



National Accreditation Board for Hospitals and Healthcare Providers

Information Brochure for NABH Digital Health Standards for HIS/EMR Systems



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About QCI:

Quality Council of India (QCI) was established as a national body for accreditation on recommendations of Expert Mission of EU after consultations in inter-ministerial Task Force, Committee of Secretaries and Group of Ministers through a Cabinet decision in 1996. Accordingly, QCI was set up through a PPP model as an independent autonomous organization with the support of Government of India and the Indian Industry represented by the three premier industry associations, (i) Associated Chambers of Commerce and Industry of India (ASSOCHAM), (ii) Confederation of Indian Industry (CII) and (iii) Federation of Indian Chambers of Commerce and Industry (FICCI).

QCI is a non-profit organization registered under the Societies Registration Act XXI of 1860. The Department of Industrial Policy and Promotion, Ministry of Commerce and Industry was designated as the nodal point for all matters connected with quality and QCI to structure and help implementation of the Cabinet decision.

QCI has been established to create a mechanism for independent third-party assessment of products, services and processes. It plays a pivotal role at the national level in propagating, adoption and adherence to quality standards in all important spheres of activities including education, healthcare, environment protection, governance, social sectors, infrastructure sector and such other areas of organized activities that have significant bearing in improving the quality of life and wellbeing of the citizens of India.

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 members 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 organizations 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 Accreditation/ Certification:

Accreditations and certifications in healthcare are critical mechanisms for ensuring and enhancing the quality and safety of patient care. These formal recognitions provided by NABH in India serve to validate that healthcare organizations meet established standards of excellence. Here's why they are essential, how they ensure quality, and why this approach is recognized internationally as a proven way to maintain high standards in healthcare:

Importance of Accreditations and Certifications:

- **Improved Patient Safety and Care Quality:** Accreditations and certifications compel healthcare organizations to adhere to stringent standards and protocols, significantly reducing the risk of medical errors and enhancing patient safety. They ensure that healthcare providers follow best practices in patient care, leading to better health outcomes.
- **Standardization of Processes:** These recognitions ensure that healthcare organizations implement standardized procedures and protocols across all aspects of patient care and hospital management. This standardization helps in maintaining consistency in service delivery, which is crucial for effective healthcare.
- **Enhanced Trust and Credibility:** Accredited and certified healthcare facilities/systems are seen as more reliable and trustworthy by patients, families, and the broader community. This trust is critical in encouraging patients to seek timely care and adhere to treatment plans.
- **Regulatory Compliance:** Accreditations and certifications ensure that healthcare organizations comply with local, national, and international healthcare regulations and standards. This compliance is essential for legal and ethical operations and helps in avoiding penalties and legal issues.

- **Continuous Improvement:** The processes involved in achieving and maintaining accreditations and certifications foster a culture of continuous improvement within healthcare organizations. Regular assessments and audits help in identifying areas for improvement and implementing necessary changes.

Ensuring Quality in Healthcare

- **Adherence to Standards:** Quality in healthcare is ensured by adhering to well-established standards and guidelines provided by accrediting bodies. These standards cover various aspects of healthcare delivery, including patient rights, infection control, medication management, staff qualifications, and facility safety.
- **Regular Assessments and Audits:** Accredited organizations undergo regular assessments and audits to ensure ongoing compliance with standards. These evaluations help in identifying gaps and areas that need improvement, ensuring that high-quality care is consistently provided.
- **Training and Development:** Continuous education and training for healthcare staff are integral to maintaining high standards of care. Accreditations often require that staff undergo regular training to stay updated with the latest best practices and innovations in healthcare.
- **Patient Feedback and Engagement:** Incorporating patient feedback into quality improvement initiatives is crucial. Accredited organizations actively seek and incorporate feedback from patients and their families to enhance service delivery and patient satisfaction.
- **Data-Driven Decision Making:** Utilizing data and analytics to monitor performance and outcomes is essential for quality assurance. Accredited healthcare organizations use data to identify trends, measure performance, and make informed decisions to improve care delivery.

Accreditations and certifications are thus pivotal in ensuring and enhancing the quality and safety of healthcare services. They provide a structured framework for continuous improvement, standardize processes, and foster a culture of excellence. Recognized internationally, these mechanisms validate that healthcare organizations meet the highest standards, thereby improving patient outcomes and building trust within the global community.

Introduction to HIS/EMR Standards

The National Accreditation Board for Hospitals and Healthcare Providers (NABH) has taken a significant stride in advancing healthcare quality by releasing its new standards for Health Information Systems (HIS) and Electronic Medical Record (EMR) products in India. In this evolving landscape of digital technology, it is imperative that the systems being used in the hospitals are standardized, usable, scalable, ensure data security and at the same time ease the burden of the clinical and administrative staff. That is where these standards come in.

In the vast and diverse healthcare landscape of India, the rapid integration of digital technology has the potential to revolutionize healthcare delivery. With a burgeoning population and increasing healthcare demands, the need for reliable and secure digital health solutions has never been more critical. In this context, the HIS and EMR Standards play a pivotal role in ensuring that these technologies meet the unique challenges and requirements of the Indian healthcare system.



This program is specifically targeted towards all companies of Hospital Information System (HIS) and Electronic Medical Records (EMR) products who are offering their services to hospitals within India. Adherence to the standards set forth by NABH is indicative of an unwavering commitment to quality.

Compliance with these standards ensures that the products are standardized and equipped with all the essential functionalities required for efficient and effective healthcare service delivery. The process of obtaining NABH certification enhances the brand value of the products, thereby making them more appealing to potential adopters.

Hospitals, in turn, are more inclined to adopt products that have been certified by NABH, as this certification serves as a testament to the product's quality, reliability, and adherence to established healthcare standards. Thus, NABH certification not only elevates the status of the product but also contributes to the overall improvement of healthcare service delivery in India.

The HIS and EMR products would be tested against a pre-defined validation criterion. Certain third parties, to be referred to as, NABH Empaneled Software testing agencies (NESTA) would be onboarded. These NESTA are professional testing agencies who would manually test the HIS and EMR products, suggest corrective actions, if any and provide their report to NABH. NABH will appoint a NABH Software testing Assessor (NSA) to oversee the testing process. Post the report is vetted by NSA, it will go to NABH technical committee and a decision on certification would be taken.

The NABH Standards for HIS and EMR products aim to complete the loop of Digital Health Standardization in India. We have the 6th edition standards which revolve around the hospital processes, we have the Digital Health standards which aim to digitize the processes and now, we have the HIS and EMR standards which aim to standardize the products being used in hospitals, thereby creating a well-established digital ecosystem in the country.

Program Overview: NABH Digital Standards for HIS and EMR Systems:

NABH Standards for Hospital Information System (HIS) and Electronic Medical Records (EMR) are designed to establish a benchmark and lay the groundwork for the expectations of a standard product.

Under this program, companies of HIS and EMR systems are invited to apply for NABH certification, which could be at the Basic or Advanced level. The products in question will be subjected to testing based on various objective elements that have been outlined across eight distinct chapters.

This evaluation process will be conducted by an independent third party, referred to as the NABH Empaneled Software Testing Agency (NESTA). The NESTA will conduct testing based on standards, objectives, predefined validation criteria, test cases, and test data defined by NABH. Upon completion of the testing phase, the NESTA will compile their findings into a report, which will then be submitted to NABH for review.

It is important to note that the final decision regarding the certification of a product rests solely with NABH. This ensures an unbiased and rigorous certification process, maintaining the integrity and credibility of the NABH certification. The validity of this certification will be 2 years.

In order to apply for the NABH certification for HIS and EMR products, it is mandatory to be compliant with the Ayushman Bharat Digital Mission (ABDM). ABDM compliance ensures that the systems used in healthcare settings meet specific criteria related to data management, security, interoperability, and other important factors.

Our aim is to support and facilitate the adoption of industry best practices and standards in healthcare data management for the benefit of patients, healthcare providers, and the overall healthcare ecosystem.

NABH Standards for HIS and EMR Systems

The HIS/EMR standards focus on the key points required for providing patient-centered, safe, high-quality care. The interests of various stakeholders have been incorporated into the standard. They provide a framework for quality assurance and quality improvement. The focus is on patient safety, data security and quality of patient care delivered with technological interventions. It sets forth the basic standards that HIS/EMR systems must achieve to improve the quality of care.

The eight chapters are

1. Access, Assessment and Continuity of Care (AAC)
2. Care of Patients (COP)
3. Management of Medication (MOM)
4. Digital Application Control (DAC)
5. Digital Operations Management (DOM)
6. Finance and Procurement Management (FPM)
7. Human Resource Management (HRM)
8. Information Management System (IMS)

NABH Standards for HIS and EMR products are divided into different chapters based on different clinical and non – clinical touchpoints. Further, these standards contain objective elements, which are in-turn divided as Core, Commitment, Achievement, and Excellence, to assess maturity at different levels.

NABH is offering two levels of certification i.e. Basic and Advanced.

The total number of objective elements for HIS are 171 divided across the four categories while the total number of objective elements for EMR systems is 166.

HIS	Objectives
Core	51
Commitment	78
Achievement	27
Excellence	15
Total	171

EMR	Objectives
Core	49
Commitment	69
Achievement	28
Excellence	20
Total	166

Total of 106 technical objectives are common across standards for HIS/ EMR systems.

The required percentage for the **two maturity levels** is as follows:

Base Level	
Category of OE	Percentage
Core	100%
Commitment	60%
Achievement	30%
Excellence	NA

Advanced Level	
Category of OE	Percentage
Core	100%
Commitment	80%
Achievement	60%
Excellence	60%

Methodology for Certification:

Eligibility:

HIS/EMR systems will be eligible for applying for NABH certification only if their version of product that is intended to be certified is deployed in at least three (3) hospitals. First and last page of MoU would be required as proof, at the time of registration.

Application:

- The HIS/ EMR companies can apply for the NABH certification online on the NABH website.
- Under 'New Portal', there is a category for HIS/EMR certification.
- HIS/EMR companies need to first register themselves and then fill in the application form.
- An online SAT will then be taken which will decide the scope of certification and application fee.
- Post the application fee is submitted; NABH will assign 3 NESTA to each HIS/EMR companies.
- The HIS/EMR companies is expected to negotiate the efforts and commercials with the three NESTA and finalize one NESTA. The same should be communicated to NABH.
- Once the NESTA is finalized, an NABH approved Statement of Work (SoW) will be signed between the HIS/EMR company and NESTA.

Testing process:

As part of the rigorous quality assurance process, Health Information Systems (HIS) and Electronic Medical Record (EMR) products will undergo thorough testing and validation. This ensures that these critical healthcare technologies meet predefined criteria, adhere to standards, and function effectively.

Testing and validation will be conducted by certain third parties which will be empaneled with NABH. These are NABH Empaneled Software Testing Agencies (NESTA).



- All testing by NESTA will be done on the NABH Software Assessment portal (incl. documentation of testing results, remarks, non-compliances, and name of tester conducting the tests).
- All HIS/EMR systems testing will be done as per NABH Test Cases for HIS/EMR (Available free of cost on NABH website : [Test cases](#))
- NABH will appoint a NABH Software Assessor (NSA) for each system being assessed by NESTA.
- NSA will monitor the quality, coverage, and consistency of testing by each NESTA for each system being assessed.
- NESTA will test the HIS/EMR systems and raise non-compliances (NCs), if needed. An interim report will then be generated which will be sent to NSA.
- The interim report will be validated by the NSA.
- HIS/EMR company will resolve the NCs within 90 days including one round of NCs that will be validated by the NESTA as a part of the same SoW. For any additional NCs, NESTA can demand for extra efforts.
- NSA will give final scores and resolve all NCs and validate the final report before being submitted to the NABH Technical Committee for approval.
- NABH Technical Committee will review the results of the testing along with the comments of the NSA and decide on the granting of the certification.
- NABH will review testing process of NESTA and provide periodic feedback to NESTA, where needed

Self-Attestation:

Some OEs require self-attestation by the HIS/EMR companies. HIS/ EMR companies would need to declare compliance with specific standards or features in order to complete certification. Documentation supporting self-attestation, the relevant documentation, as defined in the standards, must accompany the validation process.

In summary, the validation process ensures that HIS and EMR products meet high standards of quality, security, and usability. By adhering to these validation criteria, companies contribute to safer and more efficient healthcare delivery.

External Certifications:

Some OEs will require an external certification to be validated. The HIS/ EMR company must keep this external certification ready at the time of testing to ensure that the relevant OEs are marked correctly.

Process Overview

An overview of the entire process is presented below:

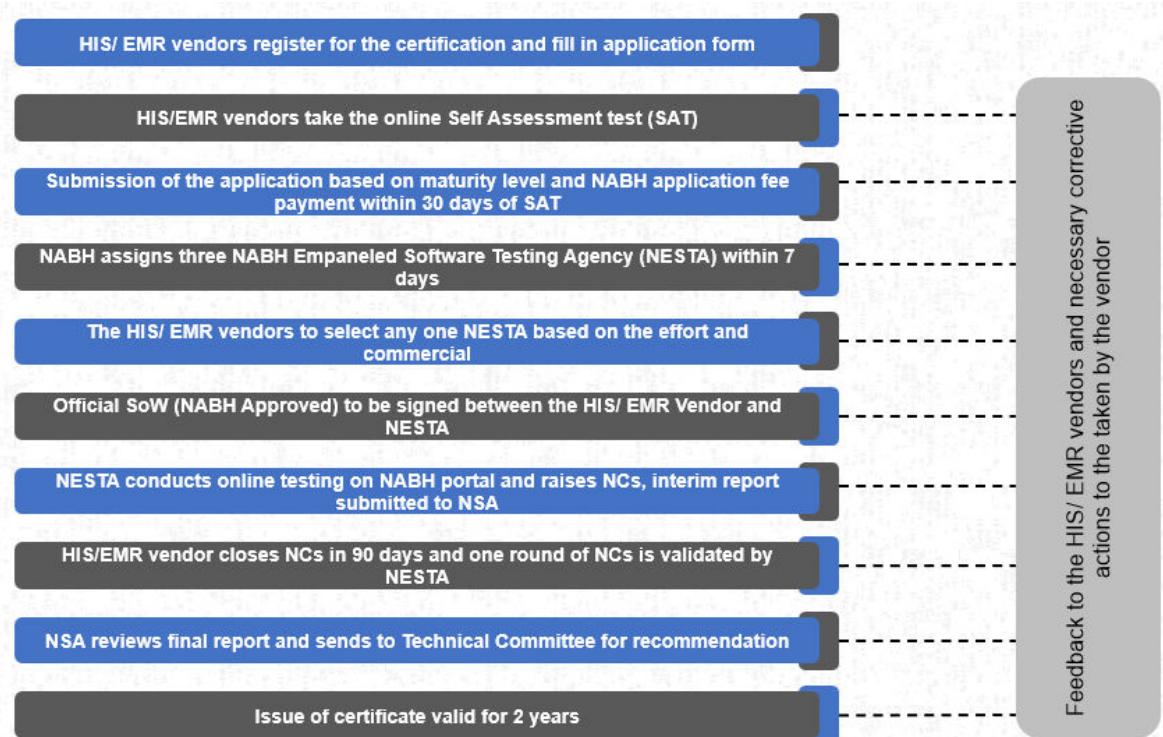


Figure 1: Process Overview

Guidelines for using the certification mark:

Certified HIS/ EMR systems 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 HIS/EMR company, by NABH besides legal action. HIS/ EMR companies are requested to adhere to guidelines related to use NABH logo / certification mark by visiting the following link.

Standard Agreement:

HIS/ EMR companies certified by NABH have to enter into an agreement with NABH from the date of certification. The certificate will be dispatched only after this agreement has been received by NABH secretariat.

Disclaimer and Indemnity:

NABH reserves the right to take action or even cancel the certification awarded to an HIS/ EMR company in the following conditions:

- If the required fee is not paid on time
- Any adverse actions taken by any regulatory bodies against the company
- Failure to comply with the standards at any given point of time etc.

HIS/EMR companies 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 the certified systems.

Training:

NABH Secretariat organizes training sessions on understanding of NABH standards and implementing them in form of workshops, onsite/online trainings, Programme on Implementation (POI). 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.

Fee Structure:

The fee structure of the HIS/EMR systems certification is as follows:

NABH Certification Fees Across 2 years (HIS/EMR Certification validity is 2 years)			
	HIS Only	EMR Only	Both HIS & EMR
Level - Basic	50,000	50,000	75,000 (if both HIS & EMR are at Basic level)
Level – Advanced	100,000	100,000	150,000 (if any one or both HIS & EMR are at Advance level)

NOTE:

- Certification Fees is charged one time for 2 years validity, to be paid to NABH at the time of application and is **NOT** refundable, if the HIS/EMR fails to achieve the desired certification.
- The fees once paid is non- refundable and non- transferable.
- **Excludes Testing Charges:** The Certification fee in this table **DOES NOT** include testing charges, which will be required to be paid by HIS/EMR companies directly to NABH empanelled Testing Agencies (NESTAs) for conducting the software testing.
- **GST @ 18% will be applicable.**

CONTACT DETAILS

NATIONAL ACCREDITATION BOARD FOR HOSPITALS AND HEALTH CARE PROVIDERS

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