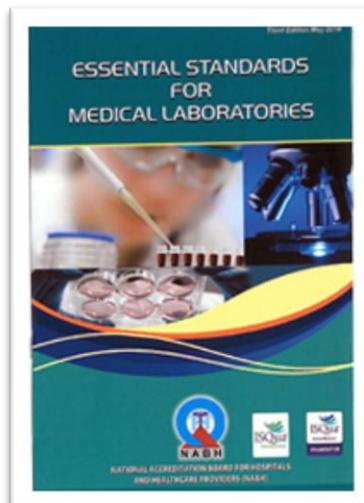


**NATIONAL ACCREDITATION BOARD FOR HOSPITALS
& HEALTHCARE PROVIDERS (NABH)**



**Medical Laboratory Program (MLP)
Certification Program**

General Information Brochure



August 2020





About NABH

National Accreditation Board for Hospitals and Healthcare Providers (NABH) is a constituent board of Quality Council of India (QCI), set up to establish and operate accreditation programme for healthcare organizations. NABH has been established with the objective of enhancing health systems & promoting continuous quality improvement and patient safety. The board while being supported by all stakeholders, including industry, consumers, government, has full functional autonomy in its operation.

NABH offers accreditation services to hospitals and other clinical establishments. NABH provides accreditation in a non-discriminatory manner regardless of their ownership, legal status, size, and degree of independence.

International Society for Quality in Healthcare (ISQua) has accredited NABH as an Organization. The hospitals accredited by NABH have international recognition. This provides boost to medical tourism in the country.

NABH is an Institutional Member as well as a member of the Accreditation Council of the International Society for Quality in HealthCare (ISQua). NABH is one of the founder member of Asian Society for Quality in Healthcare (ASQua).

There has been demand from SAARC/ASIAN countries for NABH accreditation and to meet this requirement, NABH has launched NABH International and to begin with Philippines is the first overseas destination for extending NABH accreditation services.



About NABH

NABH provides accreditation to Healthcare organisations in a non-discriminatory manner regardless of their ownership, legal status, size and degree of independence.

The objective of NABH standards is to improve healthcare quality and patient safety.

NABH currently operates the following accreditation, certification and empanelment programs

Accreditation programs:

1. Hospitals
2. Small Healthcare Organizations
3. Blood Banks
4. Medical Imaging Services
5. Dental Facilities/Dental Clinics
6. Allopathic Clinics
7. AYUSH Hospitals
8. Primary Health Centre
9. Clinical Trail (Ethics Committee)
10. Panchakarma Clinics
11. Eye Care Organization

Certification programs:

1. Entry Level Hospital
2. Entry Level Small Healthcare Organizations
3. Entry Level AYUSH Centre
4. Entry Level AYUSH Hospital
5. Nursing Excellence
6. Medical Laboratory Programme
7. Emergency Department
8. MVTF Empanelment Certification

Empanelment programs:

NABH is the nodal body representing Quality Council of India for conducting assessments of healthcare organizations for empanelment under Central Government Health Scheme (CGHS) and Ex-Servicemen Contributory Health Scheme (ECHS).





Introduction to Certification

In India, Health System currently operate within an environment of rapid social, economical and technical changes. Such changes raise the concern for the quality of health care. Medical laboratories are an integral part of health care system. Certification of Medical laboratories strives to improve the quality of test results. The certification programme assesses the quality and operational systems in place within the facility. The certification includes compliance with the NABH standards, applicable laws and regulations.

This certification shall be applicable only to the site where sample processing, testing and reporting of the results is being done and shall not be applicable to any collection centres attached to the laboratory. The certificate issued shall be for two years and the laboratories are encouraged to show improvements and go for certification. In case, laboratory wishes to continue with this certification program, they can apply for renewal.

Certification is the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements.

The medical lab certification program started in the year 2014, the standards were named as essential standards for medical laboratories. The program was started in Kerala after agreement was signed between NRHM-Kerala and Quality Council of India. The Kerala government had made this certification mandatory for its labs run by the government. Later it was open for all labs. The program was projected as the stepping stone for quality in Medical Labs i.e. even a lab with 1-2 persons were able to join the program for certification of their labs. The significance of this certification for labs include awareness about quality management systems in the medical labs, for example very small labs which cannot afford to go for NABL accreditation found it easy to join the program. It was also a public recognition for them.



Benefits of Certification

Benefits for Patients

- Patients are the biggest beneficiary among all the stakeholders.
- Certification results in high quality of care and patient safety.
- The patients are serviced by credential medical staff.
- Rights of patients are respected and protected. Patient's satisfaction is regularly evaluated.

Benefits for Medical Laboratories

- Certification to Medical Laboratories stimulates continuous improvement.
- It enables the organization in demonstrating commitment to quality care and patient safety thereby ensures best clinical outcomes.
- It raises community confidence in the services provided by the Medical Laboratories as services provided by credentialed medical staff.
- It also provides opportunity to healthcare unit to benchmark with the best.
- Certification status also provides marketing advantage in a competitive health care.

Benefits for Staff

- The staff in a Certified Medical Laboratories is satisfied lot as it provides for continuous learning, good working environment and leadership.
- Efficiencies and competencies of staff also gets improved in a certified Medical Laboratories.
- It improves overall professional development, knowledge and competencies in systematic ways with defined ownership and accountability of all the staff including Medical and Para Medical Staff.





Benefits to paying and regulatory bodies

Finally, certification provides an objective system of empanelment by insurance and other third parties. Certification provides access to reliable and certified information on facilities, infrastructure and level of care.



Eligible Medical Laboratories

This Programme is for laboratories that conduct 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

Eligibility Conditions:

Medical Laboratories **can only apply** for NABH Certification, if meets any one of the following condition:

- Standalone or a hospital based laboratory
- Currently in operations as Medical Laboratories
- Medical Laboratories should have implemented NABH standards in the Medical Laboratories for a minimum of three months.

This program is open for all laboratories including those have only the most basic of equipment (such as a microscope) and perform the most routine tests, such as:

- Simple qualitative urine strip tests for sugar and protein.
- Microscopic analysis.
- Blood smear for MP (malarial parasite) and for TC (total leukocyte count) and DC (differential leukocyte count), and/or blood grouping and Rh testing.

Scope of Certification:

A laboratory must apply for all its facilities (discipline and tests) as NABH certification is based on the principle of All or None.



Laboratory Disciplines Covered

- 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)



Values & Winning Edge for the Laboratory

- **Improve Safety, Accuracy of Laboratory Results and Patient Care**

Through adherence to the Essential Standards, laboratory testing errors are reduced, weaknesses in workflow, processes, and procedures are addressed, and overall operations are aligned with accepted practices.

- **Earn a Credible Mark of Compliance with Standards**

Your Laboratory will earn a mark of compliance (certification mark) on compliance with the standards.

- **Achieve Greater Efficiency, Profitability, and More Productive Operations**

The Internal Audit/Self-Assessment, continual learning, Onsite Assessment and required improvement components of standards facilitate a thorough examination of your Laboratory's entire operation that improves "error detection", reduces "false rejections", and relieves your entire organization from unnecessary tasks.

- **Become More Competitive, Gain Public Recognition, and Grow Revenue**

Your laboratory's name will be featured on NABH website. Your Laboratory will become better positioned for potential medical tourism and clinical trial opportunities.

- **Improve Customer and Employee Satisfaction**

Higher quality, more consistent test results with fewer delays and errors will lead to increased trust and confidence from current patients and new patients, via word-of-mouth and other marketing means. You will notice improved internal staff and management work relations, commitment and staff retention.

- **Anticipate Government and Insurance Provider Policies and Regulations**

There are many State, Centre and Insurance Provider standards, restrictions, policies and regulations that are either in place or being considered across the country, including the national Clinical Establishment Act. The NABH Programme will be updated to continually meet these new requirements.



Methodology for Certification

Medical Laboratory management shall first decide about getting Medical Laboratory Certification from NABH. It is important for a Medical Laboratory to make a definite plan of action for obtaining certification and nominate a responsible person to co-ordinate all activities related to seeking certification. An official nominated should be familiar with existing Medical Laboratory quality assurance program.

Medical Laboratory shall procure a copy of standards online from the NABH portal against payment. Further clarification regarding standards can be obtained from NABH Secretariat in person, by post, by e-mail or on telephone.

The Medical Laboratory looking for Medical Laboratory Certification shall understand the NABH assessment procedure. The Medical Laboratory shall ensure that the standards are implemented in the organization.

The Medical Laboratory can fill the application form for NABH Medical Laboratory certification online (www.nabh.co) through the website. The applicant lab must have conducted self-assessment against NABH Medical Laboratory Standards for hospitals at least 3 months before submission of application and must ensure that it complies with it.

How to apply?

Once the standards are implemented in the hospital, the organization can apply for certification online from the website www.nabh.co

- (a) Use a new email id for registration
- (b) Choose 'Medical Laboratory' as Application Type
- (c) NABH shall activate the email id and provide you the login and password

Using the above login and password – you can fill the application form.



Certification Process



NABH Certification Procedure

Preparation of Policies and Manuals:

The Medical Laboratory shall prepare the Quality Manual, Policies and Procedures and other Manuals required as per the NABH standard.

Application for NABH Medical Laboratory Certification Program:

The Medical Laboratory shall apply to NABH as per the instructions given in the online application portal. Medical Laboratories should fill the application and provide the information details very carefully as this is relevant to determine the scope of services and to take the process further.

Scrutiny of application:

Reference ID for the application is generated once the Medical Laboratory pays the application fees from 'Make Payment' option of the online application form. NABH officer shall scrutinize the application form for its completeness. Hospital may correspond to NABH via writing in 'Remarks column' of online portal of the Medical Laboratory.

Notification of Principal Assessor and Assessment Team:

NABH shall appoint Principal Assessor who shall have the overall responsibility of conducting the assessment for the lab and a team of other assessors. He/ She will evaluate the adequacy of all the documents including the quality manual, policies and procedures and other departmental manuals as mandated by the standards.

Types of Assessment conducted by NABH

NABH in coordination with the Medical Laboratory may choose to follow one of the following methods for conduct of the assessments based on environmental factors prevailing in the region in order to ensure business continuity in its operations without compromising on quality.





Onsite assessment: In onsite assessment, the assessors nominated by the NABH Secretariat makes a visit to the Medical Laboratory for a predefined man day based on the size of the medical lab, the assessors verifies the documents, facilities and conducts interviews in person at the HCO.

Remote assessment: In this type of assessment, the assessor (ors) does not go to the Medical Laboratory in person, but conducts the entire assessment from a remote location through the use of virtual platforms.

Hybrid assessment: In this type of assessment, one assessor may be physically present in the Medical Laboratory during the audit, and the other assessor(ors) will be doing the audit from a remote location through the use of virtual platform.

Communication Channel

All applicant and certified healthcare Medical Laboratory are strongly advised to use the "Remarks column" at the online portal for all communication. Medical Laboratories are strongly discouraged to communicate through telephone or emails to secretariat members as this communication cannot be saved as part of particular Medical Laboratory record and may not be available for future references. The matrix for communication is available at NABH website.

<https://www.nabh.co/Announcement/NABH%20Communication%20Matrix.pdf>



NABH Certification Procedure

Final Assessment:

The final assessment involves comprehensive review of Medical Laboratory functions and services. NABH shall appoint an assessment team. The date of final assessment shall be agreed upon by the Medical Laboratory management and NABH.

Based on the assessment by the Assessment team, the assessment report is submitted by the assessor online at NABH website.

The details of non-conformity(ies) observed during the assessment are handed over to the Medical Laboratory by the Assessment team and detailed assessment report is uploaded at NABH portal using assessor login account.

Review of assessment report:

The Medical Laboratory shall take necessary corrective action on the non-conformity (ies) and upload the requisite document as evidence for corrective action for each non-conformity. On successful submission of the corrective action by the Medical Laboratory, the same shall be reviewed by the Principal Assessor.

Healthcare organisations can avail only two cycles of corrective action on non-conformities.

After satisfactory corrective action is taken by the Medical Laboratory, the accreditation committee examines the assessment report, additional information received from the Medical Laboratory and consequent verifications. The accreditation committee shall make appropriate recommendations regarding certification of the Medical Laboratory.





Issue of Certification:

NABH shall issue a certificate to the Medical Laboratory with a validity of two years. The certificate has a unique number, date of validity and scope of services.

The applicant must make all payment due to NABH, before the issue of the assessment visit.

Re assessment:

Certification to a Medical Laboratory shall be valid for a period of two years.

The Medical Laboratories may apply for renewal of certification at least six months before the expiry of validity of certification for which reassessment shall be conducted.

Focus Assessment:

Focus assessments are done in Medical Laboratory when there are any significant changes with regard to the Medical Laboratory's activities and operations, such as change in scope of certification, change of address/ location, change in environment, key technical personnel etc. Medical Laboratory are requested to view policy and procedure related to Focus visit to an certified Medical Laboratory by visiting the following link.

https://www.nabh.co/Policy_for_Focus_Assessment.aspx

NABH Policy & Procedure for Focus Assessment of an Accredited/Certified Healthcare Organisation (HCO) - PFAC_2018



POLICY & PROCEDURE FOR
FOCUS ASSESSMENT OF AN
ACCREDITED/CERTIFIED
HEALTHCARE ORGANISATION
(HCO)

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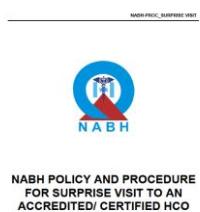


NABH Certification Procedure

Surprise Assessment:

NABH may conduct surprise assessments at certified Medical Laboratory periodically to evaluate the compliance to the certification standards, as labs are expected to adhere to the NABH certification standards at any given point of time once Medical Laboratory is certified. Surprise visit can also happen in response to adverse media report. Medical Laboratories are requested to view policy and procedure related to Surprise visit to a certified Medical Laboratory by visiting the following link.

<https://www.nabh.co/SURPRISE-VISIT.aspx>





NABH Certification Procedure

Guidelines for using the Certification mark:

Certified Medical Laboratory should ensure the guidelines related to display NABH Logo / certification mark are adhered. Any misuse of the logo / certification mark can lead to adverse action being taken against the Medical Laboratory by NABH besides legal action. Medical Laboratory are requested to view guidelines related to use NABH logo / certification mark by visiting the following link.

https://www.nabh.co/Images/pdf/Policy_and_Guidelines_for_use_of_NABH_Accreditation_Certification_Mark.pdf



Standard Agreement:

Medical Laboratories certified by NABH has to enter into an agreement with NABH from the date of certification. The certificate will be dispatched to the Medical Laboratory only after this agreement has been received by NABH secretariat. Medical Laboratories are requested to view standard agreement by visiting the following link.

https://www.nabh.co/Images/PDF/Agreement_hos.pdf



NABH Certification Procedure

Disclaimer & Indemnity:

NABH reserves the right to take action or even cancel the Certification awarded to a Medical Laboratory in following conditions -

1. If the required fee is not paid on time
2. Any adverse actions taken by any regulatory bodies against the Medical Laboratory,
3. Serious patient safety issues, etc.
4. Failure to comply with the standards at any given point of time etc.

Medical Laboratories are also advised to check the NABH portal time to time for any important announcements, change in standards etc. which needs to be adhered by certified Medical Laboratory



Training

The journey of Accreditation/Certification i.e. from applying to grant of Accreditation/Certification involves the awareness & training of all the members of the healthcare organizations about the various Chapters, Standards & Objective Elements of NABH Standards booklet. The staff needs to imbibe the culture of NABH by getting trained in the standards, understanding the applicable standards in a right way so that the same can be implemented, measured and monitored in the right manner by the healthcare organization.

NABH Secretariat organizes training sessions on understanding of NABH standards and implementing them in the organizations in form of Programme on Implementation (POI), for healthcare organizations desirous of taking their organizations for certification. These sessions are taken by faculty from NABH who are senior assessors. The details of these trainings, dates, venue and fee information are available in the NABH website

NABH has taken a new initiative to conduct free master classes on various topics under the rubric "NABH Quality Connect-Learning with NABH". The master classes are conducted every month. The topics include: Key Performance Indicators (KPI), Hospital Infection Control, Management of Medication, Document Control, Clinical Audits, Continual Quality improvement, Hospital infection prevention etc

Apart from this guidance material is available at "Resource" page of NABH web portal

Kindly visit the below link to attend training programmes being conducted by NABH.

<https://www.nabh.co/EducationTraining.aspx>



Fee Structure

General information brochure : Free of cost

NABH Medical Laboratory Certification Standards for hospital : Rs. 300/-

Size of Laboratory	Assessment Day(s)	Application cum Certification fee
Micro sized Laboratory (up to 25 Patients per day)	Half Day	12500
Small sized Laboratory (26 – 100 Patients per day)	Half Day	25000
Medium sized Laboratory (101 – 300 Patients per day)	One Day	50000
Large sized Laboratory (301 & above Patients per day)	Two Days	80000

*The fee structure is based on the number of man days required for assessment. In case the scope of services is more than the above, then proportionately higher man days and fee structure may be charged.

GST: w.e.f. 01.06.2016 a GST of 18% or as applicable will be charged on all the above fees. HCOs are required to include the service tax in the fees accordingly while making payment to NABH.

CONTACT DETAILS

NATIONAL ACCREDITATION BOARD FOR HOSPITALS AND HEALTH CARE PROVIDERS

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