

NABL 100B



# National Accreditation Board for Testing and Calibration Laboratories (NABL)

## Accreditation Process & Procedure

ISSUE NO.: 01  
ISSUE DATE: 23-Nov-2022

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## AMENDMENT SHEET

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## 1. SCOPE

This document describes the procedure that would be followed for processing the application for NABL accreditation.

## 2. ACCREDITATION TERMINOLOGY

### 2.1. Accreditation

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. (Source ISO/IEC 17011: 2017)

*NABL provides accreditation to Conformity Assessment Bodies.*

*NABL accreditation is granted to the following conformity assessment bodies:*

- *Testing Laboratories & Calibration Laboratories as per ISO/IEC 17025: 2017*
- *Medical Testing Laboratories as per ISO 15189: 2012*
- *Proficiency Testing Provider (PTP) as per ISO/IEC 17043: 2010*
- *Reference Material Producers (RMP) as per ISO 17034: 2016*

### 2.2. Accreditation Body

Authoritative body that performs accreditation (Source ISO/IEC 17011: 2017)

**Note: The authority of an accreditation body is generally derived from government.**

*In the context of this document, NABL is an accreditation body.*

*NABL was previously an autonomous body under Department of Science and Technology, Ministry of Science and Technology, Government of India.*

*Presently, NABL is a constituent board of Quality Council of India.*

*Quality Council of India is an autonomous body under Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India.*

### 2.3. Conformity Assessment Body

Body that performs conformity assessment activities and that can be the object of accreditation (Source ISO/IEC 17011: 2017)

*In the context of this document, Conformity Assessment Bodies are:*

- *Laboratories performing testing activities,*
- *Laboratories performing calibration activities,*
- *Laboratories performing medical testing activities,*
- *Proficiency Testing Providers providing proficiency testing programs, and*
- *Reference Material Producers producing reference materials.*

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## 2.4. Conformity assessment activity

Activity conducted by a conformity assessment body when assessing conformity (Source ISO/IEC 17011: 2017)

*Conformity assessment activities are:*

- *Testing performed by Testing Laboratories,*
- *Calibration conducted by Calibration Laboratories,*
- *Medical/ Clinical Testing performed by Medical Testing Laboratories,*
- *Proficiency Testing Programs offered by Proficiency Testing Providers,*
- *Production of reference materials by Reference Material Producers*

## 2.5. Scope of Accreditation

Specific conformity assessment activities for which accreditation is sought or has been granted (Source ISO/IEC 17011: 2017)

*Scope of accreditation is the formal statement issued by an Accreditation Body (e.g., NABL) to its accredited CAB for conformity assessment activities (such as testing/ calibration). The CAB is accredited for these activities and hence competent to perform these activities.*

## 2.6. Accreditation Scheme

Rules and processes relating to the accreditation of conformity assessment bodies to which the same requirements apply (Source ISO/IEC 17011: 2017)

*NABL provides accreditation for the following accreditation schemes:*

- *Testing laboratories as per ISO/IEC 17025*
- *Calibration laboratories as per ISO/IEC 17025*
- *Medical testing laboratories as per ISO 15189*
- *Proficiency Testing Providers (PTP) as per ISO/IEC 17043*
- *Reference Material Producers (RMP) as per ISO 17034*

## 2.7. Accreditation Process

Activities from application through to granting and maintenance of accreditation as defined in the accreditation scheme (Source ISO/IEC 17011: 2017)

*The accreditation process followed by NABL has been described in the subsequent sections of this document.*

## 2.8. Assessment Programme

Set of assessments consistent with a specific accreditation scheme that the accreditation body performs on a specific conformity assessment body during an accreditation cycle (Source ISO/IEC 17011: 2017)



*NABL applies an assessment programme comprising of annual surveillance during each accreditation cycle of 2 years. The frequency may be increased to 6 monthly surveillances based on risk and/or performance of the CAB.*

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## 2.9. Accreditation Body Logo

Logo used by an accreditation body to identify itself (Source ISO/IEC 17011: 2017)




NABL uses two types of Logos. **Both logos can be used by NABL only.**  
NABL identify itself as follows:



NABL Logo 1	NABL Logo 2
	

## 2.10. Accreditation Symbol

Symbol issued by an accreditation body, to be used by accredited conformity assessment bodies to indicate they are accredited (Source ISO/IEC 17011: 2017)

*NABL Accredited Conformity Assessment Bodies are formally authorized to use NABL symbol on the basis of accreditation granted to them. NABL provides accreditation symbol to its accredited CABs. The certificate number may vary from 4 to 5 digits. Accredited Conformity Assessment Bodies are required to follow NABL 133: Policy for Use of NABL Symbol and / or Claim of Accreditation by Accredited Conformity Assessment Bodies (CAB) & NABL Accredited CAB Combined ILAC MRA Mark.*

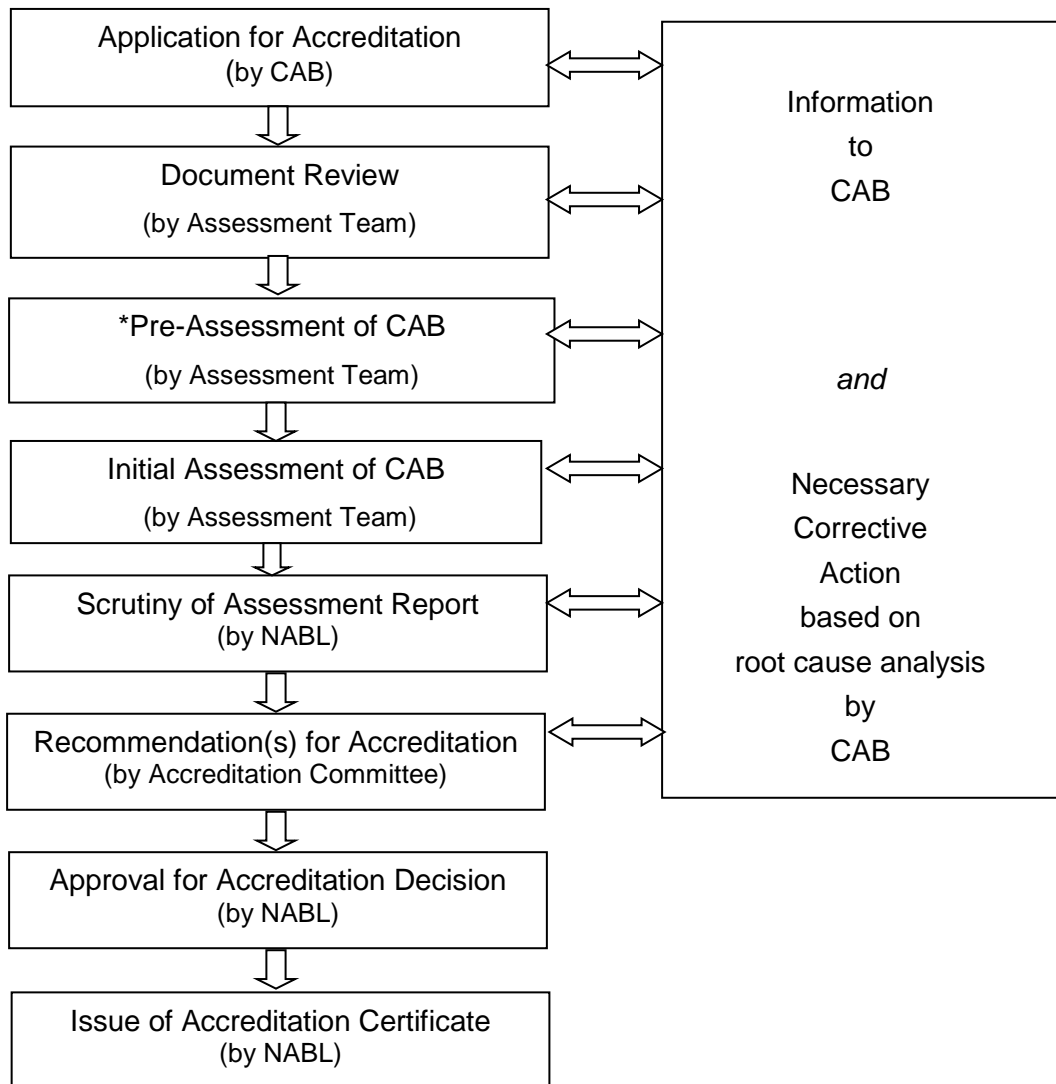
NABL Symbol for Testing Laboratories	NABL Symbol for Calibration Laboratories	NABL Symbol for Medical Testing Laboratories
		

NABL Symbol for Proficiency Testing Providers	NABL Symbol for Reference Material Producers
	

**Note:** CABs cannot use NABL logo. Use of NABL logo will be considered as non-compliance to NABL 133 and violation of NABL 131 "Terms & Conditions for Obtaining and Maintaining NABL Accreditation".

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### 3. ACCREDITATION PROCESS



\*Optional for laboratories (Testing/Calibration/Medical Testing)

**Flow Diagram of Accreditation Process**

#### 4. APPLICATION FOR ACCREDITATION

The CAB is required to apply through NABL Web Portal ('Apply Now' option on website ([www.nabl-india.org](http://www.nabl-india.org)) to NABL in prescribed application form viz. NABL 151, NABL 152, NABL 153, NABL 180, NABL 190 for Testing Laboratories, Calibration Laboratories, Medical Testing Laboratories, Proficiency Testing Providers and Reference Material Producers respectively. Medical testing laboratories are required to declare all sources of samples including Sample Collection Centre/Facilities (SCF). CABs situated outside India are required to apply for accreditation with relevant application form through electronic media (e.g., scanned copy).

NABL Accreditation is location specific and accordingly accreditation is granted to a specific location of a CAB. Each CAB shall apply separately for each location, if operating from multiple locations.

The applicant CAB shall implement the management system in accordance with relevant standard. For example, Testing and Calibration laboratories as per ISO/IEC 17025: 2017, Medical testing laboratories as per ISO 15189: 2012, Proficiency Testing providers as per ISO/IEC 17043:2010, Reference Material Producers as per ISO 17034: 2016.

The application shall be complete in its contents and accompanied by management system document/ Quality Manual, requisite information and prescribed application fee as detailed in document NABL 100A.

The applicant CAB shall read and understand the terms and conditions for obtaining and maintaining NABL accreditation (as mentioned in document NABL 131) on the web portal and accept.

(For the CABs situated outside India, equivalent scanned copy shall be submitted).

The CAB shall ensure correctness of the information provided in the application with a special care in filling the scope of accreditation (uploading on the Web Portal). The CAB shall also submit "declaration form" as provided in the application. For any changes, the CAB shall provide the updated "declaration form" within 15 days.

The CAB is also required to specifically mention about their site testing or calibration and/or mobile facilities, if any, and scope of accreditation is also required to be specified accordingly. For more details about site testing or calibration and/or mobile facility, refer the document NABL 130 "Specific Criteria for Site Testing and Site Calibration Laboratories".

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On receipt of complete application for accreditation, an acknowledgement with a unique ID number shall be provided to the CAB.

The unique ID of the CAB will be used for further correspondence between NABL and CAB. Successful submission of application on portal (Initial acknowledgement) is not deemed as acceptance of application.

NABL reviews the information provided by the CAB to determine the suitability of the application for accreditation before acceptance and processing for accreditation. During and after scrutiny of application for its completeness in all respects, NABL may seek additional information/ clarification(s) at this stage, as deemed necessary and required for the purpose of accreditation.

Application may be rejected in case information provided in the application and Management System Document/ Quality Manual uploaded are not relevant to NABL accreditation. In case CAB has applied as per any standard other than ISO/IEC 17025, ISO 15189, ISO/IEC 17043 & ISO 17034, application can be rejected.

The application can also be rejected if the applicant CAB is found to have applied under 'First Accreditation' category (New CAB) but in actual it is an accredited CAB (validity mentioned in Accreditation Certificate not yet over) or an accredited CAB with its accreditation currently under adverse action (adverse action communicated and cooling-off period is not over/adverse action initiated but not yet completed or a New CAB but its previous application is under inactive category/closed with cooling period not over).

The application shall be rejected or assessment process terminated, if CAB has provided false information or concealed information or if there is evidence of fraudulent behavior and bringing NABL to disrepute through its activities, forcing its interest on NABL to deviate from accreditation procedure.

In all the above cases, the fee paid is non-refundable/non-transferable/non-adjustable.

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## 5. DOCUMENT REVIEW

The review of documented information (Management system document, procedure etc.) submitted by the CAB is carried out by an assessment team (one or more assessors/NABL officers). The assessment team reviews the documents and submits the report.

The names and details of the assessment team members are conveyed to the CAB for identifying any conflict-of-interest issue. NABL will consider any objection on merits and decide whether to reconstitute the assessment team. NABL decision shall be final and binding in case there is no proven conflict of interest.

*Note: The assessment team for review of documented information will be different from the assessment team deputed for assessment (Pre-assessment/ Initial Assessment).*

NABL informs CAB regarding the document review, indicating inadequacies (if any). The CAB shall review the findings and while taking the corrective actions, the CAB may decide to amend the relevant documents and/or make changes in the management system accordingly within seven days (7 days) to complete the document review process.

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## 6. ASSESSMENT

**Assessment Team:** For any type of assessment, NABL appoints an assessment team which consists of lead assessor/technical assessor(s)/Technical expert(s)/NABL officer(s)/Observer(s) depending on the type of assessment. The number of team members depends upon the applied scope for accreditation i.e., Disciplines, Groups, subgroups, product matrix.

**Assessment Duration:** The assessment is generally carried out for two days. It may vary and depends on the applied scope of accreditation (Disciplines/ Groups/ subgroups, product matrix as applicable), consideration of resources and facilities available with the CAB w.r.t. applied scope for accreditation. The duration of assessment for CABs applying under integrated assessment is five (05) days.

***In case of natural disaster, declared pandemic situation or any other emergency declared by Government of India/ State Government, the man days may vary.***

**Accreditation standard:**

International Standard	Applicable for
ISO/IEC 17025: 2017	Testing Laboratories
ISO/IEC 17025: 2017	Calibration Laboratories
ISO 15189: 2012	Medical Testing Laboratories
ISO/IEC 17043: 2010	Proficiency Testing Providers
ISO 17034: 2016	Reference Material Producers

### 6.1. Pre-assessment

Once the Document Review process is completed, a pre-assessment of the CAB may be conducted by the assessment team appointed by NABL.

Pre-assessment is optional for testing laboratories, calibration laboratories and medical testing laboratories. CAB shall express its decision (say in 2 to 5 days) in writing to opt for preassessment (or) not. However, it does not preclude the decision of NABL to conduct pre-assessment for any other situations/ reasons (if the document review does not provide confidence in the CAB's management system, recommended by assessment team/ NABL officer, etc.).

The pre-assessment of the CAB is conducted to:

- a) evaluate degree of preparedness and readiness to undergo assessment
- b) determine the number of assessors and number of days required to conduct the assessment (based on the scope of accreditation/facilities/resources/ infrastructure, etc.) in discussion with the CAB.
- c) Explain NABL procedure (including various documents), assessment process (including how the assessment will be conducted/ assessment methodology), etc.
- d) Sample audit to inform the major gaps.

The assessment team submits, a pre-assessment report to NABL with a copy to the CAB. The CAB shall take appropriate corrective actions on the findings/ gaps and submit a report to NABL within fifteen days.

## 6.2. Initial Assessment

Initial Assessment shall be conducted after completion of Pre-assessment process or Document Review Process (Where pre-assessment is not done).

NABL appoints an assessment team to conduct the assessment. Entire disciplines/groups are assessed during initial assessment. The date(s) for assessment are decided in agreement with the CAB.

The assessment team verifies CAB's implementation of the documented information and checks its compliance with the relevant international standard, specific criteria (wherever applicable) and NABL policies. The documented information (Management system document, SOPs, work instructions, test methods etc.) is assessed for their implementation and effectiveness. The CAB's technical competence to perform specific tasks is evaluated and witnessed during the assessment.

The assessment report contains the evaluation of competency (includes personnel, facilities, equipment), all relevant material examined, tests/ calibration witnessed including those of retained samples recommended scope of accreditation, compliance to relevant international standard, NABL specific criteria (wherever applicable) and NABL Policies.

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The non-conformities, if any, are reported in the assessment report. It also provides a recommendation towards grant of accreditation or otherwise.

The report prepared by the assessment team is submitted to NABL. Summary of assessment report, non-conformities (if any) and recommended scope of accreditation, are provided to the CAB at the end of the assessment visit.

In case of medical testing laboratories, all the declared Sample Collection Centres/ Facilities (SCFs) will be assessed in each accreditation cycle. This may be done along with the assessment of the laboratory or separately as the case may be.

The CAB shall take necessary corrective action on non – conformities based on root cause analysis and submit documentary evidences for taking corrective actions and implementation records to NABL within 30 days.

After 30 days, the assessment report will be reviewed by accreditation committee. However, under the following cases, the assessment report will be placed in accreditation committee at the earliest possible:

1. If no nonconformity is observed by assessment team.
2. If there is total system failure (significant failure in implementation of the accreditation standard, non-availability of the equipment/ inadequate facilities by which results are affected, etc.) or technical competence is not established for entire applied scope or fraudulent behaviour is noticed, or any other situation which may warrant denial of accreditation.

### **6.3. Surveillance assessment**

NABL conducts annual surveillance which is aimed at evaluating continued compliance to the relevant international standard, specific criteria (wherever applicable) and NABL Policies. The types of surveillance assessments are given below:

#### **6.3.1. On-Site Surveillance**

On-site surveillance is conducted for the newly accredited CABs, in the first cycle of Accreditation. It is conducted within 12 months (preferably in the 10<sup>th</sup> month) from the date of accreditation.

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### 6.3.2. Desktop Surveillance

During the second and subsequent accreditation cycles, the desktop surveillance is conducted within 12 months (preferably in the 10<sup>th</sup> month) from the date of each re-accreditation.

For laboratories accredited under integrated assessment, annual on-site surveillance is conducted in each accreditation cycle.

The desktop surveillance consists of seeking records (as per NABL 218 document) from the CAB to ascertain that the CAB continues to comply to the requirements of relevant international standard, NABL specific criteria (wherever applicable), and NABL policies.

NABL may decide to convert desktop surveillance to on-site surveillance based on feedback, complaint or in case of major deficiency observed in the submitted records.

### 6.4. Reassessment

The CAB shall apply for renewal of accreditation at least six (6) months before the expiry of accreditation to allow NABL to organize assessment of the CAB timely, so that the continuity of the accreditation status is maintained. In case application is submitted late, there could be break in accreditation cycle.

An application submitted after expiry of accreditation is not considered for renewal of accreditation. In such a case, the CAB shall apply afresh. CAB also has to apply afresh if there is change in information related to legal identity, name of the CAB, ownership, address from the previously issued Accreditation certificate. Under these situations, new CAB ID and accreditation certificate number will be allotted to the CAB.

NABL will conduct the reassessment within 24 months (preferably 20<sup>th</sup> to 22<sup>nd</sup> month from the date of grant/renewal of accreditation). The accredited CAB is subjected to re-assessment every 2 years before expiry of the validity of accreditation cycle.

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**6.5. Unannounced assessment**

NABL conducts unannounced assessment (continued compliance and effectiveness is viewed in natural state). This may also be conducted to investigate the complaint issues. Unannounced assessment report is not shared with the CAB.

If findings of any unannounced assessment indicate that the CAB no longer complies with the requirements of the relevant international standard, specific criteria (wherever applicable) and NABL policies, it shall be dealt with as per NABL 216

If findings of any unannounced assessment indicate compliance, then CAB shall be informed of continued compliance.

**6.6. Change in Name of the CAB / Legal entity / Location/ Ownership / Premises change/ Acquisition / take over / purchase / selling, merger / de-merger of CAB**

**6.6.1. Dealing with change in Name/Legal Identity**

For change in name of a CAB under the same ownership, CAB shall inform NABL within 15 days and shall apply afresh about the name change through CAB's NABL portal account and upload the relevant documents (such as legal identity / resolution etc.) and applicable fee for name change (refer NABL fee structure). In case of foreign CABs, they should inform NABL through email and proceed as per the instruction of NABL. The existing accreditation certificate will no longer be valid. **New Lab ID and new accreditation certificate number will be allotted.** The effective date of issue of certificate will be the date of approval from the competent authority and the validity of accreditation shall remain the same as that of the previous certificate. CAB shall not use NABL Symbol and / or claim NABL accreditation till the new name is approved by NABL.

*Note: In case of any change in the information contained in the accreditation certificate, CAB shall apply and NABL will issue a fresh certificate with or without assessment depending on the nature of the change, except in case of change in location, on-site assessment at the new location shall be conducted.*

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### 6.6.2. Dealing with Acquisition/ Take over/ Purchase/ Selling, Merger/ De-Merger of CAB

For any change in ownership of the existing accredited CAB due to Acquisition/ Takeover/ Purchase/ Selling, Merger/ De-merger, CAB shall inform NABL in advance. On completion of Acquisition/ Takeover/ Purchase/ Selling, Merger/ De-merger, the accredited CAB shall inform NABL within 15 days and shall apply afresh. In case of foreign CABs, they should inform NABL through email and proceed as per the instruction of NABL. The existing accreditation certificate will no longer be valid. **New Lab ID and new accreditation certificate number will be allotted.** If the new firm/company/entity/organization acquiring the CAB or merging with the accredited CAB/ de-merging of accredited CAB, desires to continue NABL accreditation. then, the new top management shall submit the declaration/documents on NABL Portal. The effective date of issue of certificate shall be the date of approval from the competent authority and the validity of accreditation shall remain the same as that of the previous certificate. CAB shall neither claim to be NABL accredited nor use NABL symbol till the further approval from NABL. Foreign CABs shall return the existing accreditation certificate in original to NABL.

If the new firm/ company / entity fails to submit the declarations / documents the accreditation status of the CAB shall be withdrawn and CAB file shall be closed by NABL.

*Note: In case of any change in the information contained in the accreditation certificate, CAB shall apply and NABL will issue a fresh certificate with or without assessment depending on the nature of the change, except in case of change in location, on-site assessment at the new location shall be conducted.*

### 6.6.3. Dealing with change in CAB's premises

For any change in premises (within the same building/ campus, within the same district) of an accredited CAB, the lab shall apply afresh, once the shifting is completed CAB shall submit the documents to NABL through NABL Portal. The existing accreditation certificate will no longer be valid. **New Lab ID and new accreditation certificate number will be allotted.** NABL shall inform CAB about the decision. In case of foreign CABs, they should inform NABL. through email and proceed as per the instruction of NABL. The effective date of issue of certificate shall be the date of approval from the competent authority and the validity of

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accreditation shall remain the same as that of the previous certificate. Foreign CABs shall return the existing accreditation certificate to NABL. CAB shall neither claim to be NABL accredited nor use NABL symbol at the new premises till decision on grant is communicated by NABL to the CAB. In case CAB shifts to premises in another district, it has to surrender the accreditation to NABL by clearing the outstanding amount, if any.

*Note: In case of any change in the information contained in the accreditation certificate, CAB shall apply and NABL will issue a fresh certificate with or without assessment depending on the nature of the change, except in case of change in location, on-site assessment at the new location shall be conducted.*

## **6.7. Change in scope of accreditation of CAB**

### **6.7.1. Extension in scope of accreditation**

CAB shall submit application for extension in scope of accreditation. Assessment shall be conducted and decision shall be communicated following the assessment process.

On grant of accreditation for the applied additional scope, NABL will issue revised scope of accreditation as amendment to the existing scope of accreditation, to include the additional scope. The effective date of scope extension will be from the date of approval by the competent authority of NABL and same will be mentioned as amendment date in the accreditation certificate/scope of accreditation. The date of expiry of the extended scope shall be the same as that of the existing accreditation certificate.

Application for extension in scope of accreditation will not be accepted at the time of scheduled assessment (Surveillance assessment and Re-assessment).

### **6.7.2. Scope reduction**

The CAB shall inform NABL through NABL Portal if the CAB wishes to voluntarily withdraw a part of the accredited scope at any stage during the valid accreditation period. In case of CABs situated outside India, the CAB shall inform NABL through email. NABL will accept the request and inform the CAB. Amended scope will be issued to the CAB.

NABL shall also reduce scope of accreditation if CAB failed to demonstrate competency, outlier in proficiency testing, outcome of complaint issues, etc. (refer NABL 216 'Procedure for dealing with adverse decisions for more details).

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**6.8. Change in test / calibration method or equipment in respect of accredited scope**

The CAB shall inform NABL through NABL portal about the change in test/calibration method or equipment. In case of CABs situated outside India, they should inform NABL through email and proceed as per the instructions of NABL. CAB shall submit evidence for competency (as per CAB's procedure) for the changes made. For example, it can be a validation record and/or calibration certificate, as relevant to the changes. The CAB shall submit a declaration by the Head of Organization that it fulfills the requirements of the relevant international standard and corresponding NABL criteria (wherever applicable) for the changes in the scope in respect of the test / calibration method or equipment. The same shall be verified in subsequent onsite assessment.

**6.9. Change (addition/deletion) in CAB's key personnel**

For any change in CAB's personnel, CAB shall inform NABL (through NABL Portal) about the change (either addition or deletion). In case of CABs situated outside India, information shall be provided through email.

CAB shall maintain all the records pertaining to the changes in personnel and their authorizations, which shall be verified by NABL during the next on-site assessment.

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## 7. ACCREDITATION DECISION-MAKING

NABL has a system of independent review for accreditation decisions through accreditation committee. Accreditation decisions are taken by Sr. Director/ Director, NABL based on the recommendations of accreditation committee, members of which are different from the assessment team which carried out the assessment. NABL always ensures that the decisions on accreditation are made by competent persons.

The Accreditation Committee is provided with adequate information, to enable them to take a decision regarding recommendation for grant, renewal, reduction, extension, suspension, or withdrawal of accreditation.

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## 8. ISSUE OF ACCREDITATION CERTIFICATE

NABL issues an accreditation certificate to the accredited CAB which has a unique number and QR Code, field, date of validity along with the scope of accreditation. The NABL accreditation certificate is valid for a period of 2 years as NABL follows a 2-year accreditation cycle for all Schemes which are covered under APAC/ILAC MRA.

The scope of accreditation for testing laboratory defines Discipline/Group, Materials or Products tested, Component, parameter or characteristic tested/ Specific Test Performed/Tests or type of tests performed, Test Method Specification against which tests are performed and/or the techniques/ equipment used.

The scope of accreditation for calibration laboratory defines Discipline/Group, Measurand or Reference Material/Type of instrument or material to be calibrated or measured/Quantity Measured/Instrument, Calibration or Measurement Method or procedure, Measurement range and additional parameters where applicable (Range and Frequency), Calibration and Measurement Capability (CMC) ( $\pm$ ).

The scope of accreditation for medical testing laboratory defines Discipline, Component, parameter or characteristic tested/ Specific Test Performed/Tests or type of tests performed, Test Method Specification against which tests are performed and/or the techniques/equipment used. The annexure to the accreditation certificate will also contain the details of Sample Collection Centres/Facilities associated.

The scope of accreditation for proficiency testing provider defines Proficiency Testing Scheme/Type of PT Item/Matrix, Measurand/Characteristic/Type of measurand/Type of characteristic/Analyte/Parameter.

The scope of accreditation for reference material producer defines Types of reference materials (Certified Reference Materials, Reference Materials or both) Category & Subcategory, Reference Material Matrix or Artefact, Property/Properties Characterized, Approach used to assign property values/Characterization Technique.

NABL issues accreditation certificate for the permanent facility. However, scope of accreditation is having all details of site testing/calibration, mobile facility (if applicable) and scope of accreditation is clearly identified for each site facility, mobile facility (whichever is applicable). Site testing/calibration are clearly identified in the scope of accreditation while issuing the certificate. The CAB shall clear all due payments to NABL. Accreditation certificate will be issued/ visible to the CAB on Portal and/or website only after clearance of all the due payments to NABL.

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## **9. MAINTAINING ACCREDITATION**

### **9.1. Conformance to Applicable standards and NABL requirements**

The accredited CABs, at all times shall conform to the requirements of relevant international standard, specific criteria (wherever applicable) and NABL Policies.

### **9.2. Terms and Conditions**

The accredited CABs are required to comply at all times with the terms and conditions of NABL given in NABL 131 'Terms & Conditions for obtaining and maintaining NABL Accreditation'. The acceptance is to be submitted through NABL web portal. The CABs situated outside India are required to submit a signed copy of NABL 131 indicating their willingness to abide by the terms and conditions given in NABL 131.

### **9.3. Modifications to the Accreditation Criteria**

If the relevant international standard, APAC, ILAC requirements and NABL documents, are modified/amended, the CAB is informed. In case, the transition period is defined by ISO/ILAC/APAC then it is to be followed by the CAB. In cases there is change in the NABL documents, the transition period of at least 6 months shall be given to align its operations. However, the transition period may be reduced depending upon the nature of the changes.

### **9.4. Adverse decision against CABs**

If CABs fails to submit corrective action within stipulated time frame, then NABL shall initiate action as per NABL 216 and subsequently accreditation shall be denied and application shall be closed. Once application is closed by NABL, then the CAB shall apply afresh with applicable fee.

If the CAB at any point of time does not conform to the applicable standards and NABL criteria; or does not maintain the NABL terms and conditions; or is not able to comply with the modified criteria, NABL may take adverse decision against the CAB like denial of accreditation, reduction in scope of accreditation, suspension of accreditation, withdrawal of accreditation (and/or leading to debar from re-applying) as appropriate. The detailed procedure regarding adverse decision is given in the document NABL 216 'Procedure for dealing with adverse decisions'.

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## 10. RIGHTS AND OBLIGATIONS OF NABL

### 10.1. Rights of NABL

- NABL requires all CABs to conform to ISO/IEC 17025: 2017 or ISO 15189: 2012 or ISO/IEC 17043: 2010 or ISO 17034: 2016 whichever is applicable and also to the NABL policy documents & relevant NABL specific criteria (wherever applicable) to seek and maintain accreditation and adapt to the changes in the requirements of accreditation.
- NABL requires that all CABs shall accept and/sign document NABL 131 'Terms and conditions for obtaining and maintaining NABL accreditation' and abide by it.
- During the application or assessment process, if there is evidence of any fraudulent activities, furnishing of false information or concealment of information, NABL shall reject the application or terminate the assessment procedure and initiate the process for adverse decision.
- NABL may also refuse provision of services to a CAB because of its antecedents, availability of proven evidence of fraudulent behaviour, falsification of information, violation of terms and conditions for Obtaining and Maintaining NABL Accreditation or deliberate violation of accreditation requirements. The refusal of services due to these reasons based upon the historical evidences is not treated as discriminatory act against any CAB.
- NABL has the right to:
  - i. effect changes in standards on which CAB accreditation is based in accordance with international norms
  - ii. prescribe additional requirements to supplement international standards as application documents/ criteria documents
  - iii. decide on policies related to accreditation in consultation with stakeholders
  - iv. appoint assessment teams
  - v. decide on implementation schedules in consultation with the CABs
  - vi. take action against CAB in accordance with the accreditation requirements
  - vii. take adverse decisions in accordance with the accreditation requirements and giving reasons for the same
  - viii. Publish accreditation status of CAB on its website/ Newsletter etc.

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## 10.2. Obligations of NABL

- The information given by CABs in application form as well as obtained during the processing of application, assessment visit and grant of accreditation will be kept confidential by NABL (unless required by law) . However, if any information of CAB is shared in public domain like accreditation status, scope of accreditation, adverse decisions, and other common information then impartiality will be maintained. When NABL is required by law or authorized by contractual arrangements to release confidential information, the CAB shall, unless prohibited by law, be notified of the information provided.
- NABL is obliged to make available information on CABs' scope of accreditation, validity dates for its certificate and contact details to users of the CABs. This information is provided on NABL website.
- NABL is obliged to provide information on Mutual Recognition Arrangement (MRA) with APAC and ILAC partners and other international arrangements. The information is provided on NABL public domain and more information can also be provided on request.
- NABL provides the CAB with information about suitable ways to obtain metrological traceability relevant to the scope for which accreditation is granted. The information is provided in the document NABL 142 'Policy on Metrological Traceability of Measurement Results'.
- NABL communicates changes to the requirements of accreditation such as ISO/ IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034, ILAC & APAC documents, NABL specific criteria (wherever applicable) documents or any other requirements through NABL website. NABL gives sufficient notice to the CABs to enable them to implement the changes and where necessary verifies implementation through assessment activities.
- NABL provides adequate mechanism to resolve/ address complaints received against its accreditation related activities and the activities of accredited CAB which fall under the ambit of accreditation (Refer NABL 132 and NABL 132A document).
- NABL provides adequate mechanism to address the appeals received from the CABs against its adverse decisions (Refer NABL 134 document).

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## 11. RIGHTS AND OBLIGATIONS OF CONFORMITY ASSESSMENT BODY (CAB)

### 11.1. Rights of CAB

- CAB is entitled to receive information related to CAB accreditation. They can access NABL website [www.nabl-india.org](http://www.nabl-india.org) which gives information necessary for NABL accreditation.
- CAB has the right that its scope of accreditation, validity dates for its accreditation certificate(s) and contact details are made available on NABL website for users of the CABs.
- CAB has the right to object to appointment of specific member(s) of assessment team by giving valid reasons.
- NABL accredited CAB has the right to use 'NABL Symbol' on the test/ calibration reports issued by it as long as the test/ calibration is included in its scope of accreditation. Detailed requirements governing use of 'NABL Symbol' and claim of accreditation have been stated in NABL 133.
- CAB has the right to appeal against any adverse decision taken against it by NABL in respect of the CAB's accreditation.
- CAB has a right to complain about the services of NABL.
- CAB has the right to access the documents published by NABL for use by CABs.

### 11.2. Obligations of the CAB

- CAB shall comply with all the requirements of relevant international standard at all times.
- An accredited CAB is obliged to fulfill requirements of NABL Specific Criteria (wherever applicable) and other applicable documents e.g. NABL 131 'Terms and conditions for maintaining NABL accreditation', NABL 133 "Policy for Use of NABL Symbol and / or Claim of Accreditation by Accredited Conformity Assessment Bodies (CAB) & NABL Accredited CAB Combined ILAC MRA Mark", NABL 142 "Policy on Metrological Traceability of Measurement Results", and NABL 163 "Policy for Participation in Proficiency Testing Activities", at all times.
- An accredited CAB is obliged to provide accurate, current/updated, and complete information as required by NABL at the time of initial application for accreditation and during subsequent stages of accreditation.
- An accredited Calibration laboratory is obliged to fulfill requirements of NABL 143 "Policy on Calibration and Measurement Capability (CMC) and

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Measurement Uncertainty in Calibration”,

- The CAB is obliged to disclose name of the consultant/ advisor at the time of applying for accreditation, wherever engaged.
- CAB must have satisfactorily (Z score < 2) participated in a proficiency testing program, as applicable, conducted by an accredited PT provider before submission of application to NABL. For more details, CABs are required to refer NABL 163 “Policy for Participation in Proficiency Testing Activities’. The satisfactory performance shall be defined in terms of z-score and En number respectively or any other internationally accepted criteria. For unsatisfactory performance, the CAB is to take corrective action and inform NABL.
- The applicant CAB must have conducted at least one internal audit (including all activities) and a management review (covering all agenda points as per the relevant standard) before the submission of application.
- The CAB is expected to provide access to all facilities/ area of the CAB where CAB’s activities are carried out and other relevant management system documents/ records to establish and evaluate the competency, continuing compliance related with relevant international standard, NABL criteria (wherever applicable) and NABL policies.
- The CAB is expected to facilitate the assessment team for carrying out assessment activities and provide necessary information including arrangement of appropriate test samples/ devices for calibration and staff to demonstrate tests/ calibrations/ PTP and RMP activities.
- An accredited CAB can claim accreditation only with respect to the scope for which it has been granted accreditation as per the details provided in NABL 133.
- An accredited CAB shall not use NABL accreditation in such a manner as to bring NABL into disrepute.
- The CAB is required to notify NABL of any change that may affect the ability of the CAB to fulfill requirements of accreditation, within 15 days. Notifiable changes include (but are not limited to): change in legal status, change in ownership, changes in organization, change in top management, change in scope, change in personnel, major change in policies, change in location, address etc.
- The CAB is required to pay necessary fees as decided by NABL from time to time.
- The CAB shall offer co-operation to NABL assessment team in carrying out

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unannounced visits as a part of compliance monitoring activity by NABL for its accredited CABs and/ or investigation of complaint issue.

- The CAB shall offer co-operation to NABL in investigating complaint issues.
- The CAB shall not indulge in fraudulent activities nor provide false information to NABL or conceal information. Such acts may result in withdrawal of accreditation.
- The CAB must also ensure that the procedures described in the Management system document and other documents are being implemented. CAB shall not, for the purpose of seeking any undue favour from the Assessment team offer any gift, whether in cash or in kind including reimbursement of any expenses incurred by Assessment team members during the course of assessment.
- The CAB should get fully acquainted with relevant NABL documents and understand the assessment procedure and methodology for filing the online application. NABL accepts online application and does not entertain any applications in hard copy (kindly refer website [www.nabl-india.org](http://www.nabl-india.org)), except for cross-frontier CABs. List of NABL documents is as below:

S. No.	Name of Document	Doc. No.
1.	Duties and Responsibilities of NABL Staff	NABL 015
2.	General Information Brochure	NABL 100A
3.	Accreditation Procedure	NABL 100B
4.	Procedure for Recognition of Sample Collection Centre/ Facility declared by Medical Laboratories (CABs)	NABL 111
5.	Specific Criteria for Accreditation of Medical Laboratories	NABL 112
6.	Guidance for Classification of Product Groups in Testing & Calibration Field	NABL 120
7.	Specific Criteria for Calibration of Medical Devices	NABL 126
8.	Procedure for Integrated Assessment & Additional Requirements of Regulatory Body (ies)/Govt agencies for Testing Laboratories	NABL 127
9.	Criteria and Procedure for NABL Medical (Entry Level) Testing Labs {NABL M(EL)T Labs} Program	NABL 128
10.	Specific Criteria for Accreditation of Calibration Laboratories (Mechanical, Fluid flow, Radiological, Electro-Technical & Thermal Calibration)	NABL 129
11.	Specific Criteria for Site Testing and Site Calibration Laboratories	NABL 130
12.	Terms & Conditions for Obtaining and Maintaining NABL Accreditation	NABL 131
13.	Procedure for Dealing with Complaints	NABL 132
14.	Procedure for Dealing with Complaints related to NABL and its activities/ services	NABL 132A
15.	Policy for Use of NABL Symbol and / or Claim of Accreditation by Accredited Conformity Assessment Bodies (CAB) & NABL Accredited CAB Combined ILAC MRA Mark	NABL 133

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16.	Procedure for Dealing with Appeals against Adverse Decisions taken by NABL	NABL 134
17.	Specific Criteria for Accreditation of Medical Imaging- Conformity Assessment Bodies	NABL 135
18.	Specific Criteria for Accreditation of Quality Assurance Agencies for Diagnostic Radiology X-ray Equipment	NABL 136
19.	Specific Criteria for Accreditation of Software & IT System testing	NABL 137
20.	Guidelines for Estimation and Expression of Uncertainty in Measurement	NABL 141
21.	Policy on Metrological Traceability of Measurement Results	NABL 142
22.	Policy on Calibration and Measurement Capability (CMC) and Measurement Uncertainty in Calibration	NABL 143
23.	Guidance on conducting Remote Assessment	NABL 144
24.	Application Form for Testing Laboratories	NABL 151
25.	Application Form for Calibration Laboratories	NABL 152
26.	Application Form for Medical Testing Laboratories	NABL 153
27.	Application Form for Integrated Assessment of Testing Laboratories	NABL 154
28.	Application Form and Checklist for NABL Medical (Entry Level) Testing labs {NABL M(EL)T Labs} Program	NABL 155
29.	Application Form for Medical Imaging- Conformity Assessment Bodies (MI-CAB)	NABL 156
30.	Application Form for Accreditation of Product Based Testing Laboratories	NABL 158
31.	Guide for Preparing a Quality Manual	NABL 160
32.	Guide for Internal Audit and Management Review for Conformity Assessment Bodies (Laboratories / PTP / RMP)	NABL 161
33.	Policy for Participation in Proficiency Testing Activities	NABL 163
34.	Guidelines for Inter-Laboratory Comparison for Calibration Laboratories where formal PT programs are not available	NABL 164
35.	Sample Calculations for Uncertainty of Measurement in Electrical Testing	NABL 174
36.	Application Form for Proficiency Testing Providers (PTP)	NABL 180
37.	Specific criteria for PT Provider Accreditation	NABL 181
38.	Pre-assessment guidelines and forms (based on ISO/IEC 17043:2010)	NABL 182
39.	Assessment forms and checklist (based on ISO/IEC 17043: 2010)	NABL183
40.	Application Form for Reference Material Producers (RMP)	NABL190
41.	Specific Criteria for Reference Material Producer Accreditation	NABL191
42.	Pre-Assessment Guidelines & Forms (based on ISO 17034:2016)	NABL192
43.	Assessment Forms and Checklist (based on ISO 17034:2016)	NABL 194
44.	Pre-Assessment Guidelines and Forms (based on ISO 15189:2012)	NABL 208
45.	Pre-Assessment Guidelines and Forms (based on ISO/IEC 17025)	NABL 209

46.	Assessor Guide	NABL 210
47.	Operational Manual for online Assessment (For Assessors)	NABL 213
48.	Procedures for Dealing with Adverse Decisions	NABL 216
49.	Assessment Forms & Checklists (based on ISO 15189: 2012)	NABL 217
50.	Desktop Surveillance	NABL 218
51.	Assessment Forms and Checklist (Based on ISO/IEC 17025:2017)	NABL 219
52.	Document Review Checklist (as per ISO/IEC 17025:2017)	NABL 220
53.	Document Review Checklist (as per ISO 15189: 2012)	NABL 220A
54.	Document Review Checklist (as per ISO/IEC 17043: 2010)	NABL 220B
55.	Document Review Checklist (as per ISO 17034: 2016)	NABL 220C
56.	Assessment Forms and Checklist (Medical Imaging- Conformity Assessment Bodies)	NABL 222
57.	Bio-data of Assessors	NABL 221
58.	Contract between NABL and Assessors	NABL 230
59.	Directory of Accredited Testing Laboratories	NABL 400
60.	Directory of Accredited Calibration Laboratories	NABL 500
61.	Directory of Accredited Medical Testing Laboratories	NABL 600
62.	Directory of Accredited PTP	NABL 700
63.	Directory of Accredited RMP	NABL 800
64.	Directory of Laboratories Recognized under NABL Medical (Entry Level) Testing Labs {NABL M(EL)T Labs} Program	NABL 900
<p><b>Note:</b> Above NABL documents can be downloaded free of cost from NABL website: <a href="http://www.nabl-india.org">www.nabl-india.org</a>. Directories of accredited CABs are updated monthly. To know the current accreditation status of CAB, the user must visit the NABL website or contact NABL (info@nabl.qcin.org).</p>		

**National Accreditation Board for Testing and Calibration Laboratories  
(NABL)**

**NABL House**

Plot No. 45, Sector 44,  
Gurugram - 122003, Haryana  
Tel. no.: 91-124-4679700 (30 lines)  
Fax: 91-124-4679799  
Website: [www.nabl-india.org](http://www.nabl-india.org)