ISAB MD 9:2023: Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

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Foreword

The International Standards & Accreditation Board (ISAB) facilitates trade and supports industry and 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 ISAB members can be accepted globally.
Accreditation reduces risk for business and its customers by assuring them that accredited CABs are competent to carry out the work they undertake within their scope of accreditation. ABs that are members of ISAB and their accredited CABs are required to comply with appropriate international standards and ISAB mandatory documents for the consistent application of those standards.

Introduction to ISAB 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.

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 ISAB Multilateral Recognition Arrangement (MLA) among Accreditation Bodies.

2. Normative References

- 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

3. Terms and Definitions

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.

4. Principles

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.

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:

- involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device, or any associated parts and services
- involved in the design, construction, implementation, or maintenance of the quality management system being audited
- an authorized representative of the client organization, nor represent the parties engaged in these activities

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:

- 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.
- 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.

9. Process Requirements

9.1 Pre-certification Activities

MD 9.1.4 Determining audit time

The requirements from ISAB 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).

Annex A (Normative) - Medical Devices Technical Areas

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

- help define the scope of certification
- identify if any technical qualification, including competence in sterilization processes of its auditors is necessary for that particular technical area
- select a suitably qualified audit team

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, injection, infusion, transfusion, dialysis.
Active Medical Devices (Non-Implantable)	General active medical devices	Devices for extra-corporal circulation, infusion and haemopheresis, respiratory devices.

Annex B (Normative) - Required types of knowledge and skills

The 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.

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.

Annex D (Normative) - Determination of Audit Time

Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)
1-5	3
6-10	4
11-15	4.5

Further Information

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