Internal Auditing

ISO 9001:2015

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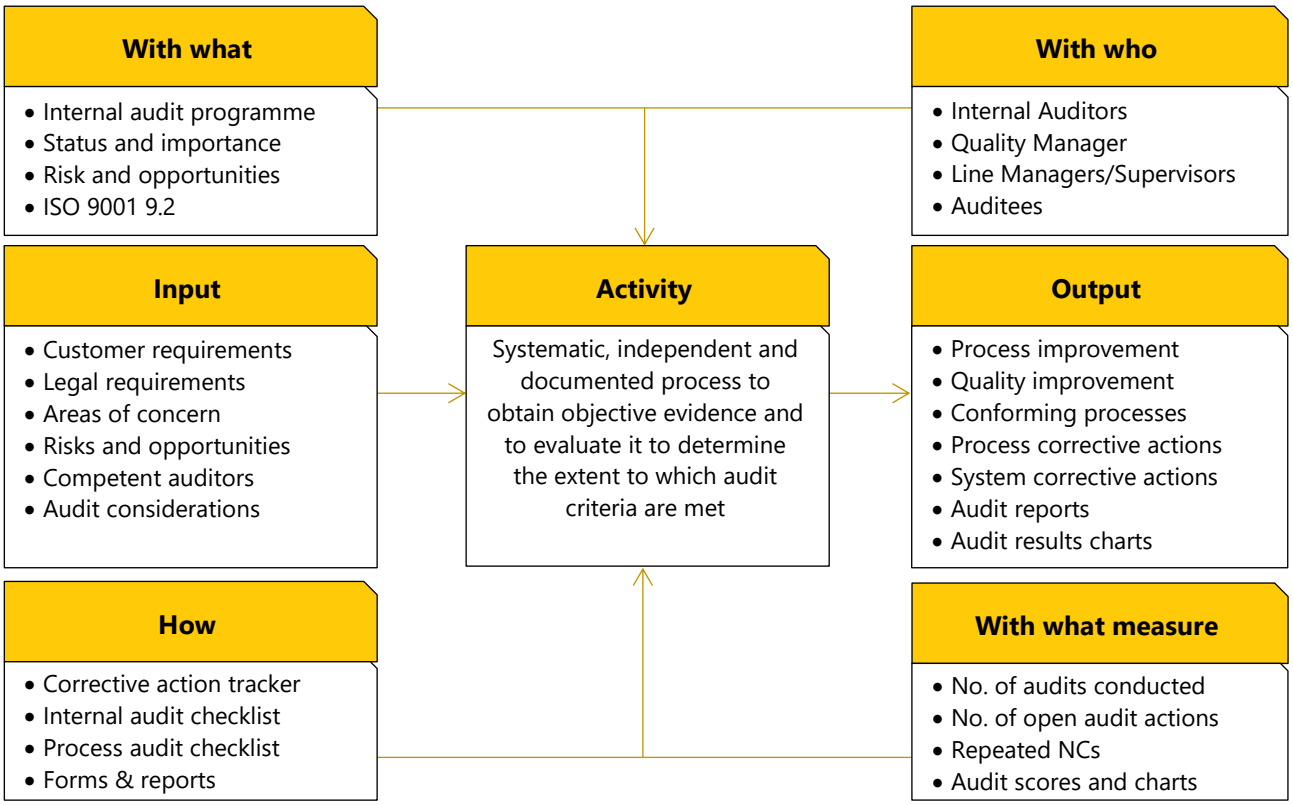
1 Procedure

1.1 Introduction & Purpose

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

1.1.1 Process Overview

The process overview (turtle diagram) provides internal and external auditors, process owners, and participants an overview of the elements that are required by the internal audit process:



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 9001:2024	Quality management systems	Amendment 1 Climate action changes 2024-02
BS EN ISO 9004:2018	Quality management	Guidance to achieve sustained success
BS EN ISO 19011:2018	Auditing management systems	Guidelines for auditing

1.1.3 Terms & Definitions

Term	Definition
Audit	Systematic, independent, and documented process for obtaining objective evidence
Conforms	All indicators and audit results show stability
Minor NC	Poor performance, adverse trends, expected results not achieved
Major NC	Practices are nonconforming, likely to cause compliance issues
OFI	Minor problems exist, with bottlenecks or potential deficiencies

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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 completes the Process Matrix Worksheet. 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 directly interacting with the customer are audited annually or 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 nonconformities attributable to system or process failures may result in the audit programme being updated to include additional audits in the area(s) concerned.

1.4.3 Conducting Internal Audits

1.4.3.1 General

General housekeeping, work environment, knowledge of the quality policy, product identification and traceability, document and data control, and control of records are observed in all audited areas every audit. If not reviewed, the reason is noted in the comments space on the *Internal Audit Report*.

The Internal Auditors collect evidence through interviews, examination of documents and records, and observation of activities and conditions in areas of concern. All information gathered through interviews is tested or investigated by acquiring the same information from other independent sources, such as physical observation, measurements, and records.

All audit observations are documented, even if not covered initially on the *Internal Audit Checklist*. Process Owners are constantly informed of the audit findings to ensure there are 'no surprises' at the closing meeting. During the audit, the Internal Auditor may change the scope, if necessary, to achieve the audit objectives. Any nonconformity raised at an internal audit is recorded on the *Internal Audit Report;* a separate nonconformity report is not used.

1.4.3.2 Internal Audit Scoring

The following qualitative scoring criteria are used to identify the level of compliance and effectiveness during internal audits:

Finding	Criteria Description
Conforms	Audit findings indicate conformity (3.6.11). See ISO 9000:2015. Conforms [+100]. Criteria: All performance indicators, metrics, objectives, audit results, etc., show stability and consistently achieve targets. The process is fully documented and implemented and demonstrates compliance and effectiveness. Continue to monitor trends and indicators to determine ongoing stability.
Minor NC	Audit findings indicate a nonconformity (3.6.9). See ISO 9000:2015. Minor [-25]. Criteria: Poor performance, adverse trends, expected results not achieved. Current practices conform but are not documented. Deviation from practice is unlikely to result in the failure of the or process or will not result

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1.5 Supplier Audits

1.5.1 General

The Purchasing Manager plans 2nd Party audits of our suppliers in conjunction with the Quality Manager and any other internal, interested parties; they are conducted to determine whether a supplier or contractor's processes conform to the specified purchase controls and arrangements.

1.5.2 Supplier Self-Evaluation

Your organization is responsible for evaluating and selecting suppliers on their ability to supply products per our quality requirements, expressed and implied. The initial selection of suppliers is determined using the *Supplier Self-Evaluation* form and is coordinated by the Purchasing Manager.

1.5.3 2nd Party Supplier Audits

On-site supplier audits may be conducted for a variety of different reasons and to address concerns that may have arisen from the completed *Supplier Self-Evaluation*. We may audit our suppliers to ensure that:

1. Management system procedures are implemented;
2. Processes are controlled;
3. Safety is maintained;
4. Conformance to the specified purchase controls;
5. Continued compliance.

The Quality Manager, in conjunction with the Purchasing Manager, arranges and attends supplier audits, utilizing input from self-evaluation forms, purchasing requests, corrective actions, supplier ratings, and nonconformities. The Purchasing Manager coordinates the audit with the supplier to ensure that key personnel are available for the audit.

The audit is performed utilizing the *Supplier Audit Checklist*. For each question addressed, the auditor(s) record the personnel interviewed and verify by examining and evaluating objective evidence to the depth necessary to determine compliance. Objective evidence is documented in the audit checklist.

Potential findings and observations encountered during the audit are reviewed with the supplier's representatives, and the results are summarized upon completion of the audit. The Purchasing Manager prepares the audit report within 30 days of the meeting unless the Quality Manager approves an extension.

1.6 Corrective Action

The corrective actions are identified on the *Corrective Action Tracker,* along with the person responsible and the timescales for completion. The process or procedure is re-audited, and the issue is closed out when all corrective actions are completed. A member of the audit team will then sign off on the internal audit report. An audit summary is prepared as input for management review.

1.7 Documentation

All documentation and records generated by the internal audit process are retained and managed in accordance with the *Documented Information Procedure* by the Document Controller on the local area network.

Retention of documented information to show that the audit programme has been effectively implemented includes the audit programme, audit plans, audit reports, questionnaires, audit evidence, corrective action, audit close out, auditor qualification, and audit performance metrics.

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