Pacific Certifications
INSPECTION & CERTIFICATION

ISO 9001:2015 Audit Checklist

Quality Management Systems

Downloadable Website Resource for Internal Review and Certification Readiness

Pacific Certifications

For ISO 9001 certification assessment, application review and certificate issuance, contact support@pacificcert.com

Suggested downloads: ISO 9001 Application Form | ISO 9001 Gap Analysis Template | ISO 9001 Implementation Guide | Certification Cost Calculator

Purpose of This Checklist

This checklist is designed to support organizations preparing for ISO 9001:2015 quality management system certification. It can be used for internal review, gap analysis, supplier assessment, pre-certification readiness checks and management system improvement planning. The checklist follows the clause structure of ISO 9001:2015 without replacing the official standard.

Important note: This document is a general reference tool. Organizations should use it with their own process documentation, statutory and regulatory requirements, customer requirements and the official ISO 9001:2015 standard.

How to Use This Checklist

- Review each checkpoint against your actual process evidence, not only against written procedures.
- Use the status column to mark C for conforming, NC for nonconforming, OFI for opportunity for improvement and NA for not applicable.
- Record objective evidence such as procedure numbers, records, interviews, sample references, observations and performance data.
- Assign actions with responsibility and target dates where gaps are identified.
- Review results during management review and before proceeding with certification assessment.

Audit Details

Organization:		**Site / Location:**	
Scope reviewed:		**Audit date:**	
Audit type:	Internal / Supplier / Readiness	**Auditor:**	
Departments covered:		**Standard:**	ISO 9001:2015
Status key:	C / NC / OFI / NA	**Report reference:**	
Prepared by:		**Reviewed by:**	

ISO 9001:2015 Clause-Wise Audit Checklist

Use the following clause-wise checklist to evaluate whether the quality management system is implemented, maintained and effective. The examples of evidence are indicative and should be adapted to the organization's scope, products, services and operational controls.

Context of the Organization

Ref.	Audit checkpoint	Objective evidence to review	Status	Finding / notes	Action required
4.1	Has the organization determined internal and external issues relevant to its purpose, strategic direction and quality management system?	Context analysis, SWOT/PESTLE review, business plan, risk register, management review inputs.	C / NC / OFI / NA		
4.2	Has the organization identified interested parties and their relevant requirements?	Interested party register, customer requirements, statutory and regulatory requirements, supplier or contract requirements.	C / NC / OFI / NA		
4.3	Is the scope of the QMS defined, documented and aligned with products, services, sites and exclusions?	QMS scope statement, certificate scope draft, site list, process map, justification for non-applicable requirements.	C / NC / OFI / NA		
4.4	Are QMS processes identified with sequence, interaction, criteria, resources, responsibilities, risks and performance indicators?	Process interaction map, SOPs, process KPIs, responsibility matrix, process monitoring records.	C / NC / OFI / NA		

Leadership

Ref.	Audit checkpoint	Objective evidence to review	Status	Finding / notes	Action required
5.1	Does top management demonstrate leadership and accountability for the effectiveness of the QMS?	Management review records, quality objectives, communication records, resource allocation evidence.	C / NC / OFI / NA		
5.1.2	Are customer focus requirements addressed, including customer satisfaction and applicable statutory or regulatory requirements?	Customer feedback, complaint records, contract reviews, compliance obligations, delivery performance data.	C / NC / OFI / NA		
5.2	Is the quality policy established, communicated, understood and appropriate to the organization?	Approved quality policy, display/communication evidence, induction material, employee awareness records.	C / NC / OFI / NA		
5.3	Are roles, responsibilities and authorities assigned, communicated and understood?	Organization chart, job descriptions, responsibility matrix, appointment letters, interview evidence.	C / NC / OFI / NA		

Planning

Ref.	Audit checkpoint	Objective evidence to review	Status	Finding / notes	Action required
6.1	Are risks and opportunities determined and actions planned to address them?	Risk and opportunity register, mitigation plans, process risk review, monitoring records.	C / NC / OFI / NA		
6.2	Are measurable quality objectives established at relevant functions and levels?	Quality objectives, KPI dashboard, target review records, action plans, trend analysis.	C / NC / OFI / NA		
6.3	Are changes to the QMS planned and controlled?	Change request records, impact assessments, approval records, communication and implementation evidence.	C / NC / OFI / NA		

Support

Ref.	Audit checkpoint	Objective evidence to review	Status	Finding / notes	Action required
7.1.1	Are resources determined and provided for QMS implementation and improvement?	Resource plans, budget approvals, manpower plans, infrastructure plans.	C / NC / OFI / NA		
7.1.2	Are competent personnel available for QMS processes?	Competency matrix, qualification records, training records, evaluation records.	C / NC / OFI / NA		
7.1.3	Is infrastructure provided and maintained for conformity of products and services?	Maintenance plans, equipment list, breakdown logs, facility records.	C / NC / OFI / NA		
7.1.4	Is the work environment suitable for achieving conformity?	Workplace inspection records, environmental controls, safety/housekeeping records, production area controls.	C / NC / OFI / NA		
7.1.5	Are monitoring and measuring resources suitable, calibrated or verified where required?	Calibration certificates, equipment master list, verification records, traceability records.	C / NC / OFI / NA		
7.1.6	Is organizational knowledge determined, maintained and made available?	Knowledge base, lessons learned, process notes, technical references, succession or cross-training plans.	C / NC / OFI / NA		
7.2	Is competence determined, achieved and evaluated for people performing work affecting quality?	Competency criteria, training plan, evaluation records, authorization records.	C / NC / OFI / NA		
7.3	Are personnel aware of the quality policy, objectives, contribution and implications of nonconformity?	Awareness records, interview evidence, induction material, toolbox talks.	C / NC / OFI / NA		
7.4	Are internal and external communications relevant to QMS planned and implemented?	Communication matrix, meeting minutes, customer communication records, supplier correspondence.	C / NC / OFI / NA		
7.5	Is documented information controlled for creation, update, availability, protection, retention and disposition?	Document control procedure, master list, revision history, record retention list, access controls.	C / NC / OFI / NA		

Operation

Ref.	Audit checkpoint	Objective evidence to review	Status	Finding / notes	Action required
8.1	Are operational processes planned, controlled and documented as required?	Operational plans, SOPs, work instructions, process controls, acceptance criteria.	C / NC / OFI / NA		
8.2.1	Are customer communications controlled for product/service information, enquiries, contracts, feedback and complaints?	Customer communication records, enquiry logs, complaint records, contract correspondence.	C / NC / OFI / NA		
8.2.2	Are product and service requirements determined, including legal and regulatory obligations?	Contract review, customer specifications, statutory requirements, tender documents.	C / NC / OFI / NA		
8.2.3	Are requirements reviewed before commitment to supply products or services?	Approved quotations, contract review forms, order acceptance records, amendment records.	C / NC / OFI / NA		
8.3	Where design and development is applicable, are design inputs, controls, outputs and changes managed?	Design plan, design inputs, verification/validation records, design outputs, change records.	C / NC / OFI / NA		
8.4	Are externally provided processes, products and services controlled?	Approved supplier list, supplier evaluation, purchase orders, incoming inspection, outsourced process controls.	C / NC / OFI / NA		
8.5.1	Are production and service provision controlled under defined conditions?	Work instructions, process parameters, inspection records, service delivery records, release criteria.	C / NC / OFI / NA		
8.5.2	Is identification and traceability maintained where required?	Batch/serial records, job cards, labels, traceability matrix, service records.	C / NC / OFI / NA		
8.5.3	Is property belonging to customers or external providers identified, verified and protected?	Customer property register, custody records, damage/loss communication records.	C / NC / OFI / NA		
8.5.4	Is preservation controlled during production and service provision?	Storage records, packaging controls, handling procedures, inventory controls.	C / NC / OFI / NA		
8.5.5	Are post-delivery activities determined and controlled where applicable?	Warranty records, service support records, maintenance obligations, customer feedback.	C / NC / OFI / NA		
8.5.6	Are operational changes reviewed and controlled?	Change records, approvals, revised procedures, impact assessment records.	C / NC / OFI / NA		
8.6	Are products and services released only after planned arrangements are completed?	Final inspection records, release approvals, certificates of conformity, delivery authorization.	C / NC / OFI / NA		
8.7	Are nonconforming outputs identified, controlled and corrected?	Nonconformity reports, segregation records, concession approvals, rework/reinspection records.	C / NC / OFI / NA		

Performance Evaluation

Ref.	Audit checkpoint	Objective evidence to review	Status	Finding / notes	Action required
9.1.1	Does the organization monitor, measure, analyze and evaluate QMS performance?	KPI reports, process monitoring records, analysis reports, trend charts.	C / NC / OFI / NA		
9.1.2	Is customer satisfaction monitored and analyzed?	Customer surveys, complaints analysis, repeat business data, feedback records.	C / NC / OFI / NA		
9.1.3	Are data and analysis used to evaluate conformity, performance, supplier performance and improvement needs?	Data analysis reports, supplier scorecards, management review inputs, KPI dashboards.	C / NC / OFI / NA		
9.2	Are internal audits planned and conducted at defined intervals?	Internal audit program, audit plan, checklists, findings, corrective actions, auditor competence records.	C / NC / OFI / NA		
9.3	Does management review the QMS for suitability, adequacy, effectiveness and alignment with strategic direction?	Management review agenda, minutes, inputs, outputs, decisions and action tracking.	C / NC / OFI / NA		

Improvement

Ref.	Audit checkpoint	Objective evidence to review	Status	Finding / notes	Action required
10.1	Are opportunities for improvement determined and implemented?	Improvement register, project records, process improvement actions, performance trends.	C / NC / OFI / NA		
10.2	Are nonconformities and corrective actions managed effectively, including root cause and effectiveness review?	Corrective action reports, root cause analysis, action plans, effectiveness verification.	C / NC / OFI / NA		
10.3	Is continual improvement demonstrated through QMS performance and management decisions?	Improvement plans, KPI improvement trends, management review actions, lessons learned.	C / NC / OFI / NA		

Summary of Audit Results

Area	Total checked	NC / OFI identified	Remarks
Context of the Organization			
Leadership			
Planning			
Support			
Operation			
Performance Evaluation and Improvement			

Recommended Next Steps

- Close identified nonconformities with documented root cause analysis and corrective action evidence.
- Update quality objectives, risk actions, process controls and documented information where gaps are found.
- Ensure management review records include audit results, customer feedback, process performance and improvement actions.
- Confirm that the certification scope, sites, activities and exclusions are accurate before submitting the application form.
- Contact Pacific Certifications at support@pacificcert.com for ISO 9001 certification application review and quotation.

Ready to Apply for ISO 9001 Certification?

Email support@pacificcert.com to request the application form, scope review and certification quotation.

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