Medical Imaging Services Accreditation Programme

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.

International Society for Quality in Healthcare (ISQua) has accredited NABH as an Organization. The HCO accredited by NABH have international recognition. This provide boost to medical tourism in 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.
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. Blood Storage Centre
5. Medical Imaging Services
6. Dental Facilities/Dental Clinics
7. Allopathic Clinics
8. AYUSH Hospitals
9. Primary Health Centre
10. Clinical Trial (Ethics Committee)
11. Panchakarma Clinics
12. Eye Care Organization
13. Wellness Centres
14. OST
15. IRCA

**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 Accreditation

Medical Imaging Centre should be places of safety not only for patients but also for staff and other stakeholders. Quality and patient safety at Medical Imaging Centre is of great interest to government bodies, NGOs, insurance agencies, professional organizations representing healthcare workers and patients. Accreditation focuses on establishing quality and safety in relation to predetermined standards. Accreditation encourages healthcare organization to pursue continual excellence.

According to ISQua “A self-assessment and external peer review process used by health and social care organisations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health or social care system.”

In recent decades medical imaging has experienced a technological revolution. Clinical advantages of these services are enormous and affect critical decision making during patient management. However they could be hazardous if the quality of the service provided is less than optimal. Hence to assess the quality and safety of medical imaging services and to represent a method for monitoring of quality standards, a basic accreditation program needs to be implemented in the country for Medical Imaging Services. These standards reflect the expectation of good imaging radiology and nuclear medicine services from the viewpoint of the service providers, of the patients; of the referrers; as well as of safety regulatory bodies like AERB and PC-PNDT.

The NABH standards document is a product of a rigorous continuous development process during which it has been through a number of iterations. The current standards reflect the professional judgment of the expert panels of radiologists, nuclear medicine physicians and medical imaging services providers. The standards have been externally evaluated by the panel of Radiologists as well as it has been subjected to a full public consultation exercise prior to their finalization. The process of formulating these standards is evolutionary, dynamic and shall be kept updated as required.
Medical Imaging Services (MIS) standards are developed to be patient-focused, to cover the functions and systems of a whole diagnostic imaging and interventional radiology service, & to address quality in service delivery and support quality improvement. These standards can be used by the MIS Centres to enter the realm of systematic quality management across a healthcare organization. The standards cover the vitals of quality and safety management and would facilitate in delivering high-quality care.

These set of standards, cover all Medical Imaging Services including conventional radiation-based diagnostic radiology as well as a wide variety of specialized techniques including Ultrasound scans, Doppler studies, Bone densitometry, CT, MRI, PET-CT, SPECT, Radionuclide imaging and therapy, Interventional procedures, etc.

A Medical Imaging Department in the Hospital or an Imaging centre must maintain certain standard of services (statutory or otherwise); as well as, strive for continuous improvement in the quality of services they provide. Close collaboration with clinical colleagues, verification of result as well as proper maintenance and calibration of the equipments are also a part of quality management in the department of medical imaging.

Confidence in accreditation is mutual and is obtained by a transparent system of control over the accredited center by the accreditation body and an assurance given by the accreditation body that the accredited center constantly fulfills the accreditation criteria.

The MIS accreditation was launched in the year January, 2010. The standards were developed with the main goal to improve the diagnostic accuracy and patient safety. MIS accreditation helps the centers to increase the confidence of the customer in the community. The target customers for MIS Accreditation program are standalone/corporate/hospital based medical imaging services providers / centres.
How Accreditation Assists in Improving Safety?

- Measures organizations’ compliance against standard’s Quality & Safety
- Promotes teamwork - mobilizes teams & clinicians towards safety: More aware and participative in patient safety, own and team safety
- Increased capacity for managing quality improvement & Safety
- Improved communication, collaboration, and team building
- Higher level of integration of services
- Provides organizations with a critical path to achieve improvement
Benefits of Accreditation

Benefits for Patients

- Patients are the biggest beneficiary among all the stakeholders.
- Accreditation 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 Organization

- Accreditation to a Medical Imaging Services Centre 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 Imaging Services Centre as services provided by credentialed medical staff.
- It also provides opportunities to healthcare unit to benchmark with the best.
- An accreditation status also provides marketing advantage in a competitive health care.
- Finally, accreditation provides an objective system of empanelment by insurance and other third parties.

Benefits for Staff

- The staff in an accredited Medical Imaging Services Centre is satisfied lot as it provides for continuous learning, good working environment and leadership.
- Efficiencies and competencies of staff also gets improved in an accredited Medical Imaging Services Centre.
- 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, accreditation provides an objective system of empanelment by insurance and other third parties. Accreditation provides access to reliable and certified information on facilities, infrastructure and level of care.
NABH Standards for Medical Imaging Services

NABH Accreditation Standards for Medical Imaging Services prepared by technical committee contains complete set of standards for evaluation of Medical Imaging Service for grant of accreditation. The standards provide framework for quality of care for patients and quality improvement for Medical Imaging Service with the goal to improve diagnostic accuracy and safety, as well as, enhancing the overall patient experience. The standards help to build a quality culture at all level and across all the function of Medical Imaging Service.

The standards for NABH Accreditation for Medical Imaging Services provide general guidelines pertaining to all diagnostic and interventional imaging services. The Standards are divided into 7 chapters containing 36 standards and 237 objective elements.

Main clauses of NABH Medical Imaging Services Standards are

1. Access Assessment and Patient Care (AAPC)
2. Imaging Procedures and Interpretation (IPI)
3. Facility Management and Safety (FMS)
4. Equipment, Material, and Medications (EMM)
5. Human Resource Management (HRM)
6. Management of Quality and Safety (MQS)
7. Information Management System (IMS)
Methodology for Accreditation

Medical Imaging Services shall be able to demonstrate to NABH assessment team that all NABH standards, as applicable, are followed.

Medical Imaging Services (MIS) participating in accreditation program will be expected to provide following types of evidence:

- Compliance to/with Statutory requirements for imaging services and facility.
- Approved documents that identify relevant service policy, protocols and/or strategies that set out, the service plans to deliver each standard statement and objective element therein.
- Evidence that demonstrate that the Medical Imaging service is implementing these policies, protocols and/or strategies.
- Practical demonstration of randomly selected procedures
- Evidence that demonstrates that the service is monitoring its performance regularly in the implementation of its policies, protocols and strategies

Eligibility to apply for Medical Imaging Services Centre Accreditation

Medical Imaging Services Centre that fulfils the following requirements:

- Currently in operation as Medical Imaging Services Centre
- Medical Imaging Services should have been implemented NABH standards in the Medical Imaging Services for a minimum of three months.
- The organization that commits to comply with relevant NABH standards, its policies and procedures and applicable legal/statutory/ regulatory requirements.

These standards are to be used by the whole organisation and not for a specific service within the organisation. Organisations may have different services and it is equally applicable to all services and both public and private Medical Imaging Centre.
Methodology for Accreditation

The management of the Medical Imaging Services shall first decide about getting accreditation for its center from NABH. It is important for a Medical Imaging Services to make a definite plan of action for obtaining accreditation and nominate a responsible official to coordinate all activities related to seeking accreditation and the official nominated should be familiar with the Medical Imaging Services standards and its quality assurance system.

MIS need to procure a copy of the Accreditation standard. One can purchase the standards by registering and making the payment at the website https://www.nabh.co/NABHStandards.aspx

The Medical Imaging Services looking for accreditation shall understand the NABH accreditation process. The Medical Imaging Services shall ensure that the standards are implemented in the organization.

The applicant Medical Imaging Services must have conducted self-assessment against NABH standards at least 3 months before submission of online application and must ensure that it complies with NABH Standard for Medical Imaging Services.

How to apply?

Once the standards are implemented in the Medical Imaging Services Centre, the centre can apply for accreditation online from the website www.nabh.co

(a) Use a new email id for registration, preferably an organisation specific email ID.
(b) Choose ‘Medical Imaging Services’ as Application Type
(c) NABH shall activate the email id and the centre may login using their credentials.

Using the above login and password – MIS centre can fill the application form.
Preparing for NABH Accreditation

1. Acknowledgment and Scrutiny of application
2. Application Form + Documents + Application Fee (Submit Online at NABH website)
3. Pre Assessment (Optional) Onsite / Remote / Desktop / Hybrid
   - Within 3 months of fee deposition
4. Final Assessment Onsite / Remote / Desktop / Hybrid
   - Within six months of Pre Assessment if conducted
5. Two Cycles of Corrective Preventive
   - CAPA CYCLE 1
   - Within 3 months
   - CAPA CYCLE 2
6. Review of Assessment Report
   - Within four months of Final Assessment
7. Approval of Accreditation by Accreditation Committee
8. Issue of Accreditation Certificate
9. Implement the standards for minimum 3 months procured through NABH Website
10. Apply for Renewal of Accreditation Before 6 months of expiry of accreditation
11. Surveillance Assessment Onsite / Remote / Desktop / Hybrid
    - Send corrective action report within 45 days
12. Continuous Quality Improvement
    - Within 12-18 Months of Accreditation
NABH Accreditation Procedure

Preparation of Policies and Manuals:
The Medical Imaging Services Centre shall prepare the Quality Manual, Policies and Procedures and other Manuals as required.

Application for accreditation:
The Medical Imaging Centre shall apply to NABH as per the instructions given in the online application portal. Medical Imaging Centre 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 Imaging Centre pays the application fees through ‘Make Payment’ option of the online application form. NABH officer shall scrutinize the application form for its completeness. In case of any queries, MIS may correspond with NABH via ‘Remarks column’ of its online application portal.

Notification of Principal Assessor and Assessment Team:
NABH shall appoint Principal Assessor who shall have the overall responsibility of conducting the assessment for the Medical Imaging Centre 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 Assessments conducted by NABH

NABH in coordination with the Medical Imaging Centre 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 NABH makes a visit to the Medical Imaging Centre for a predefined man days based on the size and scope of services provided by the Medical Imaging Centre, the assessors verifies the documents, facilities and conducts interviews in person at the HCO. The Medical Imaging Centre needs to bear the cost of the assessor’s travel and stay.

Desktop assessment: In this type of assessment the Medical Imaging Centre will submit information & documents as per the checklist which is based on applicable standards for Medical Imaging Centre & the same shall be reviewed by NABH assessor. The decision on continuation of accreditation shall be based on the recommendations made by the assessor.

Remote assessment: In this type of assessment, the assessor (s) does not go to the Medical Imaging Centre in person, but conducts the entire assessment from a remote location through the use of virtual platforms. Medical Imaging Centre need to have facilities to support the virtual platform. There are nominal overhead charges which the Medical Imaging Centre needs to pay.

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

Communication Channel

NABH has adopted a communication Matrix which needs to be followed by all applicant and accredited medical imaging centers. It emphasizes that all applicant and accredited Medical Imaging Centre are strongly advised to use the “Remarks column” of their online portal for all communications with NABH. Medical Imaging Centre are strongly discouraged to communicate through telephone or emails to secretariat members as these communications cannot be saved for record purpose 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 Accreditation Procedure

Pre-Assessment (Optional):

NABH has made pre-assessment optional. Those Medical Imaging Centre which do not want to undergo pre-assessment shall declare in writing in the remark column of online application form.

However, NABH shall conduct the pre-assessment for those Medical Imaging Centre which are desirous for the same.

The Principal Assessor and other assessors (as applicable) are assigned the job of pre-assessment. Principal assessor shall submit the pre-assessment report online.

The Medical Imaging Centre shall take corrective actions on the non-conformities raised by the Principal Assessor/team.

The Medical Imaging Centre shall in any case be required to pay the requisite Annual fee before the final assessment.

Final Assessment:

Medical Imaging Centre’s can directly go for final assessment without opting for pre-assessment. For Medical Imaging Centres which underwent Pre-Assessment, Final assessment shall be conducted after the Medical Imaging Centre has taken necessary corrective action to the non-conformities raised during the pre-assessment. NABH shall propose to constitute an assessment team for the final assessment. However as mentioned earlier the total number of assessors appointed shall depend on the size of the Medical Imaging Centre and scope of services provided. The date of final assessment shall be agreed upon by the Medical Imaging Centre management and assessors. Assessment shall be conducted on all the facilities covered under accreditation. The assessment team reviews the Medical Imaging Centre’s documented management system and verifies its compliance to the NABH standards. The documented quality system, policies and procedures, other manuals etc. shall be assessed for their implementation and effectiveness.

Based on the assessment by the assessors, the assessment report is prepared by the Principal assessor in a format prescribed by NABH.
NABH Accreditation Procedure

The details of non-conformity(ies) observed during the assessment are handed over to the Medical Imaging Centre by the Principal assessor and a detailed assessment report is sent to NABH.

**Review of assessment report:**

The Medical Imaging Centre 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 Imaging Centre, 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 Imaging Centre, the accreditation committee examines the assessment report, additional information received from the Medical Imaging Centre and consequent verifications. The accreditation committee shall make appropriate recommendations regarding accreditation of the Medical Imaging Centre or otherwise.

**Issue of Accreditation Certificate:**

NABH shall issue an accreditation certificate to the Medical Imaging Centre with a validity of three years. The certificate has a unique number and date of validity. The certificate is accompanied by the scope of accreditation.

The applicant Medical Imaging Centre must make all payments due to NABH, before the issue of the certificate.
NABH Accreditation Procedure

Surveillance and Reassessment:
Accreditation to the Medical Imaging Centre shall be valid for a period of three years. NABH shall conduct surveillance before completion of 15-18 months since the date of accreditation of the accredited Medical Imaging Centre.

The Medical Imaging Centre shall pay the annual fees every year. The first annual fees is paid before the final assessment and is valid till the end of first year from the date of accreditation. Since then, the annual fees shall be due on the same date/month every year.

The Medical Imaging Centre need to apply online for renewal of accreditation at least six months before the expiry of validity of accreditation for which reassessment shall be conducted.

Focus Assessment:
Focus assessments are done for an accredited Medical Imaging Centre when there are any significant changes with regard to the Medical Imaging Centre’s activities and operations, such as change in scope of accreditation, change of address/location etc. Medical Imaging Centre are requested to view policy and procedure related to Focus visit of an accredited Medical Imaging Centre by visiting the following link.

https://www.nabh.co/Policy_for_Focus_Assessment.aspx
NABH Accreditation Procedure

**Surprise Assessment:**

NABH shall conduct surprise assessments of an accredited Medical Imaging Centre to evaluate the continued compliance to the accreditation standards, as Medical Imaging Centre are expected to adhere to the NABH accreditation standards at any given point of time once Medical Imaging Centre is accredited. NABH may call for un-announced visit, based on any concern or any serious incident reported upon by an individual or an organization or media. Medical Imaging Centre are requested to view policy and procedure related to Surprise visit of an accredited hospital by visiting the following link.

https://www.nabh.co/SURPRISE-VISIT.aspx
Guidelines for using the accreditation mark:
Accredited Medical Imaging Centre should ensure the guidelines related to display of NABH Logo / accreditation mark are adhered to. Any misuse of the logo / accreditation mark can lead to adverse action being taken against the Medical Imaging Centre by NABH, besides legal action. Medical Imaging Centre are requested to view guidelines related to use NABH logo / accreditation mark by visiting the following link.

Standard Agreement:
Medical Imaging Centres accredited by NABH has to enter into an agreement with NABH from the date of accreditation. The certificate of accreditation will be dispatched to the Medical Imaging Centre only after this agreement has been received by NABH secretariat. Medical Imaging Centres are requested to view standard agreement by visiting the following link.
https://www.nabh.co/Images/PDF/Agreement_hos.pdf
Disclaimer & Indemnity:
NABH reserves the right to take action or even cancel the accreditation awarded to a Medical Imaging Centre in following conditions:

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

Medical Imaging Centre 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 accredited Medical Imaging Centres.
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 accreditation. 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 materials are 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
Application form for Medical Imaging Services: Free of cost
Self assessment toolkit: Free of cost
NABH Standards for Medical Imaging Services accreditation: Rs. 1000/-
Application fee & NABH Accreditation charges:

<table>
<thead>
<tr>
<th>Practice Category (based on no. of modalities present)</th>
<th>Assessment Criteria</th>
<th>Accreditation Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Practice, 1 modality</td>
<td>One man-day</td>
<td>Two man-days (2x1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Medium Practice, 2 modalities</td>
<td>One man-day</td>
<td>Two man-days (2x1)</td>
</tr>
<tr>
<td>Large Practice, 3 or more than 3 modalities</td>
<td>Two man-days (2x1)</td>
<td>Four (2x2) man-days</td>
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*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.
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