# Implementation of Lab Accreditation Requirements in India

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# About NABL Introduction

- NABL accreditation is a formal recognition of the technical competence of a medical testing laboratory
- Third party assessment
- NABL has Mutual Recognition Arrangement with APLAC and ILAC

# Contd…

- NABL accredited labs are all member of global family of accredited labs
- NABL provides efficient and transparent mechanism to the labs
- Labs prove technical competence by participation in proficiency test
- NABL is an autonomous body under DST

# Key steps towards accreditation

- Management defines project owner
- Project owner studies details of standard ISO15189:2007
  - Understands carefully all 15 clauses under the management requirement

# Contd..

- Understands carefully all 8 clauses under the technical requirement
- Defines scope of accreditation
- Performs a gap analysis
- Estimates the cost of accreditation and presents to management

# Contd...

- Management decides to proceed with accreditation
- Project owner leads implementation steps
- Conduct atleast one internal audit followed by Management Review Meeting

# Requirements Overview

- Sampling as per the plan
- All samples to be uniquely identified
- Monitor quality of test results
- % CV, LJ Charts

# Contd...

- Maintain proper records
- Validate all procedures
- Calibration of equipment
- Document all non conformance

# Contd...

- Monitor environmental conditions
- Prepare documentation as per standard
- Follow up all complaints from the clients
- A formal program to manage suppliers

# Management Requirements

## 4.1 Organization and Management

### 4.1.1 Legal Identification

### 4.1.2 Needs of patients and clinical personnel

### 4.1.3 Requirements of the standard

# Contd…

4.1.4 Personnel responsible for primary sample examination

4.1.5 Design, implementation maintenance and improvements of quality management system

4.1.6 Communication in the lab

# Contd…

## 4.2 Quality Management System

### 4.2.1 Policies and Procedure

### 4.2.2 ILC, IQC

### 4.2.3 Quality Policy

### 4.2.4 Quality Manual

### 4.2.5 Calibration of instruments

# Contd…

## 4.3 Document Control

### 4.3.1 Documented procedures

### 4.3.2 Review, Approval and Control

### 4.3.3 Unique identification

# Contd…

4.4 Review of Contacts

4.4.1 Procedure for review of contacts

4.4.2 Records of review

4.4.3 Referrals

4.4.4 Information on deviations to customers

# Contd…

4.4.5 Amendments

4.5 Examination by Referral Laboratories

4.5.1 Documented procedure for evaluation and selection

4.5.2 Review the arrangements

4.5.3 Maintain a register of all referral labs

# Contd…

4.5.4 Examination results to the request

## 4.6 External services and supplies

4.6.1 Documented procedure for selection and evaluation

4.6.2 Verification of purchased material

4.6.3 Inventory control

4.6.4 Critical reagents suppliers

# Contd...

4.7 Advisory Services

4.8 Resolution of Complaints

4.9 Identification and Control of Non Conformities

4.9.1 Documented procedure for non conformities

# Contd...

4.9.2 Route analysis of non conforming examinations

4.9.3 Release of results in case of non conformities

4.10 Corrective Action

4.10.1 Causes of problem

# Contd...

4.10.2 Changes in the operational procedures

4.10.3 Monitor the results of CA

4.10.4 Investigations causing doubts

# Contd...

## 4.11 Preventive Action

### 4.11.1 Develop action plan for PA

### 4.11.2 Procedure for preventive action

# Contd...

4.12 Continual Improvement

4.12.1 Review of procedures at regular intervals

4.12.2 Review of effectiveness of the CA

4.12.3 Implementation of actions

4.12.4 Monitoring of quality indicators

# Contd...

## 4.12 Continual Improvement

### 4.12.5 Training opportunities to laboratory personnel

# Contd...

4.13 Quality and Technical Records

4.13.1 Index, storage, maintenance and save disposal of quality records

4.13.2 Easy retrieval of records

4.13.3 Retention period of records

# Contd...

4.14 Internal Audit

4.14.1 Internal quality audit at refined intervals

4.14.2 Planning, implementation and documentation of the audits

4.14.3 Results of audits to the management

# Contd...

4.15 Management Review

4.15.1 MRM once in a year

4.15.2 Input for MRM

4.15.3 Laboratory's contribution to patient care, monitoring and evaluation

4.15.4 Record of findings and actions of MRM

# Technical Requirements

5.1 Personnel

5.2 Accommodation and Environmental Conditions

5.3 Examination Procedures

5.4 Laboratory Equipments

# Contd...

5.5 Examination Procedures

5.6 Assuring the Quality of Examination Procedures

5.7 Pre-Examination Procedures

5.8 Reporting of Results

# Stages of NABL Accreditation

- Quality System Manual adequacy study by NABL lead Assessor
- Pre-assessment visit by the Lead Assessor
- Final Assessment by the NABL team
- Report to NABL by Lead Assessor

# Contd...

- Report review by NABL Technical Committee
- Communication to laboratory about accreditation status
- Periodic surveillance with annual fees

# Policies and Procedures

- Quality Policy Statement
- Quality Manual
- Lab Safety Manual
- Waste Management Manual
- Control of Documents

# Contd...

- Selection and Evaluation of Supplier
- Client Complaints
- Control of Non-Conformities
- Corrective and Preventive action
- Control of Records

# Contd...

- Internal Quality Audit
- Management Review
- External Quality Assessment Scheme (EQUAS)
- Standard Operating Procedures of each lab
- Calibration Procedures

# Benefits of Implementation of NABL Standard

- Having access to more contracts for testing
- Potential increase in business
- Improved national and global reputation and image of the laboratory
- Time and money saving due to reduction in re-testing

# Contd...

- Continually improving quality data and laboratory effectiveness
- Having a basis for most other quality systems related to laboratories, such as Good Manufacturing Practices and Good Laboratory Practices

# Contd...

- Standard has been developed by health care experts and tested
- Ensure a safe and efficient work environment that contributes to staff satisfaction

# Contd...

- Establish collaborative leadership that strives for excellence in quality
- Understand how to continuously improve diagnostic processes and outcomes

# Difficulties and Bottlenecks in the process of implementation

- Poor Quality Management
- Poor Sample Control
- Poor Results Verification
- Quality Control and assessment

# Contd…

- Non Validated Tests
- Time pressures
- Poor workload Management
- Understaffed
- Inadequate Attention to Detail
- ILC and EQAS


THANK YOU