

## Section 7



# **QCI - AIMED Voluntary Initiative on Medical Devices**

## **Indian Certification of Medical Devices (ICMED) Scheme**

### **Provisional Approval System for Certification Bodies**

## Provisional Approval System for Certification Bodies

### 1. Introduction

- 1.1. The Certification Bodies (CBs), desirous of operating under the Indian Certification for Medical Devices (ICMED) Scheme, hereinafter referred to as the Scheme, shall need to primarily comply with the requirements specified in ISO 17021-1: 2015 and/or ISO17065: 2012, as applicable, and the additional requirements prescribed by QCI and AIMED, as the joint Scheme Owners.
- 1.2. 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 17021-1: 2015 for scope sector 19 and / or ISO 17065: 2012, would need to undergo a limited Office Assessment and a Witness Assessment of an actual audit under the Scheme.
- 1.3. 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.
- 1.4. Further, in order to launch the Scheme, it is necessary that some certification bodies are available right at the beginning.
- 1.5. 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.
- 1.6. This document sets out the requirements to be fulfilled by the CBs desirous of operating under the Scheme pending formal accreditation.
- 1.7. Since initially only management systems-based certification is being launched, this document covers requirements only for such certification bodies and requirements for certification bodies.

### 2. Scope

- 2.1. This document defines the process for Certification Bodies (CBs) to obtain provisional approval to operate under the Scheme for ICMED 9000, ICMED 13485 & ICMED 13485 Plus pending formal accreditation for the Scheme by NABCB as per the prescribed international standard(s).
- 2.2. This approval shall be valid for a period of one year within which the approved CBs would have to obtain formal NABCB accreditation.

### 3. Criteria for Approval

- 3.1. The CB shall be a legal entity in its economy 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.

**4. Accreditation**

- 4.1. For ICMED 9000 certification scope, the CB shall hold NABCB accreditation for QMS certification as per ISO 17021-1:2015 for IAF Scope 19 covering the scope of medical devices, NACE (Rev 1.1) DL33.1 and shall have undergone a witness for the scope in the last 3 years;
- 4.2. For ICMED 13485 scope, the CB shall be accredited for ISO 13485 certification by NABCB or be accredited for scope DL 33.1 for QMS as per ISO 17021-1:2015 and in case of latter, offer the first audit for ISO 13485 for witnessing to NABCB.
- 4.3. For ICMED 13485 Plus, the CB shall be accredited for ISO 13485 certification by NABCB or be accredited for scope DL 33.1 for QMS as per ISO 17021-1:2015 and also as per ISO 17065: 2012 and in case of latter, offer the first audit for ISO 13485 for witnessing to NABCB.

**5. Competence**

- 5.1. The CBs auditors for the Scheme ICMED 9000 shall have the qualifications and experience as described in document “ICMED – Requirements for CBs”, Section 5.
- 5.2. The CBs auditors for the Scheme ICMED 13485 and ICMED 13485 Plus shall have the qualifications and experience as described in document “ICMED – Requirements for CBs”, Section 5 and in scheme document “ICMED – CBs Auditor Competence Requirements”, Section 6 to 10.

**6. Publicly Available Information**

- 6.1. The certification body shall maintain a website for providing information about the Scheme.
- 6.2. 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.
- 6.3. The certification body shall make publicly available information about applications registered and certifications granted, suspended or withdrawn.
- 6.4. On request from any party, the certification body shall confirm the validity of a given certification.

**7. Procedure**

- 7.1. The CB desirous of approval shall apply to QCI in the prescribed format for approval.
- 7.2. It shall submit the documents related to auditor competence system and certification process for the ICMED Schemes along with its application.
- 7.3. QCI shall designate an assessment team (AT) comprising an assessor for ISO 17021-1: 2015 or/ 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 office assessment as per defined man-day and fee structure to verify competence and review certifications done 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.

- 7.4. 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.
- 7.5. The approval shall be for a period of one year within which the CB shall obtain NABCB accreditation as needed under the Scheme.
- 7.6. During the validity of approval, QCI shall undertake at least one witness assessment to confirm the CB's competence until it obtains NABCB accreditation.
- 7.7. 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 17021-1: 2015 or/and ISO 17065:2012 is suspended/withdrawn.
- 7.8. 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;
  - 7.8.1. Its legal, commercial, ownership organizational status,
  - 7.8.2. The organization, top management and key personnel
  - 7.8.3. Main policies
  - 7.8.4. Resources and premises
  - 7.8.5. Scope of approval, and
  - 7.8.6. 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.

## 8. **Fee**

- 8.1. The following fee structure shall apply:

Application fee	Rs. 20,000/-
Man-day charges	Rs. 20,000/- per man day
Travel / stay	on actuals

Corrective actions review Charges – shall be charged after one round of review based on extent of review required. In addition, QCI shall charge fee per certificate for certified clients through approved CBs.

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