IAS INTERNATIONAL ACCREDITATION SERVICE®

IAF MD 8: 2017 - Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485)

Introduction

- 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.
- It is also appropriate as a requirements document for the peer evaluation process for the IAF Multilateral Recognition Arrangement (MLA) among Accreditation Bodies

Note :
IAF MD 8 :2017 (issue 3) was published prior to publication of ISO/IEC 17011:2017 (second edition)

Terms & Definition

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

Additional Requirements

- Witness during initial assessment shall cover higher risk class of technical areas (MD 7.5.6).
- When developing a witnessing schedule, the AB should consider, 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 .

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

Requirements for Reassessments and Surveillance

- 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
- 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.
- All premises where one or more key activities are performed shall be assessed during the accreditation cycle.
- Records on the CAB shall additionally include concerns, opinions and feedback received from Regulatory Authority on the performance of the CAB pertaining to the scope of accreditation.

ANNEX 1 – Scopes of Accreditation Medical Devices Technical Areas

- The accreditation certificate issued by the AB should use only the Main Technical Areas and Technical Areas. When using technical areas other than specified in the table 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 nonmanufacturing 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.
- 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
		• 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 • 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)	
	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.