

ISO 9001:2026 Clause-Wise Audit & Implementation Checklist

Clauses 4–10 • Key Requirements • Audit Evidence • Auditor Questions • Documents & Records • Implementation Checks • Transition Preparation

How to use this checklist: Mark each item as ✓ Compliant, ■ Partially Compliant, or ✗ Action Required. Record objective evidence and assign an owner/date for gaps.

Clause 4 – Context of the Organization

Context and interested parties

Status	Checklist / Evidence
■	Have relevant internal and external issues affecting the QMS been identified and reviewed?
■	Have relevant interested parties been identified?
■	Have relevant requirements of interested parties been determined and monitored?
■	Is the QMS scope clearly defined and consistent with actual activities, products, services and locations?
■	Are QMS processes identified, controlled and their interactions understood?
■	Are process inputs, outputs, responsibilities, criteria, resources and performance measures defined where appropriate?

Typical audit evidence

Status	Checklist / Evidence
■	Context analysis / business review
■	Interested-party register and requirements
■	QMS scope statement
■	Process map / SIPOC / process interaction map
■	Process KPIs and process-owner records

Auditor questions

Status	Checklist / Evidence
■	What are the major internal and external issues affecting your QMS?
■	Who are your relevant interested parties and what do they require?
■	How was the QMS scope determined?
■	How do you monitor changes in your organizational context?

Clause 5 – Leadership

Leadership and commitment

Status	Checklist / Evidence
■	Does top management demonstrate accountability for QMS effectiveness?
■	Is customer focus evident in management decisions?
■	Does management provide appropriate resources for the QMS?

Status	Checklist / Evidence
■	Does management promote process thinking, risk-based thinking and continual improvement?
■	Is quality culture actively encouraged?

Quality policy and responsibilities

Status	Checklist / Evidence
■	Is the Quality Policy appropriate to the organization's purpose and strategic direction?
■	Is the policy communicated, understood and available as appropriate?
■	Are QMS roles, responsibilities and authorities defined?
■	Can employees explain their relevant quality responsibilities?

Typical audit evidence

Status	Checklist / Evidence
■	Quality Policy
■	Organization chart and responsibility matrix
■	Management decisions and action records
■	Quality KPI reviews
■	Resource approvals and improvement projects

Auditor questions

Status	Checklist / Evidence
■	How does top management demonstrate leadership?
■	How does management promote quality culture?
■	How does the Quality Policy guide your objectives?
■	Who owns this process and what authority do they have?

Clause 6 – Planning

Risks, opportunities and objectives

Status	Checklist / Evidence
■	Have relevant risks and opportunities been identified?
■	Are actions planned to address significant risks and opportunities?
■	Are quality objectives measurable where appropriate and consistent with the Quality Policy?
■	Are responsibilities, resources, timelines and evaluation methods defined for objectives?
■	Are quality objectives monitored and reviewed?

Planning of changes

Status	Checklist / Evidence
■	Are QMS changes planned before implementation?

Status	Checklist / Evidence
■	Are consequences of changes considered?
■	Are QMS integrity, resources and responsibilities considered during changes?

Typical audit evidence

Status	Checklist / Evidence
■	Risk and opportunity register
■	Process risk assessments
■	Quality objectives and KPI dashboards
■	Action plans
■	Change-management records

Auditor questions

Status	Checklist / Evidence
■	What are your major QMS risks?
■	What opportunities have you identified?
■	How do you determine quality objectives?
■	Show me how a recent significant change was planned and controlled.

Clause 7 – Support

Resources and infrastructure

Status	Checklist / Evidence
■	Are sufficient people and resources available to operate and control QMS processes?
■	Is infrastructure suitable and maintained?
■	Is the work environment suitable for process operation and conformity?
■	Are monitoring and measuring resources suitable for their intended purpose?

Competence and awareness

Status	Checklist / Evidence
■	Are competence requirements defined for relevant roles?
■	Are training and competence records maintained?
■	Is training effectiveness evaluated where appropriate?
■	Are employees aware of the Quality Policy and relevant objectives?
■	Do employees understand their contribution to QMS effectiveness and consequences of nonconformity?

Documented information

Status	Checklist / Evidence
■	Are required documents and records identified and controlled?

Status	Checklist / Evidence
■	Are documents approved and current at points of use?
■	Are obsolete documents prevented from unintended use?
■	Are records protected, retrievable and retained for defined periods?

Typical audit evidence

Status	Checklist / Evidence
■	Training and competence records
■	Skill matrix
■	Calibration records
■	Maintenance records
■	Master document list
■	Controlled procedures and work instructions

Auditor questions

Status	Checklist / Evidence
■	How do you determine competence requirements?
■	How do you evaluate training effectiveness?
■	How do you control measuring equipment?
■	How do you ensure employees use the current work instruction?

Clause 8 – Operation

Operational planning and customer requirements

Status	Checklist / Evidence
■	Are operational processes planned and controlled?
■	Are customer, statutory and regulatory requirements determined and reviewed?
■	Are changes to customer requirements communicated to relevant functions?
■	Are product/service acceptance criteria defined?

Design and development — where applicable

Status	Checklist / Evidence
■	Are design inputs, outputs, reviews, verification and validation controlled where applicable?
■	Are design changes identified, reviewed and controlled?

External providers

Status	Checklist / Evidence
■	Are suppliers evaluated, selected, monitored and re-evaluated using defined criteria?
■	Are purchasing requirements clearly communicated?

Status	Checklist / Evidence
■	Is supplier performance monitored?
■	Are externally provided processes controlled according to their impact on conformity?

Production and service provision

Status	Checklist / Evidence
■	Are work instructions and process parameters available where needed?
■	Are competent personnel and suitable equipment used?
■	Are identification and traceability controls implemented where required?
■	Are product/service release criteria defined and records retained?
■	Are nonconforming outputs identified and controlled?

Typical audit evidence

Status	Checklist / Evidence
■	Customer requirement review
■	Purchase specifications
■	Approved supplier list and evaluations
■	Supplier performance records
■	Production records and work instructions
■	Inspection and test records
■	Traceability records
■	NCR/rejection records

Auditor questions

Status	Checklist / Evidence
■	How do you review customer requirements?
■	How do you control suppliers?
■	How do you ensure production uses the latest requirements?
■	How do you control nonconforming output?

Clause 9 – Performance Evaluation

Monitoring and measurement

Status	Checklist / Evidence
■	Are relevant QMS and process KPIs defined?
■	Are data collected, analyzed and evaluated?
■	Are trends used for decision-making and improvement?
■	Is customer satisfaction monitored using suitable information?

Internal audit

Status	Checklist / Evidence
■	Is an internal audit programme planned based on process importance, changes and previous results?
■	Are auditors competent and sufficiently objective?
■	Do audits evaluate conformity and effectiveness?
■	Are findings communicated and corrective actions followed up?

Management review

Status	Checklist / Evidence
■	Is management review conducted at planned intervals?
■	Are required performance and QMS inputs reviewed?
■	Are decisions and actions recorded?
■	Are opportunities for improvement and resource needs addressed?

Typical audit evidence

Status	Checklist / Evidence
■	KPI dashboards and trend charts
■	Customer feedback and complaint analysis
■	Internal audit programme and reports
■	Auditor competence records
■	Management review minutes and action plans

Auditor questions

Status	Checklist / Evidence
■	Which KPIs tell management whether the QMS is effective?
■	How do you evaluate customer satisfaction?
■	How do you determine the internal audit programme?
■	What decisions resulted from the latest management review?

Clause 10 – Improvement

Nonconformity and corrective action

Status	Checklist / Evidence
■	Are nonconformities controlled and corrected?
■	Are causes investigated using appropriate root-cause methods?
■	Are corrective actions proportionate to the effects of nonconformities?
■	Is effectiveness of corrective action verified?
■	Are relevant QMS changes made after corrective action?

Continual improvement

Status	Checklist / Evidence
■	Are improvement opportunities identified and acted upon?
■	Are process performance and QMS effectiveness used to identify improvements?
■	Are improvement results measured where appropriate?

Typical audit evidence

Status	Checklist / Evidence
■	NCR and CAPA records
■	5 Why / Fishbone / 8D / other RCA
■	Effectiveness verification
■	Kaizen and improvement projects
■	Trend analysis

Auditor questions

Status	Checklist / Evidence
■	How do you determine root cause?
■	How do you verify corrective-action effectiveness?
■	Show me an example of a completed corrective action.
■	What continual improvement activities have produced measurable results?

ISO 9001:2026 Transition Preparation Checklist

Status	Checklist / Evidence
☐	Obtain and review the official ISO 9001:2026 standard.
☐	Conduct a clause-by-clause gap assessment against the existing QMS.
☐	Identify changes needed in leadership, quality culture, risks and opportunities, strategic alignment and awareness.
☐	Review the QMS scope, context and interested-party information.
☐	Review Quality Policy, objectives and responsibilities.
☐	Review documented information and update only what is necessary.
☐	Review process risks and opportunities and related action plans.
☐	Review operational controls, supplier controls and customer requirements.
☐	Review internal audit criteria and update the audit programme.
☐	Train relevant employees on applicable changes.
☐	Conduct an internal transition audit and close identified gaps.
☐	Review transition readiness with top management.
☐	Coordinate transition arrangements and timing with the certification body.
☐	Verify effectiveness of implemented changes before the transition audit.

Quick Management Review of Readiness

Area	Status	Evidence / Action Owner
Clauses 4–5: Context & Leadership	☐ Ready ☐ Gap	_____
Clause 6: Planning	☐ Ready ☐ Gap	_____
Clause 7: Support	☐ Ready ☐ Gap	_____
Clause 8: Operation	☐ Ready ☐ Gap	_____
Clause 9: Performance Evaluation	☐ Ready ☐ Gap	_____
Clause 10: Improvement	☐ Ready ☐ Gap	_____
Employee awareness / quality culture	☐ Ready ☐ Gap	_____
Internal audit completed	☐ Yes ☐ No	_____
Management review completed	☐ Yes ☐ No	_____

Note: This checklist is a practical implementation and audit-readiness aid. It is not a reproduction of ISO 9001:2026 and does not replace the official standard. Requirements and evidence should be assessed in the context of the organization's processes, products, services, risks and applicable requirements.

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