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PART II

Statutory Notification (S.R.O)

GOVERNMENT OF PAKISTAN

PAKISTAN NUCLEAR REGULATORY AUTHORITY

NOTIFICATIONS

Islamabad, the 5th October, 2004

S.R.O. 836(I)/2004. — In exercise of the powers conferred by section 56 of Pakistan Nuclear Regulatory Authority Ordinance, 2001(III of 2001), the Pakistan Nuclear Regulatory Authority is pleased to make the following regulations:-

1. Short title and commencement.- (1) These regulations may be called the Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s)-PAK/908.

(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 this 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) "authorization" means an authorization granted under section 20 or, as the case may be, sections 21,22 or 23 of the Ordinance;

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

(e) "inspection" means an examination, observation, measurement or test undertaken to assess structure, systems, components and materials as well as operation activities, processes, procedures and personnel competence;

- (f) "license" means a license issued under section 19 of the Ordinance;
- (g) "licensee" means the holder of a current license;
- (h) "Ordinance" means the Pakistan Nuclear Regulatory Authority Ordinance (III of 2001).
- (i) "person" means any individual, corporation, partnership, firm, association, trust, estate, public or private, institution, group, Government agency, any state or any political subdivision or any political entity within a state, any foreign Government or nation, or other entity and includes any legal successor, representative, agent or agency of any of the aforesaid;
- (j) "radiation facility" means any facility, other than a nuclear installation as defined in the Ordinance, using radiation generator(s) and/or radioactive material(s);
- (k) "radiation generator" means a device or an apparatus capable of generating ionizing radiation, such as X-rays, neutrons, electrons or other charged particles, which may be used for scientific, medical, industrial or research purposes; and
- (l) "radioactive material" means any substance which contains or consists of radioactive nuclide, naturally occurring or artificially produced, provided that the specific activity of the substance is in accordance with the levels as may be prescribed by the Authority by regulations.

3. Notification.- (1) Any person intending to carry out any of the activities specified in section 19 (1) (a), (b), (c) and (d) of the Ordinance shall notify to the Authority in writing of such an intention.

(2) Such notification shall be given as early as possible so as to initiate the licensing procedure.

4. Licensing procedure.- The licensing procedure shall comprise of the following stages, namely:-

- (a) Registration
- (b) Licensing

5. Registration.- (1) Any premises, in which a radiation facility is to be established shall require registration by the Authority.

(2) The Authority may, upon receiving an application in writing on application forms, register any premises, in the name of the applicant, if after receiving the following information-

- (a) getting plans, maps, blue prints, and statement of type, capacity, description, quality and quantity of the proposed radiation generator or radioactive material;

- (b) submission of radiological emergency plans, if required; and
- (c) getting any other information required by the Authority;

it is satisfied that the premises meets the safety requirements.

6. Licensing.- (1) After registration, the person shall apply in writing to the Authority for the licensing of radiation facility.

(2) Every application shall be submitted on application forms (available with PNRA, P. O. Box No. 1912, Islamabad” or its Regional Directorates or on its website at <http://www.pnra.org>) along with such license fee as may be notified by the Authority from time to time and any other information and documentary evidence which may be required by the Authority.

(3) The Authority may make such further inquiries, inspections or investigations either itself or through an officer or committee as may be deemed necessary and require an applicant to demonstrate by submitting the required information that the purpose for which the license is required shall not be hazardous to the workers, the public and the environment.

(4) If an applicant does not furnish all the information or the evidence required by the Authority under these regulations within specified time and unless that time is further extended by the Authority for sufficient reasons shown by the applicant, the application for the grant of such license shall be deemed to have been rejected.

(5) After considering the application, the Authority may issue a license to such person for such period, for such purpose and on such terms and conditions as may be specified in that license.

(6) The license period shall be from the date of the acquisition of the radiation generator and/or radioactive material.

(7) For the purpose of these regulations, radiation generator and radioactive material that are located in a single premises and used by the same licensee, may be treated as a single radiation facility unless requested otherwise in writing by the licensee and approved by the Authority.

(8) The Authority may reject any application and refund the fee paid by the applicant after deducting twenty percent as service charges.

7. Renewal of license.- (1) The Authority may, upon receiving an application in writing on forms prescribed by the Authority, within thirty (30) days after the expiry of the period of existing license, grant the renewal of the license on annual basis or more on the payment of renewal fee as may be notified by the Authority from time to time.

(2) A levy shall be charged in case the applicant submits an application for renewal after thirty (30) days of the expiry date of the existing license as may be specified by the Authority from time to time.

(3) If an existing license is not renewed, the Authority may after expiry, as mentioned in clause (1), issue an order requiring appropriate enforcement action.

8. Amendments and changes in license.- The licensee of the radiation facility shall notify to the Authority at least thirty (30) days prior to the installation of any new radiation generator and radioactive material or relocation of existing one to some other premises.

9. Transfer of license.- No licensee on his/her own shall transfer or assign a license to any other person without the prior approval in writing from the Authority.

10. Suspension of license .- On receiving the information or otherwise if the Authority is of the opinion that a licensee is violating any provisions of the Ordinance or the regulations or any of the terms and conditions of the license, the Authority may order immediately stoppage of the work or order such other action as may be necessary to increase the level of radiation safety.

11. Revocation of license .- After giving an opportunity of showing cause, and on being satisfied that the licensee has violated any provision of the Ordinance or of the regulations or the terms and conditions of the license, the Authority may revoke the license.

12. Surrender of license.- (1) If any licensee intends to stop operating radiation facility on permanent basis, he/she shall have the right to surrender his/her license by giving ninety (90) days prior notice to the Authority.

(2) The obligations of the licensee shall continue till such time the radiation generator and/or radioactive material is properly disposed of.

13. Grant of more than one license.- Nothing contained in these regulations shall prevent issuance of more than one license to the same person for different purposes or for similar purposes at different places.

14. Responsibilities of licensee.- (1) The licensee shall be responsible to follow all the applicable regulations issued by the Authority.

(2) The licensee shall notify in writing to the Authority of his/her intention to introduce modifications to any practice or source for which he/she is licensed whenever the modifications could have significant implications for exposure of the workers or public to radiation and shall not carry out any such modification unless specifically approved in writing by the Authority.

(3) The licensee shall ensure that only those workers who are designated in the application by name and qualification credentials and authorized by reference in the license as having key assignments related to radiation protection and other workers assigned tasks involving operation or handling of any radiation generator and radioactive material which could substantially affect radiation protection shall be permitted to fulfill such required assignments and tasks.

15. Authorization.- The licensee intending to carry out an activity other than those mentioned in the license shall apply to the Authority for an authorization. The applicant shall submit to the Authority:

- (a) information necessary to support such activity;
- (b) safety assessment reports; and
- (c) any other information required by the Authority.

16. Issuance of No Objection Certificate (NOC).- (1) Any licensee, desirous of importing or exporting any radiation generator and/or radioactive material, subject to in force import and export policies issued by the Ministry of Commerce, shall apply to the Authority for the grant of NOC on application forms prescribed by the Authority.

(2) The Authority may require the applicant to produce invoices or other documents which show the origin, technical specifications and other details as deemed necessary.

(3) The Authority shall have the right to reject an application not qualifying with the applicable regulations.

(4) The NOC shall be issued in a standard format as specified by the Authority.

17. Insurance.- (1) Every licensee when required by the Authority shall obtain an insurance cover against the risk of nuclear damage to the public in such amount as may be fixed by the Authority depending on the type of the radiation facility.

(2) No licensee or insurer shall cancel or suspend a policy obtained under clause (1) without the prior approval of the Authority, in writing.

18. Inspection.- (1) The Authority may conduct inspection of any radiation facility as and when required.

(2) The licensee on demand, shall provide records and relevant information to the inspector or any authorized person of the Authority.

19. Repeal.- The regulation nos. 10-17, 20 and 24 of Pakistan Nuclear Safety and Radiation Protection Regulations (PNSRP) 1990 are hereby repealed.

Sd/
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