

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

ISSUE NO.: 02
ISSUE DATE: 24-Aug-2021

AMENDMENT NO.: --
AMENDMENT DATE: --



Documents
Document Sharing Hub

AMENDMENTSHEET

S. No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature CEO
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							

CONTENTS

S. No.	Title	Page No.
	Amendment Sheet	1
	Contents	2
1.	Introduction	3
2.	Scope	4
3.	Legal Identity	5
4.	Regulatory Compliance	6
5.	Relevant Standards	6
6.	Infrastructure	7
7.	Personnel	9
8.	Requirements of QA System Management (Management System Document/ Quality Manual)	10
9.	Test Witness	11
10.	Grant/Denial of accreditation & continued Compliance	12
11.	Obligations of QA Testing Facility	13
	Abbreviations	14

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 and 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.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No: NABL 136	Specific Criteria for Accreditation of Quality Assurance Testing Facilities for Diagnostic Radiology X-Ray Equipment			
Issue No: 02	Issue Date: 24-Aug-2021	Amend No: --	Amend. Date: --	Page No.: 3 of 14

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.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No: NABL 136	Specific Criteria for Accreditation of Quality Assurance Testing Facilities for Diagnostic Radiology X-Ray Equipment			
Issue No: 02	Issue Date: 24-Aug-2021	Amend No: --	Amend. Date: --	Page No.: 4 of 14