Accreditation Criteria

for
Medical devices - Quality management systems - for regulatory purposes Certification

BCB 135 – October 2012

Contents

Date Effective - 10 October 2012

0. Foreword:

The Government of India and the Indian Industry came together to establish the accreditation system in response to the needs of the industry and the certification bodies of Management Systems (QMS, EMS and other Management Systems) who were largely dependent on the accreditation systems of Europe and USA.

A Council with representation from the Government, Industry, Certification Bodies, Non Government Organizations (NGOs) etc. was formed and named as the **Quality Council of India (QCI)**. This Council was entrusted with the task of establishing the accreditation system in India. A **National Accreditation Board for Certification Bodies (NABCB)** was established to implement the accreditation of the Certification/Inspection Bodies.

The NABCB has already published Accreditation Criteria and corresponding Guidance documents for QMS, EMS, FSMS, Inspection and Product Certification Bodies. The Medical Device Quality Management Systems (MDQMS) scheme has been developed to support accredited certification against the requirements of ISO 13485 - Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 13485 is a management system standard established to assist organisations that needs to consistently demonstrate regulatory and customer requirements for the delivery of medical devices and related services.

IAF mandatory document IAF MD 09 have been adopted to facilitate harmonization of certification process in India and signing of mutual/multilateral agreements with other countries, regional and international forums in future.

ISO 13485 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

ISO 13485 is based on ISO 9001; but includes some particular requirements for medical devices and excludes some ISO 9001 requirements that were determined not to be appropriate as regulatory requirements. These differences mean that those organisations certified to ISO 13485 cannot also claim ISO 9001 certification without meeting these additional requirements.

1. Scope:

This document specifies the requirements that a third party body operating an **Medical devices - Quality management systems** (MDQMS) Certification Programme shall meet if it is to be recognized by the Board as competent and reliable in the operation of MDQMS Certification.

2. Criteria

The Certification Bodies seeking accreditation for Medical Devices Quality Management Systems Certification shall comply with the requirements specified in ISO/IEC 17021

supplemented by IAF MD 09- **Medical devices - Quality management systems (ISO 13485).**

Scheme documents IAF MD 9, has been developed by the International Accreditation Forum (IAF). This document supplements the requirements for Certification Bodies in ISO/IEC 17021 including specific competencies for certification body personnel

A copy of the **IAF MD 9 documents** can be down loaded from the publications section of the IAF website - http://www.iaf.nu free of cost.

3. IAF MD 09:

The Board has adopted the IAF mandatory document **MD 09** as the criteria document of NABCB. Certification Bodies accredited to offer ISO 9001 Certification can seek an extension of scope to cover ISO 13485. Certification bodies not accredited to certify ISO 9001 Quality Management System may choose to apply only for ISO 13485 accreditation.

4. Scope of Accreditation

The Board has decided to adopt IAF MD 09 documents.

5. Certification Body (CB) Competence

5.1 Accreditation by NABCB signifies that the certification body is competent to offer MDQMS certification as per IAF MD 09 and ISO/IEC 17021. The competence of the CB shall be established by assessing compliance to relevant provisions of IAF MD 09 document.

5.2 The CB shall have a procedure for initial qualification and subsequent monitoring of its auditors and experts based on ISO 17021: 2011 and the specific requirements given in IAF MD 09.

6. Time of the Audits undertaken by the Certification Body

The Certification body shall have procedures to determine the audit man days required for audit for initial assessment, surveillance and reassessment. The procedure shall also include the policies for estimation of audit duration for multisite organizations and transfer of certificates, as needed

The CB shall give due consideration to the IAF guidance document MD 09: 2011 on the audit man days that are normally required for audit to verify compliance to ISO 13485 standard in designing its system as above.

7. Procedure for accreditation

7.1 For certification Bodies accredited to offer ISO 9001 certification, an office assessment to evaluate compliance to IAF MD 9 would be conducted followed by one witnessing. The rules for witnessing would be as in QMS accreditation procedure BCB 201. It is a requirement that the

certification body has at least 2 clients in the medical devices area and are in a position to demonstrate major certification processes during the office assessment.

7.2 For certification Bodies not accredited to offer ISO 9001 certification, the procedure outlined in BCB 201 would be followed.

Amendment Record

Date	Auth. by	Description of Amendment