

NABL TESTING

What is NABL Approval?

NABL stands for National Accreditation Board for Testing and Calibration Laboratories. This institution is an autonomous body which is a part of the Quality Council of India. The main aim of this institution is to provide an impartial assessment of the quality standards for institutions, government bodies, and primary institutions. The type of testing conducted for NABL approval will include proficiency testing, lab testing, medical testing, and testing for referenced medical producers. This would also include testing for various food industries on the quality standards.

Laboratory compliance and testing have to be according to specific standards. These standards have to be under the ISO/ IEC 17025: 2005- which provides the quality standards for testing and calibration laboratories. Laboratories have to also satisfy the standards for competence and quality, which is under ISO 15189: 2012. Apart from this, the labs have to be in accordance with quality standards as required by the ISO/IEC 17043/2010, which relates to proficiency testing in medical labs.

Hence NABL approval is required for any form of institution that gets into medical research, bioengineering, pharmacy, food processing and materialistic research and development (R & D)

Why is NABL Approval Required?

NABL approval is a form of accreditation that provides an impartial report on the quality standards on a particular product. NABL approval is required for a Conformity Assessment Body (CAB) to prove that the products developed come with the quality that meets consumers' needs. All CABs have to ensure to take NABL approval to meet the requirements of quality standards.

Hence NABL approval would provide formal recognition related to a product that is produced in a CAB. This would not only be important for domestic products but also required when products and devices are exported outside India. In the accreditation process, a third-party assessment is conducted on quality standards. These quality standards should confirm with the international requirements.

NABL approval is thus a quality assessment that provides technical standard approval when it comes to products that are produced by the CABs.

What are the objectives of NABL Approval?

- This form of approval would provide a license to the individual CABs to operate in the domestic markets.

- CABs complying with the requirements of the NABL will ensure that compliance is followed regularly.
- NABL approval would increase the standards of quality of CAB products, especially in medical testing, food tasting, and forensic testing. This will improve the quality of products developed and manufactured in India.
- NABL has entered into MOUs (Memorandum of Understandings) with different international institutions on enhancing training and access to technical R & D. Any CAB with NABL approval would get the benefits of international training.
- NABL approval will promote confidence and increase the production in medical and calibration labs.
- Quality Assurance standards would be provided through NABL.
- This approval will improve the long term performance of the CAB.

Which Conformity Assessment Bodies (CABs) require NABL Approval?

Laboratories Testing Equipment

NABL approval is required for laboratories that test different products and equipment. Such laboratories will include:

- Chemical
- Biological
- Radiology
- Forensic
- Food Processing
- Fluid / Mechanical
- Thermal

Calibration Laboratories

Calibration laboratories will also require NABL approval. The following laboratories would require NABL approval:

- Radiological
- Mechanical/ Fluid-Flow

- Thermal Optical
- Electronic

Medical Laboratories

All forms of pharmaceutical and medical companies would require NABL approval to test different medications. This approval is crucial for the medical industry. The following laboratories require this approval:

- Serology
- Microbiology
- Bacteriology
- Nuclear Medication
- Genetics
- Pathology
- Biogenetics
- Haematology

Proficiency Laboratories

Different laboratories that test the proficiency of products will require this form of approval. The following proficiency laboratories will require this approval:

- Medical
- Inspection
- Calibration

Reference Material Laboratories

Laboratories that analyze different materials' reactions would also require approval from the NABL. The following reference material laboratories require this approval:

- Biological processes
- Engineering Processes
- Genetics Industry

- Pharmaceutical Industries.

Eligibility Criteria for NABL Approval

To satisfy the requirement of the NABL, the institution (CAB) has to satisfy the following eligibility criteria:

- First and foremost, the institution must be a CAB carrying out relevant activities such as laboratory testing, calibration, food processing, research, and development.
- A CAB institution must either appoint a representative to start the formalities for the NABL approval process.
- The appointed representative must be aware of the existing quality processes followed by the CAB.
- The institution (CAB) must have developed a manual that indicates the quality standards. Such quality standards must satisfy the requirements of :
 - a) ISO/ IEC 17025: 2005; or
 - b) ISO 15189: 2012; or
 - c) ISO/IEC 17043/2010.
- The CAB must have an appointed manager who has relevant training up to 4 days on internal audit and management policies, which are followed.
- The quality necessary paper which is prepared by the CAB must be implemented immediately. The CAB must also satisfy the criteria as required, according to NABL 130- which provides the criteria for Site testing and Site Calibration Laboratories.
- Any applicant must participate in the Proficiency Training Program, which is conducted by the NABL or an international institution. If there is no form of training available, the institution can carry out an inter-lab comparison when it comes to quality assessment. If a lab wants to participate in the above event, then the minimum standard must be one parameter or one test.
- The CAB must carry out at least one internal audit and management review before applying for the NABL approval.

Procedure for NABL Approval

- **Step 1-** Make an Application

In this step, the institution must make an application to the NABL. Along with the application, respective necessary papers must be submitted to the NABL. An application must be made in triplicate (3 copies). Two copies must describe the quality manual of the

management system. This must be in accordance with the requirement of the ISO/ IEC 17025: 2005 or ISO 15189: 2012 or ISO/IEC 17043:2010 or ISO 17034:2016.

- **Step 2-** Payment of Fees

The applicant has to pay the respective fee, which is present under NABL 100. If an applicant does not want to make any form of information disclosures, then the same reasons must be provided to the authority.

- **Step 3-** Receipt of Application

When the application is received by the NABL Secretariat (along with the requisite fee), a unique identification number (UIN) will be issued. The applicant must quote this number in all correspondences with the NABL.

- **Step 4-** Pre-Assessment Visit

If there are no discrepancies in the application, then a lead assessor will be appointed to carry out a pre-assessment visit to the CAB. The assessment is carried out to understand if there are no discrepancies in the quality control adopted by the CAB. Along with this, the assessor will find out if there is any other assessment required to be carried out by the NABL.

- **Step 5-** Submission of Report

After the evaluation is carried out by the lead assessor; a report is submitted to the Secretariat of the NABL. A copy is submitted to the Secretariat, and all the records are stored in the necessary paper management system of the Secretariat.

- **Step 6-** Assessment Team

When the CAB has taken all the measures to correct the issues, the NABL will form a team constituted by the lead assessor, technical experts, and other individuals who are experienced in relevant fields and disciplines. The team analyses and finds out if compliance is met in accordance with the required standards. If there are any forms of discrepancies found in the CAB, then a report will be made and submitted to the Secretariat. In the report, remedies would also be included to address the discrepancies. A copy of this will be submitted to the respective CAB.

- **Step 7-** Follow-up Action

When the NABL secretariat reviews the report, the CAB must take follow-up action. This action must be taken within 60 days of the Report of the Assessment Team. In action, the CAB must mention the corrective action it has taken to mitigate difficulties.

- **Step 8-** Recommendations

After the follow-up action is taken by the CAB; the Accreditation Committee will make recommendations to the NABL Chairman. The Chairman's decision is not binding, and it can be appealed to the director of the NABL.

- **Step 9-** Grant of Certificate

When the accreditation is allowed, the NABL will send the following to the applicant:

- a) Unique Identification Number;
- b) Certificate of NABL Approval;
- c) Hologram having the NABL signs;
- d) Date of Validity of the Certificate; and
- e) Discipline.

- **Step 10-** Outstanding Amount

If the applicant has any outstanding amount to pay the NABL; the same must be made before the certificate is granted to the NABL.

- **Step 11-** Compliance

The Applicant must ensure that compliance has to be maintained. The following compliances have to be maintained by the applicant.

- a) ISO/ IEC 17025: 2005; or
- b) ISO 15189: 2012; or
- c) ISO/IEC 17043:2010 or ISO 17034:2016.
- d) Apart from this, the applicant also has to comply with the terms and conditions of the NABL 131.

The validity of the NABL Approval

When an applicant has received the certificate, it will be valid for two years. Annual surveillance is carried out by the NABL. The CAB has to apply for the renewal of license before the expiry. This must be carried out six months before the expiry of the license.

Necessary papers required for NABL Approval

- NABL 112- Criteria for medical laboratories.
- NABL 126- Specific Criteria for Medical Devices Calibration.

- NABL 151 for testing laboratories.
- NABL 152 for calibration laboratories.
- NABL 153 for medical laboratories.
- NABL 155 (Application form and Check List for NABL medical).
- NABL 160 Information related to the management of the quality system manual.
- NABL 180 for PTP and.
- NABL 190 for RMP.
- NABL 100 General Information of NABL.
- NABL 219- Assessment forms and checklist for NABL (ISO/IEC 17025:2017).

PRO CONNET Advantage

- PRO CONNECT is a recognized consultant for accreditation and government advisory services in India.
- We have multifaceted teams of professionals comprising Chartered Accountants, lawyers, and company secretaries.
- We have extensive experience in handling NABL approval licenses, which include advisory services.
- Our service is cost-effective.