भारत सरकार
परमाणु ऊर्जा नियामक परिषद्
विकिरण संरक्षा प्रभाग

Government of India
Atomic Energy Regulatory Board
Radiological Safety Division

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Regulatory requirements for supply and use of pre-owned (used/refurbished) medical diagnostic x-ray equipment

"In order to ensure radiation safety in the use of pre-owned (used/refurbished) diagnostic x-ray equipment and to bring the agencies involved in supply, service and quality assurance (QA) of such x-ray equipment, hereinafter called "Service Agency", into the regulatory framework, AERB has established regulatory requirements for Services Agencies. As per AERB Safety Code AERB/SC/MED-2, Section 6.12, these Service Agencies are required to obtain "Authorization" from the competent authority".

The Service Agency can undertake one or more of the following activities subject to obtaining appropriate Authorization from AERB:

a) Supply of pre-owned medical diagnostic x-ray equipment,
b) Installation, commissioning, acceptance testing, servicing and maintenance of x-ray equipment and
c) Decommissioning/dismantling of x-ray equipment.

1. The procedures for obtaining Authorization

The pre-requisite for obtaining Authorization by a Service Agency are:

a) Availability of necessary QA equipment and other associated equipment for performance evaluation of diagnostic x-ray equipment.
b) Availability of qualified and trained personnel with Personnel Monitoring Services (qualification and training as prescribed by AERB).
c) Availability of spare parts as per original equipment manufacturer (OEM) specifications or equivalent (for servicing of x-ray equipment).
d) Availability of a registered office with proper space for maintaining the records (hard copy or electronic copy) of QA reports, storage of QA equipment and communication facilities.
e) In case of refurbishing of x-ray equipment, availability of radiation test facility (as per AERB guidelines) and spare parts as per OEM specifications or equivalent.

Duly filled-in, signed and stamped application form for obtaining Authorization to be submitted to AERB through e-LORA along with relevant attachments.

2. Conditions of Authorization for Service Agency:

i) AERB type approved models of diagnostic x-ray equipment shall be supplied in the country.

ii) In case the equipment is not having AERB type approval or the approval has expired before five years, the equipment shall undergo the applicable quality assurance protocol and procedure prescribed by AERB.

iii) The pre-owned medical diagnostic x-ray equipment, which is more than seven years old, shall not be imported.

iv) The pre-owned x-ray equipment shall be supplied only to the user, who has obtained requisite permission for procurement of the x-ray equipment from AERB.

v) Installation Report of diagnostic x-ray equipment shall be submitted to AERB.

vi) Shall provide guidance and support to end user(s) for obtaining regulatory consents.

vii) In case pre-owned x-ray equipment is stored with supplier, it shall be tested for performance evaluation before supply to the new end-user and records shall be maintained.

viii) Ensuring availability of radiation protective devices (such as mobile protective barrier, lead apron, lead goggles) at the x-ray installation.

ix) Every equipment marketed, shall be labeled as pre-owned before installation.

x) Service Agency shall provide the documents mentioned in Clause No.4 (i) to the prospective user so as to facilitate him/her to obtain procurement permission from AERB.

xi) Service Agency shall provide installation report, acceptance test report and radiation survey report of x-ray equipment/installation to prospective user so as to facilitate him/her to obtain licence for operation from AERB.

xii) In case of service provided to end-user involving decommissioning of x-ray equipment, intimation shall be submitted to AERB.

3. Monitoring of Authorized Service Agency by AERB:

i) **Periodic reporting to AERB:** Service Agency shall submit periodic report to AERB.

ii) **Maintenance of records**

a) Periodic reports submitted to AERB.

b) A copy of valid Authorization issued by AERB.

c) List of authorized service engineers and their PMS records.

d) Calibration records of QA and radiation survey equipment.

e) Authenticated copies of installation report, acceptance tests and radiation survey report records of x-ray equipment supplied to end-users.

iii) **Renewal of Authorization:** Initial Authorization will be valid for a period of three years, which needs to be renewed before expiry. Renewal of Authorization will be issued based on satisfactory performance of the Service Agency during the period of Authorization.

iv) **Quality Audit of Authorized Service Agency:** Representatives of AERB will conduct Quality Audit for verifying the quality of services rendered by the Service Agency. This Audit will comprise evaluation of technical competence and appropriateness of the practices followed.

v) **Penalty**: The Authorization may be suspended, modified, or withdrawn by AERB, as per provisions of the Atomic Energy (Radiation Protection) Rules 2004, if any of the terms and conditions of the Authorization is contravened.

4. **Requirements for the prospective user to procure, install and operate the pre-owned medical diagnostic x-ray equipment :**

i) Shall obtain requisite 'Permission for procurement of x-ray equipment' from AERB by submitting the following documents:

a) Copy of "Undertaking" by the service agency (authorized by AERB) mentioning therein;
   - the expected residual (useful life) of the pre-owned x-ray equipment;
   - undertake to install, commission, carry out acceptance testing, servicing and maintenance of the pre-owned x-ray equipment till its useful life ;
   - undertake to decommission the x-ray unit after its useful life;
   - undertake to provide the technical catalogue, service, QA & design manual, exposure protocols, education and training for use of the x-ray equipment to the prospective user;

b) Submission of latest QA report (not more than six months old) authenticated by previous end-user of pre-owned diagnostic x-ray equipment;

c) Submission of copy of earlier end user's regulatory consent (Licence/Registration) for operation and

d) Submission of relevant certificates (such as Type Approval Certificate) from country of origin for the imported x-ray equipment.

ii) Compliance with regulatory requirements of AERB Safety Code [AERB/SC/Med-2 (Rev.1)] and its revision thereof.

iii) Frequency of periodic QA to be at least once in two years.

iv) Shall obtain licence for operation of diagnostic x-ray equipment from AERB

(A.U. Sonawane)
Head, RSD

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