IAF Mandatory Document

Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485)

Issue 3

(IAF MD 8:2017)

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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 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 operation of their accreditation programs. 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.

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This document shall be read in conjunction with ISO/IEC 17011:2004 and IAF/ILAC-A5, Application of ISO/IEC 17011:2004. All clauses of ISO/IEC 17011:2004 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 17011:2004 is an International Standard that sets out the requirements for bodies operating accreditation systems for Conformity Assessment Bodies.

The objective of this document is to enable Accreditation Bodies to harmonize their application of ISO/IEC 17011:2004 for the accreditation of bodies providing audit and certification to ISO 13485.

This document provides normative criteria on the application of ISO/IEC 17011:2004 for the accreditation of bodies providing audit and certification of organization's management system to ISO13485.

This document follows the structure of ISO/IEC 17011:2004. IAF normative criteria are identified by the letters "MD" followed with a reference number that incorporates the related requirements clause in ISO/IEC 17011:2004. In all cases a reference in the text of this document to "clause XXX" refers to a clause in ISO/IEC 17011:2004 unless otherwise specified.

1   SCOPE

This document specifies normative criteria for Accreditation Bodies assessing and accrediting CABs which provide audit and certification to ISO 13485, in addition to the requirements contained with ISO/IEC 17011:2004. It is also appropriate as a requirements document for the peer evaluation process for the IAF Multilateral Recognition Arrangement (MLA) among Accreditation Bodies.

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2   NORMATIVE REFERENCES

For the purposes of this document, the normative references given in ISO/IEC 17011:2004 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 17011:2004 Conformity Assessment - general requirements for accreditation bodies accrediting conformity assessment bodies.

ISO13485 Medical devices – Quality management systems – Requirements for regulatory purposes

IAF/ILAC A5 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004

IAF MD12:2016 Assessment of Certification Activities for Cross Frontier Accreditation

3   TERMS AND DEFINITIONS

MD 3.14

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   ACCREDITATION BODY

4.1   Legal responsibility

No additional requirements for ISO 13485.

4.2   Structure

No additional requirements for ISO 13485.

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4.3 Impartiality

MD 4.3.2

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

4.4 Confidentiality

No additional requirements for ISO 13485.

4.5 Liability and financing

No additional requirements for ISO 13485.

4.6 Accreditation activity

No additional requirements for ISO 13485.

5 MANAGEMENT

5.1 General

No additional requirements for ISO 13485.

5.2 Management system

No additional requirements for ISO 13485.

5.3 Document control

No additional requirements for ISO 13485.

5.4 Records

No additional requirements for ISO 13485.

5.5 Nonconformities and corrective actions

No additional requirements for ISO 13485**.**

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5.6   Preventive actions

No additional requirements for ISO 13485.

5.7   Internal audits

No additional requirements for ISO 13485.

5.8   Management reviews

MD 5.8.2

Feedback from interested parties of clause 5.8.2 d) shall include any feedback received from Regulatory Authorities.

5.9   Complaints

No additional requirements for ISO 13485.

6   HUMAN RESOURCES

6.1   Personnel associated with the Accreditation Body

No additional requirements for ISO 13485.

6.2   Personnel involved in the accreditation process

MD 6.2.1

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

6.3   Monitoring

No additional requirements for ISO 13485.

6.4   Personnel records

No additional requirements for ISO 13485.

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7   ACCREDITATION PROCESS

7.1   Accreditation criteria and information

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   Subcontracting the assessment

No additional requirements for ISO 13485.

7.5   Preparation for assessment

MD 7 5.6

In the case of initial assessment, the samples for witnessing of audits shall include an audit of the higher risk class of the Technical Areas (shown in Annex 1) covered under the scope of accreditation.

When developing a witnessing schedule, the Accreditation Body 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. Typical regulatory schemes are European Medical Devices Directives and Regulations:

   i.   Medical Device Regulation (MDR)

   ii.   In -Vitro Diagnostic Devices Directive (IVD)

   iii. Active Implantable Medical Devices Directive (AIMD)

Other jurisdictions include:

   i.   Canada – Health Canada, Canadian Medical Devices Conformity Assessment System (CMDCAS)

   ii.   Australia – Therapeutic Goods Administration, Therapeutic Goods Regulations

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Additionally other countries are adopting or considering adopting ISO 13485 into their Medical Device Regulations.

7.6   Document and record review

No additional requirements for ISO 13485.

7.7   On-site assessment

No additional requirements for ISO 13485.

7.8   Analysis of findings and assessment report

No additional requirements for ISO 13485.

7.9   Decision-making and granting accreditation

MD 7.9.5

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

7.10   Appeals

No additional requirements for ISO 13485.

7.11   Reassessments and surveillance

MD 7.11.2

The surveillance on-site office assessments shall be conducted at least once a year. Surveillance and reassessment shall include on-site assessment as well as witnessing. 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.

All premises where one or more key activities are performed shall be assessed during the accreditation cycle.

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7.12 Extending accreditation

No additional requirements for ISO 13485.

7.13 Suspending, withdrawing or reducing accreditation

No additional requirements for ISO 13485.

7.14 Records on CABs

MD 7.14.3

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

7.15 Proficiency testing and other comparisons for laboratories

No additional requirements for ISO 13485.

8 RESPONSIBILITIES OF THE ACCREDITATION BODY AND THE CAB

8.1 Obligations of the CAB

No additional requirements for ISO 13485.

8.2 Obligations of the Accreditation Body

No additional requirements for ISO 13485.

8.3 Reference to accreditation and use of symbols

No additional requirements for ISO 13485.

End of IAF Mandatory Document for the Application of ISO/IEC 17011:2004 in ISO 13485.

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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 technical areas shall be detailed.

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

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 as finished medical devices, Table 1.7 shall be used for scoping.

Any other product that does not have medical or therapeutic purposes (border line products, such as cosmetic, herbal, nutritional supplements, beauty equipment, etc.) or not directly connected to the prevention or restoration of the health state of the persons, can not be classified as a medical device. To this end, the choice of provider to fall into the classification of the medical device must be supported by a decision of the RA and indicated in official Guidelines or Specifications issued to that purpose.

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

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		• 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

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		• 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 • 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	

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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)	
	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	

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	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

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	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.

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ANNEX 2

(Normative)

Required types of knowledge and skills for personnel involved with the IAF 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						X

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for the accreditation decision						
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 conduct a certification of the manufacturers, taking into account the processes and products involved.			X	X	X	
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.

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Further Information

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