NABL 136

National Accreditation Board for Testing and Calibration Laboratories (NABL)

Specific Criteria for Accreditation of Quality Assurance Agencies 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 satisfactory in compliance with applicable national/international standards specified by the relevant regulatory authority.

The objective of QA testing of X- ray generating equipment is to ensure the accuracy of the diagnosis through the images obtained by various diagnostic radiology equipment. Quality Assurance begins with the performance evaluation of diagnostic X-ray equipment at the manufacturing stage and then acceptance testing after the installation of X-ray equipment at user’s facility 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.

The purpose of this document is:

- To specify requirements for QA organization/ agencies, for obtaining accreditation as per ISO/IEC 17025:2017 to carry out quality assurance activity of diagnostic radiology X-ray equipment.
- To achieve uniformity among the Quality Assurance agencies /assessors in assessment process so that the procedure for accreditation shall be in line with National/ International standards.
- To achieve uniformity in selection of QA equipment, testing methods, required environmental conditions, personnel with relevant qualification and experience, as per ISO/IEC 17025:2017.

1.1 Definition of Quality Assurance (QA) Agency

The Laboratory/Institute/Organization, which possesses the minimum required infrastructure and capability to perform testing of diagnostic X-ray equipment, at site, is termed as quality assurance agency. For the purpose of accreditation, such laboratory/ institute / organization carrying out quality assurance services shall be addressed as Quality Assurance Agency (QA Agency) in this document.

Quality assurance in this document shall be referred as QA.

1.2 Definition of Diagnostic X- ray Equipment

Unless specified, diagnostic 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.

 # ISO- International Organization for Standardization

 # IEC- International Electrotechnical Commission

2. Scope

This document defines the requirements that are to be complied by the Quality Assurance Agency seeking NABL accreditation as per ISO/IEC 17025:2017 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. The QA Agency shall additionally follow national, regional, local laws and regulations as applicable.

2.1 Scope of QA Activity

QA agency seeking the accreditation for activity to offer Quality Assurance services in the field of medical X-ray equipment shall carry out one or more of the followings:

- Periodic QA as well QA carried out after major repair/servicing/maintenance of the diagnostic X-ray equipment.
- QA for Acceptance testing with the approval of the supplier
- Type Approval demonstration with prior approval to assist manufacturer/supplier

A QA Agency may seek accreditation for QA testing of following X-ray equipment used with various imaging techniques such as radiographic film, computed radiography, digital radiography and image intensifier etc.

a) Radiography (Fixed, Mobile, Portable), Interventional Radiology, Fluoroscopy, C-Arm, O-Arm,
b) DEXA (Dual energy X-ray Absorptiometry)
c) Computed Tomography (CT)
d) Dental Radiography [Intra Oral Peri-apical radiograph (IOPA), Ortho Pan tomography (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

2.1. Groups for Scope of Accreditation

1) Radiography (X-ray -Fixed Portable, Mobile)
2) Computed Tomography (CT)
3) Mammography
4) Interventional Radiology & Fluoroscopy

3. Legal Identity

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

For the purpose of accreditation, prevalent NABL policy i.e. *NABL 165: NABL Policies on Accreditation (as per ISO/IEC 17025:2017)* shall be applicable.

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

1) Independent QA Agency
2) QA Agency as a part of larger organization/ Group/ Accredited laboratory,
3) QA Agency in 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 rays equipments shall lie with the QA Agency 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 QA Agency for its QA activities is required to undertake for the regulatory compliance wherever applicable e.g.

- Atomic Energy Act, 1962
- Atomic Energy (Radiation Protection) Rules-2004 {AE(RP)R-2004}
- AERB Safety Code on Radiation Safety in 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 QA agency by the Regulatory body for the purpose of implementation of various statutory Acts/ Guidelines, wherever required, shall be the binding for compliance and shall be deemed as prerequisite for accreditation of QA agency.

5. Relevant Standards

Test protocols/methods specified by national / international standards or/ and applicable authoritative body in the country, International Electro-technical Commission (IEC) and amendments wherever applicable, required to be followed in totality.

6. Infrastructure

6.1 QA Equipment

QA Agency shall have a defined procedure for procurement, handling, transportation, storage, use, planned maintenance and repair of equipment to ensure smooth functioning and to prevent malfunctioning of the equipment.

Sl.	**Equipment for the QA Activity in general**
1.	kVp Meter for R&F, BMD and CT equipment-: Range 40-150 kVp
2.	kVp Meter for Dental equipment- 45-100 kVp
3.	kVp Meter for Mammography equipment- 18-49 kVp
4.	Solid state Dosimeter (of suitable range varying from 0.01µGy – 100Gy)
5.	Timer
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 2.5 mm)
9.	Optical and Radiation field congruence test tool
10.	Beam alignment test tool
11.	Protection Accessories
11.	Appropriate Radiation Survey Meter (capable to measure scattered radiation for the operating range (kV) of the x-ray equipment)
12.	Collimator Test Tool
Sl.	**Auxiliary tools**
1)	Positioning System (sprit level for positioning)
2)	Distance Measuring Tool
3)	Aluminum filters of purity 99.99% or higher and density 2.70 g cm^{-3}
4)	Copper filters (If inbuilt in the system then not required)
	Phantoms
5)	CT imaging phantom

6)	CTDi phantom (Head and Body)
7)	CT Head Phantom applicable for Dental (CBCT) and Extremity (CBCT)
8)	DSA phantom
9)	Mammography imaging phantom
10)	Imaging Phantom for Dental Cone Beam CT
11)	CT High and Low Contrast Resolution Phantom for Dental (CBCT).

6.2 Equipment Space

The Agency 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 Agency 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-

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

6.4 Transportation

QA Agency shall ensure proper transportation of the Quality Assurance testing equipment from the QA Agency premises to the client's location maintaining the integrity, packaging and functionality of the equipment in a way that shall not affect and/or impact upon the specific requirements during carrying out QA activity. QA Agency shall ensure that equipment shall always be in custody and monitoring of qualified and competent during their transportation from QA Agency safe storage to the site and back to QA Agency safe storage. Performance of QA equipment shall be verified on return from site by a suitable mechanism, wherever possible.

7 Personnel

The QA Agency shall ensure that all personnel of the QA Agency, either internal or external, that can influence QA Agency's quality assurance activities, shall act in impartial manner, be competent to act in accordance with defined procedures of management system, qualify to meet the regulatory

requirements of education, experience, training, certification, skills and knowledge as specified time to time. The Accreditation Body needs to be satisfied through the assessments conducted by a team of assessors/ experts that QA testing carried out at site by QA Agency have at least one person who has the competence, time and authority to achieve adequate technical control of its operations.

7.1 **Technical Staff- Qualifications, Certification, Training and Experience**

(i) 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 subject /degrees in medical imaging technology or equivalent from a recognized university/institution.

(ii) Minimum six months experience/ work exposure in medical imaging/ diagnostic X rays equipment testing

(iii) 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 agency recognized by AERB.

7.2 **Person for review**

QA Agency shall nominate any competent personnel (One or more of Technical Personnel as per qualifications specified above) to review and sign the QA test reports generated after the QA testing.

8 Requirements of QA System Management (Management System Document/ Quality Manual)

QA agency 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/IEC 17025:2017 will additionally comprise the details of:

1) Personnel Monitoring Services
2) Procedures for carrying out various QA tests.
3) Radiological Safety arrangements

QA agency shall comply with the requirements of ISO/IEC17025:2017 as applicable. They should have one member, at least, who has successfully undergone 4 days training on ISO/IEC 17025. That person (howsoever designated) will be responsible for implementation; maintenance and improvement of the management system of QA Agency (*Refer NABL 165 for details*).

All the manuals/ SOPs/ Test procedures/ methods shall be readily accessible to every member of the QA Agency. These shall also be accessible to the assessors during the audit done by NABL.

The manual should be reviewed as per the frequency defined in the manual and should be updated. The agency shall maintain records of QA of radiology facilities for the period of minimum 3 years. Such records shall include raw data and test reports both.

8.1 Calibration: QA agency shall maintain the calibration requirements of Quality Assurance Equipment and comply for metrological traceability as per requirements of *NABL 142: Policy on Traceability of Measurement Results.*

8.2 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 a authorized person. Any deviation from SOP should be precisely determined.

8.3 Internal Quality Control Checks

The following Internal Quality Controls checks may be carried out by QA agency:-

(i) Functional checks
(ii) Retesting for the functional parameters
(iii) Intralaboratory Comparison (Intra QA agency Comparison)
(iv) Use of alternative instrumentation (If multiple equipment available)

Inter- Laboratory Comparison (ILC)- Further the QA agency shall be required to undertake Inter QA agency comparison (ILC) as per plan.

9 Test Witness

QA agency shall arrange to carry out the test witness of the tests under applied/ accredited scope of accreditation during NABL assessment at the user's site in presence of the assessment team for the purpose of demonstrating competency to carry out QA activity as per protocols/ standards ((Refer NABL 130).

Note1- Various QA Test Parameters (as per QA protocols or/and National and International standards). The tests are equipment specific and may be more or less depending upon the X-ray equipment.

S.N.	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 tabletop
11.	Image quality

Note2 - 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 equipments	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 + AMD-1; 2013 IEC60601-2-43 + AMD1- 2017 AMD (Amendment) in standards of Medical electrical equipment - diagnostic X-ray equipment IEC61223-2-6 :2011
Computed Tomography Cone Beam Computed Tomography	AERB prescribed QA/Acceptance test methods/IAEA Safety Standards/ Standard Operating Procedures(SOPs)/IEC60601-2-24:2009+ AMD 1 :2012 + AMD2-:2016 IEC61223-3-5:2004, IEC61223-2-6:2011

10 Grant/ Renewal of Accreditation and Continued Compliance to ISO/IEC 17025:2017

QA Agency shall apply for accreditation as per ISO/IEC 17025:2017 in duly filled application form along with all requisite documents as specified by NABL for the said purpose. (Please refer to NABL 100, NABL 130, NABL 133 & NABL 165 etc). QA Agency 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 over all QA procedures.

The assessment team (one or more depending upon the scope) of NABL shall verify the competence of the QA Agency for compliance of the requirement of the standard and shall witness the testing also. For onsite test witness in presence of assessment team, QA agency shall coordinate & arrange for all necessary approvals/permissions from any nearby /selected centre having medical diagnostic X-ray equipment.

Based on the recommendations of the assessment team and evidence of satisfactory compliance to ISO/IEC 17025:2017, NABL may make decision on grant/denial / renewal of accreditation to the QA agency. 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 assessment application in the mid of accreditation cycle.

11 Obligations of QA Agencies

11.1 **Submission of QA reports:** The QA Agency shall give a duly filled-in QA report signed by NABL approved authorized signatory in the prescribed format to the user institutions along with all the verification films. The test reports shall fulfill the requirement of ISO/IEC 17025:2017 and also comply with requirements of NABL-133 for the claim of accreditation/ use of symbol.

11.2 **Reporting of Unusual Observations to Regulatory Body:** QA Agency 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 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 Agency. Special warning and personal protection equipments (PPE) / protection devices shall be available for the safety of workers as per AE (Radiation Protection Rules)-2004.

Sample Scope

QA Agency:		Date(s) of Visit:-			
Discipline: Diagnostic Radiology			Group: Radiography (X-ray)		
SI.	Product(s) / Equipment/ Material of test	Specific tests performed	*Test Method / Protocol/ Standard against which tests are performed	#Range of Testing/ Limits of detection	Uncertainty /Tolerance of Measurement^{+} (±) at Value
	X-Ray Equipment (Mobile/ Fixed)	Congruence of radiation and optical field	AERB prescribed methods/ IAEA Safety Standards/ SOPs / IEC60601-1-3 IEC60601-2-43 + AMD12017 IEC61223-2-6 :2011 second edition	----	I X I + I X' I ≤ 2% of FFD I Y I + I Y' I ≤ 2% of FFD
		Central Beam Alignment		----	$< 1.5^{0}$
		Effective focal spot measurement FFD= 60 cm		----	1. + 0.5 f for f< 0.8 mm 2.+ 0.4 f for 0.8 ≤ f ≤ 1.5 mm 3.+ 0.3 f for f > 1.5 mm
		Accuracy of Operating Potential (kV)		40-150 kV	± 5 kV
		Accuracy of Irradiation Time(sec.)		--	--
		Total filtration		--	1.5 mm Al for kV ≤ 70 2.0 mm Al for 70 < kV ≤ 100 2.5 mm Al for kV > 100
		Linearity of mA/mAs loading Stations		----	CoL<0.1
		Consistency of radiation output		----	CoV≤ 0.05
		Radiation leakage level at 1 m from tube housing and Collimator		----	Tube Leakage < 1 mGy in one hour
		Area Survey		-----	40 mR/week (radiation worker) 2mR/week(public)

** When referring to publications like AERB, BARC, IAEA, CLSI, IP, BP, USP, ASTM, AOAC etc. kindly mention the clause /chapter / page number, as appropriate.*

$^{+}$ The value at which uncertainty of measurement estimated, shall also be specified.

 # Range / Measurement of testing shall vary depending on manufacturer's specifications.

Signature, Date & Name of Lab Representative	Signature, Date & Name of Technical Assessor	Signature, Date & Name of Lead Assessor

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