Third Edition May 2014

ESSENTIAL STANDARDS FOR MEDICAL LABORATORIES

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Taking Quality to the Last Man in the Line

HAPPY INDEPENDENCE DAY

15th August 2020

*Guidebook & printed Standards can still be bought at nominal fee

PREFACE TO THE RE-PRINT

National Accreditation Board for Hospitals and Healthcare Providers (NABH), a constituent board of Quality Council of India, established in 2005, is in its 15th year of creating an ecosystem of quality in healthcare in India. NABH standards focus on patient safety and quality of the delivery of services by the hospitals in the changing healthcare environment. Without being prescriptive, the objective elements remain informative and guide the organisation in conducting its operations with a focus on patient safety.

All NABH standards have been developed in consultation with various stakeholders in the healthcare industry and if implemented help the healthcare organizations in stepwise progression to mature quality systems covering the entire spectrum of patient safety and healthcare delivery.

The NABH organization & the hospital accreditation standards are internationally recognized and benchmarked. NABH is an Institutional as well as a Board member of the International Society for Quality in Health Care)lSQua) and Asian Society for Quality in Health Care (ASQua) and a member of the Accreditation Council of International Society for Quality in Health Care)ISQua(

Over the years, successive NABH standards have brought about not only paradigm shifts in the hospitals' approach towards delivering the healthcare services to the patients but have equally sensitised the healthcare workers and patients towards their rights and responsibilities.

In celebration of our 74th Independence Day, on 15th of August, 2020, we are pleased to announce, that starting today, in an enhanced effort to connect with people, all NABH standards, across programmes, will be available free of charge as downloadable documents in PDF format on the NABH website www.nabh.co. (The Printed copies of Standards and Guidebooks will continue to remain available for purchase at a nominal price).

NABH also announces the enriched continuation of its **"NABH Quality Connect-Learning with NABH"** initiative, connecting free monthly training classes, webinars and seminars. The various topics that will be taken up will cover all aspects of patient safety, including: Key Performance Indicators, Hospital Infection Control, Management of Medication, Document Control etc.

Recently introduced communication initiatives like **Dynamic Website Resource Center** and **NABH Newsletter *Quality Connect* (**focusing on sharing the best quality practices, news and views) will also be bettered.

It is sincerely hoped that all stakeholders will certainly benefit from the collective efforts of the Board and practical suggestions of thousands of Quality Champions form India and abroad

NABH remains committed to ensuring healthy lives and promote wellbeing for all at all ages (SDG-3-Target 2030), creating a culture of quality in healthcare and taking Quality, Safety and Wellness to the Last Man in the Line.

Jai Hind

(Dr. Atul Mohan Kochhar)
CEO-NABH **15th August 2020**

ESSENTIAL STANDARDS FOR MEDICAL LABORATORIES

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Contents

FOREWORD

Medical Laboratory Standards, are meant for a standalone Medical Laboratory, which has a desire to implement quality system to improve quality and patient safety. These standards can be used by the organizations to enter the realm of systematic quality management across the laboratory.

The standards cover the vital elements of quality and safety management, and would facilitate in delivering high quality care.

I wish every success to the organization adopting these for implementation and congratulate them on their spirit of quality and patient safety.

Dr. Atul Mohan Kochhar
CEO-NABH

1. Introduction

The number of Indian laboratories, currently estimated at 100,000, is growing and the trend is expected to continue. Indian laboratories can be segmented into three categories: small, medium and large. While it is estimated that large laboratories perform between 40% and 50% of the country's diagnostic work, the small and medium laboratories perform the bulk of it.

The reliability of test results from medical laboratories is essential, as it forms the basis of an accurate diagnosis and the proper management of patient care. Adherence to quality standards varies among Indian laboratories, and relatively few medical laboratories are currently capable of achieving accreditation to global ISO standards. Therefore, a National essential quality standard for medical laboratories and a rigorous education-based approach towards compliance with this standard are warranted.

NABH with its mission **"To operate accreditation and allied programs in collaboration with stakeholders focusing on patient safety and quality of healthcare based upon national/international standards, through process of self and external evaluation"** has taken this initiative in the right earnest to help Indian laboratories improve their quality to the desirable level.

2. Scope of the Testing Services

The testing services to be provided by the laboratory can be classified into different disciplines as follows:

i. Clinical Biochemistry
ii. Pathology
iii. Microbiology & Serology
iv. Genetics
v. Nuclear Medicine (in-vitro tests only)- Requirement as laid down by Atomic Energy Regulatory Board (AERB)

The laboratory shall determine and detail the scope of the testing services carried out on patient samples using the available resources and facilities in the laboratory.

Details of the scope should be provided by the laboratory and should be declared by laboratory management. Laboratory shall record the detailed scope (list of tests) under each of its applicable disciplines mentioned above.

Disciplines of testing should be specified by the laboratory. Laboratory may operate in all or any of the disciplines and the requirement of this standard has to be applied across the entire laboratory.

3. Essential Standards for Medical Laboratories

Medical Laboratory/Clinical Laboratory means the laboratory for the biological, microbiological, immunological, chemical, hematological, pathological, cytological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease.

The standard contains following 7 clauses.

3.1 Organization and Management

3.1.1 Organization

Name of the laboratory and its permanent location with relevant details and year of establishment shall be documented in the laboratory. Declaration of the ownership of the laboratory with legal responsibility is available.

Names and addresses of all sample resource center(s), if any, from where the samples are accepted along with the average number of samples analyzed in the laboratory per day shall be documented. Also, number of patients for which samples were received shall be documented.

Elements to be observed

1. Name of Laboratory
2. Current valid Registration Number of laboratory, as applicable.
3. Permanent location with full address
4. List of sample resource centre(s)
5. Evidence of size of laboratory (average number of patients per day for last six months)

The laboratory management, which includes designated Quality manager/ Technical manager with specified responsibility and authority, shall be responsible for the design, implementation, maintenance and continual improvement of the quality management system.

The responsibilities of quality management system and technical can be assigned to one person.

Elements to be observed

1. Designation of person(s) as Quality Manager and Technical Manager
2. Responsibilities of Quality Manager includes:
    - Developing Quality Manual, Quality System Procedure (QSP) Manual, Sample Collection Manual, and Standard Operating Procedures (SOP's) as per the scope of laboratory in discussion with Technical Manager.
    - Conduct internal audit / Gap analysis for monitoring the implements of Quality Management System.
    - Guide / Take corrective and preventive action on the basis of
        - Gap during internal audit
        - Feedback and complaints of lab-users
        - Non conformity during day to day working
    - Develop and continuous monitoring of Quality Indicator
    - Prepare and present internal audit report in Management review meeting
3. Technical Manager shall be responsible for all technical operations.

3.1.2 Quality Management

All polices including quality policy; procedures and manuals shall be documented and communicated to all

relevant personnel. The management shall ensure that the documents are understood and implemented across the laboratory.

Quality Policy:

Quality Policy **is the statement** which defines the objectives of the laboratory and commitment of the top management to comply with the requirements of this standard.

Elements to be observed

1. Quality policy of the laboratory
2. Compilation of all the policies in a document (Quality Manual)
3. All documented procedures (QSP & SOPs) applicable to the laboratory

3.1.3 Internal Audit/ Self-Assessment

The laboratory shall document the plan and conduct internal audit/self-assessment at least once in six month.

Elements to be observed

1. Internal audit plan
2. Last internal audit report(s)
3. Closure of Non-conformity found during internal audit

Certified laboratory shall submit internal audit report annually to NABH.

3.1.4 Management Review

Quality Manager or any other authorized person, at least once in six months, shall prepare and analyse the internal audit report, internal quality control report, laboratory service feedback, and the complaint record and present to the management. Proceedings of the management review meeting shall be documented.

Elements to be observed

Proceedings of the Management review meeting. Contents of the management review meeting shall include:

1. Review of the internal audit report
2. Internal quality control report
3. External Quality Assurance report/ Inter-laboratory comparison/Split sample testing/ retained sample testing
4. Laboratory Service user / customer feedback/ complaint review report

3.2 Document Control

The laboratory shall have well established document control system

Elements to be observed

1. A list of all documents

2. Documents shall have a title, unique identification number, page number and total number of pages (e.g. 1 of 10)
3. All documents shall be reviewed, approved and issued by authorized person
4. Only current, authorized editions/issues/version of applicable documents are available at point of use.
5. Obsolete documents shall be properly labeled and removed from the work place
6. Documents can be stored in either electronic format or hard copy

3.3 Personnel

The laboratory shall establish and implement a personnel management plan that includes the organizational chart, personnel policies, and a job description that contains the qualifications, responsibilities and authorities for each position.

Laboratory management shall identify appropriately qualified personnel with qualification and adequate work experience in the respective fields of activity for both supervision and signing the test reports. The laboratory shall maintain the list of its entire technical staff and their responsibilities with qualifications.

Personal Protective Equipment shall be used. Protective lab coat, gowns designated for lab use must be worn while working in the lab. Eye and face protection (goggles, mask etc.) should be used for anticipated splashes.

Hepatitis B vaccination of each employee shall be done. Immunization status to be documented.

A procedure should be defined for handling needle stick injury or exposure to blood and body fluids.

Steps of hand hygiene are documented, displayed and practiced.

Elements to be observed

1. Organogram.
2. Job description/ roles & responsibilities for all the personnel.
3. Records of all personnel working in the laboratory that includes copies of basic and professional qualification, experience and training records (both internal and external).
4. Availability and usage of personal protective equipment
5. Staff health records

Laboratory management shall conduct regular training as relevant to the laboratory activities and document the relevant details.

Elements to be observed

1. Training plan
2. Training records

3.4 Laboratory Equipment

These include equipment, instruments, reference materials, reagents and test kits. The laboratory shall have all the equipment required to provide the services being offered. List of working equipment shall be maintained with unique identification, serial number, model, name of manufacturer, date of installation and calibration status/proper functioning status. The equipment shall only be operated by authorized and trained personnel.

Elements to be observed

1. Equipment List
   a) Name of equipment/ reagent/ kit
   b) Unique Identification Number/ Batch Number
   c) Name of Manufacturer
   d) Name and Number of contact engineer in case of breakdown
   e) Calibration Status/ proper functioning status
   f) Preventive Maintenance Status
2. Evidence to ensure proper functioning of all equipment.
3. Records of training of personnel operating the equipment.

3.5 Procurement of External Supplies and Services

3.5.1 Procurement

Laboratory shall define and document its procedures for selection and use of purchased external services/ supplies. There shall be an inventory control system.

Appropriate quality records of external services, supplies and purchased products shall be established.

The laboratory shall evaluate suppliers of critical reagents, supplies and services that affect the quality of examination and shall maintain records of such evaluations. The laboratory shall maintain a list of such approved suppliers.

Display of Material Safety Data Sheet

Elements to be observed

1. List of selected and approved suppliers for equipment, reagents and consumables with contact details and their evaluation
2. Inventory Management System including Display of Material Safety Data Sheet
3. Kit verification procedure

3.5.2 Outsourced Laboratory Services

Laboratory shall document the tests that are outsourced for analysis. Laboratory tests shall only be outsourced to another certified/ accredited laboratory for those tests to

ensure that the results received from such laboratories are appropriate.

Elements to be observed

1. List and contract/MOU with outsourced laboratories.
2. List of the tests outsourced for analysis.
3. Procedure for sample storage and transport to outsourced laboratory.
4. Procedure for issuing the report to patients for such outsourced tests.

3.6 Process Control

3.6.1 Laboratory Space

The laboratory shall have sufficient space and appropriate conditions to ensure quality services.

There shall be effective separation of areas for its various activities and only authorized persons will be allowed entry into the laboratory room.

The laboratory shall monitor, control and document all environmental conditions which may affect the quality of its services.

The laboratory shall designate an appropriate area for sample collection.

Appropriate waste management and environment protection procedures shall be in place.

Basic firefighting measures should be readily available and all staff members should be oriented regarding the same.

Different categories of chemicals are used in labs. Chemicals should have warning labels which will aid for its identification. Explosives, Compressed gas, Flammable liquids, Flammable solids, Oxidizer materials, Toxic materials, Corrosive materials; each category of chemical should be stored separately and well labeled.

All electrical equipment should be properly grounded.

Elements to be observed

1. Accommodation and environment of laboratory
2. Housekeeping in laboratory
3. Sample collection area
4. Bio-medical waste disposal procedure and license/approval as per State Pollution Control Board/ Committee
5. Storage area

Display Sign boards:

As per the requirement of the facility bilingual, pictorial signage should be displayed.

a. Fire exit signage (Self illuminating, Pictorial & Bilingual)
b. Directional signage

3.6.2 Quality Assurance

Each laboratory shall have a quality assurance program designed to assure the reliability and medical usefulness of the laboratory data.

Medical laboratories shall perform internal quality control testing. Use of third party human matrix quality control is recommended for all analytes.

They are encouraged to participate in Inter-laboratory comparisons/ External quality assessment programme / retained sample testing.

Use of reference material should be documented and records are maintained.

Elements to be observed

1. Performance of internal control
2. Participation in Inter-laboratory comparisons/ External quality Assessment programme / retained sample testing
3. Corrective action taken on results of Internal and External quality checks.

3.6.3 Pre-examination Process

The lab shall document a sample collection procedure having specific instructions for patient preparation, identification, procedure for sample collection, including specification on sample container, transport conditions, sample storage before analysis and after analysis and

disposal of the samples after appropriate decontamination.

The laboratory shall provide all relevant details of patients' samples. Traceability of the sample should exist to an identified patient with the appropriate request form. The laboratory shall establish a procedure for handling samples without a request form.

The laboratory shall have criteria for acceptance or rejection of sample.

Elements to be observed

1. Sample collection procedure
2. Sample labeling procedure and maintaining traceability
3. Acceptance and rejection criteria and records

3.6.4 Examination Process

The laboratory shall use only the standard methods (published in indexed journals or standard text books or kit inserts) or validated methods for sample testing. The head of the laboratory shall annually review the methods and reference values.

The standard operating procedures should be clearly written in simple language understood by all technical staff performing the test.

Elements to be observed

1. SOP's of all the test methods
2. Work instructions/ bench aids
3. Staff awareness regarding SOP's
4. List of reference values for all tests being conducted

3.6.5 Post-examination Process

The laboratory shall designate a person to approve the test results. The unused portion of the sample shall be kept for an appropriate period of time as per the policy of laboratory. Only authorized person shall discard the unused sample as per the documented procedure.

Elements to be observed

1. List of persons with qualification who approve test results
2. Retention time of unused samples
3. Methods of discarding of unused specimens including SOP for the same.

3.6.6 Reporting

Procedure for reporting shall be established including reporting by telephone/ fax/ email.

Reporting format shall include the name of the laboratory, name and identification of the patient, tests requested, sample receiving date and time, reporting date and time, test results, biological reference interval,

names of the persons who reported and approved the results.

The laboratory shall maintain a copy (on any appropriate medium paper or electronic) of the test report for an appropriate period of time.

Laboratory shall ensure patient confidentiality.

Elements to be observed

1. Test Request Form
2. Report format
3. List of critical values for tests and reporting records
4. Test report retention time policy
5. Patient confidentiality policy

3.7 Continual Quality Improvement

The laboratory shall have a procedure to deal with the non-conformities in the work being undertaken. Root cause analysis shall be done for further planning.

A documented procedure for corrective action and preventive action shall be maintained. The laboratory shall have a mechanism for reviewing customer feedback, error/non-conformity analysis and reporting to laboratory personnel and top management. Laboratory should review its quality system periodically to keep pace with the current trends.

Performance of quality indicators shall be reported to NABH on annual basis.

Elements to be observed

1. Records and performance of Quality indicators like sample rejection rate, sample collection to processing time, internal control results, performance in quality assurance, reporting turn-around time etc. Corrective action taken of complaints, feedback and non-conformance after root cause analysis.
2. Complaint and feedback record.
3. Complaint and feedback analysis record.

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