IAF Mandatory Document

Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485)

Issue 4

(IAF MD 8:2020)

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The International Accreditation Forum, Inc. (IAF) facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement among Accreditation Bodies (ABs) in order that the results issued by Conformity Assessment Bodies (CABs) accredited by IAF members are accepted globally.

Accreditation reduces risk for business and its customers by assuring them that accredited CABs are competent to carry out the work they undertake within their scope of accreditation. ABs that are members of IAF and the CABs they accredit are required to comply with appropriate international standards and the applicable IAF application documents for the consistent application of those standards.

ABs that are signatories to the IAF Multilateral Recognition Arrangement (MLA) are evaluated regularly by an appointed team of peers to provide confidence in the operations of their accreditation programmes. The structure and scope of the IAF MLA is detailed in IAF PR 4 - Structure of IAF MLA and Endorsed Normative Documents.

The IAF MLA is structured in five levels: Level 1 specifies mandatory criteria that apply to all ABs, ISO/IEC 17011. The combination of a Level 2 activity(ies) and the corresponding Level 3 normative document(s) is called the main scope of the MLA, and the combination of Level 4 (if applicable) and Level 5 relevant normative documents is called a sub-scope of the MLA.

- The main scope of the MLA includes activities e.g. product certification and associated mandatory documents e.g. ISO/IEC 17065. The attestations made by CABs at the main scope level are considered to be equally reliable.

- The sub scope of the MLA includes conformity assessment requirements e.g. ISO 9001 and scheme specific requirements, where applicable, e.g. ISO TS 22003. The attestations made by CABs at the sub scope level are considered to be equivalent.

The IAF MLA delivers the confidence needed for market acceptance of conformity assessment outcomes. An attestation issued, within the scope of the IAF MLA, by a body that is accredited by an IAF MLA signatory AB can be recognized worldwide, thereby facilitating international trade.

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Introduction to IAF Mandatory Documents

The term “should” is used in this document to indicate recognised means of meeting the requirements of the standard. An Accreditation Body (AB) can meet these in an equivalent way. The term “shall” is used in this document to indicate those provisions which, reflecting the requirements of the relevant standard, are mandatory.

APPLICATION OF ISO/IEC 17011:2017 IN THE FIELD OF MEDICAL DEVICE QUALITY MANAGEMENT SYSTEMS (ISO 13485)

This document shall be read in conjunction with ISO/IEC 17011:2017. All clauses of ISO/IEC 17011:2017 continue to apply and this document provides additional criteria to that standard. This mandatory document is exclusively for accreditation of bodies certifying to ISO 13485.

0. INTRODUCTION

ISO/IEC 17011:2017 is an International Standard that sets out the requirements for bodies operating accreditation systems for Conformity Assessment Bodies (CABs).

The objective of this document is to enable ABs to harmonize their application of ISO/IEC 17011:2017 for the accreditation of bodies providing audit and certification to ISO 13485.

This document provides normative criteria on the application of ISO/IEC 17011:2017 for the accreditation of bodies providing audit and certification of organization’s management system to ISO 13485.

This document follows the structure of ISO/IEC 17011:2017. IAF normative criteria are identified by the letters “MD” followed with a reference number that incorporates the related requirements clause in ISO/IEC 17011:2017. In all cases a reference in the text of this document to "clause XXX" refers to a clause in ISO/IEC 17011:2017 unless otherwise specified.

1. SCOPE

This document further specifies normative criteria for ABs assessing and accrediting CABs which provide audit and certification to ISO 13485, in addition to the requirements contained with ISO/IEC 17011:2017. It is also appropriate as a requirements document for the peer evaluation process for the IAF Multilateral Recognition Arrangement (MLA) among ABs.

2. NORMATIVE REFERENCES

For the purposes of this document, the normative references given in ISO/IEC 17011:2017 and the following apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17011:2017 Conformity Assessment - Requirements for accreditation bodies accrediting conformity assessment bodies.

ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes

3. TERMS AND DEFINITIONS

MD 3.1

Regulatory Authority A government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical device products marketed within its jurisdiction comply with legal requirements.

Note: Within the European Medical Devices Regulation the Regulatory Authority as defined above is titled – Competent Authority.

4. GENERAL REQUIREMENTS

4.1 Legal entity

No additional requirements for ISO 13485.

4.2 Accreditation agreement

No additional requirements for ISO 13485.

4.3 Use of accreditation symbols and other claims of accreditation

No additional requirements for ISO 13485.

4.4 Impartiality requirements

MD 4.4.5

Interested parties may include manufacturers or manufacturer associations, CABs, non-governmental organizations (NGOs), Regulatory Authorities or other organizations and users.

4.5 Financing and liability

No additional requirements for ISO 13485.

4.6 Establishing accreditation schemes

No additional requirements for ISO 13485.

5. STRUCTURAL REQUIREMENTS

No additional requirements for ISO 13485.

6. RESOURCE REQUIREMENTS

6.1 Competence of personnel

MD 6.1.2

Normative Annex 2 specifies the type of knowledge and skills that the AB shall define for specific functions.

6.2 Personnel involved in the accreditation process

No additional requirements for ISO 13485.

6.3 Personnel records

No additional requirements for ISO 13485.

6.4 Outsourcing

No additional requirements for ISO 13485.

7. PROCESS REQUIREMENTS

7.1 Accreditation requirements

No additional requirements for ISO 13485.

7.2 Application for accreditation

No additional requirements for ISO 13485.

7.3 Resource review

No additional requirements for ISO 13485.

7.4 Preparation for assessment

MD 7.4.5

In the case of initial assessment, the samples for witnessing of audits shall include one audit minimum in a higher risk class Technical Areas in each Main Technical Area (shown in Annex 1) covered under the scope of accreditation, taking into account an appropriate national or international risk classification scheme and/or criticality of the process (e.g. Sterilization or Parts or Services).

When developing a witnessing schedule, the AB should consider, among other factors, the experience of the CAB (e.g. recognized for one or more medical device regulatory scheme(s)), in an effort to rationalize the witnessing schedule. Examples of typical regulatory schemes are:

i. (EU) 2017/745/746 – European MDR/IVDR Regulations
ii. ASEAN Medical Device Directive (AMDD)
iii. National Medical Regulations that utilize ISO 13485

7.5 Review of documented information

No additional requirements for ISO 13485.

7.6 Assessment

7.6.4.1 Prior to or during the assessment, the assessment team shall appraise publicly available information published by a sample of the certification body's certified manufacturers, including but not limited to websites, that advertise or otherwise promote the medical devices within the technical category that accredited ISO 13485 certification(s) have been issued for.

7.6.4.2 The appraisal shall be utilized during the on-site assessment activities to consider whether the technologies, intended purpose(s) and classification(s) of the medical devices as ascertained in audit reports and ISO 13485 certificates is consistent with the details of these ascertained from the publicly available information.

7.7 Accreditation decision-making

No additional requirements for ISO 13485.

7.8 Accreditation information

MD 7.8.3

The accreditation certificate shall indicate the scope of accreditation which should clearly specify the Technical Areas as defined in Annex 1 – Scope of Accreditation.

7.9 Accreditation cycle

MD 7.9.3

Surveillance and reassessment shall include on-site assessment as well as witnessing.

The surveillance office assessments and witness assessment(s), unless required by regulations, shall be conducted at least once a year.

The witnessing program shall ensure, as a minimum, that one audit from each of the Main Technical Areas (shown in Annex 1) under the scope of accreditation within an accreditation cycle (surveillances and/or reassessment) is conducted prior to the expiry of accreditation. The sampling for witnessing shall give priority to higher risk technical areas.

Witness assessments should avoid the repeated witnessing of the same CAB client organization. The AB shall take into account previous results of witnessing to establish its witness strategy.

7.10 Extending accreditation

No additional requirements for ISO 13485.

7.11 Suspending, withdrawing or reducing accreditation

No additional requirements for ISO 13485.

7.12 Complaints

No additional requirements for ISO 13485.

7.13 Appeals

No additional requirements for ISO 13485.

7.14 Records on conformity assessment bodies

MD 7.14.1

Records on the CAB shall include concerns, opinions and feedback received from a Regulatory Authority on the performance of the CAB pertaining to the scope of accreditation.

8. INFORMATION REQUIREMENTS

8.1 Confidential information

No additional requirements for ISO 13485.

8.2 Publicly available information

No additional requirements for ISO 13485.

9. MANAGEMENT SYSTEM REQUIREMENTS

9.1 General

No additional requirements for ISO 13485.

9.2 Management system

No additional requirements for ISO 13485.

9.3 Document Control

No additional requirements for ISO 13485.

9.4 Records control

No additional requirements for ISO 13485.

9.5 Nonconformities and corrective actions

No additional requirements for ISO 13485.

9.6 Improvement

No additional requirements for ISO 13485.

9.7 Internal audits

No additional requirements for ISO 13485.

9.8 Management reviews

MD 9.8.2

Feedback from interested parties of clause 9.8.2 e) shall include any feedback received from Regulatory Authorities.

MD 9.8.3

Interested parties of clause 9.8.3 b) shall include Regulatory Authorities.

End of IAF Mandatory Document for the Application of ISO/IEC 17011:2017 in ISO 13485.

ANNEX 1 – SCOPES OF ACCREDITATION

(Normative)

Medical Devices Technical Areas

Important Note for the application of the Tables:

The accreditation certificate issued by the AB should use only the Main Technical Areas and Technical Areas listed below. When using technical areas **other than specified below** as scope of accreditation, the CAB shall provide a detailed description of the technical area, e.g. with a list of medical devices and include their risk classification to the AB.

Main Technical Areas in Table 1.1 – 1.6 are applicable to finished medical devices.

Where the CAB applies for a scope of Accreditation for a technical area that has "other than specified above" in the description of technical area, the CAB shall provide a list of medical devices and include their risk classification to the AB.

The information provided shall also include a concise statement of the intended purpose of the medical device.

The technical area "Other than specified" may only be used when no other category is applicable. Risk classification of Medical Devices should be determined using appropriate regulatory sources. Examples include:

i. Medical Devices Classification GHTF/SG1/N77:2012

ii. (EU) 2017/745 Annex VIII Classification Rules

iii. National Classification Regulations

Note: A finished medical device is defined as any device or accessory to any medical device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Where the CAB is seeking accreditation for a scope, which includes non-manufacturing activities or manufacturing of parts which are not categorized or clearly associated with a finished medical device, Table 1.7 shall be used for scoping.

In addition to the scope of a medical device as specified in ISO 13485, the certification body's choice to consider the goods or services as a medical device must be supported by official Guidelines or Specifications issued by a Regulatory Authority.

Table 1.1 – NON-ACTIVE MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Non-Active Medical Devices	**General non-active, non-implantable medical devices**	• Non-active devices for anaesthesia, emergency and intensive care • Non-active devices for injection, infusion, transfusion and dialysis • Non-active orthopedic and rehabilitation devices • Non-active medical devices with measuring function • Non-active ophthalmologic devices • Non-active instruments • Contraceptive medical devices • Non-active medical devices for disinfecting, cleaning, rinsing • Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) • Non-active medical devices for ingestion
	Non-active implants	• Non-active cardiovascular implants • Non-active orthopedic implants • Non-active functional implants • Non-active soft tissue implants
	Devices for wound care	• Bandages and wound dressings • Suture material and clamps • Other medical devices for wound care
	Non-active dental devices and accessories	• Non-active dental devices/equipment and instruments • Dental materials • Dental implants
	Non-active medical devices other than specified above	

Table 1.2 – ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Active Medical Devices (Non-Implantable)	**General active medical devices**	• Devices for extra-corporal circulation, infusion and haemopheresis • Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia • Devices for stimulation or inhibition • Active surgical devices • Active ophthalmologic devices • Active dental devices • Active devices for disinfection and sterilization • Active rehabilitation devices and active prostheses • Active devices for patient positioning and transport • Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) • Software, including software design for medical devices • Medical gas supply systems and parts thereof
	Devices for imaging	• Devices utilizing ionizing radiation • Devices utilizing non-ionizing radiation
	Monitoring devices	• Monitoring devices of non-vital physiological parameters • Monitoring devices of vital physiological parameters
	Devices for radiation therapy and thermo therapy	• Devices utilising ionizing radiation • Devices utilising non-ionizing radiation • Devices for hyperthermia / hypothermia • Devices for (extracorporal) shock-wave therapy (lithotripsy)
	Active (non-implantable) medical devices other than specified above	

Table 1.3 – ACTIVE IMPLANTABLE MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Active Implantable Medical Devices	**General active implantable medical devices**	• Active implantable medical devices for stimulation / inhibition • Active implantable medical devices delivering drugs or other substances • Active implantable medical devices substituting or replacing organ functions
	Implantable medical devices other than specified above	

Table 1.4 – IN VITRO DIAGNOSTIC MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
In Vitro Diagnostic Medical Devices (IVD)	**Reagents and reagent products, calibrators and control materials for:** **Clinical Chemistry** **Immunochemistry (Immunology)** **Haematology/Haemostasis/Immunohematology** **Microbiology** **Infectious Immunology** **Histology/Cytology** **Genetic Testing**	
	In Vitro Diagnostic Instruments and software	
	IVD medical devices other than specified above	

Table 1.5 – STERILIZATION METHODS FOR MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Sterilization Method for Medical Devices	**Ethylene oxide gas sterilization (EOG)**	
	Moist heat	
	Aseptic processing	
	Radiation sterilization (e.g. gamma, x-ray, electron beam)	

	Low temperature steam and formaldehyde sterilization	
	Thermic sterilization with dry heat	
	Sterilization with hydrogen peroxide.	
	Sterilization method other than specified above	

Table 1.6 – DEVICES INCORPORATING / UTILIZING SPECIFIC SUBSTANCES / TECHNOLOGIES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Devices Incorporating / Utilizing Specific Substances / Technologies	**Medical devices incorporating medicinal substances**	
	Medical devices utilizing tissues of animal origin	
	Medical devices incorporating derivates of human blood	
	Medical devices utilizing micromechanics	
	Medical devices utilizing nanomaterials	
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed	
	Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above.	

Table 1.7 – PARTS AND SERVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Parts or Services	**Raw materials**	Raw metals, plastic, wood, ceramic
	Components	Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic
	Subassemblies	Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions
	Calibration services *	Verification/confirmation services for measuring instruments, tools or test fixtures

	Distribution services	Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices.
	Maintenance services	Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks.
	Transportation services	Trucking, shipping, air transportation service in general.
	Other services	Consulting services related to medical devices, packaging services, etc.

***Organizations providing calibration services should be accredited to ISO/IEC 17025.**

Note: As for "Components, Subassemblies, Maintenance services, Other services (Consulting services related to medical devices)" listed in Main Technical Areas Table 1.7; the CAB shall be required to have accreditation of the scope of the technical areas listed in Table 1.1 - 1.6, when the degree of influence of an organization's parts or service are clearly intended to support medical devices (e.g. fasteners **marketed with a clear intent** to support implanted medical devices) or instances of contract manufacturers making nearly complete medical devices.

ANNEX 2

(Normative)

Required types of knowledge and skills for personnel involved with ISO 13485 activities

The following table specifies the type of knowledge and skills that AB shall define for specific functions.

Accreditation functions / **Knowledge and skills**	Application review	Document review	Office assessment team	Witness assessment team	Reviewing assessment reports and making accreditation decisions	Administering program
Principles and applications of quality systems.		X	X	X	X	
Understanding of applicable GHTF SG4 and SG3 documents. (Being maintained by IMDRF)			X	X		
Understanding of ISO 13485			X	X	X (Note 1)	
Understanding of general regulatory requirements relevant to medical device manufacturers.			X	X	X (Note 1)	
Overview of medical devices, their intended use, safety and risks.			X	X		
The legal framework, including the regulatory requirements, their enforcement, and the role of the auditing organization.			X	X		
Information on CAB's client products, processes and organization to determine competence needed by the audit team and for the certification decision			X			
Information on CAB's processes and organization to determine competence needed by the assessment team and for the accreditation decision						X
Understanding CAB's client's products, processes and organization				X		
Ability to confirm that the CAB's processes are appropriate to support IAF ISO 13485 scheme.		X	X	X		
Ability to confirm that the CAB is competent to			X	X	X	

conduct a certification of the manufacturers, taking into account the processes and products involved.						
Ability to determine required appropriate duration of assessment.						X
Identification of medical devices including complexities, technologies, intended use and risk classifications.			X	X		
Deployment of assessor competences and requirements.						X
Knowledge on identifying and evaluating factors that impact an appropriate certification program for a medical device manufacturer seeking certification in a regulatory environment.			X	X		
Understanding of work performed at an accredited CAB.		X	X		X	X
Understanding of IAF Mandatory Documents for ISO 13485 scheme	X	X	X	X	X	X
Understanding of ISO/IEC 17021-1		X	X	X	X	X

Note 1: It is expected that the level of understanding for this activity would be less than that of an assessment team.

Further Information

For further Information on this document or other IAF documents, contact any member of IAF or the IAF Secretariat.

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