

[Organization's Logo]

[Organization's Name]

**Commented [170251]:** All fields in this document marked by square brackets [ ] must be filled in.

## INTERNAL AUDIT PROCEDURE

**Commented [170252]:** If you want to find out more about internal audit, see:

13 Steps for ISO 9001 Internal Auditing using ISO 19011  
<http://advisera.com/9001academy/knowledgebase/13-steps-for-iso-9001-internal-auditing-using-iso-19011/>

**Commented [170253]:** Adapt to the existing practice in organization.

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## Change History

Date	Version	Created by	Description of change
	0.1	17025Academy	Basic document outline

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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.

This procedure applies to all laboratory activities that fall under the **Scope of Accreditation** including the management of the laboratory, sampling, tests and/or calibrations, reports and records.

Users of this procedure are members of laboratory top management and laboratory personnel of [organization name] that plan, schedule, participate and report on the internal audit.

**Commented [170255]:** These are activities that the laboratory decides to have under the system that is or will be accredited. The laboratory could also perform other activities that are not under the scope of accreditation.

## 2. References

- ISO/IEC 17025:2017; Clause 8.8
- ISO 19011:2011
- Quality Manual

**Commented [170256]:** ISO 19011 provides guidance on auditing management systems, including the principles of auditing, managing an audit program and conducting management system audits. Additionally, it also provides guidance on the evaluation of competence of individuals involved in the audit process, including the person managing the audit program, auditors and audit teams.

**Commented [17A7]:** You will find this document in the ISO 17025 Toolkit folder "03\_Quality\_Manual".

## 3. Conducting an Internal Audit

### 3.1. Internal audit planning

It is the responsibility of [job title] to plan, establish, implement and maintain an **annual Internal Audit Program**. [job title] determines the frequency, methods and responsibilities for conducting the audits

**Commented [170258]:** Quality manager or CEO or other

**Commented [17A9]:** Typically, an internal audit is

The team leader and internal audit team (auditors) assemble with members of the laboratory's

audited, as well as results of previous audits.

**Commented [1702510]:** Specific principles and requirements for establishing an internal audit are found in ISO 19011, clause 5.

The internal audits are conducted at least once on an annual basis and are completed in time for the

audit.

**Commented [1702511]:** Person, who performs the audit on behalf of the registration body.

Additional internal audits may be conducted in the case of:

- **Significant** reclamation from client - decision about whether the reclamation is significant and

**Commented [1702512]:** These are three important cases,

[organization name]

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- [redacted]

### 3.2. Appointing internal auditors

[Job title] appoints internal auditors and a leader of the audit team (if there are more internal auditors).

An internal auditor may be someone from the laboratory or a person outside the organization. Criteria for appointing internal auditors are:

- [redacted]
- [redacted]
- [redacted]
- necessary competence – achieved through education and/or experience.

Internal auditors must be selected in such a way as to ensure objectivity and impartiality, i.e. to avoid [redacted]

### 3.3. Conducting internal audits

On the date of the planned internal audit, the team leader and internal audit team (auditors) assemble with members of the laboratory's management team discuss the Internal Audit Plan and review any [redacted]

Nonconformity Reports issued.

The audit must be conducted according to the Internal Audit Program by the auditors using prepared [redacted]

auditing involve steps to seek objective evidence against pre-defined audit criteria, for example:

- All documentation (internal and external) is current and complete.
- [redacted]
- [redacted]
- [redacted]
- Controls to ensure the validity of results are effective (e.g., use of internal and external quality checks).
- [redacted]
- [redacted]
- [redacted]
- The Internal Audit Process Checklist is used to record the witnessing and vertical audit findings.

**Commented [1702513]:** Quality manager or person designated by Quality manager.

**Commented [1702514]:** Specific principles and requirements for conducting an internal audit are in standard ISO 19011, clause 6.5.

[organization name]

During the audit, the audit team is required to collect objective evidence that either confirms compliance with procedures or confirms nonconformities.

### 3.4. Internal audit reporting

When the audit is complete, the audit team meets in order to review the audit. The team identifies and

[Job title] must ensure that timely action is taken for all NCRs and the results reported to management.

### 3.5. Follow-up activities

The owner of the process in which the nonconformities are identified must ensure that all necessary

After performing corrective actions, if necessary, [job title] conducts audit follow up using Audit Internal Report in order to assess the effectiveness or verification of corrective actions.

**Commented [17A15]:** You will find this procedure in the ISO 17025 Toolkit folder "13\_Complaint\_Nonconformity\_and\_Corrective\_Action"

**Commented [1702516]:** Audit team leader.

## 4. Managing Records Kept on the Basis of this Document

Documentation for the completed audit consists of completed audit documents and objective evidence

Record name	Code	Storage		Responsibility
		Retention time	Location	
Internal Audit Program	PR.18.1	5 years	[office of [job title]]	[job title]
Internal Audit Checklist	PR.18.2	5 years	[office of [job title]]	[job title]
Audit Nonconformity Report	PR.18.3	5 years	[office of [job title]]	[job title]
Internal Audit Process Checklist	PR.18.4	5 years	[office of [job title]]	[job title]
Internal Audit Report	PR.18.5	5 years	[office of [job title]]	[job title]

## 5. Appendices

- Appendix 1 – Internal Audit Program
- Appendix 2 – Internal Audit Checklist
- Appendix 3 – Audit Nonconformity Report
- Appendix 4 – Internal Audit Process Checklist
- Appendix 5 – Internal Audit Report