

NABL 100



National Accreditation Board for Testing and Calibration Laboratories (NABL)

General Information Brochure

ISSUE NO.: 02
ISSUE DATE: 18-Aug-2020

AMENDMENT NO.: 01
AMENDMENT DATE: 09-Mar-2021

AMENDMENT SHEET

S. No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature CEO
1.	13, 17,	4, 4.8, 4.9	09.03.2021	Approving authority for accreditation decision-making.	Policy decision (as per 13 th MRM)	-sd-	-sd-
2.	18	4.14		Inclusion of information regarding conducting onsite surveillance during first cycle of accreditation.			
3.	25	6.8.1.1		Inclusion of information regarding use of assessment team for scope extension.	For more clarity about the process.		
4.	25	6.8.2		Information about process to be followed by NABL after getting request from CAB for voluntary withdrawal of accredited scope			
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1. ABOUT NABL

A. History of NABL

The laboratory accreditation program in India was initially setup by Department of Science & Technology, Government of India in 1982 with its name as “National Coordination of Testing & Calibration Facilities (NCTCF)” for providing accreditation services to testing & calibration laboratories. NCTCF, with the cooperation of India’s National Metrology Institute (NMI), National Physical Laboratory (NPL), provided accreditation to calibration laboratories. Subsequently in 1993, NCTCF was renamed as “National Accreditation Board for Testing and Calibration Laboratories (NABL)”.

In the year 1996, in reference to the Indian National Scheme for Quality and Conformity Assessment, vide File no.20 (8)/90 – PP&C, Department of Industrial Development, Ministry of Industry, Government of India has approved “The National Accreditation Board for Testing and calibration laboratories to be set up as a society under the Societies Registration Act. It will be fully answerable to the QCI and at the appropriate stage be brought within the fold of the society under which the QCI is set up”.

Thereafter, NABL was registered as a society on 12th August 1998 with the objective to promote, coordinate, guide, implement and maintain an accreditation system for laboratories. NABL operated as an autonomous body under the aegis of the Department of Science and Technology, Government of India.

In the year 2016, in pursuance of cabinet decision (February 1996), NABL along with the support mechanism existing under the Department of Science and Technology, Ministry of Science and Technology was transferred to the Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce and Industry and subsequently transferred to QCI (Quality Council of India) as one of its Board.

In the year 2017, NABL society regn. no. S/33451 has been merged with QCI society regn. no. S/30832.

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B. Services provided by NABL

NABL provides accreditation to:

- ✓ 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

The fields, disciplines / sub disciplines/ category and groups for which the accreditation services are offered are listed in section 2 of this document and also given in following documents:

- NABL 120: Guidance for Classification of Product Groups in Testing & Calibration Field,
- NABL 112: Specific Criteria for Accreditation of Medical Laboratories,
- NABL 180: Application Form for Proficiency Testing Providers (PTP), and
- NABL 190: Application Form for Reference Material Producers (RMP).

NABL is committed to ensure integrity of its systems and operations at all times. NABL acts impartially and avoids any conflict of interest that may compromise its ability to make impartial decisions. (Impartiality policy is available in NABL website).

NABL ensures:

- To carry out accreditation activities in a non-discriminatory manner.
- There are no constraints that might influence decision making.
- That it does not engage in any activity which could compromise its impartiality.
- That it does not provide consultancy to conformity assessment bodies, nor does it undertake any conformity assessment activities itself. It does not promote the services of any specific body.
- Fair representation of stakeholders in NABL Board.

NABL issues documents for the conformity assessment bodies, Assessors and its own use. A list of NABL documents is given in section 9.2 of this document. All NABL documents meant for the use by persons outside NABL, are available on NABL website www.nabl-india.org, free of cost.

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C. International recognition of NABL

NABL maintains linkages with the international bodies like International Laboratory Accreditation Co-operation (ILAC) and Asia Pacific Accreditation Co-operation (APAC).

NABL is a full member and a signatory to International Laboratory Accreditation Cooperation (ILAC) since 2000 (Testing ISO/IEC 17025- 2 November 2000, Calibration ISO/IEC 17025- 2 November 2000, Medical Testing ISO 15189- 2 November 2000, Proficiency Testing providers ISO/IEC 17043- 3 October 2019 and Reference Material Producers ISO 17034-22 July 2020) as well as Asia Pacific Accreditation Cooperation (APAC) Mutual Recognition Arrangements (MRA), which is based on peer evaluation. Such international arrangements facilitate acceptance of test/ calibration results between countries which MRA partners represent.

NABL accreditation is increasingly being used by Regulators and Government to ascertain the quality of products. Accredited CABs can objectively state conformance of product or service to specified requirements.

The information on ILAC and APAC Mutual Recognition Arrangements (MRAs) is available on NABL website. On request from the laboratories or their users, a copy of ILAC/ APAC MRA is provided.

In order to achieve the objective of the acceptance of test/ calibration data across the borders, NABL operates and is committed to update its accreditation system as per international norms. NABL operations conform to ISO/ IEC 17011: 2017 and ILAC/ APAC requirements.

D. NABL Milestones:

In the year 1998, NABL established its accreditation system as per the requirements of ISO/IEC Guide 58 and was following ISO/IEC Guide 25 as the criteria for accreditation of laboratories.

NABL applied to APLAC in 1999 for evaluation of its accreditation system to become signatory to the APLAC Mutual Recognition Arrangement (MRA). An APLAC peer evaluation team evaluated NABL in July 2000 and NABL became a signatory to APLAC MRA in October 2000. NABL also became a signatory to ILAC MRA in November 2000 based on its signatory status to the APLAC MRA.

NABL changed the criteria for accreditation of laboratories, from ISO/IEC Guide 25 to ISO/IEC 17025:1999, in 2001 and completed its implementation in 2003. NABL also adopted the new standard, ISO 15189:2003, as the criteria for accreditation of Medical laboratories in May 2005.

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NABL was re-evaluated by APLAC in July 2004 and the MRA was extended for another four years.

NABL established its accreditation system in accordance with the requirements of ISO/IEC 17011:2004 "Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies" and provided a self-declaration to APLAC for its compliance to ISO/IEC 17011:2004. The continuation of APLAC MRA signatory status was re-affirmed in May, 2006 at the APLAC MRA Council meeting.

NABL was again re-evaluated by APLAC in July 2008, September 2012 and then in July 2016 and the signatory status to APLAC (Now APAC) and the ILAC MRA was reaffirmed till 2020.

In the beginning, NABL was granting accreditation to laboratories for a period of 3 years with an annual on-site surveillance. During January, 2006, NABL switched over to 2-year accreditation cycle with an annual surveillance and a re-assessment every two years. The first surveillance is conducted on-site and subsequent surveillances are desktop. The desktop surveillance is based on information and data received from laboratories. All re-assessments are conducted on-site.

During the peer evaluation in 2008, NABL extended its MRA for medical laboratory accreditation program according to ISO 15189:2007. In year 2016, NABL extended its MRA for accreditation for Proficiency Testing Providers (PTP) in accordance to ISO/IEC 17043:2010 & Reference Materials Producers (RMP) in accordance to ISO Guide 34:2009.

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2. SCOPE OF NABL ACCREDITATION

NABL Accreditation is given in the following fields and disciplines/categories. The multi-disciplinary conformity assessment bodies shall have to apply in relevant discipline(s) depending upon which discipline(s) the scope belongs to.

Testing Field

- Chemical
- Biological
- Mechanical
- Electrical
- Electronics
- Fluid Flow
- Forensic
- Non-Destructive (NDT)
- Photometry
- Radiological
- Diagnostic Radiology QA Testing
- Software & IT System

Calibration Field

- Mechanical
- Electro Technical
- Fluid Flow
- Thermal
- Optical
- Medical Devices
- Radiological

Medical Field

- Clinical Biochemistry
- Clinical Pathology
- Haematology
- Microbiology & Infectious disease serology
- Histopathology
- Cytopathology
- Flow Cytometry
- Cytogenetics
- Molecular Testing

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Proficiency Testing Providers (PTP)

- Testing
- Calibration
- Medical
- Inspection

Reference Material Producers (RMP)

- Chemical Composition
- Biological & Clinical Properties
- Physical Properties
- Engineering Properties
- Miscellaneous Properties

Medical Imaging- Conformity Assessment Bodies (MI-CAB)

- Projectional Radiography & Fluoroscopy
 - a. X-Ray, Bone Densitometry (DEXA), Dental X-Ray-OPG, Mammography etc.
 - b. Fluoroscopy
- Computed Tomography (CT)
- Magnetic Resonance Imaging (MRI)
- Ultrasound and Colour Doppler
- Nuclear Medicine
 - a. SPECT
 - b. PET CT
 - c. PET MRI
- *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*

For detailed information on classification of groups, following documents are to be referred:

- NABL 120: Guidance for Classification of Product Groups in Testing & Calibration Field,
- NABL 112: Specific Criteria for Accreditation of Medical Laboratories,
- NABL 180: Application Form for Proficiency Testing Providers (PTP), and
- NABL 190: Application Form for Reference Material Producers (RMP).

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3. ACCREDITATION TERMINOLOGY

3.1. Accreditation

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

NABL accredits Conformity Assessment Bodies {Testing Laboratories, Calibration Laboratories, Medical Testing Laboratories, Proficiency Testing Provider (PTP) and Reference Material Producers (RMP)} based on the results of independent assessment carried out for verifying competence for a specific scope as applied for by the CABs. These assessments are carried out against the relevant international standards, ISO/IEC 17025, ISO15189, ISO/IEC 17043 and ISO 17034.

3.2. Accreditation Body

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

NABL was originally set up under Department of Science and Technology, Ministry of Science and Technology in 1988 and it derived its authority from the Government having been set up under the Government Ministry.

Subsequently, since its merger with Quality Council of India (QCI) in 2016, NABL as a constituent board of Quality Council of India derives its authority from Government and industry bodies who are joint founders of QCI and signatories to its MOA. .

3.3. Conformity Assessment Body

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

Conformity Assessment Bodies are:

- Testing Laboratories,
- Calibration Laboratories,
- Medical Testing Laboratories,
- Proficiency Testing Providers, and
- Reference Material Producers

3.4. Scope of Accreditation

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

Conformity assessment Bodies can apply for accreditation for the activities they are performing and which are within the scope of accreditation activities of NABL (e.g. Testing laboratories can apply for accreditation for the test and test method). After evaluation, NABL will grant accreditation for specific scope of accreditation to Conformity assessment Bodies.

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3.5. Accreditation Scheme

Rules and processes relating to the accreditation of conformity assessment bodies to which the same requirements apply (as per 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

3.6. Accreditation Process

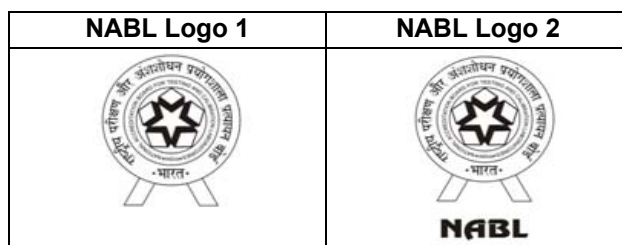
Activities from application through to granting and maintenance of accreditation as defined in the accreditation scheme (as per ISO/IEC 17011: 2017)

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

3.7. Accreditation Body Logo

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

NABL uses two types of Logo. Both logos can be used by NABL only. The CABs, accredited or otherwise do not have legal right to use the NABL Logo.








3.8. Accreditation Symbol

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

NABL Accredited Conformity Assessment Bodies are formally authorized to use NABL symbol on the basis of accreditation granted to them. 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.

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<i>NABL Symbol for Testing Laboratories</i>	<i>NABL Symbol for Calibration Laboratories</i>	<i>NABL Symbol for Medical Testing Laboratories</i>
 TC- XXXX	 CC- XXXX	 MC- XXXX

<i>NABL Symbol for Proficiency Testing Providers</i>	<i>NABL Symbol for Reference Material Producers</i>
 PC- XXXX	 RC- XXXX

3.9. Complaint

Expression of dissatisfaction, other than appeal, by any person or organization, to an accreditation body, relating to the activities of that accreditation body or of an accredited conformity assessment body, where a response is expected (as per ISO/IEC 17011: 2017)

NABL is open to receiving complaints against its accreditation related activities and the activities of accredited CABs which fall under the ambit of NABL accreditation. The details are provided in NABL 132 'Procedure for Dealing with Complaints'.

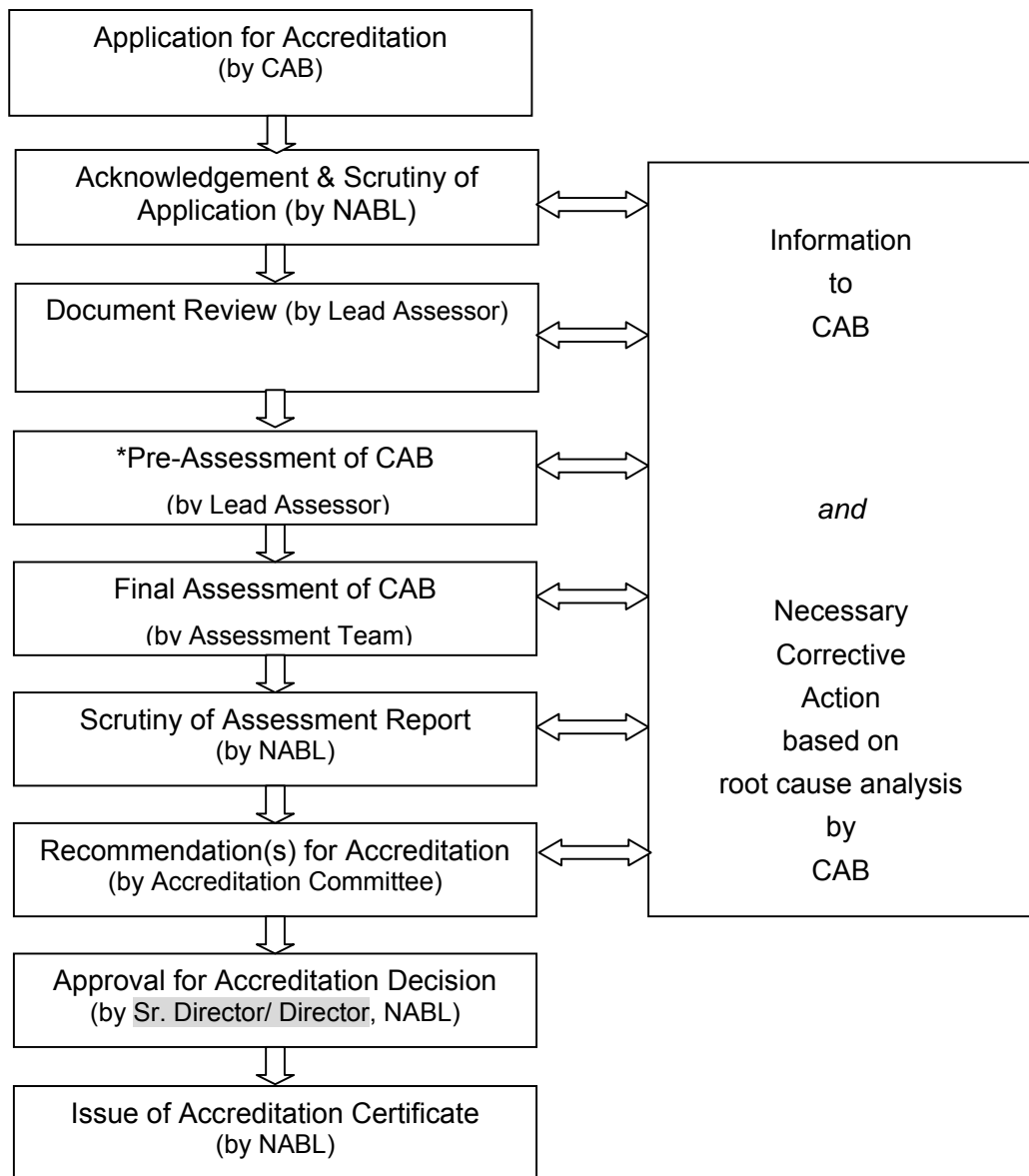
3.10. Appeal

Request by a conformity assessment body for reconsideration of any adverse accreditation decision related to its desired accreditation status (as per ISO/IEC 17011: 2017)

NABL is open to receiving appeal from the CABs against its adverse decisions such as closure of application, denial of accreditation, reduction of scope of accreditation, suspension/ withdrawal of accreditation etc. The details are provided in NABL 134 'Procedure for Dealing with Appeals against Adverse Decisions Taken by NABL'.

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4. ACCREDITATION PROCESS



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

Flow Diagram of Accreditation Process

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4.1. Application for Accreditation

CABs are required to apply through NABL Web Portal ('Apply Now' option on website www.nabl-india.org) to NABL in prescribed application form (NABL 151, NABL 152, NABL 153) for Testing laboratories, Calibration laboratories or Medical laboratories respectively along with associated Sample Collection Centre/ Facilities (SCF). The applicant laboratory should describe the management system in accordance with ISO/IEC 17025: 2017 or ISO 15189: 2012. The application fees shall be accompanied with prescribed application fee as detailed in NABL 100.

CABs seeking accreditation for Medical Imaging- Conformity Assessment Body (MI-CAB) as per ISO 15189: 2012, are required to apply in the prescribed application form NABL 156.

CABs are required to apply through NABL Web Portal ('Apply Now' option on website www.nabl-india.org) in the prescribed application form (NABL 180 and NABL 190) for Proficiency Testing Providers & Reference Material Producers which should describe the management system in accordance with ISO/IEC 17043: 2010 or ISO 17034: 2016 whichever is applicable. The application shall be accompanied with prescribed application fee as detailed in NABL 100.

CAB has to accept the terms and conditions for obtaining and maintaining NABL accreditation (as mentioned in NABL 131) on the web portal. Foreign CABs are required to submit signed copy of NABL 131 along with the application.

CAB has to take special care in filling the scope of accreditation/ uploading on the Web Portal for which the CAB wishes to apply. In case, the CAB finds any clause (in part or full) not applicable to the CAB, it is expected to furnish the reasons.

If particular scope is not covered under NABL scope of accreditation, then CAB may approach NABL (info@nabl.qcin.org).

4.2. Acknowledgement and Registration of Application

On receipt of online application form along with Management system document / quality manual and the applicable fees, an acknowledgement with a unique ID number is sent to the CAB. The unique ID of the CAB will be used for further correspondence with the CAB. After scrutiny of application for its completeness in all respects, NABL may ask for additional information/ clarification(s) at this stage, if found necessary.

Note: Application may be rejected in case information provided in the application and Management System Document/ Quality Manual uploaded are not relevant to NABL accreditation. Application can also be rejected if the CAB is found to have applied as a fresh CAB, but is under adverse action (validity mentioned in Accreditation Certificate not yet over /

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inactive in case of applicant CABs). In case CAB has applied as per any other standard, application can be rejected. Application may also be rejected if CAB has provided false information

4.3. Appointment of Lead Assessor

NABL appoints a Lead assessor from the list of empanelled assessors. The lead assessor reviews the documents on behalf of NABL and submits the report to NABL.

4.4. Document Review

The preliminary document review of the application and management system document/ quality manual submitted by the CAB is carried out by NABL whereas the detailed review is carried out by Lead Assessor.

The lead assessor informs NABL regarding the document review, indicating inadequacies (if any). The CAB amends the relevant documents and make changes in the management system accordingly within seven days.

4.5. Pre-Assessment

In case there are no inadequacies in the document review or after satisfactory corrective action by the CAB, a pre-assessment of the CAB is conducted by lead assessor appointed by NABL. Since Pre-assessment is optional (for testing laboratories, calibration laboratories and medical testing laboratories), CAB shall express its willingness in writing to undergo the same within two days. The CAB must ensure their preparedness by carrying out an internal audit and a management review before pre-assessment.

The pre-assessment of the CAB is conducted to:

- a) evaluate quality management system.
- b) assess the degree of preparedness of the CAB for the assessment
- c) determine the number of assessors required in various fields based on the scope of accreditation, number of key locations to be visited etc.

The lead assessor submits a pre-assessment report to NABL with a copy to the CAB. The CAB takes corrective actions on the non-conformities raised on the documented management system and its implementation and submits a report to NABL within fifteen days.

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4.6. Assessment

After the CAB has taken satisfactory corrective actions based on root cause analysis, NABL proposes constitution of an assessment team. The date(s) for assessment are decided in agreement with the CAB. The assessment team includes the lead assessor (generally the one who had conducted the pre-assessment), the technical assessor(s)/ expert(s) in order to cover the scope for which the accreditation has been sought. The number of technical assessor(s)/ expert(s) depend upon the type of assessment (e.g. Final assessment, Renewal assessment) and applied scope for accreditation. To evaluate conformity assessment body as per applicable international standard and to check compliance w.r.t. NABL policies etc., the assessment will be generally carried out for two days (the duration for integrated assessment is 05 days). However, NABL may enhance number of days based on workload.

NABL may also nominate an observer. NABL seeks CAB's acceptance for the proposed assessment team & date(s). The CAB may not accept one or more members of the proposed assessment team by giving specific valid reason(s) for their non -acceptance. However, final decision on assessment team is taken by NABL.

The assessment team verify CAB's documented management system and check its compliance with the requirements of ISO/IEC 17025: 2017 or ISO 15189: 2012 or ISO/IEC 17043: 2010 or ISO 17034: 2016 whichever is applicable and relevant specific criteria (wherever applicable) and other NABL policies. The documented Management system, SOPs, work instructions, test methods etc. are assessed for their implementation and effectiveness. The CAB's technical competence to perform specific tasks is also evaluated.

The assessment report contains the evaluation of technical personnel, all relevant material examined, test witnessed including those of replicate testing/ measurement, recommended scope of accreditation, compliance to ISO/IEC 17025: 2017 or ISO 15189: 2012 or ISO/IEC 17043: 2010 or ISO 17034: 2016 whichever is applicable and relevant NABL specific criteria. The non-conformities, if identified, 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 sent to NABL. However, a copy of summary of assessment report and copies of non-conformities if any, are provided to the CAB at the end of the assessment visit.

Note: During assessment, if CAB fails to demonstrate competence for applied scope of accreditation due to any reason then it will be constructed as falsification of information. Therefore, CABs are required to apply for the scope for which they have competence in all respect (personal, facilities, procedures etc.).

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Assessment of each declared Sample Collection Centre/ Facility (SCF) of a medical testing laboratory will be done in each accreditation cycle. This may be done along with assessment of the laboratory or separately as the case may be.

4.7. Scrutiny of Assessment Report

The assessment report is examined by NABL and follow up action as required is initiated. CAB has to take necessary corrective action on non - conformities/ concerns based on root cause analysis and submit a report along with evidence to NABL within 30 days. NABL monitors the progress of closure of non -conformities.

If any non-conformity is observed during the assessment of a Sample Collection Centre/ facility (SCF), the laboratory shall be asked to take corrective actions within 30 days. In case the laboratory fails to take corrective actions or there is a consistent system failure, an appropriate and proportionate action against the laboratory will be taken.

4.8. Review of Assessment Report

After the submission of corrective action(s) by the CAB, the assessment report along with corrective actions is reviewed by the Accreditation Committee. In case the Accreditation Committee finds deficiencies in the assessment report, NABL obtains clarification from the Lead Assessor/ Assessor/ CAB concerned. In case everything is in order, the Accreditation Committee makes appropriate recommendations regarding accreditation of the CAB to the Sr. Director/ Director, NABL. Based on review of assessment report, accreditation committee may also make other recommendations (denial of accreditation, verification assessment etc.) to Sr. Director/ Director, NABL.

4.9. Accreditation Decision-Making

Sr. Director/ Director, NABL is the approving authority for all accreditation related decision making.

4.10. Issue of Accreditation Certificate

When the recommendation results in the grant of accreditation, NABL issues an accreditation certificate which has a unique number and QR Code, field, date of validity along with the scope of accreditation.

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.

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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 recognized 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.

For site laboratory, tests/ calibrations performed at site are clearly identified in the scope of accreditation while issuing the certificate.

The applicant CAB must make all payments due to NABL, before the accreditation certificate is issued to it. Accreditation certificate will be visible to the CAB on Portal and/or website only once CAB will pay the Annual Accreditation Fee, generated after issue of accreditation certificate from NABL.

4.11. Maintaining Accreditation

4.11.1. Conformance to Applicable standards and NABL requirements

The accredited CABs at all times shall conform to the requirements of ISO/IEC 17025: 2017 or ISO 15189: 2012 or ISO/IEC 17043: 2010 or ISO 17034: 2016 whichever is applicable and relevant specific criteria (wherever applicable) and NABL Policies.

4.11.2. Terms and Conditions

The accredited CABs are required to comply at all times with the terms and conditions of NABL

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given in NABL 131 'Terms & Conditions for obtaining and maintaining NABL Accreditation'. The acceptance is to be given through NABL web portal. The foreign CABs are required to submit a signed copy of NABL 131 indicating their willingness to abide by the terms and conditions given in NABL 131.

4.12. Modifications to the Accreditation Criteria

If the accreditation criteria are modified by ISO/ ILAC/ APAC/ NABL, the CAB is informed of this, giving a transition period of at least 6 months to align its operations in accordance with the modified criteria and NABL verify the same through assessment.

4.13. Adverse decision against the CABs

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 align itself to the modified criteria, NABL may take adverse decision against the CAB like denial of accreditation, reduction of scope of accreditation, suspension of accreditation, withdrawal of accreditation or debar from re-applying. NABL 216 'Procedure for dealing with adverse decisions' gives the details.

4.14. Surveillance and Reassessment

NABL applies an assessment programme comprising of annual surveillance during each accreditation cycle of 2 years. At the end of the accreditation cycle, an on-site reassessment is conducted covering the entire scope of accreditation. The NABL accreditation certificate is valid for a period of 2 years. NABL conducts annual Surveillance which is aimed at evaluating continued compliance with ISO/IEC 17025: 2017 or ISO 15189: 2012 or ISO/IEC 17043: 2010 or ISO 17034: 2016 whichever is applicable and relevant NABL specific criteria (wherever applicable) and Policies. The types of assessments are given below:

4.14.1. On-Site Surveillance

For the newly accredited CABs, in the first cycle of Accreditation, NABL conducts an on-site surveillance within 12 months from the date of accreditation. The entire scope is covered in this assessment.

4.14.2. Desktop Surveillance

The desktop surveillance consists of calling of records from the CAB to ascertain that the CAB continues to maintain the requirements of ISO/IEC 17025: 2005 or ISO/IEC 17025: 2017 or ISO 15189: 2012 or ISO/IEC 17043: 2010 or ISO 17034: 2016 whichever are applicable and relevant NABL specific criteria (wherever applicable). From the second cycle onwards, the CAB is subjected to desktop surveillance within 12 months of each re-accreditation.

4.14.3. Reassessment

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The accredited CAB is subjected to re-assessment every 2 years. The CAB has to apply 6 months before the expiry of accreditation to allow NABL to organize assessment of the CAB, so that the continuity of the accreditation status is maintained. Application submitted after expiry are not considered for renewal of accreditation. In such a case, the CAB has to apply afresh.

The renewal application is to be submitted in the prescribed form (NABL 151/ NABL 152/ NABL 153/ NABL180/ NABL190) in NABL web portal along with copy of Management System document which describes the latest management system in accordance with ISO/IEC 17025: 2017 or ISO 15189: 2012 or ISO/IEC 17043: 2010, ISO 17034: 2016 whichever is applicable.

The application is to be submitted along with the prescribed fee, as detailed in the NABL 100. The CAB may request extension to the scope of accreditation, which should explicitly be mentioned in the application form. However, Premises Change and/ or Name change will not be considered during Renewal Application. CAB needs to apply for Premises Change and/ or Name change separately.

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5. INTEGRATED ASSESSMENT OF TESTING LABORATORIES BY NABL & REGULATORY BODIES

Integrated assessment is a unified approach to have a common assessment of laboratories for NABL & Regulatory Body (ies) such as Export Inspection Council (EIC), Agricultural and Processed Food Products Export Development Authority (APEDA), Indian Oilseeds and Produce Export Promotion Council (IOPEPC), other commodity board (s) under the ambit of Department of Commerce, Govt. of India and Food Safety & Standards Authority of India (FSSAI) under Ministry of Health & Family Welfare, Govt. of India. This integrated approach will ease laboratories in getting accredited by NABL in conjunction with the recognition/ approval by the concerned Regulatory Body (ies) through a single assessment/ application.

Laboratories applying towards Accreditation and Recognition/Approval by NABL & Regulatory Body (ies) under Integrated Assessment shall apply for all the parameters under applied commodity/ product group as specified by the respective Regulatory Body (ies), in the prescribed Application form; NABL 154, which is available on NABL website. Application with partial scope for product/ matrix shall not be accepted and Recognition/ Approval for partial scope shall not be granted to the laboratories.

Following are the prerequisites:

- The requirements of NABL & the Additional requirements of the relevant Regulatory Body (ies) shall be fulfilled by the laboratories seeking Accreditation/ Recognition/ Approval through single integrated assessment.
- Additional Requirements of Regulatory Body (ies) such as. EIC, APEDA, IOPEPC, other Commodity Board(s) and FSSAI as defined in NABL 127: Procedure for Integrated Assessment & Additional Requirements of Regulatory Body (ies) for testing laboratories, shall also be complied with, by the testing laboratories.
- Applicant/ accredited laboratories shall also comply with the requirements of PT participation of concerned Regulatory Body as defined in NABL 127: Procedure for Integrated Assessment & Additional Requirements of Regulatory Body (ies) for testing laboratories, for Integrated Assessment.
- The duration of assessment shall be normally of 5 days depending upon the scope applied. The assessment will cover compliance to ISO/IEC 17025, importing countries' requirements, sampling and relevant additional requirement of EIC/ APEDA/ IOPEPC/ other Commodity Boards and FSSAI.
- Minimum one assessor per discipline shall be appointed for assessment and an expert to assess the Sampling activity will also accompany the assessment team wherever applicable.

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- Accreditation and Recognition/ Approval of testing laboratories through integrated assessment, shall be subject to the annual on-site surveillance visits to verify the continued compliance to the said requirements.
- In case NABL or other authorities (who have granted approval under integrated assessment) receive any complaint about any recognized/ accredited/ approved laboratory, a team comprising of NABL, respective regulatory authority and any other technical expert as deemed fit may be constituted and joint investigation may be carried out. In case, serious violations and / fraudulent activities are observed, then action including suspension or withdrawal of accreditation and Recognition and (or) approval shall be taken.
- All the test reports issued for the accredited scope under Integrated Assessment shall bear NABL symbol in line with *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'*,

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6. OTHER ACTIVITIES DURING THE ACCREDITATION CYCLE (TWO YEARS)

6.1. Dealing with change in Name / Legal Identity

For change in name of a CAB under the same ownership, CAB shall inform NABL 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. If the documents are found satisfactory, NABL will issue the accreditation certificate with new name but with same accreditation certificate number. 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 neither claim to be NABL accredited nor use NABL symbol till the new name is approved by NABL.

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. In case of foreign CABs, they should inform NABL through email and proceed as per the instruction of NABL. 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. If the documents submitted by CAB are found satisfactory. NABL shall issue the accreditation certificate as the case may be. 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.

If the new firm/ company / entity desires to get their CAB accredited by NABL; they may apply afresh. In such cases, NABL shall process the application as a fresh application.

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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 shall inform in writing to NABL in advance about its planning to do so. Once the shifting is completed CAB shall submit the documents to NABL through NABL Portal and 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. If the documents are found satisfactory, NABL shall issue the new accreditation certificate as the case may be with same accreditation certificate number. 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. 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. After acceptance of the request of the CAB by NABL, CAB can apply afresh and will be allotted a new registration ID. CAB shall neither claim to be NABL accredited nor use NABL symbol till change in premise is approved by NABL.

6.4. Dealing with Change in test / calibration method or equipment in respect of accredited scope

CAB shall inform NABL through NABL portal about the change in test / calibration method or equipment. In case of foreign CABs, they should inform NABL through email and proceed as per the instructions of NABL. CAB to submit evidence in the form of records or competence report (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. CAB to submit a declaration by the Head of Organisation that the laboratory complies with the changes for scope in respect of the test / calibration method or equipment and fulfils the requirements of the relevant International Standard (ISO/IEC 17025 or ISO 15189) and corresponding NABL criteria.

6.5. Dealing in CAB's key personnel other than person(s) who are responsible to report, review and authorization of results

For any change in CAB's key personnel other than person(s) who are responsible to report, review and authorize the results, CAB shall inform NABL through NABL Portal about the change (either addition or deletion). In case of foreign CABs, they should inform NABL through email and proceed as per the instructions of NABL. CAB shall maintain all the records pertaining to the changes in persons and their authorizations, which shall be verified by NABL during the next on-site assessment.

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6.6. Change in person to report, review and authorize the results

6.6.1. Addition of CAB personnel for report, review, and authorizing the results CAB

For any addition of CAB personnel for review, report and authorizing the results CAB shall inform NABL through NABL Portal and submit detailed bio-data/CV of the person and applicable existing fees. In case of foreign CABs, they should inform NABL through email and proceed as per the instruction of NABL. CAB to provide recommendations of new persons from existing NABL accepted personnel who report, review and authorize results. If there are no existing NABL accepted personnel for the particular scope, then the CAB to submit a competence evaluation/ authorization report (as per lab procedure) of the person's competence. CAB to submit a declaration by the Head of organization that the person proposed meets the qualification and experience requirements for the scope as per the relevant International Standard (ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034) and NABL criteria.

6.6.2. Deletion of CAB personnel for review, report and authorizing the results CAB

For any deletion of CAB personnel for review, report and authorizing the results CAB shall inform NABL through NABL Portal. In case of foreign CABs, they should inform NABL through email and proceed as per the instruction of NABL. In case of availability of another full-time person to review, report and authorize the results, NABL will send acceptance (of the request of deletion of person) to CAB. NABL may reject the request if there is no alternate full-time person to review, report and authorize the result in a particular scope and will inform the CAB about not using NABL symbol in the intervening period for the relevant scope till another person is accepted by NABL.

6.7. Change in address without change in premises

Procedure is mentioned under s.no. 6.3 of this document.

6.8. Change in CAB's scope

6.8.1. Scope extension

6.8.1.1. Scope extension while CAB holds a valid accreditation certificate

CAB at any time while holding valid accredited certificate may apply for extension of scope. The extension of scope may add test(s) / calibration(s) / PTP / RMP Scope to existing accredited group(s) or add new group(s) to the existing discipline (s) or add a new discipline(s) and/ or field(s). In case of foreign CABs, they should inform NABL through email and proceed as per the instruction of NABL. CABs are required to apply to NABL through NABL Web Portal in prescribed format [NABL 151 – Application Form for Testing Laboratories, NABL 152 – Application Form for Calibration Laboratories, NABL 153 – Application Form for Medical Testing Laboratories, NABL

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180 – Application for Proficiency Testing Providers (PTP), NABL 190 – Application form for Reference Material Producers Accreditation (RMP). NABL will organize a supplementary visit by deputing assessment team (lead assessor/ technical assessor/ expert or any combination thereof) in consultation with the CAB to assess the competence of the CAB for the scope extension. 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 extension of the scope. The effective date of scope extension is the approval date of competent authority of NABL and same will be mentioned as amendment date in the accreditation certificate. The date of expiry of the extended scope will be the same as of the existing certificate.

6.8.1.2. Scope extension during re-assessment

CAB can apply for extension of scope along with application for renewal of accreditation to NABL through NABL Web Portal in prescribed format [NABL 151 – Application Form for Testing Laboratories, NABL 152 – Application Form for Calibration Laboratories, NABL 153 – Application Form for Medical Testing Laboratories, NABL 180 – Application for Proficiency Testing Providers (PTP), NABL 190 – Application form for Reference Material Producers Accreditation (RMP)]. In case the lab does not apply for scope requiring extension at the time of renewal of accreditation and requests for any scope extension at the time of on-site assessment, the same will not be considered. In case of foreign CABs, they should inform NABL through email and proceed as per the instruction of NABL.

6.8.2. Scope reduction

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

For cases where scope reduction is done as a result of adverse action, please refer clause 4.3 of NABL 216 'Procedure for dealing with adverse decisions. Re-enrolment procedure is also mentioned therein.

Note: Applications received after expiry of previous accreditation certificate will not be considered for renewal of accreditation. CAB has to apply afresh.

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7. COMPLAINTS

NABL is open to receive complaint against its accreditation related activities and the activities of accredited CAB which falls under the ambit of accreditation. The details are provided in NABL 132 'Procedure for Dealing with Complaints'.

Complaint Handling Process:

- a) All complaints shall undergo initial scrutiny to determine whether they fall within the ambit of NABL accreditation activities and whether they are valid, based on which any of the following action shall be taken.
- b) In case the issue pertains to the services availed by CAB customer from the CAB, the same will be forwarded to the CAB for redressal.
- c) If a complaint is outside the ambit of NABL accreditation activities, the complainant shall be informed accordingly.
- d) If information provided in the complaint is inadequate for any follow-up and the complainant is not able to provide minimum required information; the complainant will be informed accordingly and no further action would be taken.
- e) If the complaint appears to be valid, and the initial information provided is sufficient for initial investigation; the same shall be taken up for further action.
- f) The complainant will be acknowledged with unique complaint ID.
- g) The Complaint Cell will collect information and analyze the findings and accordingly initiate process for adverse action, if the issues are found to be valid.
- h) NABL will issue a show cause notice to the CAB before taking any adverse action. The CAB will be given an opportunity to send a representative (from staff only) for personal hearing to respond to the show cause notice given for initiating adverse action. If the CAB is suspended/debarred, the procedure as per NABL 216 has to be followed for re-enrollment.
- i) Investigation and decision on complaints will not result in any discriminatory actions against the complainant (person who has made the complaint).
- j) The complainant will be informed about the action taken by NABL.

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8. APPEALS

NABL is open to receive appeal from the CABs against its adverse decisions. The decisions against which appeals are entertained relate to denial of accreditation, reduction of scope of accreditation or suspension of accreditation, withdrawal of accreditation and debar from re-applying. The details are provided in NABL 134 'Procedure for Dealing with Appeals against Adverse Decisions Taken by NABL'.

Appeals Handling Process:

- a) Appeal shall be made to CEO, NABL in writing, within 30 days from the date of adverse decision against the CAB concerned.
- b) Appeals team shall send acknowledgement of receipt of appeal to CAB.
- c) At any time during the review, the appellant may withdraw the appeal in writing. However, if for any reason, an appeal is withdrawn, a future appeal on the same grounds shall not be considered.
- d) An opportunity will be given to the appellant to present the appeal in person during the process of hearing of appeal. However, the appellant shall depute representative(s) from its staff only.
- e) After examination of the appeal, the Appeals committee may seek clarifications and information from all appropriate sources.
- f) Where available assessment report / data is not sufficient to take a decision; the Appeals Committee may recommend an onsite verification, which shall be organized by the concerned Officer/ Appeals team. It shall be ensured that the same assessors who had assessed the CAB in the earlier assessment or any person who was involved in the adverse decision or appeal committee member shall not be a part of the assessment team. The appellant shall bear the expenses for on-site visit, regardless of the outcome of the appeal.
- g) Based on the data gathered through any of the above stated means, the Appeal Committee shall make the final recommendations within a reasonable time. Chairman, NABL, is the final authority for making a decision on the appeals.
- h) Approval of decision on appeal by Chairman, NABL shall be final and the CAB shall be informed accordingly. Appeals team shall also inform the concerned officer of that particular CAB regarding the outcome of appeal.
- i) No further appeal in this regard will be considered.
- j) Investigation and decision on appeals will not result in any discriminatory actions against the appellant (person who has made the appeal).

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9. RIGHTS AND OBLIGATIONS OF CONFORMITY ASSESSMENT BODIES (CABs)

9.1. Rights of CABs

- CABs are entitled to receive information related to CAB accreditation. They can access NABL website www.nabl-india.org which gives information necessary for NABL accreditation.
- CABs has 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 the right to access the documents published by NABL for use by CABs.

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9.2. Obligations of the CABs

- Conformity Assessment Body must comply with all the requirements of ISO/IEC 17025: 2017 or ISO 15189: 2012 or ISO/IEC 17043: 2010 or ISO 17034: 2016, whichever is applicable.
- An accredited CAB is obliged to fulfill requirements of NABL Specific Criteria (wherever applicable) and NABL 131 'Terms and conditions for maintaining NABL accreditation', at all times.
- The CAB is obliged to disclose name of the consultant/ advisor; if applicable, at the time of applying for accreditation.
- Conformity Assessment Body 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 Conformity Assessment Body must have conducted at least one internal audit {including all activities and location(s)} 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 premises where key activities (policy formulation, process and/ or procedure development and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessments) of CAB are performed and provide access to all relevant information, documents and records necessary to assess CAB's compliance to the relevant criteria, standards and NABL 131.
- The CAB is expected to facilitate work of the assessment team by providing necessary amenities 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, and 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 key personnel and person declared by CAB to review, report and authorize the results, major change in policies, change in locations, address etc.
- The CAB is required to pay necessary fees as decided by NABL from time to time.
- CAB shall offer co-operation to NABL assessment team in carrying out unannounced visit as a part of compliance monitoring activity by NABL for its accredited CABs.
- CAB shall not indulge in fraudulent activities nor provide false information to NABL or

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conceal information.

- Conformity Assessment Body must also ensure that the procedures described in the Management system document/ quality manual and other documents are being implemented.
- Conformity Assessment Body 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), except for foreign CABs. List of NABL documents are mentioned below:

S. No.	Name of Document	Doc. No.
1.	General Information Brochure	NABL 100
2.	Procedure for Recognition of Sample Collection Centre/ Facility declared by Medical Laboratories (CABs)	NABL 111
3.	Specific Criteria for Accreditation of Medical Laboratories	NABL 112
4.	Guidance for Classification of Product Groups in Testing & Calibration Field	NABL 120
5.	Specific Criteria for Calibration of Medical Devices	NABL 126
6.	Procedure for Integrated Assessment & Additional Requirements of Regulatory Body (ies) for Testing Laboratories	NABL 127
7.	Specific Criteria for Accreditation of Calibration Laboratories (Mechanical, Fluid flow, Radiological, Electro-Technical & Thermal Calibration)	NABL 129
8.	Specific Criteria for Site Testing and Site Calibration Laboratories	NABL 130
9.	Terms & Conditions for Obtaining and Maintaining NABL Accreditation	NABL 131
10.	Procedure for Dealing with Complaints	NABL 132
11.	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
12.	Procedure for Dealing with Appeals against Adverse Decisions taken by NABL	NABL 134
13.	Specific Criteria for Accreditation of Medical Imaging- Conformity Assessment Bodies	NABL 135
14.	Specific Criteria for Accreditation of Quality Assurance Agencies for Diagnostic Radiology X-ray Equipment	NABL 136
15.	Specific Criteria for Accreditation of Software & IT System testing	NABL 137
16.	Guidelines for Estimation and Expression of Uncertainty in Measurement	NABL 141
17.	Policy on Traceability of Measurement Results	NABL 142
18.	Policy on Calibration and Measurement Capability (CMC) and Uncertainty in Calibration	NABL 143
19.	Application Form for Testing Laboratories	NABL 151
20.	Application Form for Calibration Laboratories	NABL 152

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S. No.	Name of Document	Doc. No.
21.	Application Form for Medical Testing Laboratories	NABL 153
22.	Application Form for Integrated Assessment of Testing Laboratories	NABL 154
23.	Application Form for Medical Imaging- Conformity Assessment Bodies (MI-CAB)	NABL 156
24.	Guide for Preparing a Quality Manual	NABL 160
25.	Guide for Internal Audit and Management Review for Conformity Assessment Bodies (Laboratories / PTP / RMP)	NABL 161
26.	Policy for Participation in Proficiency Testing Activities	NABL 163
27.	Guidelines for Inter-Laboratory Comparison for Calibration Laboratories where formal PT programs are not available	NABL 164
28.	Sample Calculations for Uncertainty of Measurement in Electrical Testing	NABL 174
29.	Application Form for Proficiency Testing Providers (PTP)	NABL 180
30.	Specific criteria for PT Provider Accreditation	NABL 181
31.	Pre-assessment guidelines and forms (based on ISO/IEC 17043:2010)	NABL 182
32.	Assessment forms and checklist (based on ISO/IEC 17043:2010)	NABL183
33.	Application Form for Reference Material Producers (RMP)	NABL190
34.	Specific Criteria for Reference Material Producer Accreditation	NABL191
35.	Pre-Assessment Guidelines & Forms (based on ISO 17034:2016)	NABL192
36.	Assessment Forms and Checklist (based on ISO 17034:2016)	NABL 194
37.	Pre-Assessment Guidelines and Forms (based on ISO 15189:2012)	NABL 208
38.	Pre-Assessment Guidelines and Forms (based on ISO/IEC 17025)	NABL 209
39.	Assessor Guide	NABL 210
40.	Operational Manual for online Assessment (For Assessors)	NABL 213
41.	Procedures for Dealing with Adverse Decisions	NABL 216
42.	Assessment Forms & Checklists (based on ISO 15189: 2012)	NABL 217
43.	Desktop Surveillance	NABL 218
44.	Assessment Forms and Checklist (Based on ISO/IEC 17025:2017)	NABL 219
45.	Document Review Checklist (as per ISO/IEC 17025:2017)	NABL 220
46.	Assessment Forms and Checklist (Medical Imaging- Conformity Assessment Bodies)	NABL 222
47.	Bio-data of Assessors	NABL 221
48.	Contract between NABL and Assessors	NABL 230

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S. No.	Name of Document	Doc. No.
49.	Directory of Accredited Testing Laboratories	NABL 400
50.	Directory of Accredited Calibration Laboratories	NABL 500
51.	Directory of Accredited Medical Testing Laboratories	NABL 600
52.	Directory of Accredited PTP	NABL 700
53.	Directory of Accredited RMP	NABL 800
<p>Note: Above NABL documents can be downloaded free of cost from NABL website: www.nabl-india.org.</p>		

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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 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 accredited CABs will accept/ 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 fraudulent activities, providing of false information or concealment of information, NABL shall reject the application or terminate the assessment process.
- NABL may also refuse provision of services to a CAB because of 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.
- NABL has the right to:
 - effect changes in standards on which CAB accreditation is based in accordance with international norms
 - decide on policies related to accreditation in consultation with stakeholders
 - appoint assessment teams
 - decide on implementation schedules in consultation with the CABs
 - take action against CAB in accordance with the accreditation requirements and giving valid reasons for the same
 - take adverse decisions in accordance with the accreditation requirements and giving reasons for the same

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10.2. Obligations of NABL

- The CAB's application will be kept confidential (unless required by law) by NABL and information obtained during the processing of application, assessment visit and grant of accreditation will be safeguarded and confidentiality and impartiality will be maintained.
- 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 at 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 website and more information can also be provided on request.
- NABL provides the CAB with information about suitable ways to obtain traceability of measurement relevant to the scope for which accreditation is granted. The information is provided in the document NABL 142 'Policy on Traceability of Measurement Results'. Further, the details of calibration laboratories accredited by NABL can be obtained from Laboratory Search option provided on NABL website.
- 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 laboratories 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 falls under the ambit of accreditation.
- NABL provides adequate mechanism to address the appeals received from the CABs against its adverse decisions.

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11. NABL MEDICAL (ENTRY LEVEL) TESTING LABS {NABL M(EL)T LABS} PROGRAM

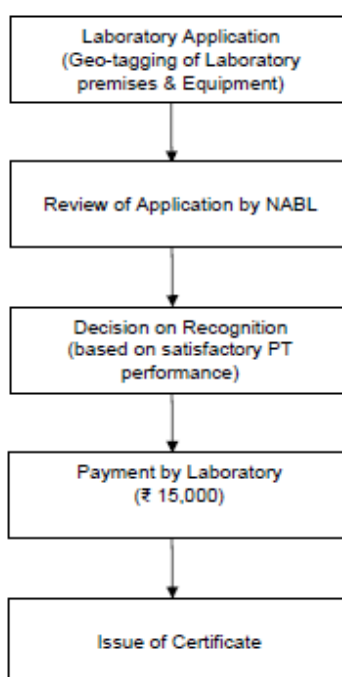
NABL has launched voluntary program namely “**NABL Medical (Entry Level) Testing Labs {NABL M(EL)T Labs} Program**” for sensitizing the medical testing laboratories performing basic testing to quality practices and access to quality health care for the majority of citizens especially those residing in villages, small towns.

This program is an independent quality assurance program, which is not covered under APAC & ILAC MRA.

The program is **based on satisfactory proficiency testing (PT) performance** and valid for one cycle of three years.

Interested laboratories are required to submit the application through NABL Web-portal <http://nablmelt.qci.org.in>. Laboratory application will be reviewed by NABL and decision on recognition will be taken based on performance in proficiency testing (PT). During the recognition period (within three years), on-site assessment (surveillance) will be conducted.

Flow Diagram of Recognition Process



Note: On-site assessment will be conducted during recognition period.

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NABL Medical (Entry Level) Testing Labs {NABL M(EL)T Labs} Program is applicable only for following Basic Routine Tests:

1. HIV-1 antibodies

2. Clinical Biochemistry

Sodium	Chloride	Potassium	Magnesium	Glucose	Amylase	Lipase	Calcium
D. Bilirubin		Glycated Hb (HbA1C)		Inorganic Phosphorus		Lactic Acid Dehydrogenase (LDH)	
Creatine Phosphokinase (CPK/CK)		Lipid Profile Cholesterol, Triglyceride		High Density Lipoprotein Cholesterol (HDL)		Gamma Glutamyl Transferase (GGT)	
Low Density Lipoprotein Cholesterol (LDL)		Renal Function Tests (Urea/Blood Urea Nitrogen, Creatinine, Uric acid)		Liver Function Tests (Total Bilirubin, Alanine Aminotransferase (ALT/SGPT), Aspartate Aminotransferase (AST/SGOT), Alkaline Phosphatase (ALP), Albumin, Total Protein)			

3. Haematology

Haemogram/ CBC (Haemoglobin, Total Leucocyte Count (TLC), Differential Leucocyte Count (DLC – Lymphocyte, Monocyte, Basophils, Eosinophils, Neutrophils), Platelet count, Red Blood Cell Count (RBC) Count, Packed Cell Volume (PCV)/ Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Haemoglobin Concentration (MCHC)

4. Clinical Pathology (Urine Routine Examination)

Protein	Glucose	pH	Leukocytes	Specific Gravity
Ketones	Bilirubin	Nitrite	Blood (Haemoglobin)	Urobilinogen

5. Infectious Serology/Immunology (Rapid tests)

Rheumatoid (RA)Factor	C-Reactive Protein (CRP)	Anti HCV/ HCV Ab	Typhoid (IgG / IgM)	WIDAL for Typhoid	Antistreptolysin O (ASO)
Hepatitis B Surface Antigen (HBsAg)		HIV Antigen + HIV Ab		Syphilis Serology (Rapid Plasma Reagin), VDRL, Treponema pallidum hemagglutination assay (TPHA)	

12. FEE STRUCTURE

A uniform fee structure is maintained for all CABs and the charges are maintained at a reasonable level so that CABs are not denied participation in the accreditation process because of unreasonable financial conditions. The information about the fee structure for various field(s)/ discipline(s) is given below:

		FY 2019-20	FY 2020-21
Application Fee (non-refundable, to be paid along with the application)	Testing Laboratories except Forensic Laboratories, Software & IT system testing and Laboratories under Integrated Assessment: For 01 product group/ discipline (e.g. Metals & alloys, Food & agricultural products, Drugs & pharmaceuticals, Textiles, Radiography, Computed Tomography etc.)	Rs. 11,000	₹ 11,000
	Forensic Laboratories and Software & IT system testing	Rs. 44,000	₹ 44,000
	Laboratories under Integrated Assessment: (For 01 product group/ discipline)	Rs. 25,000	₹ 25,000
	Medical Laboratories (covering all disciplines) & Associated Sample Collection Centre/Facility (SCF)		
	Micro Laboratories (Up to 25 patients/ day)	-	₹ 6,000 ₹ 200 per SCF
	Mini Laboratories (26 - 50 patients/ day)	-	₹ 10,000 + ₹ 200 per SCF
	Small Laboratories (51 - 100 patients/ day/location)	-	₹ 18,700 + ₹ 200 per SCF
	Medium Laboratories (101-400 patients/ day/location)	Rs. 44,000 + Rs. 200 per SCF	₹ 44,000 + ₹ 200 per SCF
	Large Laboratories (401-1000 patients/ day/location)	Rs. 1,10,000 + Rs. 200 per SCF	₹ 1,10,000 + ₹ 200 per SCF
	Very Large Laboratories (above 1000 patients/ day/location)	Rs. 2,20,000 + Rs. 200 per SCF	₹ 2,20,000 + ₹ 200 per SCF
	Medical Imaging- Conformity Assessment Bodies (MI-CAB): For 01 group/ modality (e.g. Computed Tomography, Ultrasound and Colour Doppler)	Rs. 11,000	₹ 11,000

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	Calibration Laboratories:		
	Mechanical – For 01 group (eg. Dimension, force etc)	Rs. 11,000	₹ 11,000
	Electro-Technical (all parameters)	Rs. 33,000	₹ 33,000
	Thermal (all parameters)	Rs. 22,000	₹ 22,000
	Fluid Flow (all parameters)	Rs. 22,000	₹ 22,000
	Optical (all parameters)	Rs. 22,000	₹ 22,000
	Radiological (all parameters)	Rs. 22,000	₹ 22,000
	Medical Devices (Up to two groups)	Rs. 50,000	₹ 50,000
	Proficiency Testing Providers:		
	For one Sub discipline per discipline e.g. Chemical under Testing	Rs. 25,000	₹ 25,000
	For each additional sub discipline in the same Discipline <i>Note: Chemical is sub discipline under Testing; Clinical Biochemistry is sub discipline under Medical; Mechanical is sub discipline under Calibration</i>	Rs.10,000	₹ 10,000
	Reference Material Producers:		
	Per Category – up to 2 sub-categories e.g. Metals & Organic Reference Materials under Chemical Composition <i>Note: Metals & Organic Reference Materials are Subcategories under Category Chemical Composition. Similarly, Tensile Strength and Elasticity are Subcategories under Engineering Properties</i>	Rs. 25,000	₹ 25,000
	For each additional sub-category in the same category	NA	₹ 5,000
Enhancement of Scope (apart from the scheduled re-assessment)	Testing Laboratories		
	Any extension in the existing accredited scope per discipline of testing	Rs.5,500 per group	₹ 5,500 per group
	For each additional product group in each discipline of testing	Rs.11,000	₹ 11,000
	Any extension in the existing accredited product group per discipline under Integrated Assessment	Rs. 25,000	₹ 25,000
	Forensic Laboratories and Software & IT system testing		
	Any extension in the existing accredited scope	Rs. 5,500	₹ 5,500
	Medical Laboratories & Associated Sample Collection Centre/Facility (SCF)		
	Any extension in the existing accredited scope	Rs. 5,500	₹ 5,500
	Any addition in Sample Collection Centre/Facility (SCF)	Rs. 200 per SCF	₹ 200 per SCF

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	Medical Imaging Conformity Assessment Body (MI-CAB)		
	Any extension in the existing accredited scope of MI-CAB	Rs. 5,500	₹ 5,500
	Any extension of new group/ modality in the existing accredited scope of MI-CAB	Rs. 11,000	₹ 11,000
	Calibration Laboratories:		
	Mechanical – Any extension in the existing accredited scope per group per discipline	Rs.5,500	₹ 5,500
	For each additional product group per discipline	Rs.11,000	₹ 11,000
	For extension in Electro-Technical, Thermal, Fluid Flow, Optical, Radiological disciplines	Rs. 5,500	₹ 5,500
	Medical Devices (for each additional group)	Rs. 5,500	₹ 25,000
	Proficiency Testing Providers:		
	Addition in existing Sub discipline	Rs. 5,000	₹ 5,000
	Addition of sub discipline in the existing discipline	Rs. 10,000	₹ 10,000
	Reference Material Producers:		
	For addition in existing subcategory	Rs. 2,500	₹ 2,500
	For each additional sub category	Rs. 5,000	₹ 5,000
Change in Person responsible to authorize the results	Any addition of person declared by CAB to authorize the results (apart from scheduled assessment)	Rs. 5,500 / request	₹ 5,500 / request
Change of Certificate	Testing, Calibration and Medical Laboratories-		
	Any change in the name and/ or premises/ address of the laboratory leading to issue of new accreditation certificate and / scope	Rs. 5,500	₹ 5,500
	Any change in the name and/ or premises/ address of the Medical Imaging- Conformity Assessment Body (MI-CAB) leading to issue of new accreditation certificate with scope	Rs. 5,500	₹ 5,500
	RMP & PTP-		
	Any change in the name and or premises/address of the PTP or RMP leading to issue of new accreditation certificate with scope	Rs. 3,000	₹ 3,000
Annual Accreditation Fee (per year from the date of accreditation)	Testing laboratories (including Integrated Assessment) except Forensic laboratories Software & IT System testing (per discipline):	Rs. 24,000	₹ 24,000

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<p>Note- Annual Accreditation fee is payable in advance and is non-refundable and non-adjustable.</p> <p>In case of co-terminating the accreditation validity, the fee will be charged on pro-rata basis</p>	Forensic laboratories and Software & IT System testing	Rs. 48,000	₹ 48,000
	Calibration laboratories (per discipline) except Electro-technical calibration laboratories	Rs. 24,000	₹ 24,000
	Electro-technical laboratories	Rs. 36,000	₹ 36,000
	RMP & PTP	Rs. 27,500	₹ 27,500
	Medical Laboratories (covering all disciplines) & Sample Collection Centre/Facility (SCF)		
	Micro Laboratories (Up to 25 patients/ day/location)	-	₹ 6,000 + ₹ 1,000 per SCF
	Mini Laboratories (26 - 50 patients/ day/location)	-	₹ 10,000 + ₹ 1,000 per SCF
	Small Laboratories (51 - 100 patients/ day/location)	-	₹ 20,000 + ₹ 1,000 per SCF
	Medium Laboratories (101-400 patients/ day/location)	Rs. 48,000 + Rs. 1,000 per SCF	₹ 48,000 + ₹ 1,000 per SCF
	Large Laboratories (401 -1000 patients/ day/location)	Rs. 1,20,000 + Rs. 1,000 per SCF	₹ 1,20,000 + ₹ 1,000 per SCF
Very Large Laboratories (above 1000 patients/ day/location)	Rs. 2,40,000 + Rs. 1,000 per SCF	₹ 2,40,000 + ₹ 1,000 per SCF	
Medical Imaging Conformity Assessment Body (MI-CAB)	Rs. 24,000	₹ 24,000	
Overhead Charges	For each on-site assessment, Desktop surveillance, irrespective of number of disciplines except Micro and Mini Medical testing laboratories	Rs. 11,000/-	₹ 11,000/-
Assessment Charges (payable after the completion of assessment visit to the CAB)	Comprising of - Travel, Boarding, Lodging - Honorarium for NABL Assessors - Overhead Charges		
	For Micro Laboratories charges on lump-sum basis including Honorarium, travel and overhead expenses		₹ 20,000 per SCF
	For Mini Laboratories charges on lump-sum basis including Honorarium, travel and overhead expenses		₹ 25,000 per SCF
	For Sample Collection Centre / Facility (SCF) charges on lump-sum basis including Honorarium, travel and overhead expenses		₹ 5,000 per SCF

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<p>Travel, Boarding and Lodging expenditure</p>	<p>The CAB will make the travel arrangements for assessors as per the following entitlements. Any travel or boarding and lodging beyond the following entitlement shall be agreed upon in advance by the CAB under the intimation to NABL. CAB shall not make any cash transactions with the assessor. Also, CAB shall ensure the safety and security of the assessor visiting there for conducting assessments.</p> <p>Travel If the journey is more than 300 Km, travel to be made by Air in economy class (Apex fare). If the journey is up to 300 Km, travel to be made by train in 2nd AC Class / AC Chair Class or by AC Bus. If outstation journey is made by own car, the reimbursement will be restricted to 2nd AC class fare by train. Travel within the city by taxi will be reimbursed on production of receipts / bills. In absence of taxi bills or travel by own car within the city, claim will be reimbursed @ ₹ 15 per km. Any other relevant expenses during the travel will be reimbursed only on production of receipts / bills.</p> <p>Boarding and Lodging A single occupancy AC accommodation to be provided for each Assessor in a reasonably good hotel / guest house and arrangement for local transportation from temporary residence to the CAB site and airport / railway station / bus stand to be made. The CAB shall pay for meals of Assessor/ Observer during the stay, within the reasonable limitations.</p> <p>Note: <i>The travel, boarding & lodging for NABL Officials joining assessment as Observer, shall be borne by NABL.</i></p>	
<p>Honorarium for NABL Assessors</p>	<p>Document review by Lead Assessor</p>	<p>₹ 2,000</p>
	<p>Pre-Assessment, Assessment, Verification, Special Visit</p>	
	<p>- by Lead Assessor</p>	<p>₹ 4,500 per day</p>
	<p>- by Technical Assessor/ Expert</p>	<p>₹ 4,000 per day</p>

Note: In addition to the above-mentioned fee, GST @ 18.0 % is to be paid along with said charges / fees. Additionally, 'Testing laboratory under Integrated Assessment' shall also directly pay the applicable annual approval fee as prescribed by respective Regulatory Body.

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Fee Structure for NABL Medical (Entry Level) Testing Labs {NABL M(EL)T Labs} Program

Components	Fee / Charges
Recognition Fee (For Three Years, payable before issue of certificate)	₹ 15,000/-
Surveillance Charges (payable at the time of surveillance visit)	On actual basis

Note: In addition to the above-mentioned fee, GST @ 18.0 % is to be paid along with said charges / fees.

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Fee Structure for Accreditation of Conformity Assessment Bodies outside India

FEE STRUCTURE FOR SAARC COUNTRIES	
(A) For Accreditation -	
Application Fee	400 USD/ discipline (e.g. Mechanical testing, Medical testing, Electro–technical calibration, PT- Testing, RMP-Chemical Composition, etc.)
Document Review	200 USD
Assessment Charges	100 USD/ Man day
(B) To maintain Accreditation -	
Accreditation Fee	350 USD/ Annum/ discipline
Desktop Surveillance Fee	200 USD
(C) Changes, if any -	
Any addition of person declared by CAB to authorize the results (apart from scheduled assessment)	100 USD/ Request
Any enhancement in the existing accredited scope per discipline of testing (apart from the scheduled re-assessment)	100 USD/ group
Enhancement of new group in each accredited discipline (apart from the scheduled re-assessment)	200 USD
Change of Certificate (Any change in the name/ premises / address of the CAB leading to issue of new accreditation certificate with scope)	100 USD

FEE STRUCTURE FOR FOREIGN CABs OTHER THAN SAARC COUNTRIES	
(A) For Accreditation -	
Application Fee	1000 USD / discipline (e.g. Mechanical testing, Medical testing, Electro –technical calibration, PT- Testing, RMP-Chemical Composition, etc.)
Document Review	500 USD
Assessment Charges	600 USD/ Man day
(B) To maintain Accreditation -	
Accreditation Fee	1000 USD/ Annum/ Field
Desktop Surveillance Fee	500 USD
(C) Changes, if any -	
Any addition of person declared by CAB to authorize the results (apart from scheduled assessment)	250 USD/ Request
Any Enhancement in the existing accredited scope per discipline of testing (apart from the scheduled re-assessment)	150 USD/ group
Enhancement of new group in each accredited discipline (apart from the scheduled re-assessment)	300 USD
Change of Certificate (Any change in the name / premises / address of the CAB leading to issue of new accreditation certificate with scope)	200 USD

Note: 1) Overseas CABs to contact NABL for making the payments

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2) All charges (whether in India or abroad) incurred during wire transfer in foreign currency, shall be borne by the CAB

Entitlement of Assessment-Team -

The laboratory/ PTP/ RMP shall make arrangements for Travel, boarding & lodging for the assessment team. A single occupancy accommodation may be provided for each Assessor/ Observer in a good hotel and arrangement for local transportation from temporary residence to the laboratory/ PTP / RMP site & airport.

The Laboratory / PTP/ RMP shall assist in VISA and arrange other logistics like travel insurance and accommodation.

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13. **MODES OF PAYMENT**

S. No.	Options	Remarks
1	Cheque / Demand Draft in favour of 'Quality Council of India' payable at Gurugram / Gurgaon	<ul style="list-style-type: none"> - No account number or branch to be mentioned on Cheque / DD. Payee should be only 'Quality Council of India'; - Cheque / DD to be sent to NABL Office at the following address: Plot no. 45, Sector 44, Gurugram, Haryana – 122003.
2	Payment gateway for making online payments <i>(Preferred and easiest method as payment is easily traceable and reconcilable in an accurate and timely manner)</i>	<p>Gateway may be accessed from the home page of NABL website.</p> <ul style="list-style-type: none"> - Existing CABs may obtain the Login credentials from NABL; - New CABs may pay directly through gateway without any login.
3	<p><u>NEFT to following account:</u></p> <p>Quality Council of India HDFC Bank Kanjurmarg Branch, Mumbai IFSC Code – HDFC0004989</p> <p>Virtual A/c No. – <i>Unique for each CAB, to be provided by NABL.</i></p>	<ul style="list-style-type: none"> - Virtual Account no. will be unique for each CAB and to be obtained from NABL; - Use only this virtual account no. for making all payments related to that CAB; - Use correct virtual account number to avoid the payment being accounted for against wrong CAB Id; - Do not use any other account of 'Quality Council of India' for NEFT.

14. BENEFITS OF ACCREDITATION

Formal recognition of competence of a conformity assessment body by NABL in accordance with international standard has many advantages:

- ❖ International recognition/ equivalence,
- ❖ Access to Global market,
- ❖ Time and money efficient,
- ❖ Enhanced customer confidence and satisfaction,
- ❖ Robust Quality Management System,
- ❖ Continual improvements,
- ❖ Better operational control,
- ❖ Assurance of accurate and reliable results,
- ❖ Cost Reduction,
- ❖ Prevent loss due to defects

Benefits of Laboratory Accreditation

Formal recognition of competence of a laboratory by NABL in accordance with international criteria has many advantages:

- ❖ A ready means for customers to identify and select reliable testing, measurement and calibration services that are able to meet their needs.
- ❖ Increased confidence in Testing/ Calibration Reports issued by the testing, calibration and medical testing laboratories which emphasise on accuracy and reliable results.
- ❖ The results from accredited laboratories are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.
- ❖ Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
- ❖ Helpful in participating in tenders that require independently verified laboratories.
- ❖ **Potential increase in business due to enhanced customer confidence and satisfaction:** Accredited laboratories receive a form of international recognition, which allows their data and results to be more readily accepted in overseas markets. Accreditation helps to reduce costs for manufacturers and exporters who have their products or materials tested in accredited laboratories, by reducing or eliminating the need for retesting in another country.
- ❖ Customers can search and identify the laboratories accredited by NABL for their specific requirements from the NABL website or Directory of Accredited Laboratories.
- ❖ Users of accredited laboratories enjoy greater access for their products, in both domestic and international markets.

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- ❖ Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.

Benefits of Accreditation for Proficiency Testing Providers

The benefits of proficiency testing are widely recognized. These include:

- Many laboratories operate in isolation from other laboratories and do not have ongoing opportunities to compare their data with others. Without such opportunities there are risks that the data of a laboratory may have errors, biases or significant differences when compared to data from other similar laboratories. Proficiency testing provides an opportunity to undertake such comparisons and to have an independent appraisal of the laboratory's data compared to reference values (or other performance criteria) or to the performance of similar laboratories. The results from such participation provide laboratory managers with either a confirmation that the laboratory's performance is satisfactory or an alert that an investigation of potential problems within the laboratory is required.
- Comparison of the performance of a facility's performance with that of other participating (peer) facilities
- Monitoring of the long-term performance of a facility.
- Improvement in the performance of tests/calibrations following investigation and identification of the cause(s) of unsatisfactory PT performance, and the introduction of corrective action to prevent re-occurrence
- Staff education, training and competence monitoring
- Evaluation of methods, including the establishment of method precision and accuracy
- Contribution to the laboratories overall risk management system
- Confidence building with interested parties, e.g. customers, accreditation bodies, regulators, specifiers.

Proficiency testing providers play an important role in the value chain for assurance of products and services. Being an NABL accredited PTP in accordance with ISO/IEC 17043 gives the organization credibility for their PT services.

Benefits of Accreditation for Reference Materials Producers

Formal recognition of competence of an RMP by NABL in accordance with international criteria (ISO 17034) has many advantages like:

- ✓ Confidence in measurements by establishing traceability to appropriate measurement standards such as the use of certified reference materials (CRMs) produced by a competent producer to give a reliable physical or chemical characterization of a material.
- ✓ It provides assurance that the accredited RMPs are competent to produce the RMs as listed in the scope of accreditation. It provides confidence to RM users that the reference

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materials (RMs), and certified reference materials (CRMs) in particular, are produced according to technically valid and internationally recognized principles, and fit for the intended uses.

- ✓ CRMs offer a most effective means to assess the trueness and precision of a measurement process.
- ✓ Reference materials (RMs) provide one of the most effective ways of assessing and demonstrating that the measurement process is in statistical control because the homogeneity and stability of RMs have been confirmed to be suitable for use as quality control materials.
- ✓ Accreditation is a means of determining the technical competence of RMPs to produce specific RMs. It also provides formal recognition to competent RMPs, thus providing a ready means for RMs users to identify and select the most suitable RMs that meet their needs. This recognition of competence relates to the properties of the reference materials that the accredited RMP produces, and may include, if applicable, the ranges of the assigned values and their associated uncertainties. It may also include the RMPs involvement in the performance of testing, calibration and measurements in relation to homogeneity, stability and characterization assessments and their use of subcontractors in these tasks. These are the factors that RM users need to know and consider when selecting RMs
- ✓ Accreditation is an effective marketing tool for RMPs
- ✓ Accreditation provides assurance that the accredited RMPs are competent to produce the RMs as listed in the scope of accreditation
- ✓ It provides confidence to RM users that the reference materials (RMs), and certified reference materials (CRMs) in particular, are produced according to technically valid and internationally recognized principles, and fit for the intended uses.
- ✓ These uses include the assessment of precision and trueness of measurement methods, quality control, assigning values to materials, calibration, and the establishment of conventional scales. This eliminates the needs of the users to evaluate the quality of the RMs themselves
- ✓ RMs are used globally. Many economies around the world have accreditation bodies offering accreditation to RMPs. These accreditation bodies have adopted ISO 17034: 2016 as the criteria for RMP accreditation. This has helped economies to adopt a uniform approach for determining RMP competence. This uniform approach allows accreditation bodies in different economies to establish arrangements among themselves, based on mutual evaluation and acceptance of each other's RMP accreditation systems.

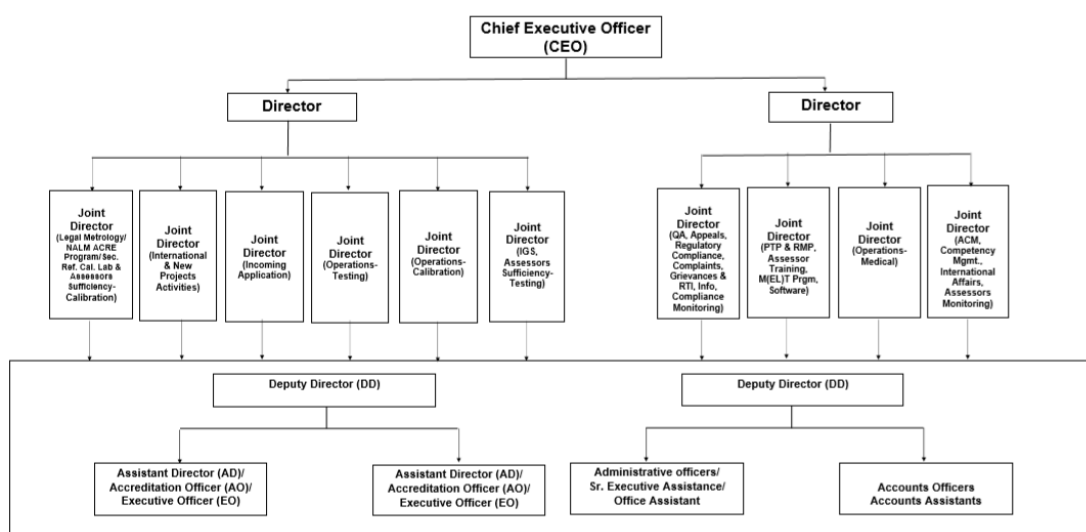
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15. ORGANIZATION STRUCTURE OF NABL

The organization structure of NABL has been designed to meet the requirements of an effective and efficient accreditation system.

The Apex body in NABL organization is the NABL Board. The Board provides policy, guidelines and direction to NABL. CEO, NABL is the Member Secretary of the NABL Board. NABL comprises of Chief Executive Officer (CEO), Senior Directors, Directors, Joint Directors, Deputy Directors, Assistant Directors, Quality Team, Complaints Team, Appeals team, Accreditation Officers and Administrative & support staff. CEO, NABL is responsible for administering and managing the day to day operations of NABL.

Organization chart of NABL:



NABL operates its accreditation process through empanelled Lead Assessors and Technical Assessors covering all fields and disciplines as specified in the scope of NABL. All Lead Assessor and Technical Assessors are personnel having considerable experience in CAB activities. They are trained by NABL as per the relevant international accreditation criteria and subsequently empanelled as assessors/ lead assessors through contractual agreements.

Recommendations of Accreditation Committee form the basis for accreditation decisions. Members to accreditation committees are drawn from National Metrology Institute (NMI), standards bodies (e.g. BIS), experienced assessors (including those from accredited conformity assessment bodies), regulatory agencies/ bodies etc. Members are selected based on their technical knowledge, understanding of Assessment principles and processes of accreditation, past performance as Assessors or committee member.

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The formulation of technical / specific guidelines and other similar tasks is performed by various technical committees set up for the purpose. Composition of any Technical Committee is mainly driven by the purpose for which the committee is set up. For multi-disciplinary fields or in areas where two or more fields overlap, care is taken to include members from relevant fields so that a balanced view emerges. Committee members are drawn from different organizations that form the spectrum of interested parties.

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16. CONTACT DETAILS

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