NABH (National Accreditation Board For Hospitals and Healthcare Providers) accreditation

NABH is constituent board of Quality Council of India and has been set up by the Government of India. It's Mission to help India achieve and sustain total quality and reliability in all areas of life, work, environment, product and services at individual, organizational, community and societal levels.

National Accreditation Board for Hospitals & Healthcare Providers (NABH) is a constituent board of Quality Council of India, set up to establish and operate accreditation programme for healthcare organizations. the board is structured to cater to much desired needs of the consumers and to set benchmarks for progress of health industry. The board while being supported by all stakeholders including industry, consumers, government, have full functional autonomy in its operation.

Accreditation Program
- Hospitals / Nursing Homes
- Blood Banks

Future Plans
- Diagnostic Centres (Imaging)
- Dental Centres
- Ayurvedic Hospitals/ Clinics

Achievements & International Linkages

NABH is an institutional member of the International Society for Quality in Health Care (ISQUA). ISQUA is an international body which grants approval to Accreditation Bodies in the area of healthcare as mark of equivalence of accreditation program of member countries.

ISQua Accreditation of NABH Standard , India

International Society for Quality in Healthcare (ISQua) has accredited “Standards for Hospitals” developed by National Accreditation Board for Hospitals & Healthcare Providers (NABH, India ). The approval of ISQua authenticates that NABH standards are in consonance with the global benchmarks set by ISQua. The hospitals accredited by NABH will have international recognition This will provide boost to medical tourism.

So far hospital standards of only 11 countries viz. Australia , Canada , Egypt , Hong Kong , Ireland , Japan , Jordan , Kyrgyz Republic , South Africa , Taiwan , United Kingdom were accredited by ISQua. India becomes the 12 th country to join in this group.
**Accreditation**

"A public recognition of the achievement of accreditation standards by a healthcare organization, demonstrated through an independent external peer assessment of that organization's level of performance in relation to the standards".

Accreditation benefits all stakeholders. Patients are the biggest beneficiary. Accreditation results in high quality of care and patient safety. The patients get services by credential medical staff. Rights of patients are respected and protected. Patient satisfaction is regularly evaluated.

The staff in an accredited hospital are satisfied lot as it provides for continuous learning, good working environment, leadership and above all ownership of clinical processes.

Accreditation to a hospital stimulates continuous improvement. It enables hospital in demonstrating commitment to quality care. It raises community confidence in the services provided by the hospital. It also provides opportunity to healthcare unit to benchmark with the best.

Finally, accreditation provides an objective system of empanelment by insurance and other third parties. Accreditation provides access to reliable and certified information on facilities, infrastructure and level of care.
National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation

NABL accreditation is a formal recognition of the technical competence of a testing, calibration or medical laboratory for a specific task following ISO/IEC 17025:2005, ISO 15189:2007 Standards. This is based on third party assessment. 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 has gone a step further and achieved the status of APLAC (Asia Pacific Laboratory Accreditation Cooperation) MRA (Mutual Recognition Arrangement) partner and signatory to ILAC (International Laboratory Accreditation Cooperation) Arrangement based on peer evaluation by a multi-disciplinary team from APLAC. This is a major step towards 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.

NABL accreditation has also assumed significance for equivalence of measurements for those manufacturing industries, which source their components from different countries. NABL therefore has an objective to set up a chain of accredited calibration laboratories with traceability to National Physical Laboratory, New Delhi, or other International Metrology Institutions such as NIST, CISO, PTB, etc. or accredited laboratories under APLAC / ILAC.

NABL has also extended its services to Clinical and Food testing laboratories having strong relevance to the society. NABL is aimed towards providing 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. Further the accredited laboratories should prove their technical competence by satisfactory participation in recognized Proficiency Testing programmes. In conformity with ISO/IEC 17011:2004 which determines the Quality System of NABL, 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.

Why Laboratory Accreditation?

The concept of Laboratory Accreditation was developed 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.

The globalisation of Indian economy 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.

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

1. Potential increase in business due to enhanced customer confidence and satisfaction.
2. Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.
3. Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
4. Increase of confidence in Testing / Calibration data and personnel performing work.
5. Customers can search and identify the laboratories accredited by NABL for their specific requirements from the Directory of Accredited Laboratories.
6. Users of accredited laboratories will enjoy greater access for their products, in both domestic and international markets, when tested by accredited laboratories.

Scope of Accreditation NABL Accreditation is currently given in the following fields:

<table>
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<tr>
<th>TESTING LABORATORIES</th>
<th>CALIBRATION LABORATORIES</th>
<th>MEDICAL LABORATORIES</th>
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<td>Biological</td>
<td>Electro-Technical</td>
<td>Clinical Biochemistry</td>
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<td>Chemical</td>
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<td>Fluid-Flow</td>
<td>Radiological</td>
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<tr>
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<td>Non-Destructive</td>
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<td>Genetics</td>
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<td>Photometry</td>
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<td>Nuclear Medicine (in-vitro tests only)</td>
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<td>Radiological</td>
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<td>Thermal</td>
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Accreditation to a laboratory 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.
Classification of the Testing Laboratories has been done on the basis of basic fields of testing. The laboratories doing inter-disciplinary testing of products, for e.g. textiles, plastics, building materials, metallurgical products, shall have to apply in relevant field(s) separately depending upon to which field(s) the test(s) belongs.

The accreditation granted to a laboratory shall remain 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

Directory of NABL Accredited Laboratories is published at regular interval, which contains laboratories' contact details and information on their Scope of Accreditation.

**Assessment Criteria**

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 as described in various clauses of ISO/IEC 17025 or ISO 15189 standard. Quality System documentation and its implementation by the laboratories shall be verified by the Assessors for its compliance in accordance with ISO/IEC 17025 or ISO 15189 standard. The laboratory management shall demonstrate to the NABL Assessment Team that all requirements as laid down in the ISO/IEC 17025/ISO 15189 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.

** Modifications to the Accreditation Criteria**

If NABL modifies the accreditation criteria, it shall inform the laboratory of this in writing giving a transition period of at least 6 months to the laboratory to align in accordance with the modified criteria.

**Appeal**

All decisions regarding accreditation to laboratories shall be open to appeal to NABL by laboratories and their users. Decision by NABL after investigation of appeal shall be final.

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**Process of Accreditation**

Stage I

- Prepare your laboratory's 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.
Formats NABL 151, NABL 152 & NABL 153 are to be used by Testing, Calibration & Medical Laboratories respectively for applying to NABL for accreditation.

- 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 Secretariat shall organise the Pre-Assessment audit, which shall normally be carried by Lead Assessor at the laboratory sites.

- The pre-assessment helps the laboratory to be better prepared for the Final Assessment. It also helps the Lead Assessor to assess the preparedness of the laboratory to undergo Final Assessment apart from Technical Assessor(s) and Total Assessment Man-days required vis-à-vis the scope of accreditation as per application submitted by the laboratory.

- A copy of Pre-Assessment Report will be provided to Laboratory for taking necessary corrective action on the concerns raised during audit, if any.

- The laboratory shall submit Corrective Action Report to NABL Secretariat.

- After laboratory confirms the completion of corrective actions, Final Assessment of the laboratory shall be organised by NABL.

Stage III

- NABL Secretariat shall organise the Final Assessment at the laboratory site(s) for its compliance to NABL Criteria and for that purpose appoint an assessment team.

- 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, by the laboratory.

• Accreditation Committee determines whether the recommendations in the assessment report is consistent with NABL requirements as well as commensurate 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" subject to convenience of the laboratory to be accessed.

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.
The National Accreditation Board for Education and Training (NABET) certifies auditors & the training courses for such auditors, which meet the Board’s criteria and provides a mechanism for international recognition of these certifications.

The main objectives of NABET are:

- To set and maintain criteria for the registration of personnel in the practice and assessment of Quality & Environment Management Systems
- To evaluate and register auditors and professionals
- To set and maintain criteria for and to endorse training courses for personnel engaged in the auditing of Quality & Environment Management Systems
- To publish the list of Certified Personnel, endorsed training courses and approved training organisations
- To closely cooperate with Registration Board for Certification Bodies to get feedback and anticipate requirements on training needs
- To seek international recognition

The Board offers registration services for Personnel and Training Courses in line with international requirements. With the growing needs of competent personnel and credible training courses in various industry sectors, NABET has been rapidly expanding its scope of services to cater to the needs of the industry.