

**International Accreditation Forum,
Inc. (IAF)**



IAF Mandatory Document

**IAF Mandatory Document
for the
Application of ISO/IEC 17011 in Medical
Device Quality Management Systems
(ISO 13485)**

Issue 1

(IAF MD 8:2011)

The International Accreditation Forum, Inc. (IAF) operates programs for the accreditation of bodies that provide conformity assessment services. Such accreditation facilitates trade and reduces demand for multiple certification.

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

AB members of the IAF Multilateral Recognition Arrangement (MLA) conduct regular evaluations of each other to assure the equivalence of their accreditation programs. The IAF MLAs operate at two levels:

- The accreditation of CABs to standards including ISO/IEC 17021 for management systems certification bodies, ISO/IEC 17024 for personnel certification bodies and ISO/IEC Guide 65 for product certification bodies, is considered a framework MLA. A framework MLA provides confidence that accredited CABs are equally reliable in the performance of conformity assessment activities.
- The accreditation of CABs that also includes the specific conformity assessment standard or scheme as a scope of accreditation provides confidence in the equivalence of certification.

The IAF MLA delivers the confidence needed for market acceptance of certification. An organization or person with certification to a specific standard or scheme that is accredited by an IAF MLA signatory AB can be recognized worldwide thereby facilitating international trade.

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Name for Enquiries: John Owen, IAF Corporate Secretary

Contact: Phone: +612 9481 7343;

Email: secretary1@iaf.nu

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.

IAF Mandatory Document for the Application of ISO/IEC 17011 in Medical Device Quality Management Systems (ISO 13485)

This document shall be read in conjunction with ISO/IEC 17011 and IAF/ILAC-A5:2009, 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 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 for the accreditation of bodies providing audit and certification to ISO 13485.

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

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

1. SCOPE

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

2. NORMATIVE REFERENCES

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

ISO 13485 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 GD3:2003 Guidance on 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.

National Regulatory Authority Regulatory Authority in the country where the AB is registered as a legal entity.

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.

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.

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.

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 cases of initial assessment and reassessment, witnessing of audits shall include the higher risk class of the Technical Areas 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 in an effort to rationalize the witnessing schedule. Typical regulatory schemes are the European Medical Devices Directives:

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- Medical Device Directive (MDD)
 - In -Vitro Diagnostic Devices Directive (IVD)
 - Active Implantable Medical Devices Directive (AIMD)

Other jurisdictions include:

- Canada – Health Canada, Canadian Medical Devices Conformity Assessment System (CMDCAS)
- Australia – Therapeutic Goods Administration, Therapeutic Goods Regulations

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. To include within the scope of accreditation, devices that are sterile or intended for end-user sterilization, the certification body shall be competent according to sterilization process detailed in Table 1.5 of Annex 1.

7.10 Appeals

No additional requirements for ISO 13485.

7.11 Reassessments and surveillance

MD 7.11.2

The surveillance on-site office assessments should be conducted at least once a year where higher risk medical devices are concerned. Surveillance and reassessment shall include witnessing. Witnessing shall take into account all the Technical Areas (shown in Annex 1) of activities under the scope of accreditation.

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 from 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.

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 shall 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.

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	<ul style="list-style-type: none"> • Non-active devices for anesthesia, 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 implants	<ul style="list-style-type: none"> • Non-active cardiovascular implants • Non-active orthopedic implants • Non-active functional implants • Non-active soft tissue implants
	Devices for wound care	<ul style="list-style-type: none"> • Bandages and wound dressings • Suture material and clamps • Other medical devices for wound care

	Non-active dental devices and accessories	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none"> • 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 sterilisation • 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
	Devices for imaging	<ul style="list-style-type: none"> • Devices utilizing ionizing rays • Devices utilizing non-ionizing rays
	Monitoring devices	<ul style="list-style-type: none"> • Monitoring devices of non-vital physiological parameters • Monitoring devices of vital physiological parameters
	Devices for radiation therapy and thermo therapy	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> 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/Immunohe- matology 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	
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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	

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.			X	X		
Understanding of relevant medical device management system standards			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 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		X	X	X	X	X
Understanding of ISO 13485			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.

End of IAF Mandatory Document for the Application of ISO/IEC 17011 in Medical Device Quality Management Systems (ISO 13485)

Further Information

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

For contact details of members of IAF see - IAF Web Site - <<http://www.iaf.nu>>

Secretariat -

John Owen,

IAF Corporate Secretary,

Telephone +612 9481 7343

email <secretary1@iaf.nu>