

INDIAN CERTIFICATION FOR MEDICAL DEVICES (ICMED)

Provisional Approval System for Certification Bodies



	SECTION	CONTENTS	PAGE
0	Introduction		3
1	Scope		3
2	Criteria for approval		3
3	Procedure		4
4	Fee		6

0. Introduction

- 0.1** The Certification Bodies (CBs), in order to operate under the Indian certification for medical devices (ICMED) manufacturer certification scheme, hereafter referred to as the Scheme, shall need to primarily comply with the requirements specified in ISO 17021: 2011 and ISO 17065: 2012 and the additional requirements prescribed by QCI, as the scheme owner.
- 0.2** In order to be formally accredited by the **National Accreditation Board for Certification Bodies (NABCB)** as above, the CBs, even if already accredited to ISO 17021: 2011 scope sector 19 ISO 17065: 2012 would need to undergo a limited Office Assessment of 2 man days and a Witness Assessment of an actual audit under the Scheme.
- 0.3** The CBs would not get a client unless they are approved under the Scheme and would not be able to offer an audit for witnessing and get the relevant scope added in their accreditation.
- 0.4** Further, in order to launch the Scheme it is necessary that some certification bodies are available right at the beginning.
- 0.5** Therefore, it is necessary to establish a procedure for provisional approval of CBs under the Scheme till such time they can get the scope added in their accreditation or get formally accredited from NABCB.
- 0.6** This document sets out the requirements to be fulfilled by CBs desirous of operating under the Scheme pending formal accreditation.

1. Scope

- 1.1** This document defines the process for Certification Bodies (CBs) to obtain provisional approval to operate under the ICMED Certification Schemes pending formal accreditation for the Scheme by the National Accreditation Board for Certification Bodies (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 CBs would have to obtain formal NABCB accreditation.

2. Criteria for Approval

- 2.1** The Certification Body shall be a legal entity in India, 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.

2.2 The CB shall hold NABCB accreditation for QMS certification as per ISO17021: 2011 for IAF Scope 19 and undergone a witness under NACE (Rev 1.1) DL33.1 in last accreditation cycle.

2.3 Competence

2.3.1 The auditors used by the CBs shall have the following qualifications and experience.

- (i) A graduate in Bio Technology or pharmacy or degree in Electrical Engineering or Electronics Engineering or Chemical Engineering or Bio Medical Engineering or Mechanical Engineering from a University recognized by the Central Government for such purposes.
- (ii) Desirable Two years' experience of manufacturing or research or Quality Assurance in Medical Device field.
- (iii) Auditor experience, For a first authorization, the auditor shall comply with the following criteria, which shall be demonstrated in audits under guidance and supervision:
 - a) For ICMED 9000 - Have gained experience in the entire process of auditing medical device quality management systems, including review of documentation and risk management of medical devices, implementation audit and audit reporting. This experience shall have been gained by participation as a trainee in a minimum of two audits for a total of at least 10 days in an accredited QMS program,
 - b) Additionally for ICMED 13485, This experience shall have been gained by participation as a trainee in a minimum of two audits for a total of at least 10 days in an accredited ISO 13485 program,
 - c) In addition to criteria a) & b), audit team leaders shall have experienced an audit team leader role under the supervision of a qualified team leader at least three ISO 9001 audits for ICMED 9000 and ISO 13485 audits for ICMED 13485.
 - d) Required types of knowledge and skills for personnel involved with the ICMED 13485 certification activities are defined in Annexure "B" of IAF MD 9 shall be applicable.

NOTE: Refer IAF MD 9 for further guidance for ICMED 13485 auditor competence and experience requirements.

2.3.2 The CBs may use auditors who do not have the requisite qualifications as prescribed above provided they are supported by technical experts (TEs) who meet the qualifications at 2.3.1 a) and b) above. The time spent by the TE on an audit shall not be counted in determining the audit time as prescribed under the 'Certification Process' which the CB is expected to spend.

2.4 Publicly available information

- 2.4.1** The certification body shall maintain a website for providing information about the Scheme.
- 2.4.2** The certification body 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.
- 2.4.3** The certification body shall make publicly available information about applications registered and certifications granted, suspended or withdrawn.
- 2.4.4** On request from any party, the certification body shall confirm the validity of a given certification.

3. Procedure

- 3.1** The CB desirous of approval shall apply to QCI in the prescribed format for approval.
- 3.2** It shall submit the documents related to auditor competence system and certification process for the ICMED Certification Schemes along with its application.
- 3.3** QCI shall designate an assessment team (AT) comprising an assessor each for ISO 17021: 2011 and ISO 17065: 2012 and a technical expert to assess the competence of the CB for undertaking certification under the Scheme. The AT shall review the application and the documents specifically related to the Scheme and undertake an onsite assessment of 2 man-days (including time of the TE) and submit a report containing both review of documents as well as onsite findings. Any non-conformities/concerns observed shall be communicated to the CB at the end of the assessment for necessary action.
- 3.4** Based on the report, and the action taken by the CB on the non-conformities/concerns, if any, QCI shall take a decision on granting provisional approval to the CB.
- 3.5** The approval shall be for a period of one year within which the CB shall obtain NABCB accreditation as needed under the Scheme.
- 3.6** During the validity of approval, QCI shall undertake at least one witness assessment to confirm the CB's competence.
- 3.7** The approval shall be subject to suspension/withdrawal with due notice of 15 days in the event of any non-compliance to the requirements of the Scheme or if the NABCB accreditation for ISO 17021: 2011 and/or ISO

17065: 2012 is suspended/withdrawn.

3.8 The approved CB shall inform QCI without delay about any significant 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
- d) Resources and premises
- e) Scope of approval, and
- f) other such matters that may affect the ability of the CB to fulfil requirements for approval.

QCI shall examine such information and decide on the issue on merits with or without an on-site verification.

4. Fee

4.1 The following fee structure shall apply:

- a) Application fee Rs. 10000/-
- b) Man-day charges Rs. 20000/- per man day
- c) Travel / stay On actuals
- d) Corrective actions review Charges - 0.5 man day for each additional rounds of review after first round of proposed corrective action and acceptance

4.2 QCI at its discretion may revise/levy any other fee necessary with due notice to the CBs

