Precision ISO
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IMPLEMENTATION GUIDE | ISO 9001:2015

The ISO 9001 Implementation Roadmap

Seven phases that take an organization from first read of the standard to a certifiable quality management system.

A PRACTICAL GUIDE FOR OWNERS, GENERAL MANAGERS, AND QUALITY LEADS

Most organizations do not fail at ISO 9001 because their people cannot do the work. They fail because they treat implementation as a documentation project and start writing procedures before they understand what the standard asks of them.

This guide sequences the work into seven phases, names the evidence an auditor expects at each one, and converts the whole project into a checklist you can assign and track.

STANDARD	APPLIES TO	OUTCOME
ISO 9001:2015	**Any size, any sector**	**Certification readiness**

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FRONT MATTER

About This Guide

What this guide covers, how to use it, and what it does not do.

This guide turns ISO 9001:2015 into a sequenced project. Each phase groups the tasks that belong together, so you can work them in order instead of chasing thirty unrelated items at once. Clause references appear throughout, so you can check every statement against your own controlled copy of the standard.

One point of vocabulary before you start, because it costs companies credibility with customers. ISO 9001 leads to **certification**, issued by a certification body. ISO/IEC 17025 leads to **accreditation**, granted by an accreditation body. The two words are not interchangeable. Certification bodies themselves hold accreditation, usually from a body such as the ANSI National Accreditation Board in the United States, and that accreditation gives your certificate its weight.

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Applies to	Organizations of any size or sector pursuing or maintaining ISO 9001 certification

How to Use This Guide

- Read Section 1 and Section 2 first to confirm the guide matches your situation.
- Work Sections 4 and 5 in phase order. Later phases depend on evidence produced by earlier ones.
- Use Section 7 as a live checklist. Assign an owner and a due date to every line.
- Verify every clause number against your organization's controlled copy of the standard before you rely on it.
- Confirm audit and certification requirements directly with your chosen certification body. Their rules sit on top of the standard.

NAVIGATION

Contents

Eight sections, seven implementation phases, and one working checklist.

FOX TIP

Do not read this guide once and file it. Print Section 7, put an owner beside every line, and review it at your weekly management meeting. The organizations that finish fastest are the ones that treat implementation as a tracked project rather than background work.

SECTION 1

Executive Summary

Give decision makers the essential message before the technical detail.

ISO 9001:2015 sets the requirements for a quality management system that consistently delivers products and services meeting customer and applicable regulatory requirements. Meeting those requirements takes a real project plan, a budget, named owners, and enough operating time to generate evidence before an auditor arrives. Organizations that underestimate any of those four run twice as long as they planned.

The common failure pattern is predictable. A company buys a generic quality manual, swaps in its name, and books a certification audit. The auditor then finds a system that exists on paper but has never operated. Findings pile up around competence records, supplier control, internal audit, and corrective action, because those areas demand evidence that only accumulates over time.

This guide replaces that pattern with a sequence. Phase 1 establishes an honest baseline through a clause-by-clause gap analysis. Phase 2 converts that baseline into a funded project with named owners. Phase 3 maps your processes and builds the management system, with document control from day one. Phase 4 brings Clause 8 operations under real control, which is where your product either conforms or does not. Phase 5 verifies the system through monitoring, internal audit, management review, and corrective action. Phase 6 engages the certification body through the Stage 1 and Stage 2 audits. Phase 7 keeps the system running afterward.

> **KEY TAKEAWAY**
>
> Sequence the work, run the system live for several months before you invite an auditor, and build your evidence as you go. A management system that has operated is the only kind an auditor can evaluate.

At a Glance

Evidence beats paperwork

Auditors evaluate records, interviews, and observed work. A binder that has never been used produces findings, not confidence.

Sequence protects you

Writing procedures before you map processes means documenting work you will restructure. Assess first, then build.

Leadership is in the standard

Clause 5 removed the management representative role on purpose. Auditors interview your general manager, not just your quality lead.

SECTION 2

Purpose and Scope

What this guide covers, who should use it, and where its recommendations apply.

Purpose

This guide gives leadership a defensible sequence for implementing ISO 9001:2015. It explains what each phase produces, which clauses drive the work, and what evidence to retain. After working through it, a reader can build a project plan, assign owners, and judge readiness before contacting a certification body.

Intended Audience

- **Owners and general managers** at small and mid-size businesses pursuing certification for the first time. No prior ISO experience is assumed.
- **Quality managers and ISO professionals** building, rebuilding, or expanding a quality management system. Clause references support your own verification.
- **Process owners** responsible for operations, purchasing, production, service delivery, and customer-facing processes under Clause 8.

Scope

Included	Project sequencing, gap analysis, resourcing, process mapping, management system build, operational control under Clause 8, monitoring and internal audit, management review, certification body engagement, and post-certification maintenance.
Excluded	Sector-specific schemes such as IATF 16949, AS9100, or ISO 13485; industry-specific regulatory frameworks; certification body fee schedules; and detailed statistical process control methods.
Dependencies	A controlled copy of ISO 9001:2015, ISO 9000:2015 for vocabulary, and your certification body's current published program requirements and mark usage rules.

USE WITH CARE

Clause numbers in this guide reference ISO 9001:2015. A revised edition of ISO 9001 is expected, and certification bodies have signaled a transition period following its publication. Confirm the current edition, its clause numbering, and the transition deadline with ISO and your certification body before relying on any reference here. Certification body policies change independently of the standard, so verify them directly rather than from any third-party summary, including this one.

SECTION 3

Key Concepts and Definitions

Build a common vocabulary before introducing requirements or methods.

TERMINOLOGY NOTE

Use **nonconformity**, not "non-conformance," unless you are quoting a source that uses the other form. Use **certification** for ISO 9001 and **accreditation** for ISO/IEC 17025. Auditors read terminology as a proxy for how well an organization understands the standard, and mixed usage invites closer scrutiny.

TERM	WORKING DEFINITION	REFERENCE
Certification	Third-party attestation that a management system conforms to a standard such as ISO 9001, issued by a certification body after a successful audit.	ISO 9001:2015
Accreditation	Attestation of competence granted by an accreditation body. Your certification body holds accreditation; your company holds certification. The words are not interchangeable.	ISO/IEC 17021-1
Scope of the QMS	The documented boundaries of your system, naming the products, services, and sites covered, plus any requirement determined not applicable with a justification.	Clause 4.3
Interested party	Anyone who can affect, be affected by, or perceive itself affected by your decisions. Customers, regulators, owners, employees, and suppliers are typical.	Clause 4.2
Process approach	Managing activities as interrelated processes with defined inputs, outputs, criteria, owners, and measures, rather than as isolated departments.	Clause 4.4
Risk based thinking	Deliberately determining and acting on risks and opportunities that could affect conformity or customer satisfaction. Replaces preventive action.	Clause 6.1
Documented information	The single term covering documents and records. You *maintain* a current document, such as a procedure. You *retain* a record proving something happened, such as an inspection result.	Clause 7.5
External provider	Any supplier of processes, products, or services from outside your organization, including outsourced processes. Requires documented selection and monitoring criteria.	Clause 8.4
Nonconforming output	A product, service, or process output that does not meet requirements. Must be identified and controlled to prevent unintended use or delivery.	Clause 8.7
Corrective action	Action taken to eliminate the cause of a nonconformity so it does not recur. Requires root cause analysis and an effectiveness review.	Clause 10.2
Stage 1 and Stage 2 audits	Stage 1 reviews readiness: your documented information, scope, process map, internal audits, and management review. Stage 2 audits implementation and effectiveness in full, through interviews, observation, and record sampling.	Body program

SECTION 4

Core Guidance: The Seven Phases

Each phase groups tasks that belong together, names the driving clauses, and ends with the evidence you retain.

4.1 Phase 1: Assess Where Your Organization Stands

Everything later depends on an honest picture of today. Rushing this phase is the most common reason a project runs twice as long as anyone planned.

Learn what the standard actually requires

Buy the standard and read it end to end before you write a single procedure. Reading a blog summary is not the same as reading the standard. Buy ISO 9000:2015 alongside it, because that document defines the vocabulary ISO 9001 uses. Clauses 1 through 3 cover scope, references, and terms, so your work starts at Clause 4.

- **Clause 4, context of the organization.** Internal and external issues, interested parties, your scope, and your processes.
- **Clause 5, leadership.** Top management commitment, customer focus, the quality policy, and assigned roles and authorities.
- **Clause 6, planning.** Risks and opportunities, quality objectives, and planning of changes.
- **Clause 7, support.** Resources, people, infrastructure, work environment, measuring equipment, organizational knowledge, competence, awareness, communication, and documented information.
- **Clause 8, operation.** Operational planning, customer requirements, design, external providers, production and service provision, release, and nonconforming outputs.
- **Clause 9, performance evaluation.** Monitoring, customer satisfaction, analysis, internal audit, and management review.
- **Clause 10, improvement.** Nonconformity, corrective action, and continual improvement.

Notice what the 2015 edition does not demand. It does not require a quality manual. It does not require six documented procedures. It requires you to maintain and retain documented information where the standard says so, and where your processes need it. That freedom helps experienced teams and paralyzes new ones, which is exactly why a structured starting point saves so much time.

Define the scope of your quality management system

Clause 4.3 asks you to determine the boundaries and applicability of the system and keep that scope as documented information. Be precise. A scope of "quality management" tells an auditor nothing. A scope of "design, manufacture, and distribution of precision machined components at our Tulsa facility" tells them exactly what to audit. You may exclude a requirement only when it cannot apply to your operation, and you must justify that call. Clause 8.3 design and development is the usual candidate, and only when you build strictly to customer prints. Your scope also drives your audit days and your certification fee, so write it deliberately.

Run a gap analysis before you write anything

A gap analysis compares what you do today against what each clause requires. Work clause by clause, and record evidence rather than opinions. "We check incoming parts" is an opinion. A signed receiving inspection record tied to a purchase order is evidence.

Build the output as a register with these columns: clause, requirement in plain language, current state, gap, owner, target date, and priority. That register becomes your project plan. It also becomes the first document you show leadership when you ask for budget.

FOX TIP

Most organizations discover the same pattern in their gap analysis. The operational work is stronger than the records that prove it. That is good news. Closing a records gap costs far less than fixing a capability gap, and you still have time to do both.

Set measurable objectives for the project

Name why you are doing this. Common drivers include a customer mandate, a contract requirement, a bid qualification, a regulatory expectation, or genuine internal frustration with rework and scrap. Then set objectives you can measure: the scope you will certify, the month you will book Stage 1, the budget you will spend, and the staff hours you will protect each week. Vague goals such as "get certified this year" collapse under operational pressure.

EVIDENCE TO RETAIN FROM PHASE 1

- Completed gap analysis register, dated and reviewed by leadership
- Documented scope statement, including any justified exclusion
- Context and interested party analysis under Clauses 4.1 and 4.2
- Project objectives and approved timeline

4.2 Phase 2: Resource the Implementation

A gap register with no owner and no budget is a wish list. This phase turns it into a funded project.

Secure genuine leadership commitment

Clause 5.1.1 places accountability for the effectiveness of the quality management system on top management. It expects leaders to integrate the system into business processes, promote the process approach and risk based thinking, provide resources, and support the people doing the work. Clause 5.1.2 adds customer focus as a leadership duty.

The 2015 edition also removed the management representative role that the 2008 edition required. That change was deliberate. Leadership can no longer hand the system to one person and step away. Clause 5.3 still asks top management to assign and communicate responsibilities and authorities, so you name owners. You just cannot park the whole system on a quality manager's desk. Auditors test this in interviews, asking the general manager about quality objectives, customer complaints, and management review outputs.

Allocate people, time, and budget

Plan for the standard itself, certification body application and audit fees, auditor travel, training, document control tooling, calibration of measuring equipment, and in some cases outside consulting support. Audit fees scale with headcount, site count, and scope complexity, so request written quotes from two or three accredited bodies rather than working from a rumor.

Staff time is the cost companies underestimate most. Someone has to map processes, write procedures, train people, run internal audits, and chase corrective actions. Appoint a project lead and give that person real authority to decide. Smaller organizations often split the load: process owners handle the operational clauses in their own areas, while one coordinator owns document control, audits, corrective action, and management review.

Identify interested parties and your external providers

Clause 4.2 asks you to determine the interested parties relevant to your quality management system and their relevant requirements, then keep that determination current. Your suppliers deserve early attention. Clause 8.4 requires you to apply criteria for evaluating, selecting, monitoring, and re-evaluating external providers, then retain records of those activities. If you have never scored a supplier, build that process now rather than three weeks before Stage 2. Clause 7.1.5.2 adds a second supplier question. Where measurement traceability matters to you or your customer, your measuring equipment needs calibration against traceable standards, which usually means an accredited calibration laboratory.

EVIDENCE TO RETAIN FROM PHASE 2

- Approved project budget and resource plan
- Appointment of the project lead and process owners, with defined authority
- Written quotes from candidate certification bodies
- Interested party register with their relevant requirements
- Supplier evaluation criteria and an approved supplier list

4.3 Phase 3: Build the Quality Management System

This is the stage where implementation either produces a system your staff use every day, or a binder that impresses an auditor once and then gathers dust.

Map your processes before you write procedures

Clause 4.4 sits at the center of the standard. It asks you to determine the processes needed for the system, their sequence and interaction, the inputs and outputs, the criteria and methods that keep them under control, the resources they need, the responsibilities, the risks and opportunities, and how you evaluate and improve them.

Start with a one page process map. Show your core value stream from inquiry through delivery, plus the supporting processes that feed it. Then take each process and define its inputs, outputs, owner, measures, and controls. A turtle diagram or a SIPOC chart handles this well. Do this before you write procedures, and your document set almost writes itself.

Write a quality policy and objectives people can use

Clause 5.2 requires a quality policy that fits your purpose and context, provides a framework for quality objectives, and commits you to satisfying applicable requirements and to continual improvement. Clause 6.2 then requires quality objectives at relevant functions, levels, and processes. Those objectives align with the policy, stay measurable, and receive regular monitoring, communication, and updates. You also plan the action, the resources, the owner, the completion date, and the method of evaluating results.

Write objectives that mean something operationally. "Improve quality" fails. "Reduce first pass scrap on line 3 from 4.1 percent to 2.5 percent by the end of Q3, owned by the production supervisor" survives an audit and moves the business.

Address risks and opportunities without overbuilding

Clause 6.1 replaced preventive action with risk based thinking. You determine the risks and opportunities that could affect your ability to deliver conforming products and services or to enhance customer satisfaction, plan actions, integrate them into your processes, and evaluate whether they worked. The standard does not mandate a formal risk management method, a risk register, or documented risk procedures. A simple table listing the process, the risk or opportunity, the potential effect, the action, the owner, and the review date satisfies most auditors and stays usable. Clause 6.3 then covers planning of changes.

Control documented information from day one

Clause 7.5 governs documented information. Clause 7.5.2 covers identification, format, and approval when you create or update it. Clause 7.5.3 covers availability, protection, distribution, access, storage, version control, retention, and disposition, including documents of external origin. Two words in this clause do a lot of work. **Maintain** means keep a current document. **Retain** means keep a record proving something happened. Sort your document list into those two buckets early, and your control scheme gets simple.

Build competence, awareness, and communication

Clause 7.1 covers resources broadly, reaching people (7.1.2), infrastructure (7.1.3), the environment for the operation of processes (7.1.4), monitoring and measuring resources (7.1.5), and organizational knowledge (7.1.6). Clause 7.2 requires you to determine competence for people whose work affects quality performance, act where gaps exist, evaluate the effectiveness of that action, and retain evidence. Clause 7.3 covers awareness and reaches further than most people expect: your staff need to know the quality policy, the relevant objectives, how they contribute to the system, and the implications of not conforming. Auditors test awareness by walking the floor and asking, so train for understanding rather than for signatures.

FOX TIP

Turn on document control before you write procedure number one. Organizations that draft forty documents first and add version control later end up revising all forty. Starting controlled costs one afternoon. Retrofitting costs a month.

EVIDENCE TO RETAIN FROM PHASE 3

- Process map showing sequence and interaction, with named process owners
- Approved quality policy and measurable quality objectives with plans
- Risk and opportunity output with planned actions
- Controlled procedures, work instructions, and forms with revision history
- Master document list showing current revisions and approval dates
- Skills matrix, training records, and competence effectiveness evidence

4.4 Phase 4: Control the Operations Behind Your Product

Clause 8 carries the operational weight of the standard, and it generates the most audit findings. This phase produces the evidence that your daily work runs under control.

Plan and control your operations

Clause 8.1 asks you to plan, implement, and control the processes needed to meet product and service requirements. You determine those requirements, set acceptance criteria, decide what resources you need, control the processes against your criteria, and keep enough documented information to show the processes ran as planned. Practically, that means writing down what "good" looks like before the work starts. Acceptance criteria belong on the traveler, the inspection form, or the service checklist.

Get customer requirements right before you commit

Clause 8.2.1 addresses customer communication, including product information, inquiries, contracts, feedback, complaints, customer property, and contingency actions. Clause 8.2.2 asks you to determine requirements, including statutory and regulatory ones. Clause 8.2.3 requires you to review those requirements before you commit. That contract review step prevents more quality problems than any inspection ever will. Confirm the specification, the quantity, the delivery date, and the special requirements before you accept the order. Where the customer states requirements verbally, confirm them in writing.

Control design, external providers, and production

Clause 8.3 applies when you design products or services, running from planning through inputs, controls, outputs, and design changes, with records at each stage. Clause 8.4 covers externally provided processes, products, and services: you determine the controls, apply selection and monitoring criteria, and communicate your requirements clearly. Clause 8.5 covers production and service provision, including identification and traceability (8.5.2), customer property (8.5.3), preservation (8.5.4), post delivery activities (8.5.5), and control of changes (8.5.6).

Clause 8.6 requires verification against requirements before release, with records showing acceptance criteria and the person who authorized it. Clause 8.7 covers nonconforming outputs: you identify them, control them to prevent unintended use, then correct, segregate, return, or obtain a concession, and record the nonconformity, the action, any concession, and who decided.

EVIDENCE TO RETAIN FROM PHASE 4

- Contract and order review records completed before acceptance
- Production or service records showing acceptance criteria were applied
- Calibration certificates and equipment identification for measuring equipment
- Supplier evaluation records, scorecards, and purchase orders carrying full requirements
- Release records identifying the authorizing person
- Nonconformance records with disposition and decision authority

4.5 Phase 5: Verify That the System Works

Building the system is not the same as proving it works. This phase generates the operating evidence your certification body will look for.

Monitor, measure, analyze, and evaluate

Clause 9.1.1 asks you to determine what you monitor and measure, the methods you use, when you perform it, and when you analyze the results. Clause 9.1.2 requires you to monitor customer perception of whether you met their requirements. Surveys count, but so do delivery performance, warranty claims, returns, repeat business, and complaint volume. Clause 9.1.3 asks you to analyze and evaluate that data, covering product conformity, customer satisfaction, process performance, the effectiveness of planning and of actions on risk, supplier performance, and improvement needs. Analysis means drawing a conclusion, not printing a chart.

Run internal audits that find real problems

Clause 9.2 requires internal audits at planned intervals, covering both your own requirements and those of ISO 9001:2015. Clause 9.2.2 asks you to plan an audit programme that considers process importance, changes, and previous results. You define criteria and scope, select auditors who ensure objectivity and impartiality, report results to relevant management, act without undue delay, and retain the evidence. Impartiality means nobody audits their own work. In a small company, that usually means training two or three people to audit each other's areas, or hiring a contract auditor.

Hold a management review with teeth

Clause 9.3.1 requires top management to review the system at planned intervals. Clause 9.3.2 lists a long set of inputs, from the status of prior actions and changes in context through customer satisfaction, objective attainment, process performance, nonconformities, monitoring results, audit results, external provider performance, resource adequacy, effectiveness of risk actions, and improvement opportunities. Clause 9.3.3 covers outputs: decisions and actions on improvement, any need to change the system, and resource needs. Cover every input, and record the discussion rather than a bare list of headings.

Drive corrective action to root cause

Clause 10.2 governs nonconformity and corrective action. You react and control or correct the problem, deal with the consequences, evaluate whether you need to eliminate the cause, act, review effectiveness, and update risks and the system where needed. Weak root cause analysis is one of the most common findings in the certification world. "Operator error, operator retrained" almost never survives scrutiny. Ask why the process allowed the error and why it reached the customer. Then fix the process.

TIMING MATTERS MORE THAN MOST ORGANIZATIONS REALIZE

Complete at least one full internal audit cycle covering every clause and process, and hold at least one management review, before your Stage 2 audit. Auditors look for evidence that the system has actually operated, not just that it exists on paper. Give yourself three to six months of live operation and real records before you invite anyone in.

EVIDENCE TO RETAIN FROM PHASE 5

- Performance data with documented analysis and conclusions
- Customer satisfaction data and the method used to obtain it
- Internal audit programme, plans, auditor independence records, and reports
- Management review inputs, minutes, and action outputs with owners and dates
- Corrective action files with root cause analysis and effectiveness review

4.6 Phase 6: Take the Implementation Through Certification

With the system running and records on file, your project reaches the certification body. Choose that body carefully, because the relationship runs for years.

Choose an accredited certification body

Not every certificate carries the same weight. A certification body accredited by a member of the International Accreditation Forum Multilateral Recognition Arrangement produces certificates that customers and other members recognize. In the United States, the ANSI National Accreditation Board accredits many of these bodies. Confirm current accreditation status directly, because scopes and statuses change. Ask each candidate the same questions:

- Does their accreditation cover your industry sector code?
- Do your key customers accept certificates from that body?
- What are the Stage 1, Stage 2, surveillance, and recertification fees, including auditor travel?
- How many audit days do they estimate for your headcount, sites, and scope?
- What is the realistic timeline from application to certificate?
- How do their rules govern use of the certification mark on your website and documents?

That last question saves an avoidable finding. A company can meet ISO 9001:2015 in full and still get cited for misusing a certification mark.

Understand the Stage 1 and Stage 2 audit

Certification runs in two stages. Stage 1 is a readiness review. The auditor examines your documented information, your scope, your process map, your internal audit and management review records, and your grasp of the standard, then identifies what needs attention before Stage 2. Stage 2 audits implementation and effectiveness in full. Auditors interview staff, watch work happen, sample records, and follow processes end to end. They test whether people actually do what your documents say.

Findings are normal. Bodies typically classify them as major or minor nonconformities plus opportunities for improvement, then give you a defined window to submit root cause analysis, correction, and corrective action with evidence. A major nonconformity usually blocks the certificate until you close it. Handle findings through your own Clause 10.2 process, and you demonstrate a working system instead of a scramble.

Prepare your people, not a script

Do not rehearse answers. Prepare your team so they can explain their own work, find the current version of a procedure, retrieve a record, and say how they know their output is acceptable. Three questions come up in nearly every audit. What do you do here? How do you know you are doing it right? What do you do when something goes wrong? Any employee who can answer those three about their own job will do fine.

4.7 Phase 7: Sustain the System After Certification

Certification is an operating mode, not a finish line. ISO 9001 certificates typically run on a three year cycle. Your body conducts surveillance audits during that period, usually annually, plus a recertification audit before the certificate expires. Confirm the exact schedule and scope with your body, because programmes differ.

Between visits, the requirements stay live every day. Internal audits run on schedule. Management review happens on time. Corrective actions close with evidence. Calibrations come due. Supplier evaluations need refreshing. Track a small set of measures and review them honestly: on time delivery and first pass yield; internal and external nonconformity volume, aging, and closure effectiveness; customer complaints and their root causes; cost of poor quality; supplier performance; internal audit findings by clause; and progress against each documented quality objective.

> **ASSESSMENT PROMPT**
>
> What objective evidence would demonstrate that each phase above is implemented consistently, not just once? If the honest answer for any phase is "we did it for the audit," that phase is a finding waiting to happen at your next surveillance visit.

> **SCOPE CHANGES**
>
> Notify your certification body when something material changes, including new sites, new products or services, significant headcount shifts, or a change of scope. Claiming certified status over work you never declared creates an entirely avoidable problem.

SECTION 5

Implementation Framework

Translate the guidance into a repeatable sequence you can assign and audit.

#	PHASE	WHAT HAPPENS	PRIMARY CLAUSES
1	**Assess**	Read the standard, analyse context and interested parties, define the scope, and complete a clause-by-clause gap analysis.	4.1 to 4.3
2	**Resource**	Secure leadership commitment, fund the project, appoint owners, and set supplier evaluation criteria.	5.1, 5.3, 4.2, 8.4
3	**Build**	Map processes, write the policy and objectives, address risk, control documented information, and build competence.	4.4, 5.2, 6.1 to 6.3, 7.1 to 7.5
4	**Control**	Bring operations under control: planning, customer requirements, design, suppliers, production, release, and nonconforming outputs.	8.1 to 8.7
5	**Verify**	Monitor and analyse, run internal audits, hold management review, and drive corrective action to root cause.	9.1 to 9.3, 10.2
6	**Certify**	Select an accredited certification body, complete Stage 1 and Stage 2 audits, and close findings.	Body program
7	**Sustain**	Operate the three year cycle, track metrics, improve continually, and manage scope changes.	10.1, 10.3, 9.3

Roles and Responsibilities

Assign each role below to a named person. In a small organization one person may hold several, provided the internal audit role stays independent of the work being audited.

ROLE	PRIMARY ACCOUNTABILITY	REQUIRED RECORD
Top management	Accountability for effectiveness, customer focus, policy and objectives, resources, and management review participation.	Management review minutes; approved policy and objectives
Project lead	Overall implementation plan, schedule, budget tracking, and phase closure.	Gap register; project plan and status reports
Quality coordinator	Documented information control, internal audit programme, corrective action, complaints, management review inputs.	Master document list; audit and corrective action files
Process owners	Process performance against defined criteria, process records, and improvement of their own processes.	Process definitions; performance data; process records
Purchasing	Supplier evaluation, selection, monitoring, re-evaluation, and communication of requirements.	Approved supplier list; scorecards; purchase orders
Internal auditor	Independent audit of the system against the standard and your own requirements.	Auditor competence record; audit plans and reports

SECTION 6

Examples and Visuals

A phase map and a worked example make the framework easier to apply.

PHASE 1	**Assess** Context, interested parties, scope, and a clause-by-clause gap analysis. Output: a prioritized register.
PHASE 2	**Resource** Leadership commitment, budget, owners, supplier criteria. Output: a funded plan.
PHASE 3	**Build** Process map, policy and objectives, risk actions, document control, competence. Output: a controlled system.
PHASE 4	**Control** Contract review, suppliers, production, release, nonconforming outputs. Output: operational evidence.
PHASE 5	**Verify** Monitoring and analysis, internal audit, management review, corrective action. Output: operating records.
PHASE 6	**Certify** Body selection, Stage 1, Stage 2, findings closure. Output: a certification decision.
PHASE 7	**Sustain** Surveillance, metrics, improvement, scope changes. Output: a system that stays ready.

Figure 1. The seven phases in sequence. Notice that each phase produces an output the next phase consumes, which is why working them out of order creates rework.

Worked Example: One Line of a Gap Analysis Register

A gap analysis only helps when each line is specific enough to assign. This example shows one clause worked through to a closure criterion.

Clause	7.2, Competence
Requirement	Determine the competence needed for people whose work affects quality performance, act where gaps exist, evaluate the effectiveness of that action, and retain evidence.

Current state	Skills matrix SM-01 rev 2 covers production only. Training happened informally on the job. No competence requirements exist for receiving inspection or shipping.
Gap	Competence requirements undefined for two functions that affect conformity. No evidence that training effectiveness was evaluated for any role.
Action	Define competence requirements for receiving inspection and shipping. Extend the skills matrix to cover them. Add an effectiveness check thirty days after each training event, recorded on the training form.
Owner	Operations manager
Priority	High. Draws findings at Stage 2 and blocks Phase 3 closure.
Closure criterion	Skills matrix rev 3 approved and covering all functions that affect conformity, supported by dated training records and completed effectiveness checks for every person named.

FOX TIP

Write the closure criterion before you start the work. If you cannot describe the record that will prove the gap is closed, the action is not defined well enough to assign.

SECTION 7

Checklist and Action Plan

Convert the guide into a practical implementation and review tool.

	READINESS CHECK	PHASE	OWNER	DUE
☐	Controlled copy of ISO 9001:2015 purchased and read end to end	1		
☐	Internal and external issues and interested party requirements documented	1		
☐	Scope statement written, with any exclusion justified	1		
☐	Clause-by-clause gap analysis complete, with owners and due dates	1		
☐	Budget approved and project lead appointed with defined authority	2		
☐	Top management able to discuss objectives, complaints, and review outputs	2		
☐	Supplier evaluation criteria defined and approved supplier list built	2		
☐	Process map complete, showing sequence, interaction, and named owners	3		
☐	Document control operating before procedure writing begins	3		
☐	Quality policy approved, communicated, and understood on the floor	3		
☐	Measurable quality objectives set at relevant functions and processes	3		
☐	Risk and opportunity actions planned, integrated, and evaluated	3		
☐	Skills matrix complete, with training effectiveness evaluated	3		
☐	Contract and order review happening before commitment, with records	4		
☐	Acceptance criteria defined and applied at every control point	4		
☐	Measuring equipment identified and calibrated against traceable standards	4		
☐	Release records identify the authorizing person and acceptance criteria	4		
☐	Nonconforming output process operating, with disposition records	4		
☐	Customer satisfaction monitored by a method that fits your customers	5		
☐	Full internal audit cycle completed across all clauses and processes	5		

	READINESS CHECK	PHASE	OWNER	DUE
☐	At least one management review held, covering every Clause 9.3.2 input	5		
☐	Corrective actions closed with root cause analysis and effectiveness review	5		
☐	Accredited certification body selected; mark usage rules obtained	6		
☐	Staff briefed on the audit format and able to locate current documents	6		
☐	Quality calendar built for surveillance, audits, calibrations, and reviews	7		

Priority Actions

First 30 days	Complete the clause-by-clause gap analysis and write your scope statement. Owner: project lead. Deliverable: a prioritized gap register with owners and dates. Completion criterion: every clause assessed with recorded evidence, reviewed by top management.
Next 60 days	Map your processes, stand up document control, then write the priority procedures from observed practice. Owner: quality coordinator with process owners. Deliverable: a process map and a controlled document set. Completion criterion: master document list current, with approval dates and revision history for every document.
Ongoing	Operate the system and accumulate evidence. Owner: quality coordinator and process owners jointly. Deliverable: audit records, management review minutes, customer satisfaction data, and closed corrective actions. Completion criterion: at least one full audit cycle and one management review before you request Stage 2.

Mistakes That Slow Down an Implementation

- **Writing procedures before mapping processes.** You document work that Clause 4.4 will force you to restructure anyway.
- **Buying a generic manual and changing the logo.** Templates give you structure and clause coverage, not your processes.
- **Treating the standard as the quality department's project.** Clause 5 wrote leadership into the system deliberately.
- **Writing objectives nobody can measure.** Clause 6.2 requires measurable objectives, and vague ones draw findings.
- **Overbuilding the risk process.** The standard asks for risk based thinking, not a corporate risk framework.
- **Running soft internal audits.** An audit that finds nothing before your first certification audit has told you nothing.
- **Weak root cause analysis.** Retraining an operator almost never addresses the actual cause.
- **Booking Stage 2 too early.** Without real operating records, the system cannot demonstrate itself.
- **Ignoring your certification body's own rules.** The standard sets the floor. Your body adds requirements on top of it.

SECTION 8

References and Resources

Authoritative sources and next-step resources. Verify each source in its current edition before you rely on it.

References

1. International Organization for Standardization. *ISO 9001:2015, Quality management systems, Requirements.* Available from iso.org and national standards bodies.
2. International Organization for Standardization. *ISO 9000:2015, Quality management systems, Fundamentals and vocabulary.* Defines the terms ISO 9001 uses.
3. International Organization for Standardization. *ISO 19011, Guidelines for auditing management systems.* Useful when building an internal audit programme under Clause 9.2.
4. International Accreditation Forum. Multilateral Recognition Arrangement and its member accreditation bodies.
5. Your certification body's published program requirements, audit day calculation, and mark usage rules.

ON THE NEXT EDITION OF ISO 9001

ISO 9001:2015 is the edition in force at the time of writing, and it remains the certifiable edition. A revised edition is expected, with a transition period of roughly three years following publication. Reported changes point toward clarified language rather than a rebuilt standard: climate change within organizational context, ethics and quality culture, sharper separation of risks from opportunities, and a new informative annex. Build to ISO 9001:2015 now, because a well built system carries forward with modest edits. Confirm the publication date, final content, and transition deadline with ISO and your certification body.

Related Precision ISO Resources

- **ISO 9001 Gap Analysis Checklist**, a 192-item workbook covering Clauses 4 through 10, with an automatic readiness score and conformance-by-clause dashboard. It is the working companion to Phase 1 of this guide.
- **ISO 17025 Implementation Roadmap**, the equivalent seven-phase guide for testing and calibration laboratories pursuing accreditation.
- **SOP-011 Document Management**, a controlled template you can tailor to your organization.
- **Template library**, SOPs, work instructions, and forms built for ISO 9001 and ISO/IEC 17025, designed to be customized rather than adopted as-is.

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