| Regulatory Requirement | Document Section |
|---|---|
| ISO 13485:2016 Section 8.2.4 | All |


## Summary

This SOP describes how internal auditing is performed for the purpose of reviewing compliance with regulatory requirements. It can be used for both internal and supplier audits.


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| **Process Owner** | *<enter role of process owner>* |
| **Key Performance Indicators** | *<enter KPIs to be tracked for the Management Review>* |

## 1. General Considerations

### 1.1 Auditor Qualification

Auditors that conduct audits must be sufficiently qualified by having attended external auditor training and by having participated in audits before.

### 1.2 Audit Guidelines

Auditors must adhere to the following guiding principles:

- **Integrity:** all participants of an audit shall give honest presentations of their views and knowledge, observe confidentiality regarding sensitive information towards third parties and conduct audit work in a thorough manner.
- **Objectivity**: auditors must act impartial, free of any favoritism and conflicts of interest regarding the subject of their work.
- **Verifiability:** auditors must collect evidence to support their assessments. Documentation must include audit plans, audit criteria and detailed evidence of audit findings so that outcomes are reliable and comprehensible for later reference.

### 1.3 Audit Findings

The following categories of audit findings are defined for the organization:

**Major Nonconformities (MNC+):**

Major nonconformities are systematic deviations from regulatory requirements that indicate disabilities of the organization's QMS to deliver intended outputs. For instance, major nonconformities would entail the lack of a process, repeated minor nonconformity regarding the same process or QMS segment and failure to eliminate the cause of that nonconformity.

**Minor Nonconformities (MNC-):**

Minor nonconformities do not indicate systematic malfunctioning of an entire process or the entire QMS. The general ability to ensure controlled, conforming processes and products is upheld nevertheless. Examples are single, isolated events like a mislabeled document or a missing review documentation.

**Recommendations (REC):**

Recommendations entail auditor advice for improved QMS effectiveness or efficacy.

## 2. Process Steps

### 2.1 Compilation or Revision of Audit Program

Audits are based on the organization's QMS processes. The QMO is responsible to maintain a perennial audit program that ensures:

1. That core processes (as defined in the quality manual) are audited at least annually,
2. That processes presenting higher compliance risks based on previous audit findings, CAPAs or changes to the QMS system are audited more frequently.

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| Participants | QMO |
| Input | Previous findings, CAPAs, QMS changes |
| Output | (Updated) audit program |

### 2.2 Conducting Audits

Audits are planned separately by respective auditors, coordination is supported by the QMO. Once a scheduled audit date approaches, the QMO informs relevant members of the organization to ensure their availability for potential auditor questions during the audit. QMO and auditor together compile an audit plan that specifies the audit scope, objectives and participants.

Audit objectives may entail: review of compliance of processes with regulatory requirements, review of compliance with processes, review of the effective implementation of corrective and preventive action (CAPA).

Audits are conducted by inspecting appropriate process records and by interviewing members of the organization. The auditor documents collected evidence, observations and findings as part of an audit report.

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| Participants | Auditor, QMO |
| Input | Audit program Quality Management System, incl. records |
| Output | Audit plan (before the audit) Audit report (after the audit) |

### 2.3 Audit Follow-Up

For all major nonconformities resulting from audit findings, a separate CAPA is initiated. The QMO reports audit findings to the Management as part of the next Management Review.

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| Participants | QMO |
| Input | Audit report |
| Output | CAPA documentation |