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Title: Guidance for Regulatory Authority Assessors on the
Method of Assessment for MDSAP Auditing
Organizations

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A handwritten signature in black ink, appearing to read 'T. Tominaga'.

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Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world.

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Introduction

This is one document in a collection of documents produced by the International Medical Device Regulators Forum (IMDRF) intended to implement the concept of a Medical Device Single Audit Program (MDSAP). Two documents, IMDRF/MDSAP WG/N3 – “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition” and IMDRF/MDSAP WG/N4 – “Competence and Training Requirements for Auditing Organizations,” are complementary documents. These two documents N3 and N4 are focused on requirements for an Auditing Organization and individuals performing regulatory audits and other related functions under the respective medical device legislation, regulations, and procedures required in its regulatory jurisdiction.

Two additional documents, IMDRF/MDSAP WG/N5 – “Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations” and IMDRF/MDSAP WG/N6 - “Regulatory Authority Assessor Competence and Training Requirements,” are complementary documents. These two documents N5 and N6 are focused on how Regulatory Authorities and their assessors will evaluate or “assess” medical device Auditing Organizations’ compliance to the requirements in the IMDRF/MDSAP WG/N3 and N4 documents.

The present document compliments the IMDRF/MDSAP WG/N5 and N6 documents. IMDRF/MDSAP WG/N8 – “Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations” provides guidance to the Regulatory Authority assessors when conducting the assessment of an Auditing Organization according to the method presented in IMDRF/MDSAP WG/N5, chapter 6.

In addition, IMDRF/MDSAP WG/N11 – “MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization” defines a method to “grade” nonconformities resulting from a Regulatory Authority assessment of an Auditing Organization and to document the decision process for recognizing an Auditing Organization or revoking recognition.

The document IMDRF/MDSAP WG/N24 – “Medical Device Single Audit Program (MDSAP): Medical Device Regulatory Audit Reports” describes the format and content of MDSAP medical device regulatory audit reports submitted to regulatory authorities. The audit report serves as a written record of the audit team’s determination of the extent of fulfillment of specified requirements. It enables the Auditing Organization to capture in a consistent manner the evidence of a manufacturer’s conformity with the audit criteria for the MDSAP, and will facilitate the exchange of information between Regulatory Authorities.

This collection of IMDRF MDSAP documents provide the fundamental building blocks by providing a common set of requirements to be utilized by the Regulatory Authorities for the recognition and monitoring of entities that perform regulatory audits and other related functions. It should be noted that in some jurisdictions the recognition process is called designation, notification, registration, or accreditation.

IMDRF developed MDSAP to encourage and support global convergence of regulatory systems, where possible. It seeks to strike a balance between the responsibilities of Regulatory Authorities to safeguard the health of their citizens as well as their obligations to avoid placing unnecessary

burdens upon Auditing Organizations or the regulated industry. IMDRF Regulatory Authorities may add additional requirements beyond this document when their legislation requires such additions.

To prevent the confusion between audits of manufacturers performed by auditors within an Auditing Organizations and audits of Auditing Organizations performed by medical device Regulatory Authority assessors, in this document, the latter are designated as “assessments.”

1.0 Scope

This document provides guidance on the process-based assessment method described in section 6 of the document IMDRF/MDSAP WG/N5.

The assessment method specific to a particular medical device regulatory audit scheme may take into account additional requirements from the jurisdictions addressed in the scheme.

2.0 References

- [IMDRF/MDSAP WG/N3](#) – Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition
- [IMDRF/MDSAP WG/N4](#) – Competence and Training Requirements for Auditing Organizations
- [IMDRF/MDSAP WG/N5](#) – Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations
- [IMDRF/MDSAP WG/N6](#) – Regulatory Authority Assessor Competence and Training Requirements
- [IMDRF/MDSAP WG/N11](#) – MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization
- [IMDRF/MDSAP WG/N24](#) – Medical Device Single Audit Program (MDSAP): Medical Device Regulatory Audit Reports
- IMDRF/MDSAP WG/N29 – Clarification of the Term “Legal Entity” for MDSAP Recognition Purposes
- ISO/IEC 17000:2004 – Conformity assessment – Vocabulary and general principles
- ISO/IEC 17021:2011 – Conformity Assessment – Requirements for bodies providing audit and certification of management system.
- [GHTE/SG1/N78:2012](#) – Principles of Conformity Assessment for Medical Device

- [GHTE/SG3/N19:2012](#) – Quality management system – Medical devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange

3.0 Definitions

- 3.1 *Audit*: A systematic, independent, and documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. (ISO 17000:2004)
- 3.2 *Auditing Organization*: An organization that audits a medical device manufacturer for conformity with quality management system requirements and other medical device regulatory requirements. Auditing Organizations may be an independent organization or a Regulatory Authority which perform regulatory audits.
- 3.3 *Regulatory Authority*: A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (GHTE/SG1/N78:2012)

4.0 Guidance on Assessment of Auditing Organization's Processes

This section is structured according to the sequence of processes and assessment tasks described in the document IMDRF/MDSAP WG/N5 – section 6 and supplements it by providing guidance to each assessment task.

When assessors detect a nonconformity, they shall follow the requirements of IMDRF/MDSAP WG/N11 – sections 6.1 and 6.2.

4.1 Process: Management

N5 task 6.1.4.1 – Review the documentation on legal responsibility, liability, and financing. Verify the eligibility as a candidate Auditing Organization.

Applicable requirements

ISO/IEC 17021:2011 clauses: 5.1.1, 5.3.1, 5.3.2

IMDRF/MDSAP WG/N3 clauses: 5.1, 5.1.1, 5.1.2, 5.1.3, 5.3.1, 5.3.2

➤ **Legal entity**

Guidance

It is important that the assessment team accurately understands the structure of the legal entity to which the Auditing Organization belongs. It is especially important in complex cases such as an Auditing Organization belonging to a larger group, where the delineation of the legal entities within the group may influence impartiality, ability to enter into contractual arrangements, and the use of external resources.

The types of legal entities and the meaning of registration of the legal entity may vary due to regional or country-specific laws and regulations.

The applicant must clearly delineate the perimeter of the legal entity, and establish a specific address, where the management responsible for the MDSAP recognition program is employed by that legal entity. (See IMDRF/MDSAP WG/N29)

Typical evidence

Information regarding the legal entity to which the Auditing Organization belongs, its organizational structure, ownership, and the legal or natural persons exercising control over the entity. The information would include documentation made publicly available by the Auditing Organization (for example website or promotional documentation), official documents (such as a record of business registration or certificate of insurance policy), or other internal documents.

➤ **Financial stability**

Guidance

The assessors should verify that the Auditing Organization has sufficient resources to support its operations and enable it to fulfill recognition criteria.

Analysis of income sources is also important to assess independence from other entities.

The Auditing Organization's business should be sufficiently diversified so that the loss of a single client does not seriously jeopardize its financial stability or compromise impartiality.

Typical evidence

Annual report, fee structure, etc.

➤ **Liability insurance**

Guidance

The Auditing Organization must provide evidence as to the method used to evaluate the risks from its activities, and utilized to determine the insurance level.

Regulatory Authority assessors should ensure that the elements listed in the requirements are documented, including:

- Geographic regions included in the coverage;
- Profile of risk for the range of medical devices that are subject to audit; and
- Scope of activities undertaken for medical device regulatory audits.

Where an Auditing Organization claims that their liability is insured through arrangements with a related legal entity, the Auditing Organization should document how those arrangements fulfill the elements of the requirement identified above.

Typical evidence

Documentation of the risk assessment, records of information provided to the insurer, certificate of insurance.

➤ **Eligibility**

Guidance

Although an on-site assessment is unlikely to reveal legal judgments against the Auditing Organization, the assessment team should still inquire about the Auditing Organization's history with respect to these matters.

Typical evidence

Verbal confirmation.

N5 task 6.1.4.2 – Verify that a quality manual and the required management system documentation has been defined and documented.

Applicable requirements

ISO/IEC 17021:2011 clauses: 10.1, 10.2.1, 10.2.2, 10.2.3, 10.3.1, 10.3.2

IMDRF/MDSAP WG/N3 clauses: 6.1.2, 6.1.4, 6.1.5, 6.1.7, 10.1.1

Guidance

Most Auditing Organizations offer a broad range of management system certification services, beyond the medical device regulatory audit scheme. The assessor should verify that the Auditing Organization's management system clearly identifies elements applicable to the medical device regulatory audit scheme.

The Auditing Organization's management system documentation should state the documents or requirements to which the Auditing Organization claims compliance, including regulations, standards, and directives. The Auditing Organization's

management system must specify whether it satisfies option 1 or 2 of ISO/IEC 17021 section 10.1.

The Auditing Organization's management system should be appropriate to the nature, and scale of its auditing activities. The management system should be capable of supporting and ensuring consistent compliance with the requirements applicable to the audit and certification program for medical devices.

Typical evidence

Quality manual and a list of related documentation on the implementation, maintenance and operation of a quality management system, which would fulfill the requirements of IMDRF documents N3 and N4.

N5 task 6.1.4.3 – Verify that a quality policy and objectives have been set at relevant functions and levels within the organization. Ensure the quality objectives are measurable and consistent with the quality policy. Confirm appropriate measures are taken to achieve the quality objectives.

Applicable requirements

ISO/IEC 17021:2011 clauses: 10.3.1, 10.3.5

IMDRF/MDSAP WG/N3 clauses: Not Applicable

Guidance

While the term “quality policy” is not explicitly used in ISO/IEC 17021 or IMDRF/MDSAP WG/N3, the Auditing Organization's top management should express its overall intentions and direction related to the fulfilment of the requirements of the medical device regulatory audit scheme.

The assessor should verify that the Auditing Organization's top management ensures that the quality policy, like other management system policies, is communicated and understood at all levels of the organization.

The assessor should verify that the Auditing Organization bases quality objectives on parameters that are critical to the conformity to requirements of the medical device regulatory audit scheme. Quality objectives relate to indicators that are critical to the ability of the Auditing Organization to conduct planned medical device regulatory audits and make informed decisions (for example: maintaining access to sufficient numbers of competent auditors and technical experts to fulfill audit obligations; and to auditors qualified for a technical area/product related to the number of audits in this technical area, etc.).

A quality objective should be expressed as a measurable target or goal in order to feedback into the management system to ensure effective implementation.

Typical evidence

Documented policy and objectives, which may include such things as: number of audit reports delivered on time, timely post audit decisions on the manufacturer's regulatory conformity that are made within a specified time after the audit, timely investigation and closure of complaints.

N5 task 6.1.4.4 Review the Auditing Organization's organizational structure and related documents to verify that they include provisions for responsibilities, authorities. This must include the identification of functions responsible for: the overall program; the timely exchange of information with regulatory authorities; and, ensuring that quality management system requirements are effectively established and maintained, reporting to top management on the performance of the quality management system, and on any need for improvement.

Applicable requirements

ISO/IEC 17021:2011 clauses: 6.1.1, 6.1.2, 6.1.3, 6.2.2, 7.2.1, 7.2.3, 10.3.1

IMDRF/MDSAP WG/N3 clauses: 5.1.3, 6.1.5, 6.1.6, 7.1.4, 8.7.1

➤ **Organizational structure**

Guidance

The assessor should verify that the Auditing Organization has documented its organizational structure to identify the different positions or roles, their responsibilities and authorities and the inter-relationships between them. It is important for the assessors to not only understand the internal organizational structure of the Auditing Organization, but also how the organization interacts with external resources.

➤ **Top management**

Guidance

As part of the organizational structure review, the assessor should identify the job functions among the Auditing Organization's top management that are responsible for:

- Implementation and reporting on the performance of the management system;
- Performance of audits;
- Decisions on conformity to regulatory requirements;
- Establishment of the contract with the medical device manufacturer and external resources;
- Responding to and investigating complaints;
- Timely exchange of information with regulatory authorities.

Top management has other responsibilities that will be assessed through other assessment tasks.

The Auditing Organization should ensure that the remuneration of top management does not depend on the result of audits. Otherwise this would affect the impartiality of the Auditing Organization.

Typical evidence

Organizational chart, job description, management system procedures, etc.

➤ **Responsibility and authority**

Guidance

The Auditing Organization may document responsibilities and authorities for each individual involved in the audit and decision process in different ways including job descriptions, process descriptions, procedures, or individual assignments, project plans, etc.

For purposes of MDSAP recognition in accordance with IMDRF/MDSAP WG/N11, the applicant for recognition as an Auditing Organization is deemed to be the legal entity and is where the management responsible for the MDSAP recognition program is employed.

The management for the MDSAP program is directly responsible for, manages, and retains authority for the following:

- Establishment of the contract with the medical device manufacturer (including the requirements of N3 – 5.1.4, 5.1.5);
- Identification of competence requirements for any internal or external auditor or technical expert to perform specific activities (N3 – 7.5.1); and,
- Final review and decision-making on conformity to regulatory requirements (N3 – 7.5.1).

These listed activities cannot be delegated outside of the applicant's legal entity, even to a related organization or a subsidiary. Under the MDSAP recognition program, these related organizations or subsidiaries are regarded as separate legal entities.

(See IMDRF/MDSAP WG/N4.)

Link with other assessment tasks

The organizational structure may be influenced by the definition of the Auditing Organization's legal entity (see [N5 task 6.1.4.1](#))

N5 task 6.1.4.5 – Verify that the Auditing Organization has analyzed the adequacy of the set of auditors (including technical experts and team leaders) and personnel to cover all of its activities and to handle the volume of audit work.

Applicable requirements

ISO/IEC 17021:2011 clauses: 7.2.2
IMDRF/MDSAP WG/N3 clauses: Not applicable

Guidance

The assessor should verify that the Auditing Organization periodically analyzes the needs of the audit program with regards to the number and scope of the competence of personnel taking into account the current number and profile of audited medical device manufacturer, and; expected changes, the evolution of auditing practices/requirements, identified issues necessitating additional resources/competence/expertise, the geographic location of their resources and clients, the time it takes to acquire new competence (in nature or volume), etc.

This analysis is important to ensure the continuity of the Auditing Organization's ability to provide auditing and certification services within the scope of recognition.

Indicators of inadequate number of auditors and personnel may include:

- Overdue audits
- Shortened audit time as compared to the planned arrangements
- Assignment of auditor with inadequate competence
- Delay in the delivery of final reports
- Delay in the issuance of certification documents

Typical evidence

Analysis report

N5 task 6.1.4.6 - Verify that the Auditing Organization has defined and implemented procedures for the management of impartiality.

Applicable requirements

ISO/IEC 17021:2011 clauses: 5.2.1 to 5.2.13, 5.3.2, 6.2.1 to 6.2.3, 7.3, 7.5.2
IMDRF/MDSAP WG/N3 clauses: 5.2.1 to 5.2.10, 6.2.1, 7.1.6, 7.3.1, 9.1.3

➤ **Sources of threats to impartiality**

Guidance

The Auditing Organization must ensure that their decisions are based on objective evidence of conformity obtained during the certification/audit activities and are not influenced by other interests or parties.

The assessor should verify that the impartiality and independence of the Auditing Organization is established at all levels via:

- Structure of the organization and its relationship with superior (parent), peer or subordinate (sister) organisations;
- The relationship of individuals involved in audit and decision related activities, including top management;

- Policies, processes and procedures on audit and decision related activities.

Threats to impartiality may come from a large number of sources, including:

- Additional services offered, or other activities and interests of the Auditing Organization;
- The activities or personal interests of the individuals involved in the audit and decision processes, including external auditors and external technical experts;
- The activities of other organizations with whom the Auditing Organization has a relationship;
- The Auditing Organization's own processes, if they don't properly enable the Auditing Organization to identify and mitigate actual conflict of interest or prevent potential conflict of interest;
- The influence that an audited manufacturer may have on the Auditing Organization;
- The influence that other external stakeholders, (for example large tenders, epidemics, shortages) may have on the Auditing Organization.
- The remuneration of personnel involved in the audit activities shall not depend on the number or the results of assessments carried out.
- Ownership of the organisation (e.g. clients being owners or co-owners);
- Influence on the direction of the organisation (e.g. clients being represented on the board).

Typical evidence

On remuneration: Income or performance targets, performance reviews, contracts

➤ **Threats to impartiality from consultancy services**

Guidance

In accordance with IMDRF/MDSAP WG/N3, an Auditing Organization shall not offer or provide any consultancy services to the manufacturer, his authorized representative, a supplier or a commercial competitor as regards to the design, manufacture or construction, marketing, installation, use or maintenance of the product or processes being audited.

A significant threat to the Auditing Organization's impartiality comes from the self-review threat arising from the incompatibility of the provision of management system auditing and consultancy services, even if the consultancy services are provided by a separate department or even a legally independent entity of the same group of enterprises. In the context of medical device regulatory audits, medical device regulatory consultancy cannot be offered by the same legal entity providing auditing services.

Consultancy includes:

- Quality management system (or good manufacturing practices);
- Device marketing authorization and facility registration;
- Medical device adverse events and advisory notices reporting; and
- Company or product specific training.

EXAMPLES:

- a) Preparing the documentation, or part of it, to be submitted for a marketing authorization (such as device license application file, premarketing notification file, premarket approval submission file, technical documentation, design dossier, etc.), with the exception of the testing reports per recognized standard or a specific pre-established protocol.
- b) Giving specific advice, instructions or solutions towards the resolution of quality management system deficiencies identified by a regulatory authority during an inspection.
- c) Preparing or producing QMS manuals or procedures;
- d) Giving specific advice, instructions or solutions towards the development and implementation of a management system; and
- e) Acting as Clinical Research Organization for the preparation of a clinical research protocol.

COUNTER-EXAMPLES:

- a) Testing or calibrating a device or calibrating equipment and issuing the corresponding report per a recognized standard or a specific pre-established protocol, as long as the organization does not provide any specific advice, instructions or solutions addressing the deficiencies detected by the testing or calibration.
- b) Offering mock audits, pre-assessment audits or gap-audit, according to the requirements of an initial audit, including an audit report. The Auditing Organization cannot give advice or recommendations on how to address nonconformities, observations and gaps; and the manufacturer does not use the audit in lieu of an internal audit. In addition, any nonconformity resulting from such an audit must be included when grading nonconformities identified during the initial audit (see IMDRF N3 item 9.2.5);
- c) Acting as a clinical research organization implementing clinical research developed by the manufacturer.
- d) Arranging training and participating as a trainer, or exchanging technical or regulatory information is not considered consultancy, provided that, where the course or exchanged information relates to management systems; other medical device technical or regulatory requirements; or auditing, it is confined to the provision of generic information that does not provide company-specific solutions.

Any reference in ISO/IEC 17021 and IMDRF/MDSAP WG/N3 to management system consultancy is to be interpreted as medical device regulatory consultancy.

(See Annex for additional interpretation of the requirements of ISO/IEC 17021:2011 and IMDRF/MDSAP WG/N3.)

Typical evidence

Organizational structure, website, advertisements, contractual agreements with external resources.

Link with other assessment task

See also [N5 task 6.3.4.1](#)

➤ **Organizational level**

Guidance

As a legal entity, the Auditing Organization must analyze the services offered and ensure none of its activity introduces a bias in its audits and decisions.

The Auditing Organization needs independence (financially and organizationally) from all parties interested in the outcome of audit activities, including the audited manufacturer, its representatives, suppliers, importers, clients, and competitors.

The Auditing Organization must not commit to an accelerated timeline for a fee to complete the auditing process. This practice is perceived as an inducement and represents a risk to the Auditing Organization's ability to conduct the audit under appropriate conditions and to critically review audit outcomes.

The Auditing Organization may receive business by referral. Referrals may reveal the Auditing Organization's relationship with external individuals or organizations having an unacceptable interest in the medical device manufacturers using the Auditing Organization's audit and certification services.

Typical evidence

Organizational structure, website, advertisements, fee structure.

➤ **Individual level**

Guidance

Policies, procedures, training and individual commitment to a Code of Conduct (see IMDRF/MDSAP WG/N3 7.1.6) ensure awareness of unacceptable behaviors by individuals involved in the audit and certification decision processes. The Auditing Organization should be aware of potential conflicts of interest affecting all individuals involved in the audit and certification decision processes and have policies in place to mitigate these.

Any individual employed by a medical device manufacturer potentially being considered as an auditor would be viewed by the Regulatory Authorities as a conflict of interest or at least an appearance of conflict of interest, and hence a threat to impartiality that would prohibit that individual from part taking in a medical device regulatory audit.

Any individual involved in the testing of the medical device should not be involved in the quality management system audit that would review the testing of this device.

Typical evidence

Policies, procedures, training material, personnel file and individual commitment to a Code of Conduct (see IMDRF/MDSAP WG/N3 7.1.6).

➤ **Policies, processes, procedures and practices**

Guidance

The assessor should verify that the Auditing Organization has a publicly accessible statement that it understands the importance of impartiality in carrying out its audit and

certification decision activities, and that it monitors and addresses any potential or actual conflict of interest.

The Auditing Organization's processes and procedures must ensure that any threat to impartiality is identified, documented, analyzed and effectively managed. When an Auditing Organization subcontracts parts of the audit related activities, processes should be in place to assure the use of the external organization does not affect its impartiality.

An Auditing Organization that only relies on signed statements from personnel involved in conformity assessment for identifying and monitoring potential conflicts of interests, and does not keep updated records of past and present consultancy activities, would fail (a) to implement an effective system (as no verification would be possible) and (b) to document consultancy activities prior to personnel taking employment, both being requirements of clauses 5.2.2 and 5.2.4 of IMDRF/MDSAP WG/N3.

The Auditing Organization should have methods in place to prevent the offering of audit services to a medical device manufacturer that (within the previous three years – see N3 5.2.3) benefited from medical device consultancy services, including internal audits from the Auditing Organization, an employee or external resource. If a mock audit, pre-assessment audit or gap-audit of a medical device manufacturer's quality management system was conducted, the Auditing Organization's management system should ensure that the subsequent initial audit is conducted by an independent audit team.

Policies, processes and procedures must ensure that an individual does not review his or her own work. In particular auditors must not decide on the compliance of the quality management system they have audited.

The composition of the audit team (and in particular the lead auditor) should change over time, at least every three years, to prevent an unreasonable risk of familiarity.

Typical evidence

Documentation of a process for monitoring impartiality at planned intervals.
Evidence of disclosure of any past or present relationship that would potentially represent a conflict of interest.

Link with other assessment task

See also [N5 task 6.4.4.6](#)

➤ **Committee for the safeguard of impartiality (Impartiality Committee)**

Guidance

The Auditing Organization must have a committee for safeguarding impartiality. ISO/IEC 17021 provides detailed requirements for this impartiality committee. This committee should be aware of the specificities of the medical device regulatory scheme.

Typical evidence

The assessors can verify the activity of the impartiality committee by:

- Reviewing the agenda, the minutes or other documents from the meetings of the impartiality committee and activities;
- Checking the participation at the meetings (including the presence of technical or other specific expertise, where necessary), and/or
- Reviewing the files of the committee members, meeting records to determine that the members were provided with information about the Auditing Organization (structure, business, certification process) and the fundamentals of the MDSAP program

Link with other assessment tasks

Threats on impartiality shall be assessed taking into account the definition of the Auditing Organization's legal entity (see [N5 task 6.1.4.1](#)) and the Auditing Organization's organizational structure (see [N5 task 6.1.4.4](#)).

N5 task 6.1.4.7 Verify that management reviews are being conducted at planned intervals, that they include a review of the suitability and effectiveness of the quality policy, quality objectives, and management system to assure that the quality management system meets all applicable requirements from ISO/IEC 17021:2011 and IMDRF/MDSAP WG/N3 and N4.

Applicable requirements

ISO/IEC 17021:2011 clauses: 10.2.4, 10.3.5

IMDRF/MDSAP WG/N3 clauses: Not Applicable

Guidance

The assessor should verify that the Auditing Organization's management review procedure specifies participants, roles and responsibilities, frequency (at least once a year), agenda inputs and deliverables.

The procedure may also specify:

- A standard agenda of topics to be discussed (with flexibility for unique agenda items to be added);
- The necessary attendees who are to participate in the management review and the quorum for decisions;
- The management review objectives, including a review of the progress on meeting the stated objectives,
- How action items resulting from the management review are recorded (including responsibilities and due dates; specifying whether the tracking tool to use, if any) and follow up until completion (including their review during the following management review); and
- The relevant outputs of the Measurement, Analysis & Improvement process, such as corrective and preventive actions.
- Changes that could affect the quality management system may include any change to
 - 1) recognition criteria, or
 - 2) regulatory requirements applicable to the medical device manufacturers and impacting the Auditing Organization's auditing program or practices;

The assessor should verify that action items resulting from the management reviews are recorded (including responsibilities and due dates; specifying whether the tracking tool to use, if any) and followed up until completion (including the review of effectiveness during the following management review);

The management review may cover activities outside the scope of the medical device regulatory audit scheme. A management review is expected to present, synthesize and analyze sufficient information for the management team to evaluate the implementation, performance, conformity and effectiveness of the activities applicable to the medical device regulatory audit scheme.

The outputs of the management review should include decision and action regarding the adequacy of the set of auditors and personnel to cover all of its activities and to handle the volume of audit work.

Typical evidence

Management review records should document dates, attendees, and results of the management reviews, including a conclusion regarding the suitability, adequacy and effectiveness of the Auditing Organization's management system.

Link with other assessment tasks

Inputs to the assessment of the management review should include (See [N5 task 6.1.4.4](#)), the analysis of the adequacy of the set of auditors (See [N5 task 6.1.4.5](#)), and outcomes from the management of impartiality (See [N5 task 6.1.4.6](#)).

4.2 Process: Use of External Resources

N5 task 6.2.4.1 – Identify when and how the Auditing Organization utilizes external resources. Verify that the controls implemented for the utilization of external resources by the Auditing Organization address competence, impartiality, confidentiality and conflict of interest.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 7.5, 8.5.1

IMDRF/MDSAP WG/N3 clauses: 5.2.7, 7.2.1, 7.5.1, 7.5.2, 8.5.1, 8.5.2

Guidance

➤ **General**

The Auditing Organization may use external resources, provided it does not delegate any of the following responsibilities outside the Auditing Organization's management system:

- Establishment of the contract with the medical device manufacturer;
- Identification of competence requirements for the auditor or technical expert to perform specific activities; and,
- Final review and decision-making on conformity to regulatory requirements.

The Auditing Organization should ensure that the use of external resources does not compromise its ability to: (1) make an independent review and decision on the manufacturer's regulatory conformity; and, (2) demonstrate conformity to recognition criteria.

The extent of the use of external resources is an important characteristic of the Auditing Organization. The use of external resources poses increased challenges in terms of control of services to the medical device manufacturer, and control of the Auditing Organization impartiality and the adherence to the Code of Conduct.

Controls over the use of external resources should cover both the evaluation of the competency of the individual or organization as a resource, and the assignment of a specific auditing activity to this external resource.

➤ **External persons**

External resources may be individuals (e.g. contracted auditors or technical experts) or organizations (e.g. an Auditing Organization recognized under different medical device regulatory audit schemes).

The process by which an Auditing Organization assures the suitability of an external auditor or an external technical expert typically includes: (1) the evaluation and ongoing monitoring of the individual's competence; (2) training in the Auditing Organization's processes and procedures; and, (3) the evaluation of potential threats to impartiality.

➤ **External organization**

An external organization is an organization that does not operate under the Auditing Organization's management system.

The process by which an Auditing Organization assures the suitability of an external organization typically includes the evaluation of the following considerations:

- Nature and range of the service the external organization is to perform on behalf of the Auditing Organization;
- If applicable, the impact of the additional services offered to the client by the external organization's (for example: joined audits);
- Potential conflicts of interests and other threats on the Auditing Organization's impartiality, due to, for example:
 - o the range of services or products offered by the external organization;
 - o the organizational structure, ownership of the external organization; and,
 - o the personal interests of the external organization's top management;
- The internal and external human resources available to conduct the activities on behalf of the Auditing Organization;
- The infrastructure, including information systems;
- Competence and impartiality of the individuals that the external organization uses to conduct the service for the Auditing Organization;
- Processes implemented by the external organization, and their compatibility with the Auditing Organization's processes;
- Ability of the Auditing Organization to control and monitor activities undertaken on its behalf by the external organization;
- Access to the records relative to the performance of the service.

The evaluation of this information, including any concerns and their resolution, and the rationale for approving the external organization as a resource should be documented.

The relationship between the Auditing Organization and the external organization may be a partnership where both organizations may be responsible for separate auditing schemes under which the manufacturer is jointly audited. For example, one Auditing Organization may act as a European Notified Body and the other as a Japanese Registered Certification Body. When this is the case, each organization may make independent decisions on the conformity of the audited quality management system. The Auditing Organization must ensure that the decision made by the external organization does not compromise its ability to make an independent review and decision regarding the conformity of the audited quality management system with the relevant regulatory requirements.

On a periodic basis, the Auditing Organization should re-evaluate the external organization's ability to satisfy contractual agreements and expectations.

The assessors should verify that the Auditing Organization implements documented arrangements (such as a memorandum of understanding, or contractual agreement) with external resources.

Typical evidence

Organizational structure, contractual arrangements with external individuals and external organizations, and competence evaluation records.

Link with other assessment tasks

The evaluation of the competency of external resources includes the identification of potential threats to impartiality (see [N5 task 6.1.4.5](#)).

N5 task 6.2.4.2 – Verify that the Auditing Organization has contractual arrangements with external resources. The arrangements shall allow the recognizing Regulatory Authority to assess or witness the activities of the external resources. The arrangements shall include a commitment by the external resource to apply the Auditing Organization’s requirements and provisions ensuring the control of confidentiality and impartiality.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 5.1.3, 7.3, 7.5, 8.5.1

IMDRF/MDSAP WG/N3 clauses: 5.2.7, 7.1.6, 7.2.1, 7.3.1, 7.3.3, 7.5.1, 7.5.3, 8.5

Guidance

The assessors should verify that the contractual arrangements do not enable the delegation to external resources of functions identified in the [N5 task 6.2.4.1](#).

The assessors should verify that the contractual arrangements are comprehensive and adequately implemented.

➤ **External auditor and external technical expert**

Since an external auditor or external technical expert may have other professional activities (including consultancy activities), the external auditor or external technical expert should confirm the absence of any conflict of interest prior to assignment to a particular auditing activity.

Contractual arrangements should be documented and approved by the Auditing Organization’s top management. The Auditing Organization should not assign any activity to an external auditor or external technical expert before the contractual arrangements are agreed.

➤ **External organization**

Contractual arrangements should be documented and approved by the Auditing Organization’s top management. The Auditing Organization should not assign any activity to the external organization before the contractual arrangements are agreed.

Typical evidence

Contractual arrangements, list of competent personnel that may identify external individuals, list of external organization if available.

N5 task 6.2.4.3 - Verify that the Auditing Organization has adequate internal competence to review the outcome and appropriateness of the activities performed by external resources and to verify the validity of the objective evidence provided in order to make decisions.

Applicable Requirement

ISO/IEC 17021:2011 clauses: Not applicable

IMDRF/MDSAP WG/N3 clauses: 7.3.2, 7.5.2

Guidance

The confidence of the Auditing Organization in the reliability of outsourced auditing activities is only achieved if the Auditing Organization has sufficient competence internally to direct the auditing activities; verify the appropriateness and validity of opinion from external technical expert, verify the competence of the external resources; critically evaluate the outcome of the outsourced activities; and understand the significance of the findings and conclusions.

The absence of such internal competence would result in the Auditing Organization relying blindly on the conclusions and recommendations of the external auditor, external technical expert, or external organization to make its certification decision. This would be equivalent to delegating the certification decision. Such a delegation is not acceptable as it would not fulfill the requirements of N3 Clause 7.2.1.

The assessor should evaluate the extent of expertise expected by an Auditing Organization of an external resource and verify that the Auditing Organization can demonstrate sufficient internal competence to verify the appropriateness and validity of objective evidence provided by the external resource.

Typical evidence

The assessor may look at the competency file for an assigned individual to ensure experience and suitability can be proven for the assigned responsibility.

4.3 Process: Measurement, Analysis and Improvement

N5 task 6.3.4.1 – Verify that the Auditing Organization has a defined and documented procedure(s) for measuring, monitoring, analyzing and improving the relevance, compliance, consistent implementation and effectiveness of the Auditing Organization’s management system.

Applicable requirements

ISO/IEC 17021:2011 clauses: 7.2.10, 7.5.4

IMDRF/MDSAP WG/N3 clauses: 6.1.4, 7.1.6, 10.1.1, 10.1.3, 10.1.4

Guidance

Most data presented during the management review are outputs of the Measurement, Analysis & Improvement process.

The Auditing Organization should have procedures to collect and monitor data relative to:

- Conflicts of interest
- Auditor conduct
- Auditor competence
- Implementation of the Audit & Certification Processes

The Auditing Organization may use various methods to collect such data, including the review of audit reports, observed audits, solicitation of feedback from audited manufacturers, internal and external audits and assessments, recording unsolicited feedback from audited manufacturers or users of the audit reports or certification documents including those prepared by regulatory authorities.

These procedures should enable the Auditing Organization to detect individual nonconformities or potential nonconformities, as well as unfavorable trends.

The assessor should verify that the Auditing Organization has procedures to address any nonconformity and potential nonconformity, including the investigation of their cause, and the determination of corrections, corrective actions and preventive actions as applicable.

Typical evidence

Procedures and resulting records for these processes.

Link with other assessment tasks

The monitoring, analysis and improvement processes provide input to the management review (see [N5 task 6.1.4.7](#))

N5 task 6.3.4.2 – Determine if appropriate sources of data and processes have been monitored by the Auditing Organization, to identify actual and potential nonconformities. This data must include internal audits, external assessments, complaints, and the use of external resources. Confirm that monitoring and measurement activities cover auditor competence, audit performance, decisions on conformity to regulatory requirements and adherence to the Code of Conduct throughout the Competence Management and Audit and Decisions Processes.

Applicable requirements

ISO/IEC 17021:2011 clauses: 5.2.10, 7.1.3, 7.2.10 – 7.2.12, 7.5.4

IMDRF/MDSAP WG/N3 clauses: 5.2.4, 6.1.5, 7.1.3, 7.1.6, 10.1.3, 10.1.4

➤ **Data sources**

Guidance

It is the Auditing Organization's responsibility to determine appropriate monitoring and analysis activities.

The data sources should at least include

- Complaints;
- Nonconformities from internal or external audits, and other sources;
- Appeals;
- Competence and conduct of the auditors, technical experts, reviewers and other personnel;
- Performance of the audits according to planned arrangements;
- Corrective actions.

The assessor should be mindful of quality problems that appear in more than one data source. It is essential that the Auditing Organization understands the full extent of the quality problem. For example, audit nonconformities noted in complaints or customer feedback should be compared with similar nonconformities noted during the organization's analysis of data from other data sources such as auditor competence assessment reports, audit report review records, internal audit reports, etc.

Typical evidence

See list above

➤ **Analysis of data**

Guidance

The Auditing Organization has the flexibility to use whatever methods of analysis are appropriate to identify existing and potential causes of nonconformities or other quality problems. However, the Auditing Organization should use appropriate statistical methods where necessary to detect potential, emerging or recurring quality problems. The Auditing Organization should not use statistics to minimize a problem or avoid addressing a problem.

Typical evidence

Records resulting from the processes. Additional record on the analysis of the data.

N5 task 6.3.4.3 – Determine if investigations are conducted to identify the underlying cause(s) of detected nonconformities as well as of potential nonconformities, where possible. Confirm investigations are commensurate with the risk of the nonconformity. Confirm that corrections, corrective actions and preventive actions, as appropriate, were determined, implemented, documented, effective, and did not adversely affect the audits performed and decisions made. Evaluate whether corrective action and preventive action is appropriate to the risk of the nonconformities or potential nonconformities encountered.

Applicable requirements

ISO/IEC 17021:2011 clauses: 10.3.7, 10.3.8

IMDRF/MDSAP WG/N3 clauses: Not applicable

Guidance

The assessor should verify that the Auditing Organization's procedures ensure that data to detect existing or potential nonconformities are analyzed and effectively reacted to when applicable.

When the Auditing Organization detects a nonconformity, it must investigate, determine and record:

- The underlying causes of the nonconformity;
- Any necessary *correction* to control or limit the effects of the nonconformity;
- Any necessary *corrective action* to prevent the re-occurrence of the nonconformity.

Potential nonconformities do not need correction; however the Auditing Organization must still investigate, determine and record:

- The underlying causes of the potential nonconformity;
- Any necessary *preventive action* to prevent the nonconformity from occurring.

The depth of the Auditing Organization's investigation of the quality problem should be commensurate with the risk. An assessment team should be mindful of the risk of the nonconformity on the reliability of the audits and the credibility of the decisions made by the Auditing Organization.

Considering the nature of the services offered by Auditing Organizations, the investigation conclusion of a nonconformity's underlying cause should not be limited to "human error", in particular if there is pattern of such human errors. The assessor should verify that the Auditing Organization evaluates whether such human error originates from a lack of (or ineffective) training, insufficient competency, poor practices, or other causes (e.g. a lack of effective supervision).

The investigation of a nonconformity should include a determination of whether the nonconformity adversely affects certification documents or audit deliverables already released to the client or any Regulatory Authority.

A nonconformity may not always warrant both correction, and corrective action.

Where a quality problem has already been identified and investigated by the Auditing Organization, and the Auditing Organization had decided not to undertake any corrective actions, the assessor should verify that records include a risk-based rationale for not taking action, and be approved by a designated individual.

The Auditing Organization is expected to implement in a timely manner the actions it decided to address an existing nonconformity, including correction, and/or corrective action. The time to implement these actions – especially the immediate correction intended to limit the effects of the nonconformity - should be inversely related to the risk of the nonconformity. The extensive nature of some actions – corrective actions in particular – may necessitate extended time to implement on the part of the Auditing Organization.

The assessor should verify that the Auditing Organization evaluates the effectiveness of any implemented corrective or preventive action. These actions should not be considered complete until this evaluation has been conducted and the actions have been confirmed to be effective. If the Auditing Organization determines that a correction, corrective action or preventive action was not effective, the assessor should verify that the Auditing Organization further investigates how to remediate the original problem, and, as appropriate, the causes that prevented the actions from being effective.

Typical evidence

Records resulting from correction, corrective actions and preventive actions.

Link with other assessment tasks

The output of the corrective and preventive actions sub-system is input to management review (see [N5 task 6.1.4.7](#)).

N5 task 6.3.4.4 – Determine whether any of the Auditing Organization's corrective actions require reporting to the recognizing Regulatory Authorities, such reporting may include changes relevant to its recognition).

Applicable requirements

ISO/IEC 17021:2011 clauses: Not applicable

IMDRF/MDSAP WG/N3 clauses: 8.7.3, 8.7.4, 8.7.5

Guidance

The assessor should verify that the Auditing Organization reports to the recognizing Regulatory Authority(s) if a corrective or preventive action represents a change that may affect the organization's recognition (e.g. legal, commercial, organizational or ownership

status; top management or key personnel; resources; or premises and critical location) or its operating processes (e.g., policies and procedures submitted to the recognizing Regulatory Authority in the application package for recognition as an Auditing Organization).

Typical evidence

Records of corrective action, competence record, record of organizational structure

N5 task 6.3.4.5 – Verify that a process is in place to ensure that an audit which does not conform to auditing requirements is identified and managed to ensure that there is sufficient information for decisions on conformity to regulatory requirements. Confirm that appropriate decisions were made, justified, and documented.

Applicable requirements

ISO/IEC 17021:2011 clauses: 9.1.15 a), 10.2, 10.3

IMDRF/MDSAP WG/N3 clauses: 9.1.1, 9.1.2, 10.1.3

Guidance

If the Auditing Organization determines as part of the final review of the audit outcomes that the prerequisite information for making a decision of conformity of the manufacturer is incomplete or contains error, the assessor should verify that a nonconformity is recorded and resolved prior to the making of a decision.

The resolution of the Auditing Organization's nonconformity may require the performance of an additional audit prior to the decision being made.

Typical evidence

Client files, record of the review of audit decisions, if available.

N5 task 6.3.4.6 – Confirm that when a nonconformity is detected after release of the report or after the decision of conformity to regulatory requirements, then appropriate action is taken commensurate with the risk, or potential risks, of the nonconformity. Confirm appropriate notification the recognizing Regulatory Authority was made.

Applicable requirements

ISO/IEC 17021:2011 clauses: 10.2, 10.3

IMDRF/MDSAP WG/N3 clauses: 8.7.3, 8.7.4, 9.6.1

Guidance

If a nonconformity affecting an audit, the audit report, or the decision on the manufacturer's regulatory conformity, is recognized after this decision has been shared with the recognizing Regulatory Authority(s); the Auditing Organization should determine if an amendment to the audit report or the decision is necessary.

If the Auditing Organization decides to amend the audit report, the decision on the manufacturer's regulatory conformity, or any other information shared with the recognizing Regulatory Authority(s), it should inform the recognizing Regulatory Authority(s) and the manufacturer of the change, and the reason for the change (i.e. the nonconformity).

A modification of the decision on a manufacturer's regulatory conformity may include the suspension or withdrawal of certification documents.

The communication between the Auditing Organization and the recognizing Regulatory Authority(s) should enable the Regulatory Authority to evaluate the impact of the nonconformity on regulatory actions undertaken based on the audit information initially provided by the Auditing Organization. This could affect marketing authorizations, as well as enforcement actions.

Typical evidence

Internal audits, complaints

N5 task 6.3.4.7 – Verify that internal audits are being conducted according to planned arrangements and documented procedures to ensure the management system is in compliance with the established requirements set out in ISO/IEC 17021:2011 and the IMDRF/MDSAP WG/N3 and N4 documents, as well as any other applicable recognizing Regulatory Authority requirements. Confirm the internal audits include provisions for auditor independence over the areas being audited, corrections, corrective actions, follow-up activities, and the verification of corrective actions.

Applicable requirements

ISO/IEC 17021:2011 clauses: 10.3.6.1, 10.3.6.2, 10.3.6.3, 10.3.6.4,
IMDRF/MDSAP WG/N3 clauses: 10.1.4

Guidance

The Auditing Organization must conduct periodic, independent and systematic examination of its management system to determine whether:

- The management system as defined, meets all applicable requirements;
- The Auditing Organization conducts its activities according to the management system;
- The management system as implemented, produces the expected deliverables and outcomes, and is suitable to achieve the Auditing Organization's quality objectives.

Internal audits may not be specific to a medical device regulatory audit scheme but the internal audit program should demonstrate sufficient coverage of this scheme. At a minimum, the entire medical device audit scheme is to be covered within the duration of the recognition cycle.

Typical evidence

The records should demonstrate that the Auditing Organization implemented the internal audits according to the internal audit program (including its schedule).

N5 task 6.3.4.8 – Confirm that the Auditing Organization has effective processes for handling complaints, and investigating the cause of nonconformities related to complaints with provision for input into the Measurement, Analysis and Improvement process. Verify that procedures have been implemented that require the Auditing Organization to forward to the recognizing Regulatory Authority information on any complaint about a medical device manufacturer that could indicate an issue related to the safety and effectiveness of medical devices or a public health risk. Confirm the proper and timely implementation of these procedures. Evaluate how the complaint process allows for forwarding to the appeals process.

Applicable requirements

ISO/IEC 17021:2011 clauses: 9.7, 9.8

IMDRF/MDSAP WG/N3 clauses: 9.5.2.2, 9.8.1

Guidance

The assessors should verify that the complaint handling process includes:

- Any feedback from an audited manufacturer or from users of the certification documents, including Regulatory Authorities, alleging that the Auditing Organization did not fulfill all applicable requirements for recognition (i.e. from IMDRF/MDSAP WG documents N3 and N4, ISO/IEC 17021, or any additional requirement specific to the medical device regulatory audit scheme; and,
- Any feedback from a user of the certification documents, including Regulatory Authorities, alleging that the products from the audited manufacturer do not meet their specifications, or that the manufacturer fails to satisfy its quality system and regulatory obligations.

The Auditing Organization may receive feedback through different channels. A complaint may result from broader feedback, and may not be designated by the sender as a complaint. For example, the appeal of an Auditing Organization decision should be supported by a rationale for reconsidering a decision on a manufacturer's conformity. This rationale may include a statement that the Auditing Organization did not fulfill its obligations.

The assessor should verify that when communicating with a complainant other than the recognizing Regulatory Authority, the Auditing Organization does not share confidential information about any third party.

Typical evidence

Complaint handling records

Link with other assessment tasks

The determination of the complaint validity may be part of the investigation of the nonconformity (See [N5 task 6.3.4.3](#)).

N5 task 6.3.4.9 – Where an investigation by the Auditing Organization determines that activities from external resources contributed to a nonconformity or a complaint, verify that records show that relevant information was exchanged between the parties involved.

Applicable Requirements

ISO/IEC 17021:2011 clauses: 9.8, 10.3.7, 10.3.8

IMDRF/MDSAP WG/N3 clauses: Not applicable

Guidance

External resources may be essential to the ability of the Auditing Organization to conduct all auditing activities. By nature, external resources are not controlled as directly as internal resources, which introduce an increased risk factor.

When an external resource contributed to a nonconformity or a complaint, the assessor should verify that the Auditing Organization has made the external organization aware of the nonconformity or complaint.

The assessor should ensure that the Auditing Organization has requested information regarding the implementation of remediation actions.

Typical evidence

Records of correction, corrective action or complaints

N5 task 6.3.4.10 – Determine if the relevant outputs of the Measurement, Analysis and Improvement Process are inputs into the management review.

Applicable Requirements

ISO/IEC 17021:2011 clauses: 10.2.4, 10.3.5

IMDRF/MDSAP WG/N3 clauses: Not applicable

Guidance

The assessor should ensure that the Auditing Organization uses relevant outputs from the Measurement, Analysis and Improvement process as inputs to management review.

Typical evidence

Records of management review.

Link with other assessment tasks

See [N5 task 6.1.4.7](#) on management review.

4.4 Process: Competence Management

N5 task 6.4.4.1 – Verify that the Auditing Organization has identified the necessary competencies for the scope of its recognition. Verify that the Auditing Organization has access to the necessary technical expertise for advice on matters directly relating to decisions of conformity to regulatory requirements.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 7.1.1, 7.1.4, 7.2.1, 7.2.9,

IMDRF/MDSAP WG/N3 clauses: 6.1.1, 6.1.3, 7.1.1, 7.1.2, 7.1.3, 7.1.5, 7.2.1, 7.3.2

IMDRF/MDSAP WG/N4 clauses: 6, 8.1, 8.2

Guidance

➤ **Competence needs for the organization**

The assessor should verify the following:

- The Auditing Organization should identify the competence needed at all levels of the organization and for all functions involved in the audit and certification related activities, to operate as a recognized auditing organization.
- The Auditing Organization should use expert opinions to identify these competencies. Such experts may be internal or external. The necessary competence may vary depending on the range of technical areas for which the Auditing Organization seeks recognition, and on the number and profile of audited medical device manufacturers, and their medical devices.
- The Auditing Organization should have an appropriate workforce, in competence and number, to operate as an Auditing Organization.
- If the Auditing Organization has several sites with separate organizational structures, the same competence criteria are consistently applied to all sites.

➤ **Identifying Competence criteria**

The assessor should verify that the documented process provides for the:

- Analysis of the requirements that a manufacturer must fulfill to effectively implement a quality management system and to fulfill the requirements that relate to products and manufacturing processes and other regulatory requirements. The analysis should consider each area of technical knowledge for which the Auditing Organization is seeking recognition.
- Determination of the aspects of the evaluation of product / process related technologies that are required to verify compliance with regulatory requirements and the extent to which these may be assessed at audit.
- Requirement that the Auditing Organization document competency criteria expressed in terms of the requisite knowledge, skills, behavior, values and experience that will ensure requirements are adequately assessed. Criteria may

also include an ability to analyze and adapt to new situations. The criteria should allow for an objective and measurable assessment of competency. (IMDRF MDSAP WG N4 - Appendix A provides an example of a scheme for the classification of technical knowledge)

- Maintenance of the competence criteria.

The IMDRF/MDSAP WG/N4 section 6 specifies pre-requisite education and experience for auditors, technical experts, program administrators and final reviewers.

The IMDRF/MDSAP WG/N4 section 8.1 specifies pre-requisite auditing experience before an individual may conduct audits independently as an auditor or lead auditor.

The IMDRF/MDSAP WG/N4 section 8.2 specifies pre-requisite experience of the review of technical documentation to confirm the competence of a technical expert.

Some competence criteria may apply to all technical areas (horizontal criteria). For example, all medical device auditors should have demonstrated competence in medical device regulations, quality management systems, and risk management applied to medical devices.

Conversely, competence criteria may only apply to specific technical areas (vertical criteria). For example, not all medical device auditors need to have competence in the safety of electrical medical devices or software.

If the Auditing Organization excludes some technical areas from its application to the recognizing Regulatory Authority(s), the Auditing Organization would not be expected to have competent auditors for these technical areas. The Auditing Organization must not commit to undertake the assessment of manufacturers for product where it does not have the requisite competence under its scope of recognition.

For each function the Auditing Organization should identify the criteria that may be used to demonstrate competence, prior to the assessment of competence against the criteria.

➤ **Technical and regulatory expertise**

The assessor should verify that the Auditing Organization has access to sufficient technical expertise necessary for the scope of its audit and certification related activities (e.g. medical devices audited, their performance and safety, clinical use, manufacture, and the regulations applicable to those devices).

The necessary expertise should serve the following purposes:

- Provide guidance while defining appropriate auditing and certification practices and processes;
- Provide guidance during the development of the Auditing Organization's management system to ensure compliance to the recognition requirements;
- Define necessary competence criteria and to train individuals involved in the audit and certification activities;

- Supporting the auditors, either remotely or on-site, when facing challenging issues during an audit; and
- Enabling the Auditing Organization to critically review an audit file, including the audit findings and the manufacturer response.

While defining auditing and certification practices and processes, and the Auditing Organization management system, the Auditing Organization should consider guidance documents that are acceptable to Regulatory Authorities.

➤ **Using external resources to meet the scope of expertise**

The outcome of the identification of competence needs should serve as an input to the selection of an external resource and to define operational processes between the Auditing Organization and the external resource.

Typical evidence

Procedure and competence criteria

Link with other assessment tasks

See [N5 tasks 6.1.4.4](#) (analysis of the adequacy of the set of auditors) and [6.2.4.3](#) (internal resources necessary to verify the work of external resources)

N5 task 6.4.4.2 – Verify that the Auditing Organization has defined, documented and implemented procedures and criteria for initial competence evaluation of auditors, technical experts, program administrators, final reviewers, and personnel involved in the audit and related activities.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 7.1.2, 7.1.3, 7.2.4, 7.3, 7.5

IMDRF/MDSAP WG/N3 clauses: 6.1.1, 7.1.1, 7.2.1, 7.3.2, 7.3.4, 7.5.2, 7.5.4

IMDRF/MDSAP WG/N4 clauses: 6, 8, 9

Guidance

➤ **Competence evaluation criteria**

Compliance with competency criteria may be demonstrated by an individual (or organization) through a combination of practical and theoretical knowledge, skills, behavior and values that are used to act effectively in an audit or certification activity.

➤ **Competence evaluation process**

The assessor should verify that the Auditing Organization has a defined process for the initial evaluation of the competence of a candidate auditor, technical expert, final reviewer, or of any other individual involved in the audit and decision activities.

Competence cannot strictly be confirmed through a document review. The evaluation process should consider various methods to initially evaluate the individual's competence, using a combination of the following:

- Review of records of education and training;

- Review of records of audits or inspections conducted or reviewed, if relevant to the function;
- Review of evidence of technical expertise (for example, involvement in the review of technical documentation, publications), if relevant to the function;
- Feedback from peers, and supervisors, and if relevant, from audited manufacturers;
- Interviews;
- Participation in audits as an observer or as supervised auditor; and
- Evaluation against competency criteria e.g. testing.

The assessor should verify that the individual(s) involved in the evaluation of competence should themselves possess the necessary competence to do so effectively. Specifically, the individual(s) involved in the evaluation of the competence of auditors or technical experts should meet the competence criteria of a lead auditor and final reviewer with adequate education, skill and experience.

Lead auditors and auditors-in-training must undergo a confirmation of skills and personal attributes through a medical device witnessed audit prior to being authorized as a lead auditor or auditor.

Note that the Auditing Organization may define different degrees of auditor competence, using designations such as auditor, lead auditor, senior auditor, supervising auditor. If applicable, the Auditing Organization should define the competence criteria for each of these designations.

Typical evidence:

Procedure for the initial evaluation of competence, and related records

N5 task 6.4.4.3 – Verify that the Auditing Organization maintains a list of personnel to include auditors, technical experts, the program administrator and final reviewer that have been assessed as competent to perform the duties associated with the audit and related activities including external resources. Verify that the list is current at all times.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 7.1.3, 7.1.4.1, 7.2.3, 9.2.2.5,

IMDRF/MDSAP WG/N3 clauses: 6.1.6, 7.2.1, 7.3.2, 7.5.2

IMDRF/MDSAP WG/N4 clauses: 11

Guidance

The assessor should verify that:

- This list is available and current for all personnel.
- The Auditing Organization has implemented the scheme for the classification of technical knowledge if prescribed by the recognizing Regulatory Authority.

Typical evidence

List of competent personnel

Link to other assessment tasks

The list must include external resources (See [N5 task 6.2.4.1](#)).

N5 task 6.4.4.4 – Verify that the Auditing Organization has identified training needs, has provided access to such training, and has ensured the identified training has been undertaken by its auditors, technical experts, the program administrator and final reviewer and all other personnel involved in the audits and related activities, including the external resources. Training shall include IMDRF MDSAP specific requirements. The Auditing Organization must ensure that personnel have access to an up-to-date set of procedures.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 7.2.3, 7.2.6, 7.2.8

IMDRF/MDSAP WG/N3 clauses: 6.1.3, 7.1.3, 7.2.1

IMDRF/MDSAP WG/N4 clauses: 7, 8

Guidance

The assessor should verify that as a result of either the evaluation of an individual's competence, the recruitment of new personnel (including auditors, technical experts, final reviewers or program administrators), or the evaluation of the adequacy of the set of auditors, technical experts and personnel to the organization needs, the Auditing Organization made arrangements to complement the competence of the individual or the organization with additional training.

Training arrangements should ensure that:

- Any gap identified in the competence evaluation are resolved;
- Any need for future professional development;
- The training is effective, for example through knowledge tests, examinations, review of work by a tutor or supervisor, observation of audits, interviews, etc.

Typical evidence

Training plans, job-specific predefined training curriculum, etc. are examples of documented arrangement.

N5 task 6.4.4.5 – Verify that the Auditing Organization has defined, documented and implemented a method (i.e. procedures and criteria) for the ongoing monitoring of competence and performance of all personnel involved in the audits and related activities. Verify that when personnel no longer meet the competence criteria their competence status is revised. Verify if any remediation plan has been implemented.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 7.1.3, 7.2.10, 7.2.11, 7.2.12,

IMDRF/MDSAP WG/N3 clauses: 6.1.1, 6.1.6, 7.4.1

IMDRF/MDSAP WG/N4 clauses: 9, 12

Guidance

➤ **Monitoring of the competence**

The assessor should verify that the Auditing Organization has defined methods and criteria for the on-going monitoring of the competence of personnel according to documented procedures.

The assessor should verify that the Auditing Organization re-evaluates for continued recognition of competence at least every three years. In addition, lead auditors and auditors must undergo confirmation of skills and personal attributes through a medical device witnessed audit at least every three years.

The monitoring should be adapted to the expected level of competence, and to the potential impact of the lack of competence of the individual(s).

The assessor should verify that if the Auditing Organization identifies concerns that relate to a lack of competence of an auditor(s) or a technical expert(s), the Auditing Organization documents the concern. The procedures should specify how these concerns should be recorded and handled (e.g. through the corrective action process).

➤ **Response to the outcomes of the competence monitoring activities**

The assessor should verify that the outcome of the competence monitoring activities is a decision on whether to maintain or renew the recognition of competence of personnel.

The decision may be either to maintain/renew the recognition of competence or to place the individual into remediation.

The assessor should verify that the Auditing Organization adjusts the monitoring methods and training arrangements of a particular individual that has been placed in remediation. For example, the monitoring methods may be changed to monitor the improvement of a particular competency.

The work performed by an individual that has been placed in remediation should be evaluated by the Auditing Organization to ensure its validity. If the outcomes of an audit performed by an individual that has subsequently been placed in remediation (i.e. the audit report and the decision on the manufacturer's conformity) should be invalidated, the

Auditing Organization should record it as a nonconformity and inform the recognizing Regulatory Authority(s) and affected manufacturers of the situation and the remediation plan.

Typical evidence

Competence re-evaluation records, audit reports, reports on witnessed audits

Link with other assessment tasks

The competence monitoring process is a source of quality data for the Measuring, Analysis and Improvement process (see [N5 Task 6.3.4.2 and 6.3.4.4](#))

Decision on the status of recognition of an assessor may impact the list of auditors (See [N5 task 6.4.4.3](#)).

N5 task 6.4.4.6 – Verify that records demonstrate the implementation of the competence evaluation, training, commitments to confidentiality, impartiality, and Code of Conduct for auditors, technical experts, the program administrator and final reviewer and all other personnel involved in the audits and related activities.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 5.2.13, 7.4

IMDRF/MDSAP WG/N3 clauses: 5.2.9, 7.1.6, 7.4.1

IMDRF/MDSAP WG/N4 clauses: 4, 5, 10, 11

Guidance

The assessors should verify records of initial and ongoing competence evaluation as well as training records. These files should include external auditors and external technical experts, including those used by external organizations.

When assessing the Auditing Organization, the recognizing Regulatory Authority's assessment team should select a representative sample of individual files, with a preference for auditors, technical experts and final reviewers, including both internal personnel and external resources. The completion of previous assessment tasks may direct the selection to specific functions or individuals.

Typical evidence

Individual files

Link with other assessment task

See [N5 Task 6.6.4.7](#) – Commitment to impartiality

N5 task 6.4.4.7 – Verify that the Auditing Organization has demonstrated the effectiveness of the competence evaluation methods and of the competence management process.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 7.1.3, 7.2.5, 7.2.7, 7.2.8

IMDRF/MDSAP WG/N3 clauses: Not applicable

IMDRF/MDSAP WG/N4 clauses: Not applicable

Guidance

Demonstrating the effectiveness of the competence evaluation methods is intrinsically difficult for both the Auditing Organization and the recognizing Regulatory Authority's assessment team. However, if the Auditing Organization or the recognizing Regulatory Authority's assessment team identifies a lack of competence of the Auditing Organization or of an individual, this may reflect a lack of the effectiveness of the competence evaluation methods and competence management process.

The assessor should note the informative annex B and C in ISO/IEC 17021 on possible assessment methods that the Auditing Organization might utilize.

Typical evidence

Records on witnessed audits, internal audits, reviews of audit reports, records of client feedback

Link with other assessment tasks

The individual's file includes information relevant to the assignment of position, including responsibilities and authorities (see [N5 task 5.1.4.4](#)), and to the management of impartiality (see [N5 task 5.1.4.6](#))

4.5 Process: Audit and Certification Decisions Process

N5 task 6.5.4.1 – Verify that the Auditing Organization has documented procedures as required in the IMDRF/MDSAP WG/N3 for clause 9 of the ISO/IEC 17021:2011.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 9.1.4.1, 9.6.1, 9.7.1
IMDRF/MDSAP WG/N3 clauses: 9.1.1

Guidance

The assessor should verify that any specific requirements for the audit of technical documentation, for the conduct of an audit, or for any other requirement, that has been prescribed by a Regulatory Authority, has been incorporated by the Auditing Organization's procedures for their audit and certification processes.

N5 task 6.5.4.2 Verify that the Auditing Organization established, reviewed and updated (as needed) the program for the full audit cycle, specific to each medical device manufacturer taking into account the review of the request for audits and notices of change, and information collected during prior audits. Verify that the Auditing Organization has planned the audits according to the program. This includes the determination of audit time according to the recognizing Regulatory Authority's requirements; and, the identification of related sites and critical suppliers to audit, considering the specific circumstances of the medical device manufacturer.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 8.6.3, 9.1.1, 9.1.2.2.1, 9.1.2.2.2, 9.1.2.2.3, 9.1.2.3, 9.1.4, 9.1.5, 9.1.7, 9.1.8, 9.2.1, 9.2.2.1, 9.2.2.2, 9.2.3, 9.3.1, 9.4.1, 9.5
IMDRF/MDSAP WG/N3 clauses: 8.8.1, 9.2.1, 9.2.2, 9.2.3, 9.3.1, 9.4.2, 9.4.4, 9.4.5, 9.5.1, 9.5.2(1&2)

Guidance

The assessor should verify that the Auditing Organization has established an audit program for each manufacturer.

The assessor should note that informative Annex F of ISO/IEC 17021 describes considerations for the audit program. The assessor should in particular verify that the Auditing Organization takes into account considerations such as:

- The differences in the regulatory definition of manufacturer and what might be required for the scope of any audit program;
- The scope of certification to ensure that it adequately reflects the activities of the manufacturer and their applicable sites/location
- Outsourced critical processes/activities and information regarding the type of controls over these suppliers;

- Product/process characteristics impacting the audit program such as the medical device classification, type of manufacturing and product technologies, software, the presence of substances of human or animal origin or medicinal substances, etc.;
- Ongoing or past certification.

The assessor should verify that the Auditing Organization establishes the audit program to cover the 3-year cycle and reviews and revises the program, as necessary, when information about the manufacturer becomes available to the Auditing Organization. Such information could include the findings of audit reports and identified nonconformities, deviations in the conduct of previous audits, notification of changes from the manufacturer, changes to regulatory requirements, directives from regulatory authorities, etc.

The assessor should verify that the Auditing Organization determines the audit duration according to established procedure and using guidelines specific to the medical device regulatory scheme. Assessors should not find the Auditing Organization's audit time calculation process acceptable if it only utilizes such methods as IAF MD9 without making provision for extension of the time calculation based on such things as risks, complexity, scope of activities, regulatory requirements, etc.

Except for the Stage 1 audit, it is a requirement for all audits to be conducted on-site.

The assessor should verify that if the Auditing Organization plans to sample facilities of a multi-site medical device manufacturer, the rationale for the sampling is recorded. A facility cannot be included in the certificate before it is audited on-site. Not all regulatory jurisdictions authorize the sampling of facilities.

➤ **Unannounced audits**

The assessor should verify that the Auditing Organization has procedures to add unannounced audits to the audit program when any of the following applies:

- If required by the recognizing Regulatory Authority(s); or
- If specific information provides reasons to suspect serious nonconformities of the devices or of their manufacture; or
- As a follow up of a routine audit that identified:
 - one or more nonconformity(s) graded as a "5", or
 - more than two nonconformities graded as a "4".

Unannounced audits should be conducted by at least two auditors, take not less than one day, and have objectives set based on what triggered the audit.

In addition, the assessor should verify that the Auditing Organization has suitable arrangements with the manufacturer that would allow for unannounced audits to be conducted as part of the audit program.

➤ **Transfer of certification from another Auditing Organization**

It is especially important for the assessor to verify the activities considered during contract review for transfer of certification.

In addition to normal considerations the assessor should specifically verify the planned arrangement for any transfer of certificates and that the Auditing Organization develops an audit program that is commensurate to the potential risks when relying on the information/work done outside their control.

Typical evidence

Sample of individual manufacturer's audit programs, client files

N5 task 6.5.4.3 – Verify that the Auditing Organization selected and assigned audit teams with the competence required for each audit. Verify that the Auditing Organization communicated to the audit teams the audit scope, objectives and tasks for planning the audit and for the assignment of responsibilities among the audit team members. Verify that the Auditing Organization informed the medical device manufacturer of the audit team composition and the audit plan.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 7.2.4, 7.2.5, 7.2.7, 9.1.3.1 to 9.1.3.4, 9.1.6, 9.1.7, 9.1.8, 9.2.2.3, 9.2.2.4

IMDRF/MDSAP WG/N3 clauses: 5.2.8, 7.3.1, 7.4.1, 7.5.1, 9.1.1, 9.5.2(1)

Guidance

The assessor should verify that the Auditing Organization has a procedure for the selection of auditors that ensures the audit team possesses the competence necessary to conduct a specific audit of the medical device manufacturer, taking into account the scope of the audit and in accordance with the medical device audit scheme.

The assessor should verify that the Auditing Organization provides the audit team with the information necessary to plan the audit, including a list of medical devices and the medical device scheme within the scope of the audit program.

The assessor should verify that the Auditing Organization has effectively implemented the planned arrangements to ensure that the auditor is not the lead auditor for more than 3 consecutive audits at the same manufacturing site.

Typical evidence

Client file

Link with other assessment tasks

See management of Impartiality in [N5 task 6.1.4.5](#)

N5 task 6.5.4.4 – Verify that the Auditing Organization conducted audits according to the audit program and the requirements of the recognizing Regulatory Authority. Verify that the requirements for audit reports including the grading of any nonconformities as prescribed in IMDRF/MDSAP WG/N3, and any requirements of the recognizing Regulatory Authority were met.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 9.1.9, 9.1.10, 9.2.3, 9.3.2.1, 9.3.2.2, 9.4.2

IMDRF/MDSAP WG/N3 clauses: 8.2, 9.1.2, 9.1.3, 9.2.1, 9.2.2, 9.2.4, 9.2.5, 9.3.1, 9.3.2, 9.4.1

Guidance

The assessor should verify that the audit program has been implemented as planned and if audits were postponed or omitted, that the Auditing Organization has provided a rationale or taken measures to rectify the problem.

The assessor should consider how unplanned audits impact the audit program.

The assessor should verify that the Auditing Organization has followed a prescribed audit model, if applicable.

The assessor should verify that the Auditing Organization has properly implemented the IMDRF/MDSAP WG/N24 for audit reporting.

The assessor should verify that the Auditing Organization has properly implemented the GHTF/SG4 N19:2012 – *Nonconformity Grading System for Regulatory Purposes and Information Exchange*.

The assessor should select a sample of audit files to review their content. The sampling should take into account:

- The outcome of their assessment of prior processes (e.g. Management, Measurement, Analysis & Improvement and Competence Management processes);
- The class of the device audited;
- Different type of audits (e.g. initial, surveillance, recertification, unannounced);
- Geographic locations;
- Various auditors;

N5 task 6.5.4.5 – Verify that the Auditing Organization reviewed any responses to nonconformities identified during an audit of the manufacturer. Verify that the Auditing Organization has appropriately required and reviewed the necessary cause analysis, and any related plans for corrections, and/or corrective action. Verify that the Auditing Organization has verified the implementation and effectiveness of such actions and conducted special audits as necessary.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 9.1.11, 9.1.12, 9.1.13, 9.5.2

IMDRF/MDSAP WG/N3 clauses: 9.5

No additional guidance

Link with other assessment tasks

See [N5 task 6.5.4.4](#)

N5 task 6.5.4.6 – Verify that the Auditing Organization reviewed the audit reports, and all other relevant information, and made consistent decisions on the conformity to regulatory requirements. Verify that the decisions made for suspending, withdrawing, or reducing the scope of any certification is consistent with the recognizing Regulatory Authority's requirements.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 5.1.3, 9.1.14, 9.1.15, 9.2.2.5, 9.2.4, 9.2.5, 9.3.3, 9.4.3, 9.6.1, 9.6.2, 9.6.4, 9.6.5,

IMDRF/MDSAP WG/N3 clauses: 6.1.7, 7.3.1, 7.5.1, 9.2.6, 9.3.3, 9.4.3, 9.4.5

Guidance

➤ **Final review of the audit report**

The assessor should verify that the Auditing Organization's final review includes the verification of the audit report conformity to IMDRF/MDSAP WG/N24 and that the identified nonconformities are relevant to the scope of certification and supported by evidence, and that this review is recorded.

➤ **Decision on the manufacturer's regulatory conformity**

If the decision is made by a committee, this does not necessarily prohibit the auditor(s) from participating in committee meetings, provided the rules governing the committee ensure the overall independence of the committee.

The assessor should evaluate on the basis of a sample of files, whether the Auditing Organization ensures the consistency and accuracy of the certification decisions taken.

The assessor should verify that the auditing organization ensures that the certificate is only renewed or extended after the recertification process is completed including the final review of the file regardless of the certificate expiration date.

Typical evidence

Client files

N5 task 6.5.4.7 – Verify that the Auditing Organization implemented the decisions and conducted follow-up reviews and audits, including unannounced audits.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 9.1.13, 9.5.2, 9.6.3, 9.6.4

IMDRF/MDSAP WG/N3 clauses: 9.5, 9.6.1

Guidance

The assessor should verify that the Auditing Organization communicates in a timely manner with the relevant recognizing Regulatory Authority(s) in case of a decision to restrict, suspend, or withdraw certification.

The assessor should verify that the Auditing Organization ensures that the follow up activities are conducted to fulfill specified objectives, according to a specified timeline, and by individuals with the necessary competence.

Typical evidence

Client files

N5 task 6.5.4.8 – Verify that the Auditing Organization evaluated and made decisions on appeals. Verify that appeals are input to the Measurement, Analysis and Improvement process.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 9.7

IMDRF/MDSAP WG/N3 clauses: 6.1.7, 9.1(Exceptions)

Guidance

The assessor should verify that the Auditing Organization's process ensures a fair review of the request, taking into account internal jurisprudence, and should prevent any pressure on the decision makers that could impact their independence.

The assessor should verify that the Auditing Organization investigates appeals as potential indicators of the need for improvement through the Measurement, Analysis & Improvement process.

The assessor should verify that the Auditing Organization does not allow the manufacturer to object to the composition of the audit team unless the manufacturer has formally gone through the appeal process. If the manufacturer raises information about the impartiality or conflict of interest of the proposed audit team, this information can be considered in the appeals process.

The assessor should verify correction and corrective action if appropriate has been taken by the Auditing Organization. An Auditing Organization may define an abbreviated appeals process specifically for handling the objection to the audit team composition.

Trends on appeal decisions may reveal signs of lack of independence.

Typical evidence

Records of appeal

Link with other assessment tasks

See [N5 task 6.3.4.8](#) on complaints

See [N5 task 6.1.4.6](#) on impartiality

N5 task 6.5.4.9 – Verify that the Auditing Organization maintained records on the audit and decision activities.

Applicable Requirement

ISO/IEC 17021:2011 clauses 9.9

IMDRF/MDSAP WG/N3 clauses: Not applicable

No additional guidance

4.6 Process: Information Management

N5 task 6.6.4.1 – Verify that procedures have been defined, documented, and implemented for the control of documents and records required by the quality management system. Confirm the organization retains records and at least one obsolete copy of controlled documents for a period of time not less than 15 years.

Applicable requirements

ISO/IEC 17021:2011 clauses: 9.9.3, 9.9.4, 10.3.3, 10.3.4

IMDRF/MDSAP WG/N3 clauses: 10.1.2

Guidance

If the Auditing Organization uses an electronic document control system, including the use of electronic signatures, the assessor should verify that the Auditing Organization ensures that the electronic signature has the same value as a handwritten signature, and validates the system to ensure the authenticity of the signature, that a signed document cannot be tampered with, and that the documents can be retrieved and read for at least 15 years.

The assessor should verify that audit records are uniquely identified, including their version. If an audit record needs to be amended, the changes and their author should also be identifiable. Optimally, the version of the audit record should be traceable to the decision on the manufacturer's conformity.

Typical evidence

Document Control and record controls procedures, client file

N5 task 6.6.4.2 – Verify that the Auditing Organization made publicly accessible or provided upon request information describing its audit programs.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 8.1.1, 8.1.2, 9.7.2, 9.8.1

IMDRF/MDSAP WG/N3 clauses: 5.2.6

Guidance

This task is related to the Auditing Organization's audit programs or schemes they offer, and not the audit program for an individual manufacturer.

The assessor should identify the ways in which the Auditing Organization provides information about its audit programs.

Link with other assessment tasks

Publicly available information may affect the Auditing Organization's impartiality (see [N5 Task 6.1.4.6](#)).

N5 task 6.6.4.3 – Verify that the Auditing Organization has provided detailed information to the medical device manufacturer regarding the audit and decisions process, including the process addressing complaints and appeals, as well as fees.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 8.6.1, 8.6.2,
IMDRF/MDSAP WG/N3 clauses: 5.2.6

Typical evidence

This information may be found in contracts, conditions on certificates, website, etc.

N5 task 6.6.4.4 – Verify that the Auditing Organization has established contractual arrangements with the medical device manufacturers specifying the responsibilities of both parties. Verify that the contractual arrangements allow for the recognizing Regulatory Authority to observe and assess the auditing organization's audits. Verify that the contractual arrangements give permission for the recognizing Regulatory Authority to exchange information with other Regulatory Authorities that maintain Confidentiality Agreements. Verify that the contractual arrangements specify requirements regarding the reference to their conformity status and potential action to deal with misuse or misrepresentation of the conformity status.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 5.1.2, 8.4, 8.5, 8.6.3, 9.5.1, 9.6.3, 9.6.6
IMDRF/MDSAP WG/N3 clauses: 5.1 (Exceptions), 5.1.4, 5.1.5, 8.7.4, 8.8.1,
9.5.1, 9.5.2(3)

Guidance

The assessor should verify that the contractual arrangements do not restrict the exchange of information in relation to the manufacturer between the Regulatory Authorities that maintain Confidentiality Agreements.

The assessor should verify that a contractual arrangement does not imply that a certification document issued by the Auditing Organization is:

- An approval of the medical device, or a guarantee of its safety and effectiveness;
- A guarantee of compliance of the manufactured products to the regulations included in the scope of the audit/certification;
- A guarantee that the product will obtain a marketing authorization from a Regulatory Authority.

Typical evidence

Contractual arrangements

N5 task 6.6.4.5 – Verify that the Auditing Organization provides the recognizing Regulatory Authorities with audit reports and certificates that meet regulatory requirements, as well as other required and requested reports and communications.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 8.2

IMDRF/MDSAP WG/N3 clauses: 6.1.3, 8.2, 8.7, 9.2.2, 9.4.6, 9.5.3, 9.6.1, 9.8.1

Guidance

The assessor should verify that the Auditing Organization communicates to the recognizing Regulatory Authority(s) within 5 working days of becoming aware of any of the following, regardless of the source of information that makes the Auditing Organization aware of such reportable situations:

- Any fraudulent activities by, or counterfeit products from, any medical device manufacturer;
- Information that indicates a public health threat;
- A decision to refuse, suspend, reinstate, restrict or withdraw a certificate; or
- Significant changes relevant to the Auditing Organization's recognition, in any aspect of its status or operations (see the list in N3 clause 8.7.5).

Typical evidence

Records of communication between the Auditing Organization and the recognizing Regulatory Authority, Client file, Suspended/Withdrawn Certificates

N5 task 6.6.4.6 – Verify that the Auditing Organization made information on conformity status or certifications granted, suspended or withdrawn, publicly accessible or provided upon request.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 8.1.3, 8.1.4, 8.3, 9.6.3, 9.6.7, 9.8.10

IMDRF/MDSAP WG/N3 clauses: 8.3.1, 8.8.1

No additional guidance

N5 Task 6.6.4.7 – Verify that the Auditing Organization has defined, documented and implemented procedures and legally enforceable arrangements to safeguard confidentiality, unless disclosure is required by the requirements of IMDRF MDSAP documents or by law.

Applicable Requirement

ISO/IEC 17021:2011 clauses: 8.5, 9.9.3

IMDRF/MDSAP WG/N3 clauses: 8.5, 8.7, 8.8

Typical evidence

Procedures, contractual agreements between an Auditing Organization and a manufacturer, and contractual agreements between an Auditing Organization and its employees or external resources.

ANNEX

Reaffirmation and Interpretation of IMDRF/MDSAP WG/N3 and ISO/IEC 17021 on Threat to Impartiality Linked to Consultancy

1. An Auditing Organization or any part of the same legal entity shall not offer or provide medical device regulatory consultancy. (ISO/IEC 17021 5.2.5)

NOTE: No deviation to this requirement can be accepted.

2. If the Auditing Organization is a legal entity that is wholly or partly owned by a larger organization, the requirements for impartiality apply to both the Auditing Organization and the organization to which it belongs. (IMDRF/MDSAP WG/N3 5.2.10)

NOTE: This requirement, as it relates to medical device regulatory consultancy means:

- ISO/IEC 17021 5.2.1: The larger organization should have corporate policies or equivalent ensuring that other legal entities within the group do not negatively impact the impartiality of the Auditing Organization.
- ISO/IEC 17021 5.2.2: Other legal entities within the group should be transparent with regards to the legal entity's activities that could represent a possible conflict of interest. In particular, the list of clients who received medical device regulatory consultancy services should be available to the Auditing Organization and to Regulatory Authority Assessors.
- ISO/IEC 17021 5.2.5: While it is not prohibited for a separate legal entity belonging to the same group as the Auditing Organization to provide medical device regulatory consultancy, the independence of the Auditing Organization from the group's Consultancy Organization must be demonstrated and documented. This demonstration should take into account: 1) organizational structure; 2) corporate branding and advertising; 3) contracts and agreements; 4) accounting; 5) top management and operational decision making; 6) individuals involved in the audit and certification activities.
- ISO/IEC 17021 5.2.6 + N3 5.2.3: While it is not prohibited for a separate legal entity belonging to the same group as the Auditing Organization to provide internal audit services, the following should be considered:
 - o this legal entity cannot offer internal audit services to a certified client of the Auditing Organization, and
 - o the Auditing Organization cannot certify a medical device manufacturer to which this other legal entity provided internal audits within three (3) years following the end of the internal audits.
- ISO/IEC 17021 5.2.7 + N3 5.2.3: The Auditing Organization cannot certify a management system on which a client has received medical device regulatory consultancy services from another legal entity of the same group within three (3) years following the end of the consultancy service or of the internal audits.

- ISO/IEC 17021 5.2.8: An Auditing Organization cannot outsource auditing services to any Consultancy Organization or to any individual that is part of the personnel of the Consultancy Organization, and
- ISO/IEC 17021 5.2.9: A Consultancy Organization belonging to the same group as the Auditing Organization cannot market its activities as linked to the Auditing Organization's activities.

3. The Auditing Organization shall not certify a management system on which a client has received management system consultancy or internal audits, where the relationship between the Consultancy Organization and the Auditing Organization poses an unacceptable threat to the impartiality of the Auditing Organization. (ISO/IEC 17021 5.2.7)

NOTE 1: A relationship that threatens the impartiality of the Auditing Organization can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing and payment of a sales commission or other inducement for the referral of new clients, etc. (Note to ISO/IEC 17021 5.2.2). For example, a relationship that represents an unacceptable threat to impartiality is an Auditing Organization and Consultancy Organization operating under the same brand name.

NOTE 2: Allowing a minimum period of three (3) years to elapse following the end of the management system consultancy is one way of reducing the threat to impartiality to an acceptable level.

4. An Auditing Organization cannot outsource audits to a Consultancy Organization. (ISO/IEC 17021 5.2.8)

NOTE: While this generally does not apply to individuals contracted as individual external auditors and external technical experts, it does apply to individuals that are part of the personnel of a Consultancy Organization belonging to the same group as the Auditing Organization. Using an employee of a Consultancy Organization belonging to the same group as the Auditing Organization as an external auditor represents an unacceptable threat to impartiality, regardless of whether the Auditing Organization would have contractual agreements with the Consultancy Organization or with the individual.

5. An Auditing Organization cannot market or offer its activities as linked with any organization that provides management system consultancy services. (ISO/IEC 17021 5.2.9)

NOTE 1: An example of unacceptable link is the promotion of both an Auditing Organization's activities and Consulting Organization activities on promotional material (e.g. on the same webpage, or with direct links between webpages), or on exhibitor booth.

NOTE 2: When an Auditing Organization and a Consultancy Organization have an evident relationship, for example if they belong to the same group, the promotion of each

organization's activities that could be perceived as presenting a conflict of interest should include a disclaimer that:

- Certification would not be simpler, easier, faster or less expensive if the linked Consultancy Organization were used,
- The Auditing Organization cannot audit and certify an organization that obtained medical device regulatory consultancy services from the linked Consultancy Organization during the preceding three (3) years.

6. Providing internal audit services to an organization prohibits the Auditing Organization from offering certification services to this organization for a period of three years following the last internal audit performed for this organization. (IMDRF/MDSAP WG/N3 5.2.3, 5.2.5)

7. Mock audits, gap audits or pre-assessment audit may be offered to certified medical device manufacturers as long as the Auditing Organization does not provide specific advice, instructions or solutions to address deficiencies. Deficiencies identified during such an audit must be taken into account when grading nonconformities identified under the medical device regulatory audit scheme. (IMDRF/MDSAP WG/N3 9.2.5)

NOTE 1: The Auditing Organization should further mitigate the appearance of conflict of interest by ensuring that the auditors performing the mock audit, gap audit or pre-assessment audit of a manufacturer are not involved in the certification audit and certification decision.

NOTE 2: The scope of a mock audit, gap audit or pre-assessment audit offered to a certified client should be different from the pre-existing scope of certification. It would otherwise be seen as an internal audit prohibited according to ISO 17011 5.2.6.

8. The Auditing Organization must document any involvement in medical device regulatory consultancy undertaken by any personnel (including top management) prior to taking up employment with the Auditing Organization at the time of employment. (IMDRF/MDSAP WG/N3 5.2.4)

NOTE: The documents should include the beneficiaries of the medical device regulatory consultancy services.

9. An individual cannot be involved in the audit and certification activities relative to a medical device manufacturer if he/she:

- Was an employee or provided medical device regulatory consultancy services of the specific manufacturer or of any company belonging to the same organization, at any time during the prior 3 years. (IMDRF/MDSAP WG/N3 5.2.5);
- Provided medical device regulatory consultancy services to this specific manufacturer, its authorized representative or its supplier in the past three (3) years. (ISO/IEC 17021 5.2.10 and IMDRF N3 5.2.3 3rd and 4th bullets); OR
- Has a spouse or child who meets the conditions specified above.

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NOTE 1: This applies to the Auditing Organization's employees, to external auditors and to external technical experts.

NOTE 2: If an individual is part of the personnel of a Consultancy Organization, this individual cannot be involved in the audit and certification activities relative to a medical device manufacturer to which the Consultancy Organization provided medical device regulatory consultancy services to this specific manufacturer, his authorized representative or a his supplier in the past three (3) years.

10. See also IMDRF/MDSAP WG/N29