

[Organization logo]

[Organization name]

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PROCEDURE FOR INTERNAL AUDIT

Commented [134852]: To handle documents in an ISO-compliant Document Management System, use Conformio: <http://advisera.com/conformio>

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Created by:	
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Signature:	

Commented [134853]: Adapt to the existing practice in organization.

Distribution list

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[organization name]

Change history

Date	Version	Created by	Description of change
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[organization name]

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 QMS is according to applicable standards and regulations and effectively implemented and 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 [134855]: E.g. CEO, Management Representative

2. Reference documents

- ISO 13485:2016 standard, clause 8.2.4
- ISO 9001:2015 standard, clause 9.2
- Quality Manual
- Procedure for Corrective and Preventive Action

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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 processes and areas of the organization that is audited, as well as results of previous audits. The annual program should be updated in the case of changes during cumulative coverage of the entire QMS scope. Internal audits are usually conducted before management review.

Commented [134857]: E.g. CEO

- significant reclamation from client (decision about whether the reclamation is significant and requires additional audit is made by [Job title])
- significant change in system (decision about whether the change in system is significant and demands additional audit is made by [Job title])

Commented [134858]: E.g. Auditor

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maintaining records.

3.2. Appointing internal auditors

[organization name]

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

Commented [1348511]: 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 [1348512]: If there are more internal auditors.

- knowledge of standards of auditing
- possession of general knowledge for specific areas of audit
- knowledge of standards for ISO 9001, ISO 14001, ISO 45001, and ISO 13485
- necessary competence – achieved through education and/or experience

Commented [1348513]: E.g. Certificate for internal auditor for ISO 13485 standard

Commented [1348514]: E.g. MDD (93/42/EEC)

[Job title] selects auditors in such a way as to ensure objectivity and impartiality, i.e. to avoid conflict of interest.

Commented [1348515]: E.g. CEO

3.3. Conducting individual internal audits

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

Commented [1348516]: E.g. The leader of the auditor team – Lead Auditor

- Document audit
- Vertical check

Commented [1348517]: Audit of all documents related to standard ISO 13485 and identified processes in organization.

Commented [1348518]: Audit that shows whether the processes are executed in accordance with corresponding procedure.

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 [1348519]: E.g. MDD (93/42/EEC)

Methods of internal audit can include document audits, vertical check, and process audits. Auditing of documents is performed through reviewing existing documentation, approved documents and interviews.

Commented [1348520]: E.g. vertical check (by hierarchical structure)

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

Commented [1348521]: 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) is delivered to [Job title].

Commented [1348522]: E.g. CEO, Management Representative, Department managers

The internal audit report must contain identified non-conformities (major and/or minor) that require corrective action. The internal audit report is delivered to top management within the deadline defined by [Job title].

Commented [1348523]: E.g. CEO

3.5. Follow-up activities

The owner of the process in which the non-conformities are identified must ensure that all necessary corrective actions are taken to eliminate the non-conformities and their causes and prevent their recurrence.

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

The following corrective actions, if necessary, will take place in accordance with the Procedure for Corrective and Preventive Actions to ensure the effectiveness of corrective actions.

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Internal Audit Checklist	PR.18.1	2 years	[office of Management Representative]	[job title]
Internal Audit Program	PR.18.2	2 years	[office of Management Representative]	[job title]
Internal Audit Report	PR.18.3	2 years	[office of Management Representative]	[job title]
Internal Audit Plan	PR.18.4	2 years	[office of Management Representative]	[job title]

Commented [1348524]: If the record is in electronic form, write the name of the folder on Management Representative's computer.

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

Commented [1348525]: 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