

The Gazette  **of Pakistan**

**EXTRAORDINARY
PUBLISHED BY AUTHORITY**

ISLAMABAD, THURSDAY, SEPTEMBER 11, 2003

PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN

PAKISTAN NUCLEAR REGULATORY AUTHORITY

NOTIFICATION

Islamabad, the 10th September, 2003.

S.R.O. 900 (I)/2003.—In exercise of the powers conferred by section 56 read with section 16 of the Pakistan Nuclear Regulatory Authority Ordinance 2001 (III of 2001), Pakistan Nuclear Regulatory Authority is pleased to make the following regulations.

1. **Short title and commencement**—(1) These regulations may be called “Regulations on the Safety of Nuclear Power Plants-Quality Assurance (PAK/912) (Rev. 1)”.

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

(2121)

Price: Rs. 10.50

(3) These regulations shall come into force at once.

Definitions.—In these regulations, unless there is any thing repugnant in the subject or context.

- (a) accident (accident state) means a state defined under “accident conditions” or “severe accidents”.
- (b) audit means a documented activity performed to determine by investigation, examination and evaluation of objective evidence the adequacy of, and adherence to, established procedures, instructions, specifications, regulations, standards, administrative or operational programs and other applicable documents and the effectiveness of implementation.
- (c) commissioning means the process during which systems and components of installation(s) and activities, having been constructed, are made operational and verified to be in accordance with design and to have met the required performance criteria.
- (d) construction means the process of manufacturing and assembling the components of an installation, the carrying out of civil works, the installation of the components and equipment and the performance of associated tests.
- (e) 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, which is closed and not decommissioned.)
- (f) design means the process and the result of developing the concept, detailed plans, supporting calculations and specifications for nuclear installation(s) and its parts.
- (g) documentation means recorded or pictorial information describing, defining, specifying, reporting or certifying activities, requirements, procedures or results related to Quality Assurance.
- (h) examination means an element of inspection consisting of investigation of materials, components, supplies or service, to determine

conformance with those specified requirements, which can be determined by such investigation.

- (i) inspection means examination, observation, measurement or test undertaken to assess structures, systems, components and materials as well as operational activities, processes, procedures and personnel competence.
- (j) licensee means the holder of current licence.
- (k) non-conformance means a deficiency in characteristics, documentation or procedure, which renders the Quality of an Item unacceptable or indeterminate.
- (l) nuclear safety (safety) means the achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of site personnel, the public and the environment from undue radiation hazards.
- (m) objective evidence means qualitative or quantitative information, record or statement of fact, pertaining to the quality of an item or service, which is based on observation, measurement or test and which can be verified.
- (n) operation means all activities performed to achieve the purpose for which installation(s) was constructed.
- (o) Pakistan Nuclear Regulatory Authority (PNRA) means the national authority as established under section 3 of the Ordinance III of 2001 by Government of Pakistan and herein called the Authority.
- (p) qualified person means the person who, having complied with specific requirements and met certain conditions, has been officially designated to discharge specified duties and responsibilities.
- (q) quality assurance means planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy given requirements for quality, for example, those specified in the licence.

- (r) records mean documents, which furnish objective evidence of the quality of items or services and activities affecting quality.
- (s) site means the geographical area containing the nuclear installation(s), and within which the management of the installation(s) may directly initiate emergency actions.
- (t) siting means process of selecting a suitable Site for nuclear installation(s), including appropriate assessment and definition of the related design bases.
- (u) specification (technical condition) means a written statement of requirements to be satisfied by a product, a service, a material or process, indicating the procedure by means of which it may be determined whether specified requirements are satisfied.
- (v) supplier evaluation means an appraisal to determine whether or not a management system is capable of producing an item or service of a stated quality, and generating evidence that supports decision on acceptability.
- (w) testing means determination or verification of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental or operational conditions

2. INTRODUCTION

Purpose

2.1. These regulations provide the basic requirements for establishing and implementing quality assurance programs related to the safety of nuclear power plants. These basic requirements apply to the overall quality assurance program of licensee/management, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate quality assurance programs in each stage of the life of a nuclear power plant.

2.2. The guidance on how to implement the basic requirements is included in the appropriate regulatory guides (See Annex).

2.3. Through these regulations and related regulatory guides on quality assurance, emphasis is made that managers of licensee/management including those

performing the work and those assessing the work, all contribute in ensuring quality and achieving safety.

2.4. Licensee/management has to demonstrate the effective fulfillment of the quality assurance requirements to the satisfaction of the Authority. These regulations are applicable to designers, constructors, operators, maintenance workers and radiation protection personnel.

Objective

2.5. The main objective of the regulations is to facilitate, support and ensure safety in nuclear power plant siting, design, construction, commissioning, operation and decommissioning. The regulations recognize that all work is a process that can be planned, performed, assessed and improved.

Scope

2.6. These regulations provide the basic requirements for establishing and implementing quality assurance programs for the stages of siting, design, manufacture, construction, commissioning, operation and decommissioning of nuclear power plants. These basic requirements apply to all individuals and organizations, including designers, suppliers, constructors, manufacturers and operators of nuclear power plants.

Interpretation

2.7. Chairman of Pakistan Nuclear Regulatory Authority (PNRA), or an officer duly authorized to act on his behalf, shall control and supervise all safety matters pertaining to the enforcement, amendment, modifications, and explanation of this safety regulation and regulatory guides referred to in these regulations.

2.8. The decision of Chairman PNRA regarding the interpretation of any word or phrase of this regulation or applicability of these regulations and regulatory guides shall be final and binding on the licensee/management.

3. LICENSEE/MANAGEMENT

Quality Assurance Program

3.1. Licensee/management shall develop, implement and maintain a quality assurance program. The quality assurance program shall include details of how

work is to be managed, performed and assessed, consistent with the basic requirements in these regulations. The quality assurance program shall include the organizational structure, functional responsibilities, levels of authority and interfaces for those managing, performing and assessing the adequacy of work. The quality assurance program shall address licensee/management measures, including planning, scheduling and resource considerations.

3.2. Licensee/management in the entire and constituent areas of work shall provide and demonstrate support for the effective implementation of the quality assurance program consistent with specified time schedules for accomplishing project activities. If the licensee/management delegates to other organizations the work of establishing and implementing all or a part of the overall program, it shall retain responsibility for the effectiveness of the program in all circumstances.

3.3. The quality assurance program shall provide an interdisciplinary approach involving many organizational components and shall not be regarded as the sole domain of any single group. The quality assurance program shall demonstrate the integration of the following principles:

- (i) managers provide planning, resources and support to achieve the organization's objectives.
- (ii) staff performing the work achieve quality; and
- (iii) staff performing assessments evaluate the effectiveness of management processes and work performance.

3.4. The quality assurance program shall be binding on every relevant employee of licensee/management.

3.5. Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the quality assurance program applies. A graded approach based on the relative importance to nuclear safety of each item; service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific quality assurance requirements.

3.6. The quality assurance program shall include measures, which ensure that all relevant documentation of research and development, designing, purchasing,

fabricating, manufacturing, handling, storing, cleaning, erecting, installing, testing, inspecting, maintaining, repairing, operation, technical support, refueling and disassembly is available in English language.

Training and Qualification

3.7. Personnel shall be trained and qualified so that they are competent to perform their assigned work and understand the safety consequences of their activities.

Non-Conformance Control and Corrective Actions

3.8. Items, services and processes that do not meet specified requirements shall be identified and the safety impact of the non-conformances assessed and reported to the appropriate level of management. Depending on the results of the assessment, the items shall be accepted, rejected, repaired or reworked, and services and processes accepted or rejected.

3.9. To ensure improvement, the causes of such non-conformances shall be determined and action taken to prevent their recurrence. Item characteristics (such as reliability), process implementation, experience and other quality related information (including licensee/management processes) shall be reviewed and the data analysed to identify improvements.

Document Control and Records

3.10. Documents such as procedures, instructions, specifications and drawings, or other media which describe processes, specify requirements or establish design, shall be prepared, reviewed, approved, issued, distributed, authorized, revised and, as required, validated. All personnel preparing, revising, reviewing or approving documents shall be specifically assigned to this work and be given access to appropriate information upon which to base their input. Personnel using documents shall be aware of and use appropriate and correct documents.

3.11. Records relating to personnel and records that describe the status, configuration and characteristics of items and services, describe the performance of processes and represent objective evidence of quality shall be specified, prepared, reviewed, approved and maintained. All records shall be legible, complete and identifiable. A records system shall be established to provide for the identification, collection, indexing, filing, storing, maintenance, retrieval and

disposal of records. Retention times of records and associated test materials and specimens shall be established to be consistent with the type of records, material and specimens involved.

4. PERFORMANCE

Work

4.1. During all stages in the life of the nuclear power plant, work shall be planned and performed in accordance with established regulations, standards, specifications, practices and administrative controls. Work shall be performed under controlled conditions, using approved current instructions, procedures, drawings or other appropriate means that are periodically reviewed to ensure adequacy and effectiveness.

4.2. Items and services shall be identified and controlled to ensure their proper use. Items shall be shipped, stored, handled, maintained, operated and used as specified to prevent their damage, loss or deterioration.

4.3. Equipment used for process monitoring, data collection, inspections and tests shall be of the proper range, type, accuracy and precision.

Design

4.4. Design, including subsequent changes, shall be carried out in accordance with established regulations and shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled.

4.5. The adequacy of design, including design tools and design inputs and outputs shall be verified or validated by individuals or groups other than those who originally performed the work. Verification, validation and approval shall be completed before implementation of the design.

5. Procurement

5.1. Procured items and services shall meet established requirements and perform as specified. Suppliers shall be evaluated and selected on the basis of specified criteria.

5.2. Requirements necessary to ensure the quality of items and services shall be developed and specified in the procurement documents. Evidence that

purchased items and services meet procurement requirements shall be available before they are used.

5.3. Requirements for reporting deviations from procurement requirements shall be specified in the procurement documents.

5.4. Inspection and testing of specified items, services and processes shall be conducted using established acceptance and performance criteria. The level of inspection and testing and the degree of independence of personnel shall be established.

5.5. Administrative controls, such as hold points and status indicators, shall be used to preclude the bypassing of required inspections and tests. Any inadvertent use, installation or operation of items, services and processes that have not passed the required inspections and tests shall be prevented.

6. ASSESSMENT

Licensee/management Self-Assessment.

6.1. Licensee/management at all levels shall regularly assess the processes for which it is responsible. Licensee/management shall determine its effectiveness in establishing, promoting and achieving nuclear safety objectives. Management process weaknesses and barriers that hinder the achievement of the nuclear safety objectives shall be identified and corrected.

Independent Assessment/Audit

6.2. Independent assessments/audit shall be conducted on behalf of licensee/management to measure the effectiveness of management processes and the adequacy of work performance, to monitor item and service quality and to promote improvement.

6.3. An organizational unit shall be established, or an outside agency assigned, with the responsibility to conduct independent assessments/audit. It shall have sufficient authority and organizational freedom to carry out its responsibilities.

6.4. Individuals conducting independent assessment/audit shall not participate directly in the work being assessed.

6.5. Licensee/management shall consider the results of the independent assessments/audit and, where necessary, actions shall be taken to implement improvements.

Annex

List of Regulatory Guides for Regulations on the Safety of Nuclear Power Plant Quality Assurance

- PAK/1301 Preparation of the quality assurance program for nuclear power plants.
- PAK/1302 Quality assurance records system for nuclear power plants.
- PAK/1303 Quality assurance in the procurement of items and services for nuclear power plants.
- PAK/1304 Quality assurance during site construction of nuclear power plants.
- PAK/1305 Quality assurance during commissioning of nuclear power plants.
- PAK/1306 Quality assurance in the design of nuclear power plants.
- PAK/1307 Quality assurance organisation for nuclear power plants.
- PAK/1308 Quality assurance in the manufacture of items for nuclear power plants.
- PAK/1309 Quality assurance auditing for nuclear power plants.
- PAK/1310 Quality assurance in the procurement, design and manufacture of nuclear fuel assemblies.
- PAK/1311 Quality assurance during operation of nuclear power plant.
- PAK/1318. Quality assurance requirements for installation, inspection, and testing of structural steel during the construction phase of nuclear power plants.

PAK/1320 Quality assurance requirements for installation, inspection, and testing of mechanical equipment and systems.

Copies of regulatory guides can be obtained from

**PAKISTAN NUCLEAR REGULATORY AUTHORITY, P.O. Box 1912,
Islamabad, Pakistan**

SYED BADSHAH HUSAIN,
Member Corporate
Pakistan Nuclear Regulatory Authority.
P.O. Box 1912
Islamabad.