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PART II

**Statutory Notification (S.R.O.)**

**GOVERNMENT OF PAKISTAN**

**PAKISTAN NUCLEAR REGULATORY AUTHORITY**

NOTIFICATIONS

*Islamabad, the 24th July, 2008*

**S.R.O. 910 (I)/2008. –** In exercise of the powers conferred by section 56 of the Pakistan Nuclear Regulatory Authority Ordinance, 2001 (III of 2001), Pakistan Nuclear Regulatory Authority is pleased to make and promulgate the following regulations.

**1. Short title and commencement.—**(1) These regulations may be called the "Regulations for Licensing of Nuclear Safety Class Equipment and Components Manufacturers – (PAK/907) (Rev. 0)".

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

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

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

(a) "applicant" means any person who applies to the Authority for a licence or/and authorization to undertake specified activities;

(b) "audit" means a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings and other applicable documents and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance;

(c) "Authority" means the Pakistan Nuclear Regulatory Authority established under section 3 of the Ordinance;

(d) "Chairman" means the Chairman of the Authority;

(e) "document" means any written, pictorial or electronic information describing, defining, specifying, reporting or certifying activities, requirements, procedures or results;

(f) "inspection" means examination or measurement to verify whether an item or activity conforms to specific requirements;

(g) "inspector" means a person who performs inspection activities to verify conformance to the specific requirements.

(h) "licence" means a licence issued under section 19 of the Ordinance;

(i) "licensee" means the holder of current licence or authorization;

(j) "manufacturer" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, or any other entity involved in the manufacturing of equipment, components or portions thereof, important to safety of a nuclear installation;

(k) "nuclear safety class equipment and component" means an equipment or a component that is part of safety system;

(l) "Ordinance" means the Pakistan Nuclear Regulatory Authority Ordinance, 2001 (III of 2001);

(m) "procedure" means a document that specifies or describes how an activity is to be performed;

(n) "quality assurance" means all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service;

(o) "safety system" means a system important to safety, provided to ensure the safe shutdown of the reactor or the residual heat removal from the core, or to limit the consequences of anticipated operational occurrences and design basis accidents.

**3. Scope**

These regulations shall apply to all organizations in Pakistan involved in the manufacturing of nuclear safety class equipment and components.

**4. Interpretation**

The decision of Chairman, PNRA regarding the interpretation of any word or phrase of these regulations or applicability of these regulations shall be final and binding on the licensee/applicant.

**5. General**

(1) The manufacturing of nuclear safety class equipment and components within the scope of these regulations shall only start after obtaining a licence from the Authority.

(2) The licensee shall be responsible for the quality of its work and product and to ensure the effectiveness of quality assurance system covering activities related to manufacturing of nuclear safety class equipment and components.

(3) The licensee shall retain its capabilities for manufacturing safety class equipment and components for which the licence is issued for the entire period of licence validity and shall inform PNRA of any change in the capabilities.

**6. Licensing Procedure**

(1) Organizations intending to manufacture nuclear safety class equipment and components shall submit a written application to the Chairman or an officer duly authorized on his behalf.

(2) The applicant shall pay licence fee as prescribed in the regulations and according to the payment mode agreed with the Authority.

(3) The applicant shall furnish three copies of the documents/information given in Annex-I along with the application. These documents shall be duly signed by the applicant or a designated person.

(4) On the basis of the review of the documents mentioned in Annex-I and subsequent audit /inspection, the Authority may issue a licence alongwith terms and conditions as deemed necessary.

(5) The organization which obtained the manufacturing licence for a certain type and safety class can be engaged in the manufacturing of same safety class and/or lower safety class equipment and components of similar type.

(6) The licence shall normally be valid for a period of up to five (05) years, subject to:

(a) payment of annual renewal fee as per existing regulations, and such revisions/amendments thereto as may be duly notified in the official gazette;

(b) compliance with the national regulations and amendments thereto and other requirements as may be formally notified from time to time.

(7) The Authority may amend, revoke or suspend the licence at any time or may take any other enforcement action under the Ordinance and regulations made thereunder.

(8) The licensee may apply for revalidation of the licence, six (06) months before the expiry along with updated copies of documents mentioned in Annex-I of these regulations.

**7. Inspections**

(1) The licensee shall submit quality plans, process flow diagrams (production technology) and manufacturing schedules to the Authority for each safety class equipment to be manufactured under the licence, well in advance, for reference and record. The Authority may select control points for inspections from the quality plans.

(2) The Authority may send nuclear safety inspector(s) to the site of manufacturer to perform inspections.

(3) The nuclear safety inspector(s) may also include third party personnel authorized by the Authority to undertake the inspections on its behalf.

(4) Nuclear safety inspector(s), so appointed, while performing their functions shall have the right of access to the facility(ies) where licensed activities are being carried out, such as fabrication, assembling, manufacturing, testing, etc., and to the relevant documents, records and persons. However, such visits will be conducted after prior notification to the licensee. All costs in this regard shall be borne by the licensee for cases in which the inspections, as per licensee requirements, will be conducted outside the licensee premises.

**ANNEX- I**

**Documents to be submitted along with application for Licence**

1. Quality assurance program.
2. Details of equipment (such as type and specifications, etc.) to be manufactured and their safety classification.
3. Details of the organizations technical manpower, their qualification and experience.
4. Detailed description of the organization's capability for the scope of work that are carried out by the organization and facilities available (including hardware and software) and past experience of the work.
5. Testing facilities including those used for destructive and non-destructive tests, material tests, seismic and environmental qualification tests, type tests, stress analysis tests, functional tests, etc.
6. Following quality assurance procedures:
   (a) Procurement control procedure.
   (b) Design modifications and change control procedure.
   (c) Technology test and assessment control procedure.
   (d) Personnel qualification procedure.
   (e) Test control procedure.
   (f) Non-conformance control procedure.
7. List of applicable codes and standards followed by the organization.
8. Training and retraining requirements of the organization for the personnel engaged in manufacturing of safety class equipment along with training facilities available.
9. Information about the related external cooperation:
   (a) Scope, content, responsibility, technical assistance and interface relation with external relevant engineering and manufacturing organizations.
   (b) The technical ability and qualification relating to the activities of the relevant external engineering and manufacturing organizations.
   (c) Quality assurance and control procedure of the external engineering and manufacturing organizations.
10. Any other document required by the Authority as deemed necessary.

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