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1. Laboratory Accreditation

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.

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 recognises 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 calibration laboratories. 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 laboratories and an assurance given by the accreditation body that the accredited laboratory fulfils the accreditation criteria, at all times.

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

The Government of India has authorized NABL as the accreditation body for testing and calibration laboratories.

NABL is a registered society under the Societies Registration Act 1860. It operates as an autonomous body under the aegis of in the Department of Science and Technology (DST), Ministry of Science and Technology, Government of India.

NABL has been established with the objective of providing Government, Industry Associations and Industry in general with a scheme of laboratory accreditation which involves third-party assessment of the technical competence of testing and calibration laboratories. NABL also provides laboratory accreditation to medical testing laboratories.

The laboratory accreditation services to testing and calibration laboratories are provided in accordance with ISO/ IEC 17025: 2005 ‘General Requirements for the Competence of Testing and Calibration Laboratories’ and ISO 15189: 2007 ‘Medical laboratories - Particular requirements for quality and competence’. The fields, disciplines and groups for which the accreditation services are offered are listed in ‘Scope of NABL Accreditation’.

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

NABL has established its accreditation system in accordance with ISO/ IEC 17011: 2004 ‘Conformity Assessment – General 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.
About NABL

NABL publishes documents for the laboratories, 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.

Organisation Structure of NABL

The organisation structure of NABL has been designed to meet the requirements of an effective and efficient laboratory accreditation system.

The apex body in NABL organisation is the NABL Governing Body. The Governing Body controls the operations of NABL and has the responsibility for providing policy guidelines and direction. The Governing Body consists of Chairman of NABL who is Secretary of the Department of Science and Technology (DST). Financial Adviser of DST and Director of NABL are ex-officio members of the Governing Body. Remaining members are drawn from the National Metrological Institute (NMI), National Standards bodies, major laboratory groups, important regulatory agencies, Industry Associations, Private bodies, etc,. The Governing Body is appointed by the Parent organization, the Department of Science and Technology in accordance with the Memorandum of Association of NABL.

NABL Secretariat comprises of Director, Technical Manager, Quality Officer, PT Officer, Training Officer, Complaints Officer, Appeals Officer, Accreditation Officers Administration and support staff. The Director NABL is responsible for administering and managing the day to day operations of NABL Secretariat and reports to the Chairman, NABL Governing Body.
About 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 laboratory activities. They are trained by NABL as per the relevant international laboratory 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 laboratories), 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 organisation 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 organisations 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 Standardisation, Testing and Quality Certification (STQC), Council for Industrial and Scientific Research (CSIR) and the Quality Council of India (QCI) 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 Laboratory Accreditation Co-operation (APLAC). NABL is a full member of ILAC and APLAC and regularly takes part in their meetings. More information on these international co-operations can be obtained from their web-sites [www.ilac.org](http://www.ilac.org) and [www.aplac.org](http://www.aplac.org) respectively.

NABL is signatory to ILAC as well as APLAC Mutual Recognition Arrangements (MRA), which is based on mutual evaluation and acceptance of other MRA Partner laboratory accreditation systems. Such international arrangements facilitate acceptance of test/calibration results between countries which MRA partners represent.

The information on ILAC and APLAC Mutual Recognition Arrangements (MRAs) is available at NABL web-site. On request from the laboratories or their users, a copy of ILAC/APLAC 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 laboratory accreditation system as per international norms. NABL operations conform to ISO/IEC 17011: 2004.
5. **Scope of NABL Accreditation**

NABL Accreditation is currently given in the following fields and disciplines or groups. The laboratories performing multi-disciplinary testing of products, for e.g. textiles, plastics, building materials, metallurgical products, shall have to apply in relevant discipline separately depending upon to which discipline the tests belong.

**Testing Laboratories**

- **Biological**
  - Food & agricultural products
  - Drugs & Pharmaceuticals
  - Water
  - Pollution & environment
  - Biocides
  - Cosmetics & essential oils
  - Industrial cultures
  - Seed Testing
  - Plants and Plant Materials for Presence of Disease
  - Molecular Biology
  - GMO Testing
  - Cell Culture
  - Resistance to Microbial Attack
  - Toxicology
  - Identification of Bacterial and Viral Pathogens in Food items
  - Residue Analysis
  - Veterinary Testing
  - Biopesticide and Biofertilizer
  - Probiotics and Nutritional supplements
  - Biological Tests on other miscellaneous test items

- **Chemical**
  - Adhesives & sealants
  - Air, gases & atmosphere
  - Biocides
  - Building Materials
  - Coal, Coke & other solid fuels
  - Cosmetics & essential oils
  - Drugs & Pharmaceuticals
  - Explosives & pyrotechnics
Scope of NABL Accreditation

- Fertilizers
- Industrial & fine chemicals
- Inks, dyes & pigments
- Leather & Leather Products.
- Food & agricultural products
- Lac & Lac products
- Metallic coatings & treatment solutions
- Metals & alloys
- Oils & lubricants
- Ores & Minerals
- Organic chemicals
- Paints & surface coatings
- Petroleum products
- Plastics & plastic products
- Pollution & effluents
- Pulp & Paper
- Residues in water & food Products
- Rubber & rubber products
- Soaps & detergents
- Textile & related products
- Water
- Miscellaneous

**Electrical**
- Cables & wires
- Capacitors
- Cells & batteries
- Conductors & conducting materials
- Domestic electrical appliances
- Electrical indicating & recording instruments
- EMI/EMC test facility
- Environmental test facility
- High voltage test facility
- Inductors & transformers
- Insulating materials & insulators
- Lamps, luminaries & accessories
Scope of NABL Accreditation

- Magnetic materials
- Power supplies & stabilizers
- Resistors, resistance boxes & potential dividers
- Power system protective relays
- Short circuit test facility
- Switch gear & protective equipment
- Transmission line equipment & accessories
- Wiring accessories
- Miscellaneous

- **Electronics**
  - Acoustic equipment
  - Computers & accessories
  - Domestic electronic appliances & accessories
  - Power supplies & stabilizers
  - Electronic components & equipment
  - Digitized frequency & time measuring instruments
  - EMI/EMC test facility
  - Environmental test facility
  - Miscellaneous

- **Fluid-Flow**
  - Air & gases
  - Liquids
  - Miscellaneous

- **Mechanical**
  - Automotive components
  - Building Materials
  - Leather & Leather products
  - Metal & metal products
  - Paper & paper products
  - Plastics & plastic products
  - Rubber & rubber products
  - Textiles & related products
  - Miscellaneous
Scope of NABL Accreditation

- Non-Destructive Testing
  - Metals and Alloys
    - Eddy current testing
    - Emerging areas testing
    - Leak testing
    - Magnetic particle testing
    - Penetrant testing
    - Radiography testing
    - Ultrasonic testing
    - Underwater testing
    - Miscellaneous
  - Building Materials – Reinforced Concrete Structures
    - Ultrasonic Pulse Velocity Tests
    - Rebound Hammer Test
    - Cover Meter Test
    - Half Cell Potential difference test
    - Carbonation test
    - Deflection measurement data (Load Test)
    - Crack width measurement in reinforcement concrete structures

- Photometry
  - Lamps, Luminaries & accessories
  - Miscellaneous

- Radiological
  - Radiation monitors
  - Radiation sources
  - Radiological/Nucleonic equipment
  - Miscellaneous

- Thermal
Scope of NABL Accreditation

- **Forensic**
  - Chemistry
  - Toxicology
  - Biology
  - Serology
  - Explosives
  - Physics
  - Ballistics
  - Questioned Documents
  - DNA Finger Printing
  - Forensic Psychology
  - Fingerprints
  - Narcotics
  - Forensic Electronics
  - Crime Scene Investigation

**Medical Laboratories**

- Clinical Biochemistry
- Clinical Pathology
- Haematology & Immunohaematology
- Microbiology and Serology
- Histopathology
- Cytopathology
- Genetics
- Nuclear Medicine *(in-vitro tests only)*

**Calibration Laboratories**

- **Electro-Technical**
  - Alternating Current
  - Direct Current
  - Electrical equipment
  - High frequency
  - Low frequency
  - Magnetics
Scope of NABL Accreditation

- Microwave
- Time & frequency
- Miscellaneous

- Mechanical
  - Acceleration & Speed
  - Acoustics
  - Density
  - Force
  - Dimension
  - Hardness
  - Mass
  - Measuring instruments
  - Precision instruments
  - Pressure & Vacuum
  - Surface topography
  - Torque
  - Volume
  - Viscosity
  - Miscellaneous

- Fluid flow
  - Flow measurement
  - Flow measuring devices
  - Miscellaneous

- Thermal
  - Infrared radiation
  - Specific heat & Humidity
  - Temperature
  - Miscellaneous

- Optical
  - Fibre optics
  - Optical
  - Miscellaneous

- Radiological
  - Radiological measurements
  - Miscellaneous
6. Preparing for Accreditation

Once the laboratory 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 laboratory's existing quality system.

A list of NABL external documents is given at the end of this document and is also available on NABL web-site under Publications – Accreditation Documents. The laboratory should get fully acquainted with relevant NABL documents and understand the assessment procedure and methodology for filing an application.

Laboratory needs to ascertain the status of its existing quality system and technical competence with regards to the requirement of ISO/ IEC 17025;2005 or ISO 15189:2007 which ever is relevant and requirements of NABL. The questions the laboratory needs to address are:

- Does the laboratory 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 quality manual is a policy document, 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 should be discussed amongst concerned staff of the laboratory. This will enable them to understand their strengths and weaknesses.

For preparing the quality manual or verifying its contents, the laboratory may get its technical personnel trained in training programs on quality system management for laboratory personnel organised by various institutes. The proposed Quality manager shall have formal certified training on laboratory management system. Information on such training are available in NABL web-site.

The laboratory must ensure that the procedures described in the Quality Manual and other documents are being implemented.
7. Eligibility for Accreditation

The applicant laboratory must comply with all clauses of ISO/ IEC 17025: 2005 or ISO 15189: 2007 which ever is applicable. The applicant laboratory must also comply with the relevant NABL specific criteria.

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 laboratory must have participated satisfactorily in the proficiency testing program conducted by NABL/ APLAC or any other national or international accredited/ recognised PT provider. If no suitable PT program is available the laboratory 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. The satisfactory performance shall be defined in term of z score and $E_n$ number respectively or any other acceptable methods as detailed in ISO 13528:2005. For unsatisfactory performance, the laboratory is to take corrective action and inform NABL. ISO/ IEC 17043, ILAC G13, NABL 162, NABL 163 and NABL 164 give details of proficiency testing.

The applicant laboratory 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 Laboratories’ provides the necessary guidance.
8. Accreditation Procedure

Flow Diagram of Accreditation Process

- Application for Accreditation (by Laboratory)
  - Acknowledgement & Scrutiny of Application (by NABL Secretariat)
    - Adequacy of Quality Manual (by Lead Assessor)
      - Pre-Assessment of Laboratory (by Lead Assessor)
        - Final Assessment of Laboratory (by Assessment Team)
          - Scrutiny of Assessment Report (by NABL Secretariat)
            - Recommendations for Accreditation (by Accreditation Committee)
              - Approval for Accreditation (by Chairman, NABL)
                - Issue of Accreditation Certificate (by NABL Secretariat)

Information to Laboratory

and

Necessary Corrective Action by Laboratory
Accreditation Procedure

Application for Accreditation

The laboratory is required to apply in the prescribed application form (NABL 151 for testing laboratories, NABL 152 for calibration laboratories and NABL 153 for medical laboratories), in three copies along with two copies of the quality manual of the laboratory that should describe the management system in accordance with ISO/ IEC 17025: 2005 or ISO 15189: 2007 which ever is applicable. The application is to be accompanied with the prescribed application fee as detailed in the application form. Laboratory has to take special care in filling the scope of accreditation for which the laboratory wishes to apply. In case, the laboratory finds any clause (in part or full) not applicable to the laboratory, it is expected to furnish the reasons.

Acknowledgement and Registration of Application

NABL Secretariat on receipt of application forms, the quality manual and the fees issues an acknowledgement to the laboratory. After scrutiny of application for its completeness in all respects, a unique laboratory ID number is allocated to the laboratory, which is used for correspondence with the laboratory. 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 evaluates the adequacy of the quality manual, conducts pre-assessment and final assessment of laboratory concerned on behalf of NABL and submits the report to NABL secretariat. Towards the task of on-site assessment, he will be assisted by a team of assessors commensurate with the scope of accreditation.
Accreditation Procedure

Adequacy of Quality Manual

The preliminary review for the adequacy of the application and quality manual submitted by the laboratory is carried out by NABL Secretariat whereas the detailed review is carried out by Lead Assessor.

The lead assessor informs NABL regarding the adequacy of the quality manual, indicating inadequacies (if any) in the quality manual. The laboratory amends the manual and also implements the management system accordingly.

Pre-Assessment

In case there are no inadequacies in the quality manual or after satisfactory corrective action by the laboratory, a pre-assessment visit of the laboratory is organised by NABL. The laboratory must ensure their preparedness by carrying out an internal audit and a management review before the pre-assessment.

The pre-assessment of the laboratory is conducted to:

a. evaluate non-conformities (if any) in the implementation of the quality system.
b. assess the degree of preparedness of the laboratory for the assessment
c. determine the number of assessors required in various fields based on the scope of accreditation, number of key location to be visited etc.

The lead assessor submits a pre-assessment report to NABL Secretariat with a copy to the laboratory. The laboratory takes corrective actions on the non-conformities raised on the documented management system and its implementation and submits a report to NABL Secretariat.
Accreditation Procedure

Assessment

After the laboratory has taken corrective actions, NABL proposes constitution of an assessment team. The team includes the lead assessor (already appointed), 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 laboratory’s acceptance for the proposed assessment team and the laboratory 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 of the laboratory in consultation with the laboratory, the lead assessor and technical assessor(s)/ expert(s).

The assessment team reviews the laboratory’s documented management system and verifies its compliance with the requirements of ISO/ IEC 17025: 2005 or ISO 15189: 2007 which ever is applicable and relevant specific criteria and other NABL policies. The documented Management system, SOPs, work instructions, test methods etc. are assessed for their implementation and effectiveness. The laboratory’s technical competence to perform specific tests/ calibrations 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 or ISO 15189: 2007 which ever 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 laboratory at the end of the assessment visit.
Accreditation Procedure

Scrutiny of Assessment Report

The assessment report is examined by NABL Secretariat and follow up action as required is initiated. Laboratory has to take necessary corrective action on non-conformities/concerns and submit a report to NABL Secretariat within 60 days. NABL monitors the progress of closing of non-conformities.

Accreditation Committee

After satisfactory corrective action by the laboratory, the Accreditation Committee examines the assessment report, additional information received from the laboratory 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/Laboratory concerned. In case everything is in order, the Accreditation Committee makes appropriate recommendations regarding accreditation of the laboratory to the Chairman, NABL.

All decision taken by NABL regarding grant of accreditation are open to appeal by the laboratory. The appeal is to be addressed to the Director, NABL.
Accreditation Procedure

**Issue of Accreditation Certificate**

When the recommendation results in the grant of accreditation, NABL issues an accreditation certificate which has an unique number and NABL hologram, discipline, date of validity alongwith the scope of accreditation.

The accreditation certificate for testing laboratory defines field of test, items/materials/products tested, specific tests performed, specification/standard methods or techniques used, range of testing/limit of detection, wherever applicable.

The accreditation certificate for calibration laboratory defines the calibration field, product/item calibrated, range of measurement, Calibration and Measurement Capability (CMC) and measurement/calibration equipment and method used.

The accreditation certificate for medical laboratory defines field of test, items/materials/products tested, specific tests performed, specification/standard methods or techniques used, range of testing/limit of detection, wherever applicable and MU/CV%.

For site testing/site calibration laboratory, tests/calibrations performed at site are clearly identified in the scope of accreditation while issuing the certificate.

The applicant laboratory must make all payments due to NABL, before the certificate(s) is/are issued to the laboratory.
9. Maintaining Accreditation

Conformance to Applicable standards and NABL requirements

The accredited laboratories at all times shall conform to the requirements of ISO/IEC 17025: 2005 or ISO 15189: 2007 which ever is applicable and relevant specific criteria and NABL Policies.

NABL Terms and Conditions

The accredited laboratories 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 laboratories 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/APLAC/NABL, the laboratory is informed of this in writing 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 laboratory 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 laboratory like denial of accreditation, scope reduction, abeyance, suspension or forced withdrawal. NABL 216 ‘Procedure for dealing with adverse decisions’ gives the details.
10. Surveillance and Re-assessment

The NABL accreditation certificate is valid for a period of 2 years. NABL conducts annual Surveillance which is aimed at evaluating continued compliance with ISO/IEC 17025: 2005 or ISO 15189: 2007 which ever is applicable and relevant NABL specific criteria and Policies. The types of surveillances are given below:

**On-Site Surveillance**

For the newly accredited laboratories, in the first cycle of Accreditation, NABL conducts an on-site surveillance within 12 months from the date of accreditation. The first surveillance is similar to initial assessment and covers entire extension to the scope, (if any).

**Desktop Surveillance**

The desktop surveillance consists of calling of records from the laboratory to ascertain that the laboratory continues to maintain the requirements of ISO/IEC 17025: 2005 or ISO 15189: 2007 whichever are applicable and relevant NABL specific criteria. From the second cycle onwards the laboratory is subjected to desktop surveillance within 12 months of each re-accreditation.
Surveillance and Re-assessment

Reassessment

The accredited laboratory is subjected to re-assessment every 2 years. The laboratory has to apply 6 months before the expiry of accreditation to allow NABL to organise assessment of the laboratory, 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) in three copies along with two copies of Quality Manual of the laboratory which describes the latest management system in accordance with ISO/ IEC 17025: 2005 or ISO 15189: 2007 whichever is applicable.

The application is to be accompanied by the prescribed renewal fee, as detailed in the application form. The laboratory may request extension to the scope of accreditation, which should explicitly be mentioned in the application form.
11. Appeals and Complaints

Appeals

NABL is open to appeals from the laboratories 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 laboratories. The details are provided in NABL 132 ‘Procedure for Dealing with Complaints’.
12. Rights and Obligations of Laboratories

Rights of Laboratories

- Laboratories are entitled to receive information related to laboratory 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 laboratories’ scope of accreditation, validity dates for its certificate(s) and contact details to users of the laboratories. This information is provided at NABL web-site.

- The laboratories are free to approach any accredited laboratory for traceability of measurements provided they fulfill the conditions laid down in NABL 142 ‘NABL Policy on Calibration and Traceability of Measurements’.

- Laboratory has the right to object to appointment of specific member(s) of assessment team by giving valid reasons.

- NABL accredited laboratory 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 laboratories.

- NABL is open to appeals from the laboratories against its decisions. The cases may involve refusal of accreditation, scope reduction, abeyance, suspension or forced withdrawal.
Rights and Obligations of Laboratories

Obligations of the Laboratories

• An accredited laboratory is obliged to fulfill requirements of relevant standard and NABL Specific Criteria and NABL 131 ‘Terms and conditions for maintaining NABL accreditation’, at all times.

• The laboratory is obliged to disclose name of the consultant; if applicable, at the time of applying for accreditation.

• The laboratory is expected to provide access to all premises where key activities of laboratory are performed and afford access to all relevant information, documents and records necessary to assess laboratory’s compliance to the relevant criteria, standards and NABL 131.

• The laboratory 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.

• An accredited laboratory 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 laboratory is required to notify NABL of any change that may affect the ability of the laboratory 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 organisation, change in top management, change in key personnel and authorized signatories, major change in policies, change in locations etc.

• The laboratory is required to pay necessary fees as determined by NABL from time to time.
13. Rights and Duties of NABL

Rights of NABL

- NABL requires that all laboratories will conform to ISO/ IEC 17025: 2005 or ISO 15189: 2007 which ever is applicable and relevant NABL specific criteria to seek and maintain accreditation and adapt to the changes in the requirements of accreditation.

- NABL requires that all accredited laboratories 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 laboratory accreditation is based in accordance with international norms
  - decide on policies related to accreditation in consultation with stakeholders
  - appoint assessment teams in consultation with laboratory and the assessors
  - decide on implementation schedules in consultation with the laboratories
  - take action against laboratory giving valid reasons for the same
  - take adverse decisions giving reasons for the same
Rights and Duties of NABL

Duties of NABL

• NABL is obliged to make available information on laboratories’ scope of accreditation, validity dates for its certificate(s) and contact details to users of the laboratories. This information is provided at NABL web-site.

• NABL is obliged to provide information on Mutual Recognition Arrangement (MRA) with APLAC 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 laboratory 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, ILAC/ APLAC guidance document, NABL specific criteria documents or any other requirements through NABL website and individual letters to laboratories. 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 laboratories.

• NABL provides adequate mechanism to address the appeals received from the laboratories against its decisions.
14. NABL Finance and NABL Fee Structure

NABL Finance

NABL derives its funds from two sources. Bulk of the NABL financial requirements are met from the grant-in-aid received from the Department of Science & Technology (DST), Ministry of Science & Technology, Government of India. The revenue generated through accreditation activities of NABL is the second source of funds.

NABL Fee Structure

A uniform fee structure is maintained for all laboratories and the charges are maintained at a reasonable level so that laboratories 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) till 2015 is given below:

<table>
<thead>
<tr>
<th>Application Fee</th>
<th>Testing Laboratories:</th>
<th>Medical Laboratories (covering all fields):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Upto 2 product groups per discipline of testing (eg. Metals &amp; alloys, Food &amp; agricultural products, Drugs &amp; pharmaceuticals, Textiles etc.)</td>
<td>Small Laboratories (below 100 patients/day/location*)</td>
</tr>
<tr>
<td></td>
<td>For each additional product group in each discipline of testing</td>
<td>Medium Laboratories (101-400 patients/day/location*)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Large Laboratories (401-1000* patients/day/location*)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Very Large Laboratories (above 1000 patients/day/location*)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Laboratories operating from multiple locations (more than one location in the same city)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing Laboratories</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Fee</td>
<td>Rs. 15,000</td>
<td>Rs. 17,000</td>
<td>Rs. 20,000</td>
</tr>
<tr>
<td>Testing Laboratories</td>
<td>Rs. 7,500</td>
<td>Rs. 8,500</td>
<td>Rs. 10,000</td>
</tr>
</tbody>
</table>

| Medical Laboratories (covering all fields): | |
|---------------------------------------------|------------------------|------------------------|------------------------|
| Small Laboratories (below 100 patients/day/location*) | Rs. 13,000 | Rs. 15,000 | Rs. 17,000 |
| Medium Laboratories (101-400 patients/day/location*) | Rs. 30,000 | Rs. 34,000 | Rs. 40,000 |
| Large Laboratories (401-1000* patients/day/location*) | Rs. 75,000 | Rs. 85,000 | Rs. 10,000 |
| Very Large Laboratories (above 1000 patients/day/location*) | NA | Rs. 1,50,000 | Rs. 2,00,000 |
| Laboratories operating from multiple locations (more than one location in the same city) | NA | Rs. 1,50,000 | Rs. 2,00,000 |
### NABL Finance and NABL Fee Structure

#### Charges For Collection Centers

<table>
<thead>
<tr>
<th>Number of Collection centers</th>
<th>Rs.2,000</th>
<th>Rs.2,500</th>
<th>Rs.3,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;10-50</td>
<td>Rs.5,000</td>
<td>Rs.6,000</td>
<td>Rs.7,000</td>
</tr>
<tr>
<td>&gt; 50- 100</td>
<td>Rs.10,000</td>
<td>Rs.12,000</td>
<td>Rs.14,000</td>
</tr>
<tr>
<td>More than 100</td>
<td>Rs.20,000</td>
<td>Rs.24,000</td>
<td>Rs.28,000</td>
</tr>
<tr>
<td>Forensic Laboratories (covering all sub disciplines):</td>
<td>Rs.30,000</td>
<td>Rs.34,000</td>
<td>Rs.40,000</td>
</tr>
</tbody>
</table>

#### Calibration Laboratories:

- Mechanical - upto 2 groups (eg. dimension, force etc)  
  - for each additional group  
- Electro-Technical (all parameters)  
- Thermal (all parameters)  
- Fluid Flow (all parameters)  
- Optical (all parameters)  
- Radiological (all parameters)

<table>
<thead>
<tr>
<th></th>
<th>Rs. 15,000</th>
<th>Rs. 17,000</th>
<th>Rs. 20,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical - upto 2 groups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- for each additional group</td>
<td>Rs. 7,500</td>
<td>Rs. 8,500</td>
<td>Rs. 10,000</td>
</tr>
<tr>
<td>Electro-Technical (all params)</td>
<td>Rs. 22,500</td>
<td>Rs. 25,500</td>
<td>Rs. 30,000</td>
</tr>
<tr>
<td>Thermal (all parameters)</td>
<td>Rs. 15,000</td>
<td>Rs. 17,000</td>
<td>Rs. 20,000</td>
</tr>
<tr>
<td>Fluid Flow (all parameters)</td>
<td>Rs. 15,000</td>
<td>Rs. 17,000</td>
<td>Rs. 20,000</td>
</tr>
<tr>
<td>Optical (all parameters)</td>
<td>Rs. 15,000</td>
<td>Rs. 17,000</td>
<td>Rs. 20,000</td>
</tr>
<tr>
<td>Radiological (all parameters)</td>
<td>Rs. 15,000</td>
<td>Rs. 17,000</td>
<td>Rs. 20,000</td>
</tr>
</tbody>
</table>

#### Testing Laboratories

- Any extension in the existing accredited scope per discipline of testing  
<table>
<thead>
<tr>
<th>Rs. 3,000 per group</th>
<th>Rs.4,000 per group</th>
<th>Rs.5,000 per group</th>
</tr>
</thead>
</table>

- For each additional product group in each discipline of testing  
  | Rs. 7,500 | Rs.8,500 | Rs.10,000 |

#### Medical Laboratories

- Any extension in the existing accredited scope  
  | Rs. 3,000 | Rs.4,000 | Rs.5,000 |

Enhancement of Scope (apart from the scheduled re-assessment)
# NABL Finance and NABL Fee Structure

## Forensic Laboratories
Any extension in the existing accredited scope

<table>
<thead>
<tr>
<th></th>
<th>Rs. 3,000</th>
<th>Rs.4,000</th>
<th>Rs.5,000</th>
</tr>
</thead>
</table>

## Enhancement of Scope (apart from the scheduled re-assessment)

### Calibration Laboratories:

- **Mechanical** – Any extension in the existing accredited scope per group per discipline
  
<table>
<thead>
<tr>
<th></th>
<th>Rs. 3,000</th>
<th>Rs. 4,000</th>
<th>Rs. 5,000</th>
</tr>
</thead>
</table>

- For each additional product group per discipline
  
<table>
<thead>
<tr>
<th></th>
<th>Rs. 7,500</th>
<th>Rs. 8,500</th>
<th>Rs. 10,000</th>
</tr>
</thead>
</table>

For extension in Electro-Technical, Thermal, Fluid Flow, Optical, Radiological disciplines

<table>
<thead>
<tr>
<th></th>
<th>Rs. 3,000</th>
<th>Rs. 4,000</th>
<th>Rs. 5,000</th>
</tr>
</thead>
</table>

## Change in Authorized signatory
Any addition of authorized signatory(s) apart from the scheduled assessment

<table>
<thead>
<tr>
<th></th>
<th>NA</th>
<th>Rs. 4,000/ request</th>
<th>Rs. 5,000 / request</th>
</tr>
</thead>
</table>

## Change of Certificate
Any change in the name and or premises of the laboratory leading to issue of new accreditation certificate with scope

<table>
<thead>
<tr>
<th></th>
<th>Rs. 3,000</th>
<th>Rs. 4,000</th>
<th>Rs. 5,000</th>
</tr>
</thead>
</table>

## Accreditation Fee
(per year from the date of accreditation)

### Testing laboratories except Forensic laboratories (per discipline):

<table>
<thead>
<tr>
<th></th>
<th>Rs.15,000</th>
<th>Rs.17,000</th>
<th>Rs.20,000</th>
</tr>
</thead>
</table>

### Forensic laboratories

<table>
<thead>
<tr>
<th></th>
<th>Rs.30,000</th>
<th>Rs.34,000</th>
<th>Rs.40,000</th>
</tr>
</thead>
</table>

### Calibration laboratories (per discipline) except Electro-technical calibration laboratories

<table>
<thead>
<tr>
<th></th>
<th>Rs.15,000</th>
<th>Rs.17000</th>
<th>Rs.20,000</th>
</tr>
</thead>
</table>

### Electro-technical laboratories

<table>
<thead>
<tr>
<th></th>
<th>Rs.22,500</th>
<th>Rs.25,500</th>
<th>Rs.30,000</th>
</tr>
</thead>
</table>
# NABL Finance and NABL Fee Structure

**Medical Laboratories** *(covering all disciplines):*
- **Small Laboratories** *(upto 100 patients/day/location)*
  - Rs. 13,000
  - Rs. 15,000
  - Rs. 17,000
- **Medium Laboratories** *(101-400 patients/day/location)*
  - Rs. 30,000
  - Rs. 34,000
  - Rs. 40,000
- **Large Laboratories** *(401 -1000* patients/day/location)*
  - Rs 75,000
  - Rs. 85,000
  - Rs. 1,00,000
- **Very Large Laboratories** *(more than 1000-patients/day/location)*
  - -
  - Rs.1,50,000
  - Rs.2,00,000
- **Laboratories operating from multiple locations in the same city** *(more than one location)*
  - -
  - Rs.1,50,000
  - Rs.2,00,000

<table>
<thead>
<tr>
<th>Number of Collection centers</th>
<th>Up to 10</th>
<th>&gt;10-50</th>
<th>&gt;50-100</th>
<th>More than 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rs.2,000</td>
<td>Rs.2,500</td>
<td>Rs.3,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rs.5,000</td>
<td>Rs.6,000</td>
<td>Rs.7,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rs.10,000</td>
<td>Rs.12,000</td>
<td>Rs.14,000</td>
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</tr>
<tr>
<td>Rs.20,000</td>
<td>Rs.24,000</td>
<td>Rs.28,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rs.7,500</td>
<td>Rs.8,500</td>
<td>Rs.10,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Overhead Charges** *(Testing, Calibration & Medical Laboratories)* *(For each assessment including Desktop surveillance, irrespective of number of disciplines)*
- Rs.7,500
- Rs.8,500
- Rs.10,000

*Applicable from financial year 2013-14*
NABL Finance and NABL Fee Structure

Assessment Charges
( payable after the completion of assessment visit to the laboratory)

Comprising of:
- Travel, Boarding, Lodging
- Honorarium for NABL Assessors
- Overhead Charges

Travel, Boarding and Lodging expenditure
Travel to be made by Air in economy class (Apex fare) or by train in 2nd AC Class or by AC Bus.

The laboratory will provide the tickets as per above entitlement. If the laboratory is not able to provide the tickets, NABL will reimburse the expenses incurred by the assessors as per above entitlement, on production of ticket/ receipt/ boarding pass. If the journey is made by own car, the re-imbursement will be restricted to 2nd AC class fare by train.

The laboratory shall also make arrangements for boarding & lodging for the Assessment team. A single occupancy AC accommodation may be provided for each Assessor/ Observer in a reasonably good hotel/ guesthouse and arrangement for local transportation from temporary residence to the laboratory site and airport/ railway station/ bus stand.

Honorarium for NABL Assessors
Adequacy Audit of Quality Manual by Lead Assessor
Pre-Assessment
- by Lead Assessor
- by Technical Assessor/ Expert
Assessment, Surveillance, Verification, Special Visit
- by Lead Assessor
- by Technical Assessor/ Expert

Rs. 1,500
Rs. 3,000
Rs. 2,500
Rs. 3,000
Rs. 2,500

Note: 1. All payments shall be made by demand draft payable in favour of NABL at New Delhi.

1. In addition to the above mentioned fee, service tax @ 12.36 % (Existing) (or) as applicable to be paid along with said charges / fees
## 15. NABL Publications

<table>
<thead>
<tr>
<th>SI</th>
<th>Name of Document</th>
<th>Doc. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>General Information Brochure</td>
<td>NABL 100</td>
</tr>
<tr>
<td>2.</td>
<td>Specific Criteria for Biological Testing Laboratories</td>
<td>NABL 102</td>
</tr>
<tr>
<td>3.</td>
<td>Specific Guidelines for Chemical Testing Laboratories</td>
<td>NABL 103</td>
</tr>
<tr>
<td>4.</td>
<td>Specific Criteria for Electrical Testing Laboratories</td>
<td>NABL 104</td>
</tr>
<tr>
<td>5.</td>
<td>Specific Criteria for Electronics Testing Laboratories</td>
<td>NABL 105</td>
</tr>
<tr>
<td>7.</td>
<td>Guidelines and Specific Criteria for Accreditation of Mechanical Testing Laboratories</td>
<td>NABL 107</td>
</tr>
<tr>
<td>8.</td>
<td>Specific Criteria for Non-Destructive Testing Laboratories</td>
<td>NABL 108</td>
</tr>
<tr>
<td>9.</td>
<td>Specific Criteria for Photometry Testing Laboratories</td>
<td>NABL 109</td>
</tr>
<tr>
<td>10.</td>
<td>Specific Criteria for Radiological Testing Laboratories</td>
<td>NABL 110</td>
</tr>
<tr>
<td>11.</td>
<td>Specific Criteria for Accreditation of Medical Laboratories</td>
<td>NABL 112</td>
</tr>
<tr>
<td>12.</td>
<td>Specific Guidelines for Accreditation of Forensic Science Laboratories and Checklist for Assessors</td>
<td>NABL 113</td>
</tr>
<tr>
<td>13.</td>
<td>NABL Guidelines for Food Testing Laboratories</td>
<td>NABL 114</td>
</tr>
<tr>
<td>14.</td>
<td>Specific Criteria for Calibration Laboratories in Electro-Technical Discipline</td>
<td>NABL 121</td>
</tr>
<tr>
<td>15.</td>
<td>Specific Criteria for Calibration Laboratories in Mechanical Discipline</td>
<td>NABL 122</td>
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<tr>
<td>16.</td>
<td>Specific Criteria for Calibration Laboratories in Radiological Discipline</td>
<td>NABL 123</td>
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<tr>
<td>17.</td>
<td>Specific Criteria for Calibration Laboratories in Thermal and Optical Discipline</td>
<td>NABL 124</td>
</tr>
<tr>
<td>18.</td>
<td>Specific Criteria for Calibration Laboratories in Fluid Flow Discipline</td>
<td>NABL 125</td>
</tr>
<tr>
<td>19.</td>
<td>Specific Criteria for Site Testing and Site Calibration Laboratories</td>
<td>NABL 130</td>
</tr>
<tr>
<td>20.</td>
<td>Terms &amp; Conditions for Obtaining and Maintaining NABL Accreditation</td>
<td>NABL 131</td>
</tr>
<tr>
<td>21.</td>
<td>Procedure for Dealing with Complaints</td>
<td>NABL 132</td>
</tr>
<tr>
<td>22.</td>
<td>NABL Policy for Use of NABL Symbol / Claim of Accreditation by Accredited Laboratories</td>
<td>NABL 133</td>
</tr>
<tr>
<td>23.</td>
<td>Procedure for Dealing with Appeals against Adverse Decisions taken by NABL</td>
<td>NABL 134</td>
</tr>
<tr>
<td>24.</td>
<td>Guidelines for Estimation and Expression of Uncertainty in Measurement</td>
<td>NABL 141</td>
</tr>
<tr>
<td>25.</td>
<td>Policy on Calibration and Traceability of Measurements</td>
<td>NABL 142</td>
</tr>
<tr>
<td>26.</td>
<td>Policy on Calibration and Measurement Capability (CMC) and Uncertainty in Calibration</td>
<td>NABL 143</td>
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<tr>
<td>SI</td>
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<td>Doc. No.</td>
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<tr>
<td>27.</td>
<td>Application Form for Testing Laboratories</td>
<td>NABL 151</td>
</tr>
<tr>
<td>28.</td>
<td>Application Form for Calibration Laboratories</td>
<td>NABL 152</td>
</tr>
<tr>
<td>29.</td>
<td>Application Form for Medical Testing Laboratories</td>
<td>NABL 153</td>
</tr>
<tr>
<td>32.</td>
<td>Guidelines for Proficiency Testing Program for Testing and Calibration Laboratories</td>
<td>NABL 162</td>
</tr>
<tr>
<td>33.</td>
<td>Policy for Participation in Proficiency Testing Activities</td>
<td>NABL 163</td>
</tr>
<tr>
<td>34.</td>
<td>Guidelines for Inter-Laboratory Comparison for Calibration Laboratories where formal PT programs are not available</td>
<td>NABL 164</td>
</tr>
<tr>
<td>35.</td>
<td>Sample Calculations for Uncertainty of Measurement in Electrical Testing</td>
<td>NABL 174</td>
</tr>
<tr>
<td>36.</td>
<td>Pre-Assessment Guidelines and Forms</td>
<td>NABL 209</td>
</tr>
<tr>
<td>37.</td>
<td>Assessor Guide</td>
<td>NABL 210</td>
</tr>
<tr>
<td>38.</td>
<td>Assessment Forms &amp; Checklists (Based on ISO/ IEC 17025: 2005) – supplementary to NABL 210</td>
<td>NABL 215</td>
</tr>
<tr>
<td>39.</td>
<td>Procedures for Dealing with Adverse Decisions</td>
<td>NABL 216</td>
</tr>
<tr>
<td>40.</td>
<td>Assessment Forms &amp; Checklists (Based on ISO 15189: 2007) – supplementary to NABL 210</td>
<td>NABL 217</td>
</tr>
<tr>
<td>41.</td>
<td>Desktop Surveillance</td>
<td>NABL 218</td>
</tr>
<tr>
<td>42.</td>
<td>Bio-data of Assessors</td>
<td>NABL 221</td>
</tr>
<tr>
<td>43.</td>
<td>Contract between NABL and Assessors</td>
<td>NABL 230</td>
</tr>
<tr>
<td>44.</td>
<td>Directory of Accredited Testing Laboratories</td>
<td>NABL 400</td>
</tr>
<tr>
<td>45.</td>
<td>Directory of Accredited Calibration Laboratories</td>
<td>NABL 500</td>
</tr>
<tr>
<td>46.</td>
<td>Directory of Accredited Medical Testing Laboratories</td>
<td>NABL 600</td>
</tr>
</tbody>
</table>

Note: All NABL documents can be downloaded free of cost from NABL website: [www.nabl-india.org](http://www.nabl-india.org).
16. Contact Addresses

Secretariat: National Accreditation Board for Testing and Calibration Laboratories (NABL)
NABL House,
Plot No. 45, Sector 44,
Gurgaon - 122002, Haryana, India
Tel. no.: +91-124-4679700 (30 lines)
Fax: +91-124-4679799
E-mail: info@nabl-india.org
Website: www.nabl-india.org

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Ministry of Science & Technology
Government of India
Technology Bhawan
New Mehrauli Road
New Delhi – 110 016, India
Tel.: +91 – 11 – 2656 7373

Chairman: Secretary, Department of Science & Technology
(Government of India)
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Fax: +91 –11 – 2686 3847

Director: Mr. Anil Relia
Scientist ‘G’, Department of Science & Technology
(Government of India)
NABL House,
Plot No. 45, Sector 44,
Gurgaon - 122002, Haryana, India
Tel. no.: +91-124-4679700
Fax: +91-124-4679799
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Email: info@nabl-india.org