

NATIONAL ACCREDITATION BOARD FOR HOSPITALS & HEALTHCARE PROVIDERS (NABH)



Blood Banks / Blood Centres and Transfusion Services Accreditation 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 system & 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 organizations accredited by NABH have international recognition. This provides 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.



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 Trial (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

Healthcare Organizations should be places of safety not only for patients but also for staff and other stakeholders. Quality and patient safety at Blood banks / 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.

In India, Health Systems currently operates within an environment of rapid social, economical and technical changes. Such changes raise the concern for the quality of health care. Blood banks/ blood centres are an integral part of health care system. Accreditation would be the single most important approach for improving the quality of blood banks. Accreditation of blood banks/ blood centres strives to improve the quality and safety of collecting, processing, testing, transfusion and distribution of blood and blood products.

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."

The blood bank accreditation program was started in the year 2007, at that time very few countries had this program. In the year 2007, NACO supported NABH to start this program. The special significance of this program includes quality standards in all areas including collections, processing, testing, compatibility, transfusions, hemovigilance and quality assurance, which includes enforcement of complete regulatory processes and national guidelines thus ensuring high quality of patient care with supply of safe blood to the right patient in right time and right quantities which boosts confidence among the patients at national and international level under medical tourism initiatives. The targeted customers include standalone blood banks which has very less knowledge of quality management system, they would benefit the most as this will impose confidence to the patients.

Benefits of Accreditation

Benefits for Patients

- Patients are the biggest beneficiary among all the stakeholders.
- Accreditation results in high quality care with supply of safe blood to the right patient in right time and right quantities
- Accreditation also results in improving the quality and safety of collection, processing, testing, transfusion and distribution of blood and blood products.
- The patients are serviced by credential medical staff.
- Rights of patients are respected and protected. Patient's satisfaction is regularly evaluated.

Benefits for Blood banks/ Blood centres

- Accreditation to a Blood banks/ Blood centres stimulates continuous improvement.
- It enables the Blood banks/Blood centres in demonstrating commitment to quality care and patient safety thereby ensures best clinical outcomes.
- It raises community confidence in the services provided by the Blood banks/ Blood centres as services provided by credentialed medical staff.
- It also provides opportunity to Blood banks/ Blood centres unit to benchmark with the best.
- An accreditation status also provides marketing advantage in a competitive health care.
- Accreditation gives definite advantages to Blood Banks/ BTS for developing confidences for patients from foreign countries visiting Indian organization under medical tourism program.



Benefits for Staff

- The staff in an Accredited Blood 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 Blood 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 Standard for Blood Centre

The Blood Bank/Blood Centre accreditation programme assesses the quality and operational systems which are in place within the facility. The accreditation includes compliance with the NABH standards, applicable laws and regulations.

NABH Standards for blood banks/ blood centres is prepared by the technical committee constituted by NABH that has eminent persons from the field of blood banks and blood transfusion services. The accreditation standard includes the requirements of various laws and regulations and guidelines set by National AIDS Control Organisation (NACO). The standard provides framework for improving quality and safety of collecting, processing, testing, transfusion and distribution of blood and blood products. NABH Standard has a total of 11 chapters and 196 Objective Elements.

Ten Chapters of NABH blood banks/ blood centres standards are:

1. Organisation and Management
2. Accommodation and Environment
3. Personnel
4. Equipment
5. External Services and Supplies
6. Process Control
7. Identification of Deviations and Adverse Events
8. Performance Improvement
9. Document Control
10. Record
11. Internal Audit and Management Review

Methodology for Accreditation

Blood banks / blood centres willing to be accredited by NABH must ensure the implementation of NABH standard in their organization.

The assessment team look for the evidences of implementation of NABH Standards in organization. The blood banks/ blood centres shall be able to demonstrate to NABH assessment team that all the requirements of NABH standards, as applicable, are implemented & followed.

Eligibility to apply for Blood banks/ blood centres

Blood banks/ blood centres that fulfills the following requirements:

- Currently in operation as Blood banks/ blood centres
- Blood Centre should have been implemented NABH standards in the Blood Centre for a minimum of three months.
- The organization that commits to comply with NABH standards 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 offer multiple services and the standards are equally applicable to all services within the centres.

Methodology for Accreditation

The Management of the Blood bank/ blood centre shall first decide about getting accreditation for its centre from NABH. It is important for the centre to make a definite plan of action for obtaining accreditation and nominate a person to co-ordinate all activities related to seeking accreditation. An official nominated should be familiar with existing blood bank/ blood centre quality management system.

Blood bank / blood centres need to procure a copy of the standard. One can purchase the standards by making the payment at the website

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

The Blood bank / blood centres looking for accreditation shall understand the NABH assessment procedure. The blood bank / blood centre shall ensure that the requirements of the standard are implemented in the organization.

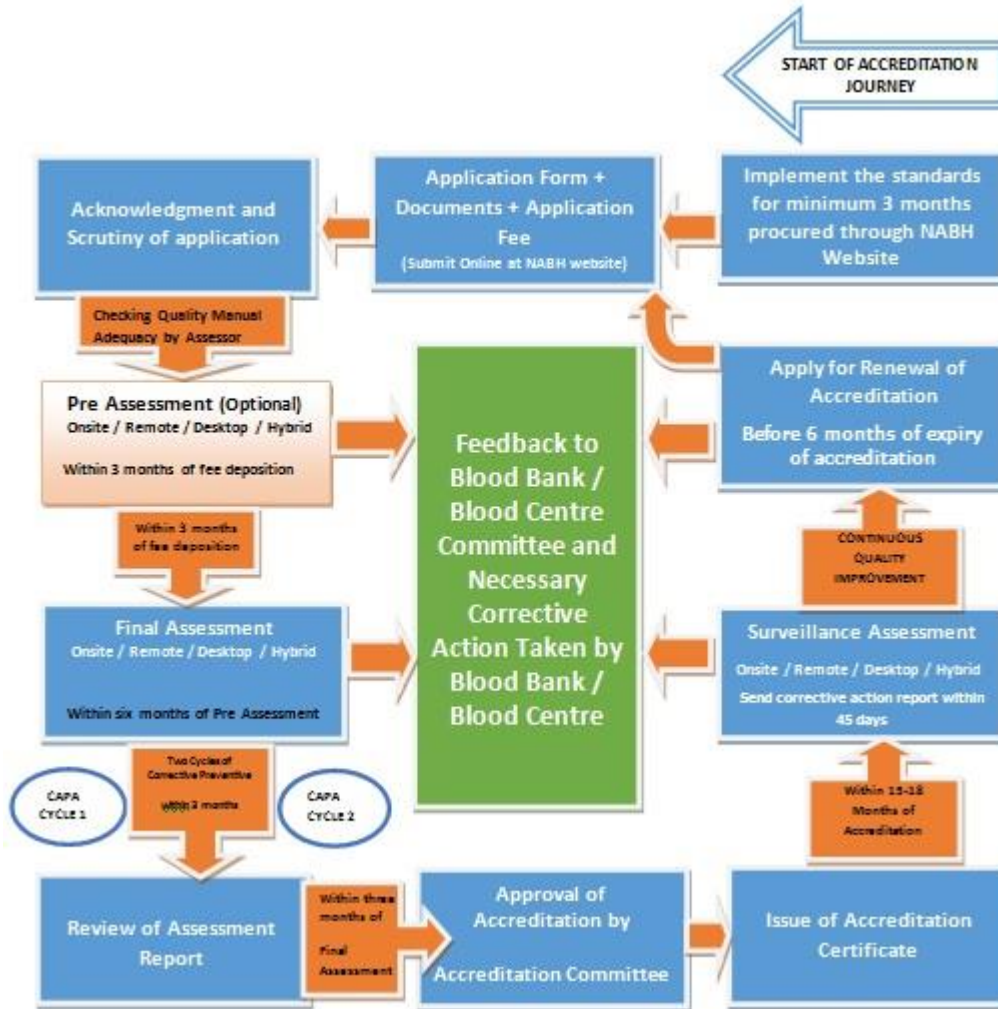
How to apply?

Once the standards are implemented in the Blood bank / blood centre, the organization can apply for accreditation online from the website www.nabh.co

- (a) Use a new email id for registration
- (b) Choose 'Blood bank / Blood centre' 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.

Accreditation Process



NABH Accreditation Procedure

Preparation of Policies and Manuals:

The blood banks/ blood centres/ blood transfusion services shall prepare a Quality Manual as per the NABH standard. The Quality Manual shall state the Quality Policy, Quality Mission and Objectives of the centre. The Quality Manual shall address all the clauses of the standards. Cross-reference to the procedures, both of quality management system and technical, shall be given in the manual.

Application for accreditation:

The Blood bank / Centre shall apply to NABH as per the instructions given in the online application portal. Blood bank / 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 blood bank pays the application fees from 'Make Payment' option of the online application form. NABH officer scrutinize the application form for its completeness. Blood Bank may correspond to NABH via writing in 'Remarks column' of application form.

Adequacy of Quality Manual:

NABH shall forward the Quality Manual of the blood bank to the Principal Assessor for adequacy before the assessment. The Principal Assessor provides the report on the Quality Manual. If there are non-conformities, the report is forwarded to Blood bank / Blood Centre so that updated Quality Manual is uploaded in the application form before the assessment.

Notification of Principal Assessor and Assessment Team:

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

Types of Assessment conducted by NABH

NABH in coordination with the Blood bank / Blood 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 Blood bank / Blood Centre for a predefined man days based on the number of blood units collected annually of the Blood bank / Centre, the assessors verifies the documents, facilities and conducts interviews in person at the Blood bank / Blood Centre. The Blood bank / Blood Centre needs to bear the cost of the assessor's travel and stay.

Desktop assessment: In this type of assessment the Blood Bank / Blood Centre to submit information & documents as per the checklist which is based on applicable standards for Blood 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 Blood bank / Blood Centre in person, but conducts the entire assessment from a remote location through the use of virtual platforms. Blood bank / Blood Centre need to provide the online platform, there are nominal overhead charges which Blood bank / Blood Centre need to pay.



Hybrid assessment: In this type of assessment, one assessor may be physically present in the Blood bank / Blood 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

All applicant and accredited healthcare organizations (HCO/ Blood Banks) are strongly advised to use the "Remarks column" at the online portal for all communication. Blood Banks/ Centers are strongly discouraged to communicate through telephone or emails to secretariat members as this communication cannot be saved as part of particular HCO 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 Accreditation Procedure

Pre-Assessment (Optional):

NABH has made pre-assessment optional. Those Blood bank / Blood Centre which does not want to undergo pre-assessment shall provide in writing in the remark column of online application form.

However, NABH shall conduct the pre-assessment for those Blood bank / Blood 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 Blood bank / Blood Centre shall take corrective actions on the non-conformities raised by the Principal Assessor/ team.

The Blood bank / Blood Centre shall in any case be required to pay the requisite Annual fee before the final assessment.



NABH Accreditation Procedure

Final Assessment:

After the Blood bank / Blood Centre has taken necessary corrective action to the non-conformities raised during the pre-assessment, NABH shall constitute an assessment team for the final assessment. The total number of assessors appointed shall depend on the size of the Blood bank / Blood Centre (units of blood collected). The date of final assessment shall be agreed upon by the Blood bank / Blood Centre management and assessors. Assessment shall be conducted on all the facilities covered under accreditation. The assessment team reviews the blood bank's/centre's documented management system and verifies its compliance to the NABH standards. The documented quality system, SOPs, work instructions etc. shall be assessed for their implementation and effectiveness. The technical competence of the blood bank shall also be evaluated.

Based on the assessment by the assessors, the assessment report is prepared and uploaded by the Principal assessor in the online application.

The details non-conformity (ies) observed during the assessment is visible to the Blood bank / Blood Centre once the Principal Assessor submits the report.

Scrutiny of assessment report:

The blood bank/ blood centre shall take necessary corrective action on the non-conformity (ies) and upload the requisite document for each non-conformities. On successful submission of the corrective action by the Blood bank / Blood Centre, the same shall be reviewed by the Principal Assessor.

After satisfactory corrective action taken by the blood bank/ blood centre the accreditation committee examine the assessment report, additional information received from the blood bank/ blood centre. The accreditation committee shall make appropriate recommendations regarding accreditation of a blood bank/ blood centre to NABH.

In case the accreditation committee finds deficiencies in the assessment report to arrive at the decision, the secretariat obtains more clarification from the Principal assessor/assessors/ blood bank/ blood centre concerned to complete the process.

Issue of Accreditation Certificate

NABH shall issue an accreditation certificate to the Blood bank / Blood 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 Blood bank / Blood Centre must make all payment due if any to NABH, before the issue of certificate.

Surveillance and Re assessment:

Accreditation to a blood bank/ blood 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 blood bank/ blood centre.

The blood bank/ blood centre shall pay the annual fees every year. The first annual fees paid before the final assessment is valid till the end of first year since the date of accreditation. Since then, the annual fees shall be due on the same date/ month every year.

The blood bank/ blood centre may apply online for renewal of accreditation at least six months before the expiry of validity of accreditation for which reassessment shall be conducted.

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.

NABH Accreditation Procedure

Focus Assessment:

Focus assessments are done in Blood banks/ blood Centres when there are any significant changes with regard to the HCOs activities and operations, such as change in scope of accreditation, change of address/ location, change in environment, key technical personnel etc. Blood banks/ blood Centres are requested to view policy and procedure related to Focus visit to an accredited Blood banks/ blood Centres by visiting the following link.

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



NABH Accreditation Procedure

Surprise Assessment:

NABH may conduct surprise assessments at accredited blood banks/blood centres periodically to evaluate the compliance to the accreditation standards, as blood banks/blood centres are expected to adhere to the NABH accreditation standards at any given point of time once Blood bank is accredited. Surprise visit can also happen in response to adverse media report. Blood Banks/Blood centres are requested to view policy and procedure related to Surprise visit to an accredited Blood banks/ blood Centres by visiting the following link.

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



NABH Accreditation Procedure

Guidelines for using the accreditation mark:

Accredited blood banks/blood centres should ensure the guidelines related to display NABH Logo / accreditation mark are adhered. Any misuse of the logo / accreditation mark can lead to adverse action being taken against the Blood banks/ blood Centres by NABH besides legal action. Blood Banks/Blood centres are requested to view guidelines related to use NABH logo / accreditation mark by visiting the following link.

[https://www.nabh.co/Images/pdf/Policy and Guidelines for use of NABH Accreditation Certification Mark.pdf](https://www.nabh.co/Images/pdf/Policy_and_Guidelines_for_use_of_NABH_Accreditation_Certification_Mark.pdf)



Standard Agreement:

Blood Banks/blood 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 blood banks only after this agreement has been received by NABH secretariat. Blood banks are requested to view standard agreement by visiting the following link.

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



NABH Accreditation Procedure

Disclaimer & Indemnity:

NABH reserves the right to take action or even cancel the accreditation awarded to a blood bank/blood centre in following conditions -

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

Blood Banks 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 Blood banks/ blood 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 blood bank/blood centre in form of Programme on Implementation (POI), for 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 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 Standards for blood bank/ blood centre accreditation : Rs. 1000/-

Application fee and NABH Accreditation charges:

Size of Blood Bank (units collected)	Assessment Criteria			Accreditation Fee (Rs.)	
	Pre-assessment	Assessment	Surveillance	Application Fee	Annual Accreditation Fee
< 5000/ annum	One man-day	Four man days (2x2)	Two man days (2x1)	Rs. 10,000/-	Rs. 50,000/-
5001 – 20000/ annum	One man-day	Six man days (3x2)	Four man days (2x2)	Rs. 25,000/-	Rs. 75,000/-
> 20, 000/ annum	Two man-days	Nine man days (3x3)	Four man days (2x2)	Rs. 40,000/-	Rs. 1,00,000/-

***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% will be charged on all the above fees. You are requested to please include the service tax in the fees accordingly while sending to NABH.

CONTACT DETAILS

NATIONAL ACCREDITATION BOARD FOR HOSPITALS AND HEALTH CARE PROVIDERS

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