IAS INTERNATIONAL ACCREDITATION SERVICE®

IAF MD 9:2017 - application of ISO/IEC 17021-1 in the field of medical device quality management systems (ISO 13485)

Introduction

- The MD 9 provides additional requirements and guidance to ISO/IEC 17021-1 for CABs auditing and certifying organizations' Quality Management Systems to ISO 13485, in addition to the requirements contained with ISO/IEC 17021-1
- 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 other wise specified.

Additional requirements - Principles

Responsibility :

- 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 CB is responsible for verifying the compliance
- **Openness :**

  CB to have agreement with the client to release the audit report information to regulators

Management of Impartiality

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

Some of the examples -

i) the auditor having a financial interest in the client organization being audited (e.g. holding stock in the organization)
ii) the auditor being employed currently by a manufacturer producing medical devices
iii) 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

Resource Requirements

Competence of personnel :

- The general requirements of 17021-1 to be understood as competence relevant to 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.

Personnel involved in the certification activities

- 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.
- CAB shall ensure personnel making the certification decision fulfill the competence in Annex B.

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Requirements

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) Have gained experience in the entire process of auditing medical device QMS, including review of documentation and risk management of applicable medical devices, parts or services, implementation audit and audit reporting.

This experience shall have been gained by participation 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:

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

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Requirements

Public information

- 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.

Certification documents

- 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.

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Requirements

Pre-certification activities

CAB shall determine specific competence for the audit team to evaluate the control of the outsourced processes (If applicable).

Determining audit time:

- The requirements of MD5 apply
- Annex D, table D.1 replaces table QMS 1 and provides a starting point
- Audit duration 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 QMS with respect to the relevant regulatory requirements.
- Any additional time required to audit national or regional regulatory requirements and dossier reviews must be justified.

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Requirements

- Audit duration for all types of audits includes on site time at a client's premises 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 duration should be adjusted to take into account the factors listed in Annex D, which may increase or decrease the estimated audit time.
- If both ISO 9001 and ISO 13485 are considered, the audit time shall be able to demonstrate sufficient time to cover all requirements of both standards.

Multi-site sampling :

Sites involved in design, development and manufacturing of medical devices cannot be sampled.

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Requirements

Planning audits :

- The audit team shall have the competence for the Technical Area (Annex A & B) for the scope of audit.
- If the audit is performed for only parts and services, the audit team does not have to demonstrate technical competence at the same level as that for a manufacturer producing medical devices.
- To include devices that are sterile or intended for end-user sterilization, the audit team shall be competent according to sterilization process.

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Requirements

Initial certification :

- When regulatory scheme is audited including or go beyond the requirements (Ex - European Medical Device Directives and Regulations) of ISO 13485, it does not need to repeat the audit for conformity with the elements of ISO 13485 previously covered, providing the CAB can demonstrate that all of the requirements of this document have been complied with.
- Where higher risk medical devices (e.g. GHTF C and D) are concerned, the stage 1 should be performed on-site.

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Requirements

Conducting audits :

Some examples of nonconformities are added to section for Identifying and recording audit findings:

- failure to address and/or implement applicable requirements for QMS.
- failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects.
- 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.
- the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements.
- repeated nonconformities from previous audits

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Requirements

Maintaining certification :

The surveillance programme shall include a review of actions taken for notification of adverse events, advisory notices, and recalls.

Short notice or unannounced audits may be required when :

i) external factors apply such as :

a. available post-market surveillance data known to the CAB on the subject devices indicate a possible significant deficiency in the quality management system
b. significant safety related information becoming known to the CAB

ii) 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

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Requirements

Annex A (Normative) - Medical Devices Technical Areas
The CAB shall use the Technical Areas described in the tables of this Annex

Annex B (Normative) - Required types of knowledge and skills for personnel involved with the ISO 13485 activities

Annex C (Normative) - Auditor qualification, training and experience

Annex D (Normative) - Table D.1
Relationship between effective number of personnel and audit duration(Initial Audit only)

Factors used to determine the audit time (increase / decrease audit time)

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Thank you!

Q & A