

AYUSH QUALITY MARK PROGRAMME

Accreditation Procedure For Ayush Wellness Centres

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0. Introduction

This procedure has been developed to support healthcare accreditation bodies and Ayush wellness centres to get accreditation from a recognised Healthcare Accreditation Body as defined in the system document.

1. Scope

This document describes the process to be followed by a healthcare accreditation body for accreditation of Ayush wellness centres to any standard recognized under the Ayush Quality Mark programme.

2. Normative references

No normative reference for this document. However, this document is to be read with standards recognised under Ayush Quality Mark programme.

3. Abbreviations

AB – Accreditation Body

4. Preparing for accreditation

The AYUSH WELLNESS CENTRE management should first decide about getting accreditation for its services. It is important that the AYUSH WELLNESS CENTRE makes a definite plan of action for obtaining accreditation and nominates a responsible person to co-ordinate all activities related to seeking accreditation. The person nominated should be familiar with the AYUSH WELLNESS CENTRE's services, functions and existing quality system, if any.

A request can be made to the Secretariat for procurement of relevant accreditation documents. Clarifications on any document/ process may be obtained from the Secretariat either in person, by post, on telephone or through e-mail. The AYUSH WELLNESS CENTRE should get fully acquainted with relevant documents and understand the assessment procedure & methodology of making an application.

Before an application is made, it is required that the AYUSH WELLNESS CENTRE does a self-assessment using self-assessment tool kit or any other mechanism to ascertain whether the AYUSH WELLNESS CENTRE is fulfilling Accreditation requirements, and if any gaps are identified, take necessary measures to fill those gaps.

Relevant requirements for Accreditation should be discussed amongst the concerned staff of the AYUSH WELLNESS CENTRE. This will enable them to understand their weaknesses and strengths. The AYUSH WELLNESS CENTRE must ensure that policies, procedures and other documents for various sections/ departments and services being provided are available and implemented.

The AYUSH WELLNESS CENTRE interested in going for accreditation should understand the assessment procedure and prepare accordingly.

5. Eligibility for applying for Accreditation

The applicant AYUSH WELLNESS CENTRE must comply with all applicable Standards and regulatory/ statutory requirements.

The applicant AYUSH WELLNESS CENTRE must ascertain the fulfilment of the eligibility requirements before making an application to Accreditation body.

6. Accreditation Procedure

6.1 Application for accreditation

The AYUSH WELLNESS CENTRE shall apply to the AB in the prescribed application form along with supporting documents of the AYUSH WELLNESS CENTRE in accordance with relevant accreditation standard. The application shall be accompanied with the prescribed application fee.

6.2 Registration and Acknowledgements of application

Within 10 days of receipt of the application from the AYUSH WELLNESS CENTRE, the following actions shall be taken:

- Review application to see for which accreditation programme the application is made and accordingly allocate a Unique Registration Number
- Open a client file
- Update the database maintained
- Transfer the Fee received as DD/ cheque from the AYUSH WELLNESS CENTRE to the account
- Performing a completeness check of the application including its supporting documents and fee received
- Issue acknowledgement mentioning unique Registration number to the AYUSH WELLNESS CENTRE. If deficiencies are identified, in the application fees or the application, they shall be recorded and the AYUSH WELLNESS CENTRE should be informed for corrective actions within 10 working days.
- This unique Registration number shall be allocated as a record of the application in the system and also for correspondence with the AYUSH WELLNESS CENTRE. All Ayush wellness centres are advised to use this registration number while communicating with AB.
- The AB shall maintain confidentiality of application submitted by the AYUSH WELLNESS CENTRE.

6.3 Appointment of Lead Assessor and Team

The AB shall appoint a qualified Lead assessor and communicate his name to the applicant AYUSH WELLNESS CENTRE along with his CV for raising any conflict of interest issues. Similarly, the name of the AYUSH WELLNESS CENTRE would be communicated to the Lead Assessor to declare any conflict of interest.

In case the AYUSH WELLNESS CENTRE has any issue, they may write to the AB with the justification for their objection. Similarly, the Lead Assessor may also declare any conflict of interest to the AB, if any.

The AB shall examine the issue on merits and decide whether it is valid in which case, it shall change the Lead assessor. The decision of the AB shall be final.

The Lead assessor shall have the overall responsibility of conducting the assessment of the concerned AYUSH WELLNESS CENTRE. Towards the task of assessment (on-site, remote, hybrid), the Lead Assessor may be assisted by a team of assessors/technical experts commensurate with the scope of accreditation. The AYUSH WELLNESS CENTRE is also informed about the team members and consent is taken to avoid any conflict of interest as already indicated in case of Lead assessor. A declaration of no conflict of interest is also taken from the team as indicated in the case of the Lead Assessor

6.4 Assessment

Thereafter the AB shall fix up dates for assessment of the AYUSH WELLNESS CENTRE in consultation with the AYUSH WELLNESS CENTRE and the assessment team. An AB representative may also participate in the assessment as an observer/ coordinator during the assessment and convey his/ her observations to the Lead Assessor. This AB representative, if

present, is also required to provide clarification on requirements to the Lead Assessor and other assessors, whenever necessary.

The AYUSH WELLNESS CENTRE is informed about the finalised assessment team and date(s) and a copy of this communication is marked to the members of assessment team, along with the requisite documents. The assessment team is required to reach the place of assessment, preferably a day before the start of assessment.

The assessment team shall assess the AYUSH WELLNESS CENTRE's services and functions and verify its compliance with the accreditation standards, for this purpose the assessment team may carry out various assessment activities (opening & closing meetings, document/records review, functional interview, facility tours, visit to healthcare provider, if applicable and special interviews etc.). The team shall assess the extent of implementation of standards, and any non-compliances / partial compliances identified shall be reported to AYUSH WELLNESS CENTRE during the Closing meeting in writing. In case AYUSH WELLNESS CENTRE has any comments, it may convey to the Lead assessor who shall decide whether to accept them or not.

The assessment report shall be prepared in the formats prescribed by AB and shall contain the evaluation of manpower, all services, functions and departments/sections examined, along with the details of non-compliances / partial compliances and a final summary. The report shall be prepared and sent by the Lead Assessor to the AB Secretariat, within 10 days of completion of the Assessment. The AB Secretariat shall share this assessment report with the AYUSH WELLNESS CENTRE thereafter.

6.5 Review of assessment report

The assessment report shall be examined by the AB. The AB shall seek any clarification, if required from assessment team or the AYUSH WELLNESS CENTRE on the report. The AB shall communicate to AYUSH WELLNESS CENTRE to submit corrective actions along with necessary evidence for all non-compliances / partial compliances observed during assessment. The AYUSH WELLNESS CENTRE shall submit their corrective actions along with appropriate evidence to the AB within 30 days of this communication.

6.6 Decision Making

After corrective action by the AYUSH WELLNESS CENTRE are accepted by the assessment team, the AB shall prepare a brief summary of all relevant information and documents gathered during the processing of the application, the assessment report, additional information received from the AYUSH WELLNESS CENTRE and any other information relevant to the case. The summary report with recommendation of the AB secretariat shall be placed before the Accreditation Committee which shall comprise of an individual or group of individuals in the AB Secretariat, the members of which do not overlap with the members of the assessment team. This Accreditation Committee is authorised to review and take decision for the recommendation for grant of accreditation. In case during this review the Accreditation Committee finds any deficiencies in the assessment report or the summary report to arrive at the decision, suitable clarification from the secretariat/Lead assessor/ assessment team members/ the AYUSH WELLNESS CENTRE concerned shall be obtained before considering the recommendation further.

Based on the findings in the assessment report and reviewers' recommendation, the AB shall make appropriate decision regarding accreditation.

6.7 Issue of accreditation certificate

When the recommendation of the reviewer(s) results into accreditation, the AB officer concerned shall prepare an Accreditation Summary in a prescribed format. This accreditation summary shall be submitted to the authorised personnel for approval. Once the authorised personnel accord their approval, the concerned AB officer shall prepare the an accreditation certificate. A unique certificate number shall be allotted to AYUSH WELLNESS CENTRE. The Certificate shall carry name of AYUSH WELLNESS CENTRE, effective date of accreditation, date of expiry and unique certificate number. The effective date of accreditation will be the date of approval by the authority. If the certificate pertains to the already accredited facility (renewal cases), 'Date of first Accreditation' shall also be mentioned above the accreditation date to display continuity of Accreditation.

The applicant AYUSH WELLNESS CENTRE must make all payments due to AB, before the certificate is issued to the AYUSH WELLNESS CENTRE.

7. Maintaining Accreditation

7.1 Validity

The accreditation certificate shall be valid for a defined period as per the policy of the AB. On grant of accreditation, the AYUSH WELLNESS CENTRE can use the prescribed Accreditation mark on its letterheads, brochures and any other material issued to its customers. The guidelines for using Accreditation/ Certification Mark are given in the document 'Policy and guidelines for use of Accreditation/ certification mark'.

The AB shall conduct surveillance assessment (on-site/ virtual) of the accredited AYUSH WELLNESS CENTRE as per the policy.

During the validity of accreditation, the AYUSH WELLNESS CENTRE must continuously comply with the requirements of the relevant AB Standards and 'Terms and conditions for maintaining Accreditation.

7.2 Surprise/ Short notice/ Verification/ Unannounced visit

Besides the regular (announced) surveillance and reassessment, the AB may also organise Surprise/ short notice/Verification/ unannounced visit at any time because of any of the following reasons:

- **Changes in the accreditation standards and requirements**

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

- **Changes affecting the AYUSH WELLNESS CENTRE operations**

In the event of the AYUSH WELLNESS CENTRE informing the AB about any changes in the information affecting the Ayush wellness centres activities and operations, such as equipment, accommodation/premises, environment, scope of accreditation or changes in key managerial/ technical personnel, etc. a verification visit may be conducted.

8. Surveillance

AB Secretariat shall inform the accredited AYUSH WELLNESS CENTRE at the end of 9 months regarding the annual surveillance to be conducted. Surveillance assessment may be on-site/ virtual based on situations.

Surveillance is aimed at examining whether the accredited AYUSH WELLNESS CENTRE is maintaining the requirements of prescribed standards and other applicable criteria.

The surveillance visit is similar to the first assessment visit. The non-compliances, if any, shall have to be addressed through an action plan to be submitted within 15 days of conduct of surveillance. The summary of the surveillance report along with other relevant information shall be placed before the reviewer(s) for their recommendation for continuation of accreditation or otherwise. The AB shall inform the AYUSH WELLNESS CENTRE, in writing, about such decision.

9. Reassessment and Renewal of Accreditation

AB Secretariat shall remind the AYUSH WELLNESS CENTRE, 12 months before the expiry of accreditation for making application for renewal of accreditation 6 months in advance.

The AYUSH WELLNESS CENTRE may apply for renewal of accreditation by submitting an application in the prescribed form. The application shall be accompanied with the prescribed renewal fee as applicable.

The request for renewal must be submitted before the expiry of the validity of accreditation as per the policy of the AB. If the AYUSH WELLNESS CENTRE does not apply for renewal of accreditation, well in advance before the expiry of accreditation, it shall be presumed that the AYUSH WELLNESS CENTRE is no longer interested in accreditation and the accreditation status of the AYUSH WELLNESS CENTRE shall expire on the validity date mentioned in the certificate. In such a case the AYUSH WELLNESS CENTRE shall have to apply afresh and the continuity of the certificate shall be void.

Once applied within the time frame as prescribed above, the AYUSH WELLNESS CENTRE must be prepared for assessment. The AB shall conduct the renewal assessment (on-site/ virtual/ hybrid), based on situations as appropriate before the expiry of the accreditation to ensure that the decision on the renewal assessment can be arrived at before the expiry of the accreditation. In circumstances, where the decision for renewal could not be arrived at before the expiry of the accreditation, The AB may take a decision to extend the certificate validity upto a period not exceeding three months.

The procedure for processing of renewal application is similar to that of initial application. The procedure for the reassessment visit is similar to that of initial assessment visit. The scope changes if any, as proposed by the AYUSH WELLNESS CENTRE to seek, be considered by the secretariat and the assessment team shall include this for assessing the requirements.

If the results of reassessment visit are satisfactory and all non-compliances / partial compliances are addressed through an appropriate action plan as observed by the assessment team and recommended by the accreditation committee before the expiry of the accreditation, then the validity of the accreditation is extended by another three years without any discontinuity.

A new certificate of accreditation is issued on renewal; however, the certificate number granted initially remains the same.

10. Misuse of accreditation mark

Whenever any information regarding misuse of Accreditation Mark is received by the AB, it shall be investigated and objective evidence of such misuse shall be collected. A verification/ unannounced verification visit may be organised based on the severity of the outcome of the investigation. Should the investigation establish misuse, suitable action shall be taken by the AB which shall include suspension or withdrawal of accreditation depending on severity of misuse. If any unethical practice is detected, it shall invariably lead to withdrawal of accreditation.

11. Adverse Decisions

AB may take an adverse decision on the accredited AYUSH WELLNESS CENTRE, if the AYUSH WELLNESS CENTRE at any time during the validity of accreditation, does not fulfil the requirements of prescribed standards and other relevant criteria. The conditions of taking adverse decisions, like a reduction in scope of accreditation, suspension and withdrawal shall be described in the document 'Policies & Procedures for Dealing with Adverse Decisions'.

In case of adverse decisions like suspension and withdrawal, the AYUSH WELLNESS CENTRE shall ensure that the use Accreditation mark is as per policy. The suspension and forced withdrawal status shall also be publicised by the AB on its website.

In case the AYUSH WELLNESS CENTRE's accreditation has been withdrawn by AB, it is debarred to participate in the accreditation programme for a period of at least one year. The AYUSH WELLNESS CENTRE may apply afresh by giving valid justification to the previous withdrawal and pay all fees & expenses, as then applicable.

12. Complaint against an AYUSH WELLNESS CENTRE

In case, a complaint is received from any stakeholder about the AYUSH WELLNESS CENTRE, it shall be dealt with as per the Complaints procedure of the AB. The decision on the complaint shall be independent of those involved in complaint.

13. Appeal

All adverse decisions taken by AB regarding accreditation shall be open for appeal by the AYUSH WELLNESS CENTRE, and shall be dealt with by an independent individual or group of individuals as per the Appeals Procedure of the AB.

14. Public information

The AB shall publish details of accredited Ayush wellness centres on its website along with their Accreditation status with validity and date of accreditation.

15. Confidentiality

The members of the Accreditation Body, Accreditation Committee, if any, Assessors, Experts and AB officials shall maintain strict confidentiality of the information gathered regarding the Ayush wellness centres from their various documents and any other related information that might have been provided by the AYUSH WELLNESS CENTRE or AB, during the process of accreditation. AB shall impose the same obligation of maintaining secrecy on those, whom they entrust the tasks of a confidential nature, as described above. All such persons who have access to confidential information sign a declaration of confidentiality.

16. Liability

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

17. Amendments to the Policies and Procedures

The AB 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. The AB shall inform the Ayush wellness centres regarding such amendments indicating the transition period set for compliance.