NABL 100A



National Accreditation Board for Testing and Calibration Laboratories (NABL)

General Information Brochure

ISSUE NO.: 01 ISSUE DATE: 23-Nov-2022 AMENDMENT NO.: 01 AMENDMENT DATE: 21-Feb-2024

AMENDMENT SHEET

S. No.	Amendment No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature Competent Authority
1.	01	5	Employee Chart of NABL	21-Feb- 2024	As highlighted	Inclusion of Regional Offices	-Sd-	-Sd-
2.		6	Services provided by NABL			Release of ISO/IEC 17043: 2023	-Sd-	-Sd-
3.		12	5.1			Release of ISO 15189:2022	-Sd-	-Sd-
4.		17-18	Table (S. No. 20, 30, 32, 40, 42, 44, 50, 62, 63, 65, 66)			Release of new NABL documents	-Sd-	-Sd-
5.		19	7			i. Inclusion of SHEFEXI L, Spices Board, Tea Board ii. Internal Review	-Sd-	-Sd-
6.		19, 20	8			Inclusion of NABL Recognition Programs	-Sd-	-Sd-
7.								
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10.								
11.								
12.								

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1. HISTORY OF NABL

Department of Science and Technology started accreditation of laboratories during 6th Plan period (1980-85). The name of the program was National Coordination of Testing and Calibration Facilities (NCTCF).

In 1993, the program was renamed from NCTCF to National Accreditation Board for Testing and Calibration Laboratories (NABL).

The Union Cabinet in its meeting held on 9th February 1996 considered a proposal of the Ministry of Industry to set up Quality Council of India (QCI) with Accreditation Boards (National Accreditation Board for Products and Quality Systems Certification and National Accreditation Board for Quality Management Personnel and Training Organization) in its fold. It was also decided to set up NABL as a registered society under the Department of Science and Technology Government of India and bring it under ambit of QCI at an appropriate stage.

NABL was registered as a Society under Societies Registration Act 1860 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.

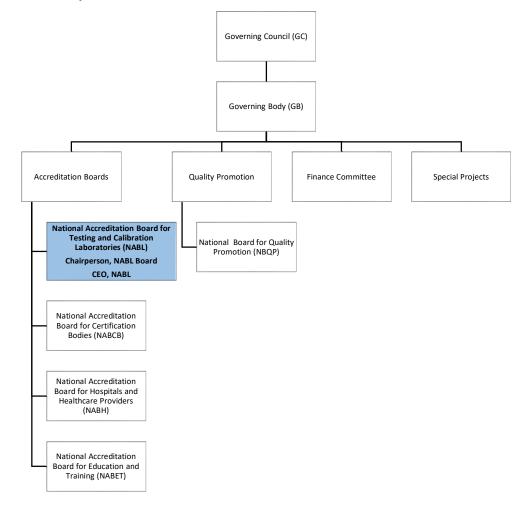
In February 2016, in pursuance of cabinet decision, NABL along with its existing support mechanism under the Department of Science and Technology, Ministry of Science and Technology was transferred to the Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce and Industry and subsequently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

On 15th June, 2017, NABL society regn. no. S/33451 was merged with QCI society regn. no. S/30832.

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Organization Structure

NABL is one of the constituent boards of Quality Council of India (QCI), an autonomous body under Department for Promotion of Industry & Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India.



NABL Board is chaired by Chairperson and has 25 members drawn from various organizations of repute including representative of the Government, Industry, and other stakeholders to guide and monitor the activities and progress of the Board.

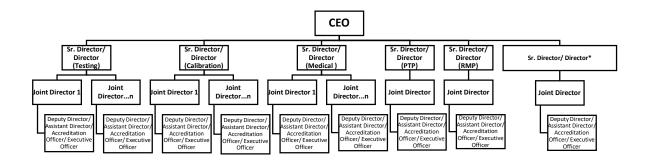
The day to day functions of NABL are carried out by the staff of technical cadre and is headed by the Chief Executive Officer (CEO).

NABL staff comprises of Chief Executive Officer (CEO), Senior Directors/Directors, Joint Directors, Deputy Directors, Assistant Directors, and Accreditation & Executive Officers.

CEO, NABL is responsible for administering and managing the operations of NABL.

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Employee Chart of NABL:



*QA, Complaints, Appeals, Accreditation Committee Meeting, Assessor Monitoring Committee, etc. Above chart is inclusive for NABL Offices at Ahmedabad, Bengaluru and Kolkata

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Services provided by NABL

NABL provides voluntary accreditation services as per international standards to:

- Testing laboratories in accordance with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories'
- Calibration laboratories in accordance with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories'
- Medical testing laboratories in accordance with ISO 15189 'Medical laboratories -Requirements for quality and competence'
- Proficiency Testing Providers (PTP) in accordance with ISO/IEC 17043 "Conformity assessment - General requirements for (the Competence of) Proficiency Testing Providers" and
- Reference Material Producers (RMP) in accordance with ISO 17034 "General requirements for the competence of Reference Material Producers".

In addition, NABL also provides the following services (not covered under APAC/ILAC MRA):

- NABL Medical (Entry Level) Testing Labs {NABL M(EL)T LABS} Program
- Government Block Level Drinking Water Testing Laboratory Recognition Program

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International recognition of NABL

NABL has an established accreditation system in accordance with the requirements of ISO/IEC 17011:2017 "Conformity Assessment – Requirements for accreditation bodies accrediting conformity assessment bodies"

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

NABL is a full member of the Asia Pacific Accreditation Cooperation (APAC) and International Laboratory Accreditation Cooperation (ILAC), a signatory to its Mutual Recognition Arrangement (MRA) since 2000 as mentioned below.

Field	Standard	Program started in	APAC MRA	ILAC MRA
Testing & Calibration	ISO/IEC 17025	1982	26.10.2000	02.11.2000
Medical Testing		1998		
Medical Testing	ISO 15189	2003	11.12.2008	30.11.2012
Proficiency Testing Providers	ISO/IEC 17043	2011	30.11.2016	03.10.2019
Reference Material Producers	ISO 17034	2014	30.11.2016	22.07.2020

The information on APAC and ILAC Mutual Recognition Arrangements (MRAs) is available on NABL website.

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Impartiality

NABL is committed to ensure integrity and impartiality at all levels while implementing its systems and operations.

NABL offers accreditation services in a non-discriminatory manner. These services are accessible to all testing laboratories, calibration laboratories, medical testing laboratories, proficiency testing providers and reference material producers of India and other countries, regardless of the size of the applicant CAB or its membership of any association or group or number of CABs.

The Impartiality policy of NABL is given below and also available on the NABL website. (<u>https://nabl-india.org</u>).

IMPARTIALITY POLICY

NABL and its personnel and committee members are 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. NABL ensures:

- 1. To carry out accreditation activities in a non-discriminatory manner.
- 2. There are no constraints that might influence decision making.
- 3. That it does not engage in any activity which could compromise its impartiality.
- 4. 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.
- 5. Fair representation of stakeholders in NABL Board.

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2. SCOPE OF NABL ACCREDITATION

NABL Accreditation is given in the following fields and disciplines. The multi-disciplinary conformity assessment bodies 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
- Medical Imaging

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Proficiency Testing Providers (PTP)

Categories for PTP

- Testing
- Calibration
- Medical
- Inspection

Reference Material Producers (RMP)

Categories for RMP

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

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

- NABL 120: Guidance for Classification of Product Groups in Testing & Calibration Fields,
- 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. COMPLAINTS

Complaint is an expression of dissatisfaction, other than appeal, by any person or organization to a conformity assessment body or an accreditation body, relating to the activities of that body, where a response is expected. *(Source ISO/IEC 17000: 2020)*

The relevant documents (NABL 132 and NABL 132A) are available on NABL website (<u>https://nabl-india.org</u>).

4. APPEALS

Appeal is a request by the person or organization that provides, or that is, the object of conformity assessment to a conformity assessment body or an accreditation body for reconsideration by that body of a decision it has made relating to that object. *(Source ISO/IEC 17000: 2020)*

The relevant document (NABL 134) is available on NABL website (https://nabl-india.org).

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5. RIGHTS AND OBLIGATIONS OF NABL

5.1. Rights of NABL

- NABL requires all CABs to conform to ISO/IEC 17025: 2017 or ISO 15189: 2012 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 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 process.
- If there is evidence of fraudulent activities, providing of false information or concealment of information at any time during the accreditation cycle, NABL will 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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5.2. 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 (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 website 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, APAC & ILAC 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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6. RIGHTS AND OBLIGATIONS OF CONFORMITY ASSESSMENT BODY (CAB)

6.1. Rights of CAB

- CAB is entitled to receive information related to CAB accreditation. They can access NABL website <u>www.nabl-india.org</u> 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.

6.2. 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 Obtaining And 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 Measurement Uncertainty in Calibration",

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- 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 or any other internationally accepted criteria. For unsatisfactory performance, the CAB is required 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 as per the details provided in NABL 133 with respect to the scope for which it has been granted accreditation.
- An accredited CAB shall not use NABL accreditation in such a manner as to bring NABL into disrepute.
- The CAB is required to inform 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 unannounced visits as a part of compliance monitoring activity by NABL for its accredited CABs and/or investigation of complaint issue.

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- The CAB shall offer co-operation to NABL in investigating complaint issues.
- The CAB shall neither 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 offer any gifts or any kind of payments in cash or by any other mode of payment or any undue favour to the assessment team members.
- 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 <u>www.nabl-india.org</u>), except for cross-frontier CABs. List of NABL documents is given below:

SI.	Name of Document	Doc. No.
1.	Duties and Responsibilities of NABL Staff	NABL 015
2.	General Information Brochure	NABL 100A
3.	Accreditation Process & 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) 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
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

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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.	Criteria for NABL Recognition for Government Drinking Water Testing Laboratory at Block Level / Sub-Divisional Level	NABL 139
21.	Guidelines for Estimation and Expression of Uncertainty in Measurement	NABL 141
22.	Policy on Metrological Traceability of Measurement Results	NABL 142
23.	Policy on Calibration and Measurement Capability (CMC) and Measurement Uncertainty in Calibration	NABL 143
24.	Guidance on conducting Remote Assessment	NABL 144
25.	Application Form for Testing Laboratories	NABL 151
26.	Application Form for Calibration Laboratories	NABL 152
27.	Application Form for Medical Testing Laboratories	NABL 153
28.	Application Form for Integrated Assessment of Testing Laboratories	NABL 154
29.	Application Form and Checklist for NABL Medical (Entry Level) Testing labs {NABL M(EL)T Labs} Program	NABL 155
30.	Application Form and Checklist for NABL Recognition for Government Drinking Water Testing Laboratory at Block Level / Sub-Divisional Level	NABL 157
31.	Application Form for Accreditation of Product Based Testing Laboratories	NABL 158
32.	Application form for Recognition of Temporary Site Laboratories Testing Aggregates and Concrete in Building Projects	NABL 159
33.	Guide for Preparing a Quality Manual	NABL 160
34.	Guide for Internal Audit and Management Review for Conformity Assessment Bodies (Laboratories / PTP / RMP)	NABL 161
35.	Policy for Participation in Proficiency Testing Activities	NABL 163
36.	Guidelines for Inter-Laboratory Comparison for Calibration Laboratories where formal PT programs are not available	NABL 164
37.	Sample Calculations for Uncertainty of Measurement in Electrical Testing	NABL 174
38.	Application Form for Proficiency Testing Providers (PTP)	NABL 180
39.	Specific criteria for PT Provider Accreditation	NABL 181
40.	Specific Criteria For PT Provider Accreditation (as per ISO/IEC 17043: 2023)	NABL 181A
41.	Pre-assessment guidelines and forms (based on ISO/IEC 17043:2010)	NABL 182
42.	Pre-Assessment Guidelines and Forms (based on ISO/IEC 17043: 2023)	NABL 182 A
43.	Assessment forms and checklist (based on ISO/IEC 17043: 2010)	NABL183
44.	Assessment Forms and Checklist (based on ISO/IEC 17043: 2023)	NABL 183 (A)
45.	Application Form for Reference Material Producers (RMP)	NABL190
46.	Specific Criteria for Reference Material Producer Accreditation	NABL191
47.	Pre-Assessment Guidelines & Forms (based on ISO 17034: 2016)	NABL192
48.	Assessment Forms and Checklist (based on ISO 17034: 2016)	NABL 194

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49.	Pre-Assessment Guidelines and Forms (based on ISO 15189: 2012)	NABL 208
50.	Pre-Assessment Guidelines and Forms (based on ISO 15189:2022)	NABL 208 (A
51.	Pre-Assessment Guidelines and Forms (based on ISO/IEC 17025)	NABL 209
52.	Assessor Guide	NABL 210
53.	Operational Manual for online Assessment (For Assessors)	NABL 213
54.	Procedures for Dealing with Adverse Decisions	NABL 216
55.	Assessment Forms & Checklists (based on ISO 15189: 2012)	NABL 217
56.	Desktop Surveillance	NABL 218
57.	Assessment Forms and Checklist (Based on ISO/IEC 17025: 2017)	NABL 219
58.	Document Review Checklist (as per ISO/IEC 17025: 2017)	NABL 220
59.	Document Review Checklist (as per ISO 15189: 2012)	NABL 220A
60.	Document Review Checklist (as per ISO/IEC 17043: 2010)	NABL 220B
61.	Document Review Checklist (as per ISO 17034: 2016)	NABL 220C
62.	Document Review Checklist (as per ISO 15189: 2022)	NABL 220D
63.	Document Review Checklist (as per ISO/IEC 17043: 2023)	NABL 220E
64.	Bio-data of Assessors	NABL 221
65.	Assessment Forms and Checklist (Based on ISO 15189:2022)	NABL 223
66.	Specific Criteria for Recognition of Temporary Site Laboratories Testing Aggregates and Concrete in Building Projects	NABL 224
67.	Contract between NABL and Assessors	NABL 230
68.	Directory of Accredited Testing Laboratories	NABL 400
69.	Directory of Accredited Calibration Laboratories	NABL 500
70.	Directory of Accredited Medical Testing Laboratories	NABL 600
71.	Directory of Accredited PTP	NABL 700
72.	Directory of Accredited RMP	NABL 800
73.	Directory of Laboratories Recognized under NABL Medical (Entry	NABL 900

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7. INTEGRATED ASSESSMENT FOR ACCREDITATION OF LABORATORIES

(Regulatory Body(ies) / Govt. agencies involved;

- Agricultural and Processed Food Products Export Development Authority (APEDA),
- Export Inspection Council (EIC),
- Food Safety & Standards Authority of India (FSSAI))
- Indian Oilseeds and Produce Export Promotion Council (IOPEPC),
- Marine Products Export Development Authority (MPEDA),
- Shellac and Forest Products Export Promotion Council (SHEFEXIL)
- Spices Board
- Tea Board

Integrated assessment is a unified approach for accreditation / approval / recognition of the laboratories, which provides several benefits to the regulatory agencies, users, and laboratories, in terms of resources, time and control.

A single assessment is being conducted in which representative of all the agencies / Boards (according to application of the laboratory) is involved and cycle of the recognition / accreditation is same for all.

Please refer following documents for more details:

- i. NABL 127 Procedure for Integrated Assessment & Additional Requirements of Regulatory Body(ies) For Testing Laboratories
- ii. NABL 154 Application Form for Integrated Assessment of Testing Laboratories

8. NABL RECOGNITION PROGRAMS:

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

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

This program is not covered under APAC & ILAC MRA.

Please refer following documents for more details:

- i. NABL 128 "Criteria and Procedure for NABL Medical (Entry Level) Testing Labs {NABL M(EL)T Labs} Program"
- ii. NABL 155 "Application Form and Checklist for NABL Medical (Entry Level) Testing labs {NABL M(EL)T Labs} Program"

National Accreditation Board for Testing and Calibration Laboratories					
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8.2 NABL SOIL TESTING LABS PROGRAM

NABL has launched scheme to sensitize the Soil Testing Laboratories performing basic testing to ensure the quality of soil for the majority of citizens especially those residing in villages, small towns.

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

8.3 RECOGNITION OF TEMPORARY SITE LABORATORIES TESTING OF AGGREGATES AND CONCRETE IN BUILDING PROJECTS

Civil engineering projects have temporary site testing facilities for the testing of building materials such as fine aggregates, coarse aggregates, and concrete cubes at construction sites. Testing of all these building materials is normally being done at temporary construction sites which is required across the construction industry in which the project size is more than 50,000 Sq.ft area (Constructed area). To ensure the quality and competency of the temporary site testing laboratories, NABL has launched a recognition scheme for such laboratories.

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

Please refer following documents for more details:

NABL 159 "Application form for Recognition of Temporary Site Laboratories Testing Aggregates and Concrete in Building Projects"

NABL 224 "Specific Criteria for Recognition of Temporary Site Laboratories Testing Aggregates and Concrete in Building Projects"

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9. FEE STRUCTURE

NABL charges fee to Conformity Assessment Bodies (CAB) to cover operational costs and other expenditure.

		FY 2017-18 FY 2018-19 FY 2019-20	FY 2020-21	01.10.2021 onwards
Application Fee (non- refundable, to be paid along with the application)	TestingLaboratoriesexceptForensicLaboratories,Software & ITsystem testingandLaboratoriesunderIntegrated Assessment:For 01 product group/ discipline(e.g., Metals & alloys, Food &agricultural products, Drugs &pharmaceuticals,Textiles,Radiography etc.)	Rs. 11,000	₹ 11,000	₹ 11,000
	Forensic Laboratories and Software & IT system testing	Rs. 44,000	₹ 44,000	₹ 44,000
	Laboratories under Integrated Assessment: (For 01 product group/ discipline)	Rs. 25,000	₹ 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	₹ 6,000 ₹ 200 per SCF
	Mini Laboratories (26 - 50 patients/ day)	-	₹ 10,000 + ₹ 200 per SCF	₹ 10,000 + ₹ 200 per SCF
	Small Laboratories (51 - 100 patients/ day/location)	-	₹ 18,700 + ₹ 200 per SCF	₹ 18,700 + ₹ 200 per SCF
	Medium Laboratories (101-400 patients/ day/location)	Rs. 44,000 + Rs. 200 per SCF	₹ 44,000 + ₹ 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	₹ 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	₹ 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	₹ 11,000
	Calibration Laboratories: Mechanical – For 01 group (e.g. Dimension, force etc)	Rs. 11,000	₹ 11,000	₹ 11,000
	Electro-Technical	Rs. 33,000	₹ 33,000	₹ 33,000

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	(all parametera)			
	(all parameters)	D- 00.000	₹ 00.000	₹ 00,000
1	Thermal (all parameters)	Rs. 22,000	₹ 22,000	₹ 22,000
	Fluid Flow (all parameters)	Rs. 22,000	₹ 22,000	₹ 22,000
	Optical (all parameters)	Rs. 22,000	₹ 22,000	₹ 22,000
	Radiological	Rs. 22,000	₹ 22,000	₹ 22,000
	(all parameters)			
	Medical Devices	Rs. 50,000	₹ 50,000	₹ 50,000
	(Up to two groups)			
	Proficiency Testing Providers:			
	For one Sub discipline per	Rs. 25,000	₹ 25,000	₹ 25,000
	discipline		,	
	e.g. Chemical under Testing			
	Note: Chemical is sub discipline			
	under Testing; Clinical			
	Biochemistry is sub discipline			
	under Medical; Mechanical is			
	sub discipline under Calibration			
	For each additional sub	Rs.10,000	₹ 10,000	₹ 10,000
	discipline in the same Discipline	110.10,000	(10,000	(10,000
	Reference Material Producers:			
	Per Category – up to 2 sub-	Rs. 25,000	₹ 25,000	₹ 25,000
	categories	RS. 20,000	₹ 25,000	x 25,000
	e.g. Metals & Organic Reference Materials under Chemical			
	Composition			
	Note: Metals & Organic			
	Reference Materials are			
	Subcategories under Category			
	Chemical Composition. Similarly,			
	Tensile Strength and Elasticity			
	are Subcategories under			
	Engineering Properties			
	For each additional sub actorsom	NIA	Ŧ C 000	Ŧ C 000
	For each additional sub-category	NA	₹ 5,000	₹ 5,000
	in the same category			
Enhancement	Testing Laboratories			
of Scope	Any extension in the existing	Rs.5,500 per	₹ 5,500 per	₹ 5,500 per
	Any extension in the existing accredited scope per product	Rs.5,500 per product group	₹ 5,500 per product	₹ 5,500 per product group
of Scope	Any extension in the existing		· · ·	
of Scope (apart from the	Any extension in the existing accredited scope per product		product	
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of		product	
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing	product group	product group	product group
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product	product group	product group	product group
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing	Rs.11,000	product group ₹ 11,000	product group ₹ 11,000
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing	product group	product group	product group
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing accredited product group per	Rs.11,000	product group ₹ 11,000	product group ₹ 11,000
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing accredited product group per discipline under Integrated	Rs.11,000	product group ₹ 11,000	product group ₹ 11,000
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing accredited product group per	Rs.11,000	product group ₹ 11,000	product group ₹ 11,000
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing accredited product group per discipline under Integrated Assessment	Rs.11,000	product group ₹ 11,000	product group ₹ 11,000
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing accredited product group per discipline under Integrated Assessment Forensic Laboratories and	Rs.11,000	product group ₹ 11,000	product group ₹ 11,000
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing accredited product group per discipline under Integrated Assessment Forensic Laboratories and Software & IT system testing	product group Rs.11,000 Rs. 25,000	product group ₹ 11,000 ₹ 25,000	product group ₹ 11,000 ₹ 25,000
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing accredited product group per discipline under Integrated Assessment Forensic Laboratories and Software & IT system testing Any extension in the existing	Rs.11,000	product group ₹ 11,000	product group ₹ 11,000
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing accredited product group per discipline under Integrated Assessment Forensic Laboratories and Software & IT system testing	product group Rs.11,000 Rs. 25,000	product group ₹ 11,000 ₹ 25,000	product group ₹ 11,000 ₹ 25,000
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing accredited product group per discipline under Integrated Assessment Forensic Laboratories and Software & IT system testing accredited scope	product group Rs.11,000 Rs. 25,000	product group ₹ 11,000 ₹ 25,000	product group ₹ 11,000 ₹ 25,000
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing accredited product group per discipline under Integrated Assessment Forensic Laboratories and Software & IT system testing accredited scope Medical Laboratories &	product group Rs.11,000 Rs. 25,000	product group ₹ 11,000 ₹ 25,000	product group ₹ 11,000 ₹ 25,000
of Scope (apart from the scheduled re-	Any extension in the existing accredited scope per product group in each discipline of testing For each additional product group in each discipline of testing Any extension in the existing accredited product group per discipline under Integrated Assessment Forensic Laboratories and Software & IT system testing accredited scope	product group Rs.11,000 Rs. 25,000	product group ₹ 11,000 ₹ 25,000	product group ₹ 11,000 ₹ 25,000

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	Centre/Facility (SCF)				
	Any extension in the e accredited scope	existing R	s. 5,500	₹ 5,500	₹ 5,500
	Any addition in Sample Collection Centre/Facility (SCF)	. 200 per SCF	₹ 200 per SCF	₹ 200 per SCF
	Medical Imaging Conf Assessment Body (MI-C				
	Any extension in the e accredited scope of MI-CA		s. 5,500	₹ 5,500	₹ 5,500
	Any extension of new	group/ Re	s. 11,000	₹ 11,000	₹ 11,000
	Calibration Laboratories	:			
	Any extension in the e accredited scope per gro discipline	existing F	Rs.5,500	₹ 5,500	₹ 5,500
	group per discipline (Medical Devices)	Except	s.11,000	₹ 11,000	₹ 11,000
	Medical Devices a) For each ado group	ditional R	s. 5,500	₹ 25,000	₹ 25,000
	.	pto 2 existing			₹ 5,500
	Proficiency Testing Prov	viders [.]			
	Addition in existing discipline		s. 5,000	₹ 5,000	₹ 5,000
	Addition of sub discipline in the existing discipline		s. 10,000	₹ 10,000	₹ 10,000
	Defense an Material Drad				
	Reference Material Produ For addition in e		s. 2,500	₹ 2,500	₹ 2,500
	subcategory			₹ 5,000	
	For each additional sub ca		s. 5,000	¢ 5,000	₹ 5,000
Change in Person responsible to authorize the results	Any addition of person de by CAB to authorize the (apart from sch assessment)		s. 5,500 / request	₹ 5,500 / request	₹ 5,500 / request
Change of Certificate	Testing, Calibration and Medical Laboratories-				
	Any change in the name a premises/ address of laboratory leading to iss new accreditation certifica / scope	f the sue of	s. 5,500	₹ 5,500	₹ 5,500
	Any change in the name a premises/ address of the M Imaging- Conformity Asses Body (MI-CAB) leading to of new accreditation cen with scope	Medical R ssment o issue	s. 5,500	₹ 5,500	₹ 5,500
	RMP & PTP-		0.000	T 0 000	T 0.000
	Any change in the name	and or R	s. 3,000	₹ 3,000	₹ 3,000
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	unus in a standard a status				
	premises/address of the				
	RMP leading to issue of accreditation certificate				
		with			
	scope				
Annual	Testing laboratories (inc	luding	Rs. 24,000	₹ 24,000	₹ 24,000
Accreditation	Integrated Assessment)		13. 24,000	X 24,000	X 24,000
Fee (per year	except Forensic laborate				
from the date of	Software & IT System te				
accreditation)	(per discipline):	- sing			
Note-	Forensic laboratories	and	Rs. 48,000	₹ 48,000	₹ 48,000
Annual	Software & IT System te	sting			·
Accreditation				•	
fee is payable in	Calibration laboratories	(per	Rs. 24,000	₹ 24,000	₹ 24,000
advance and is	discipline)				
non-refundable	except Electro-technical				
and non-	calibration laboratories				
adjustable.	Electro-technical laborator	ries	Rs. 36,000	₹ 36,000	₹ 36,000
In appendix					
In case of co-	RMP & PTP		Rs. 27,500	₹ 27,500	₹ 27,500
terminating the accreditation					
validity, the fee	Medical Laboratories (co	overing			
will be charged	all disciplines) & Sample				
on pro-rata	Collection Centre/Facilit	y			
basis.	Micro Laboratories			₹ 6,000 +	₹ 6,000 +
	(Up to 25 patients/ day/loc	cation)	-	₹ 1,000 per	₹ 1,000 per
In case of				SCF	SCF
Medical	Mini Laboratories		-	₹ 10,000 +	₹ 10,000 +
laboratory	(26 - 50 patients/ day/loca	tion)		₹ 1,000 per	₹ 1,000 per
having Multi-		,		SCF	SCF
locations,	Small Laboratories		-	₹ 20,000 +	₹ 20,000 +
Annual Accreditation	(51 - 100 patients/ day/loc	ation)		₹ 1,000 per	₹ 1,000 per
fee shall be				SCF	SCF
charged only for	Medium Laboratories		Rs. 48,000 +	₹ 48,000 +	₹ 48,000 +
the location with	(101-400 patients/ day/loc	ation)	Rs. 1,000 per	₹ 1,000 per	₹ 1,000 per
maximum			SCF	SCF	SCF
number of	Large Laboratories		Rs. 1,20,000	₹ 1,20,000 +	₹ 1,20,000 +
patients per	(401 -1000 patients/		+ Rs. 1,000	₹ 1,000 per	₹ 1,000 per
day.	day/location)		per SCF	SCF	SCF ₹ 2.40.000 L
	Very Large Laboratories (above 1000 patients/ day	,,	Rs. 2,40,000 + Rs. 1,000	₹ 2,40,000 + ₹ 1,000 per	₹ 2,40,000 + ₹ 1,000 per
Multilocation	location)		per SCF	SCF	SCF
laboratory – A	Medical Imaging Conform	mitv	Rs. 24,000/-	₹ 24,000	₹ 24,000
laboratory with	Assessment Body (MI-C		110. 2 1,000/	(21,000	(21,000
more than one location in the	· · · · · · · · · · · · · · · · · · ·				
same district.					
with same legal					
identity.					
Overhead	For each on-site assessm	ent.	Rs. 11,000/-	₹ 11,000/-	₹ 11,000/-
Charges	Desktop surveillance,	,	,		,
	irrespective of number of				
	disciplines except Micro a				
	Medical testing laboratorie	es			
Assessment	Comprising of				
Charges	- Travel, Boarding, Lodgin				
(payable after	- Honorarium for NABL As	sessors			
the completion	- Overhead Charges				
National Accre	ditation Board for Tes	ting and	d Calibration	Laboratories	
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		₹ 20,000 per			
of assessment visit to the CAB)	For Micro Laboratories charges on lump-sum basis including Honorarium, travel and overhead expenses	₹ 20,000			
	For Mini Laboratories charges on lump-sum basis including Honorarium, travel and overhead expenses	SCF	₹ 25,000		
	For Sample Collection Centre / Facility (SCF) charges on lump-sum basis including Honorarium, travel and overhead expenses	SCF	₹ 5,000 per SCF		
Travel, Boarding and Lodging expenditure	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 / money transfers in any mode etc. with the assessor. Also, CAB shall ensure the safety and security of the assessor visiting their premises for conducting assessments.				
	 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 may 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. 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. 				
	Note: The travel, boarding & lodging for Ob assessment as Observer, shall be borne by NABL.				
Honorarium for NABL	Document review by Lead Assessor	₹ 2,000	₹ 3,000 per CAB		
Assessors	Pre-Assessment, Assessment, Verification, Special Visit				
	- by Lead Assessor	₹ 4,500	₹ 5,500		
	- by Technical Assessor/ Expert	per day ₹ 4,000	per day ₹ 5,000		
		per day	per day		

Note: In addition to the above-mentioned fee, GST @ 18.0 % (or as applicable from time to time decided by Govt. of India) 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% (or as applicable from time to time decided by Govt. of India) is to be paid along with said charges / fees.

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Fee Structure for Accreditation of Conformity Assessment Bodies of SAARC Countries (w.e.f. 01.10.2021)

		SAARC Countries
Application Fee (non-refundable,	Testing Laboratories For up to 02 product group/ discipline (e.g., Metals & alloys, Food & agricultural	500 USD
to be paid along	products, Drugs & pharmaceuticals, Textiles, Radiography,	
with the application)	Computed Tomography etc.)	
	For each additional product group in each discipline of testing	200 USD
	Medical Laboratories (covering all disciplines) & Associated Sample Collection Centre/Facility (SCF)	
	Small Laboratories	500 USD +
	(upto 100 patients/ day/location)	100 USD per 20 SCF
	Medium Laboratories	1175 USD +
	(101-400 patients/ day/location)	100 USD per 20 SCF
	Large Laboratories	1350 USD +
	(401-1000 patients/ day/location)	100 USD per 20 SCF
	Very Large Laboratories	2700 USD +
	(above 1000 patients/ day/location)	100 USD per 20 SCF
	Calibration Laboratories:	
	Mechanical – For 02 groups (e.g. Dimension, force etc.)	500 USD
	For each additional group in mechanical discipline.	200 USD
	Electro-Technical	1000 USD
	(all parameters)	1000 000
	Thermal (all parameters)	500 USD
	Fluid Flow (all parameters)	500 USD
	Optical (all parameters)	500 USD
	Radiological	500 USD
	(all parameters)	
	Medical Devices	1200 USD
	(Up to two groups)	
	Profisionary Tasting Providers	
	Proficiency Testing Providers: For one Sub discipline per discipline	600 USD
	e.g. Chemical under Testing	000 030
	Note: Chemical is sub discipline under Testing; Clinical	
	Biochemistry is sub discipline under Medical; Mechanical is	
	sub discipline under Calibration	
	For each additional sub discipline in the same Discipline	500 USD
	Reference Material Producers:	
	Per Category – up to 2 sub-categories	600 USD
	e.g. Metals & Organic Reference Materials under Chemical Composition	

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	Noto: Motolo & Organia Deference Materiale are	
	Note: Metals & Organic Reference Materials are Subcategories under Category Chemical Composition.	
	Similarly, Tensile Strength and Elasticity are Subcategories	
	under Engineering Properties	
	For each additional sub-category in the same category	200 USD
Enhancement	Testing Laboratories	100 USD
of Scope (apart	Any extension in the existing accredited scope per	
from the	discipline of testing	
scheduled re-	For each additional product group in each discipline of	200 USD
assessment)	testing	
	Medical Laboratorica & Accessisted Sample Collection	
	Medical Laboratories & Associated Sample Collection Centre/Facility (SCF)	
	Any extension in the existing accredited scope	100 USD
	Any addition in Sample Collection Centre/Facility (SCF)	USD 100 per 20
	· · · · · · · · · · · · · · · · · · ·	SCF
	Calibration Laboratories:	
	Mechanical – Any extension in the existing accredited	100 USD
	scope per group per discipline	000 1100
	For each additional product group per discipline For extension in Electro-Technical, Thermal, Fluid Flow,	200 USD 100 USD
	Optical, Radiological disciplines	100 030
	Medical Devices	
	For each additional group	600 USD
	Addition of upto 2 equipment in existing accredited group	100 USD
	<u> </u>	
	Proficiency Testing Providers:	
	Addition in existing Sub discipline	100 USD
	Addition of sub discipline in the existing discipline	200 USD
	Poteronan Material Producers:	
	Reference Material Producers: For addition in existing subcategory	100 USD
	For each additional sub category	200 USD
		200 000
Change in	Any addition of person declared by CAB to authorize the	100 USD
Person	results (apart from scheduled assessment)	
responsible to		
authorize the		
results		
Change of	Testing, Calibration and Medical Laboratories-	
Certificate	Any change in the name and/ or premises/ address of the	200 USD
	laboratory leading to issue of new accreditation certificate	200 0 00
	and / scope	
	Any change in the name and/ or premises/ address of the	200 USD
	Medical Imaging- Conformity Assessment Body (MI-CAB)	
	leading to issue of new accreditation certificate with scope	
	RMP & PTP-	
	Any change in the name and or premises/address of the	200 USD
	PTP or RMP leading to issue of new accreditation	200 000
	certificate with scope	

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*Annual	Testing laboratories /discipline	500 USD		
Accreditation	Accreditation			
Fee (per year	Calibration laboratories (per discipline)	500 USD		
from the date of	except Electro-technical calibration laboratories			
accreditation)	Electro-technical laboratories	1000 USD		
	RMP & PTP	500 USD		
	Medical Laboratories (covering all disciplines) & Sample	1000 USD		
	Collection Centre/Facility (SCF)			
Desktop	Irrespective of number of disciplines.	200 USD		
Surveillance Fee	Surveillance Fee			
Document Review		200 USD/ CAB		
Assessment Charges		100 USD/ Man Day/		
(Payable after the	(Payable after the completion of assessment visit to the CAB)			

Note:

- CABs situated outside India to contact NABL for making the payments
 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 CAB shall make arrangements for travel, boarding & lodging for the assessment team. A single occupancy accommodation to 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 CAB shall assist in VISA and arrange other logistics like travel insurance and accommodation.

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Fee Structure for Accreditation of Conformity Assessment Bodies of other than SAARC Countries (w.e.f. 01.10.2021)

		Other than SAARC Countries
Application Fee (non-refundable, to be paid along with the	Testing Laboratories For up to 02 product group/ discipline (e.g., Metals & alloys, Food & agricultural products, Drugs & pharmaceuticals, Textiles, Radiography, Computed Tomography etc.)	1000 USD
application)	For each additional product group in each discipline of testing	500 USD
	Medical Laboratories (covering all disciplines) & Associated Sample Collection Centre/Facility (SCF)	
	Small Laboratories (upto 100 patients/ day/location)	1000 USD + 100 USD per 20 SCF
	Medium Laboratories	2350 USD +
	(101-400 patients/ day/location)	100 USD per 20 SCF
	Large Laboratories	2700 USD +
	(401-1000 patients/ day/location)	100 USD per 20 SCF
	Very Large Laboratories	5400 USD +
	(above 1000 patients/ day/location)	100 USD per 20 SCF
	Calibration Laboratories:	
	Mechanical – For 02 group (e.g. Dimension, force etc.)	1000 USD
	For each additional group in mechanical discipline.	500 USD
	Electro-Technical (all parameters)	2000 USD
	Thermal (all parameters)	1000 USD
	Fluid Flow (all parameters)	1000 USD
	Optical (all parameters)	1000 USD
	Radiological	1000 USD
	(all parameters)	
	Medical Devices	2400 USD
	(Up to two groups)	
	Proficiency Testing Providers:	
	For one Sub discipline per discipline e.g. Chemical under Testing Note: Chemical is sub discipline under Testing; Clinical Biochemistry is sub discipline under Medical; Mechanical	1200 USD
	is sub discipline under Calibration	
	For each additional sub discipline in the same Discipline	1000 USD
	Reference Material Producers:	
	Per Category – up to 2 sub-categories e.g. Metals & Organic Reference Materials under Chemical Composition	1200 USD
	Note: Metals & Organic Reference Materials are Subcategories under Category Chemical Composition. Similarly, Tensile Strength and Elasticity are	
	Subcategories under Engineering Properties	

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	For each additional sub-category in the same category	400 USD
F	Testing Laboratoria	000 1100
Enhancement of Scope (apart from the scheduled re-	Testing Laboratories Any extension in the existing accredited scope per discipline of testing	200 USD
assessment)	For each additional product group in each discipline of testing	500 USD
	Medical Laboratories & Associated Sample Collection Centre/Facility (SCF)	
	Any extension in the existing accredited scope	200 USD
	Any addition in Sample Collection Centre/Facility (SCF)	200 USD per 20 SCF
	Calibration Laboratories:	
	Mechanical – Any extension in the existing accredited scope per group per discipline	200 USD
	For each additional product group per discipline	500 USD
	For extension in Electro-Technical, Thermal, Fluid Flow, Optical, Radiological disciplines	200 USD
	Medical Devices	4000 LICD
	For each additional group Addition of upto 2 equipment in existing accredited group	1200 USD 200 USD
		200 030
	Proficiency Testing Providers:	
	Addition in existing Sub discipline	200 USD
	Addition of sub discipline in the existing discipline	500 USD
	Reference Material Producers:	
	For addition in existing subcategory	200 USD
	For each additional sub category	500 USD
Change in Person responsible to authorize the results	Any addition of person declared by CAB to authorize the results (apart from scheduled assessment)	200 USD
Change of	Testing, Calibration and Medical Laboratories-	
Certificate	Any change in the name and/ or premises/ address of the laboratory leading to issue of new accreditation certificate and / scope	500 USD
	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	500 USD
	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	500 USD
*Annual	Testing laboratories /discipline	1000 USD
Accreditation		
Fee (per year from the date of	Calibration laboratories (per discipline) except Electro-technical calibration laboratories	1000 USD
accreditation)	Electro-technical laboratories	2000 USD

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	RMP & PTP	1000 USD	
	Medical Laboratories (covering all disciplines) & Sample		
	Collection Centre/Facility (SCF)		
Desktop	Irrespective of number of disciplines.	500 USD	
Surveillance Fee			
Document Review	Document Review		
Assessment Charges		600 USD/ Man Day/	
(Payable after the completion of assessment visit to the CAB)		Assessor	

Note:

- 1. CABs situated outside India to contact NABL for making the payments
- 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 CAB shall make arrangements for travel, boarding & lodging for the assessment team. A single occupancy accommodation to 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 CAB shall assist in VISA and arrange other logistics like travel insurance and accommodation.

Instructions for conformity assessment bodies

- The application fee is non-refundable and non-adjustable.
- An overhead charge is applicable for all on-site and off-site assessments.
- To minimise assessment cost, NABL policy is to select/ assign assessor (assessment team) from
 - i. Local,
 - ii. Regional,
 - iii. National

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10.MODES OF PAYMENT

S. No.	Options	Remarks				
1.	Payment gateway for making online payments (Preferred and easiest method as payment is easily traceable and reconcilable in an accurate and timely manner)	 Gateway may be accessed from the home page of NABL website. Existing CABs may obtain the Login credentials from NABL; New CABs may pay directly through gateway without any login. 				
2.	<u>NEFT to following account</u> : Quality Council of India HDFC Bank Kanjurmarg Branch, Mumbai IFSC Code – HDFC0004989 Virtual A/c No. – <i>Unique for</i> <i>each CAB</i>	 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 ld; Do not use any other account of 'Quality Council of India' for NEFT. 				

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11.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

Benefits of Laboratory Accreditation

Formal recognition of competence of a laboratory by NABL in accordance with international standard (ISO/IEC 17025 or ISO 15189) has many advantages:

- A ready means for customers to identify and select reliable testing, measurement and calibration services that can 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.
- Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.

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Benefits of Accreditation for Proficiency Testing Provider (PTP)

Formal recognition of competence of a PTP by NABL in accordance with international criteria (ISO/IEC 17043) has many advantages:

• Recognition of Competence:

ISO/IEC 17043 specifies the general requirements for conducting a proficiency testing scheme. PTP accredited by NABL as per ISO/IEC 17043 confirms its competence to conduct the PT Scheme. PT providers demonstrate ability in preparation, testing and statistical approaches for handling, homogeneity and stability of PT items/artifacts as well as the analysis of participants data.

• Establishment of Credibility and trust of the Proficiency Testing Provider

Proficiency Testing Provider accredited by NABL as per ISO/IEC 17043 confirms its competence in the planning, development, and execution of proficiency testing schemes as per ISO/IEC 17043. This builds confidence in laboratories, regulators and other stakeholders.

• Continuous development of Proficiency Testing Provider

NABL regularly assesses the competence of its accredited Proficiency Testing Providers. Hence, Proficiency Testing Provider gets an opportunity and scope for further improvement and development.

Global acceptance

NABL is an MRA signatory to APAC and ILAC as per ISO /IEC 17043. PT scheme conducted by accredited PT providers is accepted worldwide.

• Competitive Market Edge

NABL provides the details of accredited proficiency testing providers, like contact details, field, product and parameters along with the schedule of available PT programs on NABL website. Details of accredited PT providers are also getting updated on the APAC website. Laboratories and interested parties throughout the world can get the details of the PT program and contact PT providers for participation.

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Benefits of Accreditation for Reference Material Producers (RMP)

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

• Recognition to competence

ISO 17034 specifies the general requirements for the competence of reference material producers. Accreditation as per ISO 17034 gives recognition to RMP that it is competent to carry out the production of Reference Materials. RMP demonstrates its ability in preparation, characterization, homogeneity, and stability assessment of Reference Materials.

• Establishment of Credibility and trust on the Reference Material Producers

Reference Material Producer accredited by NABL as per ISO 17034 confirms its competence in the planning, preparation, and production of Reference Material as per the internal standard. This builds confidence in laboratories, regulators, and other stakeholders.

• Continuous development of RMP

NABL regularly assesses the competence of its accredited Reference Material Producers. Hence, Reference Material Producers get an opportunity for further improvement and development.

• Global acceptance of Reference material:

NABL is ILAC MRA signatory for ISO 17034. Hence reference materials produced by NABL Accredited RMPs are accepted globally in countries that are signatory to the ILAC MRA.

Benchmark to competence

RMPs are re-assessed periodically by NABL to ensure their continued compliance to the requirements of ISO 17034. Hence, RMP can develop benchmark to maintain its competence.

• Competitive Market Edge

NABL provides the details of accredited Reference Material Producers, like contact details, type of Reference Materials along with property value, available Reference Materials on NABL website. Laboratories and interested parties throughout the world can get the details of the Reference Material and contact the RMP directly.

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12.CONTACT DETAILS

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