

NABL 100



National Accreditation Board for Testing and Calibration Laboratories (NABL)

General Information Brochure

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1. Conformity Assessment

International Standard ISO/IEC 17000 defines Conformity Assessment as a “Demonstration that specified requirements related to a product, process, system, person or body are fulfilled.” Conformity Assessment procedures, such as testing / calibration, inspection and certification, offers assurance that products fulfill the requirements specified in regulation and standards.

Each organization must decide which type of conformity assessment is necessary for which purpose. This decision should be based on an assessment of the risk involved with a particular product or process, and on an understanding of the impact the associated costs and benefits will have on achievable development.

Successive reviews of the WTO/TBT agreement have noted the usefulness of ISO/IEC conformity assessment standards and guide in harmonizing the conformity assessment practice and as benchmarks for the technical competence of assessment bodies, thus enhancing the credibility and confidence in their results. ISO/IEC conformity assessment work therefore helps to overcome technical trade barrier.

Accreditation is the third-party attestation related to a conformity assessment body conveying the formal demonstration of its competence to carry out specific conformity assessment task. Conformity Assessment Body (CAB) is a body which includes Testing including Medical Laboratory, Calibration Laboratory, Proficiency Testing Provider and Reference Material Producers.

Laboratory accreditation is a procedure by which an authoritative body gives formal recognition of technical competence for specific tests/ measurements, based on third party assessment and following international standard.

The general requirements for laboratories or other organizations, to be considered competent to carry out sampling, testing including Diagnostic Radiology QA Testing and Software & IT System testing (other than medical) and calibration are specified in the International Standard ISO/IEC 17025:2005 or ISO/IEC 17025:2017.

Another very important area under testing, which plays a vital role in human health, is medical / clinical diagnostic testing. Requirements for quality and competence to carry out sampling and testing in medical field are specified in the International Standard ISO 15189:2012. NABL also grants accreditation to Medical Imaging- Conformity Assessment Body (MI-CAB) based on ISO 15189:2012.

Further, to strengthen the pre-examination process performed in sample Collection Centres / Facility(ies), NABL also recognizes these Sample Collection Centres / Facility(ies) declared by its associated accredited medical laboratories. NABL recognition of Sample Collection Centres/ Facility (ies) (SCF) declared by medical testing laboratories, is of paramount significance in ensuring the quality services rendered by the Sample Collection Centres/ Facilities (SCF). The assessment of all declared Sample Collection Centres/ Facility(ies) will ensure integrity of samples and better control on pre-examination processes as quality of test results largely depends on these processes. Moreover, this will also enhance the confidence of Sample Collection Centres / Facility (ies) and accord due recognition to these Centres / Facilities (SCF). The laboratory shall be responsible for the operation of the recognized Sample Collection Centres / Facility (ies).

Proficiency Testing is the use of inter-laboratory comparison for determining the performance of individual laboratories for specific tests. Participation in proficiency testing programmes provides laboratories with an objective means of assessing and demonstrating the reliability of data they are producing. The International Standard ISO/IEC 17043:2010 provides a consistent basis for all interested parties to determine the competence of organizations that provide proficiency testing.

Certified Reference Materials (CRMs) are 'controls' or standards used to check the quality and metrological traceability of products, to validate analytical measurement methods, or for the calibration of instruments. The reference material producer is fully responsible for project planning and management, assignment of and decision on property values and relevant uncertainties, authorization of property values and issue of the certificate and other statement for the reference materials it produces. ISO 17034:2016 specifies General Requirements in accordance with which a reference material producer has to demonstrate that it operates, if it is to be recognized as competent to carry out the production of reference materials.

In the current global scenario, an essential pre-requisite of trade is that any product or service accepted formally in one economy must also be free to circulate in other economies without having to undergo extensive re-testing. WTO recognizes that non-acceptance of test results and measurement data is a Technical Barrier to Trade. Global sourcing of components calls for equivalence of measurement, which can be facilitated by a chain of accredited CABs. Accreditation is considered as the first essential step for facilitating mutual acceptance of test results and measurement data.

Confidence in accreditation is obtained by a transparent system of control over the accredited CABs and an assurance given by the accreditation body that the accredited CAB fulfils the accreditation criteria, at all times.

Accredited CABs can objectively state conformance of product or service to the specified requirements. It is important for the purchaser, regulator, government and public to be able to identify the accredited CABs.

2. Benefits of Accreditation

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

- Increased confidence in Testing/ Calibration Reports issued by the laboratory.
- Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
- Potential increase in business due to enhanced customer confidence and satisfaction.
- Customers can search and identify the laboratories accredited by NABL for their specific requirements from the NABL Web -site 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.

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

- Comparison of a facility's performance with that of other participating (peer) facilities
- Monitoring of a long-term facility performance
- 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
- Estimation of measurement uncertainty
- Contribution to the facility's 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 accredited PTP gives the organization credibility for their PT services.

Formal recognition of competence of a RMP by an Accreditation body in accordance with international criteria has many advantages

- 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 fitted 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 Guide 34: 2009 / 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.

3. About NABL

NABL is a constituent Board of Quality Council of India (QCI). QCI is a registered society under the Societies Registration Act, 1860. Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India is the nodal Department for QCI.

NABL has been established with the objective of providing Government, Industry Associations and Industry in general with a scheme of Conformity Assessment Body's accreditation which involves third-party assessment of the technical competence of testing including medical and calibration laboratories, proficiency testing providers and reference material producers.

The laboratory accreditation services to testing and calibration laboratories are provided in accordance with ISO/ IEC 17025: 2005 or ISO/IEC 17025:2017 'General Requirements for the Competence of Testing and Calibration Laboratories' and ISO 15189: 2012 'Medical laboratories -- Requirements for quality and competence' The accreditation to Proficiency testing providers are based on ISO/IEC 17043 :2010 "Conformity assessment -- General requirements for proficiency testing" and to Reference Material Producers based on ISO 17034:2016 - General requirements for the competence of reference material producers "The fields, disciplines and groups for which the accreditation services are offered are listed in 'Scope of NABL Accreditation'.

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

NABL has established its accreditation system in accordance with ISO/ IEC 17011: 2017 'Conformity Assessment –Requirements for Accreditation bodies accrediting conformity assessment bodies'. NABL accreditation system also takes note of the requirements of Mutual Recognition Arrangements (MRAs) of which NABL is a member.

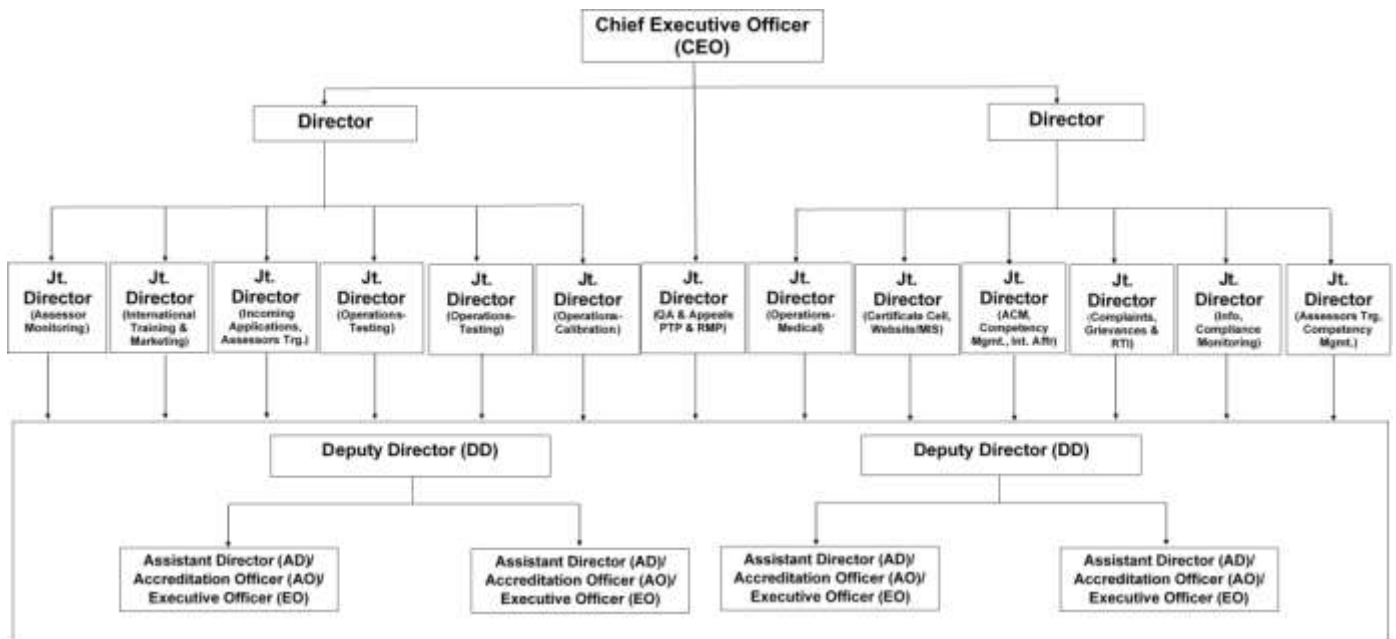
NABL publishes documents for the CABs, Assessors and its own use. A list of NABL documents is given at the end of this document. All NABL documents meant for the use by persons outside NABL, are available on NABL website www.nabl-india.org, free of cost.

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 Secretariat comprises of Chief Executive Officer (CEO), Director, Joint Director, Deputy Director, Assistant Director, Quality Manager, Complaints Manager, Appeals Officer, Accreditation Officers, Administration and support staff. The CEO, NABL is responsible for administering and managing the day to day operations of NABL Secretariat.

The 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. Membership of accreditation committees is drawn from NMIs and standards bodies, experienced assessors (including those from accredited CABs), academic institutions, important professional bodies, regulatory agencies/ bodies etc. The members of the Accreditation Committee are selected on the basis of their technical knowledge and familiarity with accreditation process. However, care is taken while selecting composition of an Accreditation Committee that expertise in all areas covered under the committee is available and no single group or organization pre-dominates the committee.

The formulation of technical/ specific guidelines and other similar tasks is derived from various ad-hoc technical committees set up for the purpose. Composition of 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.

Related bodies

The National Metrological Institutes (NMIs) namely National Physical Laboratory (NPL) and Bhabha Atomic Research Centre (BARC); the Standards Bodies namely Bureau of Indian Standards (BIS) and Standardization, Testing and Quality Certification (STQC), Council for Industrial and Scientific Research (CSIR), the other Boards of Quality Council of India (QCI), the other organizations under nodal department of QCI i.e. Department for Promotion of Industry and Internal Trade, the other Departments / organizations under nodal Ministry i.e. Ministry of Industry and Commerce are the bodies related to NABL. Due care is taken to determine and avoid potential for conflict of interest from the activities of the related bodies in the operation of NABL.

4. International Linkages

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 of ILAC and APAC and regularly takes part in their meetings. More information on these international co operations can be obtained from their web-sites www.ilac.org and www.apac-accreditation.org respectively.

NABL is signatory to ILAC as well as APAC Mutual Recognition Arrangements (MRA) for accreditation of Testing including Medical and Calibration laboratories, which is based on mutual evaluation and acceptance of other MRA Partner accreditation systems. Such international arrangements facilitate acceptance of test/ calibration results between countries which MRA partners represent. NABL is also signatory to APAC MRA for accreditation of Proficiency Testing Providers (PTP) and Reference Material Producers (RMP)

The information on ILAC and APAC Mutual Recognition Arrangements (MRA s) is available at NABL web-site. 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.

5. Scope of NABL Accreditation

NABL Accreditation is currently given in the following fields and disciplines. The multi-disciplinary CABs shall have to apply in relevant discipline separately depending upon to which discipline the scope belongs.

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- 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

PROFICIENCY TESTING PROVIDERS (PTP)

- Testing
- Calibration
- Medical
- Inspection

REFERENCE MATERIAL PRODUCERS (RMP)

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

For classification of product groups in each field, refer **NABL 120** for Testing & Calibration, **NABL 126** for Medical Devices Calibration, **NABL 180** for PTP & **NABL 191** for RMP.

6. Preparing for Accreditation

Once the CAB decides to seek NABL accreditation, it should make a definite plan of action for obtaining accreditation and nominate a responsible person to co-ordinate all activities related to seeking accreditation. The person nominated should be familiar with CAB's existing quality system.

A list of NABL external documents is given at the end of this document and is also available on NABL website under Publications – Accreditation Documents. The CAB should get fully acquainted with relevant NABL documents and understand the assessment procedure and methodology for filing the on-line application. NABL only accepts online application and do not entertain any applications in hard copy (kindly refer website www.nabl-india.org).

CAB needs to ascertain the status of its existing quality system and technical competence with regards to the requirement of ISO/ IEC 17025:2017 or ISO 15189:2012 or ISO/IEC 17043:2010 or ISO 17034:2016 whichever is relevant and requirements of NABL. The questions the CAB needs to address are:

- Does the CAB have a quality management system?
- If yes, is the quality management system documented and effective?
- If no, what are the corrective steps needed?

It must be remembered that CAB has to prepare a Management system document/ quality manual, which has to be supplemented by a set of other documents like procedural manuals, work instructions etc. Requirements of the applicable standard and relevant NABL specific criteria (wherever applicable) should be discussed amongst concerned staff of the CAB. This will enable them to understand their strengths and weaknesses.

For preparing the Management system document/ quality manual or verifying its contents, the CAB may get its technical personnel trained in training programs on quality management system for CAB personnel organized by various institutes. The proposed person responsible for quality management system shall have undergone 4-days formal training on management system and internal audit based on relevant standard or any other equivalent training on the relevant standard in case of overseas CABs (Please refer NABL 165 for the training requirement).

The CAB must ensure that the procedures described in the Management system document/ quality manual and other documents are being implemented.

7. Eligibility for Accreditation

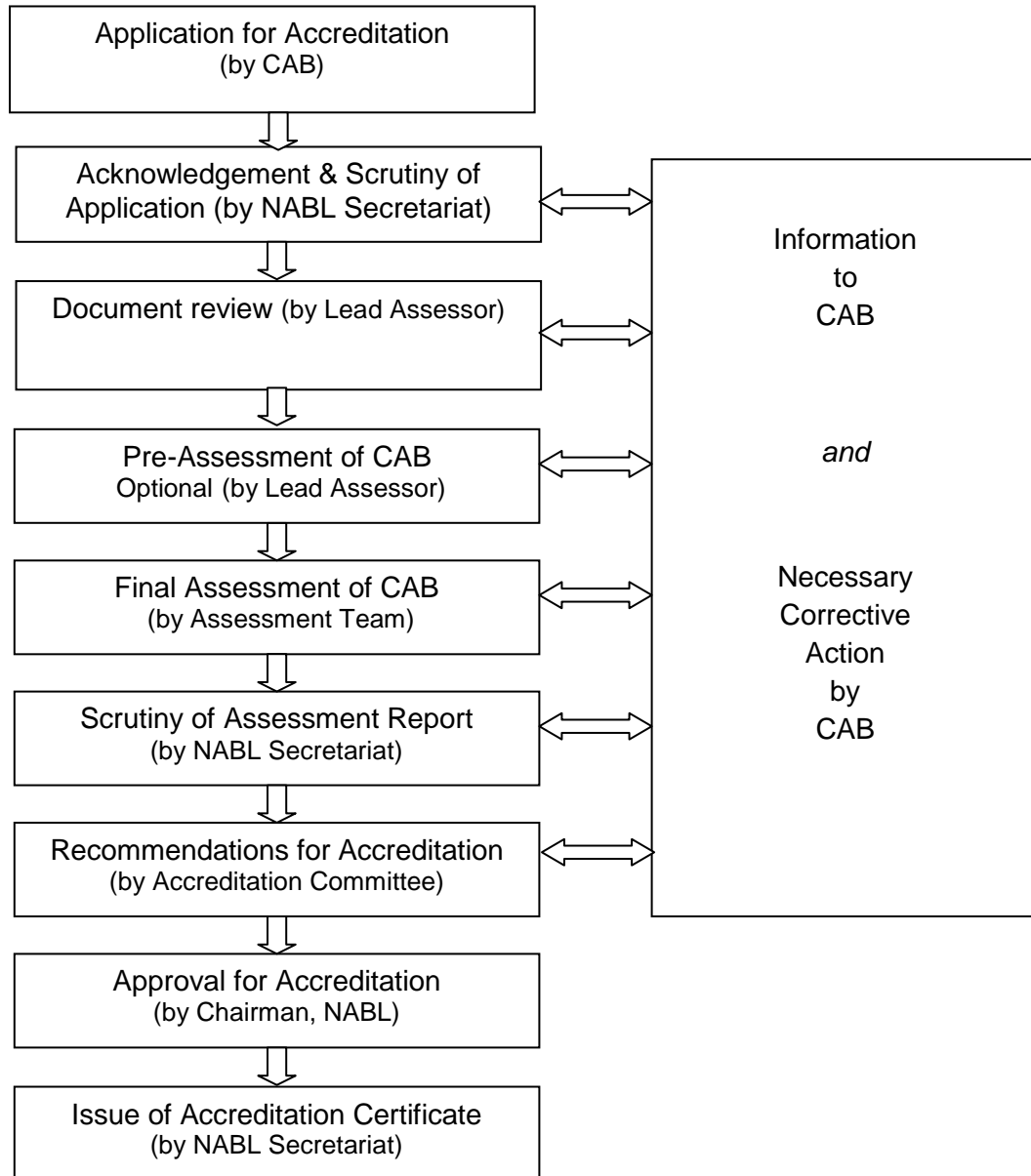
The applicant CAB must comply with all clauses of ISO/IEC 17025:2005/ ISO/IEC 17025:2017 or ISO 15189: 2012 or ISO/IEC 17043:2010 or ISO 17034:2016 whichever is applicable. The applicant CAB must also comply with the relevant NABL specific criteria (wherever applicable).

In case the laboratory performs site testing/ calibration, it must also comply with NABL 130 'Specific criteria for site testing and site calibration laboratories.

The applicant CAB must have participated satisfactorily in the proficiency testing program, wherever applicable, conducted by NABL/ APAC or any other national or international accredited/ recognized PT provider. If no suitable PT program is available the CAB can initiate an inter-laboratory comparison with adequate number of accredited laboratories. The minimum stipulated participation for laboratories is one parameter/ type of test/ calibration per discipline, prior to grant of accreditation and an on-going program as per NABL 163. The satisfactory performance shall be defined in term of z-score and En number respectively or any other acceptable internationally accepted method. For unsatisfactory performance, the CAB is to take corrective action and inform NABL. ISO/ IEC 17043, NABL 163 and NABL 164 give details of proficiency testing.

The applicant CAB must have conducted at least one internal audit and a management review before the submission of application. ISO 19011 'Guidelines for auditing management systems' and NABL 161 'Guide for Internal Audit and Management Review for CABs' provides the necessary guidance for CABs.

8. Accreditation Procedure



Flow Diagram of Accreditation Process

Application for Accreditation

CABs are required to apply through NABL Web Portal (through website www.nabl-india.org) to NABL in prescribed application form (NABL 151, NABL 152, NABL 153) for Testing including Medical along with associated Sample Collection Centre/ Facilities (SCF) / Calibration Laboratories which 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 prescribed application form NABL 156.

However, CABs are required to apply to NABL in prescribed application form (NABL 180 and NABL 190) for Proficiency Testing Providers & Reference Material Producers in one copy along with one copy of the Manual of the CAB 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. A signed copy of NABL 131 shall also be submitted 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.

Acknowledgement and Registration of Application

NABL Secretariat through Web Portal, on receipt of online application form along with Management system document / quality manual and the fees, send an acknowledgement with a unique ID number 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 Secretariat may ask for additional information/ clarification(s) at this stage, if found necessary.

Appointment of Lead Assessor

NABL secretariat appoints a Lead assessor from the list of empanelled assessors. The lead assessor does the document review on behalf of NABL and submits the report to NABL secretariat.

Document Review

The preliminary document review of the application and management system document/ quality manual submitted by the CAB is carried out by NABL Secretariat 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 also implements the management system accordingly.

Pre-Assessment

In case there are no inadequacies in the document review 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, CAB shall express its willingness in writing to undergo the same. The CAB must ensure their preparedness by carrying out an internal audit and a management review before the pre -assessment.

The pre-assessment of the CAB is conducted to:

- a. evaluate non-conformities (if any) in the implementation of the quality 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 Secretariat 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 Secretariat.

Assessment

After the CAB has taken corrective actions, NABL proposes constitution of an assessment team. The team includes the lead assessor (generally same who is already appointed for pre-assessment), the technical assessor(s)/ expert(s) in order to cover various fields within the scope of accreditation sought. NABL may also nominate an observer. NABL seeks CAB's acceptance for the proposed assessment team and the CAB is free not to accept one or more members of the proposed assessment team by giving specific reason(s) for their non - acceptance.

After the constitution of assessment team is finalized, NABL fixes dates for on-site assessment in consultation with the CAB, the lead assessor and technical assessor(s)/ expert(s).

The assessment team reviews the CAB 's documented management system and verifies its compliance with the requirements of ISO/ IEC 17025: 2005/ 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 manpower, all relevant material examined, test witnessed including those of replicate testing/ measurement, compliance to ISO/ IEC 17025: 2005/ 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 Secretariat. 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.

Assessment of each declared Sample Collection Centre/ Facility (SCF) of a medical 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.

Scrutiny of Assessment Report

The assessment report is examined by NABL Secretariat and follow up action as required is initiated. CAB has to take necessary corrective action on non - conformities/ concerns and submit a report to NABL Secretariat within 30 days. NABL monitors the progress of closing 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 time. 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.

Accreditation Committee

After satisfactory corrective action by the CAB, the Accreditation Committee examines the assessment report, additional information received from the CAB and the consequent verification, if any.

In case the Accreditation Committee finds deficiencies in the assessment report, the NABL Secretariat 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 Chairman, NABL.

All decisions taken by NABL regarding grant of accreditation are open to appeal by the CAB. The appeal is to be addressed to the CEO, NABL.

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, discipline, 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 and Tests or Type of tests performed and, where appropriate, the techniques, methods and / or equipment used.

The scope of accreditation for calibration laboratory defines Discipline/ Group, Measurand or reference material, type of instrument or material to be calibrated or measured, and Calibration or measurement method or procedure and Measurement range & additional parameters where applicable and CMC in terms of Measurement uncertainty.

The scope of accreditation for medical laboratory defines Discipline/ Group, Materials or products tested component, Parameter or characteristic tested and Tests or type of tests performed and, where appropriate, the techniques, methods and / or 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 Proficiency testing item / Matrix and Measurand (s) or characteristic or type of measurand or type of characteristic or analyte or parameter.

The scope of accreditation for reference material producer defines Type of Reference material (CRM, RM or both), Category & Subcategory and reference material matrix or artefact, and Property/ properties characterized and the 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(s) is/ are issued to them.

9. Integrated Assessment of Testing Laboratories by NABL & Regulatory Body (ies)

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.

Followings are the framework:

- The requirements of NABL & Additional Requirements of 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 by the testing laboratories.
- The laboratory shall successfully participate in PT program as per NABL 163.
- Laboratories shall continuously participate in PT programs for the coverage of the scope in a block of 4 years. Format for the submission of PT plan is available (Form 18 of NABL 163 available on NABL website).

- Participation in PT program can be from National or International PT Provider who are accredited as per ISO/IEC 17043. If accredited PT Providers are not available, then participation in applicant PT provider is acceptable.
- When there is no PT program available nationally or internationally, the laboratory will follow the requirements as defined by respective Regulatory Body's additional requirement document; NABL 127: Additional Requirements of Regulatory Body (ies) for 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 Integrated Assessment.
- In case of unsatisfactory results of PT (Quantitative score $|Z| \geq 3$) is scored, the same shall be informed to NABL & other relevant Regulatory Body (ies) immediately. Laboratories shall take appropriate corrective actions in case of poor performance in PT programs within two months period.
- Apart from the above defined minimum requirements, lab shall abide by the PT participation required by the respective Regulators, NABL & regional bodies like APAC.
- 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.
- Accreditation and Recognition/ Approval of testing laboratories through integrated assessment shall be subject to the annual Onsite surveillance visits to adjudge the continued compliance to the said requirements. However, the Onsite surveillance will be less comprehensive than re-assessment.

- In case NABL or other authorities (who has granted approval under integrated assessment) receives 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 are observed, then joint action including withdrawal/ suspension 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; *NABL Policy for Use of NABL symbol / Claim of Accreditation by Accredited Conformity Assessment Bodies & NABL Accredited CAB Combined ILAC MRA Mark.*

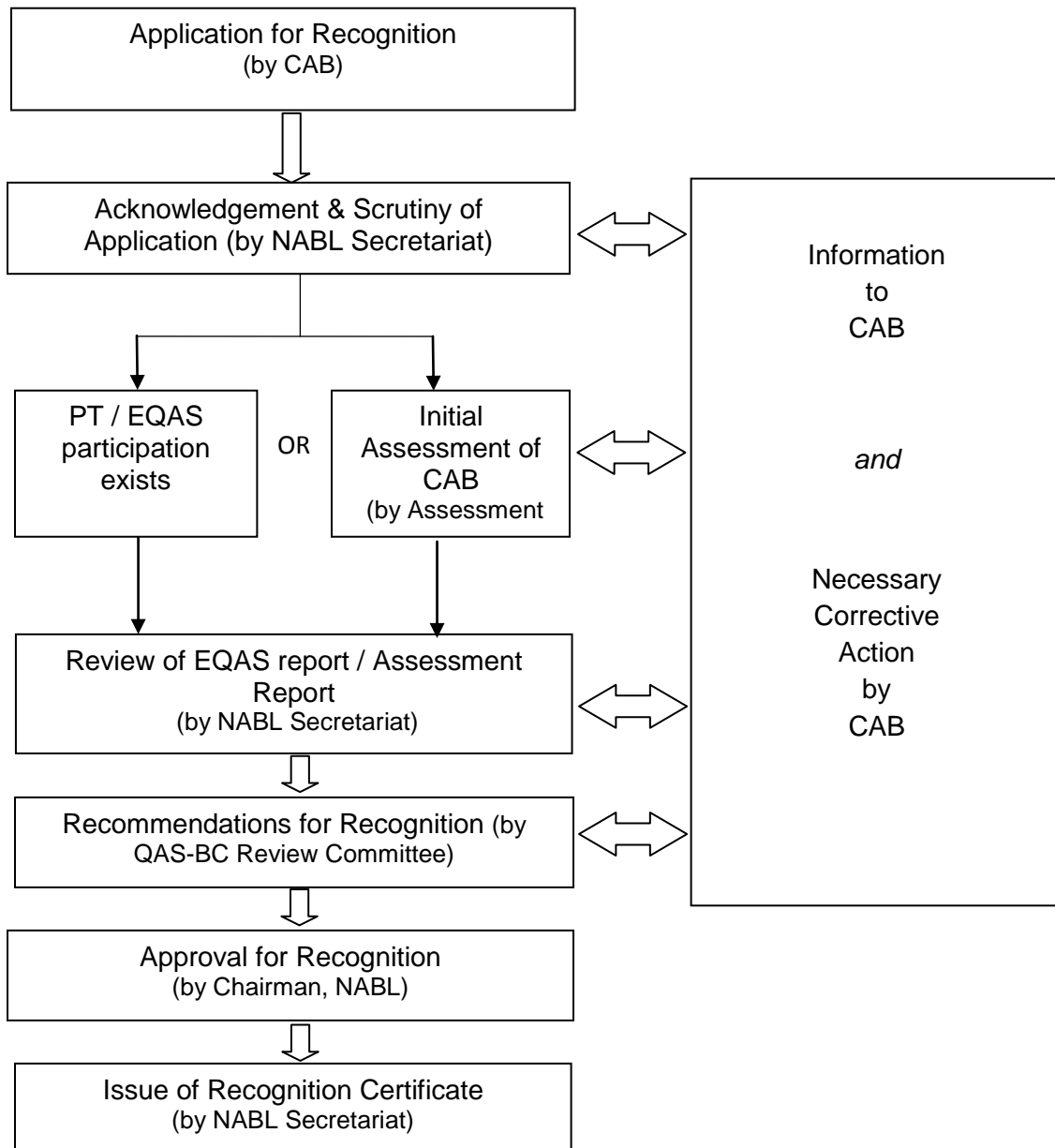
10. Quality Assurance Scheme for Basic Composite Medical Laboratories (Entry Level)

For sensitizing the 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, NABL has launched voluntary scheme namely Quality Assurance Scheme for Basic Composite Medical Laboratories (Entry Level). The criteria is based on the requirements enlisted in Gazette notification dated 18th May, 2018 by MoHFW to amend Clinical Establishments (Central Government) Rules, 2012. Components of competence assessment have been added for assuring Quality and validity of test results.

This scheme of Basic Composite Medical Laboratories (Entry Level) is an independent quality assurance scheme, which is not covered under APAC & ILAC MRA.

Interested laboratories are required to submit application and undergo third party assessment by NABL. The assessment process is based on the checklist. Laboratories are required to pay towards application fee, assessment charges and annual membership fee (*Please refer section of 'NABL Finance and Fee Structures' of this document for details*). The laboratories will be recognized for a period of three years. It is desired that subsequently the laboratories achieve accreditation as per ISO 15189.

The Scheme Documents, Application for Quality Assurance Scheme for Basic Composite Laboratories (NABL 155) and Procedure for Quality Assurance Scheme for Basic Composite Laboratories (NABL 128) are available on the website of NABL www.nabl-india.org.



Flow Diagram of Recognition Process under Quality Assurance Scheme for Basic Composite Medical Laboratories (Entry Level)

11. Maintaining Accreditation

Conformance to Applicable standards and NABL requirements

The accredited laboratories 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.

NABL Terms and Conditions

The accredited CABs are required to comply at all times with the terms and conditions of NABL given in NABL 131 'Terms & Conditions for obtaining and maintaining NABL Accreditation'. The 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.

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.

Adverse decision against the laboratories

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, scope reduction, abeyance, suspension or forced withdrawal. NABL 216 'Procedure for dealing with adverse decisions' gives the details.

12. Surveillance and Re-assessment

NABL applies an assessment programme comprising of annual desktop surveillance during each accreditation cycle of 2 years. At the end of the accreditation cycle, an on-site re-assessment is conducted covering representative scope of accreditation. The NABL accreditation certificate is valid for a period of 2 years. NABL conducts annual Desktop Surveillance which is aimed at evaluating continued compliance with ISO/IEC 17025:2005 or 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:

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). NABL conducts annual desktop surveillance during each accreditation cycle of 2 years.

Reassessment

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.

The renewal application is submitted in the prescribed form (NABL 151/ NABL 152/ NABL 153/ NABL180/ NABL190) in three copies along with two copies of Quality Manual of the CAB 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 accompanied by the prescribed renewal fee, as detailed in the application form. The CAB may request extension to the scope of accreditation, which should explicitly be mentioned in the application form.

13. Appeals and Complaints

Appeals

NABL is open to appeals from the CABs against its decisions. The decisions against which appeals are entertained relate to denial of accreditation, reduction of scope of accreditation or abeyance/ suspension/ forced withdrawal of accreditation. The details are provided in NABL 134 'Procedure for Dealing with Appeals against Adverse Decisions Taken by NABL'.

Complaints

NABL is open to receiving complaints for any of the activities performed by its officials, assessors, accreditation committee members and the accredited CABs. The details are provided in NABL 132 'Procedure for Dealing with Complaints'.

14. Rights and Obligations of CABs

Rights of CABs

- CABs are entitled to receive information related to CAB accreditation. They can access NABL's website www.nabl-india.org which gives information necessary for NABL accreditation.
- NABL is obliged to make available information on CAB's scope of accreditation, validity dates for its accreditation certificate(s) and contact details to users of the CABs. This information is provided at NABL web -site.
- The CABs are free to approach any accredited CAB for traceability of measurements provided they fulfill the conditions laid down in NABL 142 'NABL Policy on Calibration and Traceability of Measurements'.
- 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.
- NABL is open to receiving complaints for any of the activities performed by its officials, assessors, accreditation committee members and the accredited CABs.
- NABL is open to appeals from the CABs against its decisions. The cases may involve refusal of accreditation, scope reduction, abeyance, suspension or forced withdrawal.

Obligations of the CABs

- An accredited CAB is obliged to fulfill requirements of relevant standard and 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; if applicable, at the time of applying for accreditation.
- The CAB is expected to provide access to all premises where key activities of CAB are performed and afford 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 detailed in NABL 133, and not use accreditation in a manner to bring disrepute to NABL.
- 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 restricted to): change in legal status, change in ownership, changes in organization, change in top management, change in key personnel and authorized signatories, major change in policies, change in locations etc.
- The CAB is required to pay necessary fees as determined by NABL from time to time.

15. Rights and Duties of NABL

Rights of NABL

- NABL requires that all CABs will conform 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 (wherever applicable) to seek and maintain accreditation and adapt to the changes in the requirements of accreditation.
- NABL requires that all accredited CABs will sign NABL 131 'Terms and conditions for obtaining and maintaining NABL accreditation' and abide by it.
- 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 in consultation with CAB and the assessors
 - decide on implementation schedules in consultation with the CABs
 - take action against CAB giving valid reasons for the same
 - take adverse decisions giving reasons for the same

Duties of NABL

- NABL is obliged to make available information on CABs' scope of accreditation, validity dates for its certificate(s) and contact details to users of the CABs. This information is provided at NABL web -site.
- 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 web -site 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 NABL 142 'Policy on Calibration and Traceability of Measurement'. 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.
- NABL provides adequate mechanism to resolve complaints received for any of the activities performed by its officials, assessors, accreditation committee members and the accredited CABs.
- NABL provides adequate mechanism to address the appeals received from the CABs against its decisions.

16. NABL Finance and NABL Fee Structure

NABL Finance

NABL derives its funds from the revenue generated through accreditation activities.

NABL 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 2018-19	FY 2019-20
Application Fee (non-refundable, to be paid along with the application)	Testing Laboratories: For 01 product group/ discipline (eg. Metals & alloys, Food & agricultural products, Drugs & pharmaceuticals, Textiles, Radiography, Computed Tomography etc.)	Rs. 11,000	Rs. 11,000
	Forensic Laboratories	Rs. 44,000	Rs. 44,000
	Software & IT system testing	N/A	Rs. 44,000
	Laboratories under Integrated Assessment: (For 01 product group/ discipline)	Rs. 25,000	Rs. 25,000
	Medical Laboratories (covering all fields) & Associated Sample Collection Centre/Facility (SCF)		
	Small Laboratories (below 100 patients/ day/location+)	Rs. 18,700 + Rs. 200 per SCF	Rs. 18,700 + Rs. 200 per SCF
	Medium Laboratories (101-400 patients/ day/location+)	Rs. 44,000 + Rs. 200 per SCF	Rs. 44,000 + Rs. 200 per SCF
	Large Laboratories (401-1000 patients/ day/location+)	Rs. 1,10,000 + Rs. 200 per SCF	Rs. 1,10,000 + Rs. 200 per SCF
	Very Large Laboratories (above 1000 patients/ day/location+)	Rs. 2,20,000 + Rs. 200 per SCF	Rs. 2,20,000 + Rs. 200 per SCF
	+ <i>Multilocation laboratory - A Medical laboratory with more than one location in the same district, with same legal identity.</i>		
	Note: <i>Application fee for Multi-location Medical laboratory shall be the fee of one location based on number of patients received per day at that location plus the fee of second location based on number of patients received per day and so on.....</i>		
	Medical Imaging- Conformity Assessment Bodies (MI-CAB): For 01 group/ modality (e.g. Computed Tomography, Ultrasound and Colour Doppler)	N/A	Rs. 11,000
	Calibration Laboratories:		
	Mechanical – For 01 group (eg. Dimension, force etc)	Rs. 11,000	Rs. 11,000
	Electro-Technical (all parameters)	Rs. 33,000	Rs. 33,000
Thermal (all parameters)	Rs. 22,000	Rs. 22,000	
Fluid Flow (all parameters)	Rs. 22,000	Rs. 22,000	

	Optical (all parameters)	Rs. 22,000	Rs. 22,000
	Radiological (all parameters)	Rs. 22,000	Rs. 22,000
	Medical Devices (Upto two groups)	Rs. 50,000	Rs. 50,000
	Proficiency Testing Providers:		
	*Per Discipline - upto one Sub discipline e.g. Chemical under Testing	Rs. 25,000	Rs. 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	Rs.10,000
	Reference Material Producers:		
	*Per Category – upto 2 sub-categories e.g. Metals & Organic Reference Materials under Chemical Composition <i>Note: Metals & Organic Reference Materials are Subcategory under Category Chemical Composition. Similarly, Tensile Strength and Elasticity are Subcategory under Engineering Properties</i>	Rs. 25,000	Rs. 25,000
Enhancement of Scope (apart from the scheduled re-assessment)	Testing Laboratories Any extension in the existing accredited scope per discipline of testing (including Diagnostic Radiology QA testing)	Rs.5,500 per group	Rs.5,500 per group
	For each additional product group in each discipline of testing (including Diagnostic Radiology QA testing)	Rs.11,000	Rs.11,000
	Any extension in the existing accredited product group per discipline under Integrated Assessment	Rs. 25,000	Rs. 25,000
	Forensic Laboratories		
	Any extension in the existing accredited scope	Rs. 5,500	Rs. 5,500
	Software & IT system testing		
	Any extension in the existing accredited scope	N/A	Rs. 5,500
	Medical Laboratories & Associated Sample Collection Centre/Facility (SCF)		
	Any extension in the existing accredited scope	Rs. 5,500	Rs. 5,500
	Any addition in Sample Collection Centre/Facility (SCF)	Rs. 200 per SCF	Rs. 200 per SCF
	Medical Imaging Conformity Assessment Body (MI-CAB)		
	Any extension in the existing accredited scope of MI-CAB	NA	Rs. 5,500
	Any extension of new group/ modality in the existing accredited scope of MI-CAB	NA	Rs. 11,000
Calibration Laboratories:			
Mechanical – Any extension in the existing accredited scope per group per discipline	Rs.5,500	Rs.5,500	
For each additional product group per discipline	Rs.11,000	Rs.11,000	
For extension in Electro-Technical, Thermal, Fluid Flow, Optical, Radiological disciplines	Rs. 5,500	Rs. 5,500	

	*Medical Devices (for each additional group)	Rs. 5,500	Rs. 25,000
	Proficiency Testing Providers:		
	*Addition in existing Sub discipline	NA	Rs. 5,000
	*Addition of sub discipline in the existing discipline	NA	Rs. 10,000
	Reference Material Producers:		
	*For addition in existing subcategory	N/A	Rs. 2,500
	*For each additional sub category	N/A	Rs. 5,000
Change in Authorized signatory	Any addition of authorized signatory(s) apart from the scheduled assessment	Rs. 5,500 / request	Rs. 5,500 / request
Change of Certificate	Testing, Calibration and Medical Laboratories-		
	Any change in the name and or premises of the laboratory leading to issue of new accreditation certificate with scope	Rs. 5,500	Rs. 5,500
	Any change in the name and or premises of the Medical Imaging- Conformity Assessment Body (MI-CAB) leading to issue of new accreditation certificate with scope	NA	Rs. 5,500
	RMP & PTP-		
	Any change in the name and or premises of the laboratory leading to issue of new accreditation certificate with scope	Rs. 3,000	Rs. 3,000
Annual Accreditation Fee (per year from the date of accreditation)	Testing laboratories including Diagnostic Radiology QA testing) (# including Integrated Assessment) except Forensic laboratories (per discipline):	Rs. 24,000	Rs. 24,000
	Forensic laboratories	Rs. 48,000	Rs. 48,000
	Software & IT System testing	N/A	Rs. 48,000
	Calibration laboratories (per discipline) except Electro-technical calibration laboratories	Rs. 24,000	Rs. 24,000
	Electro-technical laboratories	Rs. 36,000	Rs. 36,000
	RMP & PTP	Rs. 27,500	Rs. 27,500
	Medical Laboratories (covering all disciplines) & Sample Collection Centre/Facility (SCF)		
	Small Laboratories (upto 100 patients/ day/location+)	Rs. 20,000 + Rs. 1,000 per SCF	Rs. 20,000 + Rs. 1,000 per SCF
	Medium Laboratories (101-400 patients/ day/location+)	Rs. 48,000 + Rs. 1,000 per SCF	Rs. 48,000 + Rs. 1,000 per SCF

Note- Annual Accreditation fee is payable in advance and is non-refundable and non-adjustable.

In case of co-terminus of accreditation validity, the fee will be charged on pro-rata basis

	Large Laboratories (401 -1000* patients/ day/location+)	Rs. 1,20,000 + Rs. 1,000 per SCF	Rs. 1,20,000 + Rs. 1,000 per SCF
	Very Large Laboratories (above 1000 patients/ day/location+)	Rs. 2,40,000 + Rs. 1,000 per SCF	Rs. 2,40,000 + Rs. 1,000 per SCF
	Medical Imaging Conformity Assessment Body (MI-CAB)	NA	Rs. 24,000
	+ Multilocation laboratory – A Medical laboratory with more than one location in the same district, with same legal identity. Note: In case of Medical laboratory having Multi-locations, Annual Accreditation fee shall be charged based on the location with maximum number of patients per day.		
Overhead Charges	For each assessment including Desktop surveillance, irrespective of number of disciplines	Rs. 11,000/-	Rs. 11,000/-
Assessment Charges (payable after the completion of assessment visit to the CAB)	Travel, Boarding, Lodging Honorarium for NABL Assessors Overhead Charges		
	For Sample Collection Centre / Facility (SCF) charges on lump-sum basis including Honorarium, travel and overhead expenses		Rs. 5,000 per SCF
Travel, Boarding and Lodging expenditure	<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 upto 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 @ Rs.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 and Observer in a reasonably good hotel / guesthouse 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: The travel, boarding & lodging for NABL Officials joining assessment as Observer, shall be borne by NABL.</p>		

Honorarium for NABL Assessors	Document review by Lead Assessor	Rs. 2,000
	Pre-Assessment, Assessment, Verification, Special Visit	
	- by Lead Assessor	Rs. 4,500 per day
	- by Technical Assessor/ Expert	Rs. 4,000 per day

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.

*Revised fee structure is effective from 01.10.2019

Fee Structure for Quality Assurance Scheme-Basic Composite Medical Laboratories (Entry Level)

Components	Fee / Charges
Application Fee (non-refundable, to be paid along with the application)	Rs. 1,000/-
Annual Membership Fee (for cycle of 03 years)	Rs. 3000/-
Assessment Charges (payable after the completion of assessment visit to the CAB)	Rs. 10,000/-

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

Fee Structure for Accreditation of Overseas Conformity Assessment Bodies outside India

FEE STRUCTURE FOR SAARC COUNTRIES <i>(Effective from 15.01.2018)</i>	
(A) For Accreditation -	
Application Fee	400 USD/ discipline (e.g. Mechanical testing, Medical testing, Electro-technical calibration 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
© Changes, if any -	
Change in Authorized signatory	100 USD/ Request
#Any enhancement in the existing accredited scope per discipline of testing (apart from the scheduled re-assessment)	100 USD/ Product group
#Enhancement of new product group in each accredited discipline (apart from the scheduled re-assessment)	200 USD
Change of Certificate <i>(Any change in the name and or premises of the laboratory leading to issue of new accreditation certificate with scope)</i>	100 USD

FEE STRUCTURE FOR OVERSEAS CABs OTHER THAN SAARC COUNTRIES <i>(Effective from 15.01.2018)</i>	
(A) For Accreditation -	
Application Fee	1000 USD / discipline (e.g. Mechanical testing, Medical testing, Electro -technical calibration 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 -	
Change in Authorized signatory	250 USD/ Request
#Any Enhancement in the existing accredited scope per discipline of testing (apart from the scheduled re-assessment)	150 USD/ Product group
#Enhancement of new product group in each accredited discipline (apart from the scheduled re-assessment)	300 USD
Change of Certificate <i>(Any change in the name and or premises of the laboratory leading to issue of new accreditation certificate with scope)</i>	200 USD

- Note:** 1) Overseas CABs 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
 # Revised fee structure is effective from 01.10.2019

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.

17. 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	<u>NEFT to following account :</u> Quality Council of India HDFC Bank Kanjurmarg Branch, Mumbai IFSC Code – HDFC0004989 <i>Virtual A/c No. – Unique for each CAB, to be provided by NABL.</i>	<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.

18. NABL Publications

Sl.	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.	Procedure for Quality Assurance Scheme for Basic Composite Medical Laboratories (Entry Level)	NABL 128
8.	Specific Criteria for Accreditation of Calibration Laboratories (Mechanical, Fluid flow, Radiological, Electro-Technical & Thermal Calibration)	NABL 129
9.	Specific Criteria for Site Testing and Site Calibration Laboratories	NABL 130
10.	Terms & Conditions for Obtaining and Maintaining NABL Accreditation	NABL 131
11.	Procedure for Dealing with Complaints	NABL 132
12.	NABL Policy for Use of NABL Symbol / Claim of Accreditation by Accredited Conformity Assessment Bodies (Laboratories / PTP / RMP) & NABL Accredited CAB Combined ILAC MRA Mark	NABL 133
13.	Procedure for Dealing with Appeals against Adverse Decisions taken by NABL	NABL 134
14.	Specific Criteria for Accreditation of Medical Imaging- Conformity Assessment Bodies	NABL 135
15.	Specific Criteria for Accreditation of Quality Assurance Agencies for Diagnostic Radiology X-ray Equipment	NABL 136
16.	Specific Criteria for Accreditation of Software & IT System testing	NABL 137
17.	Guidelines for Estimation and Expression of Uncertainty in Measurement	NABL 141
18.	Policy on Calibration and Traceability of Measurements	NABL 142
19.	Policy on Calibration and Measurement Capability (CMC) and Uncertainty in Calibration	NABL 143
20.	Application Form for Testing Laboratories	NABL 151
21.	Application Form for Calibration Laboratories	NABL 152
22.	Application Form for Medical Testing Laboratories	NABL 153
23.	Application Form for Integrated Assessment of Testing Laboratories	NABL 154
24.	Application Form and Checklist for Quality Assurance Scheme for Basic Composite Medical Laboratories (Entry Level)	NABL 155
25.	Application Form for Medical Imaging- Conformity Assessment Bodies (MI-CAB)	NABL 156
26.	Guide for Preparing a Quality Manual	NABL 160
27.	Guide for Internal Audit and Management Review for Conformity Assessment Bodies (Laboratories / PTP / RMP)	NABL 161
28.	Policy for Participation in Proficiency Testing Activities	NABL 163

29.	Guidelines for Inter-Laboratory Comparison for Calibration Laboratories where formal PT programs are not available	NABL 164
30.	NABL's Policies for Accreditation (as per ISO/IEC 17025:2017)	NABL 165
31.	Sample Calculations for Uncertainty of Measurement in Electrical Testing	NABL 174
32.	Application Form for Proficiency Testing Providers (PTP)	NABL 180
33.	Specific criteria for PT Provider Accreditation	NABL 181
34.	Pre-assessment guidelines and forms (based on ISO/IEC 17043:2010)	NABL 182
35.	Assessment forms and checklist (based on ISO/IEC 17043: 2010)	NABL183
36.	Application Form for Reference Material Producers (RMP)	NABL190
37.	Specific Criteria for Reference Material Producer Accreditation	NABL191
38.	Pre-Assessment Guidelines & Forms (based on ISO Guide 34:2009)	NABL192
39.	Assessment Forms And Checklist (based On ISO Guide 34:2009)	NABL 193
40.	Assessment Forms And Checklist (based On ISO 17034:2016)	NABL 194
41.	Procedure for dealing with Changes in Accredited Conformity Assessment Body's Operations	NABL 201
42.	Pre-Assessment Guidelines and Forms (based on ISO 15189:2012)	NABL 208
43.	Pre-Assessment Guidelines and Forms (based on ISO/IEC 17025)	NABL 209
44.	Assessor Guide	NABL 210
45.	Operational Manual for online Assessment (For Assessors)	NABL 213
46.	Assessment Forms & Checklists (based on ISO/ IEC 17025:2005)	NABL 215
47.	Procedures for Dealing with Adverse Decisions	NABL 216
48.	Assessment Forms & Checklists (based on ISO 15189:2012)	NABL 217
49.	Desktop Surveillance	NABL 218
50.	Assessment Forms and Checklist (Based on ISO/IEC 17025:2017)	NABL 219
51.	Document Review Checklist (as per ISO/IEC 17025:2017)	NABL 220
52.	Assessment Forms and Checklist (Medical Imaging- Conformity Assessment Bodies)	NABL 222
53.	Bio-data of Assessors	NABL 221
54.	Contract between NABL and Assessors	NABL 230
55.	Directory of Accredited Testing Laboratories	NABL 400
56.	Directory of Accredited Calibration Laboratories	NABL 500
57.	Directory of Accredited Medical Testing Laboratories	NABL 600
58.	Directory of Accredited PTP	NABL 700
59.	Directory of Accredited RMP	NABL 800
<p><i>Note: All NABL documents can be downloaded free of cost from NABL website: www.nabl-india.org.</i></p>		

19. Contact Details

Secretariat: **National Accreditation Board for Testing and Calibration Laboratories (NABL)**
NABL House,
Plot No. 45, Sector 44,
Gurugram - 122002,
Haryana, India
Tel. no.: +91-124-4679700 (30 lines)
Fax: +91-124-4679799

Website: www.nabl-india.org

Email: info@nabl.qcin.org

National Accreditation Board for Testing and Calibration Laboratories (NABL)

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