GOVERNMENT OF INDIA
ATOMIC ENERGY REGULATORY BOARD

Manual for Accreditation of Agencies for Quality Assurance of Diagnostic X-ray Equipment

Atomic Energy Regulatory Board
Mumbai 400 094

FOREWORD

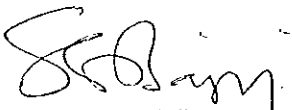
The wide spread diagnostic radiology practice with varied modalities such as Computed Tomography, Radiography & Fluoroscopy, Mammography etc; use X-rays to provide the diagnostic information. The benefit to the patients, by the use of these devices is no doubt indisputable. However, the exposures to radiation must be optimized to be truly beneficial. One important way to optimize the radiation exposures, and thus ensure the radiation safety of patient as well as the occupational worker is to ensure that the Quality Assurance (QA) of diagnostic radiology equipment is carried out periodically.

Quality Assurance is a pre-requisite to obtain licence as per Atomic Energy (Radiation Protection) Rules 2004.Thus, the regulatory body in keeping with its mission has felt the necessity to accredit suitable agencies that can cater to the QA requirements of the large number of diagnostic radiology installations in the country.

Accordingly, the AERB Safety Code AERB/SC/Med-2 (Rev-1, 2001) was amended (Amendment to Code, 2012) to incorporate the accreditation of service agencies for carrying out QA of diagnostic x-ray equipment. AERB has prepared this document with the objective of providing the detailed requirements/obligations to be met by QA agencies to qualify for the issue of regulatory consent at each stage, up to their eventual operation.

It is hoped that this document will clarify all the requirements that need to be met by the QA agency for obtaining Accreditation. This document will be revised as and when necessary in the light of new developments in the field and the experience and feedback from users.

The task Group, involved in preparation of the document along with their affiliations, is appended in the document. This document has been reviewed by experts in the field and has been vetted by AERB Advisory Committees on Radiological Safety.



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DEFINITIONS

1. **Quality Assurance (QA):** Planned and systematic actions necessary to ensure the optimum performance of diagnostic x-ray equipment. The QA is required to be carried out on periodic basis as well as after major repair/servicing/maintenance of the equipment.

2. **Quality Control (QC):** All those actions necessary to maintain the baseline performance of diagnostic x-ray equipment.

3. **Regulatory Inspection:** An examination by review of documents, observations, measurements or tests undertaken by or on behalf of AERB taken up during any stage of the regulatory consenting process to ensure conformance of equipment, components, systems and structures, as well as operational activities, processes, procedures, practices and personal competence, with the specified requirements.

4. **Type Approval:** All those planned and systematic procedures to verify the performance specifications of diagnostic x-ray equipment and its compliance with national / international standards.

SPECIAL DEFINITIONS

1. **Acceptance test:** The procedure to verify the performance specifications of diagnostic x-ray equipment by the user at the time of commissioning of the equipment.

2. **Accreditation:** A regulatory consent required to be obtained by a laboratory/an agency for conducting the Quality Assurance (QA) tests on diagnostic x-ray equipment

3. **Agency (QA):** The Laboratory/Institute, which possesses the minimum required infrastructure for Accreditation as QA service provider for diagnostic x-ray equipment.

4. **Calibration/Recalibration:** The procedure of converting the instrument reading into the physical quantity (e.g. Dose, KERMA, kV, time, mA, etc.) / the procedure of verifying the stability of the test instruments/gadgets.

5. **Enforcement**: Actions initiated by Regulatory Body in case the consentee does not comply with the terms and conditions of the Accreditation.

6. **Licensee:** Licensee is the person, in whose name License in the form of “Accreditation” is issued, under AE(RP)R-2004, and would have the responsibilities of “licensee” prescribed in AE(RP)R-2004.

7. **Personnel Radiation Monitoring Device (PRMD):** The devices (e.g. TLD/OSLD badges, pocket dosimeters) designed for measuring the radiation dose to the workers.

8. **Personnel Radiation Monitoring Service:** Service rendered by an Authorized Laboratory to the users by providing the PRMDs.

9. **Periodic Quality Assurance:** The QA procedures conducted at a given temporal frequency (as prescribed by the Competent Authority).

CONTENTS

1. INTRODUCTION

1.1 General

Quality Assurance (QA) of diagnostic x-ray equipment is an important tool to ensure conformance to built-in design safety of the equipment, consistent and accurate exposures to obtain optimal images for correct and accurate diagnosis of diseases which effectively results in optimized radiation safety of the staff and patients. Therefore, requirement of periodic quality assurance by all the users of medical diagnostic x-ray equipment is mandatory.

There are large numbers of x-ray installations in the country. Though initial QA is carried out by the supplier/manufacturer of the medical x-ray equipment, providing services for regular periodic QA to all the users is a difficult task. Further, It is gathered that several agencies/institutions have adequately trained personnel and facilities for rendering the QA services for diagnostic x-ray equipment. Therefore, AERB, in order to facilitate the services of QA, intends to set up a procedure to accredit the qualified agencies. These agencies can provide periodic QA to diagnostic x-ray facilities; carry out acceptance testing with approval of supplier, assist manufacturer/supplier for Type Approval demonstration with their prior approval

This document has been prepared with the objective to provide detailed guidance to Service Agencies for obtaining Accreditation to carry out QA of diagnostic x-ray equipment.

1.2 Purpose

This purpose of this document is to provide guidelines to the Agencies who intend to provide QA services for medical X-ray equipment in India. The document specifies the necessary requirements for a Service Agency to carry out QA of medical diagnostic x-ray equipments and requisite guidance for obtaining Accreditation from the Atomic Energy Regulatory Board (AERB). This document outlines requirements in respect of the following:

1. Infrastructure
2. Procedure for Accreditation
3. Regulatory Requirements

1.3 Scope

The scope of this document is limited to QA of medical diagnostic x-ray equipment, CT part of PET-CT, SPECT-CT and CT simulator facilities. This document does not deal with QA of other radiation facilities of radiotherapy, nuclear medicine and industrial radiography equipments.

1.4 Regulatory clearance for the Service Agency

The Agency intending to provide QA services shall obtain regulatory permission i.e. “Accreditation” from the AERB prior to providing services.

2. INFRASTRUCTURE

2.1 General

The requirements with respect to equipment and infrastructure needed by the Agencies for obtaining Accreditation as QA service providers are given in the following sections.

2.2 QA equipment

Agency shall have complete set of QA equipment for various modalities of diagnostic x-ray equipment for which QA service is intended to be provided. The minimum QA equipment set consists of following:

-kVp Meter : Range 40-150 kVp for R&F, BMD and CT equipment, 45-110 kVp for dental equipment, 18-49 kVp for mammography equipment
-Dosimeter (ranges vary from µGy – Gy)
- Timer
-Low contrast resolution test tool

-High contrast resolution test tool

-Focal spot test tool (should measure the value from 0.1mm to 2.5 mm)

-Optical and Radiation field congruence test tool

-Beam alignment test tool

Protection instruments

-Appropriate Radiation Survey Meter

Auxiliary tools

-Positioning System

-Distance Measuring Tool

- Aluminum filters

-Copper filters

Phantoms

-CT imaging phantom (e.g. CATPHAN)

-CTDI phantom (Head and Body)

-DSA phantom

-Mammography imaging phantom

2.3 Personnel Requirement

Service Agencies shall employ qualified and trained personnel for conducting Quality Assurance of diagnostic x-ray equipment. The minimum qualification and training requirements for personnel shall be as follows**:**

Servicing personnel:

i) Degree/ Diploma in Electrical /Electronic /Biomedical /Mechanical engineering or in an associated discipline/Basic degree in Science with Physics as one of the subject/Degree in medical imaging technology or equivalent from a recognized University/Institution, and

ii) Certification of successful completion of training course on “Quality Assurance in Diagnostic Radiology” conducted by authorized Agencies.

Radiological Safety Officer (RSO):

The Agency shall nominate a qualified person (qualifications as above) as RSO, who will be responsible for providing periodic training to QA personnel for ensuring overall radiation safety practice and correct methodology followed for conducting QA. He/she shall also be responsible for submission of periodic reports to AERB as per the prescribed format.

The certification programme(as per training module given in Annexure - I) for the prospective QA personnel will be conducted by RP&AD, BARC. The training will extend over a period of about three weeks and cover the theory and practical aspects of QA and radiation safety aspects for various diagnostic radiology equipment. Training will be followed by written and viva voce examinations. Candidates after successful completion of training programme will be issued a competency certificate with a unique identification number for conducting QA tests on diagnostic x-ray equipment. These candidates will only be eligible to provide QA service to the user through the accredited agencies.

2.4 Registered office

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.

3. PROCEDURE FOR ISSUANCE OF ACCREDITATION

3.1 General

The procedures for issuance of Accreditation to the Agency for carrying out QA of Diagnostic Radiology equipments are given in the following sections.

3.2 Submission of Application

The duly filled in, signed and stamped application form for obtaining Accreditation (Annexure-II) shall be submitted to Head, RSD, AERB by the authorized representative of the QA Agency.

The following documents shall be submitted along with the application:

a. List of staff and their detailed bio-data, experience along with the work responsibilities.
b. Copy of the qualification and training certificates of the staff (ref. section 2.3)
c. List and details of QA equipment available
d. Proof of registered office

3.3 Review of applications, training and selection:

The filled-in application forms of the prospective Service Agency will be reviewed by the Committee for Accreditation of QA Agency (CAQA) constituted by AERB for the Accreditation of QA Agencies. Once the details given in the application form are found to be satisfactory by the CAQA, the selected candidates will be required to

undergo training followed by written examination and viva. All the successful candidates will be issued passing certificate, which would make them eligible for conducting QA of diagnostic x-ray equipment.

3.4 Physical verification of QA equipment

Physical verification of QA equipments as per details provided in the application form will be carried out by AERB.

3.5 Accreditation

After the committee is satisfied on all the aspects based on the review of information submitted by the QA Agency through the application, successful completion of the training and compliance verification, the committee will submit its recommendations to Head, RSD, AERB. Based on the recommendations of the committee, AERB may issue the Accreditation under the AE(RP)R,2004.

4. QUALITY ASSURANCE PROGRAMME

The Licensee of the QA Agency shall undertake following measures to ensure the quality of their services:

i. All the QA equipment shall be calibrated periodically,
ii. Only authorized personnel shall be allowed to carry out QA,
iii. Periodic training of the service personnel shall be ensured.
iv. All the service personnel shall be provided with the personnel monitoring devices and
v. Dose records of all the service personnel shall be maintained.

5. OPERATIONAL REQUIREMENTS

5.1 Submission of QA reports to diagnostic x-ray facilities

The QA service agency shall give a duly filled-in, signed and stamped QA report in the prescribed format to the user institution along with all the verification films. The test report should include Accreditation number allotted by AERB.

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6. REGULATORY REQUIREMENTS

6.1 Manuals and Record-keeping

The QA Agency shall prepare and maintain a manual comprising of the procedures followed for QA, details of the QA equipment, quality assurance programme, organizational set-up and responsibilities of personnel working in the field. This manual shall be readily accessible to any member of the Agency and also during the visit of the representatives of AERB. The manual should be reviewed and updated every three years. Also the Agency shall maintain records of QA of x-ray facilities for the period of 4 years (electronic copy).

6.2 Reporting to AERB

6.2.1 Periodic Reporting

Agency shall submit six monthly report to AERB in the prescribed format about all the facilities for which QA is carried out during the period.

6.2.2 Reporting of Unusual Observations

Any unusual observations during QA shall be immediately reported to AERB (e.g. excessive radiation leakage from the equipment, non-approved equipment, non-availability of protective accessories etc. at the user institution).

6.3 Renewal of Accreditation

Initial Accreditation will be valid for a period of 3 years, which needs to be renewed before expiry. The application form for renewal of Accreditation shall be submitted by the Agency at least two months prior to its expiry. Renewal of Accreditation will be issued based on satisfactory performance of the agency during the period of Accreditation.

6.4 Regulatory Inspection

AERB will conduct regulatory inspection of authorized Agency periodically. This will comprise examination by review of documents, observations, measurements or tests, process to ensure conformance of equipment, components, systems and structures, as well as operational activities, processes, procedures, practices and personal competence, with the specified requirements. The Agency shall co-operate for the regulatory inspection.

6.5 Quality Audit of the services rendered by Accredited Agency

AERB/Representatives of AERB will conduct Quality Audit for verifying the quality of services rendered by the Accredited Agency. This audit will comprise evaluation of technical competence and appropriateness of the practices followed for the QA of diagnostic x-ray equipment. The Accredited Agency shall allow the representatives of AERB, access to the facility and the site of QA for this purpose.

6.6 Cancellation/Suspension of Accreditation

The Accreditation can be withdrawn, amended, revoked or suspended by AERB, as provided in the Atomic Energy (Radiation Protection) Rules, 2004, if any of the terms and conditions of the Accreditation is contravened. Where deemed appropriate, AERB may initiate penal action against the Service Agency in the event of offences, as provided in the Atomic Energy Act, 1962.

References

1. Atomic Energy Act (AEA), 1962
2. Atomic Energy (Radiation Protection) Rules-2004 {AE(RP)R-2004}
3. AERB safety Code on Medical X-ray Equipment and Installations [AERB/SC/MED (Rev.1), 2001] and its amendment dated 26/11/2012
4. International Electro-technical Commission (IEC) 60601-1-3, edition 2.0, 2008-01

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