Quality Procedure

Internal Audit

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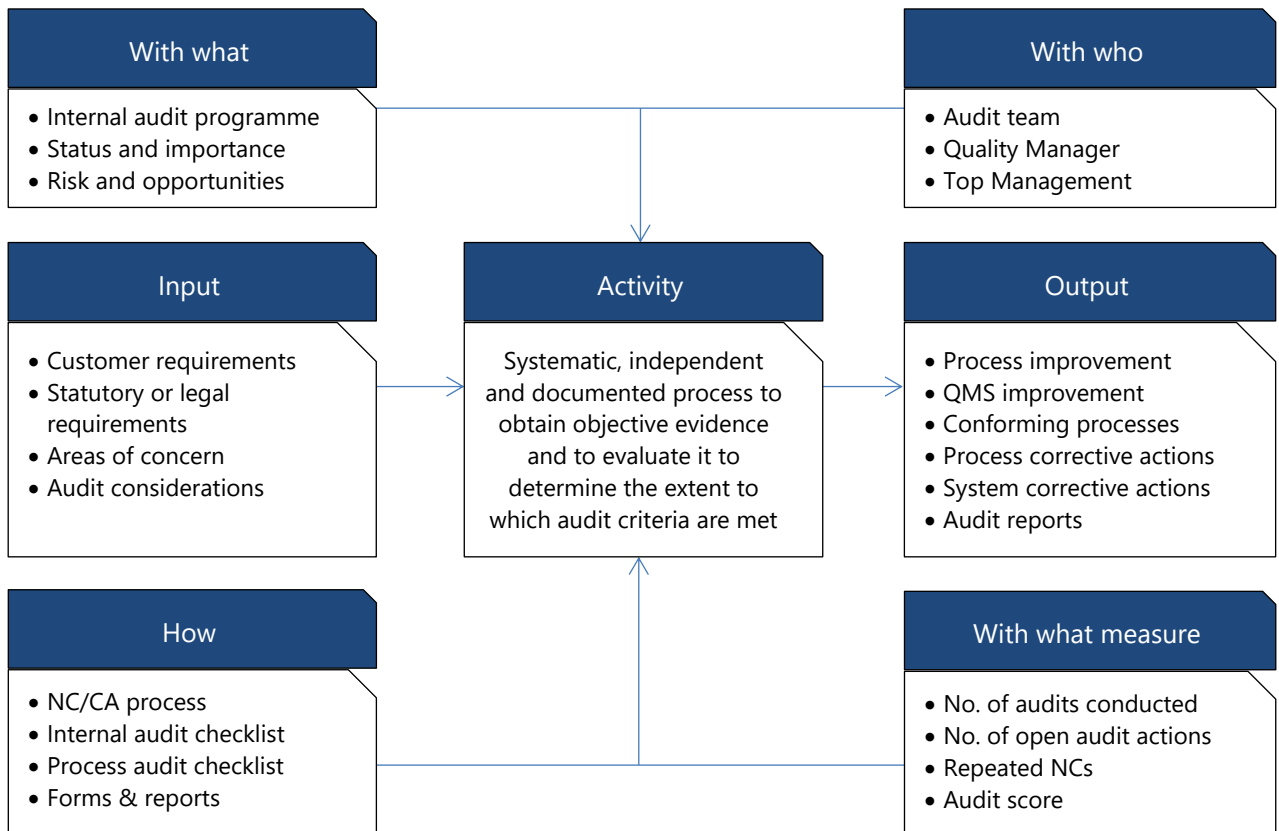
1   Internal Audits

1.1   Introduction & Purpose

The purpose of this procedure is to define your organization's process for undertaking QMS audits, process audits, and supplier and legislation audits in order to assess the effectiveness of the application of our quality management system and its compliance to ISO 9001:2015. This procedure also defines the responsibilities for planning and conducting audits, reporting results and retaining associated records.

1.1.1   Process Activity Map

With what	With who
• Internal audit programme • Status and importance • Risk and opportunities	• Audit team • Quality Manager • Top Management

Input	Activity	Output
• Customer requirements • Statutory or legal requirements • Areas of concern • Audit considerations	Systematic, independent and documented process to obtain objective evidence and to evaluate it to determine the extent to which audit criteria are met	• Process improvement • QMS improvement • Conforming processes • Process corrective actions • System corrective actions • Audit reports

How	With what measure
• NC/CA process • Internal audit checklist • Process audit checklist • Forms & reports	• No. of audits conducted • No. of open audit actions • Repeated NCs • Audit score

1.1.2   References

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2015	Quality management systems	Requirements
BS EN ISO 9004:2000	Quality management systems	Guidelines for performance improvements
BS EN ISO 19011:2011	Auditing management systems	Guidelines for auditing

1.1.3   Terms & Definitions

Term	ISO 9000:2015 Definition
Audit	A documented process for obtaining and evaluating evidence
Conformity	Fulfilment of a requirement (3.6.4)
Corrective action	Action to eliminate the cause of a non-conformity (3.6.9) and to prevent recurrence

1.2   Application & Scope

The scope of this procedure is focused on assessing the effectiveness of your organization's quality management system. Where such processes are found to be deficient, the audit will lead to improvement in those processes. By applying the principles of auditing, outlined by ISO 19011:2011, your organization ensures that all internal audits are conducted with due professional care, integrity and independence. All conclusions derived from the audit are based upon objective and traceable evidence.

1.3   Responsibilities

It is the responsibility of the Quality Manager <amend as appropriate> to coordinate the whole internal audit programme. The Quality Manager <amend as appropriate> is required to:

- Determine the root causes of non-conformities;
- Maintain a system for reporting audit results;
- Determine conformity to planned arrangements;
- Determine proper implementation and maintenance;
- Provide the results of audits to top management;
- Review the effectiveness of corrective actions taken.

1.4   Internal Audit Process

1.4.1   Selecting Internal Auditors

To ensure impartiality and objectivity, the audit team will include personnel from departments not directly associated with the area, process or department being audited. The Internal Auditors are selected on the basis of their:

- Education: secondary or higher;
- Work Experience: more than 5 years;
- Relevant Training: provided in-house or externally;
- Audit Experience: demonstrable knowledge/skills.

1.4.2   Developing the Audit Programme

The Quality Manager <amend as appropriate> is required to:

- Determine the status and importance of each process;
- Establish audit frequency based on the status and importance of each process;
- Develop and communicate the audit schedule;
- Appoint audit team leader where required;
- Select audit team;
- Assign audit duties to the auditor team.

1.4.3   Preparing for the Audit

The Internal Auditors <amend as appropriate> are required to:

- Review relevant management system documents and records;
- Determine their adequacy with respect to the audit criteria and with ISO 9001;
- Review and prepare the internal audit checklist;

1.8 Internal Audit Process Map

Quality Manager	Auditor	Auditee	Top Management

Audit Considerations

- Standards
- Customer feedback
- QMS requirements
- Corrective actions
- 3rd party audits
- Process status
- Non-conformances
- Process importance

Audit Considerations

- Legal requirements
- Employee concerns
- Management review
- Risks
- Opportunities
- Policies
- Objectives
- PESTLE
- SWOT

Prepare Audit Programme

Assign Audit Duties

Document Review

Prepare Audit Checklist

Review Recommendations

Non-compliances Found?

YES → Initiate Corrective Actions

NO

Review Audit Findings

Prepare Audit Report

Close-out Corrective Actions

Update System Metrics

Verify Close-out

Submit Audit Report