



POLICIES & PROCEDURES FOR ASSESSMENT, SURVEILLANCE AND RE- ASSESSMENT OF HCO

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1. PREPARING FOR HEALTH CARE ORGANISATION (HCO) ACCREDITATION

In this document HCO means hospital, small healthcare organisation, blood bank, wellness center, dental facility, AYUSH hospital, etc. HCO management should first decide about getting accreditation for its HCO from NABH. It is important for a HCO to make a definite plan of action for obtaining accreditation and nominate a responsible person to co-ordinate all activities related to seeking accreditation. The person nominated should be familiar with HCO's services, functions and existing quality system.

A request can be made to NABH Secretariat for procurement of relevant NABH documents against the payment, if any. A list of NABH documents is given on the website. Clarifications on the document to be procured may be obtained from NABH Secretariat in person, by post, on telephone or through e-mail. The HCO should get fully acquainted with all NABH documents and understand the assessment procedure & methodology of making an application.

HCO needs to conduct self-assessment to ascertain whether HCO fulfilling NABH accreditation criteria or whether HCO complied with NABH Standards, If find the gap during self-assessment take corrective action to fill the gap.

Relevant requirements for NABH accreditation should be discussed amongst concerned staff of the HCOs. This will enable them to understand their weaknesses and strengths. The HCO must ensure that the policy and procedures for various departments and services provided by HCO and other documents are available and implemented.

The HCO looking for accreditation should understand the NABH assessment procedure and prepare for facilitated the assessment procedure.

2. ELIGIBILITY FOR APPLYING FOR NABH ACCREDITATION

The applicant HCO must apply for all its facilities and services being rendered from the specific location. NABH accreditation is only considered for HCO's entire activities and not for a part of it.

The applicant HCO must comply with all applicable Standards of NABH and regulatory/statutory requirements.

The applicant HCO must have conducted self-assessment against NABH Standards before the submission of application. Self-assessment report should give enough confidence to HCO about documentation and implementation of the requirements.

3. ACCREDITATION PROCEDURE

3.1 APPLICATION FOR ACCREDITATION

The HCO shall apply to NABH online in the prescribed application form, along with self-assessment tool kit and supporting documents of the HCO which should describe the requirements in accordance with relevant accreditation/ certification standard. The application shall be accompanied with the prescribed application fee as detailed in the application form. However in certain cases, offline application form shall be accepted in cases of continued technical problems faced either from NABH or HCO.

Blood Banks are required to apply to NABH online in prescribed application form, along with Quality Manual and supporting documents which should describe the requirements in accordance with blood bank accreditation standard. The application shall be accompanied with prescribed application fee as detailed in the Application Form. However in certain cases, offline application form shall be accepted in cases of continued technical problems faced either from NABH or HCO.

3.2 ACKNOWLEDGEMENTS AND REGISTRATION OF APPLICATION

On receipt of the application from a HCO, the following actions shall be taken by the Programme Officer:

- i. Review application to see for which accreditation program application is made and accordingly allocate a unique Registration Number.
- ii. Open a hard copy document file and also a folder with Registration number.
- iii. Update the database maintained in MS-Excel.
- iv. Transfer application fees to the NABH accounts section.
- v. Scrutinize the completeness of application including supporting documents.
- vi. Examine the Self-Assessment tool-kit/ Quality Manual to verify if all the requirements of standard have been adequately addressed.

Issue acknowledgement mentioning unique Registration number. If deficiencies are noticed, in application fees, completeness of the application, or the self-assessment tool kit, it shall be recorded and the HCO be informed for corrective actions within 30 days.

This unique Registration number shall be used for NABH's own recording system and also for correspondence with the HCO.

NABH shall maintain confidentiality of application submitted by HCO and provide appropriate storage for the same.

3.3 APPOINTMENT OF PRINCIPAL ASSESSOR

The principal assessor shall have the overall responsibility of conducting the assessment and shall be responsible for pre-assessment of the HCO and for conducting the on-site assessment of the concerned HCOs. Towards the task of on-site assessment, he shall be assisted by a team of assessors commensurate with the scope of accreditation.

The principal assessor shall be competent to manage assessment programme.

3.4 APPOINTMENT OF PRE-ASSESSMENT TEAM

Depending upon the assessment criteria mentioned in the application form as well as size and scope of HCO, team for pre-assessment is appointed. It is therefore, team may consist of one or more members. In any case, team is led by a Principal Assessor.

Qualifying Requirements for Assessment team:

The Assessment team for the applicant HCO shall be appointed by the concerned Programme Officer. While appointing the following shall be ensured that the Principal Assessor/ Assessor is:

- i) from the approved list
- ii) for team selection-Criteria for Assessment team selection document shall be followed.
- iii) acceptable to the applicant HCO. In case, HCO has objection for the assigned team, HCO may communicate to NABH within 48 hours with valid reason (s).
- iv) CEO/ Director/ Joint Director shall check the team allocation on random basis. All efforts will be made that one Assessor/ Principal Assessor is not selected repeatedly and each assessor is given a chance

3.5 PRE-ASSESSMENT

A pre-assessment visit of the HCO shall be organised by NABH in consultation with the HCO within three months of submitting application. HCO must ensure their preparedness by carrying out its self-assessment and internal audit before the pre-assessment. The principal assessor and his team member are responsible for conducting pre assessment.

The Programme Officer shall then request the Assessment Team for on-site pre-assessment visit to:

- i. check the implementation of the standards as per the documented Manual/ SOP
- ii. study the services being offered/scope of accreditation and size of HCO so that the time frame, number of assessors required for the assessment can be determined. The Principal Assessor shall also assess whether the Assessment is required to be split, based on the location of HCO.
- iii. assess the degree of preparedness of the HCO for the Assessment.
- iv. ensure that HCO has submitted NABH Standard Agreement to NABH.

- v. explain to the HCO regarding the methodology to be adopted for Assessment and the obligations of the HCO.
- vi. instruct HCO to submit the corrective actions within 3 months from the date of assessment

The principal assessor shall submit a pre-assessment report to NABH Secretariat with a copy to the HCO within seven days of completion of pre-assessment.

The HCO shall comply with the inadequacies and ensure its implementation and submit a corrective action report within 90 days from the date of pre-assessment to NABH Secretariat.

Programme officer shall sent a copy of the corrective action taken by the HCO alongwith the copy of NCs raised by the assessment team to Principal Assessor for his/ her remarks. Principal Assessor shall submit the remarks to NABH Secretariat within 7 days.

3.6 ASSESSMENT

Once the Principal Assessor has accepted the pre-assessment NC closure report, the concerned Programme Officer shall constitute an assessment team for final assessment. Final assessment must be conducted within six months of conducting pre-assessment. The team shall include the Principal Assessor, assessor(s) & technical expert(s) (if required) in order to cover the scope of accreditation sought. In the final assessment, atleast one member (Principal Assessor/ Assessor) shall be sent from the pre-assessment team, if available. In case of certain specific scope, it may be necessary to obtain the services of an expert, who may not be an assessor under NABH scheme. The CEO/Director NABH is empowered to take an appropriate decision in such cases.

Thereafter Programme Officer shall fix up dates for on-site assessment of the HCO in consultation with the HCO, the Principal Assessor and Assessors. The Programme Officer from NABH may also participate in the assessment as an observer/ coordinator during the on-site assessment and convey his/ her observations to the Principal Assessor. The Programme Officer is also required to provide clarification on NABH requirements to the Principal Assessor and other technical assessors, whenever necessary.

The HCO is informed about the assessment team. A copy of this communication is marked to the members of assessment team, along with the requisite documents. The assessors are required to reach the place of assessment, a day before the start of assessment.

The assessment team review the HCO's departments, services and functions and verifies its compliance with the NABH Standards, for this assessment team carried out various assessment activities (document review, visit to patient care area, functional interview, facility tours and special interview etc.) the team will assess the extent of implementation of standards, the non-compliances, if identified are reported in the assessment report

The assessors report shall be prepared in the formats prescribed by NABH as per the Assessors' Guide (NABH-AG) and sent by the Principal Assessor to NABH Secretariat, within 7 days of completion of on-site Assessment. The assessment team shall share the assessment report with the HCO representative (Accreditation coordinator) after the assessment is over.

The assessment report shall contain the evaluation of manpower, all services, functions areas and departments examined, non-conformances, if any found during assessment. The assessment report is prepared by the principal assessor, in the formats prescribed. The details of the non-conformances observed during the assessment is handed over to the HCO by the Principal Assessor and the detailed assessment report is sent to NABH Secretariat, within ten days of completion of on-site assessment.

3.7 SCRUTINY OF ASSESSMENT REPORT

The assessment report shall be examined by NABH, who shall communicate the outcome of the assessment to the HCO and shall ensure that the non-conformances raised by the assessment team and not closed during the assessment, are available with and well understood by the HCO.

HCO shall take necessary corrective action on the remaining non-conformance(s)/ other concerns and shall submit a report to NABH Secretariat within a maximum period of three months. NABH shall monitor the progress of closing of non-conformances.

Programme officer shall sent a copy of the corrective action taken by the HCO alongwith the copy of NCs raised by the assessment team to Principal Assessor for his/ her remarks. Principal Assessor shall submit the remarks to NABH Secretariat within 7 days.

For Certification Program: Only one assessment shall be scheduled and time frame to close the corrective actions from HCO is 1 month.

3.8 ACCREDITATION COMMITTEE

After satisfactory corrective action by the HCO, the Officer in NABH prepares a brief summary of all relevant information gathered during the processing of the application, the assessment report, additional information received from the HCO. The summary report is placed before the Accreditation Committee for their recommendation for grant of accreditation.

The Accreditation Committee's observations on the assessment report and its recommendations shall be the deciding factors for grant of accreditation or otherwise. All decisions taken by the Accreditation Committee shall be recorded in the form of minutes.

In case the Accreditation Committee finds deficiencies in the assessment report to arrive at the decision, the Officer obtains clarification from the Principal assessor/ assessor/ HCO concerned. Also, committee may recommend for a verification visit to check compliance to the requirements before a decision on accreditation is recommended.

Accreditation Committee shall make appropriate recommendations regarding accreditation of a HCO through NABH Secretariat to Chairman, NABH.

HCOs are free to appeal against the findings of assessment or decision on accreditation.

3.9 ISSUE OF ACCREDITATION CERTIFICATE

When the recommendation results in the grant of accreditation, the Officer shall prepare the accreditation certificate.

The accreditation certificate is accompanied by “Scope of Accreditation” which shall define services being offered by HCO. As NABH accreditation is based on all or none principle, every service being offered is to be assessed and included.

A unique certificate number shall be allotted to HCO. Final certificate duly signed by the Chief Executive Officer is signed by the Chairman, NABH as a symbol of his approval, and issued to the HCO.

NABH Poster is also provided to HCO along with certificate and scope of accreditation for Hospital, SHCO, Pre-entry (Hospital) and Pre-entry (SHCO).

The applicant HCO must make all payments due to NABH, before the certificate is issued to the HCO.

All decisions taken by NABH regarding grant of accreditation shall be open to appeal by the HCO to the Chairman NABH.

4. MAINTAINING ACCREDITATION

4.1 VALIDITY

The NABH accreditation certificate shall be valid for a period of 3 years. On grant of accreditation, the HCO can NABH accreditation mark on all its reports certificates, letterheads, brochures and any other material issued to its customers. The guidelines for using NABH Accreditation Mark are given in the document “Policy and guidelines for use of NABH accreditation mark”.

NABH shall conduct surveillance assessment within fifteen to seventeen months of accreditation and re-assessment of the accredited HCO before the expiry of the accreditation certificate.

During the validity of accreditation, the HCO must continuously comply with the requirements of NABH Standards and “Terms and condition for maintaining accreditation”.

4.2 EXTENSION/ REDUCTION OF SCOPE OF ACCREDITATION

The HCO during the validity of accreditation may enhance or reduce the scope of accreditation for which NABH shall assess during surveillance/ reassessment visit or

organise a supplementary/ special visit. The reduction of scope is only permitted if HCO ceases to provide services in that specific area.

4.3 FOCUS /SURPRISE / VERIFICATION / UNANNOUNCED VERIFICATION VISIT

Besides the surveillance and reassessment, NABH may also organise Focus/ Surprise/ Verification/ unannounced Verification visit at any time because of following reasons:

4.3.1 CHANGES IN THE ACCREDITATION STANDARDS AND REQUIREMENTS

If there is a change in the general accreditation criteria, NABH shall inform the HCO of this in writing indicating the transition period, which shall be at least 6 months. On receipt of the aforesaid information, the HCO must confirm to NABH, its willingness to modify its quality system in accordance with the changes. On confirmation from the HCO, NABH may conduct a verification visit to assess the implementation of the same.

4.3.2 CHANGES AFFECTING THE HCO OPERATIONS

In the event of the HCO informing NABH about any changes in the information affecting the HCOs activities and operations, such as equipment, accommodation, environment, scope of Accreditation or changes in key managerial/ technical personnel, the Officer may organize a verification visit with the approval of CEO/Director NABH.

In the event of transfer of accreditation, when the legal status or the ownership of the accredited HCO changes, the HCO shall communicate this with relevant documentary evidence. The final decision is communicated to the HCO along with an amended certificate.

4.3.3 MISUSE OF ACCREDITATION MARK

Whenever any information regarding misuse of Accreditation Mark is received in NABH Secretariat, the concerned Programme Officer shall investigate and collect objective evidence of such misuse and report to the CEO NABH. Verification/ unannounced Verification visit shall be organised.

4.3.4 COMPLAINT AGAINST A HCO

In case, a complaint has been received and the facts need to be verified. The procedure has been detailed in clause 12 of this document.

4.3.5 ACCREDITATION COMMITTEE RECOMMENDATION

Based on Accreditation Committee recommendation to cross checks the evidences/ documents submitted by HCO. Verification/ unannounced Verification visit may be conducted either mutually decided assessment dates or within notice of 24 hours, as required respectively.

4.4 VOLUNTARY WITHDRAWAL

The HCO at any time during the validity of accreditation may discontinue their accreditation, voluntarily by making a written request to NABH. If the HCO decides to regain the accreditation status, after it has sought voluntary withdrawal it is treated as a new HCO and has to pay all fees for application & accreditation and assessment expenses, as applicable at that time.

5. SURVEILLANCE

- 5.1 NABH Secretariat shall inform the accredited HCO at the end of 12 months regarding the surveillance to be conducted within fifteen to seventeen months of obtaining accreditation.
- 5.2 Surveillance is aimed at examining whether the accredited HCO is maintaining all the requirements of NABH Standards and other applicable criteria.
- 5.3 The HCO during the validity of accreditation may request to enhance the scope of accreditation for which they should preferably apply two months before the conduct of surveillance. Scope extension request at the time of assessment/ surveillance would be considered only if the assessment team has the necessary expertise and extra time available. If a HCO requests scope extension independent of surveillance visit, NABH will arrange separate assessment visit.
- 5.4 The surveillance visit is similar to the first assessment visit. The non-conformances, if any, shall have to be closed within six weeks of conduct of surveillance. The summary of the surveillance report along with other relevant information shall be placed before the accreditation committee for their recommendation for continuation of accreditation or otherwise. NABH shall inform the HCO, in writing, about such decision.

6. REASSESSMENT AND RENEWAL OF ACCREDITATION

- 6.1 NABH Secretariat shall remind the HCO, 12 months before the expiry of accreditation for making application for renewal of accreditation to ensure that HCO applies for renewal.
- 6.2 The HCO may apply for renewal of accreditation by submitting an application in the prescribed form.
- 6.3 The application shall be accompanied with the prescribed renewal fee, as detailed in the application form. The HCO may request for extension of scope of accreditation, which should explicitly be mentioned in the application form.
- 6.4 The request for renewal must be submitted at least 6 months before the expiry of the validity of accreditation. If the HCO does not apply for renewal of accreditation, 3 months before the expiry of accreditation, it shall be presumed that the HCO is no longer interested in accreditation and the accreditation status of the HCO shall expire on the validity date mentioned in the certificate. In such a case the HCO shall have to apply afresh and the continuity of the certificate shall be disturbed.
- 6.5 Once applied within the time frame given vide 6.3, the HCO must be prepared for assessment. NABH shall conduct the renewal assessment anytime during this period to ensure that the decision on the renewal assessment can be arrived at before the expiry of the accreditation certificate. In circumstances, where the decision for renewal could not be arrived at before the expiry of the accreditation, the CEO of the Board in consultation with the Accreditation Committee Chairman shall take a decision to extend the certificate validity upto a period not exceeding 03 months.
- 6.6 The procedure for processing of renewal application is similar to that of first application except that no pre-assessment is conducted.
- 6.7 The procedure for the on-site reassessment visit is similar to that of first assessment visit.
- 6.8 If the results of reassessment visit are positive and all non-conformances are closed and recommended by the accreditation committee before the expiry of the certificate, then the validity of the certificate is extended by another three year without any discontinuity.

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- 6.9 A new certificate of accreditation is issued on renewal; however the certificate number remains same.

7. ADVERSE DECISIONS

- 7.1 NABH may take an adverse decision on accreditation of a HCO, if the HCO at any time during the validity of accreditation, does not fulfill the requirements of NABH Standards and other relevant criteria. The conditions of taking adverse decisions, like a reduction in scope of accreditation, abeyance, suspension and forced withdrawal is described in the document “Policies & Procedures for Dealing with Adverse Decisions”.

In case of adverse decisions like inactive, abeyance, suspension and forced withdrawal, the HCO shall discontinue the use NABH accreditation mark, in any form. The suspension and forced withdrawal status shall also be publicized.

- 7.2 In case the HCO's accreditation has been withdrawn by NABH, it is debarred to participate in the accreditation programme for a period of at least one year. The HCO may apply afresh by giving valid justification for earlier withdrawal and paying all fees & expenses, as applicable at that time.

8. APPEAL

All decisions taken by NABH regarding grant/ continuation/ renewal of accreditation shall be open to appeal by the HCO, to the Chairman NABH.

9. PUBLICITY

NABH shall publish details of scope of accreditation & accreditation status of the accredited HCOs on its website.

10. CONFIDENTIALITY

The members of the Board, Accreditation Committee, Assessors and NABH officials are required to maintain strict confidentiality of the information gathered regarding the HCOs from their various documents like procedure manual, work instructions, internal reports etc. and any other related information that might have been given by NABH, during the process of evaluation for grant of accreditation. NABH shall impose the same obligation of maintaining secrecy on those, whom they entrust the tasks of a confidential nature, as described above.

11. LIABILITY

NABH shall not be responsible for any damages, which the HCO may suffer as a result of any action or negligence by those who are carrying out the tasks on behalf of NABH and any failure to the grant of accreditation or abeyance/ suspension/ forced withdrawal of the accreditation.

12. AMENDMENTS TO THE POLICIES AND PROCEDURES

NABH may at any time amend the policies and procedures related to grant of accreditation, maintaining accreditation, surveillance, renewal of accreditation and the adverse decisions thereon. NABH shall inform the HCOs regarding such amendments indicating the transition period.

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

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