



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



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1. HEALTH CARE ORGANISATION (HCO) PREPARING FOR ACCREDITATION

In this document HCO means hospital and other Health Care Organizations like blood bank, wellness centre, dental facility, AYUSH hospital, etc. for which an accreditation or certification programme is provided by NABH. The provisions of this document shall be applicable to all accreditation and certification programmes.

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 Standards and other documents against the payment, as applicable. 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. All the relevant policies, procedures and documents are available on NABH website www.nabh.co for the reference and use of HCO.

Before applying to NABH, HCO needs to conduct self-assessment to ascertain whether HCO fulfilling NABH accreditation criteria or whether HCO complied with NABH Standards. If there are any gaps during self-assessment, HCO should take corrective action to fill the gap. Self-assessment report should give enough confidence to HCO about documentation and implementation of the requirements. Relevant requirements for NABH accreditation standards and process 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 facilitating the assessment procedure.



2. ELIGIBILITY FOR APPLYING FOR NABH ACCREDITATION

A Health Care Organization should be functioning atleast six months prior to applying for NABH accreditation or certification. The average bed occupancy (calculated for last 6 months) should be minimum of 30% at the time of application.

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 the provisions of the applicable accreditation Standards and other law of land.

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 along with applicable taxes. The application fee shall be calculated on the sanctioned beds in the hospitals. The details of the fees for various NABH programmes are displayed on NABH website (https://www.nabh.co/Images/PDF/RevisedFeeStructure_NABH.pdf). Application fee once paid is non-refundable and non-transferable. In case a HCO decides to shift to other accreditation programme (eg. From Hospital accreditation programme to SHCO programme etc.) during the process of accreditation, the fees paid is non-transferable.

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.



3.2 ACKNOWLEDGEMENTS AND REGISTRATION OF APPLICATION

On receipt of the application form of an HCO, the following actions shall be taken by NABH Secretariat:

- i. Review of application to see under which program application has been made.
- ii. Allocation of a unique Registration Number and issue of an acknowledgement letter upon receipt of the fee confirmation from accounts department to the HCO. This unique Registration number shall be used for NABH's own recording system and also for correspondence with the HCO.
- iii. Examine the application form for completeness and self-Assessment tool-kit/ Quality Manual/ other supporting documents to verify if all the requirements of documentation of standard have been adequately addressed.
- iv. Information regarding the application to designated staff for updating the web-site accordingly shall be done by the programme officer.

If deficiencies are noticed, in application fees, application form, self-assessment tool kit and other documents submitted, it shall be recorded and the HCO shall be informed to take corrective actions within 30 days.

The cost towards travel, boarding and lodging of the assessment team during all on-site assessment (except surprise assessment) shall be borne by HCO.

3.3 PRE-ASSESSMENT

Once the activities as mentioned at point 3.2 above are completed, a Pre-assessment shall be planned. The pre-assessment process is optional for Healthcare Organizations (HCOs). HCO may decide to undergo the final assessment directly. A written request shall have to be made by a HCO to NABH Secretariat for the same. In case the HCO has opted for pre-assessment, a pre-assessment team is allotted by NABH Secretariat.

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 assigned in the online portal. The number of man days required shall be as per the assessment criteria already defined by NABH and has been mentioned in the application form.



Pre-Assessment Process

The Assessment Team for on-site pre-assessment shall:

- 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. explain to the HCO regarding the methodology to be adopted for final Assessment and the obligations of the HCO.

The Principal Assessor shall upload pre-assessment report in the prescribed formats on the HCO portal within 7 days of completion of pre-assessment. Once uploaded, the assessment report is available to the HCO. The HCO is required to submit the corrective action report on the non-compliances raised within three months from the date of pre-assessment.

Before uploading the corrective action, the HCO shall submit the feedback for Principal Assessor, Assessor (s). On submission of the corrective action by HCO, the same is forwarded to the Principal Assessor. The corrective action report submitted by the HCO shall be reviewed by the Principal Assessors within 10 days of submission.

The HCO shall be given two cycles for submitting the corrective action. The Principal Assessor after going through the uploaded documents (corrective actions) for each non-conformance, gives comments viz. 'Accepted' in case if corrective action document is satisfactory or 'Not Accepted' in case if corrective action document is not satisfactory mentioning the reasons for the same.

On completion of two cycles of submission of corrective actions and Principal Assessor giving comments, the Programme Officer shall ~~now~~ plan for final assessment for HCO.

Desktop Assessment:

Under Entry Level Certification Programmes (AYUSH, Hospital and SHCO) a desktop assessment shall be carried out before the onsite assessment.



3.4 FINAL ASSESSMENT

Once the Principal Assessor has accepted the pre-assessment non-conformity closure report, the NABH Secretariat shall constitute an assessment team. The team shall include the Principal Assessor & assessor(s) in order to cover the scope of accreditation sought. In the final assessment, at least 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 also be deputed by NABH Secretariat.

NABH Secretariat 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 HCO shall be informed about the assessment team and dates of assessment. In case, HCO has objection for the assigned team, HCO shall communicate to NABH within 48 hours with valid reason (s).

The assessment team shall review the HCO's departments, services and functions and verifies its compliance with the NABH Standards, for this assessment team will carry 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.

Principal assessor shall upload the report within 7 days of completion of on-site Assessment. Once the assessment report is uploaded, the same is available to the HCO.

The detailed assessment report containing the evaluation of all relevant material examined on site and the non-compliance shall also provide summary of strengths and weaknesses of the HCO.

The assessment report in the prescribed format shall be examined by the concerned Programme Officer. The HCO shall submit the corrective action report to NABH in the online portal within the defined time frame. Before uploading the corrective action, the HCO shall submit the feedback for Principal Assessor and Assessor (s).



The corrective action report submitted by the HCO shall be reviewed by the Principal Assessor within 10 days of submission.

The HCO shall be given two cycles for closing the corrective action. The Principal Assessor after going through the uploaded documents (corrective actions) for each non-conformance, gives comments viz. 'Accepted' in case if corrective action document is satisfactory or 'Not Accepted' in case if corrective action document is not satisfactory mentioning the reasons for the same.

Subsequent to completion of two cycles of submission of corrective actions and submission of comments by Principal Assessor, the case shall be placed before the Accreditation Committee for recommendation of decision of accreditation.

For Certification Programs: For all certification programmes there shall be only one assessment.

3.5 FEE PAYMENT

The HCO shall be required to pay the first year annual accreditation fee before the final assessment is scheduled. This fee covers the cost of the final assessment. In case the HCO is recommended for accreditation, thereafter this fee shall be considered as the first-year annual accreditation fees. Once paid, this fee is non-refundable.

An accredited HCO is required to pay the annual accreditation fee for each year of accreditation at the beginning of each accreditation year along with applicable taxes.

HCO can also pay the fees for all the three years in advance at this stage. A 10% discount shall be given on the total fees shall be given on this advance payment. However, in case the HCO has not been recommended for accreditation, the fees for two year of accreditation already as advance fees shall be refunded after deduction of all the necessary taxes.

Fees shall be calculated on the sanctioned beds in the hospital.



3.6 NEW ASSESSMENT METHODOLOGIES

Virtual, Hybrid and Desktop Assessments: In view of the pandemic of COVID19, NABH initiated the new methodologies of assessment viz. Virtual assessments, Hybrid assessments and Desktop assessments.

Virtual assessments: This shall involve assessment on a Virtual mode where HCO and assessment team are connected through video conferencing. HCO shall upload the documents as specified in NABH document 'Technical Mandatory Photographs for Virtual Assessment' in 'HCO Document' of online portal.

NABH Secretariat shall ensure the testing for the internet connectivity with the HCO a day before the assessment. One moderator shall be assigned preferably for each assessment.

Hybrid assessments: This methodology involves combination of virtual and on-site assessment. Hybrid assessments are applicable where more than one assessor is appointed in the assessment team. One or more assessor will visit on-site and assess on ground and rest of the team members will assess remotely through video. This methodology is used for conducting Pre-Assessment, Final Assessment and Re-Assessment.

Desktop Surveillance assessments: The objective of this assessment is to verify the continued compliance of the accredited HCO to the applicable standards. For the purpose of Desktop Surveillance, the HCO shall provide the information as per the defined criteria and the same shall be considered for verifying the continued compliance. The information provided by the HCO shall be evaluated and on the basis of this evaluation, decision regarding continuation of accreditation shall be taken. The details are available in the document namely 'Desktop Assessment Surveillance'.

3.7 ACCREDITATION COMMITTEE

After satisfactory corrective action by the HCO, the NABH Secretariat shall 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 same 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.

Committee may recommend for a verification visit to check the compliance of corrective actions taken by the HCO onsite 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. The guidelines for the same are given in the document "Procedure for Handling of Appeals" document.

3.8 ISSUE OF ACCREDITATION CERTIFICATE

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

A unique certificate number shall be allotted to each HCO. Certificate shall carry name of HCO, effective date of accreditation, date of expiry and unique certificate number. The effective date of Accreditation will be the date on which accreditation committee is held. If the certificate pertains to the already accredited facility (RA cases), 'Date of first Accreditation' shall be mentioned above the accreditation date. 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.

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NABH Certificate Cell shall have the responsibility for dispatch of the Letter for Accreditation/ Certification, Certificate and Scope in consultation with the Programme Officer.



The HCO shall submit the signed copy of NABH Standard Accreditation Agreement at the time of grant of accreditation. The agreement is required to be submitted on a stamp paper. An accredited HCO shall abide by the conditions as mentioned in the agreement at all times during the duration of accreditation. Any deviation or noncompliance of the conditions of the agreement of grant of accreditation shall invite the action from NABH as mentioned in the document "NABH policies and procedures for dealing with Adverse and Other Decisions".

4. MAINTAINING ACCREDITATION

4.1 VALIDITY

The NABH accreditation certificate shall be valid for a period of 4 years under Hospital accreditation programme, 3 years for other accreditation programmes and 2 years for certification programmes. On grant of accreditation, the HCO can use 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/Certification mark".

5. SURVEILLANCE

- 5.1 Surveillance assessment shall be conducted at 24 months under Hospital accreditation programme and at 18 months for other accreditation programmes. There will be no surveillance assessment under Certification programmes.
- 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 i.e. Focus Assessment.



5.4 The surveillance visit is similar to the first assessment visit. The non-conformances, if any, shall have to be closed. 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 application 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, 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 four, three and two years as per the programme applied under.
- 6.9 A new certificate of accreditation is issued on renewal; however, the certificate number remains same.

7 OTHER ASSESSMENTS:

In addition to the assessments as mentioned above (Pre, Final, Surveillance and Reassessment), NABH may also undertake following additional assessments:

Focus Assessments:

A Focus assessment of an accredited/certified Health Care Organization (HCO) is conducted on receipt of request from the HCO in the following cases a) addition / extension of scope of services granted. b) change in the address/ location of premises c) change in the name of HCO/ legal identity of HCO. NABH document 'NABH Policy & Procedure for Focus Assessment of an Accredited/ Certified Healthcare Organisation' can be referred for detailed procedure for Focus Assessment.

Verification Assessments:

Verification assessments are conducted based on Accreditation Committee recommendation to cross checks the implementation of the evidences/documents/corrective actions submitted by HCO, a verification/ unannounced verification visit may be conducted either mutually decided assessment dates or within notice of 24 hours, as required.

Surprise Assessment

Surprise visit of accredited HCO shall also be conducted by NABH Secretariat to ensure that quality assurance systems are in compliance of NABH Standards on an ongoing basis to foster a culture of continuous quality improvement. Surprise



assessments can also be carried out by NABH Secretariat in an event of any complaint/ adverse report received against an HCO. The guidelines for the same are given in the document NABH Policy and 'NABH Policy and Procedure for Surprise Visit to an Accredited/ Certified HCO' and 'Policy & Procedure for Handling of Complaints'.

8. ADVERSE DECISIONS

8.1 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 'NABH Policy & Procedure for Dealing with Adverse and Other 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.

8.2 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.

9. APPEAL

All decisions taken by NABH regarding grant/ continuation/ renewal of accreditation shall be open to appeal by the HCO, to the Chairman NABH. NABH document 'Policy & Procedure for Handling of Appeals' can be referred for detailed procedure for Appeals.

10. PUBLICITY

NABH shall publish the list of applicant HCOs, accreditation status and details of scope of accreditation of the accredited HCOs on its website.



11. CONFIDENTIALITY

The members of the Board, Accreditation Committee, Assessors and NABH officials shall 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 gathered 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.

12. 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.

13. 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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