SUBJECT: Accreditation Program for Medical Device Quality Management Systems

APPLIES TO: ISO 13485 (Medical Devices) ANAB-Accredited and Applicant Certification Bodies

PREFACE
This Accreditation Rule is to inform certification bodies (CBs) of ANAB requirements for accreditation to certify organizations for management systems conforming with ISO 13485.

ACCREDITATION RULE
1. Requirement Documents (current versions unless specified)
   1.1. ISO 13485, Medical Devices – Quality management systems – Requirements for regulatory purposes
   1.2. IAF MD 8, Application of ISO/IEC 17011 in Medical Device Quality Management Systems (ISO 13485)
   1.3. IAF MD 9, Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485)
   1.4. ISO/IEC 17021-1, Conformity assessment – Requirements for bodies providing audit and certification of management systems
   1.5. MA 5000, ANAB Accreditation Manual, and applicable ANAB Accreditation Rules
   1.6. Other IAF Mandatory Documents as applicable
2. Application Process
   2.1. CBs can obtain applications for informational use at www.anab.org.
   2.2. The application process outlined at www.anab.org must be completed via ANAB’s Enterprise Quality Manager (EQM) database when the CB is ready to apply for accreditation.
   2.3. The application fee includes the cost of one assessor day for the off-site documentation review.
3. Initial Assessments for Accreditation
   3.1. An ANAB accreditation assessor shall conduct a full documentation review.
   3.2. After the documents are found acceptable, ANAB shall conduct an office assessment and required witnessed audits.
      3.2.1. The office assessment normally shall be conducted on site or remotely (at ANAB’s discretion) and is conducted to ensure the CB’s certification process for ISO 13485 conforms with ISO/IEC 17021-1 and IAF MD 9 and is effective.
      3.2.2. ANAB shall witness the CB conducting a two-stage audit process (stage 1 and stage 2).
         3.2.2.1. The ANAB assessment team shall have the same number of members as the CB audit team.
4. Surveillance Assessments

4.1. ANAB shall conduct an annual office assessment and annually witness a CB team conducting an ISO 13485 audit.

4.1.1. When possible, the office assessment shall be conducted concurrently with assessments for other ANAB accreditation programs for which the CB is accredited.

4.1.2. During the accreditation cycle, ANAB shall evaluate the CB’s full system audit process during at least one annual witnessed audit (stages 1 and 2 certification audit or recertification). The additional witnessed audits required in the accreditation cycle are based on the CB’s audit activity and management system findings, and include audit types such as surveillance, special, multi-site, scope expansion, transfer, integrated, ASRP, and/or CAAT. ANAB Accreditation Rule 18 outlines the witnessed audit scheduling process and the process for potentially altering the types of audits witnessed.

4.1.2.1. The number of required witnessed audits will be based on the number of main technical areas included in the CB’s scope of accreditation. During the accreditation cycle, ANAB shall witness an audit in each main technical area included in the scope of accreditation.

5. Re-accreditation Assessments

5.1. ANAB shall conduct a document review and an on-site full system office assessment at approximately six months prior to the expiration of accreditation.

6. Scope of Accreditation

6.1. The scope of accreditation shall be for the technical areas as specified in Annex A of IAF MD MD 8 and Annex 1 of IAF MD 9, and any technical area not specified in Annex A. Witnessing is required to gain accreditation for any main technical area, and the need for witnessing for any of the technical areas/product categories shall be determined on a case-by-case basis.

6.2. During the initial accreditation process, ANAB will determine the witnessing needed for the scopes sought by the CB.

6.3. To expand the scope of accreditation, the CB shall provide a completed scope application (via EQM) that includes evidence demonstrating an appropriate level of competence for the desired scopes.

6.3.2. A competent accreditation assessor or technical reviewer will review the application and documentation, including the CB’s competencies and processes for the specific scopes, and prepare a written response on the CB’s conformance, which shall result in one of the following recommendations:

a. Require a witnessed audit prior to granting the scope.

b. Grant the scope without a witnessed audit.

c. Grant the scope with a witnessed audit required at the first opportunity after accreditation.

d. Not grant the scope.