Quality Procedure

Internal Auditing

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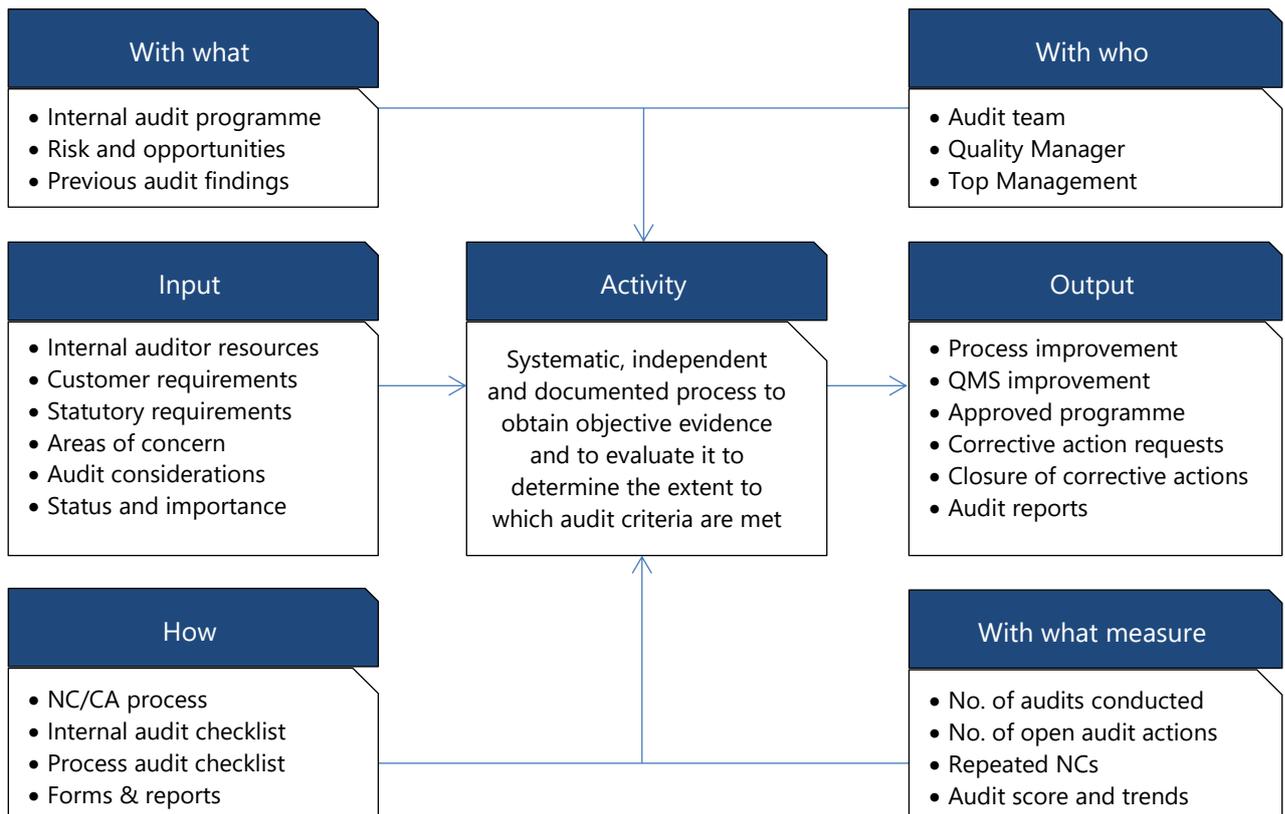
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Quality Procedure
Internal Auditing

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

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

Input	Activity	Output
• Internal auditor resources • Customer requirements • Statutory requirements • Areas of concern • Audit considerations • Status and importance	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 • Approved programme • Corrective action requests • Closure of 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 and trends

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 19011:2018	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

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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:

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

1.3 Responsibilities

It is the responsibility of the Quality Manager to coordinate the internal audit programme in order to:

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

The Internal Auditors are required to:

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

The Auditees are required to undertake timely corrections to fix any immediate problems and corrective actions to prevent recurrence:

- Ensure corrective actions are implemented and are closed-out within the agreed timeframe;
- Minor areas of non-conformance are taken care of immediately;
- Ensure the status of corrective actions and any non-conformances are kept up-to-date.

1.4 Internal Audit

1.4.1 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:

- Determine the status and importance of each process;
- Establish audit frequency based on the status and importance of each process;

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actions are completed. A member of the audit team will then sign off the audit report. An audit summary is prepared as an input for management review.

1.7 Forms & Records

All documentation and records generated by the internal audit process are retained and managed in accordance with the _Documented Information Procedure_. Retention of documented information to show that that the audit programme has been effectively implemented include the audit programme, audit plans, audit reports, questionnaires, audit evidence, corrective action, audit close out, auditor qualification, audit performance metrics.

Title & Description
Internal Audit Report.docx
Internal Audit Feedback.docx
Internal Audit Programme.xlsx (Includes the process matrix and the 10-year & 2-year audit programmes)
Gap Analysis Checklist.docx
Process Audit Template.xlsx
Supplier Audit Checklist.docx
Supplier's Self-Assessment.docx
Internal Audit Checklist.xlsx
Corrective Action Report.docx
Corrective Action Log.xlsx