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1.7. Audit Planning (P)

A successful audit begins with a detailed **Audit Plan**. A well-planned audit will involve six steps:

1. **Select the Audit Team** – While an individual may carry out an audit, a team approach provides objectivity and encourages involvement in the Quality Management System. The audit team is best assembled from a diagonal cross section of the organization. A lead auditor should always be placed in charge. The auditor, or audit team, is selected on the basis of technical ability and/or past audit experience. Auditors have no direct responsibility or involvement in the process or department under audit, except under special circumstances that may require highly skilled inspections or specialist knowledge of a process, and where the lack of technical ability would clearly hinder the effectiveness of the audit. Audit team members must be qualified by the Quality Manager based on their demonstration as objective and impartial individuals.

2. **Determine Audits Objective and Scope** – Defining the objective and scope of the audit involves answering the following four questions:

1. Where am I auditing from?
2. What am I auditing to?
3. At what point in the process am I starting?
4. At what point in the process am I finishing?

To identify the scope of the audit, review the relevant documentation, and identify the beginning and ending points of the audit. After review, meet with the department manager or supervisor and identify the key processes involved and use this information to prepare an audit checklist.

3. **Identify Information Sources** – Audits are a comparison between source information and what is actually happening. Source information is usually quality documentation or written operating procedures. Source information can be based on a verbal explanation of the process being audited, if a written procedure is not required according to the QCM. If source information is obtained through a verbal explanation of the process, the auditor shall summarize the conversation and document this as the source information on the audit report. Source information also includes samples that may be required to verify the process. An example may be purchase orders when auditing the purchasing process.



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4. **Develop the Audit Program** – The audit program serves as your road map during the audit. It should be designed to keep you on track and on schedule. As a minimum it should identify the duration of the audit, the areas of the organization that will be subject to assessment, and the people who should be available to answer the auditors questions.

Key issues in developing the program include:

- Is it well planned? – Have you thought through the process? Have you identified a beginning and an end? Can you take a sample from the system that will enable you to follow the process in a logical way?
 - Have you set achievable objectives? – Can you verify that something is actually happening? Can you find evidence of an effective system? Can you verify that the system or process you are examining is working? If so, how?
5. **Confirm the Program with the Auditee** – Review the entire audit program with the department managers or supervisors of the processes to be audited. Confirm the dates and time for the audit, and review the source information identified.
 6. **Develop a Checklist** – The audit checklist is the backbone of the actual audit. Thought must be given to structuring the checklist so it will flow with the process being audited. Details of the samples you will need and where they will be taken from are included on the checklist. Checklist questions need to be open-ended ones that will enable the auditee to explain the process and show how that process is documented.

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1.8. Audit Execution (E)

The actual execution of the audit consists of a number of distinct events:

- The opening meeting,
- The audit itself: collecting information,
- Verifying information,
- Recording discrepancies.

The Opening Meeting – The opening meeting is designed to explain the purpose of the audit, and the nature of the audit process, to the managers and supervisors responsible for the activity to be audited. This meeting takes place well in advance of the audit to minimize any interference with normal production and to provide cooperation with the affected personnel. The only exception to this requirement is a spot quality audit performed under direct management instruction. While most opening meetings are informal, it is important to follow an agenda for the meeting to ensure all necessary points are covered in as short a time as possible.

Items to include in the opening meeting agenda:

- Explain the audits purpose, scope and range of activities to be reviewed.
- Confirm the details of the program are acceptable to the auditee and that the necessary employees will be available at the scheduled times.
- Confirm the status of the procedures and any relevant documents prior to the actual audit. Clarify any ambiguities.
- Explain the manner of identifying and recording nonconformities.

Collecting Information – The purpose of the audit is to collect objective evidence regarding the effectiveness of our Quality Management System. The actual audit is a tour through the processes and areas being audited along a path prescribed by the program and checklist.

Most of the information collected will be through interviews with the staff involved in the process, observing activities, or documented evidence found in a record.

As stated previously, the auditor should ask open-ended questions that cannot be answered by a simple yes or no. Yes-and-No questions do not allow individuals to elaborate on their work and do not give the auditor confidence that the employee understands their operations. Open questions allow you to determine what is not recorded in the procedures and to determine the level of understanding of the people who are responsible for undertaking various functions.

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Verifying Information – Auditors have to examine samples of documents, equipment, products, and so on to verify the information collected and their observations. The auditor determines the size or quantity of the samples examined. While one sample is typically not enough it is not practical to select tens or hundreds of samples. If one sample is incorrect, it would be wise to select another sample to determine whether it is an isolated occurrence or a larger problem.

The auditor has the authority to select the sample.

Recording Discrepancies – When nonconformity is identified the auditor is required to document the findings. The audit is very much a “show me” exercise that looks for factual evidence. In this respect, a nonconformance report is a concise record of the facts relating to the nonconformance.

When recording the nonconformance the following information should be included:

- Where the nonconformance was found,
- An exact observation of the facts surrounding the discrepancy,
- The reason why the facts constitute a nonconformity,
- Sufficient references to allow traceability.

1.9. Audit Reporting (R)

At the completion of the audit the audit team meets to evaluate the information collected and all nonconformities identified during the audit. An audit report is created to document the findings of the audit activity. (The completed checklist(s) become the basis of the audit report).

What the Report needs to accomplish – The audit report should do the following:

- Assure a customer or third party inspector that the Quality Management System is periodically checked for effectiveness.
- Evaluate the adequacy of the Quality Management System as compared to past performance.
- Identify areas that need improvement.
- Assign responsibilities and timetables to monitor progress of corrective action.

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What the report needs to contain – The audit report should provide enough detail to prove your findings and validate your conclusions.

The following is considered minimum audit report information:

- The department audited,
- The audits scope/objective,
- Duration and extent of the audit and dates it was conducted,
- The standard against which the auditee was audited,
- The total number of discrepancies and where they were found,
- Areas where there were no nonconformities,
- The overall effectiveness of the system,
- Recommendations for corrective action,
- Report distribution list.

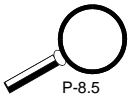
1.10. Corrective Action (C)

The details of nonconformities uncovered and recorded as a result of the audit process must be agreed upon between the auditor and the auditee. Effective corrective action must be documented and agreed upon. The NCR form provides a space to document corrective action.

In addition, the following must be documented on the NCR:

- Who is responsible for the corrective action,
- When it will be completed.

Reference: **P-8.5 Improvement**



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1.11. Responsibilities

Lead Auditor

- To ensure this procedure is followed by all audit staff.
- To ensure the entire audit findings are promptly reported to the manager in the area audited.
- To ensure any adverse findings are followed up and closed out as quickly as possible.
- To prepare audit reports for review at the Management Review meetings.

Audit Team Members

- To take direction from the Lead Auditor.
- To assist in the creation of the audit plan and checklists as directed.
- To maintain a professional, objective attitude.
- Perform the actual audit, including the completion of all required forms.

Department Manager

- To cooperate in scheduling and attending internal audits.
- To respond promptly to audit findings.
- To take steps to resolve any deficiencies reported in an effective and prompt fashion.

Quality Manager

- For ensuring the full cooperation of management and supervision within the activity under audit.
- The Quality Manager has overall responsibility for implementing and maintaining the internal audit system.
- Selecting and qualifying auditors.
- Ensure complete reports are issued to executive management.
- To establish and verify record keeping.

Executive Management

- To review audit reports and findings as required.
- To ensure actions are taken, without undue delay, to eliminate nonconformities and their causes.
- Verify corrective action with appropriate follow up.

All COMPANY NAME Employees

Other personnel involved in the processes or areas being audited are responsible for cooperating fully in the internal audit process and enable it to be a driver for continuous improvement.

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1.12. Reference Documents

The effective implementation of this procedure produces the following records:

Form No.	Description	Purpose
S-8.2.2	Audit Schedule	Used for notification regarding audit activity and ensuring all processes are audited at least once a year.
F-8.2.2	Audit Worksheet	Used to develop the Audit Plan and Audit Checklist. Also provides report for Management Review.
F-8.3	Nonconformance Report (NCR)	Reference: P-8.3 Used to report any nonconformance found during the audit and document corrective action required.

Maintaining Records – All Quality records and audit forms shall be maintained and remain on file for a period of three (3) years.

Reference: **P-4.2.4 Control of Quality Records Procedure**

1.13. Procedure References and Links

P-8.3 Control of Nonconformance Procedure

P-8.5 Improvement Procedure

P-4.2.4 Control of Quality Records Procedure