NABL136

National Accreditation Board for Testing and Calibration Laboratories (NABL)

Specific Criteria for Accreditation of Quality Assurance Testing Facilities for Diagnostic Radiology X-Ray Equipment

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1. INTRODUCTION

Accreditation in accordance with ISO/IEC 17025: 2017 “General Requirements for the Competence of Testing and Calibration Laboratories” for the testing and calibration activities is granted by National Accreditation Board for Testing and Calibration Laboratories (NABL) to Conformity Assessment Bodies (CABs) for their competence to carry out such activities. Quality Assurance (QA) of medical diagnostic X-ray equipment means systematic actions necessary to provide adequate confidence to the end-user that medical diagnostic X-ray equipment will perform satisfactorily in compliance with applicable test protocol/ National/ International standards specified by the relevant regulatory authority.

The objective of performing QA checks/tests of QA testing of diagnostic radiology X-ray emitting equipment is to ensure the accuracy of the diagnosis through the images obtained by such various diagnostic radiology equipment. Quality Assurance begins with the performance evaluation of diagnostic X-ray equipment at the manufacturing stage by performing QA Check sand then acceptance testing after the installation of X-ray equipment at user’s facility by OEM / OEM authorized suppliers to ensure its conformity with the specifications. The QA tests should be carried out thereafter at regular intervals and after repairs of the equipment or when equipment malfunction is suspected.

The QA tests are necessary to ensure that the functional performance of the equipment is similar to its baseline values and within the tolerance values as specified by regulatory authority and to convey the results with the associated measurement uncertainties to the users and subsequently to regulatory authority.

The purpose of this document is:

- to specify requirements for QA Testing Facilities for obtaining accreditation as per ISO/IEC 17025:2017 to carry out quality assurance activity of diagnostic radiology X-ray equipment during its life cycle.
- to achieve uniformity in understanding requirements of the Quality Assurance testing facilities/assessors in assessment process so that the procedure for accreditation is smooth, seamless and aligned with the NABL policies for accreditation.

1.1 To achieve uniformity in selection of QA equipment, testing methods, required facilities & environmental conditions, personnel with relevant qualification, training and experience, as per regulatory requirements and in accordance with ISO/IEC17025:2017.

1.2 Definition of Quality Assurance (QA) Testing Facility

Any Testing Facility owned/ operated/ contracted / set up by any legally registered Entity/Testing facility/ Laboratory/ Institute/ Manufacturer of X-ray Equipment (Refurbished/ New)/ Suppliers of X-ray equipment (Refurbished/ New) and possessing the required infrastructure and capability to perform the Quality assurance Testing/ Checks of Diagnostic Radiology X-ray emitting Equipment at its Permanent facility or site facility Quality Assurance Testing Facility for the purpose of accreditation in accordance with ISO/IEC 17025:2017

#Quality assurance in this document shall be referred as QA.

As per terminology of ISO/IEC 17025, CAB shall be alternatively used for QA Testing Facility in NABL documents and during and after accreditation for the purpose of uniformity of terminology within NABL.

1.3 Definition of Diagnostic X-ray Equipment

Unless specified, Diagnostic Radiology X- ray equipment, mentioned in this document, refers to a general term that covers all such medical diagnostic equipment that are generating X- ray and requiring quality assurance testing as per the requirements of regulating body.

2. SCOPE OF THE DOCUMENT

This document defines the requirements that are to be complied by the DR-Quality Assurance Testing Facility seeking NABL accreditation as per ISO/IEC17025:2017 and other relevant documents for Quality Assurance (QA)/ performance testing of Medical Diagnostic X-ray equipment. The scope of the document is to supplement the requirements specified in ISO/IEC 17025: 2017. This specific criteria document must be used in conjunction with ISO/IEC 17025: 2017. It provides an interpretation of the later document and describes specific requirements.

2.1 Scope of QA Testing

Quality Assurance Testing Facility seeking the accreditation shall carry out one or more of the followings:

- Type Approval demonstration by manufacturer/ supplier
- QA Checks/ Testing of X ray Equipment at manufacturer's site.

- QA Checks/ Testing for Acceptance testing (e.g. pre & post commissioning)
- Periodic QA
- QA carried out after major repair/ servicing/ maintenance of the diagnostic X-ray equipment.

Quality Assurance Testing Facility may seek accreditation for QA testing of following X-ray equipment used for various imaging techniques such as Computed Tomography

a) Radiography (Fixed, Mobile, Portable), Interventional Radiology, Fluoroscopy, C-Arm, O-Arm,

b) DEXA (Dualenergy X-ray Absorptiometry)

c) Computed Tomography (CT)

d) Dental Radiography [Intra Oral Periapical radiograph (IOPA) Ortho Pantomography (OPG), Cone Beam Computed Tomography (CBCT)]

e) Mammography

f) Extremity Cone Beam CT

g) Any of the above X-ray equipment mounted on vehicles.

h) Any other type of X-ray equipment used for medical diagnosis purpose

2.2 Groups for Scope of Accreditation

2.2.1 Radiography (X-ray–Fixed, Portable, Mobile)

Also includes Dental Radiography (IOPA, OPG, Dental hand held), BMD

2.2.2 Computed Tomography (CT)

Also includes Cone Beam Computed Tomography (CBCT) for general as well as dental.

2.2.3 Mammography

2.2.4 Interventional Radiology & Fluoroscopy,

It includes C-ARM, O-ARM, Radiography & Fluoroscopy

3. LEGAL IDENTITY

The applicant Quality Assurance Testing Facility seeking accreditation for QA testing shall be established in accordance with applicable laws of the country as notified by Government of India from time to time and maintain a valid legal identity at all times during its period of accreditation.

A Quality Assurance Testing Facility for Testing of Diagnostic Radiology X Ray Equipment can operate in various forms such as:

- Independent QA Testing facility (proprietorship/ partnership)
- Apart of larger organization/ Group/ Accredited laboratory/ Manufacturer/ Supplier/ OEM Authorized Agency /testing facility
- Public Private Partnership (PPP) mode etc.

However, for any mode of operations as above, the accountability of test reports issued after performance/ acceptance testing of diagnostic radiology X-ray equipment shall lie with the Quality Assurance Testing Facility in all cases and by way of an agreement in case of 2) and 3). Such agreements may be devised on long term basis.

4. REGULATORY COMPLIANCE

The Quality Assurance Testing Facility for its QA activities is required to undertake the regulatory compliance wherever applicable e.g.

- Atomic Energy Act,1962
- Atomic Energy (Radiation Protection) Rules-2004{AE(RP)R-2004}
- Regulatory Requirements for Manufacturers and Suppliers of X ray Equipment and X ray tubes in accordance with AERB Safety Code “Radiation Safety in Manufacture, Supply and Use of Medical Diagnostic X-ray Equipment [AERB/RF-MED/SC-3(Rev.2)2016] or AERB’s Regulatory document prevalent time to time.
- AERB Guidelines for Personal Protective Equipment
- Any other guidelines specified by the regulatory authority time to time.

The action/ requirement initiated upon Quality Assurance Testing Facility by the Regulatory body for the purpose of implementation of various statutory Acts/ Guidelines, wherever required, shall be binding for compliance and shall be deemed as prerequisite for grant/ maintain / continuation of accreditation by NABL.

The Quality Assurance Testing Facility is solely liable for any action/ charges for violation of applicable acts/ rule etc.

5. RELEVANT STANDARDS

Test protocols prescribed by AERB

National / International standards wherever specifically applying for QA testing in totality.

6. INFRASTRUCTURE

6.1 QA Equipment

QA Testing Facility shall have adequate number of QA kits and test carrying equipment along with auxiliaries to match the scope of accreditation and QA testing undertaken for different users.

QA Testing Facility shall mandatorily maintain the valid calibration of equipment as per NABL 142 “Policy on Metrological Traceability of Measurement Results”.

The application for accreditation may be rejected by NABL at any stage of accreditation process in case of inadequate number of equipment/QA kits w.r.t. volume of work and applied scope.

Some of the equipment required for the QA Testing Facility are given below. The testing facility is required to possess equipment as per their requirement. The list give below is only an illustration.

	Equipment for the QA Activity in general
1.	R/F sensor/detector of Range40-150kVp
2.	Mamo Sensor of range 20-49 kVp
3.	CT Sensor /detector of Range 80-140 kVp
4.	Survey Detector/ Sensor
5.	Collimator Test Tool
6.	Low contrast resolution test tool
7.	High contrast resolution test tool
8.	Focal spot test tool (should measure the value from 0.1mm to 2.5mm)
9.	Optical and Radiation field congruence test tool
10.	Beam alignment test tool
11.	CT imaging phantom
11.	CTDI phantom (Head and Body)
12.	CT Head Phantom applicable for Dental (CBCT) and Extremity (CBCT)
13	Mammography imaging phantom
	Auxiliary tools
1.	Positioning System (sprit level for positioning)
2.	Distance Measuring Tool
3.	Aluminum filters of purity 99.99% or higher and density 2.70gcm^{-3}
4.	Copper filters (If inbuilt in the system, then not required)

	Phantoms
1.	CT imaging phantom
2.	CTDI phantom (Head and Body)
3.	CTDI Head Phantom applicable for Dental (CBCT) and Extremity (CBCT)
4.	DSA phantom
5.	Mammography imaging phantom
6.	Imaging Phantom for Dental Cone Beam CT

6.2 Equipment Space

The QA Testing Facility shall have adequate storage space for suitably keeping the QA equipment complying with the requirements of storage & upkeep specified by the original equipment manufacturer (OEM)/suppliers.

The QA equipment shall be kept in properly identified blocks in the boxes / containers individually marked& labeled for the instruments and shall not override each other. The QA equipment shall always be maintained under safe and secure condition with proper packaging during storage and transportation.

6.3 Records Room

QA Testing Facility shall ensure clean and sufficient space to store the records of management system and raw data of their clients. It shall have a laboratory information management system with facility to retrieve the data as and when required. Raw data can be of following types:

- QA equipment generated measurement files, or/and Snapshots of the measurements where measurement files are not directly available from equipment and Calculation Sheets.
- Image quality films for the image quality tests performed at the testing site.
- Copy(s) of the QA test reports submitted to the customer(s).

6.4 Transportation

QA Testing Facility shall ensure proper procedure for transportation of the Quality Assurance testing equipment from its premises to the site of client's location or from one site to another site, maintaining the integrity, packaging and functionality of the equipment

in a way that shall not affect and/or impact upon the specific requirements during QA activity. QA Testing Facility shall ensure that equipment shall always be in custody and monitoring of qualified and competent personnel. Records shall be maintained for entire sequence of such transportation from its premises to the site and back to QA Testing Facility safe storage and from one site to another. QA Testing Facility shall ensure through a suitable mechanism to verify the performance of QA equipment on its return from site.

7. PERSONNEL

The QA Testing Facility shall ensure that all personnel of the QA Testing Facility, either internal or external, who can influence QA Testing facility's quality assurance activities, shall act in impartial manner, maintain confidentiality and be competent to act in accordance with regulatory requirements and requirements of ISO/IEC 17025:2017. Wherever specified and required, the personnel of QA Testing Facility shall meet the regulatory requirements of education, experience, training, certification, skills and knowledge as specified from time to time. QA Testing Facility shall have the technical person/persons having competence as mentioned at cl.7.1 and authority as assigned by their management to achieve adequate technical control of its operations.

Personnel performing QA checks/ testing of diagnostic radiology X-ray equipment, reporting and reviewing the test reports shall be considered as technical staff.

7.1 Technical Staff- Qualifications, Certification, Training and Experience

7.1.1 Degree/ Diploma in Electrical/ Electronics/ Biomedical/ Mechanical/ Post Graduate Degree in Medical Physics/ P.G. Diploma in Radiological Physics or in an associated discipline/ Basic degree in science with physics as one of the subjects/ degrees in medical imaging technology or equivalent from a recognized university/ institution.

7.1.2 Minimum six months' experience/ work exposure in medical imaging/ diagnostic X rays equipment testing.

7.1.3 Successful completion of the Training in Quality assurance of diagnostic Radiology X-ray Equipment, imparted by Radiological Physics & Advisory Division (RP&AD), BARC or any other equivalent testing facility recognized by AERB.

7.2 Personnel for review, report and authorization of results

QA Testing facility shall nominate any competent personnel (One or more technical personnel asper qualifications specified above) to review, report and authorize the QA test reports generated after the QA testing.

8. REQUIREMENTS OF QA SYSTEM MANAGEMENT (MANAGEMENT SYSTEM DOCUMENT/ QUALITY MANUAL)

8.1 QA Testing Facility shall prepare and maintain a system document that may be in the form of quality manual/ management system document, comprising of the procedures followed for carrying out QA testing as per defined scope. The manual addressing the requirements of ISO/IEC17025:2017 will additionally comprise the details of:

8.1.1 Personnel Monitoring Services,

8.1.2 SOP for carrying out various QA tests, while maintaining the radiological safety measures.

8.2 All the manuals/ SOPs/ Test procedures/ methods shall be readily accessible to every technical staff of the QA Testing Facility. These shall also be accessible to the assessors during the assessment scheduled by NABL.

8.3 The manual should be reviewed as per the frequency defined in the manual and should be updated. The testing facility shall maintain records of QA of radiology facilities for the period ofminimum3 years. Such records shall include raw data and test reports both.

8.4 **Calibration:** QA testing facility shall maintain the calibration requirements of Quality Assurance Equipment and comply with metrological traceability requirements given in *NABL 142: Policy on Metrological Traceability of Measurement Results.*

8.5 **Measurement:** Working Instructions for operating each equipment and SOP shall be readily available for use by the staff members. Same should be carried also at the site of Quality Assurance testing under the control of an authorized person. Any deviation from SOP should be precisely determined.

8.6 Internal Quality Control Checks

The following Internal Quality Controls checks may be carried out by QA testing facility:

8.6.1 Functional checks,

8.6.2 Retesting for the functional parameters,

8.6.3 Intra-Laboratory Comparison

8.6.4 Use of alternative instrumentation (If multiple equipment available),

8.6.5 Intermediate Checks

8.7 PT /ILC

8.7.1 Inter-Laboratory Comparison (ILC)-The QA testing facility shall be required to undertake Inter QA testing facility comparison (ILC)as per plan. ILC can either be organized or participated by a QA Testing Facility. The QA Testing Facility, organizing the ILC shall have the responsibility to provide the ILC results to the participating QA Testing Facilities.

9. TEST WITNESS

QA testing facility shall arrange to carry out the test witness of the tests under applied/ accredited scope of accreditation during NABL assessment at suitable sites (at permanent/ site facility) for the purpose of demonstrating competence to carry out QA activity as per protocols/ standards (Refer NABL 130).

The QA Testing Facility shall inform NABL before assessment about the details of the 'suitable sites' (permanent/site facility) where the QA test witness is arranged and ensure that necessary permissions for conducting test witness at those sites have been obtained from relevant authorities of those sites.

Note 1: *Various QA Test Parameters (as per QA protocol or/and National and International standards). The tests are equipment specific and may be more or less depending upon the X-ray equipment.*

S. No.	QA Tests
1.	Central beam alignment
2.	Congruence of radiation and optical fields
3.	Effective Focal spot size measurement
4.	Timer Accuracy
5.	Accuracy of Accelerating Tube Potential
6.	Linearity of radiation output
7.	Reproducibility of radiation output
8.	Total filtration
9.	Radiation leakage through tube housing including collimator area
10.	Exposure rate at table top
11.	Image quality

Note 2*: The details of QA Tests are to be specified equipment wise along with work load requirement and the conditions in which the test is required to be carried out.*

Examples of few applicable protocols for QA activity/ basic safety, radiation protection & essential performance of diagnostic X –ray equipment.

Diagnostic X-ray equipment	Test Methods/ standards/ Protocols
Radiography-Fixed/ Mobile/ Portable Fluoroscopy C-arm, O-arm Interventional Radiology Dental X-Ray, OPG, Dental (CBCT), Extremity (CBCT)	AERB prescribed QA/ Acceptance test methods/ IAEA Safety Standards/ SOPs IEC60601-1-3:2008 + AMD-1: 2013 IEC60601-2-43: 2010 + AMD1: 2017+AMD 2: 2019 AMD (Amendment) in standards of Medical electrical equipment - diagnostic X-ray equipment IEC 61223-3-5: 2019
Computed Tomography Cone Beam Computed Tomography	AERB prescribed QA/Acceptance test methods/IAEA Safety Standards/ Standard Operating Procedures (SOPs)/ IEC 60601-2-24: 2012 IEC 61223-3-5: 2019

10. GRANT/ RENEWAL OF ACCREDITATION AND CONTINUED COMPLIANCE TO ISO/IEC 17025

10.1 QA Testing Facility shall apply for accreditation as per ISO/IEC17025:2017 in duly filled application form along with all requisite documents as specified by NABL for the said purpose. (Please refer to NABL 100, NABL 120, NABL 130, NABL 133 & NABL 142). QA Testing Facility will be assessed as per the established accreditation procedure of NABL. The emphasis of NABL assessments in the field of Quality Assurance testing is to ensure that effective technical control and quality management system are being exercised overall QA procedures.

10.2 The assessment team of NABL shall verify the competence of the QA Testing Facility for compliance of the requirements of the standard and shall witness the QA testing also. For onsite test witness in presence of assessment team, QA Testing Facility shall coordinate & arrange for all necessary approvals/permissions from any nearby /selected center having medical diagnostic X-ray equipment.

10.3 Based on the recommendations of the assessment team and evidence of satisfactory compliance to ISO/IEC 17025:2017, NABL may take decision on grant/denial / renewal of accreditation to the QA Testing Facility. The period of accreditation shall be 2 years from

the date of grant/ renewal of accreditation, with the essential requirement of continued compliance to ISO/IEC 17025:2017, to be evaluated by various means, including mandatory desktop surveillance / onsite surveillance within one year from start of accreditation cycle as per prevalent policies of NABL.

11. OBLIGATIONS OF QA TESTING FACILITY

11.1 Submission of QA reports: The QA Testing Facility shall give a duly filled-in QA report (authorized by person declared by the QA Testing Facility to report, review and authorize the results) in the prescribed format to the user institutions along with all the verification films. The test reports shall fulfill the requirements of ISO/IEC 17025:2017 and also comply with the requirements of NABL-133 for the claim of accreditation/ use of NABL symbol and / or NABL accredited CAB combined ILAC MRA Mark.

11.2 Reporting of Unusual Observations to Regulatory Body: QA Testing Facility shall have evidence to report any unusual observation of the excessive radiation, leakage of radiation to AERB as a measure of following good radiological safety practices (GRP) whenever it comes across such incidents during the QA testing.

11.3 Radiation Safety Precautions (at site): Means shall be ensured for safety against radiation hazards at the testing sites by QA Testing Facility. Special warning and personal protection equipment (PPE) / protection devices shall be available for the safety of workers as per AE (Radiation Protection Rules)-2004 wherever applicable

Abbreviations:

AERB : Atomic Energy Regulatory Board

APAC : Asia Pacific Accreditation Cooperation

BARC : Bhabha Atomic Research Centre

BMD : Bone Mineral Density

CAB : Conformity Assessment Body

CBCT : Cone Beam Computed Tomography

CTDi : Computed Tomography Dose Index

DR : Diagnostic Radiology

DRXEq : Diagnostic Radiology X Ray Equipment

DEXA : Dual Energy X-ray Absorptiometry

DSA : Digital Subtraction Angiography

IAEA : International Atomic Energy Testing facility

IEC : International Electrotechnical Commission

ILAC : International Laboratory Accreditation Cooperation

ILC : Inter Laboratory Comparison

IOPA : Intra Oral Peri Apical Radiograph

IR : Interventional Radiology

ISO : International Organization for Standardization

MRA : Mutual Recognition Agreement

NABL Laboratories : National Accreditation Board for Testing and Calibration

OEM : Original equipment Manufacturer

OPG : Orthopantomogram

PT : Proficiency Testing

SOP : Standard Operating Procedure

QA : Quality Assurance

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