NABL ACCREDITATION

Certification of the competence of a laboratory

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2010

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NABL Accreditation

Laboratory accreditation

- This to provide a means for third-party certification of the competence of laboratories to perform specific type(s) of testing and calibration.
- Laboratory Accreditation provides formal recognition of competent laboratories, thus providing a ready means for customers to find reliable testing and calibration services in order to meet their demands.
- Laboratory Accreditation enhances customer confidence in accepting testing / calibration reports issued by accredited laboratories.

National Accreditation Board for Testing and Calibration Laboratories (NABL)

- NABL accreditation is a formal recognition of the technical competence of a testing, calibration or medical laboratory for a specific task.
- This is to check the compliance of the laboratory to ISO/IEC 17025:2005, ISO 15189:2007 Standards.
- WTO recognizes non-acceptance of test results and measurement data as Technical Barrier to Trade (TBT).
- Accreditation is considered to be the first essential step towards removing such technical barriers.

NABL

- National Accreditation Board for Testing and Calibration Laboratories (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.
- NABL is an autonomous body under the aegis of Department of Science & Technology, Government of India, and is registered under the Societies Act.
- Government of India has authorized NABL as the sole Accreditation body for Testing and Calibration laboratories in India.
- NABL provides laboratory accreditation services to laboratories that are performing tests and calibrations in accordance with ISO/ IEC 17025: 1999 (General requirements for the competence of Testing and Calibration Laboratories).
- NABL has established its accreditation system in accordance with ISO IEC Guide 58, which is followed internationally.
- NABL is signatory to APLAC (Asia Pacific Laboratory Accreditation Cooperation) & ILAC (International Laboratory Accreditation Cooperation) Mutual Recognition Arrangement (MRA) since October 2000 & November 2000 respectively. Current APLAC and ILAC MRAs is valid till October 2012.
- MRA is essential for mutual acceptance of test results and measurement data amongst 52 accreditation bodies representing 45 countries. NABL accredited laboratories have therefore emerged as a member of global family of accredited laboratories.
- Based on mutual evaluation and acceptance of other country's laboratory accreditation systems, international agreements called Mutual Recognition Arrangements (MRA) have been established for realizing the ideal of having products "tested once and accepted everywhere".
- Such agreements are crucial in enabling test data by an accredited laboratory to be accepted in overseas markets and facilitate trade.
- NABL has also extended its services to Clinical and Food testing laboratories having strong relevance to the society.
- NABL provides an efficient and transparent mechanism to the laboratories and their users.
- Accredited laboratories have the responsibility of satisfying the criteria of laboratory accreditation at all times, which are verified during Surveillance and Re-assessment visits by NABL.

- The accredited laboratories should prove their technical competence by satisfactory participation in recognized Proficiency Testing programmes.
- The accredited laboratories can be suspended or its scope of accreditation can be reduced or even withdrawn in cases of negligence and gross non-compliance of ISO/IEC 17025:2005, ISO 15189:2007 standard detected during routine or surprise Surveillance or Re-assessment.
- NABL provides laboratory accreditation services to laboratories that are performing tests / calibrations in accordance with ISO/IEC 17025:2005 and ISO 15189:2007 for medical laboratories.
- These services are offered in a non-discriminatory manner and are accessible to all testing and calibration laboratories in India and abroad, regardless of their ownership, legal status, size and degree of independence.
- NABL has established its Accreditation System in accordance with ISO/IEC 17011:2004, which is followed internationally.
- NABL has to also comply with the requirements of APLAC MR001, which requires the applicant and the accredited laboratories to take part in recognized Proficiency Testing Programmes in accordance with ISO/IEC Guide 43.
- An applicant laboratory has to satisfactorily participate in at least one Proficiency Testing programme.
- The accredited laboratories are expected to cover the major scopes of accreditation in a cycle time of four years.
- NABL has been conducting Proficiency Testing with the help of selected accredited laboratories as nodal laboratories in different fields.
- The performance remains confidential between NABL and each participating laboratory by using laboratory code numbers.
- In case of unsatisfactory performance, laboratory is expected to investigate and take the necessary corrective actions.
- In case of repeated failure or gross failure indicated by Z factor, En ratio etc. scope of accreditation is reduced by NABL.
- Annual Surveillance are carried out to ensure that the accredited laboratories are continuing to comply the accreditation criteria.
- NABL conducts One-day Awareness Programmes on key issues such as Uncertainty in Measurement, Proficiency Testing, Validation etc., at different parts of India so that applicant and accredited laboratories can take the appropriate action.
- Information regarding NABL accredited laboratories (status and their scope of accreditation) is available in the NABL website (www.nabl-india.org)
- The list of laboratories which are either suspended or their scope of accreditation is partially or fully withdrawn is also available.

Mutual Recognition Arrangement (MRA)

- Many countries around the world have a formally recognized organization responsible for the accreditation of their laboratories. Most of these accreditation bodies are presently following ISO/IEC 17025 as the basis for accrediting their country's testing and calibration laboratories.
- Adoption of international standards has helped countries employ a uniform approach to determine laboratory competence. It has also encouraged laboratories to adopt internationally accepted testing and measurement practices.
- This uniform approach allows accreditation bodies to establish arrangements between themselves through APLAC and ILAC (International Laboratory Accreditation Cooperation), based on mutual evaluation and acceptance of each other's laboratory accreditation systems. Such international arrangements, called Mutual Recognition Arrangement, are crucial in enabling test data to be accepted between countries.

Advantages of laboratory accreditation

- Provides formal recognition to competent laboratories and ensures that they perform their work in accordance with international criteria.
- Minimises the risk of unreliable results which, in turn, reduces the risk for manufacturers or suppliers to produce or supply a faulty product.
- Minimises the chances of retesting and hence reduces chances of additional financial burden and time delays.
- Enhances Customer confidence and Satisfaction.
- International acceptability of test results.
- Laboratory Accreditation provides formal recognition of competent laboratories, thus providing a ready means for customers to find reliable testing and calibration services in order to meet their demands.
- Laboratory Accreditation enhances customer confidence in accepting testing / calibration reports issued by accredited laboratories.
- The globalisation and the liberalisation policies initiated by the Government in reducing trade barriers and providing greater thrust to exports makes it imperative for Accredited Laboratories to be at international level of competence.
- Potential increase in business due to enhanced customer confidence and satisfaction.
- Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.
- Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
- Increase of confidence in Testing / Calibration data and personnel performing work.
- Customers can search and identify the laboratories accredited by NABL for their specific requirements from the Directory of Accredited Laboratories.
- Users of accredited laboratories will enjoy greater access for their products, in both domestic and international markets, when tested by accredited laboratories.

What types of laboratories can seek accreditation...?

The laboratories should be legally identifiable & appropriately registered.

They can be a part of a big organization or an independent entity. NABL can provide accreditation to:

- Laboratories undertaking any sort of testing or calibration in the specified fields.
- Private or government laboratories.
- Small operations to large multi-field laboratories.
- Site facilities, temporary field operations and mobile laboratories.

NABL Accreditation given to

Testing laboratories

- Biological
- Chemical
- Electrical
- Electronics
- Fluid-Flow
- Mechanical
- Non-Destructive
- Photometry
- Radiological
- Thermal

Calibration laboratories

- Electro-Technical
- Mechanical
- Fluid Flow
- Thermal & Optical
- Radiological

Medical laboratories

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

Accreditation to a laboratory

- Accreditation is given on the basis of its capability to perform test(s) / calibration(s) and provide accurate and reliable results.
- A laboratory may apply for accreditation from as little as one to as many tests / calibrations provided it is performing these in accordance with NABL criteria.
- The accreditation granted to a laboratory is valid for a period of 2 years subject to satisfactory periodical (annual) surveillance.
- Laboratory also has an option to widen the scope of accreditation in terms of specific tests and calibrations.
- NABL has established policies and procedures for granting, suspending and withdrawal of accreditation of accreditation in accordance with ISO/IEC 17011:2004.
- The laboratories seeking accreditation are assessed in accordance with ISO/IEC 17025:2005 for testing and calibration laboratories and ISO 15189:2007 for medical laboratories.
- A laboratory wishing to be accredited by NABL must have a Quality Manual on its Quality System satisfying the requirements.
- Quality System documentation and its implementation by the laboratories shall be verified by the Assessors for its compliance with standard.
- The laboratory management shall demonstrate to the NABL Assessment Team that all requirements as laid down in the standard, Specific Criteria and other Guidelines / Requirements of NABL are being followed.
- All applications for accreditation shall have to be in accordance with ISO/IEC 17025 or ISO 15189 Standard.

Evaluating the competence of a laboratory

Methods used by Accreditation Body for evaluating the competence of a laboratory

- On the spot assessment of the laboratory by the experts for its technical competence and its adherence to quality system practices.
- By analysing the test data of a particular test/measurement as a result of its participation in a proficiency testing programme.

Management requirements of ISO/IEC 17025

- Organization
- Documentation
- Review of requests and sub-contracting
- Purchasing services
- Service to the client & Complaints
- Control of non-conforming work
- Corrective & preventive action
- Records
- Internal audit & Management review etc.

Technical requirements of ISO/IEC 17025

- Knowledge of the laboratory personnel
- Technical validity of the methods
- Adequacy and calibration of equipment
- Sampling and handling of test items
- Environmental factors
- Traceability of measurements
- Uncertainty in measurement
- Assuring the quality of tests (participation in proficiency testing programmes, use of certified reference materials, retesting etc)

Pre-requisites for laboratories seeking NABL accreditation

- Laboratory or the organisation of which it is part shall be legally registered so that it can be held responsible for the testing and / or calibration activities it carries out.
- Laboratory should have adequate facilities and technically competent qualified staff to carry out the testing and / or calibration for which it wishes to seek accreditation.
- Laboratory must comply with all the requirements as laid down in the Standard ISO/IEC 17025, relevant Specific Criteria and other NABL documents.
- Laboratory to ensure that all test equipment in the laboratory are properly calibrated and have traceability to National / International standards.
- Laboratory must have completed one Internal Audit covering all clauses of ISO/IEC 17025 and a Management Review.
- Laboratory must have satisfactorily participated in at least one Proficiency Testing Program conducted by NABL or other reputed national or international organizations in accordance with the international standard ISO/IEC Guide 43.

Preparations before applying for accreditation

- Laboratory management should first decide about getting accreditation for its laboratory from NABL.
- The laboratory should make a definite plan of action for obtaining accreditation and nominate a responsible person to coordinate all activities related to seeking accreditation. The person nominated should be familiar with laboratory's existing Quality System and should be formally designated as the Quality Manager.
- Procure all relevant NABL documents from NABL Secretariat and get fully acquainted with each of these.
- Laboratory needs to ascertain the status of its existing Quality System and Technical Competence with regards to requirements for NABL Accreditation. (like - Is the system documented and effective or does it need modification? Does it need to build the Quality System of the laboratory from scratch?)
- Prepare a Quality Manual: This is a policy document, which has to be supplemented by a set of other documents like Procedural Manuals, Work Instructions etc., to align the Quality System in accordance with NABL Criteria. The laboratory must ensure that the procedures described in the Quality Manual and other documents are being implemented.
- For preparing Quality Manual or verifying its contents, the laboratory may take help of “Guide for Preparing Quality Manual" (NABL 160). The laboratory may also get its personnel trained in NABL's training programme on Laboratory Quality System, Management and Internal Audit.
- Relevant requirements for NABL accreditation should be discussed amongst concerned staff of the laboratory. This will enable them to understand their weaknesses and strengths.
- Quality Manager must conduct an Internal Audit and take corrective actions before applying for accreditation.

Process of accreditation at NABL

Stage I

- Prepare application for NABL accreditation, giving all desired information and enlisting the test(s) / calibration(s) along with range and measurement uncertainty for which the laboratory has the competence to perform. Laboratory can apply either for all or part of their testing / calibration facilities.

- 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 shall furnish the reasons.
- Laboratories are required to submit three sets of duly filled in application forms for each field of testing / calibration along with two sets of Quality Manual and Application Fees.
- NABL Secretariat on receipt of application will issue acknowledgement to the laboratory. After scrutiny of application for it being complete in all respects, a unique Customer Registration Number will be allocated to laboratory for further processing of application.
- NABL Secretariat shall then nominate a Lead Assessor for giving Adequacy Report on the Quality Manual / Application submitted by the laboratory. A copy of Adequacy Report by Lead Assessor will be provided to Laboratory for taking necessary corrective action, if any. The laboratory shall submit Corrective Action Report.
- After satisfactory corrective action by the laboratory, a Pre-Assessment audit of the laboratory will be organised by NABL. Laboratories must ensure their preparedness by carrying out its internal audit before Pre-Assessment.

Stage II

- NABL will organise the Pre-Assessment audit, which shall normally be carried by Lead Assessor at the laboratory sites.
- Pre-assessment of the laboratory is conducted to:
  - check the preparedness of the laboratory to undergo Final Assessment.
  - have better understanding of documentation and operations of the laboratory.
  - ascertain number of assessor / man-days required for Final Assessment commensurate with the Scope of Accreditation.
- A copy of Pre-Assessment Report will be provided to Laboratory for taking necessary corrective action, if any.
- The laboratory shall submit Corrective Action Report to NABL.
- After laboratory confirms the completion of corrective actions, Final Assessment of the laboratory shall be organised by NABL.

Stage III

- NABL Secretariat shall appoint an assessment team for the Final Assessment at the laboratory site(s) for its compliance to NABL Criteria.
- The Assessment Team shall comprise of a Lead Assessor and other Technical Assessor(s) in the relevant fields depending upon the scope to be assessed.
- Assessors shall raise the Non-Conformance(s), if any, and provide it to the laboratory in prescribed format so that it gets the opportunity to close as many Non-Conformance(s) as they can before closing meeting of the Assessment.
- The Lead Assessor will provide a copy of consolidated report of the assessment to the laboratory and send the original copy to NABL Secretariat.
- Laboratory shall take necessary corrective action on the remaining Non-Conformance(s) / other concerns and shall submit a report to NABL within a maximum period of 2 months.

Stage IV

- After satisfactory corrective action by the laboratory, the Accreditation Committee examines the findings of the Assessment Team and recommend additional corrective action, if any.
- Accreditation Committee determines whether the recommendations in the assessment report is consistent with NABL requirements as well as commensurate (match with) with the claims made by the laboratory in its application.

- Laboratory shall have to take corrective action on any concerns raised by the Accreditation Committee.
- Accreditation Committee shall make the appropriate recommendations regarding accreditation of a laboratory to NABL Secretariat.
- Laboratories are free to appeal against the findings of assessment or decision on accreditation by writing to the Director, NABL.
- Whenever possible NABL will depute its own technical personnel to be present at the time of assessment as Coordinator and NABL Observer. Sometimes, NABL may at its own cost depute a newly trained Technical Assessor as "Observer".

Stage V

- Accreditation to a laboratory shall be valid for a period of 2 years and NABL shall conduct periodical Surveillance of the laboratory at intervals of one year.
- Laboratory shall apply for Renewal of accreditation to it at least 6 months before the expiry of the validity of accreditation.

NABL accreditation Vs ISO 9000 certification

NABL	ISO 9000
Applicable to laboratories	Applicable to all organizations
recognition of technical competence of the Lab	Certification of Quality System Management
involves the auditing of an laboratory's quality management system.	involves the auditing of an organization's quality management system.
Covers both technical competence and quality management	Covers only quality management

Accreditation is a higher level activity than system certification.

NABL Secretariat & Registered office

NABL Secretariat administers and co-ordinates all activities of NABL including accreditation related activities for Testing and Calibration laboratories.

NABL Secretariat office situated at 3rd Floor, NISCAIR, 14, Satsang Vihar Marg, New Mehrauli Road – New Delhi 110067.

Registered Office of NABL is located in Department of Science & Technology, Technology Bhavan, New Mehrauli Road, New Delhi – 110016.

(Courtesy: NABL website)