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# *NABL accreditation: Principles and procedures*

## INTRODUCTION

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.

**Principle 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.

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 - conformances 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**

**MANGEMENT 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 nonconformitis
- 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

**Reference: A.S .Kanagasabapathy and Pragna Rao LABORATORY ACCREDITATION - PROCEDURAL GUIDELINES. (2005)** ***Indian Journal of Clinical Biochemistry 186-188.***