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**PROCEDURE FOR INTERNAL AUDIT**

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# 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.

# 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

# Conducting of internal audit

## 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. One or more internal audits should be conducted in the course of one year, ensuring cumulative coverage of the entire QMS scope. Internal audits are usually conducted before Management review.

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])
* …

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