



भारत सरकार Government of India
परमाणु ऊर्जा नियामक परिषद् Atomic Energy Regulatory Board
विकिरण संरक्षा प्रभाग Radiological Safety Division

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Sub: Regulatory Requirements for Agencies involved in supply, service and quality assurance of pre-owned (used/refurbished) Diagnostic x-ray equipment and its end users.

Introduction:

In order to ensure radiation safety in the use of pre-owned 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 such 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:

- Supply of pre-owned diagnostic x-ray equipment;
- Installation, commissioning, acceptance testing, servicing and maintenance of x-ray equipment;
- Decommissioning/dismantling of x-ray equipment;

1. The procedures for obtaining Authorization

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

- Availability of necessary QA equipment and other associated equipment for performance evaluation of diagnostic x-ray equipment.
- Availability of qualified and trained personnel including Radiological Safety Officer (RSO), with Personnel Monitoring Services (qualification and training as prescribed by AERB).
- Availability of spare parts as per Original Equipment Manufacturer (OEM) specification or equivalent (for servicing of x-ray equipment).
- In case the pre-owned equipment has been refurbished before supply, permission/consent from OEM or principal supplier and availability of dedicated testing facility as per AERB guidelines for performance evaluation before supply to the new end-user(s).
- The Agency should have a registered office with proper space for maintaining the records (hard copy or electronic) of QA reports, storage of QA equipment and communication facilities.
- Duly filled-in, signed and stamped application form for obtaining Authorization to be submitted to AERB along with documents as prescribed in the application form.**

2. Conditions of Authorization for Service Agency:

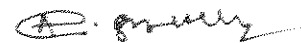
- i) Only type approved models shall be marketed.
- ii) Report on installation of x-ray equipment shall be submitted to AERB.
- iii) Shall provide guidance and support to end user(s) for obtaining regulatory consents.
- iv) Pre-owned equipment shall be tested for performance evaluation before supply to the new end-user, in case it is stored with supplier and records shall be maintained.
- v) Ensure availability of radiation protective devices (such as MPB, lead apron, lead goggles, etc) at the x-ray installation.
- vi) Every equipment marketed, shall be labeled as PRE-OWNED before installation.
- vii) Service Agency shall provide the following documents to new end user(s) at the time of supply:
 - a) Installation report, acceptance test report and radiation survey report of x-ray equipment/installation.
 - b) The latest QA report (not more than six months old) of pre-owned diagnostic x-ray equipment authenticated by previous hospital authority/performance test report carried out after servicing.
 - c) In case of imported pre-owned equipment, the Service Agency should provide the relevant certificate from country of origin to end-user(s).
 - d) Copy of earlier end users' regulatory consent (Licence/Registration).
 - e) Technical catalogues, service, QA and Design Manual of the equipment.
 - f) Undertaking that the equipment will be under warrantee.
 - g) Submission of exposure protocols for patient examinations.
 - h) Education and Training to end users.
- viii) In case of service provided to end-user involving decommissioning/dismantling of x-ray equipment, intimation shall be submitted to AERB in the prescribed format.

3. Monitoring of Authorized Service Agency by AERB:

- i) **Periodic reporting to AERB:** Service Agency shall submit quarterly report to AERB in the prescribed format
- ii) **Maintenance of records**
 - a) Quarterly 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 equipment supplied to end-users (maintained for period of two years).

- iii) **Renewal of Authorization:** Initial Authorization will be valid for a period of three years, which needs to be renewed well before expiry. The application form for Renewal of Authorization shall be submitted by the Service Agency at least two months prior to the expiry of the Authorization. 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 can be suspended, modified, or withdrawn by AERB, as specified in the Atomic Energy (Radiation Protection) Rules 2004, if any of the terms and conditions of the Authorization is contravened. Where deemed appropriate, AERB may initiate penal action against the concerned Service Agency in the event of offences, as per the provisions of the Atomic Energy Act 1962.
- **Requirements for end-users using pre-owned (used/refurbished) diagnostic x-ray equipment :**
 - i) Satisfactory QA report by an authorized agency,
 - ii) An "Undertaking" from the principal supplier or its authorized agency for installation, servicing and maintenance,
 - iii) Compliance with regulatory requirements of AERB Safety Code [AERB/SC/ Med-2 (Rev.1)] and
 - iv) Frequency of periodic QA to be once in two years.

** The Authorization to Service Agencies shall be issued on the basis of radiological safety aspects in marketing and use of medical diagnostic x-ray equipment. It is to be noted that all other approvals and clearances required under applicable laws will have to be obtained by the applicant prior to marketing and use of medical diagnostic x-ray equipment.*



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Head, RSD

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