

VOLUNTARY CERTIFICATION SCHEME FOR MEDICINAL PLANT PRODUCE

REQUIREMENTS FOR CERTIFICATION BODIES

1. Scope

1.1 This document describes the requirements the Certification Bodies (CBs) are expected to meet in order to be approved under the Scheme for undertaking certification.

2. General Requirements

2.1 The Certification Body shall be registered as a legal entity in India, or 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.

2.2 The Certification Body shall be accredited to ISO/IEC Guide 65 by NABCB/approved by QCI for its Produce certification for this Scheme.

2.3 The Certification Body shall ascertain produce conformity to the applicable Certification criteria.

2.4 Certification agreement

2.4.1 The certification body shall have a legally enforceable agreement for the provision of certification activities to its clients. Contracts and agreements for certification shall take into account the responsibilities of the parties.

2.4.2 The certification body shall ensure their certification agreement require that the client comply with the following:

- a) always fulfil the certification requirements including produce requirement and changes communicated by the certification body;
- b) the certified produce always fulfils the requirements;
- c) makes all necessary arrangements for the conduct of the evaluation, including provision for examining documentation and records, and access to the relevant location(s), area(s), and personnel and for investigation of complaints;
- d) makes claims regarding certification only in respect of the scope for which certification has been granted;
- e) does not use its certification in such a manner as to bring the certification body into disrepute and does not make any statement regarding its certification which the certification body may consider misleading or unauthorized;
- f) upon suspension or cancellation/withdrawal of certification, discontinues its use of all advertising matter that contains any reference thereto and returns as required by the certification scheme any certification documents and takes any other measure;
- g) endeavours to ensure that no certificate or report nor any part thereof is used in a misleading manner;
- h) if the client provides copies of the certification documents to others, the documents shall be reproduced in their entirety
- i) in making reference to its medicinal produce certification in communication media such as documents, brochures or advertising, complies with the requirements of the certification body if applicable ;
- j) uses the certification mark only on produce it has found to comply with the requirements if applicable;
- k) applies a mark to each certified produce, or to produce packaging, or on information accompanying each produce if applicable;
- l) keeps a record of all complaints made known to the client relating to the compliance with certification requirement and to make these records available to the certification body when requested, and
 - i) takes appropriate action with respect to such complaints and any deficiencies found in produces, processes or services that affect compliance with the requirements for certification;
 - ii) Document the actions taken.
 - iii) Verification by the certification body of (l) is performed only when certification scheme mandates it.

- m) The client shall inform the certification body, without delay, of matters that may affect ability to conform to the certification requirements.

2.5 Responsibility for certification decisions

2.5.1 The certification body shall be responsible for and shall retain authority for its decisions relating to certification. This includes the granting, maintaining, recertifying, extending, reducing, suspending and withdrawing of certification.

2.5.2 The certification body shall only grant authority to make a certification decision, or any decision in the handling of complaints and appeals, to an individual or group that is impartial with respect to the produce.

2.6 Management of impartiality

2.6.1 The certification body shall have top management commitment to impartiality.

2.6.2 The certification body shall make a publicly available statement that it understands the importance of impartiality in carrying out its certification activities manages conflict of interests and ensures the objectivity of its certification activities.

2.6.3 The body shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. A relationship that threatens the impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing and payment of a sales commission or other inducement for the referral of new clients, etc. However, such relationships do not necessarily present a body with a risk to impartiality.

2.6.4 If a risk to impartiality is identified, the body shall be able to demonstrate how it eliminates or minimizes such risk.

2.6.5 When a relationship poses an unacceptable threat to impartiality (such as a wholly owned subsidiary of the certification body requesting certification from its parent or the same when the certification body belongs to a corporation or holding and other parts of it, the requests for certification to its related certification body), then certification shall not be provided.

2.6.6 Certification bodies shall document how they manage their certification business and any other activities so as to eliminate actual conflict of interest and minimize any identified risk to impartiality. This information shall be made available to the mechanism specified in the documentation shall cover all potential sources of conflict of interests that are identified, whether they arise from within the certification body or from the activities of other persons, bodies or organizations.

2.6.7 The certification body and any group within its control or personnel employed or contracted, in an organization within its control shall not offer or provide consultancy on the product that it certifies.

2.6.8 The certification body and any group within its control or personnel employed or contracted, in an organization within its control shall not offer or provide training on the aspects that it certifies.

2.6.9 The certification body is allowed to explain its findings and/or clarify the requirements of the normative documents but shall not give prescriptive advice or consultancy as part of an evaluation. This does not preclude normal exchange of information with the clients and other interested parties or the provision of different determination activities e.g. inspection, testing, audit, required for specific product certification schemes which is considered acceptable.

2.6.10 The certification body and (and any group within its control; or personnel, employed or contracted, in an organization within its control or organizational control) shall not offer or provide internal management system evaluations to the client or other legal entities involved in the certification process in those schemes that require the client or other legal entities involved in the certification process to perform internal management system evaluations. This also applies to that part of government identified as the certification body.

2.6.11 The certification body shall not certify GAP/GFCP on which a client has received consultancy or internal evaluations, where the relationship between the consultancy organization and the certification body poses an unacceptable threat to the impartiality of the certification body. Allowing a minimum period of two years to elapse following the end of the consultancy is one way of reducing the threat to impartiality to an acceptable level.

2.6.12 The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides consultancy. The certification body shall take action to correct inappropriate claims by any consultancy organization stating or implying that certification would be simpler, easier, faster or less expensive if the certification body were used. A certification body shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

2.6.13 To ensure that there is no conflict of interests, personnel who have provided consultancy for, or been employed by a client, including those acting in a managerial capacity, shall not be used by the certification body to make a certification decision nor resolution of a complaint or appeal for that client within two years following the end of the consultancy or employment.

2.6.14 The certification body shall take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organizations

2.6.15 All certification body personnel, either internal or external, or committees, who could influence the certification activities, shall act impartially and shall not allow commercial, financial or other pressures to compromise impartiality.

2.6.16 The certification body shall not provide any service to the clients other than third party conformity assessment.

2.7 Mechanism for safeguarding impartiality

2.7.1 The certification body shall safeguard the impartiality of its activities and shall provide for an Impartiality Committee mechanism through which significantly interested parties like producer, suppliers, users, consumers and conformity assessment experts, can provide input on:

- a) the policies and principles relating to the impartiality of its certification activities,
- b) counteracting any tendency on the part of a certification body to allow commercial or other considerations to prevent the consistent impartial provision of certification activities,
- c) matters affecting impartiality and confidence in certification, including openness and public perception

2.7.2 The terms of reference, duties, authorities and responsibilities of the mechanism shall be formally documented to ensure:

- a) representation of a balance of interests such that no single interest predominates (internal or external personnel of the certification body are considered to be a single interest, and shall not predominate),
- b) access to all the information necessary to enable it to fulfill all its functions (see 2.6.6)

2.7.3 If impartiality is not being achieved by the certification body, the mechanism will be authorized to take appropriate action (e.g. informing authorities, accreditation bodies, and stakeholders). In taking appropriate action, the confidentiality requirements of 2.19 relating to the client and certification body shall be respected.

2.7.4 Although every interest cannot be represented in the mechanism, a certification body shall identify and invite key interests.

2.7.5 The meetings of the Impartiality Committee may be witnessed by NMPB/NABCB and/or they may seek representation on the same which shall be provided by the Certification body.

2.8 Liability and financing

2.8.1 The certification body shall have the financial stability and resources required for the operation of the certification system.

2.8.2 The certification body shall evaluate the risks arising from its certification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations.

2.8.3 The certification body shall together with its senior executive and staff, be free from any commercial, financial and other pressures which might influence the results of the certification process

2.9 Resource requirements

2.9.1 Competence of management and personnel

2.9.1.1 The certification body shall have processes to ensure that personnel have appropriate knowledge of medicinal plant produce, produce certification, produce standards, related normative references and relevant Regulations for the produce for which certification is being offered.

2.9.1.2 It shall determine the competence required for each technical area of medicinal plant produce and for each function in the certification activity.

2.9.1.3 It shall determine the means for the demonstration of competence prior to carrying out specific functions.

2.9.1.4 In determining the competence requirements for its personnel performing certification, the certification body shall address the functions undertaken by management and administrative personnel in addition to those directly performing evaluations, and certification activities.

2.9.1.5 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.

2.9.2 Personnel involved in the certification activities

2.9.2.1 The certification body shall have, as part of its own organization, personnel having sufficient competence for managing the agricultural/medicinal plant produce certification scheme.

2.9.2.2 The certification body shall employ, or have access to, a sufficient number of evaluators and technical experts to cover all of its activities and to handle the volume of medicinal plant produce certification evaluations performed.

2.9.2.3 The certification body shall make clear to each person concerned their duties, responsibilities and authorities.

2.9.2.4 The certification body shall have defined processes for selecting, training, formally authorizing evaluators and for selecting technical experts used in the certification activity. The initial competence evaluation of an evaluator shall include a demonstration of applicable personal attributes and the ability to apply required knowledge and skills during evaluations, as determined by a competent evaluator or observing the evaluator conducting an evaluation. (See cl. 2.9.2.16 for competence requirements of evaluators)

2.9.2.5 The certification body shall have a process to achieve and demonstrate effective evaluation.

2.9.2.6 The certification body shall ensure that evaluators (and, where needed, technical experts) are knowledgeable of its evaluation processes, certification requirements and other relevant requirements. The certification body shall give evaluators and technical experts access to an up-to-date set of documented procedures giving instructions and all relevant information on the certification activities.

2.9.2.7 The certification body shall identify training needs and shall offer or provide access to specific training to ensure its evaluator, technical experts and other personnel involved in certification activities are competent for the functions they perform.

2.9.2.8 The group or individual that takes the decision on granting, maintaining, renewing, extending, reducing, suspending or withdrawing certification shall understand the applicable standard and certification requirements, and shall have demonstrated competence to evaluate the processes and related recommendations of the evaluation team.

2.9.2.9 The certification body shall ensure the satisfactory performance of all personnel involved in the evaluation and certification activities. There shall be documented procedures and criteria for monitoring and measurement of the performance of all persons involved, based on the frequency of their usage and the level of risk linked to their activities. In particular, the certification body shall review the competence of its personnel in the light of their performance in order to identify training needs.

2.9.2.10 The documented monitoring procedures for evaluators shall include a combination of on-site observation, review of evaluation reports and feedback from clients or from the market and shall be defined in documented requirements drawn up in accordance with the relevant guidance provided in ISO 19011. This monitoring shall be designed in such a way as to minimize disturbance to the normal processes of certification, especially from the client's viewpoint.

2.9.2.11 The certification body shall periodically observe the performance of each evaluator on-site. The frequency of on-site observations shall be based on need determined from all monitoring information available.

2.9.2.12 The personnel performing the application review shall be qualified for their understanding of the certification criteria, regulatory requirements, evaluation methods and the certification scheme.

2.9.2.13 The personnel performing the certification decision shall be qualified for their understanding of the certification criteria, certification scheme and their ability to correctly grant or expand the scope of certification (if a scope of certification is used) on the basis that the evaluation activities, information and results are a demonstration of fulfilment of requirements of the certification criteria in accordance with the certification scheme.

2.9.2.14 **Competence of evaluators** - Every person undertaking medicinal plant produce certification evaluations must have the appropriate qualification, training, experience and skills to perform an evaluation against the relevant criteria for certification.

a) Education- The certification body shall ensure that evaluators have the knowledge corresponding to a post-secondary education in agriculture including knowledge of basic processes. The education includes courses in agriculture in which they conduct evaluation of medicinal plant produce. An appropriate higher educational qualification such as a degree or diploma in agriculture is acceptable.

b) Work Experience- The evaluators shall have at least 5 years of full time post qualification experience with agricultural produce handling including at least two years of work in quality assurance within agricultural produce handling, retailing, inspection or enforcement, or the equivalent.

c) Evaluator 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 10 evaluations in at least 5 organizations for agricultural produce 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.

2.9.2.16 For the first time qualification, an ISO 9001/ISO 22000/GAP audit experience or inspection experience in either agriculture or plantation crops is acceptable.

2.9.3 Use of individual external evaluators and external technical experts

2.9.3.1 The certification body shall normally not use external evaluators except in exceptional situations with a recorded justification. It may however use external technical experts. It shall require external evaluators and technical experts to have a written agreement by which they commit themselves to comply with applicable policies and procedures as defined by the certification body. The agreement shall address aspects relating to confidentiality and to independence from commercial and other interests. It shall require the external evaluators and external technical experts to disclose any relationship or situation which may pose a risk to the impartiality of the certification body and notify the certification body of any existing or prior association with any organization they may be assigned to evaluate.

2.10 Outsourcing.

2.10.1 The CB shall not outsource any activity other than testing.

2.10.2 When the certification body outsources testing, the body doing the outsourced work shall meet the applicable requirements of ISO/IEC 17025 and shall be NABL accredited or evaluated by the CB for compliance to ISO 17025.

2.11 Selection of the evaluation team

2.11.1 The evaluation team shall comprise of duly qualified evaluators meeting the competence requirements prescribed above. The CB shall ensure the competence of the evaluation team. The evaluation team shall have appropriate knowledge of the medicinal plant produce, the process and the Good Agricultural/Collection practices adopted.

2.11.2 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 GAP/GFCP.

2.11.3 A Technical expert shall be a part of every Evaluation Team where the process have been identified as highly technical, for ensuring the competence of the evaluation team..

2.12 Determination of evaluation time

2.12.1 The certification body shall have documented procedures for determining time required for on site evaluation. The on site evaluation time determined by the certification body, and the justification for the determination, shall be recorded. In determining the on site evaluation time, the certification body shall consider, among other things, the complexity of operations and the number of products offered for certification.

2.12.2 The certification body shall not carry out any on site evaluation of duration lesser than one day. This includes all evaluations including those for surveillance, extension of scope etc.

2.13 Publicly available information

2.13.1 The certification/inspection body shall maintain a website for providing information about its services.

2.13.2 The certification body shall maintain and make publicly accessible, or provide upon request, information describing its evaluation processes and certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and about the certification activities and geographical areas in which it operates.

2.13.3 Information provided by the certification body to any client or to the marketplace, including advertising, shall be accurate and not misleading.

2.13.4 The certification body shall make publicly available a directory of clients including applicants and provide as minimum, information on name, address, contact details, scope of certification, and status of certificate.

2.13.5 The certification body shall make publicly available the list of suspended/withdrawn certificates.

2.14 Certification documents

2.14.1 The certification body shall provide certification documents to the certified client by any means it chooses.

2.14.2 The effective date on a certification document shall not be before the date of the certification decision.

2.14.3 The certification document(s) shall identify the following:

- a) the name and geographic location of each client who have been certified under the product certification scheme ;
- b) the dates of granting, extending or renewing certification;
- c) the expiry date or recertification due date consistent with the recertification cycle;
- d) a unique identification code;
- e) the certification criteria document, including issue number and/or revision, used for evaluation of the certified client and the products ;
- f) the scope of certification with respect to product , as applicable at the site;
- g) the Certification mark for which certified;
- h) the name, address of the certification body,
- i) other marks (e.g. accreditation symbol) may be used provided they are not misleading or ambiguous;
- j) any other information required by the certification criteria document used for certification;
- k) in the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents.

2.15 Directory of certified clients

2.15.1 The certification body shall maintain and make publicly available a directory of valid certifications that as a minimum shall show the name, relevant certification criteria (normative document), scope and geographical location (e.g. city and country) for each certified client.

2.16 Reference to certification and use of marks

2.16.1 The certification body shall ensure that the applicants are not applying the Certification mark on products prior to certification.

2.16.2 The certification body shall ensure that the Certification mark is affixed only to produce covered under the scope of the certificate.

2.16.3 The certification body shall ensure that the size, colour of the Certification mark is as prescribed.

2.16.4 The certification bodies shall monitor the usage and application of the Certification Mark(s) by the clients.

2.16.5 The certification body shall not allow the accreditation mark to be used on products.

2.17 Confidentiality

2.17.1 The certification body shall, through legally enforceable agreements, have a policy and arrangements to safeguard the confidentiality of the information obtained or created during the performance of certification activities at all levels of its structure, including committees and external bodies or individuals acting on its behalf.

2.17.2 The certification body shall inform the client, in advance, of the information it intends to place in the public domain. All other information, except for information that is made publicly accessible by the client, shall be considered confidential.

2.17.3 The certification/inspection body shall provide previous reports and/details to other certification/inspection bodies in case of change of certification/inspection bodies. It shall inform the

client that in case of change of certification/inspection body, it shall provide information to other certification/inspection bodies, as required under this Scheme.

2.17.4 Except as required in this document, information about a particular client or individual shall not be disclosed to a third party without the written consent of the client or individual concerned. Where the certification body is required by law to release confidential information to a third party, the client or individual concerned shall, unless regulated by law, be notified in advance of the information provided.

2.17.5 Information about the client from sources other than the client (e.g. complainant, regulators) shall be treated as confidential, consistent with the certification body's policy.

2.17.6 Personnel, including any committee members, contractors, personnel of external bodies or individuals acting on the certification body's behalf, shall keep confidential all information obtained or created during the performance of the certification body's activities.

2.17.7 The certification body shall have available and use equipment and facilities that ensure the secure handling of confidential information (e.g. documents, records).

2.17.8 When confidential information is made available to other bodies (e.g. accreditation body, agreement group of a peer assessment scheme), the certification body shall inform its client of this action.

2.18 Information exchange between a certification body and its clients

2.18.1 Information on the certification activity and requirements- The certification body shall provide and update clients on the following:

- a) a detailed description of the initial and continuing certification activity, including the application, initial evaluation, surveillance evaluation, and the process for granting, maintaining, reducing, extending, suspending, withdrawing certification and recertification;
- b) the certification criteria defined by the standard for certification to clients whose produce has been certified;
- c) information about the fees for application, initial certification and continuing certification;
- d) the certification body's requirements for prospective clients
 - i) to comply with certification requirements,
 - ii) to make all necessary arrangements for the conduct of the on site evaluations, including provision for examining documentation and the access to all processes and areas, records and personnel for the purposes of initial certification, surveillance, recertification and resolution of complaints, and
 - iii) to make provisions, where applicable, to accommodate the presence of observers (e.g. accreditation auditors or trainee evaluators);
- e) documents describing the rights and duties of certified clients, including requirements, when making reference to its certification in communication of any kind;
- f) information on procedures for handling complaints and appeals.

2.18.2 Notice of changes by a certification body - The certification body shall give its certified clients due notice of any changes to its requirements for certification. The certification body shall verify that each certified client complies with the new requirements.

2.18.3 Notice of changes by a client - The certification body shall have legally enforceable arrangements to ensure that the certified client informs the certification body, without delay, of matters that may affect the capability of the clients system to continue to fulfil the requirements of the standard used for certification. These include, for example, changes relating to

- a) the legal, commercial, organizational status or ownership,
- b) organization and management (e.g. key managerial, decision-making or technical staff), c) production sites,
- d) scope of operations under certification, and
- e) major changes to the production unit and processes.

2.19 Transfer of Certification

2.19.1 Certificates granted by an approved CB are eligible for transfer to another approved CB.

2.19.2 Transfer should normally only be of a current valid accredited certificate but, in the case of a certificate issued by a certification body that has ceased trading, or that has had its accreditation withdrawn, the accepting certification body may, at its discretion, consider such a certificate for transfer on the basis described in this guidance.

2.19.3 The accepting Certification body shall ascertain the reasons for seeking a transfer, establish that the client's certified activities fall within the accredited scope of the accepting certification body.

2.19.4 The accepting certification body shall verify the validity of certification, status of outstanding nonconformities with the issuing certification body unless it has ceased trading. Outstanding nonconformities should be closed out, if practical, with the issuing certification/registration body, before transfer. Otherwise they should be closed out by the accepting certification/registration body.

2.19.5 Certificates which are known to have been suspended or to be under threat of suspension should not be accepted for transfer.

2.19.6 The accepting certification body shall issue a certificate, dated from the date of completion of the review, following the normal decision making process.

3. Obligations of the product certification body approved under the Scheme

3.1 The approved product certification body shall commit to fulfill continually the requirements for approval set by National Medicinal Plant Board, Department of Ayush for the areas where approval is sought or granted.

3.2 The approved product certification body shall claim approval only with respect to the scope for which it has been granted accreditation.

3.3 The approved certification body shall not use and permit the use of the Mark in such a manner as to bring National Medicinal Plant Board, Department of Ayush or QCI into disrepute.

3.4 The approved certification body shall inform without delay, any significant changes relevant to its accreditation, 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,
- d) resources and premises,
- e) scope of accreditation, and
- f) other such matters that may affect the ability of the CB to fulfill requirements for accreditation.