

**Provisional Approval System for Certification Bodies
For
Voluntary Certification Scheme for AYUSH Products**



QUALITY COUNCIL OF INDIA

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0. Introduction

- 0.1 The Certification Bodies (CB), in order to operate under the **voluntary certification scheme for AYUSH products**, hereinafter referred to as the Scheme, shall need to primarily comply with the requirements specified in ISO 17065 and the additional requirements prescribed by the Ministry of AYUSH/Quality Council of India (QCI) as the Scheme owners.
- 0.2 The CB would not get an applicant and would not be able to offer their evaluation of any AYUSH manufacturer for witnessing as part of the accreditation process to the accreditation body to get accreditation, or to get the relevant scope added in their accreditation, if already accredited, unless they are approved under the Scheme.
- 0.3 Further, in order to launch the Scheme, it is necessary that some CB are available at the beginning.
- 0.4 Therefore, it is necessary to establish a procedure for provisional approval of CBs under the Scheme till such time that they can get the scope added in their accreditation or get formally accredited from the **National Accreditation Board for Certification Bodies (NABCB)** and approved by the Scheme owners.
- 0.5 This document sets out the requirements to be fulfilled by CBs desirous of operating under the Scheme pending formal accreditation and approval.

1. Scope

- 1.1 This document defines the system for provisional approval for Certification Bodies to enable them to operate under the **Voluntary Certification Scheme for AYUSH Products**, pending formal accreditation for the Scheme by NABCB as per the prescribed international standard(s).
- 1.2 This approval shall be valid for a period of one year within which the approved CB shall have to obtain formal NABCB accreditation.

2. Criteria for Approval

- 2.1 The CB desirous of operating under this Scheme shall meet the criteria as prescribed in clauses 3 and 4 of this document.

3. General Requirements

- 3.1 **Legal Entity:** The CB shall be a legal entity, or shall be a defined part of a legal entity, such that it can be held legally responsible for all its Certification activities. A governmental certification body is deemed to be a legal entity on the basis of its governmental status. A CB, that is part of an organization involved in functions other than certification, shall be separate and identifiable within that organization.
- 3.2 **Integrity:** The CB and its personnel shall maintain integrity at all times. The CB shall implement adequate measures to ensure integrity.

3.3 Impartiality

3.3.1 The Certification Body shall be impartial.

3.3.2 The Certification Body shall be so structured and managed as to safeguard impartiality.

3.3.3 The Certification Body and its personnel/ staff shall not engage in any activities that may conflict with their Impartiality.

3.3.4 The Certification Body shall require personnel involved in the certification process to sign a contract or other document by which they commit themselves to declare any prior and/or present association with the Ayush manufacturer.

3.3.5 The Certification Body and any part of the same legal entity and entities under its organizational control shall not be the designer, manufacturer, installer, distributor or maintainer of the certified product or processes. The CB shall not provide any service to its clients which may compromise impartiality.

3.3.6 The Certification Body shall ensure that activities of separate legal entities, with which the Certification Body or the legal entity of which it forms a part, has relationships, do not compromise the impartiality of its certification activities.

3.3.7 When the separate legal entity in 3.3.6 offers or produces the certified product (including products to be certified), the Certification Body's management personnel and personnel in the review and certification decision-making process shall not be involved in the activities of the separate legal entity. The personnel of the separate legal entity shall not be involved in the management of the Certification Body, the review, or the certification decision.

3.3.8 The Certification Body shall act impartially in relation to its applicants and certified clients.

3.3.9 The Certification Body shall have a process to identify, analyze, evaluate, monitor, and document the threats to impartiality arising from its activities including any conflicts arising from its relationships, or from the relationships of its personnel on an ongoing basis.

NOTE Sources of threats to impartiality of the Certification Body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, training, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.

3.3.10 The Certification Body shall not certify a product of any manufacturing units on which it has provided consultancy relating to production of AYUSH products, or a minimum of two years following the completion of consultancy.

3.3.11 The Certification Body shall not use personnel in audits /inspections /evaluations or other certification / inspection activities if they have been employed by or involved in consultancy /training towards the client, for a minimum of two years following the end of the employment/ consultancy / training.

3.3.12 The Certification Body shall not have any relationship with its clients other than third party conformity assessment.

3.4 **Liability and Financing**

- 3.4.1 The CB shall evaluate its finances and sources of income and demonstrate that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.
- 3.4.2 The CB shall be able to demonstrate that it has evaluated the risks arising from its certification/inspection activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.

3.5 **Organizational Structure**

- 3.5.1 The CB shall define and document the duties, responsibilities and reporting structure of its personnel and any committee and its place within the organization. When the CB is a defined part of a legal entity, documentation of the organizational structure shall include the line of authority and the relationship to other parts within the same legal entity.

3.6 **Publicly Available Information**

- 3.6.1 The CB shall maintain a website for providing information about the Scheme and its certification activities under the Scheme.
- 3.6.2 The CB shall maintain and make publicly available information describing its certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and about the certification activities and geographical areas in which it operates.
- 3.6.3 The CB shall make publicly available information about applications registered and certifications granted, suspended or withdrawn.
- 3.6.4 The CB shall make publicly available its processes for handling appeals and complaints.

- 3.7 **Confidentiality:** The CB shall ensure confidentiality of information obtained in the course of its certification activities by having a suitable system.

- 3.8 **Certification agreement:** The Certification Body shall have a legally enforceable agreement for the provision of certification activities to its client. In addition, the Certification Body shall ensure its certification agreement requires that the client comply at least, with the specific requirements as prescribed in the relevant accreditation standards (ISO 17065) and the Scheme document.

3.9 **Responsibility for decision on certification**

- 3.9.1 The CB shall be responsible for, shall retain authority for, its decisions relating to certification, including the granting, maintaining, recertifying, expanding and

reducing the scope of the certification, and suspending or withdrawing the certification.

3.10 Integrity:

3.10.1 The Certification Body and its personnel shall maintain integrity at all times.

3.10.2 The Certification Body shall implement adequate measures to ensure integrity.

3.11 Use of certificates and marks of conformity

3.11.1 The certification body shall ensure that the Rules for Use of Certification Mark as described in Section 7 of the Scheme documents are adhered to.

3.12 Fee

3.12.1 A fee shall be charged to the client for various activities of the scheme, without any discrimination between clients, geographical location, size of the client. The CB's fee structure shall be publicly accessible and also be provided on request. The CB shall notify and obtain consent for its fee structure from the clients prior to grant of certification. As and when the fee undergoes a change, the same shall be communicated to all applicants and clients certified under this Scheme for their acceptance.

4. Technical Requirements

4.1 Personnel

4.1.1 The CB shall have, as part of its own organization, personnel, either employed or on contract, having sufficient competence for managing the certification operations for this Scheme.

4.1.2 The CB shall have defined processes for selecting, training, and formally authorizing and monitoring the performance its personnel involved in carrying out the various certification / inspection activities and for selecting technical experts, if needed, as per the requirements of this Scheme.

4.1.3 Competence

4.1.3.1 The Certification Body shall define the competence of the personnel involved in application review, evaluation and review and decision making.

4.1.3.2 The certification body shall have processes to ensure that personnel have appropriate knowledge of product certification, product standards, GMPs, related normative references and relevant Regulations for the products for which product certification is being offered.

4.1.3.3 It shall determine the competence required for each technical area (stream of AYUSH as relevant for the specific certification scheme), and for each function in the certification activity.

4.1.3.4 The certification body shall have access to the necessary technical expertise for advice on matters directly relating to certification for technical areas in which the

certification body operates. Such advice may be provided externally or by certification body personnel.

4.1.3.5 Evaluators – The evaluators shall meet the following requirements:

- a) **Education** – The certification body shall ensure that evaluators have at least post-secondary education in any stream of science relevant to AYUSH, and knowledge of basic processes, good manufacturing and hygienic conditions in the production and testing of these products.
- b) **Work Experience** – – The evaluator shall have at least 5 years of full time post qualification experience in AYUSH stream of industry, including at least two years of work in quality assurance within manufacturing, retailing, inspection or enforcement, or the equivalent. The number of years of total work experience may be reduced by one year if the evaluator has completed appropriate post graduate education in the concerned stream of AYUSH.
- c) **Training** –The certification body shall ensure that evaluators have successfully completed training in audit techniques based on ISO 19011.
- d) **Evaluation experience** – The certification body shall ensure that within the last three years, the evaluator has performed at least 12 mandays of Ayush evaluation in at least 4 organizations for Ayush product certification as an observer/trainee, under the leadership of a qualified Evaluator, and this demonstration has met with acceptance of the qualified Evaluator. The time spent by the observer/trainee shall not count towards time spent on evaluation.
- e) For maintaining the qualification of the evaluator, the certification body shall ensure that evaluators have performed a minimum of 4 AYUSH evaluation mandays per year.

4.1.4 **Selection of evaluation team** - The evaluation team may consist of one or more members. The certification body shall ensure the competence of the evaluation team as stated below:

- a) The evaluation team shall have appropriate knowledge of the product, the applicable regulatory requirements, the process and the Good manufacturing practices adopted and practiced in manufacturing of AYUSH Products of the organization to be evaluated Section V – CB Requirements.
- b) The evaluation team shall comprise of duly qualified evaluators supplemented by technical experts, if need be, meeting the competence requirements prescribed above. Initially, the certification body may use ISO 9001/ISO 22000 auditors or product certification evaluators as evaluators provided they have education and work experience similar to that prescribed above under CI 4.1.3.5, and experience in GMP/GHP auditing/evaluation in the areas of pharmaceutical or food sector.
- c) Whenever such evaluators are used, the evaluation team shall be supplemented by a technical expert. All such evaluators shall also be employed or contracted full time with the CB. The certification body shall identify and provide the competence needed to perform the Initial Evaluation of the

applicant at site considering the processes employed in manufacturing of AYUSH Products, and availability of laboratory in the manufacturing unit.

4.1.5 **Use of Individual Evaluators and Technical Experts**

- a) The certification body shall use evaluators who are employed or contracted full time with it. The ISO 9001/22000 auditors, if used as evaluators by certification body, shall also be employed or contracted full time. In exceptional cases, it may with justification use external evaluators. However, it may use external technical experts who shall have the same education and work experience as the evaluator but may not have audit/evaluation training or experience.
- b) All external evaluators and technical experts shall have a written agreement by which they commit themselves to comply with applicable policies and procedures as defined by the certification body.
- c) The agreement shall address aspects relating to confidentiality and independence from commercial and other interests, and shall require the external evaluators and technical experts to notify the certification body of any existing or prior association with any organization they may be assigned to evaluate.

4.1.6 **Personnel records** - The CB shall maintain up-to-date personnel records, as per requirements of the Scheme, of each of its personnel involved in its certification / inspection activities.

4.2 **Outsourcing/subcontracting**

4.2.1 The certification body shall not outsource any activity other than testing.

4.2.2 When the certification body outsources testing, the body doing the outsourced work shall meet the applicable requirements of ISO/IEC 17025 and/or shall be NABL accredited.

4.2.3 **Test Laboratory**

4.2.3.1 The certification body shall test all samples of AYUSH product drawn for independent evaluation, in testing laboratories either compliant with or accredited to ISO 17025 with scope of accreditation, for ascertaining conformance to specified criteria.

4.2.3.2 The certification criteria against which the product is to be tested shall be clearly mentioned and communicated to the testing laboratory. The sample(s) shall be so dispatched that they do not get damaged and or contaminated, undergo deterioration, and the product integrity is maintained.

4.3 **Certification Process**

4.3.1 The CB shall manage the process of certification as per the document "Certification Process" prescribed under the 'Voluntary Certification Scheme for AYUSH Products'.

4.3.2 The Certification Body shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process.

- 4.3.3 Recommendations for a certification decision based on the review shall be documented, unless the review and the certification decision are completed concurrently by the same person.
- 4.3.4 The CB shall maintain records to demonstrate that the certification process is effectively fulfilled.
- 4.3.5 The CB shall ensure the requirements of the Scheme are met with at any point in time.
- 4.3.6 The CB shall certify only under the Scheme and shall use the logo of the Scheme in the certificates issued to the certified organization.
- 4.3.7 The CB shall have written agreement with the certified organization on the use of the certificate and the Scheme logo.
- 4.3.8 The CB shall have a process to handle appeals by the applicant/certified organization against any CB decision.
- 4.3.9 The CB shall have a process to handle complaints from the users of the services of the CB or any other stake holder.

5. Approval Process

5.1 Application

- 5.1.1 Any organization interested in approval as a CB for the purpose of this Scheme may apply to QCI in the prescribed application format along with the prescribed application fee. The applicant shall also enclose the required information and documents as specified in the application form.
- 5.1.2 The filled in application form for approval shall be duly signed by the CEO/ authorized representative/s of the CB seeking approval.
- 5.1.3 On receipt of the application form, it will be scrutinized by the secretariat at QCI and those found complete in all respects will be processed further.

5.2 Assessment Process

- 5.2.1 On review of the application for completeness, an assessment team comprising a team leader and member(s)/technical expert(s) will be nominated by QCI for the purpose of assessment at applicant's office and other locations, if required. Under normal circumstances, the assessment at Head Office will be for a total of 2 man days including the TE. In case the applicant CB already holds an accreditation as a CB, the assessment duration may be reduced.
- 5.2.2 The names of the members of the assessment team along with their CVs will be communicated to the applicant CB giving it adequate time to raise any objection against the appointment of any of the team members, which will be dealt with by QCI on merits. All assessors/technical experts nominated by QCI have signed undertakings regarding confidentiality and conflict of interest.

- 5.2.3 QCI may decide, based on the report of office assessment or otherwise, to undertake witness assessment(s) of actual evaluation or any part of the certification process by the applicant CB.
- 5.2.4 The assessment team leader shall provide an assessment plan to the applicant CB in advance of the assessment.
- 5.2.5 The date(s) of assessment shall be mutually agreed to between the applicant CB and the QCI/assessment team.
- 5.2.6 The Office assessment will begin with an opening meeting for explaining the purpose and scope of assessment and the methodology of the assessment. The actual assessment process shall cover review of the documented system of the organization to assess its adequacy in line with the assessment criteria as specified. It will also involve verification of the implementation of the system including scrutiny of the records of personnel competence and other relevant records and demonstration of personnel competence through means like interviews, etc. In short, it will be an assessment for verifying technical competence of the applicant CB for operating under the Scheme.
- 5.2.7 At the end of the Office assessment, through a formal closing meeting, all the nonconformities and concerns observed in the applicant CB's system as per the assessment criteria and the assessment team's recommendation to QCI, shall be conveyed to the applicant CB.
- 5.2.8 The applicant CB may apply formally to NABCB for accreditation or addition of scope of AYUSH scheme and produce a report of satisfactory office assessment by NABCB in lieu of QCI assessment for grant of provisional approval

5.3 **Decision**

- 5.3.1 Based on the report of assessment, and the action taken by the applicant on the nonconformities/concerns, if any, QCI shall take a decision on whether to;
- a) undertake witness assessments(s) of actual evaluation or any part of the certification process by the applicant prior to granting of provisional approval or
 - b) grant provisional approval to the applicant as CB under the Scheme.

6. **Validity of Approval**

- 6.1 The approval shall be valid for a period of one year, after ensuring
- a) complete compliance to these provisional approval criteria based on evaluation reports,
 - b) certification scheme requirements, and

c) satisfactory resolution of nonconformities and concerns raised, if any.

- 6.2 The CB shall obtain formal accreditation as per ISO 17065 from NABCB within one year of approval by QCI.
- 6.3 QCI shall witness at least one evaluation during the period of approval. This may be waived of in case a witness report from NABCB is provided.
- 6.4 Based on the request of CB and review of previous approval status, it may be decided to extend the period of validity; in such a case, the CB shall be assessed covering both office and witnessing on site, as decided by QCI, prior to such an extension.
- 6.5 The approval shall be subject to suspension/withdrawal with due notice of 15 days in the event of any noncompliance to the requirements of the Scheme.
- 6.6 The approved CB shall inform QCI without delay about any changes relevant to its approval, in any aspect of its status or operation relating to;
- a) Its legal, commercial, ownership or organizational status,
 - b) The organization, top management and key personnel,
 - c) Main policies, resources, premises and scope of approval, and
 - d) Other such matters that may affect the ability of the CB to fulfill requirements for approval.
- 6.7 QCI shall examine such information and decide on the issue on merits with or without an on-site verification.

7. Fee

- 7.1 The following fee structure shall apply:
- a) Application fee - INR 10,000
 - b) Man day charges - INR 20,000
 - c) Travel / stay - On actuals
- 7.2 In addition, the CB shall pay to QCI an amount of INR 1000 per certificate, for the certificates issued to the certified clients.
- 7.3 QCI at its discretion may revise/ levy any other fee necessary with due notice to the CB.