

ISO 9001:2026 Audit Checklist

Quality Management Systems - Requirements | Clause-wise assessment checklist

Resource Type	Audit Checklist	Standard	ISO 9001:2026
Prepared For	Website users and organizations preparing QMS transition	Organization	Pacific Certifications
Use	Internal readiness review, supplier preparation, certification planning, and transition planning	Contact	support@pacificcert.com

Important Use Note

This document is a practical support tool for ISO 9001:2026 readiness review. It does not reproduce the full ISO standard and should not be treated as a replacement for the official ISO 9001:2026 publication. Organizations should use it together with their own documented information, process evidence, applicable statutory/regulatory requirements, and certification planning records.

- ISO 9001:2026 is the current edition of the quality management system requirements standard and replaces ISO 9001:2015.
- The revised edition retains the familiar management system structure while improving clarity and usability.
- Key focus areas include leadership, quality culture, accountability, improved understanding of risks and opportunities, and better alignment with other ISO management system standards.
- Organizations already certified to ISO 9001:2015 should plan transition activities based on their certification body and accreditation transition arrangements.

Checklist Instructions

- Use C = Conforming, PC = Partially Conforming, NC = Nonconforming and NA = Not Applicable.
- Record objective evidence in the evidence column and use comments for risks, corrections, responsible persons or follow-up actions.
- Review both system-level controls and process-level implementation. Interview process owners where possible.
- For transition planning, compare existing ISO 9001:2015 documentation and practices against ISO 9001:2026 expectations.

ISO 9001:2026 Audit Checklist

Clause / Area	Checklist Question	Evidence / Records to Review	Status	Comments / Action
4. Context	Has the organization reviewed current internal and external issues that affect the QMS?	Context analysis, strategic review notes, risk/opportunity inputs	■ C ■ PC ■ NC ■ NA	
4. Context	Are relevant interested parties and their requirements identified, reviewed and considered in QMS planning?	Interested-party register, legal/customer/contractual requirements	■ C ■ PC ■ NC ■ NA	
4. Context	Is the QMS scope clear, justified and aligned with products, services, locations and outsourced processes?	Scope statement, process map, exclusions/justifications where applicable	■ C ■ PC ■ NC ■ NA	
4. Context	Are process inputs, outputs, sequence, interactions, responsibilities, criteria and resources defined?	Process maps, SIPOC, procedures, KPI matrix, process owner assignments	■ C ■ PC ■ NC ■ NA	
5. Leadership	Does top management demonstrate responsibility for QMS effectiveness and customer focus?	Leadership meeting records, objectives, review outputs, customer feedback actions	■ C ■ PC ■ NC ■ NA	
5. Leadership	Is quality culture promoted through accountability, communication and behavior expectations?	Culture initiatives, awareness records, performance discussions, communications	■ C ■ PC ■ NC ■ NA	
5. Leadership	Is the quality policy suitable, communicated, available and aligned with the organization direction?	Quality policy, communication evidence, worker interviews, website/intranet posting	■ C ■ PC ■ NC ■ NA	

Clause / Area	Checklist Question	Evidence / Records to Review	Status	Comments / Action
5. Leadership	Are QMS roles, responsibilities and authorities assigned and understood?	Organization chart, job descriptions, process responsibilities, interviews	■ C ■ PC ■ NC ■ NA	
6. Planning	Are risks and opportunities determined for the QMS and processes?	Risk/opportunity register, process risks, action plans	■ C ■ PC ■ NC ■ NA	
6. Planning	Are actions to address risks and opportunities integrated into processes and evaluated for effectiveness?	Action tracker, KPI results, review minutes, effectiveness checks	■ C ■ PC ■ NC ■ NA	
6. Planning	Are quality objectives measurable, monitored, communicated and updated as needed?	Quality objectives, targets, dashboards, review records	■ C ■ PC ■ NC ■ NA	
6. Planning	Are changes to the QMS planned and controlled?	Change requests, transition plan, change impact assessments, approval records	■ C ■ PC ■ NC ■ NA	
7. Support	Are people, infrastructure, environment, monitoring resources and organizational knowledge adequately provided?	Resource plans, maintenance records, calibration records, knowledge base	■ C ■ PC ■ NC ■ NA	
7. Support	Are competence needs identified and fulfilled for personnel affecting quality performance?	Competence matrix, training records, evaluations, qualification evidence	■ C ■ PC ■ NC ■ NA	
7. Support	Are employees aware of policy, objectives, their contribution and implications of nonconformity?	Awareness training, interviews, communications, onboarding records	■ C ■ PC ■ NC ■ NA	
7. Support	Is documented information created, updated, controlled and retained appropriately?	Document master list, revision history, approval workflow, record retention controls	■ C ■ PC ■ NC ■ NA	
8. Operation	Are operational processes planned and controlled to meet product/service requirements?	Operational plans, work instructions, process criteria, production/service records	■ C ■ PC ■ NC ■ NA	
8. Operation	Are customer requirements reviewed before commitment and are changes controlled?	Contract/order review, customer communications, change records	■ C ■ PC ■ NC ■ NA	
8. Operation	Where design and development applies, are inputs, controls, outputs and changes managed?	Design plans, review/verification/validation records, design change approvals	■ C ■ PC ■ NC ■ NA	
8. Operation	Are externally provided processes, products and services controlled based on risk and performance?	Supplier evaluation, purchase specifications, incoming checks, supplier scorecards	■ C ■ PC ■ NC ■ NA	
8. Operation	Are production/service provision, identification, traceability, preservation and release controls effective?	Job records, traceability logs, inspection results, release authorization	■ C ■ PC ■ NC ■ NA	
8. Operation	Are nonconforming outputs identified, controlled, corrected and reviewed?	Nonconformity reports, segregation records, concessions, rework/release evidence	■ C ■ PC ■ NC ■ NA	
9. Performance	Are monitoring and measurement methods suitable and linked to QMS performance?	KPI plans, dashboards, process performance data, analysis records	■ C ■ PC ■ NC ■ NA	
9. Performance	Is customer satisfaction monitored and used to drive improvement?	Surveys, complaints, feedback logs, trend analysis, action records	■ C ■ PC ■ NC ■ NA	
9. Performance	Is an internal review program planned and implemented based on importance and past performance?	Program, schedules, reports, findings, follow-up records	■ C ■ PC ■ NC ■ NA	
9. Performance	Does management review cover QMS performance, changes, risks, opportunities and improvement needs?	Management review agenda, inputs, outputs, decisions, action tracker	■ C ■ PC ■ NC ■ NA	
10. Improvement	Are nonconformities addressed with correction, root cause review and corrective action where required?	Corrective action reports, root cause methods, action closure evidence	■ C ■ PC ■ NC ■ NA	
10. Improvement	Is continual improvement demonstrated through performance trends and process enhancements?	Improvement log, projects, KPI gains, lessons learned, management decisions	■ C ■ PC ■ NC ■ NA	
Transition	Has the organization identified ISO 9001:2026 transition gaps and planned updates?	Transition gap analysis, project plan, responsibilities, target dates	■ C ■ PC ■ NC ■ NA	

Findings Summary

Finding / Opportunity	Clause / Process	Risk Level	Responsible Person	Target Date

Prepared as a downloadable website resource by Pacific Certifications. For certification support, contact support@pacificcert.com.