# NABL Accreditation



National Accreditation Board for Testing and Calibration Laboratories (NABL) is an accreditation body, with its accreditation system established in accordance with ISO/ IEC 17011.

Accreditation is the formal recognition, authorization and registration of a laboratory that has demonstrated its capability, competence and credibility to carry out the tasks it is claiming to be able to do. It provides feedback to laboratories as to whether they are performing their work in accordance with international criteria for technical competence.



Quality Council of India (QCI) was established as a National body for Accreditation on recommendations of Expert Mission of EU after consultations in Inter-ministerial Task Force, Committee of Secretaries and Group of Ministers through a Cabinet decision in **1996.** 

QCI has been established to create a mechanism for independent third party assessment of products, services and processes.

It plays a pivotal role at the national level in **propagating**, **adoption and adherence to quality standards** in all important spheres of activities including **education**, **healthcare**, **environment protection**, **governance**, **social sectors**, **infrastructure sector** and such other areas of organized activities that have significant bearing in **improving the quality of life and wellbeing of the citizens of India**.



## NABL has been established with the **objective**:

to provide Government, Industry Associations and Industry in general with a scheme for third-party assessment of the quality and technical competence of testing and calibration laboratories.

# The disciplines and groups for which the accreditation services are offered in the respective fields are listed in –

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

#### NABL provides voluntary accreditation services to:

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

assess the performance of laboratories for their conduct of specific test, measurements or calibrations.

 Reference material producers (RMP) in accordance with ISO 17034 "General requirements for the competence of reference material producers".



# Scope of NABL

#### **TESTING FIELD**

- Chemical
- Biological
- Mechanical
- Electrical
- Electronics
- Fluid Flow
- Forensic
- Thermal
- Non-Destructive Testing (NDT)
- Photometry
- Radiological
- 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
  - X-Ray, Bone Densitometry (DEXA), Dental X-Ray-OPG, Mammography
  - Fluoroscopy Computed Tomography (CT)
- Magnetic Resonance Imaging (MRI)
- Ultrasound and Colour Doppler
- Nuclear Medicine
  - SPECT nuclear imaging scan that integrates computed tomography (CT) and a radioactive tracer.
  - PET CT
  - PET MRI

# **PROFICIENCY TESTING PROVIDERS (PTP)**

- Testing
- Calibration
- Medical
- Inspection

# **REFERENCE MATERIAL PRODUCERS (RMP)**

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



## Benefits of Accreditation

Customer Laboratory Others

Accreditation benefits all stake holders.

# BENEFITS OF ACCREDITATION CUSTOMER



## • Customers can search laboratories

 Customers can search and identify the laboratories accredited by NABL for their specific requirements from the NABL website or Directory of accredited laboratories.

# Increased confidence in reports

• The labs are required to participate in proficiency testing which is again demonstration of competence. So, there is increased confidence in the reports released by the laboratory.

# • The customers get services by credential staff.

 Savings in terms of time and money as it reduces or eliminates the need of re-testing.

# BENEFITS OF ACCREDITATION LABORATORY



# •Use of NABL symbol

• The accredited laboratories can issue test reports bearing the accreditation body's symbol or endorsement, as an indication of accreditation.

# International Recognition

 Lab accreditation is highly regarded both nationally and internationally as an indicator of technical competence

# Satisfaction of the staff

• The staff in an accredited laboratory is satisfied as it provides for continuous learning ,good working environment, leadership.

#### BENEFITS OF ACCREDITATION LABORATORY

# Continuous improvement

 Accreditation to a laboratory stimulates continuous improvement .It enables the laboratory in demonstrating commitment to quality test reports.

## Systematic Control of lab work

• Better control of laboratory operations and feedback to laboratories

#### • Benchmark with best laboratories

• It also provides opportunity to the laboratory to benchmark with the best

#### • Rise in business

• There is marked increase in the business of the labs as the accredited status can be seen by the clients on NABL website.

#### **BENEFITS OF ACCREDITATION - OTHER**

It raises community confidence in the services provided by the laboratory.
Finally, Accreditation provides an objective system of empanelment by insurance and other third parties.





#### **1. Application for Accreditation**

CABs are required to apply through NABL Web Portal ('Apply Now' option on website www.nablindia.org) to NABL in prescribed application form (NABL 151, NABL 152, NABL 153) for Testing laboratories, Calibration laboratories or Medical laboratories respectively along with associated Sample Collection Centre/ Facilities (SCF).

#### 2. Acknowledgement and Registration of Application

On receipt of online application form along with Management system document / quality manual and the applicable fees, an acknowledgement with a unique ID number is sent to the CAB. The unique ID of the CAB will be used for further correspondence with the CAB.

#### **3. Appointment of Lead Assessor**

The lead assessor reviews the documents on behalf of NABL and submits the report to NABL.

#### **4. Document Review**

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

#### 5. Pre-Assessment

In case there are no inadequacies in the document review or after satisfactory corrective action by the CAB, a pre-assessment of the CAB is conducted by lead assessor appointed by NABL.

Since Pre-assessment is **optional** (for testing laboratories, calibration laboratories and medical testing laboratories), CAB shall express its willingness in writing to undergo the same within two days.

#### 6. Assessment

After the CAB has taken satisfactory corrective actions based on root cause analysis, NABL proposes constitution of an assessment team. The date(s) for assessment are decided in agreement with the CAB. The assessment team includes the lead assessor (generally the one who had conducted the pre-assessment), the technical assessor(s)/ expert(s) in order to cover the scope for which the accreditation has been sought.

#### 7. Scrutiny of Assessment Report

The assessment report is examined by NABL and follow up action as required is initiated. CAB has to take necessary corrective action on non - conformities/ concerns based on root cause analysis and submit a report along with evidence to NABL within 30 days. NABL monitors the progress of closure of non -conformities. If any non-conformity is observed during the assessment of a Sample Collection Centre/ facility (SCF), the laboratory shall be asked to take corrective actions within 30 days.

#### 8. Review of Assessment Report

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

#### 9. Accreditation Decision-Making

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

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





