QUALITY GURUS INC.

ISO 9001:2026

Internal Audit Checklist

Clauses 4 to 10, with the 2026 changes flagged

What this checklist does

This is a full internal audit checklist for a quality management system audited against ISO 9001:2026. It covers every requirement in Clauses 4 to 10, written as audit questions with the evidence to look for. Requirements that are new or changed in the 2026 edition carry a red 2026 marker, so a transition audit can start there.

Use it for your first internal audit cycle after transition, or as the basis for your own clause matrix. It complements the Transition Gap Analysis Checklist, which covers only what changed.

Audit details

Organization and site	
Audit objectives (9.2.2 a)	
Audit criteria	
Audit scope	
Lead auditor and team	
Dates	

How to use this checklist

Read this page once before the opening meeting.

Working method

1. Define the objectives, criteria and scope of the audit before you start. In the 2026 edition, audit objectives are explicitly required for each audit.
2. Select the clauses in scope. Not every audit needs every row. Prioritise by the importance of the processes, previous results and recent changes.
3. Ask the question, then sample. A finding of Conforms needs objective evidence you can name, not a description of the procedure.
4. Record the evidence you sampled in the right hand column: document number, record identifier, interviewee role, date.
5. Log every OFI and NC in Section C and report to the relevant managers.

Finding key

C Conforms. Requirement met, with evidence sampled.

OFI Opportunity for improvement. Conforms, but the arrangement is weak or at risk.

NC Nonconformity. Grade it minor or major in Section C, using your own programme's definitions.

Markers

2026 New or changed in the 2026 edition.

AMD 2024 From Amendment 1:2024. Already required if you implemented it.

Two distinctions that decide findings

Available as documented information means a current, controlled document must exist. **Available as evidence of** means a retained record must exist. Annex A.2 of the 2026 edition sets out the difference. Check which one a clause asks for before raising a finding about missing paperwork.

Consider means the organization thought about the topic. **Take into account** means it thought about it and it shaped the decision. The evidence you need for the second is stronger.

Auditing quality culture and ethical behaviour

Clauses 5.1.1 i), 7.1.4 and 7.3 e) are rarely evidenced by documents. No documented information is required for any of them. Audit them by interview and observation, using the prompts in Section B, and triangulate what top management says against what people at other levels say and do.

Section A. Clause by clause audit

Every requirement in Clauses 4 to 10, as an audit question. Red markers show what is new or changed in 2026.

Clause	Audit question and what to look for	Finding	Objective evidence and notes
Clause 4			Context of the organization
4.1 Understanding the organization and its context			
4.1	Has the organization determined the external and internal issues relevant to its purpose and strategic direction that affect the intended results of the QMS? **Look for.** Context analysis (PESTLE, SWOT or equivalent), dated, owned, and consistent with what top management describes in interview.	☐ C ☐ OFI ☐ NC	
4.1	Has the organization determined whether climate change is a relevant issue, and recorded the conclusion? AMD 2024 **Look for.** A recorded yes or no with reasoning. Not relevant is a valid answer if it was considered.	☐ C ☐ OFI ☐ NC	
4.1	Is information about these issues monitored and reviewed? **Look for.** Review frequency, evidence of update when an issue changed, link to management review input.	☐ C ☐ OFI ☐ NC	
4.2 Needs and expectations of interested parties			
4.2 a) b)	Have the relevant interested parties and their relevant requirements been determined? **Look for.** Interested party register. Check it includes regulators, key providers and people in the organization, and any climate related requirements.	☐ C ☐ OFI ☐ NC	
4.2 c)	Has the organization determined which of those requirements will be addressed through the QMS? 2026 **Look for.** A column or decision record showing which requirements are in and which are out, with the reason for any left outside the QMS.	☐ C ☐ OFI ☐ NC	
4.2	Is information about interested parties and their requirements monitored and reviewed? **Look for.** Review date and evidence of change when a party or requirement changed.	☐ C ☐ OFI ☐ NC	
4.3 Determining the scope of the QMS			
4.3	Was the scope determined considering the issues in 4.1, the requirements in 4.2, and the products and services of the organization? **Look for.** Traceability from context and interested party analysis to the scope decision.	☐ C ☐ OFI ☐ NC	
4.3	Does the scope state the types of products and services covered, justify any requirement determined not applicable, and exist as documented information? **Look for.** Scope statement. Test each not applicable claim against Annex A.3: it must not affect conformity or customer satisfaction.	☐ C ☐ OFI ☐ NC	
4.4 QMS and its processes			
4.4.1 a)–d)	Are the processes determined, with their inputs, outputs, sequence and interaction, and the criteria, methods and indicators needed to control them? **Look for.** Process map, turtle diagrams or equivalent, with named performance indicators.	☐ C ☐ OFI ☐ NC	

Clause	Audit question and what to look for	Finding	Objective evidence and notes
4.4.1 e)–g)	Are resources, responsibilities and authorities assigned for each process, and are the risks and opportunities from 6.1 addressed? **Look for.** Process owners named. Risk and opportunity entries linked to processes.	☐ C ☐ OFI ☐ NC	
4.4.1 h) i)	Are processes evaluated and changed where needed, and are both the processes and the QMS improved? 2026 **Look for.** Process reviews, changes made as a result, and improvements to the QMS itself.	☐ C ☐ OFI ☐ NC	
4.4.2	Is documented information available to support process operation, and as evidence that processes are carried out as planned? **Look for.** Procedures or instructions in use at the point of work. Records sampled against them.	☐ C ☐ OFI ☐ NC	
Clause 5			Leadership
5.1.1 Leadership and commitment, general			
5.1.1 a) b)	Are the quality policy and objectives compatible with strategic direction, and are QMS requirements integrated into business processes? **Look for.** Strategy documents, business plans or budgets that reference quality objectives.	☐ C ☐ OFI ☐ NC	
5.1.1 c)–f)	Does top management ensure resources, communicate the importance of quality management, ensure intended results are achieved, and direct and support people to contribute? **Look for.** Interview top management. Ask for examples, then verify one in the records.	☐ C ☐ OFI ☐ NC	
5.1.1 g) h)	Does top management promote continual improvement and support other relevant roles to demonstrate leadership in their areas? 2026 **Look for.** Improvement programme sponsorship; evidence of line managers leading in their areas.	☐ C ☐ OFI ☐ NC	
5.1.1 i)	Does top management promote quality culture and ethical behaviour? 2026 **Look for.** Dated, specific examples. Triangulate against Section B interviews at other levels. Note 2 to 5.1.1: culture is reflected in shared values, attitudes, practices and actions.	☐ C ☐ OFI ☐ NC	
5.1.1 j) k)	Does top management promote the process approach, and both risk-based and opportunity-based thinking? 2026 **Look for.** Two separate concepts now. Look for opportunity-based thinking in decisions, not only risk.	☐ C ☐ OFI ☐ NC	
5.1.1 l)	Does top management take accountability for the effectiveness of the QMS? 2026 **Look for.** Accountability stated and exercised. Moved to the final item in 2026; substance unchanged.	☐ C ☐ OFI ☐ NC	
5.1.2 Customer focus			
5.1.2 a)	Are customer and applicable statutory and regulatory requirements determined, understood and consistently met? **Look for.** Requirements register, delivery and complaint performance.	☐ C ☐ OFI ☐ NC	
5.1.2 b) c)	Are risks and opportunities that affect conformity and customer satisfaction addressed, and is the focus on enhancing satisfaction maintained? **Look for.** Customer related entries in the risk and opportunity registers; satisfaction trends reviewed.	☐ C ☐ OFI ☐ NC	

Clause	Audit question and what to look for	Finding	Objective evidence and notes
5.2 Quality policy			
5.2.1 a)–d)	Is the policy appropriate to purpose, a framework for objectives, and does it commit to meeting applicable requirements and to continual improvement? **Look for.** Current approved policy.	☐ C ☐ OFI ☐ NC	
5.2.1 e)	Does the policy take into account the context of the organization and support its strategic direction? 2026 **Look for.** Policy content traceable to the context analysis and strategy. Now a separate item.	☐ C ☐ OFI ☐ NC	
5.2.2	Is the policy available as documented information, communicated, available to interested parties as appropriate, and implemented, understood and applied? 2026 **Look for.** Ask people what the policy means for their work. Applied is new wording.	☐ C ☐ OFI ☐ NC	
5.3 Roles, responsibilities and authorities			
5.3	Are responsibilities and authorities for relevant roles assigned and communicated? **Look for.** Role descriptions, organization chart, delegation records.	☐ C ☐ OFI ☐ NC	
5.3 a)–f)	Are all six responsibilities assigned, including reporting on QMS performance and, separately, reporting on opportunities for improvement? 2026 **Look for.** Named persons for each. The improvement reporting duty is often missing.	☐ C ☐ OFI ☐ NC	
5.3 f)	Is QMS integrity maintained when changes to the QMS are planned and implemented? **Look for.** Links to 6.3 change records.	☐ C ☐ OFI ☐ NC	
Clause 6		Planning	
6.1.1 Determining risks and opportunities			
6.1.1	Were risks and opportunities determined considering 4.1 and 4.2, to give assurance of intended results, prevent or reduce undesired effects, achieve continual improvement and enhance desired effects? 2026 **Look for.** Traceability from context and interested parties into the registers.	☐ C ☐ OFI ☐ NC	
6.1.2 Actions to address risks			
6.1.2	Are risks determined, analysed and evaluated for their effect on conformity and customer satisfaction? 2026 **Look for.** Analysis and evaluation visible, not just a list. Formal risk methods are not required (Annex A.6.1.2).	☐ C ☐ OFI ☐ NC	
6.1.2 a) b)	Are actions planned, integrated into QMS processes, and evaluated for effectiveness? 2026 **Look for.** Action status and a documented effectiveness conclusion for a sample of risks.	☐ C ☐ OFI ☐ NC	
6.1.2	Are actions proportionate to the potential impact of the risks, including risks to provision during and after a disruption? 2026 **Look for.** High impact risks carry stronger actions. Disruption scenarios considered.	☐ C ☐ OFI ☐ NC	
6.1.3 Actions to address opportunities			
6.1.3	Are opportunities determined, analysed and evaluated for their effect on conformity and customer satisfaction? 2026 **Look for.** Opportunities handled separately from risks. A blank opportunity column is a likely finding.	☐ C ☐ OFI ☐ NC	

Clause	Audit question and what to look for	Finding	Objective evidence and notes
6.1.3 a) b)	Are opportunity actions planned, integrated into processes, evaluated for effectiveness, and appropriate to context? 2026 **Look for.** Sample one opportunity from identification through to outcome.	☐ C ☐ OFI ☐ NC	
6.2 Quality objectives and planning to achieve them			
6.2.1	Are objectives set at relevant functions, levels and processes, consistent with policy, measurable, relevant to conformity and satisfaction, monitored, communicated, updated and available as documented information? 2026 **Look for.** Objective register. Documented information is now item g) of the list.	☐ C ☐ OFI ☐ NC	
6.2.2	For each objective, is it determined what will be done, what resources are needed, who is responsible, when it will be completed and how results will be evaluated? **Look for.** Action plans for a sample of objectives, with progress data.	☐ C ☐ OFI ☐ NC	
6.3 Planning of changes			
6.3	Are changes to the QMS carried out in a planned manner? **Look for.** Change register or change requests for the last twelve months.	☐ C ☐ OFI ☐ NC	
6.3 a)–d)	For each change, were purpose and consequences, potential impact on QMS integrity, resources and information, and responsibilities considered? 2026 **Look for.** Change records. Information and potential impact on integrity are new wording.	☐ C ☐ OFI ☐ NC	
6.3 e)–g)	Was the change communicated, and was it determined how its effectiveness would be monitored and evaluated and how its results would be reviewed? 2026 **Look for.** Three new considerations. A record that stops at approval does not meet them.	☐ C ☐ OFI ☐ NC	
Clause 7			Support
7.1 Resources			
7.1.1 7.1.2	Are the resources and people needed for the QMS determined and provided, considering internal capability and constraints and what is obtained externally? **Look for.** Resource plans, headcount against plan, use of external resources.	☐ C ☐ OFI ☐ NC	
7.1.3	Is the infrastructure needed determined, provided and maintained, for all types of work, including remote and hybrid? 2026 **Look for.** Maintenance records, ICT and remote working arrangements.	☐ C ☐ OFI ☐ NC	
7.1.4	Is the environment for operation of processes determined, provided and maintained, including social, psychological and physical factors? 2026 **Look for.** Determination covering all three factor types. The note now links some factors to quality culture and ethical behaviour.	☐ C ☐ OFI ☐ NC	
7.1.5.1	Are monitoring and measuring resources suitable and maintained, with documented information as evidence of fitness for purpose? **Look for.** Equipment list, maintenance and verification records.	☐ C ☐ OFI ☐ NC	
7.1.5.2	Where traceability of measurement results is required, is equipment calibrated or verified, identified and safeguarded, with the basis available as documented information where no traceable standard exists? 2026 **Look for.** Calibration certificates and status labels. Clause renamed to Traceability of measurement results.	☐ C ☐ OFI ☐ NC	

Clause	Audit question and what to look for	Finding	Objective evidence and notes
7.1.5.2	When equipment is found unfit, is the validity of previous results assessed and action taken? **Look for.** Out of tolerance records with impact assessments.	☐ C ☐ OFI ☐ NC	
7.1.6	Is the knowledge needed for processes and the intended results of the QMS determined, and is it retained, applied and shared? 2026 **Look for.** Evidence that knowledge is applied and shared, not only stored. Handovers, lessons learned.	☐ C ☐ OFI ☐ NC	
7.1.6	When needs and trends change, does the organization consider current knowledge and acquire or access what is missing? **Look for.** Response to a recent change in technology, regulation or product.	☐ C ☐ OFI ☐ NC	
7.2 Competence and 7.3 Awareness			
7.2	Is necessary competence determined, are people competent, are actions taken where they are not, and is the effectiveness of those actions evaluated? **Look for.** Competence matrix, training records, effectiveness evaluation for a sample.	☐ C ☐ OFI ☐ NC	
7.3 a)–d)	Are people aware of the quality policy, their contribution, the implications of not conforming, and relevant quality objectives? **Look for.** Ask people at different levels. Answers in their own words.	☐ C ☐ OFI ☐ NC	
7.3 e)	Are people aware of the organizational quality culture and ethical behaviour? 2026 **Look for.** Interview. People can say what is expected of them and what they would do if something was not right. See Section B.	☐ C ☐ OFI ☐ NC	
7.4 Communication and 7.5 Documented information			
7.4	Are internal and external communications determined: what, when, with whom, how, and who communicates? **Look for.** Communication plan or matrix; a sample communication traced end to end.	☐ C ☐ OFI ☐ NC	
7.5.1	Does the QMS include the documented information required by the standard and that determined as necessary by the organization? **Look for.** Document register; the organization's own determination of what it needs.	☐ C ☐ OFI ☐ NC	
7.5.2	When documented information is created and updated, is identification, format and review and approval appropriate? 2026 **Look for.** Approval evidence on sampled documents. Clause renamed; substance unchanged.	☐ C ☐ OFI ☐ NC	
7.5.3	Is documented information available where needed, protected, and controlled for distribution, storage, change, retention and disposition, including external origin? **Look for.** Current versions at point of use, version history, retention schedule.	☐ C ☐ OFI ☐ NC	
7.5.3	Is documented information available as evidence of conformity protected from unintended alteration? **Look for.** Access controls on records; audit trail in electronic systems.	☐ C ☐ OFI ☐ NC	

Clause	Audit question and what to look for	Finding	Objective evidence and notes
Clause 8			Operation
8.1 Operational planning and control			
8.1 a)–e)	Are product and service requirements determined, with acceptance criteria for products and services and, separately, criteria for the processes, and are processes controlled against them with resources determined? 2026 **Look for.** Control plans or specifications. Acceptance criteria and process criteria are now two items.	☐ C ☐ OFI ☐ NC	
8.1	Is documented information available to give confidence processes ran as planned and as evidence of product and service conformity? 2026 **Look for.** Two separate requirements in 2026. Sample both.	☐ C ☐ OFI ☐ NC	
8.1	Are planned changes controlled, and the consequences of unintended changes reviewed and mitigated? **Look for.** Change records; one unintended change traced to its review.	☐ C ☐ OFI ☐ NC	
8.1	Are externally provided processes, products or services relevant to the QMS controlled? 2026 **Look for.** Replaces outsourced processes in the 2015 text. Links to 8.4.	☐ C ☐ OFI ☐ NC	
8.2 Requirements for products and services			
8.2.1 a)–d)	Does customer communication cover product and service information, enquiries, contracts and changes, feedback including complaints, and customer property? **Look for.** Customer communication channels, complaint log.	☐ C ☐ OFI ☐ NC	
8.2.1 e)	Does the organization provide information related to contingency actions, including any related to disruptions to provision, when relevant? 2026 **Look for.** Broadened wording. Contingency and disruption communication to customers.	☐ C ☐ OFI ☐ NC	
8.2.2	Are requirements defined, including statutory and regulatory ones, and can the organization meet the claims it makes for its products and services? **Look for.** Product specifications, marketing claims checked against capability.	☐ C ☐ OFI ☐ NC	
8.2.3	Before committing to supply, is a review conducted covering customer, implied, organizational, statutory and changed requirements, with differences resolved? **Look for.** Contract or order review records, including confirmation where requirements were not written.	☐ C ☐ OFI ☐ NC	
8.2.3.2	Is documented information available as evidence of review results and any new requirements? **Look for.** Records attached to the order or contract.	☐ C ☐ OFI ☐ NC	
8.2.4	When requirements change, is documented information updated and communicated to the relevant interested parties? 2026 **Look for.** Communication beyond internal staff. Suppliers and others affected by the change.	☐ C ☐ OFI ☐ NC	
8.3 Design and development of products and services			
8.3.1 **8.3.2**	Where design and development applies, is a process established, and does planning consider nature, duration, complexity, stages, reviews, verification, validation and responsibilities? **Look for.** Design procedure and a project plan. If not applicable, confirm the justification in 4.3.	☐ C ☐ OFI ☐ NC	

Clause	Audit question and what to look for	Finding	Objective evidence and notes
8.3.3	Are inputs determined, including functional, previous design, statutory, standards and consequences of failure, and are they complete, unambiguous and conflict free? **Look for.** Design input record for a sampled project.	☐ C ☐ OFI ☐ NC	
8.3.4	Are reviews, verification and validation conducted, problems acted on, and documented information retained? **Look for.** Review minutes, verification results, validation evidence.	☐ C ☐ OFI ☐ NC	
8.3.5	Do outputs meet inputs, suit subsequent processes, reference acceptance criteria, and specify characteristics and the information on products and services essential for their intended purpose? 2026 **Look for.** The information on products and services is new. Labels, instructions, safety information.	☐ C ☐ OFI ☐ NC	
8.3.6	Are design changes identified, reviewed, authorized and controlled, with documented information retained? **Look for.** Change records with review and authorization.	☐ C ☐ OFI ☐ NC	
8.4 Control of externally provided processes, products and services			
8.4.1	Are controls determined, and are criteria for evaluation, selection, monitoring and re-evaluation of external providers applied, with documented information? **Look for.** Approved provider list, evaluation and re-evaluation records.	☐ C ☐ OFI ☐ NC	
8.4.2 a) b)	Are externally provided processes within QMS control, with controls defined for both the provider and the resulting output? **Look for.** Supplier agreements, incoming inspection plans.	☐ C ☐ OFI ☐ NC	
8.4.2 c)	Does the organization take into account the potential impact of what is provided and the effectiveness of the controls applied by the external provider? 2026 **Look for.** Second consideration is new. Provider certification, audits, their own control data.	☐ C ☐ OFI ☐ NC	
8.4.2 d)	Are verification or other activities determined to ensure requirements are met? **Look for.** Receiving inspection, certificates of conformity, source inspection records.	☐ C ☐ OFI ☐ NC	
8.4.3	Are requirements checked for adequacy before being communicated to providers? **Look for.** Purchase order review.	☐ C ☐ OFI ☐ NC	
8.4.3 a)–f)	Do communications to providers cover the outputs, approvals, competence, interactions with the organization, its customers and other relevant interested parties, performance monitoring, and any verification at their premises? 2026 **Look for.** Purchase orders and agreements. Interactions with interested parties is new wording.	☐ C ☐ OFI ☐ NC	
8.5 Production and service provision			
8.5.1 a) b)	Is documented information defining characteristics, activities and results, and suitable monitoring and measuring resources, both available and used? 2026 **Look for.** Availability and use. Observe work against the instruction, not just the instruction's existence.	☐ C ☐ OFI ☐ NC	
8.5.1 c)–e)	Are monitoring activities performed at appropriate stages, with suitable infrastructure and environment, by competent persons? **Look for.** Inspection records at stages; competence of the operators observed.	☐ C ☐ OFI ☐ NC	

Clause	Audit question and what to look for	Finding	Objective evidence and notes
8.5.1 f)–h)	Are special processes validated and periodically revalidated, are actions taken to prevent human error, and are release, delivery and post-delivery activities implemented? **Look for.** Validation records, error proofing, delivery records.	☐ C ☐ OFI ☐ NC	
8.5.2	Are outputs identified, their status known, and unique identification controlled where traceability is required? **Look for.** Labels, travellers, system status, traceability records.	☐ C ☐ OFI ☐ NC	
8.5.3	Is property belonging to customers or external providers identified, protected and safeguarded, and is loss or damage reported? **Look for.** Include intellectual property and personal data.	☐ C ☐ OFI ☐ NC	
8.5.4 8.5.5	Are outputs preserved, and are post-delivery requirements met considering statutory needs, consequences, lifetime, customer requirements and feedback? **Look for.** Storage and handling conditions; warranty and service records.	☐ C ☐ OFI ☐ NC	
8.5.6	Are changes to production or service provision reviewed and controlled, with documented information on the review, the person authorizing and any actions? **Look for.** Change records. Wording unchanged from 2015 apart from the documented information verb.	☐ C ☐ OFI ☐ NC	
8.6 Release and 8.7 Nonconforming outputs			
8.6	Are planned arrangements implemented to verify requirements are met, with release held until complete unless authorized, and evidence of conformity and the releasing person? **Look for.** Release records for a sample; any release under authority.	☐ C ☐ OFI ☐ NC	
8.7.1	Are nonconforming outputs identified and controlled, dealt with by correction, segregation, informing the customer or concession, and verified after correction? **Look for.** Nonconformance log, quarantine area, concessions.	☐ C ☐ OFI ☐ NC	
8.7.2	Is documented information available on the nature of the nonconformity, the actions, any concessions and the authority deciding? **Look for.** Sampled nonconformance records complete on all four points.	☐ C ☐ OFI ☐ NC	
Clause 9			Performance evaluation
9.1 Monitoring, measurement, analysis and evaluation			
9.1.1	Has the organization determined what to monitor and measure, the methods, when to measure and when to analyse, and does it evaluate QMS performance and effectiveness? **Look for.** Measurement plan; KPI dashboard; documented results.	☐ C ☐ OFI ☐ NC	
9.1.2	Is customer satisfaction monitored, with methods for obtaining, monitoring and reviewing the information determined? 2026 **Look for.** Simplified wording. Evidence the data was reviewed, not only collected.	☐ C ☐ OFI ☐ NC	
9.1.3 a)–d)	Is data analysed and used to evaluate conformity, satisfaction, QMS performance and the effectiveness of planning implementation? 2026 **Look for.** Analysis reports and the decisions they led to.	☐ C ☐ OFI ☐ NC	
9.1.3 e) f)	Are the effectiveness of actions on risks and of actions on opportunities evaluated separately? 2026 **Look for.** Two separate evaluations. A combined line is a likely finding.	☐ C ☐ OFI ☐ NC	

Clause	Audit question and what to look for	Finding	Objective evidence and notes
9.1.3 g) h)	Is analysis used to evaluate external provider performance and the need for improvement? **Look for.** Supplier scorecards; improvement actions arising from analysis.	☐ C ☐ OFI ☐ NC	
9.2 Internal audit			
9.2.1	Are internal audits conducted at planned intervals to determine conformity to the organization's requirements and the standard, and effective implementation? **Look for.** Audit schedule and completed audits against it.	☐ C ☐ OFI ☐ NC	
9.2.2	Does the audit programme consider process importance, previous results and changes, and define frequency, methods, responsibilities, planning and reporting? **Look for.** Programme document and its rationale.	☐ C ☐ OFI ☐ NC	
9.2.2 a)	Are objectives, criteria and scope defined for each audit? 2026 **Look for.** Audit objectives are newly required. Check the audit plan for this audit, too.	☐ C ☐ OFI ☐ NC	
9.2.2 b)–d)	Are auditors objective and impartial, results reported to relevant managers, and correction and corrective action taken without undue delay? 2026 **Look for.** Auditor independence; report distribution; correction added to the 2026 wording.	☐ C ☐ OFI ☐ NC	
9.3 Management review			
9.3.1	Does top management review the QMS at planned intervals for suitability, adequacy, effectiveness and alignment with strategic direction? 2026 **Look for.** Review minutes. Alignment with strategic direction is new.	☐ C ☐ OFI ☐ NC	
9.3.2 a)–c)	Do inputs include previous actions, changes in external and internal issues, and changes in the needs and expectations of interested parties? 2026 **Look for.** Item c) is new. Look for it on the agenda.	☐ C ☐ OFI ☐ NC	
9.3.2 d)–f)	Do inputs include QMS performance trends, improvement opportunities and adequacy of resources? **Look for.** Trend data across all seven performance sub-items.	☐ C ☐ OFI ☐ NC	
9.3.2 g) h)	Are the effectiveness of risk actions and of opportunity actions reviewed as two separate inputs? 2026 **Look for.** Two agenda lines, not one.	☐ C ☐ OFI ☐ NC	
9.3.3	Do results include decisions on improvement opportunities, QMS changes and resource needs, with documented information retained? 2026 **Look for.** Decisions with owners and dates. Clause renamed from outputs to results.	☐ C ☐ OFI ☐ NC	
Clause 10		Improvement	
10.1 Continual improvement			
10.1	Does the organization continually improve the suitability, adequacy and effectiveness of the QMS, using analysis results and management review to determine opportunities? 2026 **Look for.** 2015 clauses 10.1 and 10.3 now merged. There is no 10.3.	☐ C ☐ OFI ☐ NC	
10.1 a)–c)	Do actions include improving processes, products and services, addressing future needs and expectations, and correcting, preventing or reducing undesired effects? **Look for.** Improvement register with examples of each type.	☐ C ☐ OFI ☐ NC	

Clause	Audit question and what to look for	Finding	Objective evidence and notes
10.2 Nonconformity and corrective action			
10.2.1 a)	When a nonconformity occurs, does the organization react, control and correct it, and deal with the consequences? **Look for.** Containment records.	☐ C ☐ OFI ☐ NC	
10.2.1 b)	Is the need for action evaluated by reviewing the nonconformity, determining its causes, and checking whether similar nonconformities exist or could occur? **Look for.** Root cause analysis and an extent of condition check.	☐ C ☐ OFI ☐ NC	
10.2.1 c)–f)	Are actions implemented, their effectiveness reviewed, risks and opportunities updated and the QMS changed where necessary? **Look for.** Dated effectiveness review with a conclusion.	☐ C ☐ OFI ☐ NC	
10.2.1	Are corrective actions appropriate to the effects of the nonconformities, and are customer complaints treated as a source? **Look for.** Proportionality. Complaints feeding the corrective action process.	☐ C ☐ OFI ☐ NC	
10.2.2	Is documented information available on the nature of nonconformities, actions taken and results of corrective action? **Look for.** Corrective action records sampled end to end.	☐ C ☐ OFI ☐ NC	

Section B. Culture and ethics interview prompts

For 5.1.1 i), 7.1.4 and 7.3 e). Ask the same prompts at three levels and compare the answers.

These requirements are evidenced mainly by what people say and do. Interview at least one person at each level. Ask for a specific incident, not an opinion, and verify one answer in the records. A consistent story across levels is strong evidence. A gap between what top management describes and what the front line describes is the finding.

Level	Prompt	Notes
Top management 5.1.1 i)	How do you promote quality culture and ethical behaviour? Give me a recent example, with a date.	
	Tell me about the last time a stop or hold on quality grounds cost money. What did you do?	
	What do you ask about first in your operations or performance reviews?	
Middle managers 5.1.1 h), 7.1.4	What happens here when somebody brings bad news to a manager?	
	Who decides whether a doubtful output is released, and how long does that take?	
	What are you measured on week to week, and where does quality sit in that?	
Front line 7.3 e)	What does this organization expect of you when something is not right?	
	Tell me about the last time you saw something that was not right. What did you do, and what happened next?	
	What do people do differently in the last week of the month, or near a deadline?	

Corroborating records verify at least one

Concession and deviation records, and how their reasons are worded over time. Corrective actions naming a person as the root cause. Repeat audit findings. Records of any stop, hold or recall and what happened to the person who raised it. Management review minutes showing culture discussed with evidence.

Grading culture findings

The requirement is to promote quality culture and ethical behaviour, and for people to be aware of it. It is not a requirement to have a good culture. Raise a nonconformity when there is no evidence of promotion or awareness. Raise an OFI when promotion exists but the interviews show a gap between what is said and what is done.

Section C. Findings log and sign off

Transfer every OFI and NC here. Report to the relevant managers without undue delay (9.2.2).

No.	Clause	Finding and objective evidence	Grade	Owner	Due
1			OFI Min Maj		
2			OFI Min Maj		
3			OFI Min Maj		
4			OFI Min Maj		
5			OFI Min Maj		
6			OFI Min Maj		
7			OFI Min Maj		
8			OFI Min Maj		
9			OFI Min Maj		
10			OFI Min Maj		

Audit conclusion

Were the audit objectives met?	☐ Yes ☐ Partly ☐ No
Is the QMS effectively implemented and maintained within scope?	☐ Yes ☐ With findings ☐ No
Summary	

Role	Name	Signature	Date
Lead auditor			
Auditee representative			
Report issued to			

Audit prompts in this checklist paraphrase the requirements of ISO 9001:2026 for audit use. They do not reproduce or replace the standard. Always audit against the published text. ISO 9001 is published by the International Organization for Standardization.