Accreditation Criteria

for

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

BCB 135 – Jan 2026

Effective: Immediate

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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 documents for Certification Bodies (CBs) for BCB 101 for QMS, BCB 105 for EMS, BCB 115 for FSMS, BCB 125 for ISMS, BCB 130 for OHSMS, BCB 140 for EnMS, BCB 145 for ITSMS, BCB 110 for Inspection Bodies, BCB 120 for Product Certification Bodies and BCB 150 Personnel Certification Bodies. The Medical Device Quality Management Systems (MDQMS) accreditation scheme has been developed to support accredited certification against the requirements of ISO 13485:2016 - Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 13485:2016 is a management systems standard established to assist organisations that need to consistently demonstrate regulatory and customer requirements for the delivery of medical devices and related services.

ISO 13485:2016 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 13485:2016 cannot claim ISO 9001 certification without meeting these additional requirements.

NABCB has also adopted IAF mandatory documents IAF MD 9 to facilitate harmonization of certification process in India and signing of mutual/multilateral agreements with other countries, regional and international forums in future.

1. Scope:

This document specifies the requirements that a third party body operating the 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 17021-1:2015

A copy of ISO/IEC 17021-1 can be obtained from the Bureau of Indian Standards or from ISO Secretariat.

3. Adoption of IAF/APAC documents:

The Board has adopted the IAF mandatory document **MD 9** as the criteria document of NABCB in addition to ISO/IEC 17021-1:2015.

A copy of the IAF MD 9 document can be down loaded from the publications section of the IAF

website - http://www.iaf.nu free of cost.

4. Scope of Accreditation

The Board has decided to adopt scopes as described in Annex 1 of IAF MD 8 document.

5. Certification Body (CB) Competence

5.1 Accreditation by NABCB signifies that the certification body is competent to offer MDQMS certification as per ISO 13485:2016. The competence of the CB shall be established by assessing compliance to the provisions of ISO/IEC 17021-1:2015 Standard and IAF MD 9 document.

5.2 The CB shall have a procedure for initial qualification and subsequent monitoring of its auditors and experts based on ISO/IEC 17021-1:2015 and the specific requirements given in IAF MD 9.

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 mandatory document MD 9 on the audit man days that are normally required for audit to verify compliance to ISO 13485:2016 standard in designing its system as above.

7. Transition Provisions

NABCB shall adopt transition policy enunciated by IAF from time to time in case of revision of any document which forms part of accreditation criteria or certification. If need be, it would bring out its own transition policies in line with IAF policies.

Note: For undated references, the latest edition of the referenced document (including any amendments) applies.

Amendment Record

Date	Auth. by	Description of Amendment
Sep 2017	CEO	Aligned with revision of IAF MD 9 and ISO 17021-1:2015
June 2018	CEO	Aligned with revision of IAF MD 9:2017
Mar.2019	CEO	To include adoption of IAF/APAC Requirements
Dec 2023	CEO	Minor Edits based on internal review
Jan 2026	CEO	NABCB office address changed