The Gazette of Pakistan

EXTRAORDINARY
PUBLISHED BY AUTHORITY

ISLAMABAD, TUESDAY, OCTOBER 9, 2001

PART II

Statutory Notification (S.R.O)

PAKISTAN NUCLEAR REGULATORY AUTHORITY

NOTIFICATIONS

Islamabad, September 21, 2001

S.R.O. 699(1)/2001 -In exercise of the powers conferred by Section 16 of the Pakistan Nuclear Regulatory Authority Ordinance 2001 (III of 2001), Pakistan Nuclear Regulatory Authority is pleased to make and promulgate the following Regulation -

1. Short title, extent and commencement.—(1) This regulation may be called Regulation for Licensing of Nuclear Installation(s) in Pakistan - PAK/909 (Rev. 0).

(2) This regulation extends to the whole of Pakistan.
(3) This regulation shall come into force at once.
(4) This regulation shall also apply to all the establishments of the Pakistan Atomic Energy Commission.

2. DEFINITIONS
In this Regulation, unless there is anything repugnant in the subject or context,

(a) **ALARA** means **t**he process of determining what level of protection and safety makes exposures, and the possibility and magnitude of potential exposures, " as low as reasonably achievable, economic and social factors being taken into account" (ALARA), as required by International Commission on Radiological Protection (ICRP) Systems of Radiological Protection.

(b) **Chairman PNRA** means chief executive officer of PNRA, and shall subject to the provisions of the Ordinance, the rules and regulations, is responsible for the day to day administration of the affairs of the authority.

(c) **Commissioning** means the process during which nuclear installation(s) components and systems, having been constructed, are made operational and verified to be in accordance with design assumptions and to have met the performance criteria.

(d) **Construction** means the process during which systems of installation(s) 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.

(e) **Decommissioning** means administrative and technical actions taken to allow the removal of some or all of the regulatory controls from an installation (except for 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) **Inspection** means an examination, observation, measurement or test undertaken to assess structures, systems, components and materials, as well as operational activities, processes, procedures and personnel competence.

(h) **Licence/License:** Refer to the article 2(f) of the Ordinance.

(i) **Licensee** means the holder of current licence.

(j) **Limit** means the value of quantity used in certain specified activities or circumstances that must not be exceeded and is acceptable to or/and notified by PNRA.

(k) **Normal Operation** means operation within specified operational limits and conditions.

(l) **Nuclear Installation** Refer to the article 2(k) of the Ordinance.

(m) **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.

(n) **Operating Personnel** means individual workers engaged in the operation of the authorised nuclear installation(s).

(o) **Ordinance** means Ordinance No. III of 2001 issued by Government of Pakistan, defined as Pakistan Nuclear Regulatory Authority Ordinance, 2001.

(p) **Operational States** means states defined under normal operation or anticipated operational occurrences.

(q) **Pakistan Nuclear Regulatory Authority (PNRA)** means a national authority as established under section 3 of The Ordinance III of 2001 by Government of Pakistan.

(r) **Periodic Safety Review (PSR)** means a systematic reassessment of the safety of an operational facility or activity carried out at regular intervals to deal with the cumulative effects of ageing, modifications, operating experience and technical developments, and aimed at ensuring high level of safety throughout the operating lifetime of the facility or activity.

(s) **Probabilistic Safety Analysis (PSA)** means a comprehensive, structured approach to identifying failure scenarios, constituting a conceptual and mathematical tool for deriving numerical estimates of risk.

(t) **PSA Level 1** means the assessment of plant failure leading to the determination of core damage frequency.

(u) **PSA Level 1 plus** means PSA level 1 including external fire and flood analysis.

(v) **Quality Assurance** means all those planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy the given requirements for quality, for example, those specified in the licence.

(w) **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.

(x) **Safety Function** means a specific purpose that must be accomplished for safety.

(y) **Site** means the geographical area containing the nuclear installation(s), and within which the management of the installation(s) may directly initiate emergency actions.

(z) **Siting** means the process of selecting a suitable Site for nuclear installation(s), including appropriate assessment and definition of the related design basis.

(aa) **Site Personnel** means all persons working on the Site of the installation(s), either permanently or temporarily.

(bb) **Testing** means the 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.

3. GENERAL

(1) This regulation is issued under Section 56 of the Ordinance. This regulation supercedes and replaces the document " Procedure for Licensing of Nuclear Power Plants in Pakistan" No. DNSRP-NILREG-007/90 dated February 14, 1990 issued by Directorate of Nuclear Safety and Radiation Protection, Pakistan Atomic Energy Commission.

(2) This regulation is issued to set forth, regulatory requirements for the licensing of nuclear installation(s).

(3) 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 nuclear installation(s) including the enforcement, amendment, modifications, and explanation of the safety regulations and regulatory guides referred to in Section C of this regulation for licensing.

(4) The decision of Chairman PNRA regarding the interpretation of any word or phrase of this regulation or applicability of any regulation, regulatory guide and standard shall be final and binding on the licensee.

(5) Except where otherwise specified, all communications and reports concerning this regulation shall be addressed to "Chairman, PNRA, P.O. Box No. 1912, Islamabad."

(6) "Safety first" shall be the guiding principle in the siting, design, construction, commissioning, operation and decommissioning of nuclear installation(s). During operation of nuclear installation(s), measures shall be taken to guarantee the quality and safety of operation, prevent accidents and mitigate their consequences. Dose and release limits shall be observed to protect the site personnel, public and environment. The ALARA principle shall be followed.

(7) The licensee is directly responsible for the safety of the nuclear installation(s), it operates. To this end, the licensee shall:

i. comply with national laws and technical standards to ensure the safety of the nuclear installation(s).

ii. be subject to regulatory supervision of PNRA and to report promptly the actual safety condition in case of nuclear incidents/accidents and to submit relevant information to PNRA.

iii. be responsible for the safety of the nuclear installation(s) and nuclear materials, and for the safety of site personnel, the public and the environment.

4. LICENSING PROCEDURE

(1) The applicant shall notify in writing to the Chairman PNRA as early as possible of his intention to establish and operate nuclear installation(s).

(2) Licensing procedure for nuclear installation(s) in Pakistan shall comprise of the following stages:

i. Registration of Site.
ii. Issuance of the Construction Licence.
iii. Issuance of the Operating Licence.

(3) Before applying for site registration, construction licence and the operating licence for the nuclear installation(s), the applicant shall submit "clearance" or "no objection certificates" from the relevant departments of the Federal, Provincial and Local governments.

(4) An applicant who intends to obtain the registration of site for nuclear installation(s) shall submit an application to PNRA along with a Site Evaluation Report (SER).

(5) After approval of the SER and registration of the site, the applicant shall establish design and safety criteria in accordance with the nuclear regulations and guides as specified in Section C of this regulation and submit the same for the approval by PNRA.

(6) After completion of the preliminary design the following reports shall be submitted to PNRA for review, approval and issuance of construction licence.

i. Preliminary Safety Analysis Report (PSAR).
ii. Overall Quality Assurance Program (OQAP).
iii. Models and results that a comprehensive Probabilistic Safety Analysis Report (PSA), Level 1 is being developed systematically as a starting point for risk informed discussions to support the final design. (applicable to nuclear reactors only).

(7) The applicant shall not begin the construction of nuclear installation(s) on a site until a construction licence has been issued. The pouring of the concrete in the foundation of the safety related structure on the site shall be deemed to be the beginning of the construction, but does not include site investigations.

(8) After completion of the detailed design and the safety analysis, the licensee shall submit an application for introducing nuclear materials into the system(s) of the nuclear installation(s). The following documents shall accompany the application:

i. Final Safety Analysis Report (FSAR).
ii. Probabilistic Safety Analysis Level One Plus Report (PSA Level 1 plus) for nuclear reactors only.
iii. Commissioning Reports up to introduction of nuclear materials.
iv. Technical Specifications/ Operating Policies and Principles.
v. Radiation Protection Program.
vi. Emergency Preparedness Plans.
vii. Inspection Program
viii. Fire Protection Program.
ix. Environmental Monitoring Program duly approved by appropriate Environmental Protection Agency (EPA).
x. Radioactive Waste Management Program.
xi. Pre-service Inspection (PSI) and In-service Inspection (ISI) Program.
xii. Physical Protection Program.
xiii. Decommissioning Strategy.
xiv. Any other report/technical document requested by PNRA.

On approval of these documents, permission to introduce nuclear material in the system(s) (fuel load permit in case of nuclear reactors) may be granted by Chairman PNRA subject to the availability of licensed operating personnel.

(9) After completion of commissioning but before the issuance of the Operating Licence, and in any case, no later than six months after introduction of nuclear material in the system(s) of the installation(s), the licensee shall apply for operating licence and shall submit the following documents

i. Commissioning Reports of the various systems in the Installation(s).
ii. Results of the first start-up and full capacity tests (low power tests, power ascension test and. full power tests in case of nuclear reactors).
iii. Update of all documents mentioned in para 8 of this regulation on which amendment(s) has been carried out.

(10) The licensee shall provide fifteen copies of each document or reports submitted to PNRA in the context of this regulation. These documents shall be duly signed by the licensee or his authorized agent. Documents submitted in pursuance of this regulation will be reviewed by PNRA. On the basis of the reviews and all other information that PNRA may have, Chairman PNRA shall take the decision in regard to issuance of the licence(s), and the terms and conditions to be attached thereto, as he deems fit.

(11) The licence granted shall normally be valid for a period of up to ten years, subject to:

i. payment of such initial and annual renewal fee as per existing regulation, and such revision/ amendments thereto as may be duly notified by PNRA.
ii. compliance with the requirements of Section 5 and 6 of this regulation and such other additional regulations, amendments and requirements as may be formally notified by PNRA from time to time.

Six (6) months before the expiry of licence, the licensee shall apply for revalidation of the same along with updated report of latest Periodic Safety Review (PSR).

5. APPLICABLE NUCLEAR SAFETY STANDARDS

(1) All nuclear installation(s) in Pakistan shall for the purposes of siting, design, construction, commissioning, operation and decommissioning conform with the latest regulations and regulatory guides issued by PNRA. Currently these are:

(a) For Nuclear Power Plants:

i. Regulation on the Safety in Nuclear Power Plants Siting (PAK/910) and related regulatory guides.
ii. Regulation on the Safety in Nuclear Power Plants Design (PAK/911) and related regulatory guides.
iii. Regulation on the Safety in Nuclear Power Plants Quality Assurance (PAK/912) and related regulatory guides.
iv. Regulation on the Safety in Nuclear Power Plants Operations (PAK/913) and related regulatory guides.
v. Regulation for Management of Radioactive Waste in Pakistan (PAK/915).
vi. Regulation on Decommissioning of Nuclear Power Plants and Research Reactor (PAK/917).

(b) For Research Reactors:
Regulation on the Safety in Nuclear Research Reactors and related regulatory guides (To be issued later).

(c) For Installation(s) Other Than Nuclear Reactors:
Regulation on the Safety in Installation(s) Other than Nuclear Reactors and related regulatory guides (To be issued later).

In those areas where PNRA regulations and regulatory guides do not provide the necessary guidance, the relevant latest US Nuclear Regulatory Commission regulations/guides shall be deemed to be applicable.

(2) Alternately, the licensee may choose to follow the latest revisions of the applicable IAEA Safety Standards and Requirements along with the relevant safety guides issued thereunder.

(3) However, if nuclear safety standards of another country are proposed to be used/applied, it shall be demonstrated by the licensee to the entire satisfaction of PNRA that the standards proposed to be used offer the same or better standards of quality, safety and reliability than would have been offered by the nuclear safety standards mentioned in 5 (1) or 5 (2).

6. INSPECTIONS

(1) The licensee shall submit its detail program of how it intends to inspect the various steps of manufacture, construction, commissioning, operation and decommissioning of the nuclear installation(s). Thereafter PNRA may provide its regulatory inspection program to licensee.

(2) PNRA may send inspector(s) to the site of manufacture, construction and operation of nuclear installation(s) to perform the following functions.

i. To inspect whether the information submitted relating to safety is in conformity with the actual conditions;
ii. To ensure and verify that the construction is carried out in accordance with the approved design;
iii. To ensure and verify that the licensee is proceeding in accordance with the approved program of quality assurance;
iv. To ensure and verify that the construction, commissioning and operation comply with the safety regulations and the conditions specified in the construction and operating licence for nuclear installation(s);
v. To examine whether the operator is adequately qualified for the safe operation of the nuclear installation(s) and for carrying out the emergency plan;
vi. To exercise any other regulatory function;

(3) PNRA inspector(s) (which term shall also include third party personnel acting on behalf of PNRA), so appointed, while performing their functions shall have the right of access to the site of the construction, commissioning, operation and decommissioning of nuclear installation(s) to investigate and collect information related to safety. PNRA may also require its inspectors to visit the manufacturing works, where equipment for the nuclear installation(s) is being fabricated, assembled, manufactured or tested. However, such visits will be by prior arrangement and advance notice to the licensee. All cost in this regard shall be borne by the licensee.

ANNEX-I

1. Licensing Beyond Design Life

Pakistan Nuclear Regulatory Authority (PNRA) issues and renews licences for nuclear installation(s) to operate for up to design life.

The decision whether or not to seek re-licence (licence beyond design life) rests entirely with the licensee. It is normally expected to be based on the plant's physical condition, economic circumstances and requirements of PNRA. Specifically the licensee is required to prove that structures, systems and components are capable of performing intended functions in safe manner for the duration of extended life.

A licensee may apply to PNRA for re-licence as early as 10 years before end of expected design life but no later than 3 years before expiration of its current licence.

2. Process

The re-licensing process has two major avenues of consideration:

a. review of safety issues.
b. review of environmental issues.

3. Documents

The licensee shall provide PNRA the following documents for assessment and verification as necessary:

1. Updated report of latest Periodic Safety Review (PSR).
2. Revised Final Safety Analysis Report (FSAR).
3. Probabilistic Safety Analysis Report (level one plus) based on actual plant design and operation data (for nuclear reactors only).
4. Decommissioning Program.
5. An evaluation of the potential impact on the environment.
6. Any other report/technical document requested by PNRA.

4. Inspections

PNRA may conduct as many inspections as necessary to assure itself of the submissions by the licensee. The inspections will sample the results of the process used by the licensee to identify those structures and components within the scope of the re-licence, aging management programs and design analysis changes. It is not expected that the environmental review needs to be confirmed by inspection, because the Environmental Protection Agency (EPA) will normally conduct an independent review.

5. Fee

The re-licence fee shall in no case be less than fifty percent (50%) of the “issuance of current operation licence fee” for such installation(s) existing on the day of application by the licensee, or such higher amount as may be determined by PNRA.

(Jawad A. Hashimi)
Member Executive