

NABL 135



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Specific Criteria for Accreditation of Medical Imaging – Conformity Assessment Bodies

ISSUE NO.: 01

ISSUE DATE: 09-May-2019

AMENDMENT NO.: 03

AMENDMENT DATE: 24-Jan-2024

AMENDMENT SHEET

S. No .	Amendmen t No.	Pag e No.	Claus e No.	Date of Amendment	Amendment	Reasons	Signatur e QA Team	Signature of Competen t Authority
1.	01	5	----	01.08.2019	Deletion of the text	Internal review	-Sd-	-Sd-
2.	02	9	4	20.07.2020	Type of legal identity document specified in line with NABL 131.	Harmonized requirements in all NABL documents.	-Sd-	-Sd-
3.		9	4		Reference to NABL 201 removed.	NABL 201 is withdrawn by NABL.		
4.		9	4		Removal of 4 days training requirements.	Policy Decision.		
5.		10	4		Reference to NABL 133 removed.	Internal review.		
6.		13	5.1		Term 'Authorized signatory' is replaced with 'personnel responsible for report, review and release of results'.	Policy Decision.		
7.		03	3		----	24.01.2024		
8.	4		1	Release of ISO 1589: 2022				
9.	5		2	Internal Review				
10.	7, 8		4	Release of ISO 1589: 2022 & Internal Review				
11.	10		5.1	Internal Review				
12.	12		5.2					
13.	13		5.3					
14.	16		5.6					
15.	16, 17		5.7					
16.	20		5.8	Release of ISO 1589: 2022				
17.	26		--					

CONTENTS

S. No.	Title	Page No.
	Amendment Sheet	1
	Preface	2
	Contents	3
	Abbreviations	4
1	Introduction	5
2	Scope	6
3	Description of MI-CAB	7
4	Management requirements	8-11
5	Technical requirements	12
5.1	Personnel	12
5.2	Accommodation and environmental conditions	13
5.3	Equipment, reagents and consumables	15
5.4	Pre-examination processes	17
5.5	Examination processes	17
5.6	Ensuring quality of examination results	18
5.7	Post-examination processes	19
5.8	Reporting of results	21
5.9	Release of results	21
5.10	MI-CAB information management	22
	<i>Annexure-1</i>	
	Table-1: Recommended calibration and performance checks of equipment	23
	Table-2: Requirement for digital imaging devices	26
	<i>Annexure-2 Patient Management</i>	27
	References	29

ABBREVIATIONS

AERB	- Atomic Energy Regulatory Board
APAC	- Asia Pacific Accreditation Cooperation
BARC	- Bhabha Atomic Research Centre
BMW	- Bio Medical Waste
CT	- Computed Tomography
DEXA	- Dual Energy X-Ray Absorptiometry
EQA	- External Quality Assessment
ILAC	- International Laboratory Accreditation Cooperation
ISO	- International Organization for Standardization
kV	- Kilovolt
LIS	- Laboratory Information System
mA	- Milliampere
MCI	- Medical Council of India
MI-CAB	Medical Imaging-Conformity Assessment Body
MRA	- Mutual Recognition Arrangement
MRI	- Magnetic Resonance Imaging
NABL	- National Accreditation Board for Testing And Calibration Laboratories
NIST	- National Institute of Standards and Technology
OPG	- Orthopantomogram
PC-PNDT	- Pre-Conception and Pre-Natal Diagnostic Techniques
PET	- Position Emission Tomography
PET-CT	- Position Emission Tomography – Computed Tomography
PET-MR	- Position Emission Tomography – Magnetic Resonance
PT	- Proficiency Testing
QC	- Quality Control
RF Power	- Radio Frequency Power
RSO	- Radiological Safety Officer
SD	- Standard Deviation
SOP	- Standard Operating Procedure
SNR	- Signal to Noise Ratio
SPECT	Single Photon Emission Computed Tomography
TAT	- Turnaround Time
USG	- Ultrasonography (Ultrasound)
WHO	- World Health Organization
CTDI	- Computed Tomography Dose Index

1. INTRODUCTION

Medical facilities accreditation activities are operated by National Accreditation Board for Testing and Calibration Laboratories (NABL), involving assessment team and accreditation committee as recommending authorities.

The requirements in this document are based on the International Standard, ISO 15189:2012/ISO 15189:2022 - "*Medical laboratories – Requirements for quality and competence*". It stipulates the requirements for competence and quality that are particular to medical laboratories as well as useful and appropriate for **Medical** Imaging facilities. The MI-CAB's compliance to requirements of the standard and its technical competence are assessed by NABL for accreditation.

The specific criteria document must be used in conjunction with ISO 15189:2012/ISO 15189: 2022. It provides an interpretation of the later document and describes specific requirements. Further, the MI-CAB shall additionally follow national, regional, local laws and regulations as applicable.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No: NABL 135	Specific Criteria for Accreditation of Medical Imaging-Conformity Assessment Bodies			
Issue No: 01	Issue Date: 09-May-2019	Amend No: 03	Amend Date: 24-Jan-2024	Page No: 4 of 26

2. SCOPE

The scope of accreditation is applicable to the following groups of Medical Imaging discipline:

- I. **Projectional Radiography & Fluoroscopy**
 - a. X Ray, Bone Mineral Densitometry (DEXA), Dental X Ray, OPG, Mammography, etc
 - b. Fluoroscopy
- II. **Computed Tomography (CT), Cone Beam Computed Tomography (CBCT)**
- III. **Magnetic Resonance Imaging (MRI)**
- IV. **Ultrasound and Colour Doppler**
- V. **Nuclear medicine**
 - a. SPECT
 - b. PET
 - c. PET CT
 - d. PET MRI
- VI. ***Basic Diagnostic Interventional Radiology Procedures** (Image guided Core Biopsy and/or Needle Aspiration e.g. Fine Needle Aspiration Cytology)
**For only such IR procedures that will be carried out by Radiologists*

Accreditation shall be considered only for those facilities for which the organization itself is equipped and competent to carry out consistently

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No: NABL 135	Specific Criteria for Accreditation of Medical Imaging-Conformity Assessment Bodies			
Issue No: 01	Issue Date: 09-May-2019	Amend No: 03	Amend Date: 24-Jan-2024	Page No: 5 of 26

3. DESCRIPTION OF MI-CAB

The requirements given in this document are applicable to all MI-CAB applying for NABL accreditation regardless of the level at which they function e.g. attached to a clinical Medical Imaging facility / stand-alone / Hospital based facility.

The classification of medical imaging to be based on following categories:

- a) Category A: MI-CAB using Ionized radiation
- b) Category B: MI-CAB using Sonography
- c) Category C: MI-CAB using Magnetic Resonance
- d) Category D: MI-CAB using Nuclear Medicine
- e) Category E: MI-CAB using Interventional Radiology
- f) Category F: MI-CAB having any combination of above categories.

4. MANAGEMENT/ MANAGEMENT SYSTEM REQUIREMENTS

Organization and Management Responsibility

An MI-CAB must produce relevant evidence of legal identification which can be any of the following:

Type of Legal Entity	Document / to be submitted
One Person Company	Registration certificate under The Companies Act, 2013
Limited Liability Partnership	Registration certificate under The Limited Liability Partnership Act, 2008
Company	Registration certificate under The Companies Act, 1956 or 2013
Societies/ Trust	Registration certificate under Societies Registration Act, 1860/ Registration under The Indian Trusts Act, 1882
Government	Gazette or Government Notification or self-Declaration on Letter head by Head of the organization

Organization shall also be required to comply with legislative and statutory requirement/s as mandated by local / regional / national regulatory and/or civic bodies.

Imaging equipment falling under the ambit of **PC-PNDT Act** shall be required to comply with the provisions of the Act, as applicable in respective states/UTs.

Due to statutory and legal requirement, an MI-CAB operating at more than one location within a district having the same legal identity shall be considered as multiple entities for the purpose of accreditation

The accreditation certificate for a Medical Imaging – Conformity Assessment Body (MI-CAB) is non-transferable and shall be valid only for premises for which it is issued.

Qualification norms for MI-CAB Director / Head (howsoever named)

MI-CAB Director/ Head (Howsoever named) shall have the overall responsibility of operations of the MI-CAB. For review, evaluation and release of results, he may delegate selected duties/ responsibilities to qualified personnel.

The MI-CAB Director / delegated personal shall also fulfill the other requirements of ISO 15189:2012/ISO 15189: 2022.

In case, where more than one person designated as MI-CAB Director, one of them should be available to ensure that she / he is responsible for overall operations and shall be available for consultancy wherever necessary as per statutory/regulatory requirement.

Requirements for Quality Manager

Quality Manager shall be well versed with ISO 15189. She / He should be a full-time employee, and can be delegated with additional responsibilities. Facility shall also ensure the availability of deputy quality manager (whenever required) with requisite qualification and experience as applicable for Quality Manager.

Service Agreements

The users of MI-CAB shall be explicitly informed about the non-accredited status of diagnostic services requested while entering into contract. This may be done by providing separate lists of

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No: NABL 135	Specific Criteria for Accreditation of Medical Imaging-Conformity Assessment Bodies			
Issue No: 01	Issue Date: 09-May-2019	Amend No: 03	Amend Date: 24-Jan-2024	Page No: 7 of 26

accredited and non-accredited diagnostic services to users. A copy of accredited scope shall also be made available for reference

Examination by Referral Medical Imaging Facility

Referral Medical imaging Facility is an external facility to which the management chooses to refer a subject for imaging/ examination when the imaging procedures/ examinations cannot be carried out. This differs from the diagnostic imaging services that may include public health, forensics or a central (parent) facility to which sending the subject is required by structure or regulation.

NABL allows referral for second opinion for the services of Medical imaging. Referral may also be required for confirmation of imaging findings. The referral Medical Imaging facility has to be NABL accredited, if available or equivalent status.

The imaging procedures in any group may be referred to another accredited MI-CAB at the time of temporary incapacity of services to be provided due to unforeseen circumstances such as breakdown of equipment, disasters, strikes etc.

Note: NABL allows this relaxation only under exceptional situations and it is advised that the privilege provided to the MI-CAB is not misused.

Referral Medical Imaging Facilities and consultants shall be selected as per the criteria laid down by the MI-CAB

MI-CAB shall maintain records pertaining to lists of services and the names & addresses of the referral centers from which services are obtained. The information is kept both in the 'referral' file and the 'subject' file.

The referring MI-CAB shall give prior intimation to its users about the Imaging procedures being referred.

The referring MI-CAB shall produce the original report of the referral MI-CAB or transcribe the report without alterations of clinical interpretation with additional remarks (if required) and specify the name of the referral MI-CAB, identify the imaging services performed and the results obtained by any such referral MI-CAB. Records pertaining to this shall also be made available.

Note: The Medical Imaging facility shall produce MOU (with referral) which may be maintained in a simple form.

Advisory Services

Stand-alone MI-CAB shall communicate with their clients (subject / clinicians) with regard to the choice of imaging procedures under different clinical conditions, whenever required or sought. Communication may be through direct contact, email and / or documentation. Hospital-attached medical imaging facility personnel are encouraged to participate in clinical rounds and meetings. The records of the above shall be maintained.