

# **AYUSH QUALITY MARK PROGRAMME**

## **RECOMMENDED CERTIFICATION PROCEDURE FOR WELLNESS CENTRE**

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## **0. Introduction**

It is observed that although ISO standards for wellness centres have been available, there is no formal certification against these standards. Therefore, until any specific certification scheme for Ayush wellness centres based on ISO standards comes up, it was decided to provide a certification procedure for uniformity among certification bodies (CBs), should any Ayush wellness centre decide to seek certification. Hence this recommended procedure for certification is provided to facilitate certification with immediate effect and CBs are encouraged to adopt it.

### **1. Scope**

This document explains the recommended process of certification to be adopted by the Certification Bodies in the absence of a formal certification scheme for Wellness Centres based on the prescribed certification criteria to be eligible for grant of Ayush Quality Mark under the Ayush Quality Mark Programme, hereinafter referred to as the Programme, operated by Ayushexcil.

### **2. Preparing for WELLNESS CENTRE Certification**

The Wellness Centre management should first decide about getting certification for its services. It is important for Wellness Centre to make a definite plan of action for obtaining certification and nominate a responsible person to co-ordinate all activities related to seeking certification. The person nominated should be familiar with Wellness Centre's services, functions and existing quality system, if any.

A request can be made to the Programme Secretariat for relevant certification documents. The documents can also be downloaded from <https://ayushexcil.in/ayushwellness>. A list of documents is given on the website under each programme and general documents. Clarifications on any document/ process may be obtained from the Programme Secretariat in person, by post, on telephone or through e-mail. The Wellness Centre must get fully acquainted with relevant documents and understand the audit procedure & methodology of making an application.

Before an application is made, it is required that Wellness centre does the self-audit to ascertain whether Wellness centre is fulfilling certification requirements, if any gaps are identified, take necessary measures to fill those gaps.

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

The Wellness centre interested in going for certification should understand the certification procedure and prepare accordingly.

### **3. Eligibility for applying for Certification**

The applicant Wellness centre must comply with the following:

1. All applicable certification criteria and regulatory/ statutory requirements as given in the following documents:
  - a) System for Grant of Ayush Quality Mark to Wellness Centres
  - b) Additional requirements for Wellness Centers as per ISO 9001/ 7101/ 21426, as applicable
2. Must have completed at least one self-assessment against the certification criteria. Any observations identified in this process have to be addressed before the submission of application.

NOTE: This is a mechanism of ensuring compliance to the certification criteria by the Wellness Centre themselves and therefore it would be easier for the audit teams to verify those compliances during on-site visits. It also gives confidence to Wellness Centre about documentation and implementation of the requirements.

#### **4. Description of Procedure**

##### **4.1 Application for Certification**

The Wellness centre shall apply to a CB in the prescribed application form, along with supporting documents of the Wellness centre in accordance with relevant certification criteria. The application shall be accompanied with the prescribed application fee.

##### **4.2 Registration and Acknowledgements of application**

Within one week of receipt of the application from a Wellness centre, the following actions shall be taken:

- i. Review application to see for which certification programme application is made and accordingly allocate a Unique Registration Number
- ii. Open a folder in the computer system and hard copy document file
- iii. Update the database maintained
- iv. Fee received as DD/ cheque is transferred to the account
- v. Performing completeness check of application including supporting documents and fee received on-line
- vi. Issue acknowledgement mentioning unique Registration number. If deficiencies are identified, it shall be recorded and the Wellness Centre be informed for corrective actions within one week.
- vii. This unique Registration number shall be allocated for recording system and also for correspondence with the Wellness Centre. All Wellness Centres are advised to use this registration number while communicating with CB
- viii. The CB shall maintain confidentiality of application submitted by Wellness Centre.
- ix. After the application is accepted, the CB shall define the number of mandays required to undertake this certification process for the scope applied for.

##### **4.3 Defining Man-days**

- 4.3.1 Audit time (Man-days) requirement: The certification body shall conduct the audit in two stages, offsite (desk review) and onsite audit.
- 4.3.2 The number of man-days required are decided as follows:
- i. offsite Document review and making report: max 2 mandays
  - ii. Office audit: depending upon the scope: max 2 man-days per process/activity
  - iii. Submission of Audit report by Lead auditor: within 10 working days and 1 man-day

#### **4.4 Appointment of Lead auditor and team**

**4.4.1** The CB shall identify a Lead auditor to be team leader and constitute an audit team for initial audit. The team shall include besides the Lead Auditor, auditor(s), technical expert(s) and observers or trainee auditors (if required) in order to cover the scope of certification. The Wellness centre is informed about the team members and consent is taken to avoid any conflict of interest.

**4.4.2** The Team Leader shall have the overall responsibility of conducting the audit and shall be responsible for conducting the on-site audit of the concerned Wellness centres. Towards the task of audit (on-site, remote, hybrid), he/she may be assisted by a team of auditors commensurate with the scope of certification.

#### **4.5 Audit**

##### **4.5.1 Offsite Document Review**

A Review of the Self-Audit checklist, Scope/Manuals, procedures /documents to verify if all the requirements of standard have been adequately addressed is carried out by TL (LA) and appointed team members, if any.

##### **4.5.2 Onsite audit**

- i. If the document review is satisfactory, the onsite audit shall be planned.
- ii. The CB shall fix up dates for audit of the Wellness centre in consultation with the Wellness centre and the audit team.
- iii. The Wellness centre is informed about the audit team and date(s). A copy of this communication is marked to the members of audit team, along with the requisite documents. The auditors are required to reach the place of audit, preferably a day before the start of audit.
- iv. An Audit plan is prepared by Team Leader and shared with Wellness centre and his team. It would detail the scope, methodology and the audit criteria.
- v. The audit team assess the Wellness centre's services and functions and verifies its compliance with the certification criteria, for the purpose audit team carries out various audit activities (document/records review, functional interview and special interviews, witness critical activities by way of sampling etc.). The team will assess the extent of implementation of certification criteria, the non-compliances, if identified are reported in the audit report.

- vi. The findings shall be categorised as Major/minor/concerns depending upon the severity of the findings and their impact on the output of the process. This shall be discussed with Wellness centre and their agreement on the findings is taken in the closing meeting.
- vii. A copy of the report containing final summary, details of the non-compliances (NC/PC) observed during the audit is provided to the Wellness centre within 10 days of the audit shall be sent by Lead Auditor, with action plan as detailed below (for any observations/ non-conformities.) If no comments are received, the report is submitted to the CB.
- viii. The audit report shall contain evidence of compliance to each requirement of the certification criteria and non-compliances, if any found during audit.

#### **4.6 Resolving non conformities**

**4.6.1** The Wellness Centre shall prepare an action plan to address all non-conformities or any concerns raised during audit. Wellness centre shall prepare an action plan which will include proposed corrections and corrective actions with root cause analysis and timeline to complete them and submit to Audit team within 30 days

**4.6.2** The audit team shall respond within 15 days. Once proposed correction/corrective actions are accepted by the audit team, the Wellness centre shall implement these within 30 days and provide evidence to the audit team.

**4.6.3** If the audit team accepts the implemented actions, it shall verify them onsite in case of major NCs and through documented evidence in case of minor NCs/concerns and then close the NCs.

**4.6.4** if at any stage the audits team does not accept submission by the Wellness Centre, it may be given an additional chance to submit fresh response.

#### **4.7 Recommendation and Grant of Certification**

##### **4.7.1 Recommendation for Certification:**

a) After satisfactory corrective action by the Wellness Centre as accepted by the audit team, the CB prepares a brief summary of all relevant information gathered during the processing of the application, the audit report, additional information received from the Wellness Centre.

b) The summary report is placed for review and decision by competent individual(s)

c) In case the review finds deficiencies in the audit report or otherwise, the CB shall obtain clarification(s) from the Team Leader/ auditor/ Wellness Centre concerned as needed.

d) Once the competent individual(s) are satisfied with the recommendation, the CB shall take a decision for certification. The review and decision shall be duly recorded.

#### **4.7.2 Grant of Certification:**

4.7.2.1 The CB shall grant certification after ensuring the following:

- Complete compliance to the Certification Criteria based on evaluation reports resulting in favourable certification decision,
- Certification Scheme requirements and
- Nonconformities raised have been addressed.

4.7.2.2 The effective date of certification shall not be before the date the decision to grant the certification to the organization is made.

4.7.2.3 Validity of the Certificate: The certificate shall be valid for 3 years from the decision to grant it.

4.7.2.4 The CB shall make the certification decision within a maximum of 15 calendar days after closing any outstanding non-conformances and receipt of all due payments. If no non-conformances are detected during the audit, the CB shall make the decision no later than 15 calendar days after the end of the audit.

4.7.2.5 On grant of certification, the CB shall inform the organization and issue a Certificate, uniquely identified, either a paper certificate or e-format, to the organization indicating as a minimum:

- a) the name and address of the organization & the site(s) covered under
- b) certification
- c) Scope of certification
- d) the certification criteria against which the certification has been awarded,
- e) date of initial certification
- f) date of recertification, if applicable,
- g) date of expiry
- h) Name and address of the certification body

#### **4.7.3 Use of certificate/certification mark**

4.7.3.1 The certificate is nontransferable except in case ownership of the site certified changes; the certificate may be transferred to the new owner on production of the ownership documents.

4.7.3.2 On grant of certification the MVTF can use the certification mark, if any, on its letterheads, brochures and any other material issued to its customers. The guidelines for using certification/certification mark are given by the scheme owners or the CB.

### **5.0 Maintaining Certification**

#### **5.1 Validity**

5.1.1 The certificate shall be valid for a period of three years.

5.1.2 In order to maintain certification, Wellness Centre shall undergo 2 surveillances during the validity period and a renewal audit before the end of validity of certification.

5.1.3 During the validity of certification, the Wellness Centre shall continuously comply with the requirements of the Standards and 'Terms and condition for maintaining certification.

5.1.4 At least one of the surveillances shall be a surprise unannounced audit.

## **5.2 Surprise / Unannounced visit**

5.2.1 Besides the regular surveillances, CB may also organise Surprise/ unannounced visits at any time because of any reason felt necessary including the following reasons:

### **a) Misuse of CERTIFICATION mark**

Whenever any information regarding misuse of Certification Mark is received in CB Secretariat, it shall be investigated and objective evidence of such misuse is collected and reported to the CB. Verification/ unannounced Verification visit shall be organised based on the severity of the outcome of the investigation.

### **b) Complaint against a WELLNESS CENTRE**

In case, a complaint has been received and the facts need to be verified. Complaint will be dealt with as per the CB's complaint procedure.

## **5.3 Extraordinary visits**

5.3.1 The CB may undertake extraordinary visits, if needed in situations such as:

### **a) Changes in the certification standards and requirements**

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

### **b) Changes affecting the Wellness Centre operations**

In the event of the Wellness Centre informing CB about any changes in the information affecting the Wellness Centres activities and operations, scope of certification or changes in key managerial/ technical personnel, a verification visit may be conducted.

## **6.0 Surveillance**

6.1 Each certified wellness centre shall undergo surveillance audit annually - one announced and one unannounced - the same as the initial onsite audit. Surveillance audit may be desktop review/ on-site/ virtual/ hybrid, based on situations.

6.2 The duration of unannounced audit shall be the same as surveillance audits.

6.3 In conducting Surveillance audits of the certified sites, the CB shall ensure that the gap between two surveillance evaluations does not exceed one year. The CB may allow a grace period of one month based on valid grounds, beyond which delays shall lead to suspension of the certificate.

6.4 If multiple sites are covered under the certification, all sites shall be audited during the certificate's validity period.

6.5 in case of multi-site certification, sites equal to a minimum of the square root (or the following whole number rounded upwards if there are any decimals) of the total number of the sites shall be audited.

6.6 If necessary, based on the risk perceived, the CB may increase the total number of sites to be audited. The organization can oppose the CB's decision on the number of sites to be audited.

6.7 The sites selected for surveillance shall be different from those audited earlier.

6.8 The CB may carry out any extraordinary audits based on any feedback or complaints or any other reason which may be announced / unannounced

## **7.0 Renewal of Certification**

7.1 The CB Secretariat shall remind the Wellness Centre, 6 months before the expiry of certification for making application for renewal of certification to ensure that Wellness Centre applies for renewal.

7.2 The Wellness Centre shall apply for renewal of certification by submitting an application in the prescribed form. The application shall be accompanied with the prescribed renewal fee, as detailed in the information brochure.

7.3 The request for renewal must be submitted at least 4 months before the expiry of the validity of certification. If the Wellness Centre does not apply for renewal in time before the expiry the certification status of the Wellness Centre shall expire on the validity date mentioned in the certificate. In such a case the Wellness Centre shall have to apply afresh and the continuity of the certificate shall be disturbed.

7.4 Once applied within the time frame, the Wellness Centre must be prepared for audit. CB shall conduct the renewal audit (on-site/ virtual/ hybrid), based on situations anytime during this period to ensure that the decision on the renewal audit can be arrived at before the expiry of the certification certificate. In circumstances, where the decision for renewal could not be arrived at before the expiry of the certification, CB may take a decision to extend the certificate validity up to a period not exceeding three months.

7.5 The procedure for processing of renewal application is similar to that of first application. The procedure for the on-site reaudit visit is similar to that of first audit visit.

7.6 If the results of re-audit visit are positive and all non-compliances are addressed through an action plan and recommended by the certification team, before the expiry of the certificate, then the validity of the certificate is extended by another three years without any discontinuity.

7.7 A new certificate is issued on renewal; however, the certificate number remains the same.

7.8 As this certificate pertains to the already certified facility (renewal cases), "Date of first certification" shall also be mentioned above this certification date.

7.9 If the Wellness Centre missed making an application in time, but wishes to continue the certification, a grace period of three months would be considered for the renewal audit.

## **8.0 Suspension, Withdrawal and Extension of Scope**

### **8.1 Suspension of certification**

8.1.1 A Suspension shall be issued when:

- a) Unsatisfactory performance is observed during two consecutive Surveillance evaluations.
  - i) If more than two major nonconformities are raised during the surveillance audit, it shall be considered as unsatisfactory.
  - ii) If two or more major nonconformities are repeated in surveillance from previous surveillance, it shall be considered unsatisfactory performance.
- c) a major nonconformity is not addressed within 3 months unless justified otherwise
- d) Any other noncompliance to the scheme or CB rules which merits suspension
- e) the organization who voluntarily asks for it for some (partial) or all (complete) of his products

8.1.2 The CB shall issue due notice of at least fifteen days for suspension of certification and may allow a personal hearing to the organization.

8.1.3 After the Suspension is issued, a period allowed for correction and corrective action will be set by the CB not exceeding 6 months. If the suspension is voluntary, the period for corrections and corrective actions is set by the organization, which must be agreed upon with the CB but not exceed 6 months.

8.1.4 During the suspension period, the organization shall not use the certification mark.

8.1.5 The CB shall revoke suspension only when corrective actions have been taken and verified by the CB.

8.1.6 Suspension shall not exceed six months. If the cause of the suspension is not resolved within the time period set, the certification shall be withdrawn.

### **8.2 Withdrawal of certification**

8.2.1 The CB shall withdraw the certificate, when:

- a) there is any evidence of fraudulent behaviour, submission of false information or concealment of information.
- b) misuse of certification mark or certification
- c) the organization cannot show sufficient corrective action after the suspension has been issued and six months have elapsed,
- d) major contractual nonconformities are detected.

- e) the certified organization contravenes the terms and conditions of certification and provisions of the certification scheme, such as suspension of certificate, inadequate corrective actions, lack of compliance with certification criteria, etc.
- f) Any conduct that brings certification in disrepute

- 8.2.2 The CB shall issue a show cause notice to the certified organization, giving fifteen days' notice and may allow a personal hearing to the organization.
- 8.2.3 The withdrawal of certificate shall result in the total prohibition of using the certification mark and the certificate.
- 8.2.4 An organization whose certificate has been withdrawn on grounds of fraudulent behaviour or wilful contravention of the Scheme shall not be allowed to apply for certification 12 months after the withdrawal date
- 8.2.5 The CB shall also withdraw the certificate at the request of the certified organization.

### **8.3 Extension of scope**

**8.3.1** The certified Wellness Centre shall be required to make a formal application for the purpose of inclusion of additional service process/activities in the scope of certification, on a application form, prescribed if any, to the certification body.

**8.3.2** The inclusion of each stream of medicine (ayurveda or modern medicine or homeopathy) shall be considered as extension of scope.

**8.3.3** The process steps of receipt of application information and application review, planning for evaluation, determination of competence of evaluators and others like for evaluation, review and decision- making functions shall be the same as that for initial evaluation. The evaluation time shall be estimated as per details provided above.

**8.3.4** Extension of scope of certificate for inclusion of additional service processes under the same certificate shall be done after ascertaining that the certified Wellness Centre has requisite resources required e. g. adequate infrastructure, resources, process controls, and technical skills through an on-site evaluation.

**8.3.5** The extension of scope shall be clearly mentioned in the certificate document along with its date of inclusion for avoiding any misrepresentation or misinterpretation. Irrespective of the date of inclusion, the validity of the Certificate shall remain unchanged.

## **9.0 Complaints**

### **9.1 Complaints to the CB**

9.1.1 The CB shall have a documented process to receive, evaluate and make decisions on the complaints received from any stake holder related to Wellness Centre activities.

9.1.2 The complaint-handling process shall include at least the following elements and methods:

- a) An outline of the process for receiving, validating, and investigating the complaint and for deciding as to what actions are to be taken in response to it;
- b) Tracking and recording complaints including actions undertaken in response to them; and
- c) Ensuring that any appropriate correction and corrective action is taken.

9.1.3 The CB shall make a description of the complaint-handling process publicly available.

9.1.4 Upon receipt of a complaint, the CB shall confirm whether the complaint relates to Wellness Centre certification activities that it is responsible for and, if so, shall deal with it. If the complaint relates to a certified client, then examination of the complaint shall consider the effectiveness of the system.

9.1.5 Any complaint about a Wellness Centre client shall also be referred by the CB to the client in question within 7 days from the date of receipt of the complaint, unless it requires confidentiality to be maintained.

9.1.6 The CB receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

9.1.7 Whenever possible, the CB shall acknowledge receipt of the complaint and shall keep the complainant apprised from time to time with the progress and finally, the outcome.

9.1.8 The decision to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not previously involved in the subject of the complaint.

9.1.9 Whenever possible, the CB shall give formal notice of the closure of the complaint handling process to the complainant.

9.1.10 The CB shall determine, together with the client and the complainant, whether and if so, to what extent, the subject of the complaint and its resolution is made public.

9.1.11 The CB shall determine if any action or modification is needed in relation to inspection report/certificate it may have issued to the Wellness Centre client against who complaint is received

## **10. Appeals**

10.1 The CB shall have a documented process to receive, evaluate and make decisions on appeals made by its wellness regarding its decisions.

10.2 The CB shall make a description of the complaint-handling process publicly available.

10.3 The CB shall acknowledge receipt of the appeal and shall keep the appellant apprised from time to time with the progress and finally, the outcome.

10.4 The CB shall be responsible for gathering and verifying all necessary information to validate the appeal.

10.5 The appeal shall be handled by individual(s) not previously involved in the decision of the appeal.

10.6 The CB shall be responsible for all decisions at all levels of handling appeals.

10.7 The process shall not result in any discriminatory actions.

**11. Public Information**

The CB shall publish details of applicant and certified Wellness Centres on its website. The certification status with validity date of certification of the certified Wellness Centres shall be made available on CB website.

**12. Confidentiality**

All personnel of the CB whether fulltime or part time or empanelled resources are required to maintain strict confidentiality of the information gathered regarding the Wellness Centres from their various documents and any other related information that might have been given by CB, during the process of certification. CB 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.

**13. Liability**

The CB shall not be responsible for any damages, which the Wellness Centre may suffer as a result of any action or negligence by those who are carrying out the tasks on behalf of CB and any failure to the grant of Certification or abeyance/ suspension/ forced withdrawal of the Certification. The CB shall meet liabilities arising from its operations. This can be met either maintaining adequate financial resources to ensure the continuity of its certification activities or having professional Liability Insurance which shall be valid at all times during the operation of the CB.

**14. Amendments to the Policies and Procedures**

The CB may at any time amend the policies and procedures related to grant of certification, maintaining certification, surveillance, renewal of certification and the adverse decisions thereon. CB shall inform the Wellness Centres regarding such amendments indicating the transition period set for compliance.

**15. Directory of Wellness Centres**

- a) The CB shall maintain and make publicly available on its website, directory of valid certifications that as a minimum shall show
  - i. the name,
  - ii. relevant certification criteria (normative document),
  - iii. scope of certification,
  - iv. geographical location (e.g. city and country) and
  - v. Validity of certification for each certified Wellness Centre.

- b) The information maintained by the Certification Body on its website shall also help the user to get readily the following information about the certified Wellness Centre:
  - i. the standard(s) and other normative document(s) to which conformity has been certified;
  - ii. identification of the certified Wellness Centres and other details like address, etc.
  
- c) The CB shall also display suitably on its website the names of Wellness Centres under suspension and those whose certificates have been cancelled.
  
- d) Apart from the information made available on its website the CB shall also have a provision and system for confirming validity of a certificate on request.
  
- e) The Certification Body shall have a procedure for frequent updating of the information on its website.

**16. Fee:**

16.1 The Fee structure should be available on the website of the CB.

16.2 The CB shall provide calculation of fee to each individual applicant organization before undertaking certification and obtain its acceptance.

16.3 In case of any change in fee during the validity of the certification, the organizations shall be informed and their acceptance obtained.