



ISO 9001 Internal Audit Checklist

ISO 9001:2015 · Clauses 4 to 10

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<https://www.q-hub.app/t/ia1>

HOW TO USE THIS

- **Who:** a trained internal auditor who is independent of the process being audited (clause 9.2).
- **When:** to your planned audit programme. Most organisations cover the full clause set across a 12-month cycle.
- **Evidence:** record what you actually saw. Name the document, record, interview or observation, with its reference and date.
- **Findings:** mark C (conforms), NC (nonconformity), OFI (opportunity for improvement) or N/A where a requirement is not applicable to your scope. Every NC needs a corrective action raised under clause 10.2; every N/A needs the justification recorded under 4.3.

Audit details

AUDIT REFERENCE	DATE(S)	PROCESS / AREA AUDITED
LEAD AUDITOR	AUDITEE(S)	PREVIOUS AUDIT REF

4. Context of the organisation

CLAUSE	WHAT TO LOOK FOR	EVIDENCE SEEN	RESULT
4.1	Organisational context • How has the organisation determined the external and internal issues that affect its ability to achieve intended results? • When was this last reviewed, and what changed as a result?		☐ C ☐ NC ☐ OFI ☐ N/A
4.2	Interested parties • Which interested parties are identified as relevant to the QMS, and what are their requirements? • How are changes to those requirements monitored?		☐ C ☐ NC ☐ OFI ☐ N/A
4.3	Scope of the QMS • Is the scope documented, and does it state the products and services covered? • Where a requirement is judged not applicable, is the justification recorded and still valid?		☐ C ☐ NC ☐ OFI ☐ N/A

CLAUSE	WHAT TO LOOK FOR	EVIDENCE SEEN	RESULT
4.4	QMS and its processes - Are the processes needed for the QMS determined, with their inputs, outputs, sequence and interaction? - How are process performance criteria and responsibilities defined?		☐ C ☐ NC ☐ OFI ☐ N/A

5. Leadership

CLAUSE	WHAT TO LOOK FOR	EVIDENCE SEEN	RESULT
5.1	Leadership and commitment - What evidence shows top management taking accountability for the effectiveness of the QMS? - How is the customer focus requirement of 5.1.2 demonstrated in practice?		☐ C ☐ NC ☐ OFI ☐ N/A
5.2	Quality policy - Is the policy documented, communicated and available to interested parties as required? - Can staff at different levels explain what it means for their own work?		☐ C ☐ NC ☐ OFI ☐ N/A
5.3	Roles and responsibilities Are QMS responsibilities and authorities assigned, communicated and understood?		☐ C ☐ NC ☐ OFI ☐ N/A

6. Planning

CLAUSE	WHAT TO LOOK FOR	EVIDENCE SEEN	RESULT
6.1	Risks and opportunities - How are risks and opportunities determined from the context and interested-party requirements in 4.1 and 4.2? - What actions were planned to address them, and how was effectiveness evaluated?		☐ C ☐ NC ☐ OFI ☐ N/A
6.2	Quality objectives - Are objectives measurable, monitored, communicated and updated as needed? - For each objective: what will be done, what resources are needed, who is responsible, when it completes, and how results are evaluated?		☐ C ☐ NC ☐ OFI ☐ N/A
6.3	Planning of changes When changes to the QMS are needed, how are they carried out in a planned way?		☐ C ☐ NC ☐ OFI ☐ N/A

7. Support

CLAUSE	WHAT TO LOOK FOR	EVIDENCE SEEN	RESULT
7.1	Resources - How are the people, infrastructure and process environment needed for conformity determined and provided? - For monitoring and measuring resources (7.1.5): is measurement traceability maintained where required, and is equipment status identifiable? - How is organisational knowledge (7.1.6) maintained and made available?		☐ C ☐ NC ☐ OFI ☐ N/A
7.2	Competence - How is the competence needed for each role determined, and what records demonstrate it? - Where a competence gap was found, what action was taken and how was its effectiveness evaluated?		☐ C ☐ NC ☐ OFI ☐ N/A
7.3	Awareness Are staff aware of the quality policy, relevant objectives, their contribution, and the implications of not conforming?		☐ C ☐ NC ☐ OFI ☐ N/A
7.4	Communication What internal and external communications relevant to the QMS are defined, and who is responsible for them?		☐ C ☐ NC ☐ OFI ☐ N/A
7.5	Documented information - How are creation, review and approval controlled? - How are distribution, access, version control and retention managed, including documents of external origin?		☐ C ☐ NC ☐ OFI ☐ N/A

8. Operation

CLAUSE	WHAT TO LOOK FOR	EVIDENCE SEEN	RESULT
8.1	Operational planning and control - How are the processes needed to meet requirements planned, implemented and controlled? - How are outsourced processes controlled?		☐ C ☐ NC ☐ OFI ☐ N/A

CLAUSE	WHAT TO LOOK FOR	EVIDENCE SEEN	RESULT
8.2	Customer requirements - How are enquiries, orders and changes handled, and how are requirements reviewed before commitment? - Where requirements change, how is documented information and staff awareness updated?		☐ C ☐ NC ☐ OFI ☐ N/A
8.3	Design and development - If applicable: how are design planning, inputs, controls, outputs and changes managed and recorded? - If excluded under 4.3: is the exclusion still justified?		☐ C ☐ NC ☐ OFI ☐ N/A
8.4	External providers - What criteria are used to evaluate, select, monitor and re-evaluate external providers? - How is the type and extent of control determined, and how are requirements communicated?		☐ C ☐ NC ☐ OFI ☐ N/A
8.5	Production and service provision - How is provision carried out under controlled conditions, including identification and traceability where required? - How is property belonging to customers or external providers cared for (8.5.3)? - How are preservation, post-delivery activities and changes controlled (8.5.4 to 8.5.6)?		☐ C ☐ NC ☐ OFI ☐ N/A
8.6	Release What evidence of conformity to acceptance criteria is retained, and who authorises release?		☐ C ☐ NC ☐ OFI ☐ N/A
8.7	Nonconforming outputs - How are nonconforming outputs identified and controlled to prevent unintended use? - What records are kept of the nonconformity, the action taken and any concession?		☐ C ☐ NC ☐ OFI ☐ N/A

9. Performance evaluation

CLAUSE	WHAT TO LOOK FOR	EVIDENCE SEEN	RESULT
9.1	Monitoring and measurement - What is monitored and measured, by which methods, and when are results analysed? - How is customer satisfaction monitored (9.1.2), and what did the analysis show?		☐ C ☐ NC ☐ OFI ☐ N/A

CLAUSE	WHAT TO LOOK FOR	EVIDENCE SEEN	RESULT
9.2	Internal audit - Is there an audit programme that accounts for process importance and previous results? - Are auditors objective and impartial to the area audited, and are results reported to relevant management?		☐ C ☐ NC ☐ OFI ☐ N/A
9.3	Management review - Does the review cover the required inputs, including audit results, customer feedback, objectives and resource adequacy? - Are outputs recorded, with decisions on improvement, change and resource need?		☐ C ☐ NC ☐ OFI ☐ N/A

10. Improvement

CLAUSE	WHAT TO LOOK FOR	EVIDENCE SEEN	RESULT
10.1	General How are opportunities for improvement determined and acted on?		☐ C ☐ NC ☐ OFI ☐ N/A
10.2	Nonconformity and corrective action - For each nonconformity: what was the reaction, what review of cause was carried out, and what action followed? - Was the effectiveness of the corrective action reviewed, and were risks and opportunities updated if needed?		☐ C ☐ NC ☐ OFI ☐ N/A
10.3	Continual improvement What evidence shows the suitability, adequacy and effectiveness of the QMS improving over time?		☐ C ☐ NC ☐ OFI ☐ N/A

Nonconformities and corrective actions raised

Every NC above needs an entry here and a corrective action under clause 10.2.

NC NO.	CLAUSE	STATEMENT OF NONCONFORMITY	OWNER	DUE

NC NO.	CLAUSE	STATEMENT OF NONCONFORMITY	OWNER	DUE

Auditor summary

Overall conclusion on conformity and effectiveness for the scope audited.

SIGN-OFF

AUDIT COMPLETED BY

SIGNATURE

DATE

REVIEWED BY

SIGNATURE

NEXT AUDIT DUE



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