LABORATORY ACCREDITATION - PROCEDURAL GUIDELINES

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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.

The concept of laboratory accreditation was developed to provide third-party certification that a laboratory is competent to perform the specific test or type of tests. Laboratory accreditation is a means to improve customer confidence in the test reports issued by the laboratory so that the clinicians and through them the patients shall accept the reports with confidence.

The National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of the Dept. of Science & Technology, Govt. of India, and is registered under the Societies Act. NABL, which was initially established with the objective to provide accreditation to testing & calibration laboratories, later on extended its services to the clinical laboratories in our country.

Govt. of India has authorized NABL as the sole accreditation body for testing and calibration laboratories. The objective of NABL is to provide third party assessment of quality and technical competence. Four years ago NABL established links with international bodies - Asia Pacific Laboratory Accreditation Cooperation and International Laboratory Accreditation Cooperation. This has imparted international recognition to NABL accredited laboratories. The international standard currently followed by NABL is ISO 15189, specific for medical laboratories.

Getting Ready for Accreditation

It is very important for a laboratory to make a definite plan for obtaining accreditation and nominate a responsible person as QUALITY MANAGER (who should be familiar with the laboratory's existing quality system) to co-ordinate all activities related to seeking

accreditation. The laboratory should carry out the following important tasks towards getting ready for accreditation:

1. Contact NABL Secretariat with a request for procuring relevant NABL documents (NABL Contact address and the list of NABL documents given in Annexure-3 and 1, respectively).
2. Get fully acquainted with all relevant documents and understand the assessment Procedure and methodology of making an application.
3. Train a person on Quality Management System and Internal Audit (4-day residential training courses conducted by NABL. Contact NABL Secretariat for details).
4. Prepare QUALITY MANUAL as per ISO 15189 standards.
5. Prepare Standard Operating Procedure for each investigation carried out in the laboratory.
6. Ensure effective environmental conditions (temperature, humidity, storage placement, etc.).
7. Ensure calibration of instruments / equipment.
Only NABL ACCREDITED CALIBRATION LABORATORIES are authorized to provide calibration. NABL website gives the names of NABL accredited calibration laboratories in the various fields of Accreditation.
8. Impart training on the key elements of documentation, such as document format, authorization of document, issue and withdrawal procedures, document review and change, etc. Each document should have ID No., name of controlling authority, period of retention, etc.
9. Ascertain the status of the existing quality system and technical competence with regard to NABL standards and address the question "*Is the system documented and effective OR does it need modification?*".
10. Remember Quality Manual is a policy document, which has to be supplemented by a set of other next level documents. Therefore ensure that these documents are well prepared.
11. Ensure proper implementation of all aspects that have been documented in the Quality Manual and other documents.

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12. Incorporate Internal Quality Control (IQC) practice while patients' samples are analysed.
13. Document IQC data as well as uncertainty of measurements. Maintain Levy Jennings charts.
14. Participate in External Quality Assessment Schemes (EQAS).
If this is not available for certain analytes, participate in inter-laboratory comparison through exchange of samples with NABL accredited laboratories.
15. Document corrective actions on IQC / EQA outliers.
16. Conduct Internal Audit and Management Review.
17. Apply to NABL along with appropriate fee.

Accreditation Process

An applicant laboratory is expected to submit to NABL 5 copies of the application and 5 copies of Quality Manual.

- The Quality Manual will be forwarded by NABL to a Lead Assessor to judge the adequacy of the Quality Manual as to whether it is in compliance with ISO 15189 standards.
- Thereafter the Lead Assessor will conduct a Pre-Assessment of the laboratory for one day. Based on the Pre-Assessment report the laboratory may have to take certain corrective actions, so as to be fully prepared for the final assessment.
- It is essential for the applicant as well as accredited laboratories to satisfactorily participate

ANNEXURE-1			
NABL PUBLICATIONS (Essential for clinical laboratories) (as on July 1st 2005)			
No.	Name of document	Document Number	Price Rs.
1.	General information brochure	NABL - 100	Free
2.	Specific Guidelines for Accreditation of Clinical Laboratories	NABL - 112	Free
3.	Terms and conditions for Maintaining Accreditation	NABL - 131	Free
4.	NABL Guidelines to Accredited Laboratories for use of NABL Logo	NABL - 133	Free
5.	Guidelines for Estimation and Expression of Uncertainty of Measurement	NABL - 141	250/-
6.	Policy on Calibration and Traceability of Measurements	NABL - 142	Free
7.	Application Form for Testing Laboratories	NABL - 151	Free
8.	Guide for Preparing a Quality Manual	NABL - 160	250/-
9.	Guide for Internal Audit and Management Review for laboratories	NABL - 161	200
10.	Policies and Procedures for inter-laboratory comparisons and / or Proficiency Testing	NABL - 163	Free
11.	Master list of NABL documents	NABL - 200	Free
12.	Pre-assessment Guidelines and Forms	NABL - 209	Free
13.	Interpretation of the Accreditation Criteria and Guidelines for Assessment	NABL - 211	100/-
14.	Guideline document on Validation of Test Methods	NABL - 212	100/-
15.	Policy and Procedures for assessment, Surveillance & Re-assessment of laboratories	NABL - 214	Free
16.	Policies & Procedures for dealing with Adverse Decisions	NABL - 216	Free

ANNEXURE-2		
Financial Terms & Conditions		
Lab classification	Application Fee	Annual accreditation Fee
Large > 400 Patients/day	Rs.50,000/-consolidated	Rs.50,000/-
Medium 101-300 Patients/day	Rs.20,000/-consolidated	Rs.20,000/-
Small upto 100 Patients/day	Rs.10,000/-consolidated	Rs.10,000/-
Lab to bear assessors' travel & boarding expenditure.		

in Proficiency testing/ Interlaboratory comparisons/External quality assessment programme as Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement calls for mandatory participation in such programmes.

- Finally when the laboratory is ready, the Lead Assessor and a team of technical assessors will conduct the final assessment. The number of technical assessors will depend on the number of disciplines applied for. The accreditation process involves a thorough assessment of all the elements of the laboratory that contribute to the production of accurate and reliable test data. These elements include staffing, training, supervision, quality control, equipment, recording and reporting of test results and the environment in which the laboratory operates. The laboratory may have to take certain corrective actions, after the final assessment.
- After satisfactory corrective actions are taken by the laboratory (within a period of 3 months), the Accreditation Committee will examine the report and if satisfied recommend accreditation.

The time required for the process of accreditation will depend upon the preparedness of the laboratory and its response to the non - conformance raised during the pre-assessment and final assessment. The total duration ranges between 6 and 8 months.

Surveillance and Re-Assessment

Accreditation to a laboratory shall be valid for a period of three years. NABL shall conduct annual surveillance of the accredited laboratories. The laboratories may enhance or reduce the scope of accreditation during surveillance.

The laboratories need to apply for renewal of accreditation, at least six months before the expiry of validity of accreditation for which a re-assessment shall be conducted.

ANNEXURE-3	
NABL CONTACT ADDRESSES	
NABL Secretariat :	B-4 / B-5 / B-6 Qutab Hotel Apartments, New Mehrauli Road, New Delhi - 110016 Tel : 011-26529718 / 19 / 20 Fax : 011 - 26529716 Website : nabl-india.org

ISO 15189 STANDARDS	
MANAGEMENT REQUIREMENTS	
·	Organization and management
·	Quality management system
·	Document control
·	Review of contracts
·	Examination by referral laboratories
·	External services and supplies
·	Advisory services
·	Resolution of complaints
·	Identification and control of nonconformities
·	Corrective actions
·	Preventive actions
·	Continual improvement
·	Quality and technical records
·	Internal audits
·	Management review
TECHNICAL REQUIREMENTS	
·	Personnel
·	Accommodation & environmental conditions
·	Laboratory equipment
·	Pre-examination procedures
·	Examination procedures
·	Assuring quality of examination procedures
·	Post-examination procedures
·	Reporting of results