Quality Procedure

Internal Auditing

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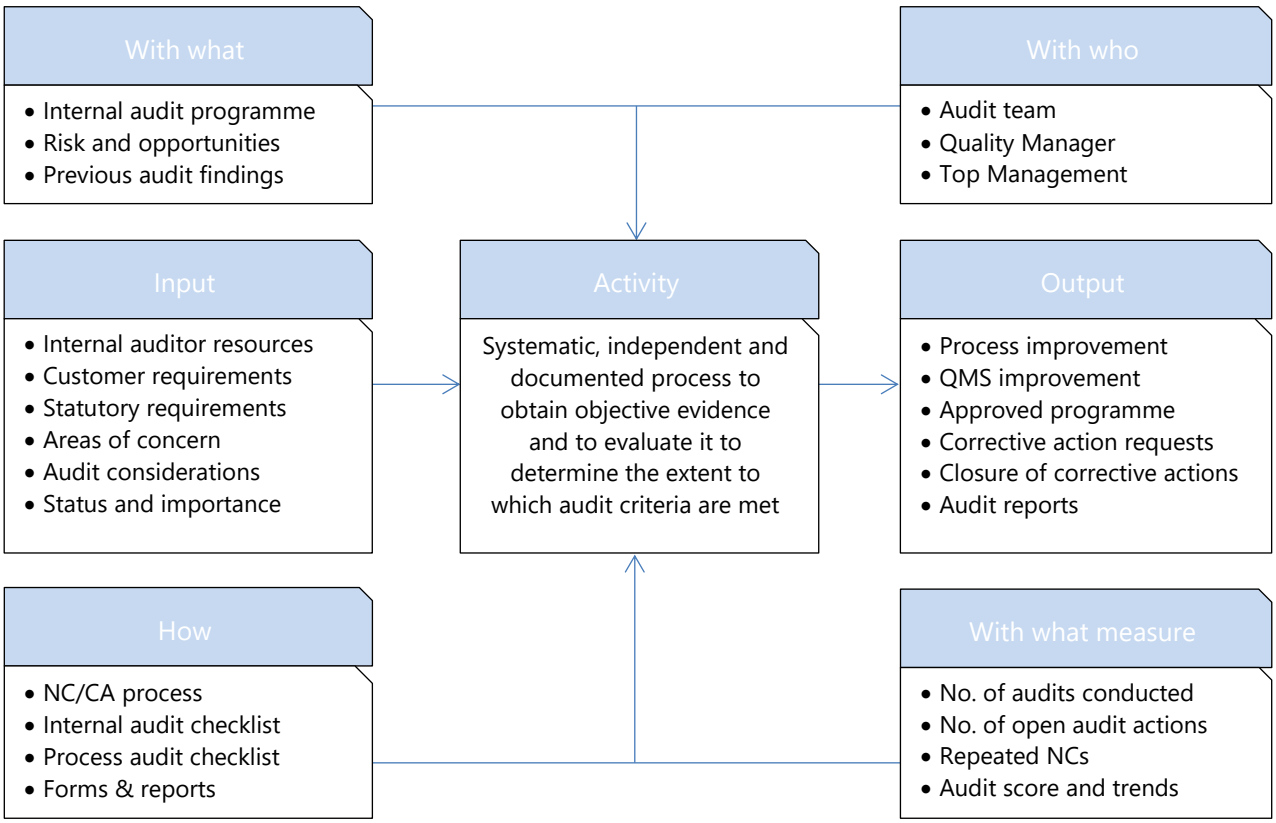
1 Internal Auditing

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



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 9004:2018	Quality management systems	Guidelines for performance improvements
BS EN ISO 19011:2018	Auditing management systems	Guidelines for auditing

1.1.3 Terms & Definitions

Term	ISO 9000:2015 Definition
Conformity	Fulfilment of a requirement (3.6.4)
Non-conformity	Non-fulfilment of requirement (3.6.9)
OFI	Opportunity for improvement
Corrective action	Action to eliminate the cause of a non-conformity (3.6.9) and to prevent recurrence

1.2 Application & Scope

By applying the principles of auditing, outlined by ISO 19011:2018, 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.

Your organization's arrangements for conducting internal audits at planned intervals, include the following audit criteria:

1. Our own requirements, e.g. policies, processes, procedures, instructions, specifications;
2. Customer requirements, e.g. flowed down by contract;
3. Applicable external standards (including ISO 9001:2015).

1.3 Responsibilities

Line Managers and Supervisors are responsible for:

1. Ensure that regular self-audits are conducted and that corrective actions are implemented;
2. Provide the Lead Auditor with evidence of current system and procedural practices in response to audit questions;
3. Follow up on the implementation of corrective actions,
4. Review the efficacy of any corrective actions implemented.

The Quality Manager is responsible for coordinating the internal audit programme in order to:

1. Obtain audit results;
2. Monitor trends, e.g., repeat audit findings or acknowledged improvement;
3. Determine the root-causes of non-conformities;
4. Provide the results of audits to Top management;
5. Track how long corrective actions remain open, versus planned closure;
6. Review the effectiveness of corrective actions taken.

The Internal Auditors are required to:

1. Review relevant management system documents and records;
2. Review and prepare the *Internal Audit Checklist*;
3. Arrange audit appointment;
4. Conduct opening meeting;
5. Sample and observe process inputs/activities/outputs;
6. Record objective evidence to verify process compliance or non-conformance;
7. Conduct the closing meeting;
8. Provide input for improvement of the audit programme and audit process.

The Auditees are required to:

1. Ensure corrective actions are implemented and are closed-out within the agreed timeframe;
2. Minor areas of non-conformance are taken care of immediately;
3. Provide the Lead Auditor with evidence of procedural practices in response to audit questions;
4. Undertake timely corrections to fix immediate problems and corrective actions to prevent recurrence
5. Ensure the status of corrective actions and any non-conformances are kept up-to-date.

1.4 Internal Audit Process

1.4.1 Auditor Competency

Internal audit resources include the personnel with the necessary skills, training and qualification. Evidence of auditor qualification is maintained in the employee training files. All auditors are appropriately trained and experienced. Minimum competency requirements have been set as:

1. Secondary or higher education;
2. Familiarity with the 5 principles of auditing and applying them to the audit process;
3. Work experience: more than 5 years;
4. Relevant training: provided in-house or externally;
5. Audit experience: demonstrable knowledge/skills.
6. Management system lead auditor training;
7. Technical understanding of the quality control requirements for the area or subject being audited.
8. Auditors are approved by the Quality Manager.

The Internal Auditors are selected to ensure objectivity and impartiality of the audit process. This is achieved by selecting a team of auditors from cross-functional departments who have received the appropriate training in the auditing process.

1.4.2 Internal Audit Programme

The Quality Manager is required to prepare and distribute the *Internal Audit Programme* that is dependent upon the size and complexity of operations, including the identification and frequency of each audit, e.g. monthly, quarterly, annually:

1. Determine the status and importance of each process;
2. Establish audit frequency based on the status and importance of each process;
3. Develop and communicate the audit programme;
4. Appoint audit team leader where required;
5. Select audit team;
6. Assign audit duties to the auditor team.

Using the *Internal Audit Programme,* the Quality Manager ensures that the *Process Matrix Worksheet* is completed. The process matrix provides a convenient overview of which ISO 9001 requirements are fulfilled by which process or function and provides an indication of their sequence and interaction.

In conjunction with Top management, the Quality Manager and Operations Manager devise the 10-year internal audit programme, while ensuring that customer feedback, organizational changes, and risks and opportunities are brought into consideration when determining frequency.

The frequency of audits depends on the criticality of each process and the perceived need to audit, but all processes and areas are formally audited at least during a 2-year audit cycle. Critical processes that interact with the customer directly are audited annually, or more regularly as required.

The Quality Manager then develops and distributes the detailed, 2-year internal audit programme with specific dates and durations of each **planned** internal audit. Any non-conformities that are attributable to system or