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Reaching Impact, Saturation, and Epidemic Control (RISE)

Standard Operating Procedures

For Getting Accreditation of Laboratory
through the National Accreditation Board
for Testing and Calibration Laboratories
(NABL)

Contents

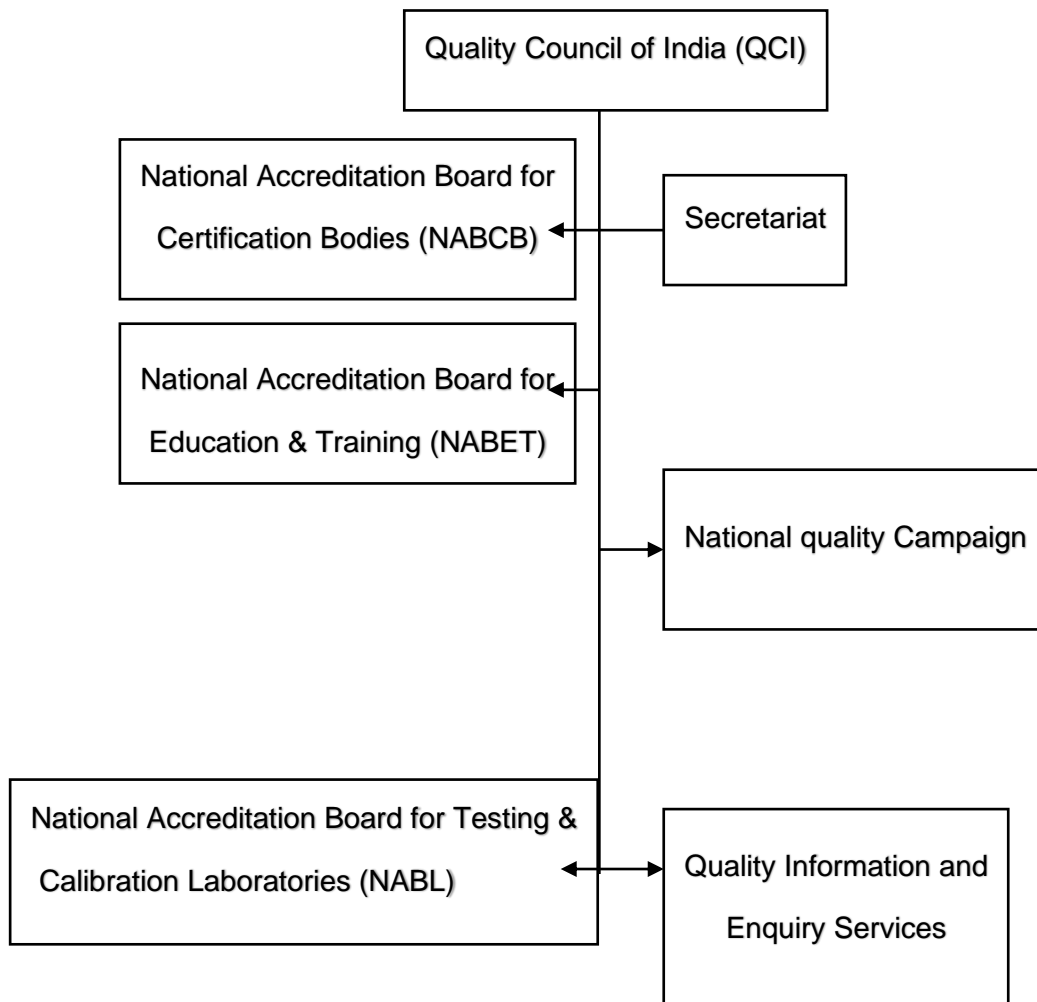
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Abbreviations

CABs	Conformity Accreditation Bodies
NABCB	National Accreditation Board for Certification Bodies
NABET	National Accreditation Board for Education & Training
NABL	National Accreditation Board for Testing and Calibration Laboratories
PTP	Proficiency Testing Programs
QCI	Quality Council of India
RMP	Reference Material Production

Introduction

National Accreditation Board for Testing and Calibration Laboratories (NABL) is a constituent board of the Quality Council of India (QCI), an autonomous body setup under Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India.



NABL is a full member with multi mutual recognition agreement. In order, to enable global acceptance of its accredited facilities known as Conformity Accreditation Bodies (CABs), NABL maintains linkages with the international bodies like International Laboratory Accreditation Co-operation (ILAC) and Asia Pacific Accreditation Co-operation (APAC).

Scope

Laboratory accreditation refers to the procedure used by the NABL to give formal recognition of technical competence for specific tests/measurements, based on third party assessment and as per international standard.

Oxygen testing falls under testing laboratories. Under NABL, it is classified as the following:

NABL Classification : Oxygen Testing Lab

Field	: Testing
Discipline	: Chemical
Group	: Chemical-Gases
Sub group	: Gases for Medical Use and Diving

A testing lab may be of three types:

- Mobile
- Permanent
- Site

For each type of laboratory, multiple and specific documents are required.

Benefits of NABL accreditation

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

- A ready means for customers to identify and select reliable testing, measurement, and calibration services that are able to meet their needs.
- Increased confidence in testing/calibration reports issued by the testing, calibration, and medical testing laboratories which emphasize 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 a sound quality assurance system and are technically competent.
- Helpful in participating in tenders that require independently verified laboratories.
- Users of accredited laboratories enjoy greater access for their products in domestic and international markets.
- Potential increase in business due to enhanced customer confidence and satisfaction as 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 domestic and international markets.
- Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.

How is NABL accreditation different from ISO 9000 certification?

ISO 9000 Certification provides Quality System Management certification only whereas the NABL Accreditation provides formal recognition of technical competence of the CABs, thus, providing a ready means for customers to find reliable testing (including medical), calibration, proficiency testing programs (PTP), and

reference material production (RMP) services in order to meet their demands as well as the quality system. Accreditation is a higher-level activity than system certification. Laboratories can be checked and certified for their compliance to international management system standards such as ISO 9000.

Can we take help from external person and/or organization (e.g., Advisor, Consultant, etc.) to prepare for NABL accreditation?

It is CAB prerogative to decide whether to take help/support from external person and/ or organization. However, NABL strongly recommends that the CAB should prepare for NABL accreditation on its own.

If a CAB is taking the help from external person and/or organization, they have to mandatorily declare the same to NABL. Further, during accreditation process (either document review or assessment), NABL does not entertain the external person. NABL officials and assessment team interact with the CAB staff only.

What types of CABs can seek accreditation?

The CABs should be legally identifiable and appropriately registered. They can be a part of a big organization or an independent entity. NABL can provide accreditation to:

- CABs undertaking any sort of testing (including medical), calibration, proficiency testing, and RMP in specified fields.
- Private or government CABs.
- Small operations and large multi-field CABs.
- Site facilities and mobile laboratories.

Is accreditation a one-time phenomenon?

NABL accreditation is not a one-time phenomenon. Once accredited, the accreditation given to a CAB is valid for two years and NABL conducts periodical surveillance of the CAB on an annual basis. The CAB needs to apply for renewal of accreditation to NABL at least six months before the expiry of the validity of accreditation.

Is it mandatory for laboratories to participate in PTP?

Applicant laboratories are required to successfully participate in at least one PTP before grant of accreditation. Accredited laboratories are required to participate in PTP covering all the major areas in their scope of accreditation in a span of two years. In medical testing, accredited laboratories shall participate in at least one PTP/external quality assurance scheme in a year per discipline, as appropriate.

Please refer to NABL 163: Policy for participation in proficiency testing activities available on the website (www.nabl-india.org) under Publications -> NABL Documents.

Please check the list of NABL Accredited PTPs available on the website (www.nabl-india.org) -> Proficiency testing provider -> List of accredited PTP.

You may also search for accredited PTP under Proficiency Testing Provider -> Available PT providers/program as per NABL 120 (group/field wise).

Medical grade oxygen – parameters and test methods*

S. no.	Components, parameter or characteristics tested/Specific test performed/Test or type of tests performed	Test method specification against which tested are performed and/or the techniques/equipment used
1	Oxygen Assay (Purity)	Indian Pharmacopoeia
2	Oxygen Alkalinity	QA
3	Oxygen Acidity	QA
4	Oxygen Arsine	QA
5	Carbon Dioxide	Indian Pharmacopoeia QA
6	Carbon Monoxide	Indian Pharmacopoeia QA
7	Oxygen Hydrogen Sulphide	QA
8	Oxygen Nitric Oxide	QA
9	Oxygen Nitrogen dioxide	QA
10	Grade Oxygen Phosphine	QA
11	Oxygen Water Vapour	Indian Pharmacopoeia

*Scope may be varied as per the testing facility available.

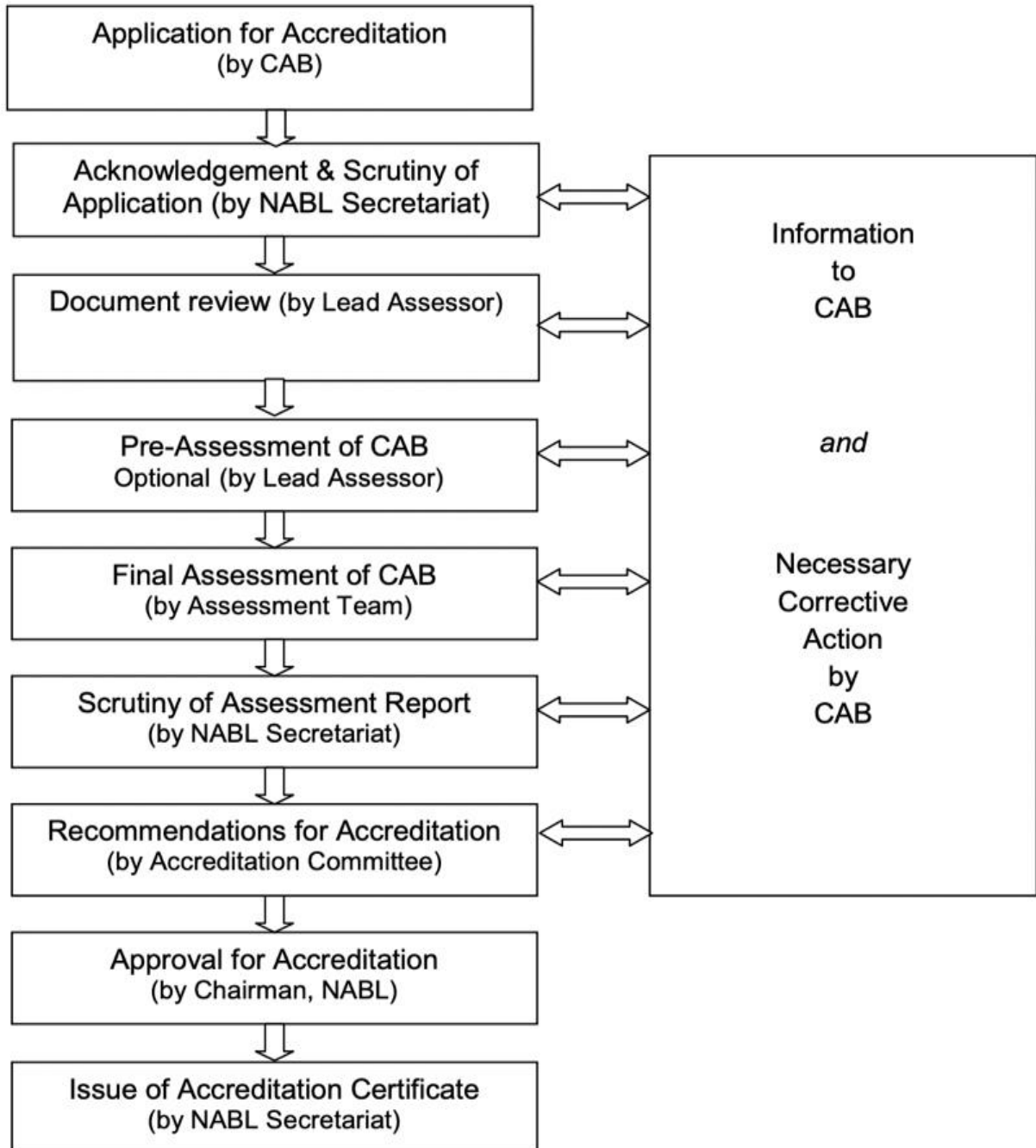
NABL Documents for Testing Laboratory

The following documents may be referred from the NABL website (<https://nabl-india.org>) to implement the system in a laboratory.

NABL 100	General Information Brochure
NABL 127	Procedure for Integrated Assessment & Additional Requirements of Regulatory Body(ies) For Testing Laboratories
NABL 130	Specific Criteria for Site Testing and Site Calibration Laboratories
NABL 131	Terms & Conditions for Obtaining and Maintaining NABL Accreditation
NABL 132	Procedure for Dealing with Complaints
NABL 132A	Procedure for Dealing with Complaints related to NABL and its activities/services
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 134	Procedure for Dealing with Appeals against Adverse Decisions Taken by NABL
NABL 141	Guidelines for Estimation and Expression of Uncertainty in Measurement
NABL 143	Policy on Calibration and Measurement Capability (CMC) and Measurement Uncertainty in Calibration
NABL 144	Guidance on conducting Remote Assessment
NABL 151	Application Form for Testing Laboratories
NABL 160	Guide for Preparing Management System Document / Quality Manual
NABL 161	Guide for Internal Audit and Management Review for Conformity Assessment Bodies (Laboratories / PTP / RMP)
NABL 163	Policy for Participation in Proficiency Testing Activities
NABL 164	Guidelines for Interlaboratory Comparison for Calibration Laboratories where Formal PT Programs are not available
NABL 209	Pre-Assessment Guidelines and Forms (based on ISO/IEC 17025)
NABL 210	ASSESSOR GUIDE
NABL 213	Operational Manual for Online Assessment (For Assessors)
NABL 216	Procedures for Dealing with Adverse Decisions
NABL 218	Desktop Surveillance
NABL 219	Assessment Forms and Checklist (Based on ISO/IEC 17025:2017)
NABL 220	Document Review Checklist (as per ISO/IEC 17025: 2017)

Process and Roadmap



What is the process for accreditation at NABL?

- The CAB is required to apply on www.nablwp.qci.org.in and fill the prescribed application form (NABL 151 for testing laboratories) along with the system document (howsoever named e.g., quality manual) of the CAB that should describe the management system in accordance with ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034, whichever is applicable. The application is to be accompanied with the prescribed application fee as detailed in NABL 100. CAB has to take special care in filling the scope of accreditation 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.
- NABL Secretariat, on receipt of the application form, quality manual, and fees, issues an acknowledgement to the CAB indicating a unique ID number, which is used for correspondence with the CAB. After scrutiny of application for its completeness in all respects, NABL Secretariat may ask for additional information/clarification(s), if necessary.
- In case there are no inadequacies in the quality manual or after satisfactory corrective action by the CAB, an optional pre-assessment visit of the CAB is organized by the lead assessor appointed by NABL. The pre-assessment of the CAB is conducted to evaluate non-conformities (if any) in the implementation of the quality system, to assess the degree of preparedness of the CAB for the assessment, to 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 the 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.
- After the CAB has taken satisfactory corrective actions, NABL finalizes the constitution of assessment team in consultation with the CAB. The team includes the lead assessor and technical assessor(s)/expert(s) in order to cover various fields/disciplines/groups within the scope of accreditation sought. NABL may also nominate an observer. The assessment team reviews the CAB's documented management system and verifies its compliance with the requirements of ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034, whichever is applicable, and relevant specific criteria and other NABL policies. The CAB's technical competence to perform specific tasks is also evaluated. 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 the summary of the assessment report and copies of non-conformities, if any, are provided to the CAB at the end of the assessment visit.
- 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 and submit a report to NABL Secretariat within 30 days. NABL monitors the progress of closing of non-conformities.
- 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 everything is in order, the Accreditation Committee makes appropriate recommendations regarding accreditation of the CAB to the CEO, NABL.
- All decision taken by NABL are open to appeal by the CAB. The appeal is to be addressed to the CEO, NABL.
- When the recommendation results in the grant of accreditation, NABL issues an accreditation certificate which has a unique number and NABL QR code, discipline, date of validity along with the scope of accreditation.
- 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.
- The accredited CABs at all times shall conform to the requirements of ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034 whichever is applicable and relevant specific criteria and NABL policies. The accredited CABs are required to comply at all times with the terms and conditions of NABL given in the NABL 131 “Terms & Conditions for obtaining and maintaining NABL Accreditation.”
- The NABL accreditation certificate is valid for two years. NABL conducts annual Surveillance of the CAB at intervals of one year which is aimed at evaluating continued compliance to the requirements of ISO/ IEC 17025 or ISO 15189: 2012 or ISO/IEC 17043:2010 or ISO 17034: 2016 whichever is applicable and relevant specific criteria and NABL Policies.
- The accredited CAB is subjected to re-assessment every two years. The CAB has to apply six 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.

What are the preparations required by a CAB before applying 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 who should be familiar with CAB’s existing quality system.
- The CAB should get fully acquainted with relevant NABL documents and understand the assessment procedure and methodology for filing an application.
- A CAB wishing to be accredited by NABL must have a quality manual on its quality system satisfying the requirements as described in various clauses of ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034 whichever is relevant and requirements of relevant NABL-specific criteria and needs to ascertain the status of its existing quality system and technical competence.
- The competence of the proposed quality manager on relevant standard shall be adjudged during the assessment.
- The CAB must ensure that the procedures described in the quality manual and other documents are being implemented. 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 PTP. If no suitable PTP 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 ongoing 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 provide details on proficiency testing.
- The applicant CAB must have conducted at least one internal audit and a management review before the submission of application.

More information on accreditation process can be found in Document NABL 100 – ‘General Information Brochure’ which is published by NABL to guide you about NABL accreditation and its procedure.’

Any enquiries for accreditation may be addressed to the Information Cell or mail at info@nabl.qcin.org.

Time Frame

The key factor in determining the time taken is CAB's readiness. CABs that have taken the time to prepare well for the on-site assessment and can respond quickly to assessment deficiencies can complete the process in a timely manner. NABL has all necessary resources, including staff and assessors, to accredit a well-prepared CAB in a reasonable time of about 90 days. Some CABs were able to gain accreditation faster, but it could also take 6 to 8 months in some cases.