



Wilkshire Consulting
Management System Experts

ISO 9001:2015 CERTIFICATION READINESS CHECKLIST

Know where you stand before
your certification audit.



**45-POINT
SELF-ASSESSMENT**



**7 COMMON
AUDIT FINDING AREAS**



**FILLABLE
SCORECARD**



CONSULTING

Strategy &
Implementation



AUDITING

Internal & Supplier
Audits



TRAINING

Build Capability &
Confidence



DOCUMENTATION

Systems, Procedures &
Templates

**START WITH A FREE
ISO 9001 READINESS CALL**



**REQUEST A FIXED-FEE
IMPLEMENTATION QUOTE**



Trusted guidance. Practical solutions. Certification success.

01 Your ISO 9001 Readiness Score

Score the 45-item checklist, identify your readiness level, and choose the right next step.

How to score each item

☐ **YES**
2 pts

☐ **UNSURE**
1 pt

☐ **NO**
0 pts

Use Unsure when evidence has not been confirmed.

Score summary

TOTAL SCORE _____ / 90

READINESS PERCENTAGE _____ %

What your score means

90-100%

SCHEDULE AN AUDIT READINESS REVIEW

Certification-track ready: verify evidence and confirm audit readiness.

60-89%

BOOK AN ISO 9001 GAP ANALYSIS

Partially ready: close gaps and de-risk your certification audit.

30-59%

REQUEST A FIXED-FEE IMPLEMENTATION ROADMAP

Implementation support likely needed: prioritize the work and build a plan.

0-29%

START A FULL ISO 9001 CERTIFICATION PROJECT

Early-stage QMS: build the system correctly from the beginning.

Recommended next step _____

Manual scoring note

This version is intentionally manual-fill to work reliably across common PDF viewers. Enter your total score, readiness percentage, and recommended next step after completing the checklist. The printed version can also be scored manually.

02 The Road to Certification

A simple path from self-assessment to audit readiness.

Certification readiness roadmap

Use this sequence to move from checklist results to an evidence-backed certification plan.



Audit readiness pyramid

A practical way to explain what auditors often verify: defined process, evidence, effectiveness, then readiness.



What auditors may look for

- ✓ Process control and consistency
- ✓ Evidence of implementation
- ✓ Monitoring, measurement and results
- ✓ Management review and improvement
- ✓ Risk-based thinking in action

COMMON CERTIFICATION DELAY

Weak evidence and inconsistent records are often what delays certification. A strong QMS must show that planned processes are actually being performed.

Organization

Completed by

Date

Target audit date

03 Wilkshire Audit Insight

Common ISO 9001 NCRs / Findings

Based on reviewed ISO 9001 audit NCRs and findings from client audit reports, the most common findings are usually not technical product failures. They are management system maintenance failures: missing records, incomplete follow-up, outdated documents, ineffective internal audits, weak management review, poor supplier re-evaluation, and lack of objective evidence that planned processes are actually being performed.

01

Internal audit process issues

Clause 9.2

Internal audit records are missing, incomplete, not retained, or auditor objectivity is not maintained.

Before certification, check:

Audit schedule, reports, evidence reviewed, findings, corrective actions, auditor independence.

02

Management review not effective

Clause 9.3

Management review is late, reused from a prior year, or missing required inputs and outputs.

Before certification, check:

Current review minutes, KPI data, audit results, customer feedback, supplier performance, actions.

03

Risk and opportunity actions not tracked

Clause 6.1

Risks are identified, but actions are not assigned, tracked, or reviewed for effectiveness.

Before certification, check:

Risk register, action owners, due dates, status, effectiveness review.

04

Documented information gaps

Clause 7.5

Master document list is outdated, forms are uncontrolled, or records cannot be located during the audit.

Before certification, check:

Current document list, approvals, revisions, retention controls, completed records.

Pattern to watch

If these areas show No or Unsure answers later in the checklist, a focused gap analysis or internal audit can reduce certification risk before Stage 2, surveillance, or recertification.

04 Common NCRs / Findings Continued

Use these areas as a pre-audit risk screen before Stage 2, surveillance, or recertification.

05

Supplier / external provider control issues

Clause 8.4

Supplier evaluations or re-evaluations are not current, or criteria for approval, monitoring, and re-evaluation are not defined.

Before certification, check:

Approved supplier list, evaluation criteria, scorecards, quality and delivery performance, critical supplier status.

06

Contract / customer requirement review records missing

Clause 8.2.3

Customer requirements are reviewed informally, but evidence is not retained or used consistently.

Before certification, check:

Order review records, quotes, purchase orders, contract review checklist, customer changes, internal communication.

07

Quality objectives / KPI monitoring not maintained

Clause 6.2 + 9.1

Objectives exist, but current data, review, trend analysis, and follow-up evidence are incomplete.

Before certification, check:

Objectives, KPI dashboard, trend data, management review inputs, action items, and evidence of follow-up.

Practical ISO 9001 audit prep focus

Before Stage 2, surveillance, or recertification audits, confirm these seven high-risk areas:

- | | |
|--|--|
| ☐ Internal audit package complete, objective, and retained. | ☐ Supplier evaluations and re-evaluations current. |
| ☐ Management review completed for the current cycle with required inputs and outputs. | ☐ Contract/customer requirement review evidence retained. |
| ☐ Risk and opportunity actions assigned, tracked, and reviewed. | ☐ Objectives and KPIs updated with supporting data. |
| ☐ Master document list and required records current. | |

1. Context, Scope, and Process Structure

SECTION SCORE

/10

Clause 4 | Confirm the QMS matches the organization, interested parties, and actual operations.

#	CLAUSE	READINESS ITEM	YES	NO	UNSURE	EVIDENCE / NOTES
01	4.1	Have you identified internal and external issues that may affect the QMS? Evidence: Context analysis, business conditions, customer expectations, technology, staffing, supply chain, regulatory factors.	☐ Y	☐ N	☐ U	
02	4.2	Have you identified interested parties relevant to the QMS? Evidence: Customers, employees, suppliers, regulators, owners, certification bodies, and other relevant parties.	☐ Y	☐ N	☐ U	
03	4.2	Have you determined which interested-party requirements are relevant to the QMS? Evidence: Interested party matrix or list showing relevant requirements and how they are monitored.	☐ Y	☐ N	☐ U	
04	4.3	Have you defined the QMS scope, including products, services, locations, and boundaries? Evidence: Scope statement, included/excluded activities, sites, products, services, and justified exclusions.	☐ Y	☐ N	☐ U	
05	4.4	Have you identified key QMS processes and how they interact? Evidence: Process map, process owners, inputs, outputs, criteria, resources, and process interactions.	☐ Y	☐ N	☐ U	

WILKSHIRE AUDIT INSIGHT

Auditors may compare your stated QMS scope, process map, customer-facing activities, and actual operations to confirm the system matches what the organization really does.

EVIDENCE PROMPT

What evidence shows these requirements are implemented? List document names, record locations, owners, dates, metrics, meeting minutes, or follow-up actions.

2. Leadership, Policy, and Responsibilities

SECTION SCORE

_____/10

Clause 5 | Confirm leadership, policy, responsibility, and customer focus evidence.

#	CLAUSE	READINESS ITEM	YES	NO	UNSURE	EVIDENCE / NOTES
06	5.1	Has top management demonstrated accountability for QMS effectiveness? Evidence: Leadership involvement, resource decisions, management review, objectives, and improvement actions.	☐ Y	☐ N	☐ U	
07	5.2	Is the quality policy appropriate to the organization and its strategic direction? Evidence: Quality policy, purpose/context alignment, commitment to requirements and continual improvement.	☐ Y	☐ N	☐ U	
08	5.2	Is the quality policy communicated, understood, and available where needed? Evidence: Employee awareness, posting, onboarding, training records, and availability to interested parties as appropriate.	☐ Y	☐ N	☐ U	
09	5.3	Are QMS roles, responsibilities, and authorities clearly assigned? Evidence: Organization chart, job descriptions, responsibility matrix, process owner assignments.	☐ Y	☐ N	☐ U	
10	5.1.2	Can employees explain how their work affects quality and customer satisfaction? Evidence: Interviews, awareness materials, training, customer focus messages, and process-level expectations.	☐ Y	☐ N	☐ U	

WILKSHIRE AUDIT INSIGHT

Leadership requirements are often underestimated. A policy statement alone is not enough. Auditors may look for evidence that leadership reviews the system, provides resources, and follows up on QMS performance.

EVIDENCE PROMPT

What evidence shows these requirements are implemented?
List document names, record locations, owners, dates, metrics, meeting minutes, or follow-up actions.

3. Planning, Risk, Opportunities, and Objectives

Clause 6 | Confirm risk actions, objectives, and planned QMS changes are tracked.

SECTION SCORE

_____/10

#	CLAUSE	READINESS ITEM	YES	NO	UNSURE	EVIDENCE / NOTES
11	6.1	Have risks and opportunities affecting the QMS been identified? Evidence: Risk register, opportunity log, SWOT, process risks, customer risks, supplier risks, operational risks.	☐ Y	☐ N	☐ U	
12	6.1	Have actions been assigned to address relevant risks and opportunities? Evidence: Owners, due dates, action plans, status tracking, and follow-up records.	☐ Y	☐ N	☐ U	
13	6.1	Are risk and opportunity actions reviewed for effectiveness? Evidence: Updated risk log, management review input, completed action reviews, objective and KPI links.	☐ Y	☐ N	☐ U	
14	6.2	Have measurable quality objectives been established at relevant functions or levels? Evidence: Objectives, targets, metrics, owners, timelines, and supporting data.	☐ Y	☐ N	☐ U	
15	6.2/6.3	Are objectives and QMS changes monitored, updated, and reviewed for progress? Evidence: KPI records, change planning records, management review minutes, and action items.	☐ Y	☐ N	☐ U	

WILKSHIRE AUDIT INSIGHT

Risks, opportunities, and objectives often exist on paper but are not actively tracked. Certification auditors may expect evidence that actions were assigned, followed up, and reviewed.

EVIDENCE PROMPT

What evidence shows these requirements are implemented?
List document names, record locations, owners, dates, metrics, meeting minutes, or follow-up actions.



4. Resources, Competence, Awareness, and Communication

Clauses 7.1-7.4 | Confirm people, infrastructure, competence, awareness, and communication

SECTION SCORE

_____/10

#	CLAUSE	READINESS ITEM	YES	NO	UNSURE	EVIDENCE / NOTES
16	7.1	Have you determined the resources needed to operate and maintain the QMS? Evidence: Staffing, equipment, software, infrastructure, inspection tools, workspace needs.	☐ Y	☐ N	☐ U	
17	7.1	Is infrastructure and work environment controlled where it affects conformity? Evidence: Facilities, equipment, maintenance, environment, IT systems, and process support resources.	☐ Y	☐ N	☐ U	
18	7.2	Have competence requirements been defined for roles affecting quality? Evidence: Job descriptions, training matrix, competency requirements, qualification records.	☐ Y	☐ N	☐ U	
19	7.2	Are employees trained or otherwise qualified for the work they perform? Evidence: Training records, certificates, skills assessments, onboarding records, supervisor sign-offs.	☐ Y	☐ N	☐ U	
20	7.3/7.4	Are employees aware of QMS requirements and communication expectations? Evidence: Awareness training, communication matrix, escalation paths, meeting records, interviews.	☐ Y	☐ N	☐ U	

WILKSHIRE AUDIT INSIGHT

Auditors may interview employees to confirm whether training and awareness are effective, not just whether a training record exists.

EVIDENCE PROMPT

What evidence shows these requirements are implemented?
List document names, record locations, owners, dates, metrics, meeting minutes, or follow-up actions.

5. Documented Information and Records

Clause 7.5 | Verify documents and records are controlled, available, retained, and retrievable.

SECTION SCORE

/10

#	CLAUSE	READINESS ITEM	YES	NO	UNSURE	EVIDENCE / NOTES
21	7.5	Do you have a method for controlling QMS documents and records? Evidence: Document control procedure, approval process, revision control, retention rules.	☐ Y	☐ N	☐ U	
22	7.5	Is the master document list current and complete? Evidence: Procedures, forms, work instructions, external documents, and required records.	☐ Y	☐ N	☐ U	
23	7.5	Are current versions of documents available where needed? Evidence: Controlled access, shared folders, shop-floor copies, intranet, document owners.	☐ Y	☐ N	☐ U	
24	7.5	Are required QMS records retained and retrievable? Evidence: Internal audits, management reviews, training, inspection, supplier, contract review, corrective actions.	☐ Y	☐ N	☐ U	
25	7.5	Are obsolete and external documents controlled to prevent unintended use? Evidence: Obsolete archive, document status, external standards/specifications, access control.	☐ Y	☐ N	☐ U	

WILKSHIRE AUDIT INSIGHT

Document control findings often come from small details: wrong revision levels, uncontrolled forms, missing approval status, outdated master lists, or records that cannot be located during the audit.

EVIDENCE PROMPT

What evidence shows these requirements are implemented?
List document names, record locations, owners, dates, metrics, meeting minutes, or follow-up actions.

6. Operational Planning and Customer Requirements

SECTION SCORE

_____/10

Clause 8.1-8.7 | Verify customer review, process control, release, and nonconforming outputs.

#	CLAUSE	READINESS ITEM	YES	NO	UNSURE	EVIDENCE / NOTES
26	8.1	Are operational processes planned and controlled to meet requirements? Evidence: Work instructions, process controls, production/service records, acceptance criteria.	☐ Y	☐ N	☐ U	
27	8.2.3	Are customer requirements reviewed before accepting orders, contracts, or projects? Evidence: Contract review records, order review checklists, quote reviews, purchase order reviews.	☐ Y	☐ N	☐ U	
28	8.2.4	Are changes to customer requirements reviewed and communicated? Evidence: Change orders, revised quotes, updated specifications, customer approvals, internal communication.	☐ Y	☐ N	☐ U	
29	8.5/8.6	Are work instructions and acceptance criteria communicated to personnel performing the work? Evidence: Work orders, job travelers, project files, service instructions, drawings, specifications, release records.	☐ Y	☐ N	☐ U	
30	8.7	Are nonconforming outputs identified and controlled to prevent unintended use or delivery? Evidence: NCRs, hold tags, segregation, disposition records, rework approvals, customer concessions.	☐ Y	☐ N	☐ U	

WILKSHIRE AUDIT INSIGHT

Many organizations review customer requirements informally. The certification risk is not always the review itself; it is the lack of retained evidence showing the review happened.

EVIDENCE PROMPT

What evidence shows these requirements are implemented? List document names, record locations, owners, dates, metrics, meeting minutes, or follow-up actions.

7. Design, Purchasing, and Supplier Controls

Clause 8.3-8.4 | Confirm design and supplier controls are defined, retained, and effective.

SECTION SCORE

_____/10

#	CLAUSE	READINESS ITEM	YES	NO	UNSURE	EVIDENCE / NOTES
31	8.3	If design and development applies, is the process planned and controlled? Evidence: Design plans, inputs, outputs, reviews, verification, validation, and change records.	☐ Y	☐ N	☐ U	
32	8.4	Have criteria been defined for selecting, approving, monitoring, and re-evaluating suppliers? Evidence: Supplier approval criteria, supplier procedure, supplier risk categories.	☐ Y	☐ N	☐ U	
33	8.4	Is the approved supplier list current and accurate? Evidence: Approved supplier list, critical supplier identification, approval status, supplier scope.	☐ Y	☐ N	☐ U	
34	8.4	Are supplier evaluations and re-evaluations completed and retained? Evidence: Supplier scorecards, quality performance, delivery performance, re-evaluation records.	☐ Y	☐ N	☐ U	
35	8.4	Are purchasing requirements clearly communicated to suppliers? Evidence: Purchase orders, specifications, terms, drawings, quality requirements, flow-down requirements.	☐ Y	☐ N	☐ U	

WILKSHIRE AUDIT INSIGHT

Supplier control issues are common when a company uses approved suppliers but cannot show how suppliers were approved, monitored, or re-evaluated.

EVIDENCE PROMPT

What evidence shows these requirements are implemented? List document names, record locations, owners, dates, metrics, meeting minutes, or follow-up actions.



8. Monitoring, Measurement, Analysis, and Evaluation

Clause 9.1 | Confirm that QMS performance is measured, analyzed, and used for decisions.

SECTION SCORE

/10

#	CLAUSE	READINESS ITEM	YES	NO	UNSURE	EVIDENCE / NOTES
36	9.1	Have you determined what needs to be monitored and measured for the QMS? Evidence: KPIs, process metrics, inspection data, customer satisfaction data, supplier performance.	☐ Y	☐ N	☐ U	
37	9.1	Is customer satisfaction monitored and reviewed? Evidence: Surveys, complaints, scorecards, reviews, repeat business, customer feedback records.	☐ Y	☐ N	☐ U	
38	7.1.5/9.1	Are measuring devices or inspection tools controlled where required? Evidence: Calibration records, equipment list, verification records, out-of-tolerance actions.	☐ Y	☐ N	☐ U	
39	9.1	Are monitoring and measurement results reviewed and analyzed? Evidence: Dashboards, trend data, performance reports, management review inputs.	☐ Y	☐ N	☐ U	
40	9.1/10	Are results used to identify improvement opportunities? Evidence: Improvement logs, corrective actions, management review actions, project plans.	☐ Y	☐ N	☐ U	

WILKSHIRE AUDIT INSIGHT

Auditors may ask how the organization knows whether the QMS is effective. Current data, trend review, and action taken from results are stronger than static objectives.

EVIDENCE PROMPT

What evidence shows these requirements are implemented? List document names, record locations, owners, dates, metrics, meeting minutes, or follow-up actions.

9. Internal Audit, Management Review, and Improvement

Clauses 9.2, 9.3, 10 | Confirm the system is audited, reviewed, and improved.

SECTION SCORE

/10

#	CLAUSE	READINESS ITEM	YES	NO	UNSURE	EVIDENCE / NOTES
41	9.2	Has a full internal audit been completed before the certification audit? Evidence: Audit schedule, audit plan, completed reports, evidence reviewed, findings.	☐ Y	☐ N	☐ U	
42	9.2	Does the internal audit cover ISO 9001 requirements and your own QMS processes? Evidence: Clause coverage, process coverage, prior findings, scope coverage.	☐ Y	☐ N	☐ U	
43	9.2	Is auditor objectivity or impartiality maintained? Evidence: Auditor assignment records, independence review, outsourced auditor records if applicable.	☐ Y	☐ N	☐ U	
44	9.3	Has management review been completed for the current cycle with required inputs and outputs? Evidence: Current minutes, agenda, KPIs, audit results, customer feedback, supplier performance, actions.	☐ Y	☐ N	☐ U	
45	10.2/10.3	Are nonconformities, corrective actions, and improvement actions assigned, tracked, and reviewed? Evidence: CAR log, root cause, action plans, owners, due dates, completion evidence, effectiveness review.	☐ Y	☐ N	☐ U	

WILKSHIRE AUDIT INSIGHT

Internal audit and management review are certification-readiness critical. If either is missing, incomplete, outdated, or unsupported by records, the organization may not be ready for Stage 2, surveillance, or recertification.

EVIDENCE PROMPT

What evidence shows these requirements are implemented? List document names, record locations, owners, dates, metrics, meeting minutes, or follow-up actions.

05 Final Readiness Summary

Use your completed checklist score to choose the right next step before certification.

TOTAL SCORE	READINESS PERCENTAGE	RECOMMENDED NEXT STEP
____ / 90	____ %	_____

What your results may mean

90-100%

Audit Readiness Review

You appear certification-track ready. Verify evidence before the certification audit.

60-89%

ISO 9001 Gap Analysis

You are close. Identify and close gaps before certification.

30-59%

Fixed-Fee Implementation Roadmap

Foundational work remains. Get a prioritized implementation plan.

0-29%

Full Certification Project

Build the QMS correctly with end-to-end consulting support.

How Wilkshire Consulting can help

Match your results to the support option that reduces certification risk fastest.

Many Unsure answers

ISO 9001 gap analysis

Internal audit not complete

Internal audit service

Weak records / document control

Documentation + implementation

Major gaps or no system

Full certification project

Training or awareness gaps

Internal auditor / awareness training

Need a fixed scope

Fixed-fee implementation quote

Action plan notes

Ready to review your results?

Close gaps. Prepare evidence. Move toward certification.

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