

Quality Procedure

Internal Auditing

Table of Contents

1	INTERNAL AUDITING PROCEDURE	3
1.1	INTRODUCTION & PURPOSE.....	3
1.1.1	Process Activity Map	3
1.1.2	References	3
1.1.3	Terms & Definitions.....	3
1.2	APPLICATION & SCOPE.....	4
1.3	ROLES, RESPONSIBILITIES & AUTHORITIES	4
1.3.1	Roles & Responsibilities.....	4
1.3.1.1	Top Management	4
1.3.1.2	Line Managers & Supervisors	4
1.3.1.3	Quality Manager.....	4
1.3.1.4	Purchasing Manager.....	5
1.3.1.5	Internal Auditors.....	5
1.3.1.6	Auditees.....	5
1.4	INTERNAL AUDIT PROCESS	5
1.4.1	Auditor Competency	5
1.4.2	Internal Audit Program.....	6
1.4.3	Conducting Internal Audits.....	7
1.4.3.1	General.....	7
1.4.3.2	Internal Audit Scoring	7
1.4.3.3	Audit Preparation.....	7
1.4.3.4	Opening Meeting.....	8
1.4.3.5	Management System Audits	8
1.4.3.6	Process Audits	8
1.4.3.7	Closing Meeting	9
1.4.3.8	Review & Reporting.....	9
1.4.3.9	Follow-up of Audit Recommendations	10
1.4.3.10	Closing the Audit Cycle.....	11
1.4.4	Auditing Techniques	11
1.4.5	Working Documents	11
1.5	SUPPLIER AUDITS	11
1.5.1	General.....	11
1.5.2	Supplier Self-Evaluation.....	11
1.5.3	2 nd Party Supplier Audits	12
1.6	CORRECTIVE ACTION	12
1.7	DOCUMENTATION	12
1.8	PROCESS MAP	14

Quality Procedure	Double click here to insert your organization's name or logo.
Internal Auditing	

Before the audit, the [Auditee](#) of the work area should ensure that current versions of the following documents are available for the auditors to review:

1. Records of induction and training completed by their staff in the area; all new staff employed in the past 12 months must have completed an induction;
2. Nonconformity and complaint reports with attachments demonstrating completion of corrective actions;
3. Risk assessments completed or local risk register for activities, including any related local procedures;
4. Current work instructions, specifications, and other documented information used in the area;
5. Monitoring and measuring equipment used in the area is identified and within its calibration due date;
6. Records of process inspections and checks completed in the past 12 months, with attachments, e.g., emails or requests to demonstrate actions taken following inspection;
7. General housekeeping is good, and products and materials are identified, handled, and stored correctly;
8. Any legal requirements applicable to the activities of the work area, products, or services, including relevant relationships with contractors or suppliers to the area;
9. Examples of quality information and/or training given to staff, e.g., quizzes, practical class notes, manuals, induction records, training, etc.

1.4.3.4 Opening Meeting

The purpose of the opening meeting is to introduce the audit team members to the [Auditee](#) and establish communication links with the activities being audited. The purpose of the opening meeting is to:

1. Confirm the audit objectives, criteria, agreed scope, and duration of the audit;
2. Explain how the audit will be conducted;
3. Confirm resources required;
4. Discuss actions to be taken in the event of an imminent safety risk encountered during the audit; and
5. Answer any questions.

During the meeting, the [Internal Auditor\(s\)](#) and the [Auditee](#) review the scope and objectives of the audit and provide a summary of the methods and procedures to be used to conduct the audit to clarify the details of the audit and confirm the time and date for the closing meeting and any interim meetings.

1.4.3.5 Management System Audits

Quality management system audits focus on the system as a whole and compare planning activities and broad system requirements across several functional groups with the desired outcomes to evaluate the system's effectiveness and identify any systematic opportunities for improvement.

Before each audit activity, the [Quality Manager](#) arranges for those concerned to be notified by email before the audit. The internal audit is conducted using the [Internal Audit Checklist](#). The audit is documented using the [Internal Audit Report](#), which documents the performance of the quality management system, identifying all documentation used and key indicators associated with the system.

1.4.3.6 Process Audits

Process audits are an in-depth analysis intended to verify that individual processes are performing and producing their outputs in accordance with desired outcomes. Process audits also investigate opportunities for improvement or identify concerns and corrective actions.

Quality Procedure	Double click here to insert your organization's name or logo.
Internal Auditing	

Standard operating process audits of the manufacturing and product realization activities are planned by the [Quality Manager](#) annually in conjunction with the [Operations Manager](#), focusing on special, vulnerable, new, or high-risk processes. The audit team then reviews the process inputs and outputs using the [Process Audit Template](#) to:

1. Identify the purpose of the process under investigation;
2. Determine what should be accomplished;
3. Identify the inputs into the process;
4. What are the expected outputs from the process;
5. What are the products or services provided to the customer;
6. What are the risks to the customer;
7. Identify the owner of the process;
8. Determine the objectives of the process;
9. What are the key performance indicators associated with the process;
10. Are there any customer-specific requirements;
11. Determine how to obtain information that indicates process performance.

Process audits are conducted [monthly/six-weekly/bi-annually](#), as appropriate, to cover all manufacturing areas over the audit cycle. Any nonconformity found during the audit is agreed upon with the [Operations Manager](#), and resolution or containment actions are agreed upon.

The audit is documented using the [Internal Audit Report](#), which documents the performance of the process, identifying all documentation used and key indicators associated with the process.

1.4.3.7 Closing Meeting

The final stage of the audit is the closing meeting with the auditees. This meeting aims to summarize the audit findings and the suggested solutions (recommendations) to correct the issues.

The findings that are discussed at the closing meeting should never be a surprise for the auditees, as they have already been informed about them during the course of the audit. In preparation for the closing meeting, the audit team reviews audit findings and audit evidence and compares them with the audit criteria and objectives. Any resulting nonconformities are:

1. Written in a clear, concise manner;
2. Supported by objective evidence;
3. Identified by the specific requirements which have not been met;
4. Identified as a major or minor nonconformity.

The closing meeting is the ultimate test for the auditors to ensure they were not mistaken when identifying conditions or interpreting criteria. The closing meeting is an excellent opportunity for the auditees to prepare for the final audit report. A final agreement on how to fix the issues will be reached at the closing meeting. Minutes of the closing meeting are distributed.

1.4.3.8 Review & Reporting

The Internal Auditor writes the [Internal Audit Report](#) to provide a permanent record of the audit conducted and to provide [Top management](#) with information on which to base corrective action and improve our quality management system.

Quality Procedure	Double click here to insert your organization's name or logo.
Internal Auditing	

The audit report is prepared to reflect the content and outcomes of the audit accurately. It is dated and signed by the [Internal Auditor](#), referencing previously issued information or, as applicable, the following items:

1. The scope and objectives of the audit, including the processes and product groups involved;
2. Details of the audit plan, the identification of audit team members, audit dates, and identification of the specific organization audited;
3. Identification of the audit criteria against which the audit was conducted (regulatory requirements for quality management systems, manual, etc.);
4. Identification of nonconformities, including:
 - a. details of each nonconformity;
 - b. the audit criterion or the specific regulatory requirement to which it applies;
 - c. the relative severity concerning regulatory requirements; and
 - d. the date for submission of any necessary corrective action plans.
5. The effectiveness of the quality management system in meeting objectives;
6. Details of any corrective action(s) taken during the audit;
7. Recommendation to the auditing organization for follow-up action, including time schedule.

The [Quality Manager](#) is required to provide routine reporting of the audit results to the relevant management via the circulation of the audit report, closing meeting minutes, and audit performance metrics as input to management review:

1. Reviewing audit conclusions;
2. Approving audit conclusions;
3. Identifying trends;
4. Making recommendations for improvement;
5. Finalizing the internal audit report;
6. Issuing the internal audit report to [Top management](#).

All internal audit results and any corrective actions are discussed at management review meetings to evaluate their effectiveness and implementation.

Trends in audit results reported to management review cover all audits of the quality management system, including first-party (internal) audits, second-party audits (e.g. by customers) and third-party audits (e.g. by the certification body or regulators).

1.4.3.9 Follow-up of Audit Recommendations

The [Internal Auditor](#) follows up on the status of the implementation of audit recommendations to determine whether the appropriate initiatives were taken to solve the issues identified during the audit. The [Quality Manager](#) is required to ensure effective and timely implementation of corrective action:

1. Review the audit evidence and conclusions and discuss recommendations for improvement;
2. Decide if process non-conformances observed should be subject to formal corrective action;
3. Prepare the audit report;
4. Review the audit report with the responsible Manager;
5. The responsible Manager reviews the corrective actions, and a close-out action is agreed upon;
6. Finalize the audit report.