

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



**GENERAL INFORMATION BROCHURE
FOR BLOOD BANKS/ BLOOD CENTRES
AND TRANSFUSION SERVICES**

2008



Blood Banks/ Blood Centres and Transfusion Services Accreditation

Accreditation is a public recognition by a National Healthcare Accreditation Body, of the achievement of accreditation standards by a Healthcare Organization, demonstrated through an independent external peer assessment of that organization's level of performance in relation to the standards.

In India, Health System 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 and blood transfusion services strives to improve the quality and safety of collecting, processing, testing, transfusion and distribution of blood and blood products.

The accreditation programme assesses the quality and operational systems in place within the facility. The accreditation includes compliance with the NABH standards, applicable laws and regulations.



Benefits of Accreditation

Benefits for Users/ Patients/ Donors

Users/ patients/ donors are the biggest beneficiary among all the stakeholders. Accreditation results in improving the quality and safety of collection, processing, testing, transfusion and distribution of blood and blood products. They all are serviced by credential medical staff and their rights are respected and protected. Users/ patients/ donors satisfaction are regularly evaluated.

Benefits for Blood banks/ blood centres

Accreditation to a blood bank/ blood centre stimulates continuous improvement. It enables blood bank/ blood centre in demonstrating commitment to quality. It raises community confidence in the services provided by the blood bank/ blood centre. It also provides opportunity to blood bank/ blood centre to benchmark with the best.

Benefits for Staff

The staff in an accredited blood bank/ blood centre is satisfied lot as it provides for continuous learning, good working environment and leadership. It improves overall professional development of all the staff including Medical and Para Medical Staff.



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.

NABH offers accreditation services to hospitals and blood banks. Hospital accreditation program is fully functional since two years. Blood Bank accreditation program is a new initiative of NABH.



NABH Standard

NABH Standard 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 eleven clauses.

Main clauses of NABH Standard

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



Assessment Criteria

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

The assessment team shall check the implementation of NABH Standard in organization. The blood banks/ blood centres and transfusion services shall be able to demonstrate to NABH assessment team that all the requirements of NABH standard, as applicable, are implemented & followed.



Preparing for NABH Accreditation

Management of the Blood bank/ blood centre and Blood Transfusion services 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.

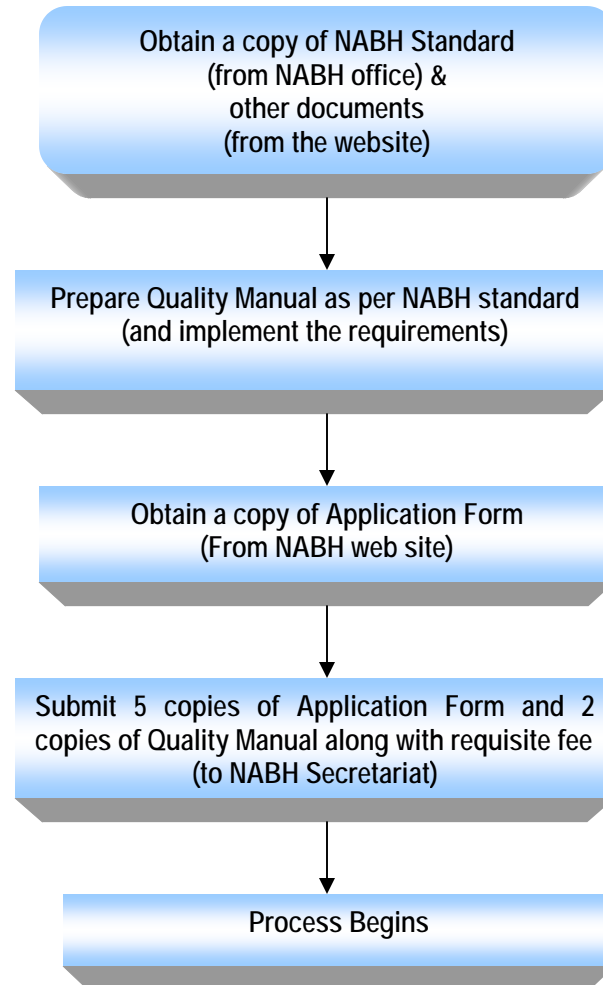
Blood bank may procure a copy of standard from the NABH Secretariat against payment. Further clarification regarding standard can be obtained from NABH Secretariat in person, by post, by e-mail or on telephone.

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

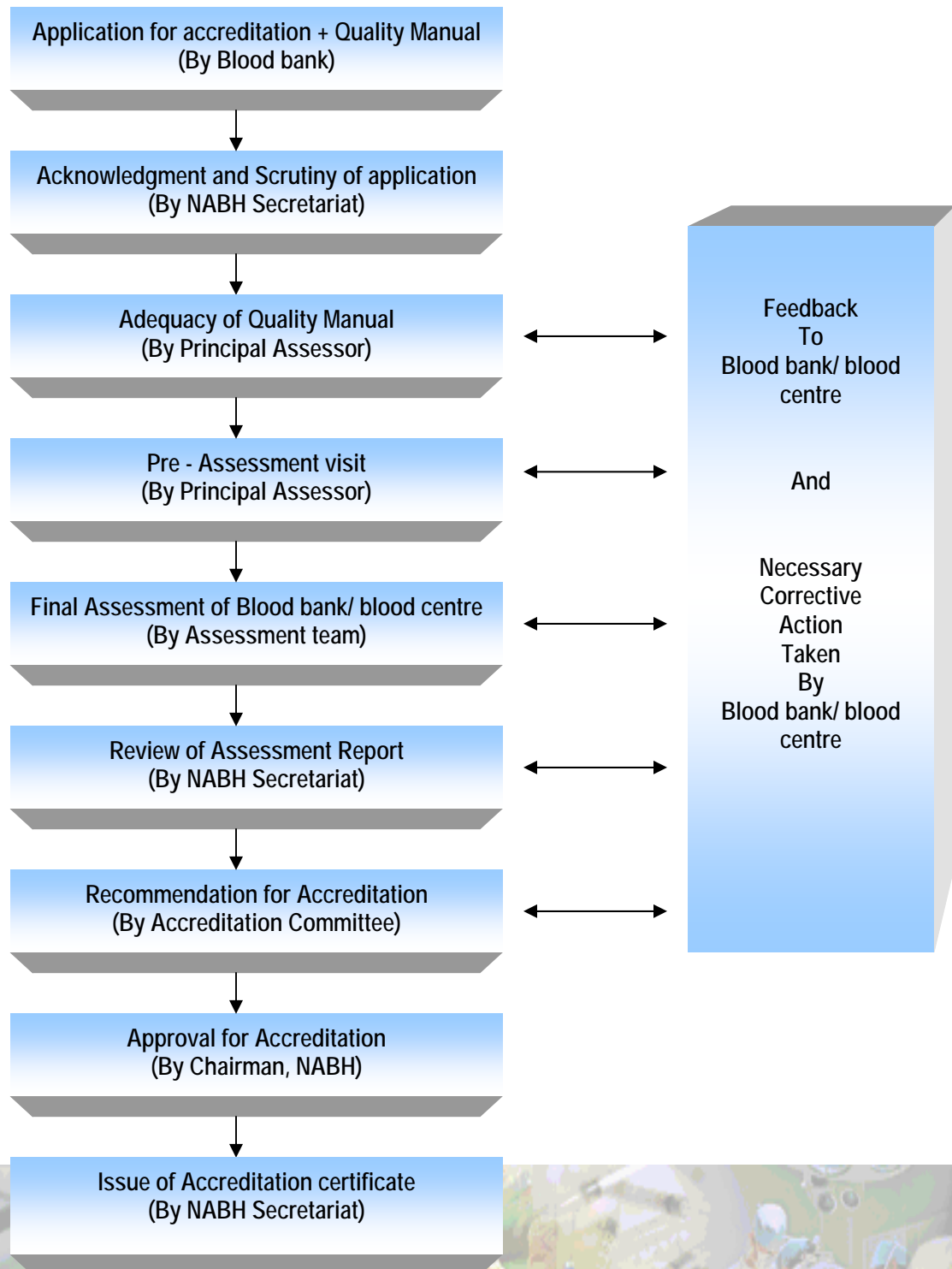
The application form for NABH accreditation can be downloaded from the web-site, www.qcin.org.



Preparing for NABH Accreditation



NABH Accreditation Procedure



NABH Accreditation Procedure

Preparation of Quality Manual:

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 to all the clauses of the standard. Cross-reference to the procedures, both of quality management system and technical, shall be given in the manual.

Application for accreditation:

The blood banks/ blood centres shall apply to NABH in the prescribed application form. The application shall be accompanied with the prescribed application fee as detailed in the application form. The application shall be submitted to NABH in five copies along with two copies of Quality Manual.

Scrutiny of application:

Application form is scrutinized at NABH Secretariat and if it is found to be complete in all respects, a unique reference number is issued to the centre. The organization shall be required to quote this reference number in all future correspondence with NABH.

Appointment of Principal Assessor:

NABH shall appoint Principal Assessor who shall have the overall responsibility of conducting the assessment for the blood bank. He/ She will evaluate the adequacy of quality manual of the blood bank, and will conduct the pre-assessment and final assessment of the blood bank. In the final assessment he/ she shall be accompanied with other team members.



NABH Accreditation Procedure

Adequacy of Quality Manual:

Principal Assessor checks the adequacy of the Quality Manual. The Principal Assessor shall inform NABH regarding inadequacies in the quality manual, if any. The blood bank shall address to the inadequacies pointed out by the Principal Assessor in their quality manual and implement the corrective actions in their management system.

Pre-Assessment:

Principal Assessor appointed by NABH is responsible for conducting the pre-assessment of blood bank. NABH shall organize the pre-assessment of the blood bank in case there are no inadequacies in the quality manual or when the blood bank has taken satisfactory corrective action. The blood bank shall ensure its preparedness by carrying out internal audit and management review before the pre-assessment.

Objective of Pre-assessment:

- To check the preparedness of the blood bank for final assessment
- To review the scope of accreditation and ascertain the requirement of the number of assessors and duration of the assessment
- To review the documentation system
- To explain the methodology to be adopted for assessment.

The Principal assessor shall submit a pre-assessment report in the format specified in the document 'Pre-Assessment Guidelines & Forms'. Copy of the report is handed over to the blood bank after the assessment and original sent to NABH Secretariat.



NABH Accreditation Procedure

The blood bank shall take corrective actions on the non-conformities raised by the Principal Assessor on the documented management system and its implementation and submits a report to NABH Secretariat.

The blood bank/ blood centre shall be required to pay the requisite Annual fee before the final assessment.

Final Assessment:

After the blood bank has taken necessary corrective action to the non-conformities raised during the pre-assessment, NABH proposes constitution of assessment team for the final assessment. The team shall include Principal Assessor (already appointed) and the assessors. The total number of assessors appointed shall depend on the size of the blood bank (unit of blood collected) and services provided. The date of final assessment shall be agreed upon by the blood bank management and assessors. Assessment shall be conducted on all the facilities covered under accreditation. The assessment team reviews the blood bank'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 by the Principal assessor in a format prescribed by NABH.

The details of partial non-conformity(ies) observed during the assessment are handed over to the blood bank/ blood centre by the Principal assessor and detailed assessment report is sent to NABH.

NABH Accreditation Procedure

Scrutiny of assessment report

NABH shall examine the assessment report and communicate any action to be taken by the blood bank/ blood centre. The report consists of identified non-conformities during assessment, with recommendation on, what improvement should be taken to the centre for eliminating non conformity.

The blood bank/ blood centre shall take necessary corrective action on the remaining non-conformity to fill the gap and shall submit a report to NABH Secretariat within a time period set by the NABH. When there are significant non-conformity identified during the final assessment, NABH may arrange for a verification visit for ensuring compliance.

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 and consequent verifications. The accreditation committee shall make appropriate recommendations regarding accreditation of a blood bank/ blood centre to the Chairman, NABH.

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

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.



NABH Accreditation Procedure

The applicant blood bank/ blood centre must make all payment due to NABH, before the issue of certificate.

All decision taken by NABH regarding grant of accreditation shall be open to appeal by the blood banks/ blood centres, to chairman NABH.

Surveillance and Re assessment

Accreditation to a blood bank/ blood centre shall be valid for a period of three years. NABH shall conduct on-site annual surveillance of the accredited blood bank/ blood centre.

The blood bank/ blood centre may apply 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.



Financial Term and Conditions

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/-

Notes on Accreditation fee:

- The accreditation fee does not include expenses on travel, lodging/ boarding of assessors. These expenses are to be borne by the blood bank/ blood centre on actual basis.
- The application fee includes pre assessment charges.
- The first annual fee is payable after pre-assessment visit and before assessment visit.
- All the payments to NABH are to be paid through a demand draft in favour of 'Quality Council of India' payable at New Delhi.

