STANDARD OPERATING PROCEDURE

Internal Audit SOP

Document no.	SOP-QA-004
Revision	1.0
Owner	Lead Auditor
Effective date	September 15, 2026
Review cycle	Every 12 months

1. Purpose

To verify through planned, independent audits that processes are being followed as documented and that the quality management system is working effectively, identifying nonconformances for correction.

2. Scope

Applies to scheduling, planning, conducting, reporting and following up on internal audits across departments and processes. External or customer audits and the execution of corrective actions are handled separately from this SOP.

Definitions

Audit criteria	The procedure, standard or requirement an auditor checks the process against.
Nonconformance	A finding where a process does not meet the defined audit criteria.
Objective evidence	Verifiable facts, such as records, observations or measurements, that support a finding.
Closing meeting	The meeting at the end of an audit where findings are presented to the auditee.

3. Responsibilities

Lead Auditor	Maintains the audit schedule and assigns independent auditors to each audit.
Auditor	Plans and conducts the audit, gathers evidence, and reports findings.
Process Owner	Participates in the audit as auditee and raises CAPAs for nonconformances found.
Quality Manager	Tracks findings to closure and summarizes audit trends for management review.

RACI matrix

Activity	Lead Auditor	Auditor	Process Owner	Quality Manager
Schedule and assign the audit	R	I	I	R/A
Plan and conduct the audit	C	R/A	C	I
Present findings at the closing meeting	C	R/A	I	I
Raise CAPA for nonconformances	I	C	R/A	I
Track findings to closure	I	C	C	R/A

R = Responsible, A = Accountable, C = Consulted, I = Informed

4. Materials and PPE

Materials, tools and systems

- Annual internal audit schedule
- Audit checklist and criteria
- Audit report template
- CAPA log cross-reference

5. Procedure

Step	Task	Owner	Done
5.1	**Maintain the audit schedule** The Quality Manager maintains an annual internal audit schedule covering every process and department in scope.	Quality Manager	☐
5.2	**Assign an independent auditor** The Lead Auditor assigns an auditor who is independent of the area being audited, so no one reviews their own work. **Warning:** An auditor should never audit their own work area, even temporarily due to staffing constraints.	Lead Auditor	☐
5.3	**Prepare the audit plan** The Auditor prepares an audit plan and checklist based on the procedure and criteria applicable to the area being audited.	Auditor	☐
5.4	**Notify the auditee** The Auditor notifies the Process Owner of the audit date, scope and plan well in advance of the audit.	Auditor	☐
5.5	**Hold an opening meeting** The Auditor holds a brief opening meeting with the Process Owner to confirm scope, criteria and logistics before starting the audit.	Auditor	☐
5.6	**Gather objective evidence** The Auditor gathers objective evidence by observing the process, interviewing staff and reviewing records against the audit criteria. **Checkpoint:** Every finding is backed by specific objective evidence rather than opinion or impression.	Auditor	☐
5.7	**Record nonconformances** The Auditor records each nonconformance found against the defined criteria, with the supporting evidence noted alongside it.	Auditor	☐
5.8	**Hold a closing meeting** The Auditor presents the findings to the Process Owner in a closing meeting before leaving the audited area. **Checkpoint:** The auditee sees every finding in the closing meeting; nothing new appears later in the written report.	Auditor	☐
5.9	**Issue the audit report** The Auditor issues the written audit report with findings, supporting evidence and due dates for a response.	Auditor	☐
5.10	**Raise CAPA for findings** The Process Owner raises a CAPA for each nonconformance identified, following the CAPA SOP for investigation and correction.	Process Owner	☐

Step	Task	Owner	Done
5.11	**Track findings to closure** The Quality Manager tracks open findings against their due dates until each one is closed.	Quality Manager	☐
5.12	**Verify prior findings** The Auditor verifies that corrective actions from the previous audit were completed and effective during the next scheduled audit.	Auditor	☐
5.13	**Summarize results for management review** The Quality Manager summarizes audit results and trends for the next management review meeting.	Quality Manager	☐

6. Quality checks

- Auditors are independent of the area they audit.
- Every finding is backed by objective evidence recorded in the audit report.
- The auditee sees findings in the closing meeting before the written report is issued.
- Open findings are tracked to closure against their due dates.

7. Records

- Audit plan and checklist
- Audit report with findings
- CAPA reference for each nonconformance
- Audit schedule and completion status

8. KPIs

- Percentage of scheduled audits completed on time
- Average time to close audit findings
- Number of nonconformances per audit
- Repeat finding rate across audit cycles

9. Common mistakes

- Assigning an auditor to audit their own process.
- Surprising the auditee with findings they never heard in the closing meeting.
- Recording a finding without supporting objective evidence.
- Not tracking findings through to CAPA closure.

10. Revision history

Revision	Date	Description	Reviewed by
1.0	September 15, 2026	Initial release	Ilia Pirozhenko

Approval

Prepared by	Approved by	Date

This is a template. Adapt it to your organization, equipment and local regulations before use.

Scan for the latest version

Opens this template online, where you can download it again in Word, PDF, Excel or CSV — free, no sign-up.

Or add it to Perfect Wiki so your team can find it and ask questions about it in Microsoft Teams, Slack, kChat or Mattermost.