IAF Mandatory Document

Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

Issue 4, Version 2

(IAF MD 9:2023)

Issued: 14 June 2023 Application Date: 01 February 2023 IAF MD 9:2023
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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 mandated standards 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 22003-1. 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. A CAB can meet these in an equivalent way provided this can be demonstrated to an AB. 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 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

This document is mandatory for the consistent application of ISO/IEC 17021-1. All clauses of ISO/IEC 17021-1 continue to apply, and this document does not supersede any of the requirements in that standard. This mandatory document is exclusively for the certification of organizations' management systems to ISO 13485.

0. INTRODUCTION

ISO/IEC 17021-1 is an International Standard that sets out the general requirements for bodies operating audit and certification of organizations' management systems. If such bodies are to be accredited as complying with ISO/IEC 17021-1 with the objective of auditing and certifying Medical Device Quality Management Systems in accordance with ISO 13485, some additional requirements and guidance to ISO/IEC 17021-1 are necessary.

This document follows the structure of ISO/IEC 17021-1. IAF specific criteria are identified by the letter "MD" followed with a reference number that incorporates the related requirements clause in ISO/IEC 17021-1. In all cases a reference in the text of this document to "clause XXX" refers to a clause in ISO/IEC 17021-1 unless otherwise specified.

1. SCOPE

This document specifies normative criteria for CABs auditing and certifying organizations' Quality Management Systems to ISO 13485, in addition to the requirements contained in ISO/IEC 17021-1. 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 17021-1 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 17021-1 Conformity Assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements

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

ISO 14971, Medical devices — Application of risk management to medical devices

IAF MD5 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems

IAF MD 11 IAF Mandatory Document for Application of ISO/IEC 17021 for Audits of Integrated Management Systems

Note: The Bibliography sets out the references to the documents which are not normative references.

3. TERMS AND DEFINITIONS

For the purpose of this document, the terms and definitions given in ISO/IEC 17021-1, ISO 13485 and the following apply.

Regulatory Authority (RA)

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 devices 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. PRINCIPLES

4.1 General

No additional principles for ISO 13485.

4.2 Impartiality

No additional principles for ISO 13485.

4.3 Competence

No additional principles for ISO 13485.

4.4 Responsibility

MD.4.4.1

ISO 13485 requires the organization to comply with the statutory and regulatory requirements applicable to the safety and performance of the medical devices.

The maintenance and evaluation of legal compliance is the responsibility of the client organization. The CAB is responsible for determining that the client organization has evaluated statutory and regulatory compliance and can show that appropriate action has been taken in cases of non-compliance with relevant legislation and regulations, including the notification to the Regulatory Authority of any incidences that require reporting.

4.5 Openness

No additional principles for ISO 13485.

4.6 Confidentiality

No additional principles for ISO 13485.

4.7 Responsiveness to complaints

No additional principles for ISO 13485.

4.8 Risk-based approach

No additional principles for ISO 13485.

5. GENERAL REQUIREMENTS

5.1 Legal and contractual matters

MD 5.1.2

The CAB shall establish appropriate agreements with their clients to release audit report information to regulators that recognize ISO 13485.

5.2 Management of impartiality

MD 5.2.3

The CAB and its auditors shall be impartial and free from engagements and influences which could affect their objectivity, and in particular shall not be:

a) involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device, or any associated parts and services

b) involved in the design, construction, implementation, or maintenance of the quality management system being audited

c) an authorized representative of the client organization, nor represent the parties engaged in these activities

The situations hereafter are examples where impartiality is compromised in reference to the criteria defined in a) to c):

a) the auditor having a financial interest in the client organization being audited (e.g., holding stock in the organization)

b) the auditor being employed currently by a manufacturer producing similar/competitive medical devices

c) the auditor being a member of staff from a research or medical institute or a consultant having a commercial contract or equivalent interest with the manufacturer or manufacturers of similar medical devices

5.3 Liability and financing

No additional requirements for ISO 13485.

6. STRUCTURAL REQUIREMENTS

6.1 Organization structure and top management

No additional requirements for ISO 13485.

6.2 Operational control

No additional requirements for ISO 13485.

7. RESOURCE REQUIREMENTS

7.1 Competence of personnel

MD 7.1.1 General considerations

Where ISO/IEC 17021-1 Clause 7.1.1 refers to (as relevant for the specific certification scheme) ISO 13485, this should be understood to mean medical devices and applicable legal requirements.

All personnel involved in ISO 13485 certification shall meet the competency requirements of Annex B.

7.2 Personnel involved in the certification activities

MD 7.2.4 Auditor

Each auditor shall have demonstrated competence as defined in Annex C.

The CAB shall identify authorizations of its auditors using the Technical Areas in Tables in Annex A.

MD 7.2.5 Auditor experience

For a first authorization, the auditor shall comply with the following criteria, which shall be demonstrated in audits under guidance and supervision:

a) Has gained experience in the entire process of auditing medical device quality management systems, including review of documentation and risk management of applicable medical devices, parts or services (see Table A.1.7), implementation audit and audit reporting.

b) Has gained experience by participating as a trainee in a minimum of four audits for a total of at least 20 days in an accredited QMS program, 50% of which shall be against ISO 13485 preferably in an accredited program, and the rest in any other accredited QMS program.

In addition to criteria a), audit team leaders shall fulfill the following:

a) Has experienced as an audit team leader role under the supervision of a qualified team leader for at least three ISO 13485 audits.

MD 7.2.8 Personnel making the certification decision

The CAB shall ensure that personnel (group or individual) making the certification decision fulfil the competence in Annex B. This does not mean that each individual in the group needs to comply with all requirements, but the group as a whole shall meet all the requirements. When the certification decision is made by an individual, the individual shall meet all the requirements.

7.3 Use of individual external auditors and external technical experts

No additional requirements for ISO 13485.

7.4 Personnel records

No additional requirements for ISO 13485.

7.5 Outsourcing

No additional requirements for ISO 13485.

8. INFORMATION REQUIREMENTS

8.1 Public information

MD 8.1.3

Where it is required by law or by relevant Regulatory Authority, the CAB shall provide the information about certifications granted, suspended, or withdrawn to the Regulatory Authority.

8.2 Certification documents

MD 8.2.1

The CAB shall precisely document the scope of certification. The CAB shall not exclude part of processes, products, or services (unless allowed by regulatory authorities) from the scope of certification when those processes, products or services have an influence on the safety and quality of products.

8.3 Reference to certification and use of marks

No additional requirements for ISO 13485.

8.4 Confidentiality

No additional requirements for ISO 13485.

8.5 Information exchange between a CAB and its clients

No additional requirements for ISO 13485.

9. PROCESS REQUIREMENTS

9.1 Pre-certification activities

MD 9.1.2.1

If the applicant organization uses outsourced processes, the CAB shall determine and document whether specific competence in the audit team is necessary to evaluate the control of the outsourced process.

MD 9.1.4 Determining audit time

The requirements from IAF Mandatory document MD5 (Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems) apply except those for EMS and OHSMS and the table QMS 1. Annex D, table D.1 replaces table QMS 1 and provides a starting point for estimating the audit time of an initial certification audit (Stage 1 + Stage 2).

Audit time is dependent on factors such as the audit scope, objectives, and specific regulatory requirements to be audited, as well on the range, class and complexity of medical devices, and the size and complexity of the organization. When CABs are planning audits, sufficient time shall be allowed for the audit team to determine the conformity status of the client organization's quality management system with respect to the relevant regulatory requirements. Time required to audit national or regional regulatory requirements and dossier reviews shall be additional and justified, so as not to diminish the audit of the QMS.

Audit time for all types of audits includes on-site time at a client's premises (physical or virtual) and time spent off-site carrying out planning, document review, interacting with client personnel and report writing. It does not consider the time required for design dossier reviews, type examinations, pre-market approval audits and other similar activities. The audit time should be adjusted to take into account the factors listed in Annex D, which may increase or decrease the estimated audit time.

For those CABs offering both ISO 9001 and ISO 13485 certification to a client, the audit time shall be able to demonstrate sufficient time to conduct an effective audit to determine conformity with all requirements of both certification standards. For information on ISO 9001 and ISO 13485 combined audits, see Annex D.

For integrated audits for standards other than ISO 9001, see IAF MD11.

MD 9.1.5 Multi-site sampling

Sites involved in design, development, and manufacturing of medical devices (Table A.1.1-1.6) cannot be sampled.

9.2 Planning audits

MD 9.2.2.1.

The audit team shall have the competence for the Technical Area (Annex A in conjunction with relevant knowledge and skills as defined in Annex B) for the scope of audit.

If the audit is performed for an organization that only manufactures parts and offers services (see Table A.1.7), the audit team does not have to demonstrate technical competence at the same level as that for a manufacturer providing medical devices.

To include devices that are sterile or intended for end-user sterilization, the audit team shall be competent according to sterilization process detailed in Table 1.5 of Annex A.

9.3 Initial certification

MD 9.3.1

When a CAB has audited a client against a regulatory scheme that includes or goes beyond the requirements of ISO 13485, it does not need to repeat the audit for conformity with the elements of ISO 13485 previously covered, provided the CAB can demonstrate that all the requirements of this document have been complied with.

Note: Some examples of regulatory schemes that include or go beyond the requirements of ISO 13485 are European Medical Device Regulations.

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

MD 9.3.1.2 Stage 1

Where higher risk medical devices (e.g., GHTF C and D) are concerned, the stage 1 should be performed on-site.

9.4 Conducting audits

MD 9.4.5 Identifying and recording audit findings

Examples of major nonconformities which require the acceptance and the verification of the effectiveness of correction and corrective actions are as follows:

a) failure to fully address applicable requirements and implement an entire process for quality management systems (e.g., failure to have a complaint handling or training system)

b) failure to implement applicable requirements for quality management systems

c) failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects

d) products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling

e) the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements

f) repeated nonconformities from previous audits

9.5 Certification decision

No additional requirements for ISO 13485.

9.6 Maintaining certification

MD 9.6.2.2

In addition to requirements of Clause 9.6.2.2, the surveillance programme shall include a review of actions taken for notification of adverse events, advisory notices, and recalls.

MD 9.6.4.2

Short notice or unannounced audits may be required when:

a) external factors apply such as:
    a. devices in scope of certification indicate a possible significant deficiency in the quality management system
    b. significant safety and performance related information becoming known to the CAB

b) significant changes occur which have been submitted as required by the regulations or become known to the CAB, and which could affect the decision on the client's state of compliance with the regulatory requirements

c) when required by legal requirements under public law or by the relevant Regulatory Authority

The following are examples of such changes which could be significant and relevant to the CAB when considering that a short notice or unannounced audit is required, although none of these changes should automatically trigger a short term or unannounced audit:

a) QMS – impact and changes:
    i) new ownership

ii) extension to manufacturing and/or design control

iii) new facility, site change

a. modification of the site operation involved in the manufacturing activity (e.g., relocation of the manufacturing operation to a new site or centralizing the design and/or development functions for several manufacturing sites)

iv) new processes, process changes

a. significant modifications to special processes (e.g., change in production from sterilization through a supplier to an on-site facility or a change in the method of sterilization)

v) QM management, personnel

a. modifications to the defined authority of the management representative that impact:

i. quality management system effectiveness or regulatory compliance

ii. the capability and authority to assure that only safe and effective medical devices are released

b) product related changes:

i) new products, categories

ii) addition of a new device category to the manufacturing scope within the quality management system (e.g., addition of sterile single use dialysis sets to an existing scope limited to haemodialysis equipment, or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment)

c) QMS & Product related changes:

i) changes in standards, regulations

ii) post market surveillance, vigilance

An unannounced or short-notice audit may also be necessary if the CAB has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

9.7 Appeals

No additional requirements for ISO 13485.

9.8 Complaints

No additional requirements for ISO 13485.

9.9 Client records

No additional requirements for ISO 13485.

10. MANAGEMENT SYSTEM REQUIREMENTS FOR CERTIFICATION BODIES

10.1 Options

10.2 Option A: General management system requirements

10.2.1 General

No additional requirements for ISO 13485.

10.2.2 Management system manual

No additional requirements for ISO 13485.

10.2.3 Control of documents

No additional requirements for ISO 13485.

10.2.4 Control of records

No additional requirements for ISO 13485.

10.2.5 Management review

10.2.5.1 General

No additional requirements for ISO 13485.

10.2.5.2 Review inputs

No additional requirements for ISO 13485.

10.2.5.3 Review outputs

No additional requirements for ISO 13485.

10.2.6 Internal audits

No additional requirements for ISO 13485.

10.2.7 Corrective actions

No additional requirements for ISO 13485.

10.3 Option B: Management system requirements in accordance with ISO 9001

10.3.1 General

No additional requirements for ISO 13485.

10.3.2 Scope

No additional requirements for ISO 13485.

10.3.3 Customer focus

No additional requirements for ISO 13485.

10.3.4 Management review

No additional requirements for ISO 13485.

End of IAF Mandatory Document for the Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

ANNEX A

(Normative)

Medical Devices Technical Areas

The CAB shall use the Technical Areas described in the tables of this Annex to:

a) help define the scope of certification

b) identify if any technical qualification, including competence in sterilization processes of its auditors is necessary for that particular technical area

c) select a suitably qualified audit team

When using technical areas other than specified in the tables, the technical areas shall be detailed.

Main Technical Areas in Table A.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 the 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.

A risk classification should be determined using an appropriate national, regional, or international risk classifications. Examples include:

a) (EU) 2017/745 Annex VIII Classification Rules
b) GHTF SG1 Principles of Medical Devices Classification GHTF/SG1/N77:2012
c) National Classification Regulations (e.g., FDA)

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 it is packaged, labeled, or sterilized.

Where the organization provides associated activities or manufacturing of parts which are not categorized as finished medical devices, Table A.1.7 shall be used for determining the scope.

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 A.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 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 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 A.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, íncluding 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 A.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 A.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**	

	IVD Instruments and software	
	IVD medical devices other than specified above	

Table A.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 A1.6 – Devices Incorporating / Utilizing Specific Substances / Technologies

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Devices incorporating/Utilizing	**Medical devices incorporating medicinal substances**	

Specific Substances/ Technologies	**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 A1.7 – 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 services are clearly intended to support medical devices.

a) when an organization promotes itself or products as supporting a medical device in one of the main technical areas (e.g., fasteners marketed with a clear intent to support implanted medical devices) on their website, or

b) instances of contract manufacturers making nearly complete medical devices

ANNEX B

(Normative)

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

The following tables specify the type of knowledge and skills that a CAB shall define for specific functions in addition to ISO/IEC 17021-1 Annex A.

Consideration for suppliers of "Parts and Services".

If the answer is "Yes" to any of the questions below, the audit team shall always include competence for the relevant Technical Areas in Tables A.1.1 – A.1.6 and the "Auditor" requirements in Table B.2. If the answer to all questions is "No", then the audit team shall satisfy only the "Parts and Services" auditor requirements in Table B.2. Documentation shall be maintained.

Table B.1

Question	**Yes**	**No**
Is the product a nearly finished and assembled medical device? (i.e., it is intended to be used for a medical purpose and only needs packaging and/or labeling)		
Is the product intended to be a component/part of a medical device?		
Is the organization contracted to carry out any activities that are regulated by a medical device regulation (e.g., relabeling, remanufacturing of other medical devices)?		
Is the product supplied sterile?		
Does the product contain software developed by the client organization or a supplier?		
Is "Design and Development" in the scope of the ISO 13485 certification (e.g., when public law permits exclusion of design and development which is the case very often for low-risk medical devices)?		
Is the product (Raw Materials, Parts, Components, Subassemblies, Maintenance Services, or Other Services) intended to support associated medical devices? Note: Refer to the note in Annex A, Table A.1.7, a) as an example.		

Table B.2 – Table of knowledge and skills

Certification functions / **knowledge and skills**	Personnel conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit time	Personnel reviewing audit reports and making certification decisions	Auditor	**Parts and Services Auditor** **REF Table A.1.7**	Personnel managing program
Knowledge of generic quality management system practices	X	X	X	X	X
Knowledge of legal framework of regulations and role of the CAB	X	X	X	X	X
Knowledge of medical device risk management, e.g., ISO 14971	X	X	X	X	X
Knowledge of intended use of medical devices			X *		
Knowledge of risks associated with the medical device			X *		
Knowledge of relevant product standards in the assessment of medical devices			X *		
Knowledge of CAB's ISO 13485 processes	X	X	X	X	X
Knowledge of Medical Device business/technology	X	X	X *	X *	X

* The knowledge in the areas marked with * could be provided by a technical expert.

ANNEX C

(Normative)

Auditor qualification, training, and experience

C.1 Education

Except for auditors performing audits solely under Table A.1.7, the CAB shall ensure that auditors have the knowledge corresponding to post-secondary education (typically 4 years) or equivalent work experience. Appropriate professional areas are listed below as examples:

i) biology or microbiology

ii) chemistry or biochemistry

iii) computer and software technology

iv) electrical, electronic, mechanical engineering or bioengineering

v) human physiology

vi) medicine

vii) pharmacy

viii) physics or biophysics

C.2 Work Experience

The CAB shall ensure that auditors have adequate experience to perform their tasks. In general, auditors shall have a minimum of four years of full-time work experience in the field of medical devices or related sectors (e.g., medical device industry, healthcare, medical device audit or research in medical devices).

Successful completion of other formal qualification (advanced degrees) can substitute for a maximum of two years of working experience.

Exceptionally, shorter duration of experience or experiences in the fields other than medical devices or related sectors may be considered as appropriate. In such cases, the CAB shall demonstrate that the experience of the auditor is equivalent and shall record the justification for the acceptance.

Auditors performing audits of organizations solely under Table A.1.7 shall only meet the requirements of ISO/IEC 17021-1 and ISO/IEC 17021-3 and not those in C.2.

C.3 Auditor Competency

See Annex B.

C.4 Development and maintenance of competency

C.4.1 Continuous Professional Development (CPD)

Each auditor shall undertake a minimum of 8 hours of CPD activities per year such as training, participation in scientific meetings, and self-study for Table A.1.7 and a minimum of 16 hours of CPD for Tables A.1.1 – A.1.6. Such activities should ensure timely awareness of new or modified regulatory requirements, policies, procedures, etc., as well as emerging technologies. Training in emerging technologies may be provided through co-operation with manufacturers developing or using the concepts. Knowledge is also gained from experience in enforcing regulatory requirements, implementing procedures, and applying policies and interpretations.

It is recognised that medical device manufacturing constitutes a highly specialised, technology driven and fast evolving sector. Additionally, new regulatory requirements, standards, policies, and procedures are introduced, and existing ones are modified from time to time. Therefore, the CAB shall ensure maintenance of the knowledge and skills of the auditors appropriate to cover the scope of audits of organizations, through appropriate and timely training and encouraging CPD.

C.4.2 Advanced training elements for auditors

As auditors gain competence in conducting audits, advanced and specialised training is recommended. The auditor's needs, weaknesses, and desires for career development may influence specific advanced training courses selected by an auditor. Subjects suggested for advanced training include:

i) risk management, including risk analysis

ii) process validation

iii) sterilization and related processes

iv) electronics manufacture

v) plastics manufacturing processes

vi) development and validation of software or hardware for devices and manufacturing processes

vii) in-depth knowledge of specific medical devices and/or technologies

ANNEX D

(Normative)

Table D.1 – Determination of Audit Time (Initial Audit Only)

Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)	Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)
1-5	3	**626-875**	15
6-10	4	**876-1175**	16
11-15	4.5	**1176-1550**	17
16-25	5	**1551-2025**	18
26-45	6	**2026-2675**	19
46-65	7	**2676-3450**	20
66-85	8	**3451-4350**	21
86-125	10	**4351-5450**	22
126-175	11	**5451-6800**	23
176-275	12	**6801-8500**	24
276-425	13	**8501-10700**	25
426-625	14	**>10700**	Follow progression above

Factors used to determine the audit time

a) Some factors which may increase the audit time from table D.1 are:

i) when more than one main technical area is required to be audited, the audit time shall be increased to address any additional requirements related to the additional main technical area(s)

ii) complexity of medical devices

iii) manufacturers using suppliers to supply processes or parts that are critical to the function of the medical device and/or the safety of the user or finished products, including own label products. When the manufacturer cannot provide sufficient evidence for conformity with

audit criteria, then additional time may be allowed for each supplier to be audited

iv) manufacturers who install product on customer's premises

Note: Time may be required for customer site visits or installation records review

v) poor regulatory compliance by the manufacturer

vi) multiple shifts, number of production lines etc. may increase audit time

b) Some factors that may reduce the audit time but not by more than 20% in total from table D.1 are:

i) the organization's scope does not include manufacturing and is activities such as wholesale, retail, transportation, or maintenance of equipment, etc.

ii) reduction of the manufacturer product range since last audit

iii) reduction of the design/or production process since last audit

c) Audit times performed solely for the certification scope of Distribution or Transportation Services" may be reduced up to 50% in total from table D.1.

Conducting ISO 9001 and ISO 13485 Together

When determining the required time for conducting an ISO 9001 and ISO 13485 audit together, a minimum of 25% will be added to the minimum number of audit days calculated per Annex D. Conditions where additional time may be required include differences in scope, effective number of personnel, etc.

This applies whether the CAB is conducting an integrated audit or a combined audit.

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- Requirements for Distributors

GHTF/SG1-N29R16:2005, Information Document Concerning the Definition of the Term "Medical Device"

GHTF/SG1/N77:2012 Principles of Medical Devices Classification

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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