UNITED ACCREDITATION FOUNDATION

Document Name	**ACCREDITATION REQUIREMENTS FOR CERTIFICATION OF MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM (MDQMS)**
Document Number	**UAF-CAB-MDQMS**
Applicable For	**All Certification Bodies for MDQMS**
Revision Number	**V00**
Revision Date	**NOV-15-2024**
Effective Date	**NOV-15-2024**

Contents

1. ACCREDITATION REQUIREMENTS

ISO/IEC 17021-1 Conformity assessment — Requirements for bodies providing audit and certification of management systems.

2. ADDITIONAL DOCUMENTS

ISO/IAF documents that are applicable for accreditation of ISO 13485 certification:

- IAF MD 1: IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization
- IAF MD 2: IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems.
- IAF MD 4: IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes
- IAF MD 9 Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485)
- IAF MD 11: IAF Mandatory Document for Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS)
- IAF MD 23:Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies
- IAF MD 28: IAF Mandatory Document for the Upload and Maintenance of Data on IAF Database (Application date October 26, 2024)

3. UAF DOCUMENTS APPLICABLE FOR ACCREDITATION OF ISO 13485 CERTIFICATION

- UAF-GEN-CAB-01-General Accreditation requirements
- UAF-GEN-CAB-02-Conditions for the use of UAF Symbol
- UAF policy 2014-01: Policy on providing conformity assessment in countries without the country's relevant authority's approval.
- UAF F-31A-Annexure A- Guidance for addition of countries, location(s), critical location(s).
- UAF policy 2016-06: UAF Policy for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance as per IAF MD 15:2014.
- UAF policy 2018-04: UAF Policy on handling misconduct & unethical practices in the certification process
- UAF policy 2019-07-01: UAF Policy on accreditation scopes & witnessing activities for accreditation of management system CBs
- UAF policy 2019-07-02: UAF Policy regarding general administration
- UAF Transition Policies as applicable.

4. CERTIFICATION DOCUMENTS

Certification bodies (CB) certify against ISO 13485; Medical devices — Quality management systems — Requirements for regulatory purposes.

5. SCOPE OF ACCREDITATION

The Scope of accreditation for ISO 13485 is defined in accordance with the requirements of IAF MD 9. It is granted as per the technical area corresponding to the directives concerning medical devices.These have been listed in Annex A. UAF may further restrict Scope to specific Technical Areas.

6. REQUIREMENTS

6.1 Legal and Contractual Matters:

The requirements from ISO/IEC 17021-1:2015, Clause 5.1 apply and in addition, the MDQMSspecific requirements and guidance apply as detailed in MD 5.1.2 of IAF MD9.

6.2 Management of impartiality

The requirements from ISO/IEC 17021-1:2015, Clause 5.2 apply and in addition, the MDQMSspecific requirements and guidance apply as detailed in MD 5.2.3 of IAF MD9.

7. RESOURCE REQUIREMENTS

7.1 Competence of management and personnel

The requirements from ISO/IEC 17021-1:2015, Clause 7.1 apply and in addition, the MDQMSspecific requirements and guidance apply as detailed in MD 7.1.1 of IAF MD9.

7.2 Personnel involved in the certification activities

The requirements from ISO/IEC 17021-1:2015, Clause 7.2 apply and in addition, the MDQMSspecific requirements and guidance apply as detailed in MD 7.2 of IAF MD9.

8. INFORMATION REQUIREMENTS

8.1 Publicly accessible information

The requirements from ISO/IEC 17021-1:2015, Clause 8.1 apply and in addition, the MDQMSspecific requirements and guidance apply as detailed in MD 8.1.3 of IAF MD9.

8.2 Certification documents

The requirements from ISO/IEC 17021-1:2015, Clause 8.2 apply and in addition, the MDQMSspecific requirements and guidance apply as detailed in MD 8.2.1 of IAF MD9.

9. PROCESS REQUIREMENTS

9.1 General requirements :

The CAB shall submit the completed application, including details of the applied technical areas, along with a detailed list where the CAB applies for a scope of accreditation for a technical area described as "other than specified above." The CAB shall provide a list of medical devices and include their risk classification to UAF. Additionally, the MDQMS-specific requirements and guidance, as detailed in MD 9.1 of IAF MD9, apply.

9.2 Initial Assessments

In addition to below, the MDQMS-specific requirements and guidance apply as detailed in MD 9.2 of IAF MD9.
The assessment extent and content depend on the requested scope of accreditation, the other activities for which the body is accredited or requests accreditation and the performance of the body at previous assessments.

The Assessment consists of following activities:

- Document Review
- Office assessment
- Witness Assessments
- Scope Verifications during extraordinary circumstances.

7. ACCREDITATION ASSESSMENTS

The extent and content of the assessment depend upon the requested Scope of accreditation, the other activities for which the body requests accreditation or is already accredited, and the body's performance during the previous assessments.

8. ASSESSMENTS

- Document Review
- Office Assessments
- Witness Assessments
- Scope Verifications during extraordinary circumstances.

9. INITIAL ASSESSMENTS

In addition to below, the MDQMS-specific requirements and guidance apply as detailed in MD of IAF MD9.

9.1 During the initial assessment, the body's policies and procedures are assessed at their office(s).

9.2 During the initial office assessments, the team makes specimen files of certification staff for every activity to screen the service for the Scope of accreditation. At least one certification personnel for each certification function and one auditor as per defined competence sectors requested shall be reviewed completely for the award of accreditation of scopes subjected to completion of witness in that particular Main Technical Area as per the requirements of IAF MD 9

9.3 The number of witness assessments depends upon the Scope applied as per IAF MD 8 and UAF's witness policy.

9.4 In the case of initial assessment, the samples for witnessing audits shall include one audit minimum in a higher risk class Technical Areas in each Main Technical Area (Annex A of this document) 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, UAF shall consider, among other factors, the experience of the CAB (e.g., recognized for one or more medical device regulatory scheme(s)), to rationalize the witnessing schedule. Examples of typical regulatory schemes are:

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

9.5 The content and extent of the assessment shall ensure that:

- At least one certification personnel for each certification function (Application Reviewer, Selection and appointment of Audit Team and Certification

Decisions) per main technical area as defined in Table in Annex A of this document shall be reviewed completely for the award of accreditation of the Scope.

- At least one Auditor per Technical Area, as defined in Table in Annex A, shall be reviewed completely for the award of accreditation of the Scope.

9.6 For CABs already accredited by IAF Full Members AB, earlier Witness reports may be accepted after review.

9.7 The application of the IAF-MD documents shall be verified as applicable.

9.8 Depending on the already accredited Scope, the UAF may decide to omit witness assessments to extend the Scope in the main Technical Area.

10. WITNESS ASSESSMENTS

For the minimum number of audits to be witnessed, the requirements of IAF MD 8:2020 shall apply.
For the selection of audits that are to be witnessed, the following rules shall apply:

9.1 The following may be considered in deciding the number of witnesses and selection of witnesses during surveillance and reassessment:

9.1.1 The CB's overall performance.

9.1.2 IAF MD 8

9.1.3 Factors such as process complexity or legislation, etc., influence the certified organization's ability to demonstrate its ability to meet the intended outcome of the MS.

9.1.4 Feedback from interested parties, including complaints about certified organizations.

9.1.5 The results of the CB's internal audit(s).

9.1.6 Scheme owner requirements, etc.

9.1.7 Change(s) in CB work patterns – growth of work within a specific region or technical area.

9.1.8 A number of clients within the CB's Scope of accreditation.

9.1.9 Confidence in the CB's auditor evaluation and approval process.

9.1.10 Previous or other office or witnessing assessment results, etc.

11. SURVEILLANCE AND REASSESSMENTS

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

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

10.3 The witnessing program shall ensure, as a minimum, that one audit from each of the Main Technical Areas (shown in Annex A) under the Scope of accreditation within an accreditation cycle (surveillances and reassessment) is conducted before 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.The number of files to be reviewed for each assessment is calculated based on the number of certificates issued since the last assessment. This is approximately one-tenth of the square root of the number of certificates, with a maximum of six files and a minimum of one file. The number of files to be reviewed may increase depending on risk-based parameters detailed in the assessment program.

10.4 The application of applicable IAF MD documents shall be verified during each assessment as detailed in the assessment plan.

10.5 In applying the above guidelines, it shall be considered whether witness assessments may serve for multiple schemes (e.g., by witnessing combined audits) and how witness assessments are performed in other schemes.

12. SCOPE EXTENSION

The assessment by UAF in case of an application for an additional scope (Main Techical Area) consists of one or more of the following assessment methods:

11.1 Documents and records review.

11.2 Verification of documents and records and interview of relevant staff during a visit to the office of the CB

11.3 A witness assessment in the main technical cluster per UAF's witness policy document is in line with IAF MD 8:2020 requirements.

At least the defined requirements for competence in that technical cluster, records of the qualification process of auditors for that cluster, and a complete certification dossier in that cluster will be verified in the scope extension assessment.

13. GENERAL REMARKS ON WITNESSING

Generally, two weeks before the witnessing, the CB shall provide the UAF team with the following:

- The CB's contract review records for the selected organization (including qualification records for the auditors used).
- A copy of the ISO 13485 certificate issued by the CB in case a surveillance or recertification audit is witnessed.
- The report of the CB's pre-assessment or stage 1 assessment of the organization's MS (or other latest report) and an audit plan.

Besides the considerations mentioned above for the selection of audits to be witnessed, UAF will also consider the following:

- UAF will normally not witness the same auditors witnessed in the same scheme before.
- UAF will normally not witness an audit at the same organization. • UAF will review of the audit report as part of the witness audit.

To select the audits to be witnessed, the CB shall plan for the audits to be conducted in a certain period at the request of UAF. The information on these audits shall include, as a minimum:

- Type of audit (initial, recertification or surveillance).
- Name and address of the auditee.
- Audit standard(s).
- Scope of certification.
- Name(s) of auditors(s) and expert(s).
- Date(s) of the audit.

14. ANNEX A: SCOPES AS PER IAF MD 8:2020

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) shockwave 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
Sterilization Method for	**Ethylene oxide gas sterilization (EOG)**	

Medical Devices	**Moist heat**	

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

	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 11.6 – 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.