FREE ISO 9001 INTERNAL AUDIT TEMPLATE

ISO 9001 Internal Audit Checklist

Use this 60-point process-based checklist to audit ISO 9001 clauses 4 to 10 across context, leadership, planning, support, operation, performance evaluation, internal audit, management review, corrective action, and continual improvement.

Current-standard note: based on ISO 9001:2015 with Amendment 1:2024. ISO currently expects a replacement edition in September 2026. Confirm the published standard status before certification use.

Site / process	Audit date	Internal auditor	Process owner

1. Audit setup, QMS scope, process map, criteria, sampling, and previous findings

1 Confirm the audit date, site, department, process, auditor, auditee, QMS scope, applicable products or services, and organizational boundaries included in the internal audit.

ISO 9001 QMS AUDIT

NAME Enter | DATE / TIME Enter | SIGN-OFF Sign

Execution tip: Plan the audit around processes and evidence, not only clause numbers. Use the ISO 9001 requirements as criteria, then follow actual work from input to output.

2 **Verify the audit criteria reference the current published ISO 9001 requirements applicable to the organization, including ISO 9001:2015 and Amendment 1:2024 while that edition remains current.** CRITICAL

ISO 9001 QMS AUDIT

Clause / Process	Evidence	Owner	Finding	Action

Execution tip: Plan the audit around processes and evidence, not only clause numbers. Use the ISO 9001 requirements as criteria, then follow actual work from input to output.

3 Map the audited process to its inputs, outputs, sequence, interactions, owners, controls, records, performance measures, risks, suppliers, and customers or downstream users.

ISO 9001 QMS AUDIT

Clause / Process	Evidence	Owner	Finding	Action

Execution tip: Plan the audit around processes and evidence, not only clause numbers. Use the ISO 9001 requirements as criteria, then follow actual work from input to output.

4 **Review previous internal and external audit findings, customer complaints, process defects, nonconforming outputs, supplier issues, missed objectives, and open corrective actions before sampling.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Plan the audit around processes and evidence, not only clause numbers. Use the ISO 9001 requirements as criteria, then follow actual work from input to output.

5 **Define the audit sampling approach across shifts, locations, records, products or services, employees, suppliers, changes, and recent problem areas based on process risk and performance.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Plan the audit around processes and evidence, not only clause numbers. Use the ISO 9001 requirements as criteria, then follow actual work from input to output.

6 Confirm auditor competence, objectivity, audit plan, interview approach, evidence requirements, finding classification, reporting method, and follow-up responsibilities.

ISO 9001 QMS AUDIT

Clause / Process	Evidence	Owner	Finding	Action

Execution tip: Plan the audit around processes and evidence, not only clause numbers. Use the ISO 9001 requirements as criteria, then follow actual work from input to output.

2. Clause 4: organizational context, interested parties, QMS scope, and process management

7 **Verify the organization has identified internal and external issues relevant to its purpose, strategic direction, and ability to achieve intended QMS results.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: For Clause 4, test whether context and interested-party analysis affects real QMS decisions. Include the 2024 climate-change amendment in the context review while ISO 9001:2015 remains current.

8 **Confirm the organization has determined whether climate change is a relevant issue to its QMS context and can explain the conclusion with appropriate evidence.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: For Clause 4, test whether context and interested-party analysis affects real QMS decisions. Include the 2024 climate-change amendment in the context review while ISO 9001:2015 remains current.

9 **Check relevant interested parties and their applicable requirements are identified, monitored, and translated into QMS or process requirements where necessary.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: For Clause 4, test whether context and interested-party analysis affects real QMS decisions. Include the 2024 climate-change amendment in the context review while ISO 9001:2015 remains current.

10 **Verify the documented QMS scope matches actual sites, activities, products, services, organizational boundaries, and justified applicability of ISO 9001 requirements.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: For Clause 4, test whether context and interested-party analysis affects real QMS decisions. Include the 2024 climate-change amendment in the context review while ISO 9001:2015 remains current.

11 **Confirm QMS processes, interactions, criteria, methods, responsibilities, resources, risks, opportunities, monitoring, records, and planned improvements are defined and operating.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: For Clause 4, test whether context and interested-party analysis affects real QMS decisions. Include the 2024 climate-change amendment in the context review while ISO 9001:2015 remains current.

12 Sample one core process end to end and verify actual practice, interfaces, controls, performance evidence, and retained records align with the organization's defined QMS process approach.

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: For Clause 4, test whether context and interested-party analysis affects real QMS decisions. Include the 2024 climate-change amendment in the context review while ISO 9001:2015 remains current.

3. Clause 5: leadership, customer focus, quality policy, roles, responsibilities, and accountability

13 **Verify top management demonstrates accountability for QMS effectiveness and integrates quality requirements into relevant business processes and decisions.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Leadership evidence should appear in decisions, resources, priorities, reviews, and customer focus, not only in signed policies or meeting attendance.

14 **Confirm leadership promotes customer focus by ensuring customer, statutory, regulatory, and other applicable product or service requirements are understood and consistently addressed.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Leadership evidence should appear in decisions, resources, priorities, reviews, and customer focus, not only in signed policies or meeting attendance.

15 Check leadership reviews risks and opportunities that can affect product or service conformity and customer satisfaction and supports actions where performance is weak.

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Leadership evidence should appear in decisions, resources, priorities, reviews, and customer focus, not only in signed policies or meeting attendance.

16 **Verify the quality policy is appropriate to organizational purpose and context, supports strategic direction, provides a basis for quality objectives, and is communicated and available as intended.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Leadership evidence should appear in decisions, resources, priorities, reviews, and customer focus, not only in signed policies or meeting attendance.

17 Interview sampled employees and confirm they understand the quality policy at a practical level and can explain how their work contributes to product, service, process, or customer quality.

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Leadership evidence should appear in decisions, resources, priorities, reviews, and customer focus, not only in signed policies or meeting attendance.

18 **Confirm QMS roles, process ownership, authorities, escalation, reporting, conformity responsibilities, and responsibility for promoting customer focus are clearly assigned and understood.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Leadership evidence should appear in decisions, resources, priorities, reviews, and customer focus, not only in signed policies or meeting attendance.

4. Clause 6: risks and opportunities, quality objectives, planning, and change management

19 **Verify QMS risks and opportunities are identified from context, interested-party requirements, process performance, customer needs, compliance obligations, and operational changes.**

CRITICAL

ISO 9001 QMS AUDIT

Clause / Process	Evidence	Owner	Finding	Action

Execution tip: Sample one risk, one objective, and one recent change from identification through action, monitoring, review, and outcome to test whether planning is genuinely implemented.

20 **Check planned actions to address significant risks and opportunities are proportionate, integrated into QMS processes, assigned to owners, and evaluated for effectiveness.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Sample one risk, one objective, and one recent change from identification through action, monitoring, review, and outcome to test whether planning is genuinely implemented.

21 **Confirm quality objectives are established at relevant functions and levels and are measurable or otherwise objectively evaluable, monitored, communicated, and updated when needed.**

CRITICAL

ISO 9001 QMS AUDIT

ACTUAL / RESULT: Enter | CRITERIA / TARGET: Enter | STATUS: Record

Execution tip: Sample one risk, one objective, and one recent change from identification through action, monitoring, review, and outcome to test whether planning is genuinely implemented.

22 **Verify each sampled quality objective has a target, owner, required resources, action plan, timing, measurement method, current result, and evidence of review or intervention when off track.**

CRITICAL

ISO 9001 QMS AUDIT

ACTUAL / RESULT: Enter | CRITERIA / TARGET: Enter | STATUS: Record

Execution tip: Sample one risk, one objective, and one recent change from identification through action, monitoring, review, and outcome to test whether planning is genuinely implemented.

23 **Check planned QMS changes consider purpose, potential consequences, system integrity, resource availability, and changes to responsibilities or authorities before implementation.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Sample one risk, one objective, and one recent change from identification through action, monitoring, review, and outcome to test whether planning is genuinely implemented.

24 Review recent changes to products, services, suppliers, systems, facilities, processes, staffing, or customer requirements and verify the QMS impact was assessed and controlled.

ISO 9001 QMS AUDIT

Clause / Process	Evidence	Owner	Finding	Action

Execution tip: Sample one risk, one objective, and one recent change from identification through action, monitoring, review, and outcome to test whether planning is genuinely implemented.

5. Clause 7: resources, people, infrastructure, environment, monitoring resources, knowledge, competence, aware

25 **Verify sufficient people, infrastructure, technology, work environment, external services, and other resources are available to operate and improve the QMS and deliver conforming outputs.**

CRITICAL

ISO 9001 QMS AUDIT

Clause / Process	Evidence	Owner	Finding	Action

Execution tip: For support controls, sample the people and documents actually used in the process. Current records and employee understanding are stronger evidence than procedure existence alone.

26 **Confirm monitoring and measuring resources are suitable for their intended purpose, maintained, calibrated or verified where required, identified, protected, and traceable when measurement traceability is necessary.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: For support controls, sample the people and documents actually used in the process. Current records and employee understanding are stronger evidence than procedure existence alone.

27 Check organizational knowledge needed for process operation and product or service conformity is maintained, available, updated, and protected against loss when key people, technology, or requirements change.

ISO 9001 QMS AUDIT

ACTUAL / RESULT Enter | CRITERIA / TARGET Enter | STATUS Record

Execution tip: For support controls, sample the people and documents actually used in the process. Current records and employee understanding are stronger evidence than procedure existence alone.

28 **Verify competence requirements are defined for quality-affecting roles and that sampled employees have evidence of education, training, skills, experience, or evaluated effectiveness of actions taken.**

CRITICAL

ISO 9001 QMS AUDIT

ACTUAL / RESULT Enter | CRITERIA / TARGET Enter | STATUS Record

Execution tip: For support controls, sample the people and documents actually used in the process. Current records and employee understanding are stronger evidence than procedure existence alone.

29 **Confirm employees are aware of the quality policy, relevant objectives, their contribution to QMS effectiveness, benefits of improved performance, and consequences of not following QMS requirements.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: For support controls, sample the people and documents actually used in the process. Current records and employee understanding are stronger evidence than procedure existence alone.

30 **Verify internal and external communications and documented information are controlled for approval, review, version, access, distribution, storage, protection, retention, retrieval, change, and prevention of unintended obsolete use.**

CRITICAL

ISO 9001 QMS AUDIT

Clause / Process	Evidence	Owner	Finding	Action

Execution tip: For support controls, sample the people and documents actually used in the process. Current records and employee understanding are stronger evidence than procedure existence alone.

6. Clause 8A: operational planning, customer requirements, design and development, and external providers

31 **Verify operational processes are planned and controlled with defined requirements, acceptance criteria, resources, process controls, documented information, and actions for risks and opportunities.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Clause 8 is best audited by following a real order, product, service, design change, or supplier transaction through the operational lifecycle.

32 **Confirm customer and applicable statutory or regulatory requirements for products and services are identified, reviewed before commitment, clarified when incomplete, and updated when requirements change.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Clause 8 is best audited by following a real order, product, service, design change, or supplier transaction through the operational lifecycle.

33 Check changes to customer requirements are communicated to relevant functions and that affected documents, systems, orders, specifications, or operational controls are updated.

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Clause 8 is best audited by following a real order, product, service, design change, or supplier transaction through the operational lifecycle.

34 **Where design and development is applicable, verify planning, inputs, controls, reviews, verification or validation as appropriate, outputs, changes, responsibilities, and retained evidence are controlled.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Clause 8 is best audited by following a real order, product, service, design change, or supplier transaction through the operational lifecycle.

35 **Confirm externally provided processes, products, and services are evaluated and controlled based on their effect on conformity, including supplier selection, monitoring, re-evaluation, requirements, and verification.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Clause 8 is best audited by following a real order, product, service, design change, or supplier transaction through the operational lifecycle.

36 **Sample a supplier or outsourced process and trace requirements from purchase or service specification through receiving or acceptance, performance monitoring, nonconformity handling, and supplier follow-up.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Clause 8 is best audited by following a real order, product, service, design change, or supplier transaction through the operational lifecycle.

7. Clause 8B: production and service provision, identification, customer property, preservation, release, changes, a

37 **Verify production or service activities are performed under controlled conditions with current instructions, suitable resources, competent people, monitoring, acceptance criteria, and required records.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Trace one accepted output and one nonconforming output. This tests release authority, evidence, traceability, disposition, correction, and re-verification together.

38 **Confirm identification and traceability controls are adequate where status, batch, order, serial, service case, customer, process stage, or other traceability is required for conformity.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Trace one accepted output and one nonconforming output. This tests release authority, evidence, traceability, disposition, correction, and re-verification together.

39 **Check customer or external-provider property is identified, protected, verified as appropriate, and reported when lost, damaged, unsuitable, or otherwise compromised.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Trace one accepted output and one nonconforming output. This tests release authority, evidence, traceability, disposition, correction, and re-verification together.

40 Verify outputs are preserved through handling, storage, packaging, transport, delivery, and post-delivery activities so conformity is maintained through the required lifecycle stage.

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Trace one accepted output and one nonconforming output. This tests release authority, evidence, traceability, disposition, correction, and re-verification together.

41 **Confirm release of products and services occurs only after planned verification is complete and records identify acceptance evidence and the person authorizing release.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Trace one accepted output and one nonconforming output. This tests release authority, evidence, traceability, disposition, correction, and re-verification together.

42 **Verify nonconforming outputs are identified, controlled, corrected or otherwise dispositioned appropriately, reverified after correction where required, and retained records describe the nonconformity, actions, concessions, and authority.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Trace one accepted output and one nonconforming output. This tests release authority, evidence, traceability, disposition, correction, and re-verification together.

8. Clause 9.1: monitoring, measurement, analysis, evaluation, customer satisfaction, and QMS performance

43 **Verify the organization has defined what QMS and process performance must be monitored or measured, the methods used, timing, responsibilities, evaluation criteria, and records retained.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Follow one KPI from source data to analysis and management action. Metrics that cannot be traced or that never trigger decisions provide weak audit evidence.

44 **Confirm customer perception or satisfaction is monitored using suitable methods and that negative trends, complaints, returns, service failures, or other feedback lead to review and action.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Follow one KPI from source data to analysis and management action. Metrics that cannot be traced or that never trigger decisions provide weak audit evidence.

45 **Check process and quality data are analyzed for conformity of products and services, customer satisfaction, QMS performance, planning effectiveness, risk actions, supplier performance, and improvement needs.** CRITICAL

ISO 9001 QMS AUDIT

ACTUAL / RESULT Enter | CRITERIA / TARGET Enter | STATUS Record

Execution tip: Follow one KPI from source data to analysis and management action. Metrics that cannot be traced or that never trigger decisions provide weak audit evidence.

46 **Verify sampled performance metrics can be traced from source data to calculation, target, analysis, reporting, owner review, and resulting action when performance is outside expectation.** CRITICAL

ISO 9001 QMS AUDIT

ACTUAL / RESULT Enter | CRITERIA / TARGET Enter | STATUS Record

Execution tip: Follow one KPI from source data to analysis and management action. Metrics that cannot be traced or that never trigger decisions provide weak audit evidence.

47 Confirm trend analysis considers recurrence, variation, systemic weaknesses, changes, and emerging issues rather than reviewing isolated monthly values only.

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Follow one KPI from source data to analysis and management action. Metrics that cannot be traced or that never trigger decisions provide weak audit evidence.

48 **Check management and process owners use performance results to make decisions about resources, controls, supplier management, objectives, corrective actions, and improvement.** CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Follow one KPI from source data to analysis and management action. Metrics that cannot be traced or that never trigger decisions provide weak audit evidence.

9. Clauses 9.2 and 9.3: internal audit programme, audit evidence, management review, and leadership decisions

49 **Verify the internal audit programme covers the QMS requirements, organization-defined requirements, key processes, sites, relevant shifts, prior findings, changes, and performance risk over the planned cycle.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Internal audit and management review should expose and act on system weaknesses. Check follow-up, decisions, and objective closure, not only calendars and minutes.

50 **Confirm audit frequency, scope, methods, responsibilities, planning, and reporting consider process importance, organizational changes, previous audit results, customer impact, and known performance issues.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Internal audit and management review should expose and act on system weaknesses. Check follow-up, decisions, and objective closure, not only calendars and minutes.

51 **Check internal auditors are competent and sufficiently objective for the areas they audit and that audit evidence supports each finding without relying on unsupported opinion.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Internal audit and management review should expose and act on system weaknesses. Check follow-up, decisions, and objective closure, not only calendars and minutes.

52 **Verify internal-audit corrections and corrective actions are completed without undue delay, assigned to responsible owners, and followed through to objective verification and closure.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Internal audit and management review should expose and act on system weaknesses. Check follow-up, decisions, and objective closure, not only calendars and minutes.

53 **Confirm management review occurs at planned intervals and considers required QMS inputs such as previous actions, context changes, customer and process performance, objectives, audits, nonconformities, supplier performance, resources, risks, and opportunities.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Internal audit and management review should expose and act on system weaknesses. Check follow-up, decisions, and objective closure, not only calendars and minutes.

54 **Verify management-review outputs include decisions and actions for improvement, QMS changes, resource needs, priorities, owners, timelines, and follow-up rather than remaining as untracked discussion.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Internal audit and management review should expose and act on system weaknesses. Check follow-up, decisions, and objective closure, not only calendars and minutes.

10. Clause 10: improvement, nonconformity, corrective action, and audit sign-off

55 **Verify improvement opportunities are identified from customer needs, process performance, audit results, data analysis, risks, complaints, defects, supplier issues, and management review.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Corrective action is complete only after effectiveness is verified. Use the final sign-off to focus on systemic findings, recurring issues, and improvement opportunities.

56 **Confirm significant nonconformities trigger immediate correction or containment, evaluation of consequences, investigation of cause where needed, and review for similar potential issues elsewhere.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Corrective action is complete only after effectiveness is verified. Use the final sign-off to focus on systemic findings, recurring issues, and improvement opportunities.

57 **Check corrective actions address verified causes, are proportionate to the effects of the nonconformity, have named owners and deadlines, and result in necessary updates to risks, controls, or the QMS.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Corrective action is complete only after effectiveness is verified. Use the final sign-off to focus on systemic findings, recurring issues, and improvement opportunities.

58 **Verify corrective-action effectiveness is reviewed using objective evidence after sufficient time or process cycles and that ineffective actions are reopened, extended, or revised.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Corrective action is complete only after effectiveness is verified. Use the final sign-off to focus on systemic findings, recurring issues, and improvement opportunities.

59 **Confirm the organization demonstrates continual improvement in the suitability, adequacy, and effectiveness of the QMS through measurable changes, learning, stronger controls, or improved results.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Observation | Nonconformity | N/A

Execution tip: Corrective action is complete only after effectiveness is verified. Use the final sign-off to focus on systemic findings, recurring issues, and improvement opportunities.

60 **Record final audit findings, clause or process reference, evidence, classification, immediate correction, corrective-action owner, due date, overall internal-audit result, follow-up date, auditor, auditee, management-system owner, and sign-off.**

CRITICAL

ISO 9001 QMS AUDIT

Conforming | Needs action | Major gap | EVIDENCE Add

Execution tip: Corrective action is complete only after effectiveness is verified. Use the final sign-off to focus on systemic findings, recurring issues, and improvement opportunities.