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PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN
PAKISTAN NUCLEAR REGULATORY AUTHORITY

NOTIFICATION

Islamabad, the 25th February, 2022

S.R.O.2307(I)/2022.—In exercise of the powers conferred by Section 16(2)(a) read with Section 56 of the Pakistan Nuclear Regulatory Authority Ordinance, 2001, the Pakistan Nuclear Regulatory Authority is pleased to make and promulgate the following regulations:

1. **Short Title, Extent, Applicability and Commencement.**—(1) These regulations may be called the “Regulations on Leadership and Management for Safety - (PAK/921)”.

(2) These regulations extend to the whole of Pakistan.

(3) These regulations shall be applicable to all the facilities and activities giving rise to risk from ionizing radiation.

5389(1—17)

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(4) These regulations shall come into force at once for the applicants whose request for grant of an authorization or a license is in the process of approval. However, the facilities and activities already authorized or licensed by PNRA shall be required to fulfill all the requirements of these regulations within two (02) years after the promulgation.

2. **Definitions.**—In these regulations, unless there is anything repugnant in the subject or context:

- (a) “*applicant*” means a person, as defined in Pakistan Nuclear Regulatory Authority Ordinance, 2001, applying to the Authority for authorization or license to undertake specified activities;
- (b) “*assessment*” means the process, and the result, of analyzing systematically and evaluating the hazards associated with the facilities and activities, and associated protection and safety measures;
- (c) “*closure*” means administrative and technical actions directed at a disposal facility at the end of its operating lifetime;
- (d) “*commissioning*” means the process by which systems and components of a facility having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria;
- (e) “*construction*” means the process of manufacturing and assembling the components of a facility, the carrying out of civil works, the installation of components and equipment and the performance of associated tests;
- (f) “*decommissioning*” means the administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility;
- (g) “*design*” means the process and the result of developing a concept, detailed plans, supporting calculations and specifications for a facility and its parts;
- (h) “*facilities and activities*” mean general term encompassing facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people may be subject to exposure to radiation from naturally occurring or artificial sources:
 - i. “*facilities*” include nuclear facilities; irradiation installations; some mining and raw material processing facilities such as uranium mines; radioactive waste management facilities; and

any other places where radioactive material is produced, processed, used, handled, stored or disposed of or where radiation generators are installed on such a scale that consideration of protection and safety is required; and

- ii. “*activities*” include the production, manufacturing, use, import and export of radiation sources for industrial, research and medical purposes; the transport of radioactive material; the decommissioning of facilities; radioactive waste management activities such as the discharge of effluents; and some aspects of the remediation of sites affected by residues from past activities.
- (i) “*graded approach*” means a process or method for a system of control, such as a regulatory system or a safety system, in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control;
- (j) “*hazard*” means the potential for harm or other detriments, especially for radiation risks; a factor or condition that might operate against safety;
- (k) “*independent assessment*” means assessments such as audits or surveillance carried out to determine the extent to which the requirements for the management system are fulfilled, to evaluate the effectiveness of the management system and to identify opportunities for improvement. They can be conducted by or on behalf of the organization itself for internal purposes, by interested parties such as customers or by other persons on their behalf, or by external independent organizations;
- (l) “*interested party*” means a person, company, etc., with a concern or interest in the activities and performance of an organization, business, system etc.;
- (m) “*knowledge management*” means an integrated, systematic approach to identifying, managing and sharing an organization’s knowledge and enabling groups of people to create new knowledge collectively to help in achieving the organization’s objectives;
- (n) “*leadership*” means the use of an individual’s capabilities and competencies to give direction to individuals and groups and to influence their commitment to achieve the fundamental safety objective, and to apply the fundamental safety principles in accordance with National Safety Policy - (NP-02/2020);

- (o) “*licensee*” means the holder of a valid license issued by the Authority;
- (p) “*management*” means a formal, authorized function for ensuring that an organization operates efficiently and that work is completed in accordance with requirements, plans and resources;
- (q) “*management system*” means a set of interrelated or interacting elements (a system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner;
- (r) “*non-conformance*” means a deficiency in characteristics, documentation or procedure, which renders the quality of an item unacceptable or indeterminate;
- (s) “*operation*” means all activities performed to achieve the purpose for which an authorized facility was constructed;
- (t) “*records*” mean documents, which furnish objective evidence of the quality of items or services and activities affecting quality;
- (u) “*resources*” mean the individuals, the number of individuals and their competencies, infrastructure, the working environment, knowledge and information, and suppliers, as well as material and financial resources;
- (v) “*safety*” means the protection of the people and the environment against radiation risks, and the safety of facilities and activities that give rise to radiation risks;
- (w) “*safety culture*” means the assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance;
- (x) “*security*” means the prevention and detection of, and response to, criminal or intentional unauthorized acts involving nuclear material, other radioactive material, associated facilities or associated activities;
- (y) “*security culture*” means the assembly of characteristics, attitudes and behaviors of individuals, organizations and institutions that serves as a means to support and enhance security;

- (z) “*self-assessment*” means a routine and continuing process conducted by senior management and also by management at other levels to evaluate the effectiveness of performance in all areas of their responsibility;
- (aa) “*senior management*” means the individual or group of individuals who direct, control and assess an organization at the highest level;
- (bb) “*siting*” means the process of selecting a suitable site for a facility, including appropriate assessment and definition of the related design bases;
- (cc) “*source*” means anything that may cause radiation exposure, such as by emitting ionizing radiation or by releasing radioactive material, and can be treated as a single entity for protection and safety purposes. It includes all types of radiation generators and radioactive material, and is also called as radiation source;
- (dd) “*supplier*” means any person or organization to whom an applicant or licensee assigns duties, totally or partially, in relation to the design, manufacture, production or construction;
- (ee) “*supply chain*” means designers, vendors, manufacturers and constructors, employers, contractors, sub-contractors, and consigners and carriers who supply safety-related items;
- (ff) “*validation*” means the process of determining whether the product or service is adequate to perform its intended function satisfactorily; and
- (gg) “*vendor*” means a design, contracting or manufacturing organization supplying a service, competence or facility.

3. **Scope.**—These regulations shall be applicable to all types of facilities and activities that directly or indirectly give rise to risk from ionizing radiation.

4. **Interpretation.**—The decision of the Chairman regarding interpretation of any word or phrase of these regulations shall be final and binding.

RESPONSIBILITY FOR SAFETY

5. Achieving the Fundamental Safety Objective.—(1) The applicant or licensee, as the case may be, shall ensure that provisions are made to achieve the fundamental safety objective of protecting the workers, the public and the environment from harmful effects of ionizing radiation in accordance with the provisions of “National Safety Policy - (NP-02/2020)”.

(2) The senior management of the organization, in accordance with their accountabilities and in the light of PNRA regulations shall ensure:

- (a) the safe siting, design, construction, commissioning, operation and decommissioning, or closure, of the facilities, as appropriate;
- (b) that equipment and activities meet the regulatory requirements and applicable standards for safety, quality and management;
- (c) the safe management and control of all radioactive materials and sources that are produced, processed, used, handled, transported, stored or disposed of;
- (d) that managers at all levels develop and maintain an understanding of radiation risks and potential consequences, and of how to manage radiation risks relevant to their responsibilities;
- (e) maintenance of skills, knowledge and continued eligibility of personnel who are separate or partly separate from the organization throughout their period of services;
- (f) that provision is made for adequate resources for all facilities and activities as per scope of these regulations, including for the long term management and disposal of radioactive waste, as well as for decommissioning or closure of facilities, with due consideration given to the protection of future generations; and
- (g) that adequate arrangements are made, where appropriate, for preparedness and response for a nuclear or radiological emergency.

LEADERSHIP FOR SAFETY

6. Demonstration of Leadership for Safety.—(1) The senior management of the organization, shall demonstrate leadership and commitment for safety by:

- (a) establishing, advocating and adhering to an organizational approach to safety which stipulates that, as an overriding priority, issues relating to protection and safety receive the attention warranted by their significance;
- (b) acknowledging that safety encompasses interactions between people, technology and the organization;
- (c) establishing organizational values, behavioural expectations and fostering a strong safety culture;
- (d) establishing the acceptance of personal accountability, on the part of all individuals in the organization, in relation to safety; and
- (e) establishing that decisions taken at all levels take account of the priorities and accountabilities for safety.

(2) Managers of the organization at all levels, taking into account their duties, shall ensure that their leadership includes:

- (a) setting goals for safety that are consistent with the organization's safety policy, actively seeking information on safety performance within their area of responsibility and demonstrating commitment to improve safety performance;
- (b) development of individual and organizational values and expectations for safety throughout the organization by means of their decisions, statements and actions; and
- (c) ensuring that their actions serve to encourage the reporting of safety-related problems, to develop questioning and learning attitudes, and to correct acts or conditions that are adverse to safety.

(3) Managers at all levels in the organization shall:

- (a) encourage and support all individuals in achieving safety goals and performing their tasks safely;
- (b) engage all individuals in enhancing safety performance; and
- (c) communicate clearly the basis for decisions relevant to safety.

MANAGEMENT FOR SAFETY

RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

7. Responsibility of the Senior Management for the Management System.—(1) The senior management of the organization shall be responsible for establishing, applying, sustaining and continuously improving the management system to ensure safety. The senior management shall:

- (a) retain accountability for the management system even where individuals are assigned responsibility for coordinating the development, application and maintenance of the management system; and
- (b) be responsible for establishing safety policy.

8. Goals, Strategies, Plans and Objectives.—(1) The senior management of the organization shall establish goals, strategies, plans and objectives for the organization that are consistent with the organization's safety policy and shall ensure that:

- (a) the same are developed in such a manner that safety is not compromised by other priorities;
- (b) the same are periodically reviewed against the safety objectives and that actions are taken where necessary to address any deviation; and
- (c) measurable safety goals that are in line with these strategies, plans and objectives are established at various levels in the organization.

9. Interaction with Interested Parties.—(1) The senior management shall ensure appropriate interaction with interested parties, identify those interested parties for the organization and define a strategy to ensure effective interaction with them.

(2) The senior management shall ensure that the processes and plans resulting from the strategy for interaction with interested parties include appropriate means:

- (a) of communicating, routinely and effectively, and informing interested parties with regard to radiation risks associated with the operation of the facilities and the conduct of activities;

- (b) for timely and effective communication with interested parties in circumstances that have changed or that were unanticipated;
- (c) for dissemination of necessary information relevant to safety to interested parties; and
- (d) of considering the concerns and expectations of interested parties, in relation to safety in decision making process.

THE MANAGEMENT SYSTEM

10. **Integration of the Management System.**—(1) The management system shall integrate its elements, including safety, health, environmental, security, quality, human and organizational factor, societal and economic elements, so that safety is not compromised.

(2) The management system shall be applied to achieve goals, to enhance safety and foster a strong safety culture by:

- (a) bringing together in a coherent manner all the necessary elements for safely managing the organization and its activities;
- (b) describing the arrangements made for management of the organization and activities;
- (c) describing the planned and systematic actions necessary to provide confidence that all requirements are met; and
- (d) ensuring that safety is taken into account in decision making and is not compromised by any decision.

(3) Arrangements shall be made in the management system for the resolution of conflicts arising in decision making processes. Potential impacts of security measures on safety and potential impacts of safety measures on security shall be identified and resolved without compromising safety or security.

(4) The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system.

(5) The applicant or licensee shall reflect the applicable regulatory requirements in the management system.

(6) The applicant or licensee shall ensure that provisions are made in the management system to identify any changes, including organizational changes and the cumulative effects of minor changes, that could have significant safety implications and to ensure that they are appropriately analysed.

(7) The applicant or licensee shall ensure that arrangements are established in the management system for an independent review to be conducted before taking decisions significant for safety. The requirements on the independent nature of review and the necessary competencies of the reviewers shall be specified in the management system.

11. Application of the Graded Approach to the Management System.—(1) The management system shall be developed and applied by using a graded approach.

(2) The criteria used to grade the development and application of the management system shall be documented in the management system taking into account the following:

- (a) The safety significance and complexity of the organization, operation of the facility or conduct of the activity;
- (b) The hazards and the magnitude of the potential impacts or risks associated with the safety, health, environment, security, quality and economic elements of each facility or activity; and
- (c) The possible consequences for safety:
 - (i) if a failure or an unanticipated event occurs; or
 - (ii) if an activity is inadequately planned or improperly carried out.

12. Documentation of the Management System.—(1) The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available for use.

(2) The documentation of the management system shall include as a minimum:

- (a) Policy statements on safety, values and behavioural expectations;
- (b) The fundamental safety objective;
- (c) Description of the organization and its structure;
- (d) Description of the responsibilities and accountabilities;

- (e) The levels of authority, including all interactions of those managing, performing and assessing work and including all processes;
- (f) Description of how the management system complies with regulatory requirements that apply to the organization; and
- (g) Description of the interactions with external organizations and with interested parties.

(3) The documentation of the management system shall be available in English or Urdu language.

(4) Documents shall be controlled. All individuals responsible for preparing, reviewing, revising and approving documents shall be competent to perform the tasks and shall be given access to appropriate information on which their inputs or decisions are based.

(5) Revisions to the documents shall be controlled, reviewed and recorded. Revised documents shall be subject to the same level of approval as the initial documents.

(6) Records shall be specified in the management system and shall be controlled. All records shall be legible, complete, identifiable and easily retrievable.

(7) A record system shall be established for identification, collection, indexing, filing, storing, maintenance, retrieval and disposal of records.

(8) Retention period of records and associated test materials and specimens shall be established to be consistent with applicable requirements and with the obligations for knowledge management of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention period specified for each record.

MANAGEMENT OF RESOURCES

13. Provision of Resources.—(1) The senior management shall determine the competences and resources necessary to carry out the activities of the organization safely and shall provide them.

(2) The senior management shall make arrangements to ensure that the organization has, in-house or maintains access to, the full range of competencies and the resources necessary to conduct its activities and to discharge its responsibilities for ensuring safety at each stage in the lifetime of the facility or activity, and during an emergency response.

(3) The senior management shall determine which competencies and resources the organization has to retain or has to develop internally, and which competencies and resources may be obtained externally, for ensuring safety.

(4) The senior management shall ensure that competence requirements for individuals at all levels are specified and training is conducted, or other actions are taken, to achieve and to sustain the required levels of competence. An evaluation shall be conducted of the effectiveness of the training and actions taken.

(5) Competencies to be sustained in-house by the organization shall include:

- (a) competencies for leadership at all management levels;
- (b) competencies for fostering and sustaining a strong safety culture; and
- (c) expertise to understand technical, human and organizational aspects relating to the facility or the activity in order to ensure safety.

(6) The senior management shall ensure that individuals at all levels, including managers and workers:

- (a) are competent to perform their assigned tasks and to work safely and effectively; and
- (b) understand the standards that they expect to apply in completing their tasks.

(7) All individuals in the organization shall be trained in the relevant requirements of the management system. Such training shall be conducted to ensure that individuals are knowledgeable of the relevance and the importance of their activities and of how their activities contribute to ensure safety in the achievement of the organization's goals.

(8) The applicant or licensee shall ensure that knowledge and information of the organization are identified and managed as a resource.

MANAGEMENT OF PROCESSES, ACTIVITIES AND SUPPLY CHAIN

14. Management of Processes and Activities.—(1) Each process shall be developed and managed to ensure that all requirements including regulatory requirements are met without compromising safety. Processes shall be

documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents. Records, to demonstrate that the results of the respective process have been achieved, shall be specified in the process documentation.

(2) The sequencing of a process and the interactions between processes shall be specified so that safety is not compromised. Effective interaction between interfacing processes shall be ensured. Particular consideration shall be given to interactions between processes conducted within the organization, and by external organizations.

(3) New processes or modifications to existing processes shall be designed, verified, approved and applied so that safety is not compromised. Processes, including any subsequent modifications to them, shall be aligned with the goals, strategies, plans and objectives of the organization.

(4) Any activity for inspection, testing, and verification and validation, their acceptance criteria and the responsibilities for carrying out such activities shall be specified. It shall be specified when and at what stages independent inspection, testing, and verification and validation are required to be conducted.

(5) Each process or activity that could have implications for safety shall be carried out under controlled conditions, by means of following readily understood, approved and current procedures, instructions and drawings. These procedures, instructions and drawings shall be validated before their first use and shall be periodically reviewed to ensure their adequacy and effectiveness. Individuals carrying out such activities shall be involved in the validation and the periodic review of such procedures, instructions and drawings.

15. Management of the Supply Chain.—(1) The applicant or licensee shall put in place arrangements with vendors, contractors and suppliers for specifying, monitoring and managing the supply of items, products and services that may influence safety.

(2) The applicant or licensee shall retain responsibility for safety when contracting out any processes and when receiving any item, product or service in the supply chain.

(3) The applicant or licensee shall have a clear understanding and knowledge of the product or service being supplied. The licensee shall itself retain the competence to specify the scope and standard of a required product or service, and subsequently to assess if the product or service supplied meets the applicable safety requirements.

(4) The applicant or licensee shall make arrangements for ensuring that suppliers of items, products and services important to safety adhere to safety requirements and meet the applicant's or licensee's expectations of safe conduct in their delivery.

(5) The management system shall include arrangements for qualification, selection, evaluation, procurement including reporting of deviations from procurement requirements and oversight of the supply chain.

CULTURE FOR SAFETY

16. Fostering a Culture for Safety.—(1) The applicant or licensee shall ensure that all individuals in the organization contribute to foster and sustain a strong safety culture.

(2) The management system and leadership for safety shall be such as to foster and sustain a strong safety culture.

(3) Senior managers and all other managers shall advocate and support the following:

- (a) A common understanding of safety and safety culture, including:
 - (i) awareness of radiation risks and hazards relating to the work and working environment;
 - (ii) an understanding of the significance of radiation risks and hazards for safety; and
 - (iii) a collective commitment to safety by the individuals and teams.
- (b) Acceptance by the individuals of personal accountability for their attitudes and conduct with regard to safety;
- (c) An organizational culture that supports and encourages trust, collaboration, consultation and communication;
- (d) The reporting of problems relating to individual, technological, and organizational factors and any deficiencies in structures, systems and components to avoid degradation of safety, including the timely acknowledgement of, and reporting back of, actions taken;

- (e) Measures to encourage a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;
- (f) The means by which the applicant or licensee seeks to enhance safety and to foster and sustain a strong safety culture, and using a systemic approach (i.e. an approach relating to the system as a whole in which the interactions between individual, technological and organizational factors are duly considered);
- (g) Safety oriented decision making in all activities; and
- (h) The exchange of ideas between, and the combination of, the safety culture and security culture.

MEASUREMENT, ASSESSMENT AND IMPROVEMENT

17. Measurement, Assessment and Improvement of the Management System.—(1) The licensee shall measure, assess and improve the effectiveness of the management system to enhance safety performance, including minimizing the occurrence of problems relating to safety.

(2) The licensee shall monitor and measure the effectiveness of the management system to confirm the ability of the organization to achieve the results intended and to identify opportunities for improvement of the management system.

(3) All processes shall be regularly evaluated for their effectiveness and ability to ensure safety.

(4) The causes of non-conformances of processes and the safety-related events that could give rise to radiation risks shall be evaluated and any consequences shall be managed and shall be mitigated.

(5) The corrective actions necessary for eliminating the causes of non-conformances, and for preventing the occurrence of, or mitigating the consequences of, similar safety-related events, shall be determined, and corrective actions shall be taken in a timely manner.

(6) The status and effectiveness of all corrective actions and preventive actions taken shall be monitored and shall be reported to the management at an appropriate level in the organization.

(7) Self-assessments and independent assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement. Lessons and any resulting significant changes shall be analysed for their safety implications.

(8) The licensee shall assign the responsibility for conducting independent assessments of the management system. The organizations, entities either in-house or external and individuals assigned such responsibilities shall be given sufficient authority to discharge their responsibilities and shall have direct access to senior management. In addition, individuals conducting independent assessments of the management system shall not be assigned responsibility to assess areas under the responsibility of their line management.

(9) The senior management shall conduct a review of the management system at planned intervals to confirm its suitability and effectiveness, and its ability to enable the objectives of the licensee to be accomplished, with account taken of new requirements and changes in the organization.

(10) The management system shall include evaluation and timely use of the following:

- (a) Lessons from experience gained and from events that have occurred, both within and outside the organization, and lessons from identifying the causes of events;
- (b) Technical advances and results of research and development; and
- (c) Lessons from good practices.

(11) The licensee shall make arrangements to learn from successes and strengths for organizational development and continuous improvement.

18. Measurement, Assessment and Improvement of Leadership for Safety and Safety Culture.—(1) The senior management of the organization shall regularly conduct assessments of leadership for safety and of safety culture in the organization.

(2) The senior management shall ensure that self-assessment of leadership for safety and of safety culture includes assessment at all organizational levels and activities. The senior management shall also ensure that such self-assessment is conducted by experts in the assessment of leadership and safety culture.

(3) The senior management shall ensure that an independent assessment of leadership for safety and of safety culture is conducted for enhancement of the organizational culture for safety, i.e. the organizational culture as it relates to safety and as it fosters a strong safety culture in the organization.

(4) The results of self-assessments and independent assessments of leadership for safety and of safety culture shall be communicated at all levels in the organization. The results of such assessments shall be acted upon to foster and sustain a strong safety culture, to improve leadership for safety and to foster a learning attitude within the organization.

19. **Repeal.**—The “Regulations on the Safety of Nuclear Power Plants-Quality Assurance (PAK/912) (Rev. 1)” notified vide S.R.O. 900(I)/2003 dated 11th September, 2003 and its corresponding amendment notified vide S.R.O. 1110(I) 2014 dated 16th December, 2014 are hereby repealed.

NAVEED MAQBUL,
Member (Corporate).