken if a dosimeter is lost or damaged or dosimetry result is lost.

xiii. Frequency for submission of periodic occupational exposure reports to the Authority. Such submission should be made preferably on annual basis.

5.10 Workplace Monitoring

This section of RPP should describe the facility arrangements for establishing, maintaining and keeping under review the programme for monitoring of workplace as per Regulation 30 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)". This section should describe:

i. Identification of areas for workplace monitoring and the frequency of measurement;

ii. Recording level and investigation level may be established by the facility with respect to workplace monitoring results and corresponding actions to be taken if such levels are exceeded;

iii. Type, list and specifications of the monitoring equipment or instruments at the facility and arrangements for calibration from authorised service provider along with calibration frequency; and

iv. Arrangements for retention of workplace monitoring records for a minimum period of five years and access of workplace monitoring record to the workers:

5.11 Effluent Monitoring

This section of RPP should describe the facility arrangements for establishing, maintaining and overseeing the implementation of the programme for monitoring of effluents. This section should describe:

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

ii. Identification of areas for effluent monitoring and the frequency of measurement;

iii. Recording level and investigation level, may be established by the facility with respect to effluent monitoring results and corresponding actions to be taken if such levels are exceeded;

iv. Type, list and specifications of the monitoring equipment or instruments at the facility and arrangements for calibration from authorised service provider along with calibration frequency.

5.12 Investigation and Reporting of Overexposure

This section of RPP should describe the mechanism for notification of an incident, accident or event of overexposure; detail of internal system for investigation; and subsequent reporting of accidental occupational exposure to PNRA. This section of RPP should also describe the arrangements for informing to the Authority in accordance with Regulation 21 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)". Suggested contents of investigation report on radiation overexposure event are given in Annexure V.

5.13 Medical Surveillance for Abnormal Situation

This section of RPP should describe the arrangements for the availability of adequate medical facilities and trained staff for the administration of first aid in case of a radiation accident and for carrying out external decontamination of the affected individuals and also describe the frequency of review of the adequacy of such facilities. This section should also information regarding necessary arrangements ensuring that individuals affected by radiation injuries are promptly transferred to the designated hospitals for the treatment of radiation injuries.

5.14 Management of Inventory of Radiation Sources

In this section, the licensee should describe the details of radiation sources (radiation generators, sealed/unsealed radioactive sources) to be used at the facility. The radioactive sources should be categorised in accordance with Schedule V of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)". A procedure should be in place for development, management, and regularly updating an inventory of sealed sources and radiation generators. This inventory should be submitted to the Authority after every quarter for category-1 sources and every six months for sources in the remaining categories and annually for radiation generators as per format mentioned as Annexure VI.

5.15 Contamination Control and Handling Arrangements

This section of the RPP should provide description:

i. Potential contamination sources and mechanism to control the spread of contamination,
ii. Arrangements to control the contamination of workers or equipment and available decontamination facilities
iii. Arrangements for decontamination of transport packages and conveyances if the regulatory limits given in Regulations 42(1) and 42(2) of the "Regulations for the Safe Transport of Radioactive Material - (PAK/916) (Rev.1)" exceeded.

5.16 Worker's 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 32 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)". This section should describe:

i. Arrangements for 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/examinations to be conducted (in line with the aforementioned PNRA Regulation) and test reports examination by a qualified medical practitioner;
iv. Policy and arrangement of the facility regarding the provision of adequate information on health risks due to their occupational exposure to the radiation worker(s) including female workers as per Regulation 34 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)";
v. Arrangements to examine the fitness of the worker for wearing respiratory protective equipment, if a worker's duties are such that the use of respiratory protective equipment is required. This evaluation should include assessments of lung function integrity; and
vi. Arrangements for keeping the record of health surveillance of the worker.

5.17 Local Rules, Procedures and Supervision

As per Regulation 27 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)", this section of RPP should describe local rules and a list of administrative procedures including standard operating procedures (SOPs) for performing different functions or activities at the facility. Description

should also include the mechanism of supervision for effective implementation of the local rules and procedures. The local rules and procedures should describe the provisions for various components of RPP, such as the following:

i. Monitoring of exposures and contamination including contamination control;
ii. Radiation Monitoring;
iii. Access Control;
iv. Engineered controls such as ventilation systems;
v. Equipment maintenance and calibration;
vi. Safe handling of radioactive materials during storage and transportation of radioactive material, where appropriate;
vii. Use of personal protective equipment;
viii. Workers' health surveillance;
ix. Training;
x. Development of a safety culture;
xi. Record Keeping; and
xii. Reporting.

5.18 Conditions of Service and Special Arrangements

As per Regulation 35 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)", this section should describe the licensee's policy regarding the employment of radiation worker, which includes refraining from provision of any benefits to workers as a substitute of proper protection and safety measures.

The licensee should also describe its policy as per Regulation 36 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)" once a female worker informs the licensee of her pregnancy or breastfeeding status, she cannot be excluded from work based on this notification. Additionally, the licensee should adjust working conditions to ensure the same level of protection for embryos, fetuses, or breastfed infants as outlined for the public in Schedule VI of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)". Furthermore, individuals under sixteen years old cannot be exposed to occupational hazards, and those under eighteen can only work in controlled areas under supervision for training and educational purposes, with dose limits specified in Schedule VI of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)".

5.19 Programme Revision Frequency

This section should describe continuous monitoring and review of the implementation and effectiveness of the RPP at the facility and its revision in the light of operating experience and feedback. Licensee should review RPP after every five years and update it accordingly, (if required). In case of any changes in the processes/practices and/or in the technology, licensee should submit the updated RPP to the Authority for approval well before its implementation.

5.20 Records

This section of RPP should describe the type and nature of records maintained at the facility along with period of time for which these records will be maintained/retained. These records should at least include, but not be limited to the following:

i. Occupational exposure;
ii. Health surveillance;
iii. Radiation survey and workplace monitoring;

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

v. Instrument or equipment calibration;

vi. Inventory of radiation monitors and protective equipment;

vii. Incidents reports

viii. Audit and inspection reports

ix. Radiation protection training; and

x. Documents (plans and procedures) review and revision.

5.21 Definitions and Abbreviations

This section should include definitions of terminology and abbreviations used in RPP.

5.22 References for Radiation Protection Programme

This section should include references to all the documents used in the preparation of RPP. 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) of United States, etc.

6 ADDITIONAL CONTENTS FOR TRANSPORT OF RADIOACTIVE MATERIAL

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

6.1 Dose Assessment

The licensee should perform assessment of radiation doses to workers and the public due to the transport of radioactive material. For the assessment and evaluation of transport-related radiation doses, the package type and category, exposure time, dose rate, frequency of operation, transport volume, the 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.

6.2 Segregation

As per Regulation 61 of the “Regulations for the Safe Transport of Radioactive Material - (PAK/916) (Rev.1)”, the licensees are required to ensure segregation of packages/materials, also maintain a safe distance 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 the public or by the use of other protective measures. This section should include information about those measures.

7 ADDITIONAL CONTENTS FOR MEDICAL RADIATION FACILITIES

Depending on the type and nature of medical radiation facility included in the scope of this regulatory guide, the RPP should additionally contain following sections:

i. Medical Exposure Control Responsibilities;

ii. Calibration and Clinical Dosimetry;

iii. Quality Assurance of Medical Exposure;

iv. Release of Patients after Radionuclide Therapy;

v. Dose Constraint for Comforter or Visitor of Patients;

vi. Arrangements for Pregnant or Breast-feeding Patients;

vii. Investigation of Unintended and Accidental Medical Exposures;

viii. Protection and Safety in Handling of Deceased Person; and

ix. Diagnostic Reference Level for Medical Exposure.

A brief description of these is given in the following sub-sections.

7.1 Medical Exposure Control Responsibilities

Regulation 42 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)" 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. The licensee should describe the facility arrangements to ensure the availability of qualified health and medical professional's (specifically in terms of number of professionals in accordance with facility workload). The designated medical and health professionals should have appropriate qualification and training in line with requirements of Regulation 11 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)" to discharge assigned tasks in the conduct of radiological procedures.

7.2 Calibration and Clinical Dosimetry

This section of RPP should describe the facility arrangement for calibration of sources used for medical exposure traceable to Standard Dosimetry Laboratory as per Regulation 44 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)". This section should describe:

i. Arrangements and frequency of calibration of all sources giving rise to medical exposure;

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

iii. 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;

iv. Arrangements and frequency of Calibration of all dosimeters used for dosimetry of patients;

v. Arrangements to ensure calibration of the equipment at time of commissioning, after any maintenance affecting calibration and adherence to frequency set by facility for calibration at regular intervals.

7.3 Quality Assurance for 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 46 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)". This frequency should not be more than 12 calendar months after the initial measurement at the time of commissioning or in-accordance with manufacturer's recommendations. This section should also describe arrangements for the measurements of the physical parameters of the medical radiological equipment after any major repair or maintenance procedure and any installation of new software or modification of existing software that could affect protection and safety of patients.

This section should also 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 or reviews of the quality assurance programme.

The applicant and licensee may refer Quality Assurance Programme (QAP) or Quality Management System of the facility for details of QA arrangements.

7.4 Diagnostic Reference Levels for Medical Exposure

This section of the RPP should describe the arrangements to ensure compliance with the Diagnostic Reference Levels for medical exposure as per Regulation 45 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)". The licensee should also maintain the relevant record of dose delivered to the patient for the review of PNRA to ensure compliance.

7.5 Release of Patients after Radionuclide Therapy

This section of RPP should describe the arrangements as required by Regulation 49 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)" to manage discharge of patients who have undergone therapeutic radiological procedures. Licensee should also describe the arrangements for retaining the patients undergoing radionuclide therapy with USRS.

7.6 Dose Constraint for Comforter or Visitor of Patients

This section of the RPP should describe the facility arrangements that no individual incurs a exposure as a comforter or visitor unless he has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure. This should also mention that the dose limits for comforters or visitors of patients as given in Regulation 47 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)" will be followed.

7.7 Arrangements for Pregnant or Breast-Feeding Patients

This section of the RPP should describe the arrangements to ensure radiation protection of expecting and nursing females as given in Regulation 48 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)".

7.8 Investigation of Unintended and Accidental Medical Exposures

This section should describe arrangements to minimise the likelihood, investigate, notify and report any unintended or accidental medical exposures in accordance with the requirements stipulated under Regulation 50 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)".

7.9 Protection and Safety in Handling of Deceased Person

This section of the RPP should describe the arrangements for handling the dead body of a patient that contains sealed or unsealed radioactive sources in light of the requirements set under Regulation 51 of the "Regulations on Radiation Protection - (PAK/904) (Rev.1)". These precautions should be determined by the RPO, on the basis of a generic safety assessment of the need for monitoring personnel who are involved in autopsy, embalming or burial procedures and the potential for contamination depending upon the radionuclide and practices being followed in the facility. Furthermore, cultural or ethical concerns should also be considered.

8 ADDITIONAL CONTENTS FOR NUCLEAR INSTALLATIONS

Depending on the type and nature of nuclear installation, the RPP should additionally contain some facility-specific sections. These include sections describing radiation work planning, radiation work permits or special work permits, zoning within radiation-controlled areas, policy for preparation of ALARA plans, system for pre-job and post-job briefings, achievement of refueling outage targets and goals, categories of radiation workers, and modes of training for different categories of radiation workers, etc. A brief description of some of these elements is provided in the subsequent subsections.

8.1 Radiation Work Planning

This section 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 optimise radiation protection. Work planning and scheduling should integrate radiation protection criteria and use experience feedback 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 day. For development of ALARA plan following may be considered:

i. Information from similar work completed previously;
ii. Other activities in the same area which could interfere with the work;
iii. Preparation and assistance in operations (e.g., isolation of the process, scaffolding and insulation work);
iv. Plant operation condition;
v. Expected duration of the job;
vi. Number of radiation workers involved;
vii. Expected dose rate or contamination level
viii. Estimation of doses during the job;
ix. Requirement of personal protective equipment;
x. Temporary shielding;
xi. Equipment required for radiation survey or monitoring;
xii. Requirement of extremity dosimetry;
xiii. Preparation of rubber area to avoid spread of contamination;
xiv. Communication necessary to ensure supervisory control and coordination;
xv. Management of any radioactive waste arising from the work;
xvi. Protective measures for industrial safety;
xvii. Handling of radioactive waste; and
xviii. Mock-up training.

A provision for a pre-job briefing should be included in ALARA plan, to make radiation workers aware with the radiological condition of area and the possibility of changes that may occur due to unforeseen problems.

8.2 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) as per Regulation 26 of “Regulations on Radiation Protection - (PAK/904) (Rev.1)”. A radiation work permit is usually a 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, should 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.

A maintenance job involving high radiation hazard should be performed after the issuance of a special radiation work permit (SRWP). In addition to a description of the work to be performed, the SRWP should include at least the following:

i. A detailed dose rate map of the working area and possible hot spots, produced from a survey made prior to the work or otherwise estimated;
ii. An estimate of contamination levels and how they could change during the course of the work;
iii. An estimate of individual exposure and collective exposure for each work step;

iv. Details of any time restrictions or dose restrictions; and

v. Instructions on when to contact the radiation protection officer.

8.3 Zoning of Radiation-Controlled Area

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 NI. The zone designations are established to reflect the design maximum dose rates that may exist in areas within the nuclear installations where facility personnel must have access to perform required activities or tasks. A radiation-controlled area can be further divided into radiation zones to ensure that the annual effective doses of radiation workers remain below the regulatory limit. The radiation zones are divided on the basis of dose rate in the particular area and different colour coding may be used for identification or re-organisation of such zones.

8.4 Monitoring of Internal Radiation Exposure

The personnel working in nuclear installations should be monitored for internal radiation exposure in addition to external exposure with respect to nature of job. This section should have a brief description of arrangement for internal radiation monitoring at the facility, e.g., whole body counting, bioassay, etc. It should also include information regarding location of the laboratories and specification of equipment used for the internal radiation monitoring and frequency of measurement.

9 REFERENCES

i. PNRA, "Regulations on Radiation Protection-PAK/904 (Rev.1)", Pakistan Nuclear Regulatory Authority (PNRA), October 2020, Islamabad.

ii. PNRA, "Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s)-PAK/908 (Rev.1)", Pakistan Nuclear Regulatory Authority (PNRA), October 2019, Islamabad.

iii. PNRA "Regulations for Licensing of Nuclear Installations in Pakistan-PAK/909 (Rev. 1)", Pakistan Nuclear Regulatory Authority (PNRA), June 2012, Islamabad.

iv. PNRA, "Regulations for the Safe Transport of Radioactive Material-PAK/916 (Rev.1)", Pakistan Nuclear Regulatory Authority (PNRA), August 2022, Islamabad.

v. PNRA, "Regulations on Radioactive Waste Management - (PAK/915) (Rev.1)", Pakistan Nuclear Regulatory Authority (PNRA), April 2019, Islamabad.

vi. IAEA, "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards", GSR-Part 3, International Atomic Energy Agency (IAEA), July 2014, Vienna.

vii. IAEA, "Occupational Radiation Protection", GSG-7, International Atomic Energy Agency (IAEA), October 2018, Vienna.

viii. IAEA, "Radiation Protection Programmes for the Transport of Radioactive Material", TS-G-1.3, International Atomic Energy Agency (IAEA), October 2007, Vienna.

ix. IAEA, "Safety Glossary, Terminology Used in Nuclear Safety and Radiation Protection", International Atomic Energy Agency (IAEA), October 2022, Vienna.

x. IAEA, "Safety Standard, Radiation Safety in Industrial Radiography", Specific Safety Guide No. SSG-11, International Atomic Energy Agency (IAEA), February 2011, Vienna.

10 GLOSSARY

Terms like *"accident", "activity", "contamination", "controlled area", "decontamination", "dose", "dose constraint", "dose limit", "effective dose", "diagnostic reference level", "medical professional", "monitoring", "occupational exposure", "optimization", "potential exposure", "Radiation, "Radiation Protection Officer (RPO)", "radioactive source", "reference levels", "radiation generator", "sealed source", "unsealed source", "worker"* shall have the same meaning as defined in the PNRA Regulations on Radiation Protection - PAK/904 (Rev. 1) and Term *"authority"* shall have the same meaning as defined in the PNRA "Regulations on Licensing Fee by Pakistan Nuclear Regulatory Authority – (PAK/900) (Rev.2)" , Radioactive material Shall have the same meaning as defined in the PNRA "Regulations for the Safe Transport of Radioactive Material - (PAK/916) (Rev.1)". Rest of the terms are defined as follows:

i. "*Action level"* means 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;

ii. *"Bioassay"* means 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;

iii. *"Predictive dose"* means estimated dose that an individual is expected to receive over a specific period, based on various factors such as the type of radiation exposure, duration of exposure, distance from the radiation source, and shielding measures in place;

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

v. *"Recording level"* means 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; and

vi. *"Workplace monitoring"* means monitoring using measurements made in the working environment.

11 ABBREVIATIONS

ALARA: As low as reasonably achievable
IAEA: International Atomic Energy Agency
ICRP: International Commission on Radiological Protection
NCRP: National Council on Radiation Protection & Measurements
NPPs: Nuclear power plants
NRECC: Nuclear and Radiological Emergency Coordination Centre
OSL: Optically stimulated luminescence
PNRA: Pakistan Nuclear Regulatory Authority
QA: Quality assurance
QAP: Quality Assurance Programme
RPO: Radiation protection officer
RPP: Radiation protection programme
RWP: Radiation work permit
SOPs: Standard operating procedures
SRS: Sealed radioactive sources
SRWP: Special radiation work permit
SSDL: Secondary Standard Dosimetry Laboratory
TLD: Thermoluminescent dosimeter

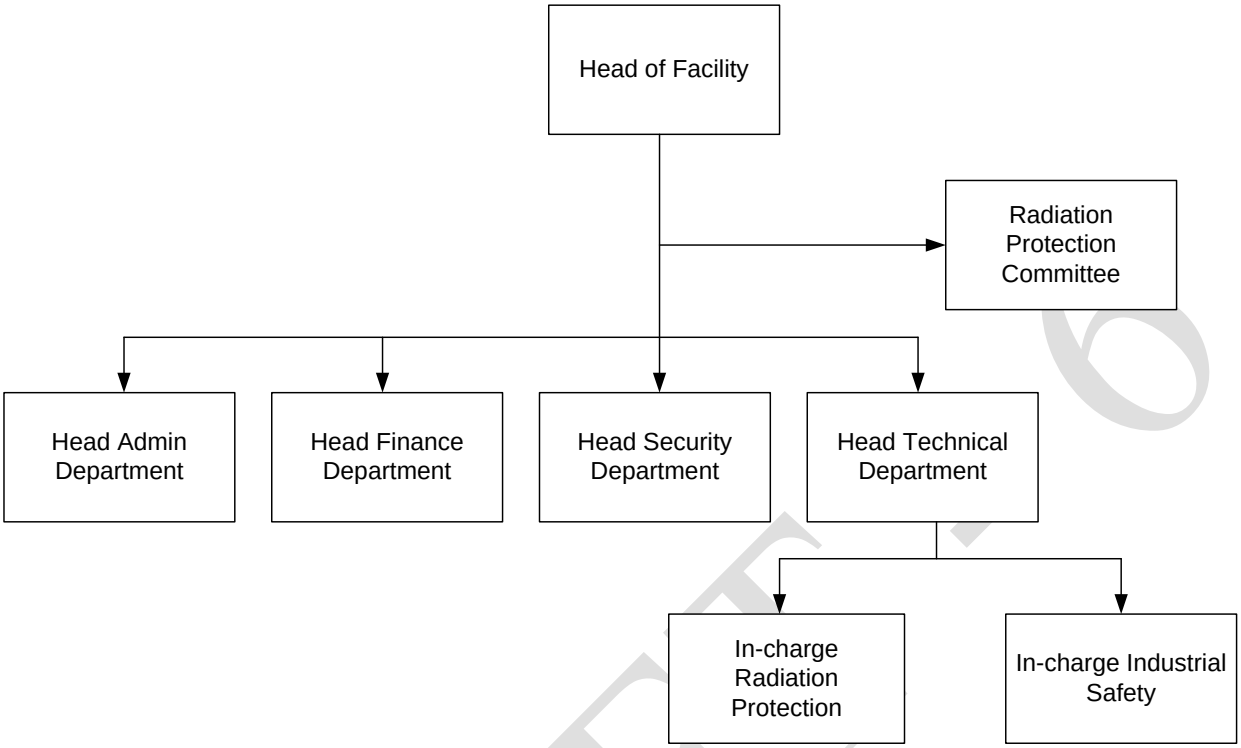
Annexure I

Applicable Sections of Regulatory Guide according to Type of Facility

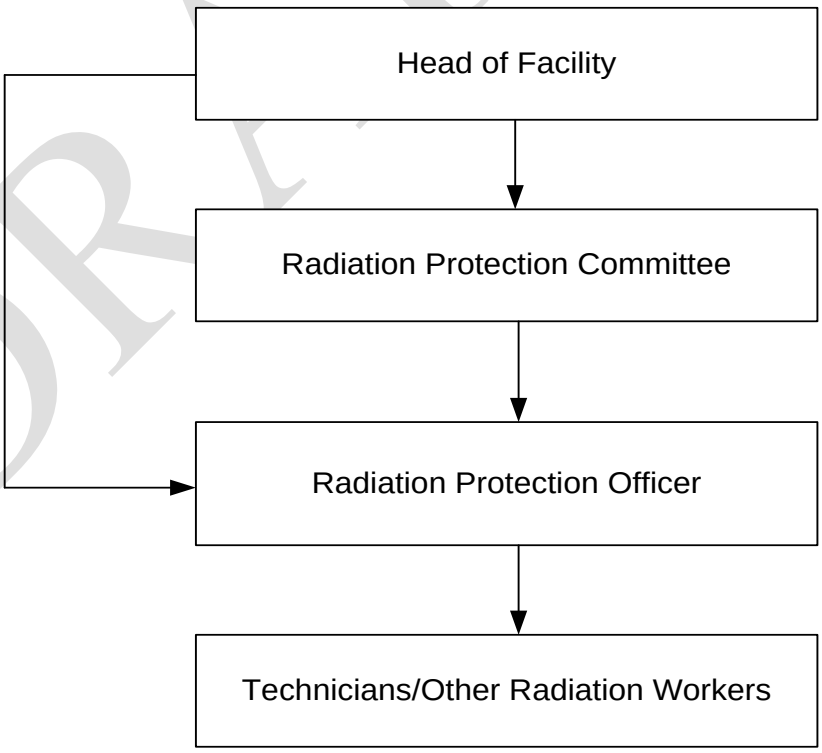
Sr. No.	Scope	Applicable Sections
1.	Nuclear installation i.e. NPP, research reactor, nuclear fuel cycle facility, or molybdenum production facility, etc.	5, 6 and 8
	i. Full-fledge medical center ii. Nuclear medicine or cardiology	5, 6 and 7
2	Radiotherapy	5 (except 5.11), 6 (if transportation from port to end-users is responsibility of authorised importer or clearing agent then this section may not be applicable) and 7
3.	i. Industrial facilities including industrial radiography, oil well logging, nuclear gauges with radioactive sources of category 1, 2 or 3 etc. ii. Scanners including vehicle or cargo scanners (using radioactive sources) iii. Importers, exporters or traders of radioactive material, sealed sources or unsealed sources iv. Any organisation or facility involved in transport of radioactive material	5 (except 5.11), and 6
4.	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 or 3	5 (except 5.11) and 6 (if transportation from port to end-users is responsibility of authorised importer or clearing agent then this section may not be applicable)
5.	i. Scanners including vehicle or cargo scanners (using X-rays). ii. Manufacturers of radiation generators iii. Research, education and training institutes having radiation generators	5 (except 5.11 and 5.15)
6.	Manufacturers of consumer products and radioactive sources. This also includes stockist having bulk storages of consumer products, or sealed or unsealed sources.	5 and 6
7.	Research, education and training institutes having radioactive sources of category 1, 2 or 3	5

Annexure II

II.A Sample Organisational Chart of a Facility



II.B Sample Organisational Chart of Radiation Protection Section



Annexure III

III.A Specimen Responsibilities of the Licensee (Owner or Management)

Responsibilities of the licensee (owner or management, i.e., CEO, director, head, etc.) may include but not limited to the following:

i. To ensure safe use of ionizing radiations at facility premises;

ii. To ensure implementation of optimization in protection and safety for workers and the public;

iii. To ensure that significant modification(s) is carried out in compliance with the relevant regulatory requirements;

iv. To perform safety assessment of the facilities and activities;

v. To ensure the provision and availability of adequate resources including qualified and trained manpower, radiation protection and detection equipment, as well as arrangements for health surveillance and quality assurance of equipment or devices, etc.

vi. To ensure that occupational exposures are within the relevant regulatory limits and prompt notification to PNRA if any relevant dose limits are exceeded;

vii. To make arrangements for notification to PNRA in case of loss or theft of a radioactive source(s) or any safety-significant incident as per relevant regulatory requirements;

viii. To ensure designation of RPO as per PNRA defined criteria;

ix. To develop a mechanism for punishment or penalties to discourage the workers from any willful actions that may contravene the regulatory requirements; and

x. To ensure adequate arrangements for medical exposure control in accordance with the relevant regulatory requirements.

III.B Specimen Responsibilities of Radiation Protection Officer

Responsibilities of RPO (in-charge of radiation protection and safety) may include but not limited to the following:

i. To develop RPP and supervise its implementation at the facility;

ii. To identify deficiencies in implementation of RPP, reporting these to the management and ensure corrective actions in this regard;

iii. To ensure that tasks requiring specific training and experience are only performed by staff fulfilling the requisite criteria;

iv. To identify the need, develop and implement approved standard operating procedures;

v. To assess that enough and appropriate radiation monitoring instruments are available and ensure that such devices are calibrated and serviced periodically as required;

vi. To ensure individual and workplace monitoring at the facility;

vii. To ensure proper use of personal protective items and personal monitoring equipment;

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

ix. To ensure that appropriate measures are taken to control the exposure of pregnant or breast-feeding workers;

x. To maintain records of occupational exposures, workplace monitoring and health surveillance, etc. as per relevant regulatory requirements;

xi. To maintain a system for using experience feedback;

xii. To ensure that transport of radioactive material or source(s) is in compliance with the regulatory requirements; and

xiii. To inform the management about any abnormal occurrence or any circumstances that could adversely affect safety conditions.

III.C Specimen Responsibilities of Technicians and other Radiations Workers

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

i. To protect themselves and others from any radiation hazard(s) associated with their work;

ii. To follow local rules and procedures for protection and safety and comply with all instructions from RPO;

iii. To wear assigned radiation dosimeter during work in radiation area and ensure its safekeeping in radiation-free area during off-working hours;

iv. To properly use the monitoring devices and protective items provided;

v. To avoid any mala fide activity(ies) that may lead to harm or undue radiation exposure to themselves or others; and

vi. To promptly report to RPO or the management about any abnormal occurrence or any circumstances that could adversely affect safety conditions.

III.D Responsibilities of Radiation Protection or Safety Committee

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

i. To review of all aspects of RPP on regular basis;

ii. To provide advice on radiation protection and safety related matters and issues;

iii. To ensure implementation of ALARA;

iv. To review the cases of abnormal radiation doses and any accident or investigation report; and

v. To make recommendations for improvements in RPP.

Annexure IV

Sample Contents for Training Programme

1. **Fundamentals of Radiation and Radiation Hazards**
   - i. Basic radiation concepts (types of radiation, radioactivity, half-life, etc.);
   - ii. Radiation quantities and units; and
   - iii. Biological effects of radiations.
2. **Radiation Detection and Measurement**
   - i. Principles of radiation detection;
   - ii. Correct operation and maintenance of radiation equipment;
   - iii. Individual monitoring instruments; and
   - iv. Workplace monitoring instruments;
3. **Principles of Radiation Protection**
   - i. System of radiation protection (justification, optimization and dose limitation);
   - ii. Designation of controlled, supervised areas and access control;
   - iii. Dose limits and dose constraints;
   - iv. Practical radiation protection measures, such as:
     - a. Effects of time, distance and shielding;
     - b. Proper use of personal protective equipment;
     - c. Contamination control and handling;
     - d. Implementation of ALARA principle;
     - e. Storage and transport of radioactive material or sources;
     - f. Security of radioactive material or sources;
     - g. Management of disused sources;
4. **Case Histories of Radiological Incidents and Accidents**
   - i. Radiological incidents and accidents; and
   - ii. Operating experience feedback and lessons learnt.
5. **Requirements of Relevant PNRA Regulations**
   - i. Relevant regulatory requirements (PNRA Regulations PAK/904, PAK/908, PAK/909, PAK/916, etc.); and
   - ii. Introduction to relevant regulatory guides.
6. **Demonstration of Applicable Programmes or Plans and Procedures**
   - i. Radiation protection programme;
   - ii. Radiation emergency plan;
   - iii. Physical protection plan;
   - iv. Radioactive waste management programme; and
   - i. Local rules and procedures.

Annexure V

Suggested Contents of Investigation Report on Radiation Overexposure Event

i. Name and address of institution or facility;
ii. Registration or 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. or 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;
xi. Methodology of investigation;
xii. Data collection methods;
xiii. Timeline of investigation process;
xiv. Findings of investigation;
xv. Corrective measures to prevent recurrence of event;
xvi. Name and signature of RPO; and
xvii. Name and signature of head of institution or facility.

Annexure VI

VI.A Inventory of Radiation Generators

Facility: _____

License No.: _____

Sr. No.	Type of Radiation Generator	Make/ Model	X-ray Tube Serial Number	mA and kV	Date of Manufacturing	Date of Installation	Status when Installed (New or Used)
1.							
2.							
3.							
4.							
5.							

(Please use extra sheets, if necessary)

Certified that the above-mentioned radiation generator(s) are in my possession and no other information of radiation generator(s) has been concealed.

_____

Signature with Date of Licensee/
Authorised Personnel

VI.B Inventory of Sealed Radioactive Sources

Facility: _____

License No.: _____

Sr. No	ID of Sealed Radiation Source(s)	Isotopes	Activity with Reference Date	Current Activity with date	Date of Import	Physical Form	NOC ID & Date of Issue	Still in use (Yes/No)	If disposed, date of disposal & reference No. of certificate	Physically Verified (Yes/No)	Remarks
1.											
2.											
3.											
4.											
5.											
6.											
7.											
8.											
9.											
10.											
11.											
12.											
13.											
14.											
15.											

Certified that the above-mentioned SRS are in my possession and no other information of SRS has been concealed.

_____
Signature with Date of Licensee/
Authorised Personnel

PAKISTAN NUCLEAR REGULATORY AUTHORITY
P.O. Box 1912, Islamabad
www. pnra.org