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# REGULATORY GUIDE ON FORMAT AND CONTENT OF THE SAFETY ANALYSIS REPORT FOR RADIATION FACILITIES

**REGULATORY GUIDE**

PAKISTAN NUCLEAR REGULATORY AUTHORITY

**For Further Details**

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## 1. INTRODUCTION

Radiation sources have many beneficial applications in medicine, industry, agriculture, security related equipment, research and education. Radiation risks to workers, public and the environment that may arise from these applications need to be assessed and, if necessary, be controlled. Such applications of radiation sources, therefore, are subjected to extended safety analysis.

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. In this regard, PNRA has established an effective regulatory framework to ensure the safe use of radiation sources in the country.

Regulation 7(1) of PNRA Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s) - (PAK/908) establishes requirements for submission of documents including Safety Analysis Report (SAR), at the time of submission of license application for radiation facilities. The SAR provides information necessary to ensure that the radiation facility can be established and operated without undue risk to health and safety of the workers, the public and the environment.

## 2. OBJECTIVE

This Regulatory Guide (RG) provides guidance to the applicant or licensee to prepare the SAR of radiation facilities on prescribed format and content.

## 3. SCOPE

This RG is applicable to following radiation facilities as listed in Schedule I of PAK/908:

i. Full-Fledged Medical Centres (including Radiotherapy Centre, Nuclear Medicine or Cardiology Centre, Radiology Department and Blood Irradiator);
ii. Radiotherapy Centres;
iii. Nuclear Medicine or Cardiology Centres;
iv. Industrial Radiography with Sources (Radioactive Material);
v. Industrial Radiography with X-ray;
vi. Agricultural Irradiators;
vii. Industrial Irradiators;
viii. Cargo or Vehicle Scanners with Sources (Radioactive Material);
ix. Manufacturers of Sources (Radioactive Material); and
x. Manufacturers of Radiation Generators.

## 4. GENERAL INSTRUCTIONS

The applicant or licensee should follow the instructions given below for preparation of SAR for radiation facilities:

i. Provide clear, concise, factual and latest information;

ii. Table of contents including sections, figures, tables, annexes, etc. along with page numbers should be included;

iii. Definitions and abbreviations should be consistent throughout the document;

iv. Duplication of information should be avoided. In case where necessary, reference of relevant section should be made:

v. Legible drawings, diagrams, layouts, and tables should be included, wherever necessary, with proper references; and

vi. The SAR should be signed by an authorized person and each page should contain a revision number (if applicable) and date.

## 5. FORMAT AND CONTENT OF SAR

Depending on the type and nature of radiation facility and associated level of radiation risk (i.e., by applying graded approach), the applicant or licensee should develop the SAR by adopting and implementing applicable guidance provided in the upcoming sections and Annexure I of this RG. Content of the SAR for radiation facility should include the following sections:

i. Introduction of the Facility;

ii. Layout of the Facility;

iii. Shielding Design;

iv. Specifications of Radiation Sources and Associated Equipment;

v. Safety Systems;

vi. Warning Systems;

vii. Ventilation Systems;

viii. Fire Safety;

ix. Accident Analysis;

x. Operational Aspects;

xi. Radiation Protection;

xii. Emergency Preparedness and Response;

xiii. Physical Protection;

xiv. Quality Assurance;

xv. Radioactive Waste Management; and

xvi. Decommissioning.

## 5.1 Introduction of the Facility

This section should provide introduction of the facility i.e., name, location, type of activities being performed at the facility, radioactive sources (unsealed or sealed), radiation generators used at the facility, types of transport packages (if any), etc.

## 5.2 Layout of the Facility

This section should include detailed description, layout of the facility and its surrounding areas. The layout of the facility should also include illustrations of classification of areas (i.e., controlled area and supervised area).

## 5.3 Shielding Design

This section should include detailed shielding calculations of all vaults, bunkers and storage rooms etc. containing radiation sources. Shielding calculations should be based on acceptable estimates of the projected workload, use and occupancy factors. The shielding design should further accommodate the future planning of the facilities.

Shielding design calculations should include the following details:

i. Maximum energy of the radiation generator or maximum activity along with reference date in case of radioactive source or material to be used at the facility;

ii. Legible scaled civil drawings (showing cross-sectional as well as plan view of the vault);

iii. Primary barriers, secondary barriers, roof, location of radiation source, isocentre inside the vault, axis of gantry rotation, maze door location and maze area (if applicable) should clearly be shown on the given drawings. It is important that all the protection points should clearly and uniquely be marked on the given drawing along with scaled distances from the radiation source. Surrounding areas (i.e., offices, corridors, parking, stairs, waiting area, etc.) of the vault or bunker should be shown on drawings or sketches;

iv. The controlled and supervised areas along with relative occupancy factors of the areas;

v. Location and design of ducts (used for cabling from outside into the vault and bunker through wall, floor or roof) on the given drawings along with shielding material and shielding calculations;

vi. Dimensions, design and materials (along with densities) of the maze door;

vii. All the assumptions used for the shielding calculations of the facility;

viii. Densities of the materials (i.e., concrete, lead, steel, bricks, etc.) used for the construction of vaults or bunkers; and

ix. Basis of the shielding calculation and reference standard document on which the shielding calculations are based.

## 5.4 Specifications of Radiation Sources and Associated Equipment

This section should include complete description of radiation sources (e.g., radionuclide, ID or Sr. No., reference activity, energy, physical form, etc.), associated equipment or devices, storage containers, packages used for transport of radioactive material and radiation sources. The said description should include principal features, operating characteristics and parameters that ensure the facility's safe operation. Sufficient drawings and schematic diagrams (where necessary) to explain and illustrate the design features of radiation sources and associated equipment should be included in the section.

## 5.5 Safety Systems

This section should include all safety systems and features (i.e., set points, interlocks, emergency stop etc.), whether built-in or installed, of equipment as well as facility to prevent accidents and to keep radiological exposures to the workers and public within the acceptable limits.

## 5.6 Warning Systems

In this section details of warning systems i.e., signs, labels, notices, indicators, audible or visual alarms, etc. used at the facility as well as on the equipment should be described.

## 5.7 Ventilation Systems

In this section, the applicant or licensee should include complete description of the ventilation systems (if applicable) including need for ventilation systems of the facility, its design, expected flow rates and filter characteristics. Sufficient drawings and schematic diagrams (to explain and illustrate the design features) should be included. The applicant or licensee should also provide the locations and specifications of the types of installed instruments (i.e., detector/sensor type, sensitivity, range and calibration; filter characteristics; set points and their bases; type and location of alarms and their corresponding actions) of the facility to be used for airborne radioactivity monitoring.

## 5.8 Fire Safety

In this section, the applicant or licensee should include description of the fire safety systems of the facility that ensures effective detection, containment, control and extinguishing of fire events at the earliest possible stage. The applicant or licensee should also include details of the design aspects i.e., escape doors, signage, fire alarm systems with smoke or heat detectors, indicator panels, call boxes, electronic sirens & wiring and escape arrangements for disabled persons, provision of fire hydrants, fixed firefighting installations, portable firefighting equipment, etc. with sufficient drawings and schematic diagrams (where necessary). Provision of Standard Operating Procedure (SOP) for fire protection as well as execution of fire drills at the facility should be included in this section. Furthermore, the applicant or licensee should include roles and responsibilities assigned to personnel or teams for handling fire emergencies.

## 5.9 Accident Analysis

In this section, the applicant or licensee should identify unintended events that can lead to potential exposure and should consider their likelihood and potential consequences. Furthermore, the applicant or licensee should also include means for preventing or minimizing unintended and accidental exposures.

## 5.10 Operational Aspects

In this section, the applicant or licensee should provide a description of arrangements of the operating organization for the safe operation which includes availability of sufficient number, qualification, training and responsibilities of staff, provision of adequate and calibrated radiation monitoring equipment and checking of safety interlocks and warning systems installed at the facility.

A list of administrative procedures including Standard Operating Procedures (SOPs) for performing different functions/activities to cater normal as well as emergency situations should be provided. Some examples are given below:

i. Entrance and Exit from Controlled Area;
ii. Radiation Survey;
iii. Contamination Monitoring;
iv. Operations of Equipment/Devices;
v. Personal Dose Monitoring;
vi. Health Surveillance;
vii. Maintenance and Testing of Equipment;
viii. Quality Control of Equipment;
ix. Declaration and Termination of Emergency;
x. Handling of Contaminated Injured Persons;

xi. Decontamination of Contaminated Area and Equipment and

xii. Fire Fighting.

## 5.11 Radiation Protection

In this section, applicant or licensee should briefly provide information of the facility about radiation monitoring arrangements (for individual, workplace and environmental), personal protective equipment, dose limits, dose constraints, distribution of roles and responsibilities relevant to radiation protection, health surveillance, condition of service and classification of areas (i.e. controlled area and supervised area) on the basis of dose rate. The applicant or licensee may refer Radiation Protection Program of the facility for details of radiation protection arrangements.

## 5.12 Emergency Preparedness and Response

In this section, applicant or licensee should describe briefly about the potential hazards and risk associated with the facility, assessment and declaration of emergency, identification of emergency response team and responsibilities of all the relevant personnel, availability of emergency equipment (e.g. long tong, shielded container, face masks, gloves, shoe cover, paper suits, lead apron, decontamination kit etc.), arrangements for communication with PNRA and other relevant response organizations (i.e. Police, Fire brigade, Rescue etc.). The applicant or licensee may refer Radiation Emergency Plan of the facility for details of emergency preparedness and response.

## 5.13 Physical Protection

In this section, the applicant or licensee should describe reporting system of security events to PNRA and other relevant organizations and should also include the provisions for conduct of periodic physical verification of radioactive sources and maintaining records of source inventory; including records of receipt, transfer and disposal of sources. The applicant or licensee may refer Physical Protection Plan of the facility for details of security arrangements.

## 5.14 Quality Assurance

In this section, the applicant or licensee should briefly describe mechanisms and procedures to review and assess the effectiveness of radiation protection, safety and security measures within the facility. This section should describe the following with respect to Quality Assurance:

i. Appropriate organizational structure;

ii. Qualification and training of personnel;

iii. Commissioning and acceptance testing;

iv. Appropriateness of equipment and its periodic tests and checks;

v. Development, review and implementation of plans and procedures;
vi. Mechanisms for surveillance and monitoring of workers;
vii. Internal and external audits;
viii. Repair, maintenance and routine inspections;
ix. Exercises and drills;
x. Maintaining records of various activities; and
xi. Codes and standards to be used for the design and manufacturing of the equipment or sources.

The applicant or licensee may refer the facility's Quality Assurance Program for details of Quality Assurance.

## 5.15 Radioactive Waste Management

In this section, the applicant or licensee should briefly explain how safety is ensured while handling of radioactive waste generated at the facility. Details needed in this section should include sources of radioactive waste, means adopted at the facility for the prevention and minimization of radioactive waste, purpose and methodology of radioactive waste storage, transfer and transport of radioactive waste or Disused Sealed Radioactive Source (DSRS) to the suppliers or designated radioactive waste management facilities. The applicant or licensee may refer Radioactive Waste Management Program of the facility for details of radioactive waste management.

## 5.16 Decommissioning

In this section, the applicant or licensee should provide a brief description about decommissioning strategy, feasibility of decommissioning, availability of sufficient resources for decommissioning, identification of categories and estimation of quantities of waste generation, identification of role and responsibilities of personnel/ groups responsible for decommissioning. The applicant or licensee may refer Initial Decommissioning Plan of the facility for details of decommissioning.

# 6. REFERENCES

[1]. Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s) - (PAK/908).
[2]. Regulations on Radiation Protection - (PAK/904).
[3]. Regulations on Management of a Nuclear or Radiological Emergency - (PAK/914).
[4]. Regulations on Radioactive Waste Management - (PAK/915).
[5]. Regulations for the Safe Transport of Radioactive Material - (PAK/916).
[6]. Regulations on Security of Radioactive Sources - (PAK/926).

[7]. Regulations on Decommissioning of Facilities Using Radioactive Material – (PAK/930).

[8]. IAEA Safety Standards Series No. SSG-46, "Radiation Protection and Safety in Medical Uses of Ionizing Radiation".

[9]. IAEA Publication "Setting up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects" Vienna: IAEA, 2008.

[10]. IAEA TECDOC 1430, "Radioisotope Handling Facilities and Automation of Radioisotope Production".

[11]. IAEA Technical Report Series No. 471, "Cyclotron Produced Radionuclides, Guidelines for Setting Up a Facility".

[12]. IAEA Safety Standards Series No. SSG-8, "Radiation Safety of Gamma, Electron and X Ray Irradiation Facilities".

[13]. IAEA Safety Standards Series No. SSG-11, "Radiation Safety in Industrial Radiography".

[14]. IAEA Safety Standards Series No. SSG-59, "Radiation Safety of Accelerator Based Radioisotope Production Facilities".

[15]. American Association of Physicists in Medicine (AAPM) Task Group 108, "PET and PET/CT Shielding Requirements".

[16]. NCRP Report No. 151, "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities".

[17]. IAEA Safety Report Series No. 47, "Radiation Protection in the Design of Radiotherapy Facilities".

## 7. GLOSSARY

i. "Acceptance Testing" means set of tests performed to ensure that the equipment meets the product specifications and the purchase agreement.

ii. "Applicant" means a person who has applied to the Authority for a license or an authorization.

iii. "Commissioning" means the process by means of which systems and components of facilities and activities, having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria.

iv. "Controlled Area" means a defined area in which specific protection measures and safety provisions are/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.

v. "Detection" means a process in a physical protection system that begins with sensing a potentially malicious or otherwise unauthorized act and

that is completed with the assessment of the cause of the alarm.

vi. "Decommissioning" means administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility (except for a repository or for certain nuclear facilities used for the disposal of residues from mining and processing of radioactive materials, which are closed and not decommissioned).

vii. "Dose Constraint" means a prospective and source related value of individual dose that is used in planned exposure situations as a parameter for the optimization of protection and safety for the source, and that serves as a boundary in defining the range of options in optimization.

viii. "Dose Limit" means the value of the effective dose or the equivalent dose to individuals in planned exposure situations from controlled practices that is not be exceeded.

ix. "Health Surveillance" means medical supervision intended to ensure the initial and continuous fitness of workers for their intended task.

x. "Licensee" means the holder of a valid license issued by the Authority.

xi. "Monitoring" means the measurement of dose, dose rate or activity for reasons relating to the assessment or control of exposure to radiation or radioactive substances, and the interpretation of the results.

xii. "Occupancy Factor" means a typical fraction of the time for which a location is occupied by an individual or group.

xiii. "Potential Exposure" means 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.

xiv. "Radiation Facility" means any premises where radiation source (radioactive material or radiation generator) is acquired, produced, manufactured, processed, reprocessed, repaired, used, handled, extracted, imported, exported, stored, installed, operated, maintained and converted.

xv. "Supervised Area" means a defined area not designated as a controlled area but for which occupational exposure conditions are kept under review, even though specific protection measures and safety provisions are not normally needed.

**ANNEXURE I**

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

| Sr. No. | Type of Facility | Application Section of RG |
|---|---|---|
| i. | Full-Fledged Medical Centre (including Radiotherapy Centre, Nuclear Medicine or Cardiology Centre, Radiology Department and Blood Irradiator) | Complete section 5 |
| ii. | Radiotherapy Centre (with sealed radioactive sources) | Complete section 5 except section 5.7 |
| iii. | Radiotherapy Centre (with radiation generators) | Complete section 5 except section 5.7, 5.8, 5.13, 5.15, 5.16 |
| iv. | Nuclear Medicine or Cardiology Centre | Complete section 5 |
| v. | Industrial Radiography (with sealed radioactive sources) | Complete section 5 except section 5.7 |
| vi. | Industrial Radiography (with radiation generators ) | Complete section 5 except section 5.7, 5.8, 5.13, 5.15, 5.16 |
| vii. | Agricultural Irradiators (with sealed radioactive sources) | Complete section 5 except section 5.7 |
| viii. | Agricultural Irradiators (with radiation generators) | Complete section 5 except section 5.7, 5.8, 5.13, 5.15, 5.16 |
| ix. | Industrial Irradiators (with sealed radioactive sources) | Complete section 5 except section 5.7 |
| x. | Industrial Irradiators (with radiation generators) | Complete section 5 except section 5.7, 5.8, 5.13, 5.15, 5.16 |
| xi. | Cargo or Vehicle Scanners (with sealed radioactive sources ) | Complete section 5 except section 5.7 |
| xii. | Manufacturers of Sources (radioactive material) | Complete section 5 |
| xiii. | Manufacturers of Radiation Generators | Complete section 5 except section 5.7, 5.8, 5.13, 5.15, 5.16 |

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