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PART II

Statutory Notification (S. R. O.)

GOVERNMENT OF PAKISTAN

PAKISTAN NUCLEAR REGULATORY AUTHORITY

NOTIFICATION

Islamabad, the 17th March, 2018

S. R. O. 564(I)/2018.— In exercise of the powers conferred by Section 16(2)(a) read with 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, Extent, Applicability and Commencement.— (1) These regulations may be called the “Regulations for Licensing of Nuclear Safety Class Equipment and Components Manufacturers – (PAK/907) (Rev.1)”.

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

(3) These regulations shall be applicable to all nuclear safety class equipment and components manufacturers.

(4) 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 license or/and authorization to undertake specified activities;

(b) “*Authority*” means the Pakistan Nuclear Regulatory Authority established under Section 3 of the Ordinance;

(c) “*cask*” means the package containing spent fuel or high level radioactive waste;

(d) “*Chairman*” means the Chairman of the Authority;

- (e) “*license*” means a license issued under Section 19 of the Ordinance;
- (f) “*licensee*” means the holder of current license or authorization;
- (g) “*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;
- (h) “*nuclear safety class equipment and component*” means an equipment or a component that is part of safety system;
- (i) “*Ordinance*” means the Pakistan Nuclear Regulatory Authority Ordinance, 2001 (III of 2001);
- (j) “*package*” means packaging and its radioactive contents prepared for transport, storage and disposal;
- (k) “*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; and
- (l) “*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 define the process for licensing of the organizations involved in manufacturing of nuclear safety class equipment and components including packages and casks.

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

5. General.— (1) The manufacturing of nuclear safety class equipment, components, packages and casks within the scope of these regulations shall only be started after obtaining a license 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 of safety class equipment and components, for which the license is issued, for the entire period of license validity and shall inform PNRA of any change in the capabilities.

(4) The manufacturer of the cask shall have safety class - 1 equipment manufacturing license from the Authority.

(5) The manufacturer of a package other than cask shall have any safety class equipment manufacturing license from the Authority.

(6) The applicant/licensee shall follow all the requirements of any other relevant government organizations and authorities.

6. Licensing Procedure.— (1) Organizations intending to manufacture nuclear safety class equipment, components, packages or casks shall submit a letter of intent to the Chairman or an officer duly authorized on his behalf.

(2) The applicant shall furnish an application for acquiring a license along with three copies of the documents/information given in Schedule of these regulations. These documents shall be duly signed by the applicant or a designated person.

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

(4) On the basis of the review of the documents mentioned in Schedule and subsequent audit/inspection, the Authority may issue a license along with terms and conditions as deemed necessary.

(5) The organization which obtained the manufacturing license 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 license 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 licensee may apply for revalidation of the license, six (06) months before the expiry along with updated copies of documents mentioned in Schedule of these regulations.

(8) The Authority may amend, revoke or suspend the license at any time or may take any other enforcement action under the Ordinance and regulations made thereunder. The decision of the Authority shall be final.

7. Inspections.— (1) The Authority may send inspector(s) to the manufacturing/testing sites to perform the following functions:

(a) to inspect whether the information submitted to the Authority is in conformity with the actual conditions;

(b) to ensure and verify that activities related to fabrication, assembling, manufacturing or testing comply with PNRA regulations, the terms and conditions of the license and agreed codes and standards;

(c) to exercise any other regulatory function as per Section 29 of the Ordinance.

(2) The licensee shall submit quality plans, process flow diagrams (production technology) and manufacturing schedules to the Authority for each safety class equipment/

component/package/cask to be manufactured under the license, well in advance, for reference and record. The Authority may select control points for inspections from the quality plans.

(3) The inspector(s) (which term may also include third party personnel acting on behalf of the Authority) while performing their functions shall have the right of access to the facility where licensed activities are being carried out, such as fabrication, assembling, manufacturing, testing, etc., and to the relevant documents, records and persons and to investigate and collect information related to safety.

(4) In cases where licensee conducts certain activities outside its premises, the inspections will be conducted with prior notification to the licensee. All cost in this regard shall be borne by the licensee.

8. Repeal.— The “Regulations for Licensing of Nuclear Safety Class Equipment and Components Manufacturers – (PAK/907) (Rev.0)” notified *vide* S.R.O. 910(I)/2008 dated 1st Sep 2008 is hereby repealed.

Schedule: Documents to be Submitted along-with the Application for License

1. 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
2. Details of the organization's technical manpower, their qualification and experience
3. Details of equipment (such as type and specifications, etc.) to be manufactured and their safety classification
4. Quality assurance program
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:
 - (i) Procurement control procedure
 - (ii) Design modifications and change control procedure
 - (iii) Technology test and assessment control procedure
 - (iv) Personnel qualification procedure
 - (v) Test control procedure
 - (vi) 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:
 - (i) Scope, content, responsibility, technical assistance and interface relation with external relevant engineering and manufacturing organizations
 - (ii) The technical ability and qualification relating to the activities of the relevant external engineering and manufacturing organizations
 - (iii) Quality assurance and control procedure of the external engineering and manufacturing organizations
10. Any other relevant information

MOHAMMAD SALEEM ZAFAR,
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