NABL Compliant Library of Laboratory in College: Requirements, Documentation and Working Framework for Accreditation Readiness

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ABSTRACT

Setting up a NABL (National Accreditation Board for Testing and Calibration Laboratories) compliant laboratory within an academic institution is a prerequisite for quality assurance, standardisation, research credibility and competency in the diagnostic and testing services. The laboratory library and documentation system of the medical and allied health colleges is highly essential to fulfil the standards of ISO 15189 and NABL accreditations. This article describes the basic structural requirements, documentation procedures, quality management system, manpower, validation of equipment, standard operating procedures (SOPs), internal audits, library resource management to establish NABL ready laboratory in college set up. The report also emphasises the necessity of ongoing quality improvement and accreditation benefits in academic health care facilities.

Keywords: NABL, ISO 15189, Laboratory Accreditation, Quality Management System, Medical Laboratory, College Laboratory, SOP, Internal Audit, Laboratory Documentation.

INTRODUCTION

The National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous agency within the Quality Council of India for accreditation of laboratories as per international standards. NABL accreditation gives formal recognition to technical competency of the laboratories. NABL is based mostly on the ISO 15189 standards for medical laboratories.

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The importance of laboratory accreditation in educational institutions like Ayurveda colleges, medical colleges and research institutes is increasing day by day for boosting diagnostic quality, research reliability, teaching standards and patient confidence. For setting up a NABL compliant laboratory, methodical planning, quality documentation, infrastructure management, skilled people and maintenance of a laboratory information and library system are required.

The laboratory library is the intellectual backbone of the quality system. It keeps the current standards, manuals, SOPs, reference books, journals, calibration records and accreditation documents that are needed for operational consistency and audit preparedness.

A laboratory is of utmost importance in healthcare, diagnostics, research, pharmaceuticals, food testing, and quality assurance. Accreditation by National Accreditation Board for Testing and Calibration Laboratories

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(NABL) is the gold standard for ensuring accuracy, dependability and international acceptability of laboratory results in India.

NABL is functional under the Quality Council of India and gives accreditation on international standards like ISO/IEC 17025 and ISO 15189. Setting up a NABL-accredited laboratory needs the right infrastructure, qualified people, quality management systems, documentation and conformity with technical requirements.

NABL Accreditation Objectives

1. To explain the requirements of setting up NABL certified laboratory at a college.
2. To describe the functions of the laboratory library and documentation system in the accreditation process.
3. To discuss the quality management techniques required for NABL accreditation.
4. To establish a framework for implementation in academic institutions.

Other Objectives

1. Provide accurate and reliable test findings
2. Enhance laboratory quality and competency
3. Improve national and international profile
4. Ensure patient and sample safety
5. Standardize lab protocols
6. Build trust between doctors and patients

NABL and ISO 15189 Requirements

NABL accreditation for medical laboratories is based on ISO 15189 standards which consist of management criteria and technical requirements.

Major fields include:

1. Structure of the organization
2. Quality Management System
3. Personnel competence
4. Calibration and maintenance of equipment
5. Quality control internally
6. Quality assurance, external
7. Safety in the laboratory
8. Records Management
9. Maintaining records
10. Continuous improvement

As per NABL guidelines, each laboratory should have legally identifiable status, defined authority, confidentiality, impartiality and structured documentation.

1. Scope

- Applies to medical laboratories seeking NABL accreditation
- Supplements ISO 15189 requirements

2. General Requirements

- Impartiality – Lab activities free from conflict of interest
- Confidentiality – Patient data protection & access control

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3. Structural Requirements

• Legal identity – Lab must be legally identifiable
• Organization & management – Defined responsibility, authority, organogram

4. Resource Requirements

4.1 Personnel

- Defined qualifications (MD/DNB/PhD/Qualified technical staff)
- Competency assessment & continuing education mandatory

4.2 Facilities & environment

- Adequate space, biosafety, temperature, contamination control

4.3 Equipment

- Authorized equipment only
- Calibration, maintenance, IQ/OQ/PQ records

4.4 Reagents & consumables

- Validated reagents, proper storage, inventory & lot traceability

4.5 External services

- Approved referral labs, documented agreements

5. Process Requirements

5.1 Pre-examination

- Patient identification
- Sample collection, labeling, transport, rejection criteria

5.2 Examination

- Method validation/verification
- IQC mandatory for each parameter

5.3 Post-examination

- Authorized signatory approval
- Result review & clinical correlation

5.4 Reporting

- NABL-compliant report format
- Units, reference intervals, critical alerts

5.5 Critical results

- Documented critical values & communication log

5.6 EQAS / PT

- Mandatory participation
- Corrective action for unsatisfactory performance

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6. Management System Requirements

6.1 Documentation

- SOPs, quality manual, records control

6.2 Risk management

- Risk identification, mitigation & monitoring

6.3 Nonconformity & CAPA

- Root cause analysis mandatory

6.4 Internal audit

- Annual audit covering all sections

6.5 Management review

- At least once a year
- Decisions documented & implemented

NABL Laboratory Infrastructure Requirements

1. Infrastructure (Physical)

The laboratory should contain:

- Working space sufficient
- Good ventilation and lighting
- Temperature and humidity controlled
- Sample collection site
- Storage Zone for Reagents
- Waste disposal system
- Biosafety precautions
- Fire fighting equipment

The environment should be kept to a minimum of contamination and accuracy of testing processes.

2. Laboratory Apparatus

All laboratory equipment must be:

- Validated prior to use
- Well calibrated
- Regularly maintained
- Traceable to national/international standard
- NABL requires NABL accredited calibration laboratories for calibration.

Some examples are:

- Microscopes
- centrifuges,
- Incubators
- Analyser biochemistry

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- pH meters
- Spectrophotometer

Laboratory Library's Contribution to NABL Accreditation

The laboratory library is an integral part of the quality management system. It provides access to up-to-date technical knowledge, reference material and regulated documents.

Basic Elements of the Laboratory Library

A. Books of Reference

The library should have up to date books in:

- Clinical pathology
- Microbiology
- Biochemistry
- Quality assurance
- Laboratory medicine
- Research methodology
- ISO 15189 standards

B. NABL documentation

Required NABL Documents Are:

- Nabl 112a – Specific Criteria for Accreditation of Medical Laboratories
- NABL 112B - Guidance Document for Medical Laboratories
- Application Form and Check List NABL 155
- NABL 160 - Requirements for Quality System Manual
- Manual of Standards ISO 15189

C. Standard Operating Procedures (SOPs)

Each laboratory technique shall have a documented SOP that includes:

- Princípio de teste
- Sample requirements
- Reagent preparation
- Procedural steps
- Intervals of reference
- Quality control procedures
- Analyse
- Safety precautions

D. Journals and Research Publications

The laboratory library should be contain access to:

- Peer-reviewed journals
- Articles
- Quality assurance (QA) publications
- Accreditation updates

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Documentation System for NABL Laboratories

Documentation is the heart of accreditation. Good records provide evidence of traceability, accountability and consistency.

Essential Documents

Document Type	Purpose
Quality Manual	Quality policy and objectives
SOP Manual	Procedures Standardisation
Equipment Records	Calibration & Maintenance
Personnel Records	Qualification and competency
Reports of Internal Audit	Monitoring for compliance
Corrective Action Log	Improvement actions
Sample Registers	Traceability
Safety Records	Bio-safety compliance

QMS (Quality Management System)

A Quality Management System is required for the continual quality of the laboratory.

The main elements are:

- Policy of Quality
- Organisational chart
- Risk management
- Internal audits
- Corrective and preventive actions
- Constantly Improving
- Management review sessions.

The quality manager has a significant role in compliance with NABL criteria.

Need for Manpower

Accreditation requires competent people

Staff Needed

- Director of Laboratory
- Quality Director
- Technical Director
- Lab Technologists
- Data Entry Operator
- Supporting Staff

All personnel should be trained in:

- Management of quality
- Biosecurity
- Equipment handling
- Internal quality assurance
- Procedures for documentation

Competency assessments should be undertaken on a regular basis.

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Internal Quality Control and External Quality Assurance

1. Internal Quality Control (IQC)

IQC facilitates daily surveillance of test performance by:

- Control samples
- Levey Jennings charts
- Procedures for corrective actions

2. External Quality Assurance Scheme (EQAS)

Participation in proficiency testing programmes is necessary in order to assess the performance of laboratories against external laboratories.

Management Review & Internal Audit

Regular internal audits aid in identifying non-conformities and corrective actions.

The audit areas include:

- SOP adherence
- Equipment maintenance.
- Records management
- Competency of staff
- Safety procedures

Management review meetings Evaluate:

- Audit Findings
- Grievances
- Corrective actions
- Quality indicator

Benefits of NABL Accreditation to the Colleges

Advantages of NABL accreditation include:

- Increased diagnostic precision
- More credence for research
- Increased patient confidence
- Standard laboratory practices
- Worldwide recognition
- Improved quality of teaching and training
- More financing and partnership possibilities

Problems in setting up NABL Laboratories

Common challenges are:

- Expensive infrastructure
- Shortage of trained manpower
- Heavy documentation required
- Expense for equipment upkeep
- Ongoing audit preparedness

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However, careful planning and institutional dedication have been successful in establishing accreditation-ready laboratories despite these hurdles.

Categories of NABL Laboratory

NABL accreditation can be earned for:

- Medical Labs
- Testing Laboratories
- Calibration Labs
- Research and Development Labs

The important norms and regulations are:

1. **ISO 15189**
   - For medical laboratories: "Medical laboratories — Requirements for quality and competence"
2. **ISO/IEC 17025**
   - Testing and calibration laboratories.
3. **Rules for Management of Biomedical Waste**
   - Biomedical waste disposal regulations should be followed by laboratories that handle biological material.
4. **Permissions from Local Health Authority**
   - Trading license
   - Fire safety approval
   - Compliance with pollution control
   - Agreement on biomedical waste
   - Requirements for infrastructure
   - Laboratory Space

NABL Accreditation Procedure

Step 1: Planning out

- Define laboratory scope and offerings.

Step 2: Set up infrastructure

- Arrange space, personnel and equipment.

Step 3: Implement the QMS

- Draft SOPs and quality manuals.

Step 4: Apply to NABL

- Submit your application online on the official NABL portal.

Step 5: Documentation Review

- NABL reviews provided documentation.

Step 6: Pre-Assessment

- The lab is visited by experts.

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Step 7: Final Evaluation

- Technical evaluation has been performed.

Step 8: Corrective Actions

- Any shortcomings are to be addressed.

Step 9: Award of Accreditation

- If the compliance is successful, NABL certificate will be awarded.

How NABL Laboratory Functions?

- Work flow
- Registration of patient/sample
- Sample collection
- Archiving and labelling of samples
- •Testing in compliance with SOPs
- Quality controls
- Generation of reports
- Keeping records
- All processes must be documented and traceable.

Advantages of NABL Accreditation

- Greater credibility
- Increased patient confidence
- Acceptance International
- Reporting standardization
- Greater institutional recognition
- Opportunities for further research

Problems in Setting Up a NABL Laboratory

- High initial investment
- Comprehensive documentation
- Requirements for staff training
- Quality monitoring on an ongoing basis
- Periodic audit and renewal

SUMMARY

Establishment of a NABL accredited laboratory in a college requires an organised infrastructure with systematic planning, technical expertise, good quality management systems, trained personnel and sufficient documentation. In laboratory accreditation the library is the main supporting system to maintain the standards, SOP's, manuals, journals and quality records. NABL certification promotes laboratory quality and patient safety, academic excellence, research standards and institutional reputation. Hence the educational institutions should emphasise on implementation of NABL requirements for sustainable quality health care and research services.

The process can be a little tedious and there is compliance involved, but NABL certification raises the standards of the lab, its reliability and professional recognition. NABL certification is becoming a must for quality and trust in laboratory services in today's healthcare and Indian system of medicine and research environment.

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