

[Organization logo]

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PROCEDURE FOR INTERNAL AUDIT

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1. Purpose, scope and users

The purpose of this Procedure is to describe all audit-related activities: writing the audit program, selecting an auditor, conducting individual audits and reporting.

The internal audit determines if the Quality Management System (QMS) is implemented according to applicable standards and regulations and effectively maintained.

This Procedure is applied to all processes and/or areas (parts of the organization) within the QMS.

Users of this document are [members of top management title] of [organization name], as well as internal auditors.

Commented [AES4]: E.g., CEO, Management Representative

Commented [AES5]: Include the name of your organization.

2. Reference documents

- ISO 13485:2016 standard, clause 8.2.4
- MDR 2017/745 Annex IX – Chapter I
- Quality Manual
- Procedure for Corrective and Preventive Action

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You can find the full text of the MDR on the following link:
<https://advisera.com/13485academy/mdr/>

Commented [AES7]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

Commented [AES8]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "25_Corrective_and_Preventive_Action".

Commented [AES9]: E.g., CEO

3. Conducting of internal audit

3.1. Internal audit planning

[Job title] approves an annual program for internal audits, considering the status and importance of the process and/or area (part of the organization) that is audited, as well as results of previous audits.

Additional internal audits may be conducted in the case of:

- significant reclamation from client (decision about whether the reclamation is significant and requires additional audit is made by [job title])
- significant nonconformity in process or repetition of the same nonconformity (decision about whether the conformity is significant and requires additional audit is made by [job title])

Commented [AES10]: E.g., auditor

Commented [AES11]: Adapt to organization's practice.

Commented [AES12]: E.g., auditor

3.2. Appointing internal auditors

[organization name]

[Job title] appoints internal auditors and a leader of the audit team.

Commented [AES13]: E.g., CEO

An internal auditor is someone from either inside or outside of the organization, who has the necessary competence to conduct the internal audit. Criteria for appointing internal auditors are:

Commented [AES14]: If there are multiple internal auditors.

- knowledge of principles of auditing
- possession of general knowledge for specific areas of audit

Commented [AES15]: E.g., certificate for internal auditor for

- knowledge of standards for ISO 9001, ISO 14001, ISO 45001, and ISO 27001
- necessary competence – achieved through education and/or experience

Commented [AES16]: E.g., MDR 2017/745

[Job title] ensures auditors have the necessary competence and independence, as required by the standards. Internal auditors are not allowed to audit their own work.

Commented [AES17]: E.g., CEO

3.3. Conducting individual internal audits

[Job title] defines criteria, audit scope, and methods of audit.

Commented [AES18]: E.g., the leader of the audit team – Lead Auditor

The internal audit is conducted in two phases:

- Document audit

Commented [AES19]: Audit of all documents related to

- Audit of compliance with requirements

Commented [AES20]: Audit that shows whether the processes

Criteria of the audit can be compliance with ISO 9001, ISO 13485, and/or alignment with legal requirements and requirements of external parties that the organization agreed to.

Commented [AES21]: E.g., MDR 2017/745

Methods of internal audit that will be applied during the internal audit are [job title] [job title] [job title]. Sampling of data is performed through reviewing existing documentation, personal observation and interviews.

Commented [AES22]: E.g., vertical check (by hierarchical levels)

A checklist for internal audit can be used for conducting the internal audit.

Commented [AES23]: E.g., Appendix 1 – Internal Audit Checklist

3.4. Internal audit reporting

On the basis of the audit findings, the internal auditor (or internal audit team leader if there are more internal auditors) makes an internal audit report that is delivered to [job title].

Commented [AES24]: E.g., CEO, Management Representative,

The internal audit report must contain identified nonconformities (major and/or minor) that require corrective actions, identified potential nonconformities that require preventive actions, good practice identified any areas within the audit scope not covered, and recommendations for improvement of the QMS. The internal audit report is delivered to the management within the deadline defined by [job title].

Commented [AES25]: E.g., CEO

3.5. Follow-up activities

The owner of the process in which the nonconformities are identified must ensure that all necessary corrections and corrective actions for removing nonconformities and their cause are undertaken without unnecessary delays.

[organization name]

Corrective and preventive actions are undertaken according to the Procedure for Corrective and Preventive Action.

After performing corrective actions, if necessary, audit follow-up can be conducted according to the Procedure for Corrective and Preventive Action in order to assess the effectiveness or verification of corrective actions.

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Internal Audit Checklist	PR24.1	1 year	Office of Management Administration	[job title]
Internal Audit Program	PR24.2	1 year	Office of Management Administration	[job title]
Internal Audit Report	PR24.3	1 year	Office of Management Administration	[job title]
Internal Audit Plan	PR24.4	1 year	Office of Management Administration	[job title]

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Only [job title] can grant other employees the right to access the Internal Audit Program, the Internal Audit Plan, the Internal Audit Report and the Internal Audit Checklist.

Commented [AES27]: E.g., CEO

5. Appendices

- Appendix 1 – Internal Audit Checklist
- Appendix 2 – Internal Audit Program
- Appendix 3 – Internal Audit Report
- Appendix 4 – Internal Audit Plan

[job title]

[name]

[organization name]

[signature]

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