

Voluntary Certification Scheme for Traditional Health Practitioner

0. Introduction

0.1 This document defines the criteria to be followed by the bodies certifying persons against specific requirements, of a certification scheme for Traditional Health Practitioner. It also describes the procedure that will be followed by the Certification Bodies (IBs) seeking approval by the Quality Council of India (QCI) as a certification body certifying personnel pending formal accreditation as per ISO 17024 from the **National Accreditation Board for Certification Bodies (NABCB)**.

0.2 In case anyone needs more information, he may contact:

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1. Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 2:1996, *Standardization and related activities — General vocabulary*

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

2. Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 2 and ISO 9000 apply.

2.1 Appeal

Request by applicant, candidate or certified person for reconsideration of any adverse decision made by the certification body related to her/his desired certification status.

2.2 Candidate

Applicant who has fulfilled specified prerequisites, allowing his/her participation in the certification Process.

2.3 Certification process

All activities by which a certification body establishes that a person fulfils specified competence requirements, including application, evaluation, decision on certification, surveillance and recertification, use of certificates and logos/marks.

2.4 Certification scheme

Specific certification requirements related to specified categories of persons to which the same particular standards and rules, and the same procedures apply.

Traditional Health Practitioner 'C' Definition to be defined.

2.5 Certification system

Set of procedures and resources for carrying out the certification process as per a certification scheme, leading to the issue of a certificate of competence including maintenance.

2.6 Competence

Demonstrated ability to apply knowledge and/or skills and, where relevant, demonstrated personal attributes, as defined in the certification scheme.

2.7 Complaint

Conformity assessment request, other than an appeal, by any organization or individual to a certification body, for corrective action relating to the activities of that body or to those of any of its customers.

2.8 Evaluation

Process that assesses a person's fulfilment of the requirements of the scheme, leading to a decision on certification.

2.9 Examination

Mechanism that is part of the evaluation, which measures a candidate's competence by one or more means such as written, oral, practical and observational .

2.10 Examiner

Person with relevant technical and personal qualifications, competent to conduct and/or score an examination.

A. Criteria and Guidance for the certification bodies for Certification of Traditional Health Practitioner (THPs)

A. 1.1 This document specifies general criteria for the competence of third party certification bodies performing certification of Traditional Health Practitioner. It also provides guidance on application of the criteria.

Note 1: 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 certification bodies use an alternative means of meeting the requirements, they would have to provide suitable and adequate justification.

Note 2: The certification bodies shall be required to establish documents in the form of manual, procedures, work instructions etc wherever the criteria has referred to a documented procedure or system. In all other cases the certification bodies shall be required to demonstrate compliance to the requirements of the criteria. However, even in these cases the certification bodies are encouraged to document their system.

A. 1.2 This document is intended for the use for assessment by the QCI for the purpose of approval of bodies certifying persons against specific criteria.

A. 3 Administrative requirements

A.3.1 The certification body, or the organization of which it forms a part, shall be a legal entity in India. A certification body that is part of an organization involved in functions other than certification shall be identifiable within that organization.

A. 3.2. The certification body shall define policies and procedures for granting, maintaining, renewing, expanding and reducing the scope of the desired certification, and suspending or withdrawing the certification. The certification body shall have documented its terms and conditions which would form the basis for its certification activities.

A. 3.3. The policies and procedures of the certification body and their administration shall be related to the criteria in which certification is sought, shall be fair and equitable among all candidates, and shall comply with all applicable regulations and statutory requirements. The certification body shall not use procedures to impede or inhibit access by applicants and candidates, except as provided for in this criteria.

A.3.4 The certification body shall confine its requirements, evaluation and decision on certification to those matters specifically related to the scope of the desired certification.

A. 4 Independence, Impartiality and Integrity related requirements

A. 4.1 General - The personnel of the certification body shall be free from any commercial, financial and other pressures which might affect their judgement. The certification body should implement adequate measures to ensure that persons or organizations external to the certification body, cannot influence the results of certifications carried out.

A. 4.2 Independence - The certification body shall be providing only third party certification services and shall be independent of the parties involved. The certification body and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their certification activities which may pose risk to impartiality.

A. 4.3 The certification body shall not offer or provide training, or aid others in the preparation of such services, unless it demonstrates how training is independent of the evaluation and certification of persons to ensure that confidentiality and impartiality are not compromised.

A. 4.4. The certification body

- a) shall have the financial resources necessary for the operation of a certification system and to cover associated liabilities,
- b) shall have policies and procedures that distinguish between the certification of persons and any other activities, and
- c) shall assure that the activities of bodies related to it do not compromise the confidentiality and impartiality of its certification.

A 5 Organizational structure

A 5.1 The certification body shall be structured so as to give confidence to interested parties in its competence, impartiality and integrity. In particular, the certification body:

- a) shall be independent and impartial in relation to its applicants, candidates and certified persons, including their employers and their customers, and shall take all possible steps to assure ethical operations;

b) shall be responsible for its decisions relating to the granting, maintaining, renewing, expanding and reducing the scope, or suspending and withdrawing the certification;

c) shall identify the management [group(s) or person(s)] which shall have overall responsibility for

- 1) evaluation, certification and surveillance as defined in this criteria document, the applicable competence standards and other relevant documents,
- 2) the formulation of policies relating to the operation of the certification body, with regard to certification of persons,
- 3) decisions on certification,
- 4) the implementation of its policies and procedures,
- 5) the finances of the certification body, and
- 6) the delegation of authority to any committees or individuals to undertake defined activities on its behalf;

A.5.2 The certification body shall define policies and procedures (e.g. code of conduct) for the resolution of appeals and complaints received from applicants, candidates, certified persons and their employers, and other parties about the certification process and criteria, as well as policies and procedures for the performance of certified persons. These policies and procedures shall ensure that appeals and complaints are resolved independently, in an unbiased manner.

A.5.3 The certification body shall employ or contract enough people with the necessary education, training, technical knowledge and experience to perform certification functions relating to the type, range and volume of work performed, under a responsible management.

A. 6 Confidentiality

The certification body shall ensure confidentiality of information obtained in the course of its certification activities. Proprietary rights shall be protected.

A. 7 Subcontracting

A. 7.1 The certification body shall normally perform the certifications which it contracts to undertake itself. However, when a certification body decides to subcontract work related to certification (e.g. examination) to an external body or person, a properly documented agreement covering the arrangement, including confidentiality and prevention of a conflict of interest, shall be drawn up. The decision on certification shall not be subcontracted.

A.7.2 The certification body

- a) shall take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, renewing, expanding and reducing the scope, and suspending or withdrawing certification;
- b) shall ensure that the subcontractor is competent and complies with the applicable provisions of this criteria document and is not involved, either directly or through their employer, with training or the maintenance of the certification of persons in such a way that confidentiality and impartiality could be compromised, and
- c) shall maintain a list of its subcontractors, and assess and monitor their performance in accordance with documented procedures

A. 8 Requirements for certification body personnel

A. 8.1. The certification body shall have a sufficient number of personnel with the range of expertise to carry out certification. These may be permanent personnel or those who are employed by or under long term contract to the certification body.

A.8.2. The certification process shall define the competence requirements for employed/contracted persons involved in the certification process. They may be employed either on a full-time basis or on a part time basis. Where it is necessary to use personnel for temporary situations, such personnel should be formally contracted for the period that the certification body uses them. The certification body should ensure that such personnel are effectively supervised and competent and that they work in accordance with the certification body's internal systems. The same competence requirements shall apply to the contracted personnel as certification bodies own staff.

A.8.3 The certification body shall require its employed or contracted persons to sign a document by which they commit themselves to comply with the rules defined by the certification body, including those relating to confidentiality and those relating to independence from commercial and other interests, and from any prior and/or present link with the persons to be examined that would compromise impartiality.

A.8.4 Clearly documented instructions shall be available to the employed or contracted persons describing their duties and responsibilities. These instructions shall be kept up to date. All personnel involved in any aspect of certification activities shall possess appropriate education, experience and technical expertise which satisfy defined competence criteria for the tasks identified. They shall be trained for their specific responsibilities and made aware of the significance of the certification offered.

A.8.5 The certification body shall establish and maintain current documentation on the relevant qualifications of each individual. The information shall include the academic or other qualifications and professional status, experience and training in the relevant field and the frequency of the updating of the records. The job descriptions of the individuals must be clearly documented.

A. 9 Requirements for Examiners

5.2.1 Examiners shall meet the requirements of the certification body based upon applicable competence standards and other relevant documents. The selection process shall ensure that examiners assigned to an examination or part of an examination at least

- a) are familiar with the relevant certification scheme
- b) have a thorough knowledge of the relevant examination methods and examination documents
- c) have appropriate competence in the field to be examined,
- d) are fluent both in writing and orally in the language of examination, and
- a) are free from any interest so that they can make impartial and non-discriminatory judgements (assessments).

5.2.2 If an examiner has a potential conflict of interest in the examination of a candidate, the certification body shall undertake measures to ensure that confidentiality and impartiality of the examination is not compromised (see A 4.3). These measures shall be recorded.

A 10. Certification process

A 10.1 The certification of THPs shall be done as per the scheme (Doc No.....) designed and jointly owned by the Centre for Traditional Knowledge Systems (CTKS), IGNOU and Quality Council of India. This scheme was prepared by a Subject Expert Committee constituted by CTKS after due consultation with the stake holders. This committee is fairly and equitably represented by all interested parties significantly concerned with the certification scheme, without any particular interest predominating. The personnel will be certified as Traditional Health Practitioners- for Diagnosis, Treatment and counselling of

patients for individual specialisations listed in the Annexure A of the scheme document. The details of the operations of the scheme are available on the QCI web site.

A 11. Records

A 11.1 The certification body shall maintain a record system appropriate to its particular circumstances and to comply with regulations, including a means to confirm the status of a certified person. The records shall demonstrate that the certification process has been effectively fulfilled, particularly with respect to application forms, evaluation reports, surveillance activities and other documents relating to granting, maintaining, renewing, expanding and reducing the scope, and suspending or withdrawing certification.

A 11.2 The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and the confidentiality of the information. The records shall be kept for an appropriate period of time to demonstrate continued confidence for at least one full certification cycle, or as required by recognition arrangements, contractual, legal or other obligations.

A. 13 Complaints and Appeals

A 13.1 The certification body shall have documented procedures for dealing with complaints received from certified personnel or other parties about the certification body's activities and these shall be publicly available.

A. 13.2 The certification body shall have documented procedures for the consideration and resolution of appeals against the results of its certifications. These shall be made known to the prospective applicants/ certified persons.

A. 13.3 A record shall be maintained of all complaints and appeals and of the actions taken by the certification body.

A. 13.4 Records shall also be maintained of any judicial proceeding subsequent to making a complaint.

B. Procedure for approval of bodies operating certification of Traditional Health Practitioner (THPs) by QCI

B. 1 Application for approval

B. 1.1 Certification bodies interested in approval of the Quality Council of India (QCI) for the purpose of certification of traditional health practitioner may apply to QCI along with information in the format enclosed vide Annex 3. The applicant shall also enclose the required information and documents as specified in the application form.

B 1.2 The filled application form for approval shall be duly signed by the authorized representative/s of the organization seeking approval and forwarded to QCI along with necessary enclosures.

B. 1.3 On receipt of the application form, it will be scrutinised by the secretariat at QCI and those found complete in all respect will be processed further.

B. 2 Assessment

B. 2.1 Assessment planning and assessment team nominations

B. 2.1.1 Based on the information supplied regarding the location of the certification body, technical areas of operation, etc, an assessment team consisting of a team and member(s)/technical expert(s) will be nominated by QCI for the purpose of assessment at the certification body's Head office and other locations, if required. Under normal circumstances the assessment at the Head office will be for a total of two man-days.

B. 2.1.2 The names of the members of the audit team along with their CVs will be communicated to the applicant body giving them adequate time to raise an objection against the appointment of any of the team members, which will be dealt with by QCI on merits. All assessors/experts nominated by QCI have signed undertakings regarding confidentiality and conflict of interest.

B. 2.1.3 The dates of the office assessment shall be decided as per mutual convenience of the assessment team and the applicant body. The certification body is informed of the assessment plan by the team leader which is finalized based on the agreement of the applicant organization. In case information collected during the office assessment requires inclusion of other locations in the assessment programme, the applicant would be informed and the assessment programme would be modified to cover such locations. The branch offices/sub-contractors would be included in the assessment programme depending on the nature of activities carried out by them and the extent of control demonstrated by the applicant IB.

C. 2.2 Assessment Process:

B. 2.2.1 Office assessment will begin with an opening meeting for explaining the purpose and scope assessment and the methodology of the assessment. The actual assessment process will cover verification of documentation system of the certification body to assess its adequacy in line with the assessment criteria as specified at A. above. It will also involve verification of records of competence of the employed and contracted personnel of the certification body for different streams of Traditional medicine. This verification includes the records of the Examiners employed and the selection process used for selecting them. The assessment will cover the entire certification process and the team will verify the relevant records and demonstration of personnel competence through means like interviews. In short, it will be an assessment for verifying generic and technical competence of the body for operating a sound certification system for certification of THPs.

B. 2.2.2 During the assessment or on demand at any time, the applicant body is required to provide unrestricted access to the documents that pertain to the certification process and the scope applied for.

B.2.2.3 At the end of the office assessment process through a formal closing meeting, all the gaps observed in certification body's system and competence requirements in line with the assessment criteria and the assessment team's recommendation to QCI, shall be informed to the applicant organization.

B. 2.2.4 The team shall submit its assessment report to QCI, who would review it and take a decision on approval. The approval or otherwise shall be duly communicated to the applicant.

B. 2.2.5. If necessary, QCI may decide based on the report of office assessment or otherwise, to undertake witness assessments of actual certifications by the applicant certification body.

B. 2.2.6 The approval shall be valid for a period of one year during which the certification body will be required to obtain formal accreditation as per ISO 17024 from NABCB. In case it

is decided to extend the period of validity, the certification body shall be liable to an assessment prior to such an extension.

B. 3 Granting of Approval

B. 3.1 The approval is granted to an applicant after the following conditions have been met by the applicant body.

a. The applicant meets the criteria of approval and all gaps found against the criteria of approval during assessment, have been closed within a reasonable time, to the satisfaction of QCI.

b. There are no adverse reports/information on judicial proceedings/de-recognition/blacklisting/ complaints.

c. The clients of the applicant body are satisfied by the conduct of the applicant body and its certification system. QCI may request feedback from selected clients of the certification body /publicize receipt of application and seek a feedback from stakeholders.

d. The applicant body has paid all assessment related dues.

B. 3.2 In the event of any adverse issue arising from the reasons specified at points b. and c., the applicant body will be given an opportunity to explain its position to QCI before a decision is taken in respect of grant of approval.

B. 4 Maintaining of Approval

B. 4.1 The approval is maintained for 3 year under the following conditions:

a. The approved body continues to meet the criteria of approval.

b. At least one actual certification is witnessed and is satisfactory.

c. There is no adverse report/information/complaint with the QCI about the approved body regarding the implementation of certification system as per the criteria.

d. The clients of the approved body are satisfied by the conduct of the applicant body and its certification system.

e. The approved certification body has to begun the process of getting accredited against the requirements of ISO 17024.

B. 4.2 In the event of any adverse issue arising from the reasons specified at points b.and c. above, the approved body will be given an opportunity to explain its position to QCI, before a decision is taken in respect of maintaining of the approval.

B.4.3 QCI at its discretion may conduct a short notice assessment or witness actual certifications during the period of approval

B. 5 Suspension/Withdrawal of approval

B. 5.1 QCI reserved the right to visit any approved certification body during the period of approval for any reason and to suspend or withdraw approval after giving due notice to the certification body.

B.6 Extension of Scope

B.6.1 The Certification body may apply for extension of scope during the period of validity. QCI will decide based on the request and other information submitted on the need for onsite/witness assessment and/or offsite review which shall be charged.

B.6.2 The period of approval shall remain one year from the date of initial approval.

B.7 Fee

B.7.1 There shall be no application fee.

B.7.2 The assessments shall be charged at Rs. 20000/- per man-day plus travel and stay for the assessment team at actuals.

B.8 Appeal

The certification body may make an appeal to the Secretary General, QCI in case it is dissatisfied with any decision of QCI. The appeal shall be considered independent of the personnel involved in the decision.