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PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN

PAKISTAN NUCLEAR REGULATORY AUTHORITY

NOTIFICATION

Islamabad, the 19th October, 2019

S.R.O. 1660 (I)/2019.–In exercise of powers conferred by Section 16(2)(a) read with Section 56 of the Pakistan Nuclear Regulatory Authority Ordinance, 2001, the 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 the Licensing of Radiation Facility(ies) other than Nuclear Installation(s) - (PAK/908) (Rev.1)".

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

(3) These regulations shall be applicable to all radiation facilities and activities.

(4) These regulations shall come into force at once. However, for the facilities and activities already licensed or authorized by PNRA, all the requirements of these regulations shall be fulfilled within two (2) years after the promulgation of these regulations.

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

(a) *"activities"* means the production, manufacturing, use, storage, sale, purchase, repair & maintenance, transfer, import and export of radiation sources; transit or transport of radioactive material; decommissioning of facilities; and radioactive waste management;

(b) *"applicant"* means a person who has applied to the Authority for a license or an authorization;

(c) *"clearance"* means the removal of regulatory control by the Authority from radioactive material or radioactive objects within licensed radiation facilities;

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

(e) *"licensee"* means the holder of a valid license issued by the Authority;

(f) *"radiation facility"* means any premises where radiation source (radioactive material or radiation generator) is acquired, produced, manufactured, processed, reprocessed, repaired, used, handled, extracted, imported, exported, stored, installed, operated, maintained and converted;

(g) *"source"* means anything that may cause radiation exposure, such as by emitting ionizing radiation or by releasing radioactive material, and can be treated as a single entity for protection and safety purposes, it includes all types of radiation generators and radioactive material, and is also called as radiation source; and

(h) *"worker"* means any individual who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection (a self-employed person is regarded as having the duties of both an employer and a worker), and is also called as radiation worker.

3. Scope.–These regulations shall apply to licensing and authorization of radiation facilities and activities. However, the activities involving sources meeting the exemption criteria as prescribed in Regulations on Radiation Protection - (PAK/904) are exempted from the requirements of these regulations.

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

5. Notification.–Any person intending to establish a radiation facility or carry out any activity involving radiation sources shall notify the Authority of such an intention as early as possible so as to initiate the licensing process.

6. Application Forms.–The application for obtaining a license or an authorization, under these regulations, shall be submitted on duly filled-in prescribed application form obtained from any of the Regional Directorates of the Authority or from its website (i.e. http://www.pnra.org).

7. Issuance of License.–(1) After notification, the applicant shall apply in writing to the Authority for licensing at least one (1) month prior to acquire radiation sources along with the documents as applicable according to Schedule I; NOC from relevant departments of the Federal,

Provincial and Local Governments (if required); and applicable licensing fee as prescribed in Regulations on Licensing Fee by Pakistan Nuclear Regulatory Authority - (PAK/900).

(2) After review and assessment of the submissions, the Authority upon its satisfaction may register the premises and grant license for acquisition of radiation sources to such person, for such period, for such purpose and on such terms and conditions as may be specified in the license.

(3) The license for acquisition shall not authorize the licensee to operate the facility without prior obtaining the license for operation. The licensee shall obtain license for operation within validity period of license for acquisition or apply for renewal of license for acquisition along with the license renewal fee as prescribed in the Regulations PAK/900 and submission of sufficient justification for not obtaining the license for operation.

(4) The Authority may make such further inquiries, conduct inspections or investigations either itself or through those authorized in that behalf by the Authority, as may be deemed necessary, and require the licensee to provide further demonstration by submitting the required information or evidence that the benefit from the operation of the facility shall outweigh the radiation risks associated with the facility.

(5) On approval of the required submissions, the Authority, may issue license for operation to such person, for such period, for such purpose and on such terms and conditions as may be specified in the license.

(6) The Authority may issue license for acquisition and operation simultaneously provided that the applicable requirements of these regulations are fulfilled.

8. Renewal of License.–(1) The licensee shall apply in writing to the Authority for the renewal of license for operation, ~~**within three (3) months after the expiry of the license**~~ **within two (2) months prior to the date of expiry of the license,**[1] along with the license renewal fee as prescribed in the Regulations PAK/900 and following information and documents:

(a) Updated list and occupational exposure data of workers;

(b) Updated information and documents as per Schedule I (in case of any changes, where applicable);

(c) Updated inventory of radiation sources; and

(d) Any other information and record, as required by the Authority.

(2) The Authority, upon its satisfaction that all the applicable regulatory requirements are fulfilled, may grant the renewal of license for one (1) year. However, in case of small radiation facilities e.g. X-ray facility, CT scanner, teaching and research institutes, etc., the license for operation may be renewed for a maximum period of five (5) years.

[1] Amended vide S.R.O. 1007(I)/2024 dated Jul 08, 2024

(3) In case where the licensee fails to pay annual renewal fee within due date, he shall pay the fee along with surcharge as prescribed in the Regulations PAK/900.

9. Amendment in License.–(1) The licensee shall apply in writing to the Authority for amendment in the license, prior to make any changes in the license (as prescribed in the Regulations PAK/900), on duly filled-in application form along with the details of proposed amendment, assessment of its impact on safety and security (if any) and the applicable amendment fee as per Regulations PAK/900.

(2) After review of the application and related information and documents, the Authority, upon its satisfaction, may issue an amended license.

10. Transfer of License.–(1) The licensee shall not transfer its license to any other person without obtaining prior approval, in writing, from the Authority.

(2) The licensee shall apply in writing at least one (1) month in advance to the Authority, for the transfer of its license, on duly filled-in application form along with the credentials, consent of the proposed transferee and the applicable license transfer fee as per Regulations PAK/900.

(3) In case, the modality of transfer of a license is not covered in the Regulations PAK/900, a new license shall be required.

(4) After review of the application and related information and documents, the Authority, upon its satisfaction, may transfer the license to proposed transferee, on such terms and conditions as may be specified in the license.

11. Surrender of License.–(1) If any licensee does not intend to possess the radiation source or operate his facility on permanent basis, he shall surrender the license by submitting three (3) months prior notice to the Authority.

(2) The licensee shall make necessary arrangements for decommissioning or safe transfer of radiation source either back to the supplier or to a designated radioactive waste management facility, with the approval of the Authority within the validity period of the license.

(3) If a licensee intends to sell his radiation source to any other person, the case shall be dealt with as per Regulation 14(1)(e) of these regulations.

12. Grant of more than one License.–(1) Nothing contained in these regulations shall prevent issuance of more than one license to the same person for same or different purposes at same or different places.

(2) For the purpose of these regulations:

(a) Radiation sources that are located in same premises and used by the same person for same purpose shall be licensed as a single radiation facility, unless requested otherwise in writing, by the applicant and approved by the Authority.

(b) Radiation sources that are located in same premises and used by the same person for different purposes shall be licensed as separate radiation facilities except Full Fledged Medical Centers as prescribed in the Regulations PAK/900.

13. Responsibilities of the Licensee.–(1) The licensee shall have the prime responsibility for the safety and security of his radiation facility or activity.

(2) The licensee shall be responsible to follow all applicable PNRA regulations; license conditions; and the directives issued by the Authority from time to time. In areas where PNRA regulations are not available, relevant latest revisions of the IAEA Safety and Security Standards shall be deemed to be applicable. In case the Safety and Security Standards of another country are proposed to be followed, the licensee shall demonstrate to the entire satisfaction of the Authority that the standards, proposed to be followed, offer the same or better standards of safety and security than would have been offered by the Safety and Security Standards of IAEA.

(3) The licensee shall notify the Authority, in writing, in case of an addition in the inventory of radiation sources along with detailed information, changes in safety measures (if required), and the licensing fee (where applicable) for the additional radiation source as prescribed in the Regulations PAK/900.

(4) The licensee shall ensure that sufficient number of workers are available for the smooth operation of his radiation facility or activity. The workers who are designated in application form by name and qualification as having key assignments related to radiation protection and the workers involved in handling of radiation sources, shall only be permitted to perform such assignments and tasks. In case of any changes, licensee shall submit the updated list of workers to the Authority.

(5) The licensee shall ensure that workers have relevant qualification, training and experience for performing their intended tasks, according to the qualification criteria and contents of training as specified by the Authority.

(6) The licensee shall be responsible for the recovery and rehabilitation of the affected workers, the public and the environment, proportional to the extent as determined by the Authority, in case the Authority determines that it has resulted by an incident or accident involving radiation source of his facility or activity.

(7) The licensee shall be responsible to ensure the availability of funds for decommissioning of his facility or disposal of radiation sources (as applicable) for which he is licensed

in accordance with the requirements of Regulations on Decommissioning of Facilities using Radioactive Material – (PAK/930).

14. Specific Authorizations other than License.–(1) The licensee shall not carry out any of the activities, as mentioned below, unless specific authorization is obtained from the Authority, for such purpose:

(a) Any changes in the approved licensing documents;

(b) Modification in the specifications of radiation sources, shielding design, facility layout, safety or security functions;

(c) Import or export of radiation sources including used or refurbished radiation generators and devices containing radioactive material;

(d) Local purchase of radiation sources including used or refurbished radiation generators and devices containing radioactive material;

(e) Transfer or sale of a radiation source to any other person, unless the transferor possesses a valid license and both the transferor and transferee have obtained authorization from the Authority;

(f) Transfer of radioactive material to a designated radioactive waste management facility;

(g) Decommissioning of the radiation facility;

(h) Clearance of radioactive material or radioactive objects;

(i) Health screening and biomedical research involving radiation exposure to humans; and

(j) Any other activity as may be determined by the Authority.

(2) The licensee shall apply in writing to the Authority, at least one (1) month prior to conduct of any activity as enlisted in Regulation 14(1) of these regulations, to obtain specific authorization along with the following:

(a) Detailed information regarding proposed activity with reasons and justification;

(b) Complete information regarding sources involved;

(c) Safety assessment report for activities enlisted in Regulation 14(1)(b) of these regulations; and

(d) Any other information required by the Authority.

(3) If the licensee intends to obtain an authorization under Regulation 14(1)(g) of these regulations, he shall submit final decommissioning plan of the radiation facility along with the application for approval by the Authority.

(4) After review and assessment of the submissions, the Authority upon its satisfaction may grant an authorization for the specific activity on such terms and conditions as may be specified in the

authorization.

15. Authorization for Transit or Transport of Radioactive Material or Contaminated Items.–(1) Any person intending to transit or transport radioactive material or items contaminated with radioactive material through Pakistan shall apply in writing to the Authority, for obtaining an authorization, on duly filled-in application form along with the applicable authorization fee as prescribed in the Regulations PAK/900.

(2) After review and assessment of the application, the Authority upon its satisfaction may grant an authorization to such person, for such period, for such purpose and on such terms and conditions as may be specified in the authorization.

16. Rejection of Application.–(1) The Authority has the right to reject any application, however, the basis for rejection may be documented and communicated to the applicant or licensee, if so requested. In case of rejection of the application, the Authority may refund the fee paid by the applicant or licensee, as the case may be, after deducting twenty percent (20%) as processing fee.

(2) The applicant or licensee, as the case may be, has the right to submit an appeal, in writing, to the Authority against the regulatory decision. In case the appeal is not accepted, the applicant or licensee, as the case may be, shall make necessary arrangements for the safe transfer of radiation source either back to the supplier or to a designated radioactive waste management facility or the case shall be dealt with as per Regulation 14(1)(e) of these regulations, as deemed appropriate, with the approval of the Authority.

17. Inspection.–(1) The Authority may conduct inspection of any radiation facility or activity as and when required.

(2) The licensee, on demand, shall provide all kinds of records and required information to the inspector or any other person authorized in that behalf by the Authority.

18. Non Compliance.–If a person contravenes any of the provisions of the Ordinance, the regulations made there under, any of the terms and conditions of the license or an authorization, or any of the directives of the Authority, the Authority may take appropriate enforcement actions against such person, as prescribed in the Pakistan Nuclear Regulatory Authority Enforcement Regulations - (PAK/950).

19. Repeal.–The "Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s) - PAK/908" notified *vide* S.R.O. 836(I)/2004 dated 5th October 2004 are hereby repealed.

Schedule I

Documents to be Submitted along with the Application Form

1. Full Fledged Medical Centre (including Radiotherapy Centre, Nuclear Medicine or Cardiology Centre, Radiology Department and Blood Irradiator)

(a) Safety Analysis Report;

(b) Radiation Protection Program;

(c) Radioactive Waste Management Program;

(d) Physical Protection Plan;

(e) Radiation Emergency Plan;

(f) Quality Assurance Program; and

(g) Initial Decommissioning Plan.

2. Radiotherapy Centre

(a) Safety Analysis Report;

(b) Radiation Protection Program;

(c) Physical Protection Plan (if applicable);

(d) Radiation Emergency Plan;

(e) Quality Assurance Program; and

(f) Initial Decommissioning Plan (if applicable).

3. Nuclear Medicine or Cardiology Centre

(a) Safety Analysis Report;

(b) Radiation Protection Program;

(c) Radioactive Waste Management Program;

(d) Radiation Emergency Plan;

(e) Quality Assurance Program; and

(f) Initial Decommissioning Plan.

4. CT-Scanner, Medical Diagnostic X-ray Machine, Fluoroscopy Machine, Dental X-ray Machine, Angiography Machine, Mammography Machine and C-Arm Machine

(a) Plan, Map, Layout of the Facility; and

(b) Shielding Design (if applicable).

5. Industrial Radiography with Sources (Radioactive Material)

(a) Safety Analysis Report;

(b) Radiation Protection Program;

(c) Physical Protection Plan;

(d) Radiation Emergency Plan;

(e) Quality Assurance Program; and

(f) Initial Decommissioning Plan.

6. **Industrial Radiography with X-ray**

(a) Safety Analysis Report;

(b) Radiation Protection Program; and

(c) Radiation Emergency Plan.

7. **Oil Well Logging**

(a) Plan, Map, Layout of the Facility;

(b) Radiation Protection Program;

(c) Physical Protection Plan (up to Category-III Sources);

(d) Radiation Emergency Plan; and

(e) Initial Decommissioning Plan.

8. **Nuclear Gauges**

(a) Plan, Map, Layout of the Facility;

(b) Radiation Protection Program (up to Category-III Sources);

(c) Physical Protection Plan (up to Category-III Sources);

(d) Radiation Emergency Plan (up to Category-III Sources); and

(e) Initial Decommissioning Plan.

9. **Blood Irradiators**

(a) Plan, Map, Layout of the Facility;

(b) Shielding Design (if applicable);

(c) Radiation Protection Program;

(d) Physical Protection Plan (if applicable);

(e) Radiation Emergency Plan; and

(f) Initial Decommissioning Plan (if applicable).

10. **Agricultural Irradiators**

(a) Safety Analysis Report;

(b) Radiation Protection Program;

(c) Physical Protection Plan (if applicable);

(d) Radiation Emergency Plan;

(e) Quality Assurance Program; and

(f) Initial Decommissioning Plan (if applicable).

11. **Industrial Irradiators**

(a) Safety Analysis Report;

(b) Radiation Protection Program;

(c) Physical Protection Plan (if applicable);

(d) Radiation Emergency Plan;

(e) Quality Assurance Program; and

(f) Initial Decommissioning Plan (if applicable).

12. **Cargo or Vehicle Scanners with Sources (Radioactive Material)**

(a) Safety Analysis Report;

(b) Radiation Protection Program;

(c) Physical Protection Plan;

(d) Radiation Emergency Plan;

(e) Quality Assurance Program; and

(f) Initial Decommissioning Plan.

13. **Cargo or Vehicle Scanners with X-ray**

(a) Plan, Map, Layout of the Facility;

(b) Shielding Design;

(c) Radiation Protection Program (if applicable); and

(d) Radiation Emergency Plan (if applicable).

14. **Manufacturers of Consumer Products (Having Radioactive Material as an Integral Part)**

(a) Plan, Map, Layout of the Facility;

(b) Shielding Design;

(c) Radiation Protection Program;

(d) Radioactive Waste Management Program;

(e) Physical Protection Plan (if applicable);

(f) Radiation Emergency Plan;

(g) Quality Assurance Program; and

(h) Initial Decommissioning Plan.

15. **Manufacturers of Sources (Radioactive Material)**

(a) Safety Analysis Report;

(b) Radiation Protection Program;

(c) Radioactive Waste Management Program;

(d) Physical Protection Plan;

(e) Radiation Emergency Plan;

(f) Quality Assurance Program; and

(g) Initial Decommissioning Plan.

16. Manufacturers of Sources (Radiation Generators)

(a) Safety Analysis Report;

(b) Radiation Protection Program;

(c) Radiation Emergency Plan (if applicable); and

(d) Quality Assurance Program.

17. Importers, Exporters, Traders (Dealing in Radiation Generators), and Non-Medical Human Imaging

(a) Plan, Map, Layout of the Facility; and

(b) Shielding Design (if applicable).

18. Importers, Exporters, Traders (Dealing in Radioactive Material)

(a) Plan, Map, Layout of the Facility;

(b) Shielding Design;

(c) Radiation Protection Program;

(d) Physical Protection Plan; and

(e) Radiation Emergency Plan.

19. Radioimmunoassay (RIA) Lab, X-ray Gauges, X-ray Diffraction (XRD), X-ray Fluorescence (XRF), Gas Chromatography, X-ray Scanner (Industrial), Baggage Scanners, and Explosive Detectors

(a) Plan, Map, Layout of the Facility

20. Teaching and Research Institutes

(a) Requirements will be applicable according to the modality

MOHAMMAD SALEEM ZAFAR,
Member (Corporate).