

AYUSH QUALITY MARK PROGRAMME

Additional Requirements for Accreditation Bodies undertaking accreditation of Ayush Product/Process/Service Certification/Testing Bodies/Laboratories as per ISO 17011

1. Introduction

1.1 This document prescribes the additional requirements to be followed by the accreditation bodies undertaking accreditation of Product/Process/Service Certification/Testing Bodies/Laboratories, in addition to compliance to ISO 17011 for the purpose of obtaining recognition by the Programme Owner (PO) under the Ayush Quality Mark Programme (hereinafter referred to as Programme) of the Ministry of Ayush.

2. Additional requirements

The additional requirements are indicated by prefix A with the clause number of ISO 17011 for ease of understanding. All provisions of ISO 17011: 2017 shall apply in addition to those given in this document.

A1 Purpose

A1.1 This document specifies additional requirements for accreditation bodies involved in accreditation of Product/Process/Service certification/Testing Bodies/Laboratories under the Ayush Quality Mark Programme. These requirements are additional to the requirements specified vide ISO 17011 “Requirements for accreditation bodies accrediting conformity assessment bodies” and the relevant certification scheme, in order to be recognized by the PO under the provisions of Ayush Quality Mark Programme.

A2. Scope

A2.1 This document specifies additional requirements for the accreditation bodies operating under the Programme.

NOTE: The term “shall” used throughout this document indicates those provisions which are mandatory in nature. The term “should” is used to indicate guidance which, although not mandatory, is provided as a means of meeting the requirements of the approval criteria. In case the accreditation body uses an alternative means of meeting the requirements, they would have to provide suitable and adequate justification.

A2.2 For the sake of ease of usage, the structure of this document has been aligned with the structure of ISO 17011: 2017. Against each requirement in the standard (ISO 17011: 2017), additional requirements have been described, where applicable. These requirements shall be in addition to those specified in ISO 17011: 2017. In respect of all other elements the existing provisions shall apply.

A 3 Terms and definitions

A3.10 Impartiality - presence of actual or perceived objectivity

A3.34 Integrity - the quality of being honest and having a consistent and uncompromising adherence to strong moral and ethical principles and values.

A4. General Requirements

A4.01 Integrity

The accreditation body (hereinafter referred to as AB) shall maintain integrity at all times. It shall implement systems and measures to require all its personnel, internal and external, to maintain integrity. The accreditation body’s system

for maintaining integrity shall include measures like having a Code of Integrity and Conduct, which is required to be signed by all individuals (internal and external) involved in AB's activities, policy on gifts (such as no gift policy), guidelines for handling situations when offered inducement, etc.

A4.02 Independence

The accreditation body, and the legal entity of which it is part, shall be an independent, body neither owned by nor linked to any entity which is engaged in prohibited activities as detailed in ISO 17011 and this document.

4.1 Legal entity

A4.1.1 For each Standard for which it offers accreditation services, the accreditation body shall define any necessary limits (e.g. geographical) to its own operations and shall not take on assessments which it does not have the capacity to complete.

A4.1.2 The official language of AYUSH QUALITY MARK PROGRAMME is English. The accreditation body shall translate any of its documents and records requested by AYUSH into English on request, at the accreditation body's expense. All regular reporting by the accreditation body shall be submitted in English.

4.2 Accreditation agreement

A4.2.1 The accreditation bodies shall require the CABs to allow the PO and its nominated representatives to conduct shadow/witness assessments or to accompany assessments on request, and to respond to any non-conformities which arise from the shadow/witness assessments.

NOTE: The PO may conduct shadow assessments for CABs, whenever needed. Shadow assessments may include document review of a completed assessment, shadowing/witnessing of a remote or on-site assessment of a certification body, and/or shadowing a certification body audit without the accreditation body present.

4.3 Use of Accreditation Symbols and Other Claims of Accreditation

A4.3.1 g) Fully conforms (accredited CAB) to the requirements of the scheme(s) for which it has been granted accreditation.

A4.3.6 The Accreditation Body shall monitor the use of Mark(s) for the schemes for which it has accredited a conformity assessment body during its assessments and otherwise.

4.4 Impartiality Requirements

A 4.4.7.1 Top management shall review any residual risk to determine if it is within the level of acceptable risk. When a relationship poses an unacceptable threat to impartiality, then certification shall not be provided.

A4.4.11.1 The AB or an individual shall be prohibited for following activities:

- a) Training and consultancy for the CABs for any conformity assessment activity covered under this Programme.
- b) Education and/or training in AYUSH scheme for which it is providing accreditation or any other training related to this scheme within the same legal entity.

A4.4.11.2 The AB shall not linked to any other entity imparting education and/or training and/or consulting in AYUSH domain related to this Programme.

A4.4.14 The accreditation body shall establish rules and procedures to prevent or minimize threats of conflict of interest. Any actual or perceived interest in an action that results in or has the appearance of

resulting in personal, organizational, or professional gain is considered to be a conflict of interest. In particular,

- a) The accreditation body shall require personnel, committee, and board members to declare existing or prior association with an organization subject to certification or a certification body subject to accreditation. Where such an association threatens impartiality, the accreditation body shall exclude the person concerned from work, discussion, and decisions at all stages of the potential conflict of interest.
- b) If a conflict of interest between accreditation personnel and a certification body or organization is found after an assessment has occurred, another unbiased person shall be assigned to determine if it has affected the accreditation process and to complete the remainder of the process, if applicable.
- c) personnel shall not be allowed to assess or review their own work.

A4.4.15 In case an accreditation body, or the legal entity of which it is part, owns conformity assessment schemes, it shall implement measures that it provides accreditation to any CAB, having its own or participating in a similar scheme, without discrimination.

5 Structural Requirements

A5.9 Accreditation Body shall have formal rules for taking feedback from interested parties on accreditation process and management of finances of accreditation body.

6 Resource Requirements

6.1 Competence of personnel

A 6.1.1 Competence of personnel for schemes under the Programme – The assessors shall meet the following minimum qualifications:

- a. Education: The accreditation body shall ensure that assessor has minimum Bachelor's degree in the relevant stream of Ayush (ayurveda, siddha, unani etc.).
- b. They shall also meet one of the following options for professional experience:
 - i) Assessor shall have relevant experience of the domain to be assessed within the Ayush stream e.g. industry experience for manufacturing, healthcare management experience for hospitals, etc. The total work experience shall be 10 years including 3 years' experience in specific domain for which he is qualified to be an assessor.
 - j) In absence of qualified auditors/assessors, technical experts with similar qualification and experience may be used.
- c. Completion of a course on auditing technique based on ISO19011.
- d. Demonstrated knowledge of the relevant Standard(s), which should include a training course where available.
- e. Demonstrated knowledge of:
 - i) the accreditation body's procedures;
 - ii) the general context of the conformity assessment body to be assessed;
 - iii) the general production methods and processes applicable to the organizations/Sector to be assessed; test procedures in case of laboratory;
 - iv) issues and risks specific to the sectors and countries of the organizations to be audited; and
 - v) the preparation of written assessment reports that are clear, accurate, and complete, and which articulate the audit findings in relation to the Standard and other applicable requirements.

Note: The above competence can be demonstrated for an individual or team appointed for the assessment of the CAB.

A6.1.1.1 The accreditation body shall ensure that personnel assigned with accreditation participate in all mandatory trainings (e.g. courses, webinars, calls) and in-person accreditation meetings nominated and/or provided by the Scheme Owners or as and when organized by the AB.

A6.1.1.2 In addition to the requirements as specified above, as relevant, the laboratory assessors shall meet the following requirements.

- a) For testing in the field of chemical testing - Post Graduate in Chemistry/Ayush related subjects for other tests and minimum 10 year's experience in relevant field of testing out of which 5 years at supervisory level. Lesser no. of years of experience may be considered for persons having post graduate degree in AYUSH related subjects.
- b) For testing in the field of biochemical/microbiology testing - Post graduate in Microbiology and minimum 10 year's experience in relevant field of testing out of which 5 years at supervisory level.

A6.1.1.3 All personnel involved with accreditation process shall have undergone internal or external training on the applicable requirements of the respective AYUSH scheme/standard and demonstrate that the assessors have the knowledge of respective AYUSH scheme.

A6.1.1.4 The accreditation decisions shall be taken by an individual or a group having knowledge of

- a) assessment principles, practices and techniques;
- b) general management system principles and tools;
- c) The requirements of the certification standard and/or scheme;
- d) Domain knowledge of technical scope e.g. specific stream of Ayush industry/laboratory testing or healthcare or education/training for which review and decision is being taken.

6.4 Outsourcing

A6.4.1.1 Outsourcing shall be limited to the following:

- a) internationally recognized accreditation bodies (e.g. signatories of the IAF Multilateral Agreement) approved under these schemes, for CAB and Labs.
- b) Specialized Ayush related organizations to induct Ayush expertise in the AB

A6.4.5.1 The accreditation body shall take responsibility for managing the competence of personnel involved in all outsourced activities unless the subcontractor is an approved accreditation body for the applicable standard(s) and the scheme(s).

A6.4.5.2 When acting as a subcontractor for another approved accreditation body, the accreditation body shall take responsibility for conforming with all applicable requirements included in the scope of the subcontracting and shall not further subcontract services to another entity.

A6.4.5.3 Decision on accreditation shall not be outsourced.

7 Process requirements

7.1 Accreditation Requirements

A7.1.1 The general requirements for accreditation shall be the relevant Standard(s), the relevant provisions of the, conformity assessment scheme, if applicable, the documented system of the conformity assessment body for the relevant Standard(s)/Scheme, and any other applicable documents.

A7.4 Preparation for Assessment

A7.4.1 Selection of team for assessment

A7.4.1.1 A qualified assessor or assessment team shall perform the Document review, office assessments and all witness (test observations in case of laboratory) assessments. In case an appropriately qualified assessor is not available, suitably qualified technical experts shall be used.

A7.4.1.2 Witness assessment team should have industry or sector specific expert, if needed.

A7.4.1.3 When translators or interpreters are used in assessments, the translators and interpreters shall be independent of the certification body and (if applicable) the organization being evaluated. The names and affiliations of translators and interpreters shall be included in audit reports.

A7.4.1.3 When technical experts are used in assessments, the technical experts shall be independent of the CAB and the organization being assessed/evaluated. The team leader shall not be involved in any type of conformity assessment activity as relevant to the Ayush Scheme being assessed. The names, qualifications, and affiliations of technical experts and their individual assignments and time for which they were present shall be included in assessment reports.

A7.4.6.1 The AB granting accreditation to a multi-location laboratory shall assess all locations before including them under the scope of accreditation and also during all subsequent surveillance and recertification activities as applicable.

A7.4.6.2 In case of accreditation of conformity assessment bodies, the AB shall evaluate all locations taking decision for grant of accreditation and square root of all locations handling key activities (Application review, auditor nomination, manday calculation etc). All offices/locations shall be evaluated during the accreditation cycle where key activities are undertaken.

A7.4.6.3 The accreditation body shall identify Key offices/location for the each scheme, which shall include all offices other than the headquarters / main office which take responsibility for certification decisions, or for issuing certificates, as well as any other offices which the accreditation body considers to be critical to the certification body's systems for the Standard including team nomination etc. The AB should have justification for selection of key offices/location

7.5 Review of Documented Information

A7.5.1.1 Upon receipt of an application form from a CAB, the accreditation body shall conduct a document review of the CAB's documented systems (all levels of documents) offsite prior to office assessment. It shall result in a comprehensive report covering all requirements of the applicable standard. The first review should be completed within one month of receipt of the application form and documents for review. The accreditation body may then recommend a grace period for taking care of inadequacies identified based on the requirements.

7.6 Assessment

A7.6.1.1 For assessment of certification bodies following additional requirements shall apply.

A7.6.1.1.1 The accreditation body shall include the following elements in its initial assessment, as a minimum:

- a) Document review;
- b) On-site assessment of the headquarters / key office/location(s) of the applicant certification body. In case any key office/location is excluded justification shall be provided to AYUSH;
- c) Witness assessment;

The accreditation body shall have a documented policy for witnessing in Ayush sector subject to the following requirements.

For initial accreditation, at least one witness assessment shall be done for each stream of Ayush like

Ayurveda, Unani etc. as separate scopes.

Within each stream of Ayush, healthcare, manufacturing, cultivation & collection, and training shall be treated as different sub scopes requiring witness assessment each.

After grant of accreditation, there shall be at least one witness assessment per stream of Ayush and all sub scopes shall be covered during the accreditation cycle.

- d) In case of multi-location laboratory the AB shall assess all locations before including them under the scope of accreditation

A7.6.1.1.2 The accreditation body shall include the following elements in its surveillance assessments, at a minimum:

- a) On-site assessment of the headquarters / 20% Key office/location of the certification body once every year.
- b) Witness assessment performed at a representative organization for each applicable Standard once every year.
- c) On-site assessment of 100% of the number of Key offices/location over five years, distributed approximately evenly during that timeframe.

NOTE: A single key office/location may be visited more than once during a five-year time period if the accreditation body identifies high risk. The above represents the minimum assessment level; the accreditation body may choose to do additional assessments. Office assessments may include remote evaluation, and may be conducted remotely in the case of virtual offices of a certification body.

7.7 Accreditation Decision Making

A7.7.1.1 The accreditation body shall keep final responsibility for the granting, maintaining, renewing, extending, suspending, or withdrawing of accreditation. Delegation of accreditation decisions to other entities is not permitted. However, external resources can be used in decision making if they are suitably contracted to comply with accreditation body's systems.

7.9 Accreditation Cycle

A7.9.1.1 Yearly surveillance of the offices of CAB and witness assessment, where applicable, is mandatory. In case of accredited Ayush laboratory, yearly surveillance is mandatory and all sites shall be assessed in case of multi-location laboratory/

7.11 Suspending, Withdrawing, or Reducing Accreditation

A7.11.3.1 In case the scheme owner withdraws recognition of any conformity assessment body for its scheme, the accreditation body shall reduce the scope of accreditation to exclude the relevant scheme.

A7.11.3.2 In case the scheme owner suspends recognition of any conformity assessment body for its scheme, the accreditation body shall consider the reasons for suspension and take appropriate actions including suspension on merit.

9 Management system requirements

A9.1.4.1 Only Option A shall be applicable

9.4 Control of records

A9.4.2.1 Record retention time shall be a minimum of five years or as per scheme or regulatory requirements, whichever is less, subject to one previous cycle plus the current cycle.

9.7 Internal audits

A9.7.4.1 The Internal Auditor(s) responsible for auditing the Ayush related accreditation activities shall have background in Ayush and be knowledgeable of the applicable scheme(s) and standard(s). In case internal auditor with relevant competence in Ayush (e.g. industry experience for products, education experience for education/training, healthcare experience for hospitals/clinics/wellness centres) is not available, an appropriately qualified and experienced technical expert shall be part of the team.