Internal Auditing

ISO 9001:2026 Edition

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Standard	Title	Description
BS EN ISO 9001:2026	Quality management systems	Requirements (clause 9.2 Internal audit addressed in full)
ISO 19011:2026	Guidelines for auditing management systems	The primary audit-methodology reference for this procedure
ISO/IEC 17021-1:2015	Conformity assessment — bodies providing audit and certification of management systems	Reference for engagement with Certification Bodies and Notified Bodies
ISO 9004:2018	Quality management	Quality of an organization — guidance on self-assessment
IATF 16949/ISO/TS 19011-style customer audits	Automotive — internal audit	Customer-flowed-down audit requirements; layered process audit (LPA); product audit (where applicable)
AS9100/AS9101/AS9114	Aerospace — internal audit	Process Effectiveness Assessment Report (PEAR) and audit-evidence requirements (where applicable)
GMP/GxP — self-inspection	Pharmaceutical/biotech self-inspection programmes	Periodic self-inspection per regulator expectation (where applicable)
ISO 13485:2016 — internal audit	Medical devices — internal audit	Medical-device-specific internal audit requirements (where applicable)
ISO/IEC 27001:2022 — internal audit	Information security — internal audit	ISMS internal audit requirements (where the organization operates an ISMS)
UK GDPR/DPA 2018 — Article 28 right of audit	Personal-data processing audit	Controller right-of-audit over processors and sub-processors
Modern Slavery Act 2015 — supply-chain audit	Anti-slavery — supplier-audit context	Section 54 transparency feeding 2nd-party supplier audit scope

Internal toolkit references

Reference	Title
M0100-01	Quality Manual (the audit-scope master)
P0410-01	Context Analysis (climate-relevance determination)
P0420-01	Interested Party Analysis (audit interest mapping)
P0611-01	Risks and Opportunities (R&O informs risk-based audit planning)
P0723-01	Competence (auditor competence and impartiality)
P0750-01	Documented Information (audit record retention)
P0820-01	Order & Contract Review (customer-mandated audit obligations)
P0830-01	Product Design Management (audit of design controls)
P0840-01	Supplier Evaluation (2nd-party supplier-audit programme)
P0840-02	Purchasing & Procurement Control (audit of purchasing controls)
P0850-01	Product Provision (audit of production controls)
P0860-01	Inspection & Testing (audit of inspection controls)

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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 an audit team leader where required;
5. Select audit team;
6. Assign audit duties to the audit 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 internal audit programme, covering every process within the two-year audit cycle, 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.

In line with ISO 9001:2026 Clause 9.2.2, the audit objective(s), audit criteria and scope are defined for each audit within the programme, not only at programme level, and are recorded on the Internal Audit Plan issued to the auditee before the audit commences. Auditors are selected to ensure objectivity and impartiality, and audit results are reported to relevant management.

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 at 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:

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KPI	Definition	Target/threshold	Frequency
3rd-party audit pre-readiness rate	% of areas audited internally within 6 months prior to a 3rd-party/Notified-Body audit	≥ 80%	Per 3rd-party audit + annual aggregate
Personal-data audit-evidence handling compliance	% of audits handling personal data with documented lawful basis and minimization	100%	Annual
Audit-programme KPI traceability	% of management-review decisions about audit programmes traceable to documented KPI evidence	100%	Per management review
Climate-relevance determination capture rate	% of audit programmes with climate-relevance determination captured per F0410-01 (ISO 9001:2026 Clause 4.1)	100% of in-scope programmes	Annual

Adverse trends are escalated to the Process Owner; persistent adverse trends are escalated to Top Management at the next management review. Audit findings are aggregated and fed to P0913-01 Analysis and Evaluation for trend analysis at the QMS level; supplier-audit-driven findings are fed to P0840-01 Supplier Evaluation for supplier re-evaluation.

1.6 Supplier Audits

1.6.1 General

2nd Party audits of our suppliers are planned by the Purchasing Manager 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.

1.6.2 Supplier Self-Evaluation

Our 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.

1.6.3 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.

1.7 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

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