

ISO 9001 IMPLEMENTATION HUB

Volume 2 • Guide 3 of 7

Clause 7: Support

Deep-Dive Practitioner Interpretation with Examples, Pitfalls, and Audit Guidance

Clause-by-Clause Practitioner's Guide • ISO 9001:2015

Resources (7.1) • Calibration (7.1.5) • Organizational Knowledge (7.1.6) • Competence (7.2) •
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How to Use This Guide

This is Guide 2.3 in Volume 2 of the ISO 9001 Implementation Hub. It provides deep-dive coverage of Clause 7 — the Support clause — which is the broadest single clause in ISO 9001:2015 and the one that most directly determines whether an organization has the capability to execute its QMS effectively. While Clauses 4 through 6 establish what the QMS is and how it is planned, Clause 7 asks whether the organization has given that QMS what it needs to actually function: the right people, the right equipment, the right environment, the right knowledge, the right information, and the right communication disciplines.

This guide covers Clause 7 in full, subclause by subclause: resources in the broad sense (7.1), with detailed attention to infrastructure (7.1.3), work environment (7.1.4), monitoring and measuring resources including calibration (7.1.5), and organizational knowledge (7.1.6); competence (7.2); awareness (7.3); communication (7.4); and documented information (7.5) including the creation, control, and retention of all QMS documents and records. Each subclause receives the same treatment: verbatim requirement, practical interpretation, implementation guidance, common pitfalls, auditor perspective, and the Meridian case study example.

Introduction: Clause 7 as the QMS Enabling Layer

Every other element of the QMS depends on what Clause 7 provides. A context analysis (Clause 4), risk register (Clause 6), and set of quality procedures (Clause 8) are only as effective as the support infrastructure that enables the people who must execute them. A procedure followed by incompetent personnel produces no quality benefit. A calibration requirement satisfied with uncalibrated equipment produces invalid data. A documented information system that exists in paper binders no one can find defeats document control. Clause 7 is where the QMS's capability is actually built.

The breadth of Clause 7 — spanning physical resources, human capability, organizational knowledge, communication, and documentation — reflects its importance as the foundational enabler of everything else. Audit findings in Clause 7 are frequently the most consequential, because a Clause 7 gap usually indicates a broader capability failure that will manifest as operational nonconformances in Clause 8 or performance failures in Clause 9. Organizations that invest seriously in Clause 7 implementation — not just compliance — build the quality capability that makes everything else possible.

Clause 7.1 — Resources

Standard Requirement

ISO 9001:2015, Clause 7.1.1 (General): "The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. The organization shall consider: a) the capabilities of, and constraints on, existing internal resources; b) what needs to be obtained from external providers."

7.1.1 — General Resource Provision

The general resource requirement is deceptively simple but has significant implications for organizational governance. "Determine and provide" means resources must be both identified and allocated — not just acknowledged as needed. An organization that determines it needs a full-time quality engineer but does not provide one has not met Clause 7.1.1. An organization that determines it needs a second CMM to control measurement uncertainty at its production volume but defers the purchase indefinitely has not met Clause 7.1.1.

The two considerations in Clause 7.1.1 — internal capabilities and constraints, and external provider contributions — require an honest assessment of what the organization can provide from within and what must be obtained externally. Quality functions that are consistently under-resourced relative to the QMS demands placed on them will eventually produce systemic conformance failures. The resource determination exercise should feed directly into the budget planning cycle and into the management review resource discussions.

7.1.2 — People

Standard Requirement

ISO 9001:2015, Clause 7.1.2: "The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes."

The people resource requirement connects directly to the competence requirements of Clause 7.2. Providing "persons necessary for the effective implementation" means not only having sufficient headcount but having the right competencies in place. An understaffed quality function that cannot execute its audit program, cannot respond to corrective actions promptly, and cannot provide adequate support to production supervisors is failing Clause 7.1.2 — regardless of the number of quality professionals on the organization chart.

People resources also include the time allocation of personnel with non-quality primary roles who carry QMS responsibilities. A production supervisor who is responsible for procedure compliance verification, operator training sign-offs, and NCR initiation but whose schedule never includes time for these activities is an under-resourced quality support role even if the organization has adequate quality staff headcount.

7.1.3 — Infrastructure

Standard Requirement

ISO 9001:2015, Clause 7.1.3: "The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology."

Infrastructure in the ISO 9001:2015 context means the physical and technological environment within which quality-affecting work is performed. The critical word is "maintain" — infrastructure that exists but is not maintained to support quality outcomes does not satisfy this clause. A CMM that is not calibrated (addressed more specifically in Clause 7.1.5), production equipment that is not maintained per a preventive maintenance program, or an IT system that stores quality records but has no backup creates infrastructure gaps that directly affect product conformance.

Infrastructure Category	Quality-Relevant Considerations
Buildings and utilities	Temperature and humidity control in areas where product quality is sensitive to environmental conditions; adequate lighting for inspection activities; secure storage for controlled documents, calibration standards, and customer-owned property; designated nonconforming material quarantine area that is physically separate from conforming product storage
Equipment — production	Preventive maintenance programs for production equipment that affect product quality; calibration for any production equipment used to verify or control a quality characteristic; change control for equipment modifications that affect process capability
Equipment — measurement and inspection	All measurement and inspection equipment that affects quality decisions must be calibrated and maintained (addressed in depth in Clause 7.1.5); measurement equipment must be adequate for the precision required by the specifications being evaluated
Hardware and software	Computer systems used for quality records management must have adequate backup, access control, and recovery capability; software used to make quality decisions (CAD systems for drawing interpretation, SPC software, CMM control software) must be validated for its intended use; ERP systems that control production scheduling and material traceability must function reliably
Information and communication technology	Network infrastructure that supports document control system access; communication systems that enable quality alert notifications; video or electronic display systems used for visual management of quality performance data

7.1.4 — Environment for the Operation of Processes

Standard Requirement

ISO 9001:2015, Clause 7.1.4: "The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. A suitable environment can be a combination of human and physical factors, such as: a) social (e.g. non-

discriminatory, calm, non-confrontational); b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective); c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise)."

Clause 7.1.4 is one of the least-implemented subclauses in most QMS systems, yet it has direct and measurable connections to quality outcomes. The social and psychological factors — often dismissed as HR concerns rather than quality management concerns — significantly affect operator attention, error rates, and willingness to report quality problems. An environment characterized by blame culture, production pressure that overrides quality concerns, or fear of reprisal for stopping production will systematically undermine the QMS regardless of how well its procedures are written.

Physical environment factors have more direct and familiar quality implications: temperature-sensitive measurement equipment that is not temperature-controlled produces unreliable results; inadequate lighting in inspection areas causes visual defects to be missed; excessive noise levels in areas where operators must communicate about quality concerns creates information transmission failures. A quality organization that does not consider the physical environment as a quality control parameter is missing a significant source of variation.

Kaizen Connection

The 5S methodology in Lean manufacturing addresses the work environment as a quality tool directly. Sort, Set in Order, Shine, Standardize, and Sustain are not housekeeping exercises — they are environment quality controls. A workplace where tools are in designated locations prevents the use of wrong tools. A clean, organized inspection area reduces the risk of product mix-up. Clear visual management reduces ambiguity about where conforming product goes versus nonconforming material. Organizations with mature 5S programs often find that Clause 7.1.4 physical environment conformance comes naturally from their Lean discipline. Organizations without 5S programs often find that their Clause 7.1.4 gaps and their Lean waste problems are the same problems viewed from different perspectives.

Clause 7.1.5 — Monitoring and Measuring Resources (Calibration)

Standard Requirement

ISO 9001:2015, Clause 7.1.5.1 (General): "The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measurement is used to verify conformity of products and services to requirements. The organization shall ensure that the resources provided: a) are suitable for the specific type of monitoring and measurement activities being undertaken; b) are maintained to ensure their continued fitness for purpose. The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measuring resources."

Clause 7.1.5.2 (Measurement Traceability): "When measurement traceability is a requirement, or considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information; b) identified in order to determine its status; c) safeguarded from adjustments, damage or deterioration that would invalidate the measurement results. The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be not conforming to its intended purpose, and shall take appropriate action as necessary."

Understanding Measurement Traceability

Measurement traceability is the property of a measurement result that it can be related to a reference through a documented, unbroken chain of calibrations, each contributing to measurement uncertainty. In practical terms: when a quality inspector measures a critical dimension with a micrometer and declares the part conforming, the reliability of that declaration depends on whether the micrometer was calibrated against a certified standard, that standard was calibrated against a higher-order standard, and so on up to a national or international measurement standard.

Without this chain of traceability, the measurement is an opinion rather than a verified result. A product declared conforming based on an uncalibrated measurement may in fact be nonconforming. A product rejected based on an uncalibrated measurement may in fact be conforming. Neither error serves quality management.

ISO 9001:2015 requires measurement traceability when it "is a requirement or considered by the organization to be an essential part of providing confidence in the validity of measurement results." In practice, any measurement used to make a conformance decision about product — accept or reject, release or hold — should be traceable. The practical threshold: if the result of the measurement determines whether product ships to a customer, the measuring equipment used should be calibrated with traceability.

Building the Calibration Program

A conforming calibration program has five essential elements:

Element 1: The Calibration Equipment Register

Every measuring device used to make quality decisions must be identified in a controlled register. The register is the authoritative inventory of calibrated equipment and the foundation of the calibration program. Each entry should capture: equipment identifier (unique ID number), description, location, calibration method, calibration frequency, last calibration date, next calibration due date, calibration provider (internal or external), and current status.

The most common calibration program failure — measured repeatedly across industries — is incomplete equipment registers. Organizations calibrate what they know about and miss what they do not. A systematic census of all measuring devices in actual use (not just what is on the existing calibration list) is the critical first step in establishing a complete program. This census should include: production floor measurement tools, receiving inspection equipment, quality lab instruments, environmental monitoring equipment, and any gauges or measuring devices used to verify production process settings.

Element 2: Calibration Frequency and Method

Every calibrated device needs a defined calibration interval — how often it must be calibrated to maintain adequate measurement confidence. Calibration intervals are typically based on: manufacturer's recommendation for the type of equipment, the severity of use (high-use equipment drifts faster), the precision required relative to the tolerance being measured, and the history of calibration results (equipment that consistently comes back in tolerance may be calibrated less frequently; equipment with out-of-tolerance history should be calibrated more frequently).

Calibration method defines whether equipment is calibrated internally by trained staff against certified standards or externally by an accredited calibration laboratory. Critical measurement equipment — precision CMMs, optical comparators, force gauges used for acceptance decisions — typically requires external calibration by an ISO/IEC 17025-accredited laboratory. Hand tools such as micrometers, calipers, and dial indicators may be calibrated internally against certified gauge blocks if appropriate methods and training exist.

Element 3: Calibration Status Identification

Every calibrated device must be physically labeled to show its calibration status — whether it is currently calibrated and when calibration is next due. The status label serves two purposes: it allows anyone using the device to immediately verify calibration currency, and it provides physical evidence during an audit that the equipment in use at the point of measurement is within calibration.

The label should show, at minimum: the device's unique identifier, the calibration due date, and the identifier of the calibration laboratory or technician. In some organizations, a color-coding system (green label = in calibration, red label = out of calibration / quarantined) provides even faster visual status identification.

Element 4: Calibration Records

Calibration records are the "documented information as evidence of fitness for purpose" required by Clause 7.1.5.1. For externally calibrated equipment, the calibration certificate issued by the accredited laboratory is the primary record. For internally calibrated equipment, the calibration record form completed by the calibrating technician serves this purpose. Records must capture: equipment identifier, calibration date, calibration results (measured values versus acceptable limits), pass/fail determination, and calibration technician or laboratory identification.

Calibration certificates from accredited laboratories should include a statement of traceability — confirming that the calibration standards used are traceable to national or international measurement standards. This traceability statement is what creates the chain of traceability from the customer-facing measurement to the national standard.

Element 5: Out-of-Tolerance Response

When a measuring device is found to be out of tolerance during calibration — meaning it has been producing measurements outside acceptable accuracy limits — the organization must determine whether previous measurements made with that device were adversely affected. This is one of the most challenging and consequential aspects of calibration management.

The out-of-tolerance response process should address:

- Identify what product was inspected or accepted using this device since its last in-tolerance calibration
- Assess whether the out-of-tolerance condition would have affected the quality of those inspection results — considering the direction and magnitude of the error relative to the tolerances being measured
- Take appropriate action: for product still in house, re-inspect using a calibrated device; for product already shipped, assess the risk to customers and determine whether notification is appropriate
- Document the investigation, findings, and actions taken
- Analyze the root cause of the out-of-tolerance condition: device damaged, improper storage, excessive wear, inappropriate calibration interval — and correct it

Measurement Adequacy — Gauge Ratio and Measurement System Analysis

Clause 7.1.5.1 requires that measuring resources be "suitable for the specific type of monitoring and measurement activities being undertaken." Suitability means not only that the device is calibrated but that it has adequate precision and accuracy for the measurements being made. A gauge that is calibrated but insufficiently precise to resolve differences within the product tolerance is not suitable for its intended use.

The practical suitability standard in manufacturing metrology is typically that the measurement system's resolution should be at least 10 times finer than the tolerance being evaluated (the 10:1 gauge ratio rule). An even more rigorous approach is Measurement System Analysis (MSA) or Gauge Repeatability and Reproducibility (GR&R) studies from the AIAG MSA reference manual — which quantify the proportion of the tolerance consumed by measurement variation itself. Organizations in sectors that require AIAG compliance (automotive, aerospace Tier 1 suppliers) must conduct formal MSA; others may satisfy Clause 7.1.5.1 with the simpler gauge ratio approach and documented rationale.

Auditor Perspective

Calibration is one of the most evidence-rich audit areas — it is almost entirely records-based and lends itself to rapid verification. Registrar auditors use a consistent approach: request the calibration equipment register, select a sample of devices (typically 10 to 20% of the register), and then do two things with each sample. First, verify in the register that the device is current (not overdue). Second, physically locate the device on the shop floor or in the inspection area and verify that the status label is present, legible, and

matches the register. The combination of records verification and physical confirmation catches both the register gap (device not listed) and the implementation gap (device listed but not found or label not matching). A single overdue device on the shop floor found by this method is a minor nonconformance. A pattern of multiple overdue devices suggests a program management failure that may warrant a major.

Meridian Case Study

Meridian Calibration Program at Year 1 Post-Certification: At implementation, the calibration census revealed 23% of measuring devices were overdue — the largest single gap identified during the gap analysis. The remediation effort consumed approximately \$3,800 in emergency external calibration services and took eight weeks to complete. Twelve months post-certification, Meridian's calibration program had achieved 100% on-schedule status for the first time in the company's recorded history. Three structural changes made this possible: (1) a monthly calibration due-date report sent automatically from the calibration tracking system to the quality technician and production supervisor, triggering scheduling of calibration 30 days before the due date; (2) a policy requiring that any device found without a current calibration label be immediately removed from service and quarantined until calibrated — with the quality technician notified the same day; (3) a quarterly calibration audit as part of the internal audit program that physically verifies the status of a 20% sample of the equipment register. The Stage 2 auditor noted Meridian's calibration program as an area of strength during the closing meeting — a direct result of treating the implementation gap as an opportunity to build genuine capability rather than a compliance checkbox.

Clause 7.1.6 — Organizational Knowledge

Standard Requirement

ISO 9001:2015, Clause 7.1.6: "The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and made available to the extent necessary. When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge. Note 1: Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It can be information such as intellectual property and lessons learned; from failures and successful projects; capturing and sharing undocumented expertise and experience; the results of improvements to processes, products and services. Note 2: To access necessary knowledge, the organization can consider: internal sources (e.g. intellectual property, knowledge gained from experience, mentoring and coaching, lessons learned from failures and near-misses, the results of improvement projects, benchmarking); external sources (e.g. standards, academia, conferences, gathering knowledge from customers or external providers)."

Why Organizational Knowledge Was Added in the 2015 Revision

Clause 7.1.6 is a new requirement in the 2015 revision, and its inclusion reflects a real and growing organizational risk: the loss of critical quality knowledge when experienced employees leave. In manufacturing environments, a significant portion of quality management capability exists not in documented procedures but in the tacit knowledge of individuals — the machinist who knows from experience that a particular raw material lot typically runs tight on a critical dimension, the quality engineer who knows which customer is particularly sensitive to a specific surface finish condition, the setup technician who understands from years of experience which of the older machines drifts and requires mid-run adjustment.

When these individuals leave — through retirement, resignation, or other turnover — the knowledge leaves with them unless the organization has deliberately captured and transferred it. The consequences of this knowledge loss can range from increased defect rates on specific jobs to customer relationship failures when product experience is lost to complete process capability collapses when the one person who understood how to reliably run a particular operation is gone.

Types of Organizational Knowledge That the QMS Requires

Organizational knowledge relevant to the QMS encompasses several distinct categories, each with different capture and maintenance approaches:

Knowledge Type	Examples and Capture Approaches
Process knowledge	How specific processes are set up and run reliably; non-obvious relationships between process parameters and quality outcomes; process quirks and adjustments that are not in the standard work instructions. Captured through structured interviews with experienced operators, work instruction updates, lessons-learned records, and process notes added to control plans.
Product knowledge	Customer-specific quality preferences and sensitivities beyond drawing requirements; historical quality issues with specific product families; supplier material characteristic variations and their quality

Knowledge Type	Examples and Capture Approaches
	implications. Captured in customer-specific quality notes, product quality history files, and supplier quality records.
Customer knowledge	Understanding of specific customers' audit approach and quality focus areas; key customer contacts and their quality concerns; customer acceptance practice for ambiguous specification situations. Captured in customer quality files, account notes, and audit debriefs.
Lessons learned	Root causes of major quality escapes and the systemic controls added to prevent recurrence; what went right in successful new product launches; what failed in challenging jobs and why. Captured in CAPA records, lessons-learned databases, project post-mortems.
Regulatory and standards knowledge	Interpretation of specific regulatory requirements as applied to the organization's products; how specific industry standards (AS9100, ITAR, NADCAP requirements) apply to particular process types. Captured in compliance notes, regulatory guidance documents, and procedure references.
Equipment and measurement knowledge	How specific measurement equipment behaves under different conditions; which machines produce better results for specific material types; equipment-specific setup knowledge that affects quality. Captured in equipment operation notes, machine-specific work instructions, and calibration records.

The Knowledge Maintenance and Availability Requirements

Clause 7.1.6 requires that organizational knowledge be "maintained and made available to the extent necessary." This means:

- "Maintained" implies that knowledge is kept current — lessons learned from recent events are captured, outdated knowledge is updated when processes or products change, and the knowledge management system is actively stewarded rather than created once and left static
- "Made available" means that the right knowledge reaches the people who need it at the time they need it — a lessons-learned record buried in a shared folder that no one knows exists is maintained but not available
- "To the extent necessary" provides proportionality — not every piece of organizational experience needs to be formally documented, only the knowledge whose loss would materially affect the organization's ability to maintain quality outcomes

Practical Knowledge Capture Approaches

Organizations resist elaborate knowledge management systems because they create administrative burden that rarely delivers value. The most effective organizational knowledge programs in manufacturing environments are simple, embedded in existing workflows, and targeted at the highest-risk knowledge gaps:

- Job-specific process notes appended to travelers or work orders: operators document non-obvious setup adjustments, material observations, and quality concerns directly on the job

documentation — captured at the point of experience, available to whoever runs the next similar job

- Structured exit interviews focused on quality knowledge: when experienced employees leave, a structured conversation specifically about what quality knowledge they carry — which customers are particular about which features, which jobs are tricky, which suppliers require extra scrutiny — captures what procedures cannot
- CAPA-linked lessons learned: every significant corrective action should include a lessons-learned record that connects the root cause to the systemic fix and communicates what the organization now knows that it did not know before
- Apprenticeship and mentoring documentation: when a new employee is being trained by an experienced employee, the training record should capture not only that training occurred but the specific knowledge elements that were transferred, providing evidence of knowledge continuity
- Pre-retirement knowledge transfer plans: for identified high-risk employees nearing retirement or departure, a structured knowledge transfer plan defines what knowledge must be captured and transferred, to whom, by what method, and by what date

Common Pitfall

The most common Clause 7.1.6 implementation failure is what practitioners call "knowledge theater" — an organization creates a lessons-learned database, populates it with a few entries during the QMS implementation, and then stops adding to it. The database exists as evidence of the knowledge management requirement but is consulted by no one and updated by no one. The actual organizational knowledge remains entirely in the heads of experienced employees. A registrar auditor who asks to see recent lessons-learned entries — anything from the past six months — and finds nothing, or who asks a process owner whether they consult the lessons-learned database when setting up a new job and gets a blank stare, has found evidence that the knowledge system is not functional. Organizational knowledge management that works is embedded in how jobs are set up, how new employees are trained, and how quality problems are investigated — not maintained as a separate system that no one engages with.

Clause 7.2 — Competence

Clause 7.2 is covered in full in Guide 1.4 of Volume 1, where it was addressed from an implementation perspective. This section provides the practitioner reference depth appropriate to a clause-by-clause guide — deeper interpretation of the requirement language, common audit findings not fully covered in Volume 1, and the Meridian post-certification competence management experience.

Standard Requirement

ISO 9001:2015, Clause 7.2: "The organization shall: a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system; b) ensure that these persons are competent on the basis of appropriate education, training, or experience; c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; d) retain appropriate documented information as evidence of competence. Note: Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons, or the hiring of or contracting with competent persons."

The "Under Its Control" Scope of Clause 7.2

A frequently missed aspect of Clause 7.2 is the scope of "persons doing work under its control." This extends beyond employees to include contractors, temporary workers, agency staff, and any other individuals performing quality-affecting work under the organization's direction. A manufacturing organization that uses staffing agency workers on its production lines, contract quality inspectors during peak periods, or outsourced engineering resources for design activities must include these personnel in its competence determination and ensure they meet the requirements for their roles.

The practical implication: organizations must either verify competence for contracted personnel at the individual level or ensure that the contracting agency provides personnel who meet defined competence requirements — with verification evidence available. A contract that specifies "qualified inspectors" without defining what qualified means and without verifying individual qualifications does not satisfy Clause 7.2.

The "Performance and Effectiveness of the QMS" Scope

The standard's phrase "that affects the performance and effectiveness of the quality management system" defines which roles require competence determination. This is broader than product quality roles alone. It includes roles that affect how the QMS functions as a management system:

- Operations roles that directly affect product conformance: operators, inspectors, setup technicians, maintenance technicians
- Quality roles that administer and develop the QMS: quality engineers, quality managers, internal auditors, Management Representatives
- Supporting roles whose work enables quality outcomes: purchasing agents who evaluate suppliers, HR managers who administer training records, engineering staff who develop work instructions
- Management roles with QMS governance responsibilities: department managers who own QMS processes, senior leaders who participate in management review

The Competence Verification Gap — The Most Persistent Finding

Guide 1.4 addressed the competence verification gap in depth from an implementation perspective. From the clause interpretation perspective, it is worth revisiting why this gap is so persistent: the standard requires the organization to "ensure that these persons are competent" — not that they have been trained. Ensuring competence requires a determination, not an assumption.

The determination of competence must be evidence-based. Three acceptable bases are explicitly named in the standard: education, training, and experience. Each requires verification: education by credential review, training by training records that demonstrate the content covered and the assessment conducted, experience by either documented prior role history or direct observation and assessment of current performance. An organization that ensures competence on the basis of experience must document how that experience was verified — "we know she is good because she has been here for fifteen years" is a defensible position when documented as a supervisor competence attestation, and indefensible when it is simply an unrecorded assumption.

Meridian Case Study

Meridian Competence Post-Certification: The competence matrix that Denise built during implementation covered 178 employees in quality-affecting roles. At the Month 18 management review — the first annual post-certification review — Denise reported that the matrix had been updated 23 times in the preceding twelve months: 7 new hire onboardings, 11 role changes, and 5 identified competence gaps closed through targeted training. The most significant competence development investment in Year 1 was model-based definition (MBD) training for four quality inspectors — driven by the context risk R-03 identified during implementation. The training cost \$4,200 for an external two-day course plus internal qualification assessments. At the Year 1 surveillance audit, the auditor selected three employees for competence record review — including one of the four MBD-trained inspectors. The inspector's training records, the competence assessment conducted by the quality manager post-training, and the updated competence matrix entry were all produced within three minutes. The auditor noted "thorough and well-organized competence records" in the positive observations section of the surveillance audit report.

Clause 7.3 — Awareness

Standard Requirement

ISO 9001:2015, Clause 7.3: "Persons doing work under the organization's control shall be aware of: a) the quality policy; b) relevant quality objectives; c) their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance; d) the implications of not conforming with the quality management system requirements."

Awareness vs. Competence — The Operational Distinction

The distinction between Clause 7.2 (competence) and Clause 7.3 (awareness) is operationally significant: competence is the ability to perform a task to the required standard; awareness is the understanding of why the QMS exists, how one's work connects to it, and what is at stake when its requirements are not met. A competent operator who is unaware of the Quality Policy, has no idea what the relevant quality objectives are, and does not understand the consequences of quality failures for the organization and its customers will not consistently make quality-preserving decisions in ambiguous situations.

Awareness matters most in the gray areas — when an operator is deciding whether to flag a borderline part for inspector review or ship it; when a supervisor is deciding whether to stop a run and investigate a process anomaly or keep running and check at end of shift; when a purchasing agent is deciding whether to push back on a supplier's delivery proposal or accept it to maintain schedule. In these moments, awareness of the Quality Policy commitments, the quality objectives at stake, and the consequences of nonconformance directly affects the decision made. An organization that has achieved awareness has quality decision-making embedded throughout its workforce, not only in its quality function.

The Four Awareness Elements in Depth

(a) The Quality Policy

Employees should be able to describe the Quality Policy's commitments in their own words — not recite it verbatim, but explain what it means for the organization and what it means for their specific role. Auditors test this directly with random employee interviews. The test reveals whether awareness has been achieved (employee gives a meaningful description) or only communication has occurred (employee says "I have seen it posted but cannot tell you what it says").

Building Policy awareness beyond initial training requires embedding the Policy in ongoing operations: supervisors referencing Policy commitments when addressing quality concerns; management review communications that connect Policy language to performance data; new employee orientation that discusses the Policy specifically and connects it to the employee's role. A Policy that is communicated once at training launch and then never referenced again will not be understood or applied twelve months later.

(b) Relevant Quality Objectives

Employees should be aware of the quality objectives that are relevant to their work — not all objectives for all employees, but the specific objectives that their daily performance affects. An operator whose work affects first-pass yield should know the first-pass yield objective and current performance. A purchasing

agent whose actions affect on-time supplier delivery should know the supplier on-time delivery objective and current status.

Visual management is the most effective tool for ongoing quality objective awareness: posting performance charts in work areas that show current metric values against targets, updated monthly. An operator who walks past a first-pass yield chart every day and sees whether the trend is moving toward or away from target has ongoing awareness without requiring repeated formal training. Supervisors who reference these charts in daily team discussions convert posting into genuine awareness.

(c) Contribution to QMS Effectiveness and Benefits of Improvement

This element asks employees to understand not just what the QMS requires but why it matters — how their specific work contributes to or detracts from quality outcomes and what the organization gains when quality performance improves. This is the most culturally demanding element of Clause 7.3 because it requires the organization to make quality performance personally meaningful to every employee, not just organizationally important.

Effective approaches connect individual roles to organizational outcomes concretely: "When you catch a dimensional nonconformance at first-piece inspection, you prevent a potential customer return. Our customer returns cost us an average of \$8,500 each — in rework, freight, and customer relationship repair. Last year we had 11 returns. If first-piece inspection catches five of those, that is over \$40,000 in saved cost and five fewer customer disappointments." This level of specificity makes the contribution tangible rather than abstract.

(d) Implications of Not Conforming

Employees should understand the consequences — for the organization, for customers, and for themselves — of not following QMS requirements. This is not a threat-based communication but an honest explanation of why the requirements exist and what happens when they are not followed. A machinist who understands that skipping the required dimensional verification on a critical feature could result in a flight-safety component being shipped with an out-of-tolerance condition has a more motivated relationship with the verification requirement than one who understands only that the inspector will write them up if they skip it.

Sustaining Awareness Beyond Initial Training

Initial QMS awareness training satisfies the communication requirement but does not sustain awareness over time. Organizations that deliver awareness training at QMS launch and then do not reinforce it find that awareness degrades to near zero within 12 to 18 months — confirmed by auditor interviews that reveal employees who "remember going to training" but cannot describe the Quality Policy or quality objectives. Sustained awareness requires:

- Regular supervisor reinforcement: quality topics in team meetings, shift briefings that reference quality performance, supervisor reactions to quality events that model the Quality Policy values
- Visual management: posted quality performance data that employees see and update regularly, creating ongoing awareness of where quality performance stands relative to objectives
- New employee onboarding: every new hire receives awareness training before beginning quality-affecting work — with the same four elements, not a shortened or generic version

- Refresher communications: periodic reminders (quarterly email from the Management Representative, annual all-hands quality performance review, recognition of quality achievements) that keep QMS commitments visible

Clause 7.4 — Communication

Standard Requirement

ISO 9001:2015, Clause 7.4: "The organization shall determine the internal and external communications relevant to the quality management system, including: a) on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate; e) who communicates."

What Clause 7.4 Requires and What It Does Not

Clause 7.4 is the most minimally prescriptive clause in Clause 7 — it requires the organization to determine its communication approach for QMS-relevant topics but does not prescribe specific communications, frequencies, or formats. The organization must have a planned approach to QMS communication — not just communicate informally and hope it works. The five elements (what, when, with whom, how, who) provide the framework for that planned approach.

Many organizations satisfy Clause 7.4 with a one-page communication plan table that maps each type of QMS communication across the five required elements. This table does not need to be elaborate; it needs to be thoughtful — covering the communications that actually matter for QMS effectiveness and assigning clear ownership. An organization that communicates about quality constantly but has no planned approach will struggle to demonstrate to an auditor that its communications are systematic rather than ad hoc.

The Communication Planning Table

The following framework covers the most important QMS communication requirements in a typical manufacturing organization:

What	When	With Whom	How	Who Communicates
Quality Policy — initial and ongoing	At onboarding; at awareness training launch; upon any revision	All employees	Awareness training session; posted in work areas; intranet posting	Management Representative + CEO
Quality objectives and performance	Monthly (current performance vs. target); at management review; upon significant off-track status	All employees for organizational objectives; department staff for function-level objectives	Posted performance boards; management review minutes distributed to dept. managers; team briefings by supervisors	MR to leadership; supervisors to teams

What	When	With Whom	How	Who Communicates
New or revised QMS procedures	Before effective date of each new or revised procedure	All personnel performing the affected process	Procedure awareness briefing; training record; change notice in document control system	Process owner + supervisor
Internal audit findings	Within 5 business days of audit closing meeting	Manager of audited area; Management Representative; relevant department managers for systemic findings	Audit report distribution; corrective action assignment notification	Lead internal auditor
Management review decisions and actions	Within 5 business days of management review	Department managers responsible for assigned actions; broader leadership where resource decisions were made	Management review minutes distribution; action tracking system notifications	Management Representative
Customer quality issues and returns	Immediately upon notification or discovery	Quality Manager, Production Manager, relevant process owner	Direct notification; customer complaint record creation; corrective action initiation	Quality Manager (receives) + MR (coordinates)
Certification status and QMS updates to customers	Upon initial certification; upon scope changes; when customers request	Customer quality contacts, procurement contacts	Certificate sharing; customer portal updates; account manager communication	Sales Manager + MR
Supplier quality requirements	At initial qualification; when requirements change; when performance concerns arise	Supplier quality contacts	Purchase order quality requirements; supplier qualification documentation; supplier quality meeting or audit	Purchasing Manager + Quality Manager


Internal vs. External Communication

Clause 7.4 explicitly covers both internal and external communications relevant to the QMS. Internal communication — the mechanisms by which quality information, requirements, and performance data flow within the organization — is addressed above. External communication — how the organization communicates about quality to customers, suppliers, regulators, and other interested parties — has specific requirements in other clauses (Clause 8.2 for customer requirements, Clause 8.4 for supplier requirements) but is also governed by the Clause 7.4 communication planning requirement.

The external communication planning element most frequently missed in QMS implementations is the decision about whether and how to communicate quality performance information externally. Clause 5.2.2(c) requires the Quality Policy to be "available to relevant interested parties as appropriate" — implying a decision about how and to whom the Policy is communicated externally. Organizations that have no planned approach to external quality communication — which customers receive which quality information, what is communicated proactively versus reactively, who is authorized to communicate externally about quality matters — have a gap in Clause 7.4 implementation.

Clause 7.5 — Documented Information

Clause 7.5 is covered in depth in Guide 1.3 of Volume 1 from an implementation perspective. This section provides clause-level reference depth — focusing on the aspects of the documented information requirements that are most frequently misunderstood or that generate audit findings in post-certification operations.

 Standard Requirement
ISO 9001:2015, Clause 7.5.1 (General): "The organization's quality management system shall include: a) documented information required by this International Standard; b) documented information determined by the organization as being necessary for the effectiveness of the quality management system."
Clause 7.5.2 (Creating and Updating): "When creating and updating documented information, the organization shall ensure appropriate: a) identification and description; b) format and media; c) review and approval for suitability and adequacy."
Clause 7.5.3 (Control of Documented Information): "Documented information required by the quality management system and by this International Standard shall be controlled to ensure: a) it is available and suitable for use, where and when it is needed; b) it is adequately protected. For the control of documented information, the organization shall address as applicable: distribution, access, retrieval and use; storage and preservation; control of changes; retention and disposition."
Clause 7.5.3.2: "For the control of documented information, the organization shall also address the applicable control of documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system."

The Maintain / Retain Distinction — A Reference Summary

The most fundamental documented information concept is the distinction between documented information that must be "maintained" (instructional documents kept current) and documented information that must be "retained" (evidence records preserved). This distinction determines how different types of QMS documents are controlled:

Type	Maintain (Instructional)	Retain (Evidence)
Nature	Describes how processes work — what to do, in what sequence, by whom. Designed to be consulted during and before process execution.	Records what happened — captures the output of a process execution as evidence that it occurred and with what result.
Control requirement	Must be current, approved, version-controlled, and accessible. Obsolete versions removed from active use.	Must be retrievable, legible, and protected from alteration or accidental loss. Not updated — records are historical.

Type	Maintain (Instructional)	Retain (Evidence)
Examples	Procedures, work instructions, the Quality Policy, process maps, forms (blank templates), the Quality Manual	Completed inspection records, training records, calibration certificates, NCR forms (completed), CAPA records, management review minutes
Retention period	Maintained while current; prior versions retained as controlled "superseded" documents for the period required by procedure	Retained for defined periods based on regulatory requirements, customer requirements, or organizational policy (typically 3 to 10 years depending on record type)

External Documents — The Frequently Missed Requirement

Clause 7.5.3.2 requires the organization to control documented information of external origin that it determines to be necessary for QMS operation. This is one of the most consistently missed requirements in ISO 9001 implementation and surveillance. External documents include: customer engineering drawings and specifications, industry standards referenced in procedures, supplier material specifications, regulatory guidance documents, calibration procedures from calibration service providers, and any other external documents that the QMS relies on.

Control of external documents means: knowing what external documents the QMS depends on, knowing what revision is current, having a process for being notified when those documents are revised, and ensuring that the organization is working to the current revision at all times. An organization that has a customer drawing in use that has been revised by the customer but is still manufacturing to the old revision has an external document control failure that directly affects product conformance.

External Document Type	Control Approach
Customer drawings and specifications	Track by revision level in the document register or job-specific control file; establish a customer change notification agreement; verify drawing revision at order receipt and compare to last revision used in production for repeat jobs
Industry and national standards (ASTM, AWS, ASME, MIL-SPEC, etc.)	List all referenced standards in the document register with current revision; subscribe to standards revision notification services; review standards references in procedures annually
Supplier material specifications and certifications	Maintain supplier-provided material specifications in the document register by part number and revision; verify that incoming material certifications reference the current specification revision
Calibration procedures from accredited laboratories	Retain calibration procedures for internally performed calibrations; verify procedures are current when calibration records are reviewed
Regulatory and statutory documents	List in the compliance obligations register (Clause 4.2); monitor for revision through regulatory subscription or legal counsel; assess impact of regulatory revisions on procedures

Record Retention — Defining and Defending the Periods

ISO 9001:2015 requires that records be retained as documented information but does not specify retention periods for any specific record type. The organization must define its own retention periods based on:

- Regulatory requirements: some industries have specific statutory record retention requirements (aerospace, medical devices, defense contracting) that must be met regardless of organizational preference
- Customer contractual requirements: purchase order terms, quality flow-down requirements, or customer quality agreements may specify record retention periods — often longer than regulatory minimums
- Statute of limitations for product liability: records that may be needed to defend against product liability claims should be retained for the relevant liability period in the applicable jurisdiction
- Organizational operational needs: how long do records provide value for quality improvement, trend analysis, or warranty support? The answer guides the minimum useful retention period independent of legal requirements

Record Type	Recommended Minimum Retention	Drivers
Product inspection and release records	7 to 10 years minimum; product life where longer	Product liability; traceability requirements; customer contractual requirements
Material certifications and traceability records	7 to 10 years; product life in regulated industries	Traceability for product recall or liability purposes; regulatory requirements in aerospace, defense, and medical
Calibration records	5 years or until device is retired + 2 years	Evidence of measurement validity for inspection records made during calibration period
Training and competence records	Duration of employment + 5 years	Evidence that employees were competent at time of quality-affecting actions
Corrective action and CAPA records	5 to 7 years from closure	Evidence of systemic response to quality problems; repeat finding identification
Internal audit records	3 complete audit cycles minimum (3 years)	Surveillance and recertification audit reference; trend analysis across cycles
Management review records	3 years minimum; duration of certification cycle + 1	Evidence of management engagement; surveillance and recertification reference
Supplier evaluation records	5 years or duration of supplier	Evidence of due diligence in supplier qualification; product liability reference

Record Type	Recommended Minimum Retention	Drivers
	relationship + 3 years	

Auditor Perspective

Document control auditing by registrars follows a consistent and thorough pattern. The starting point is the document register — auditors request it and verify that it is current, complete, and internally consistent. The second step is a sample check: select several documents from the register and verify that the current revision in the controlled system matches what the register shows. The third step is the shop floor check: locate the same documents (or others) in active use and verify they are the current revision — not an older version that was not collected when the latest revision was issued. The fourth step, often the most revealing, is the external document check: identify a procedure that references an external standard, find that standard in the document register, and verify that the standard revision listed matches what is actually being used. Missing external documents in the register are a very common minor nonconformance at surveillance audits — the calibration procedure references ASME B89 but the register has no entry for it, so there is no evidence that the organization monitors for standard revisions.

Clause 7 Integration — How the Support Subclauses Interconnect

The subclauses of Clause 7 are not independent requirements — they form an interconnected support system where gaps in any element undermine the others. Understanding these interconnections helps practitioners identify root causes when quality system failures occur, because the failure in one subclause is often driven by a gap in another:

Interconnection	Practical Consequence When the Link Breaks
7.1.5 Calibration feeds 7.5 Records validity	If measuring equipment is uncalibrated, the inspection records created using that equipment are not valid evidence of product conformance. A record that says "dimension measured: 1.0005 in., acceptable" made with an uncalibrated micrometer is not evidence of conformance — it is evidence that a measurement was taken, nothing more.
7.1.6 Organizational Knowledge feeds 7.2 Competence	Organizational knowledge that exists only in experienced employees' heads is a competence single-point-of-failure. When those employees leave, the competence basis for key quality roles is destroyed. Organizational knowledge documentation is the mechanism that makes competence transferable rather than individual.
7.2 Competence enables 7.5 Document effectiveness	A documented procedure executed by an incompetent person produces conforming paperwork and nonconforming product. The procedure cannot substitute for competence; it can only guide competent action. Competence gaps in operational roles undermine the quality of every record those roles produce.
7.3 Awareness enables 7.5 Record accuracy	Employees who do not understand what quality records are for — why they exist and what decisions depend on them — treat record completion as a checkbox exercise. Records filled out without understanding their purpose are less accurate, less complete, and less reliable as evidence. Awareness of why records matter improves record quality.
7.4 Communication enables 7.2 Competence maintenance	When procedures change, competence for the new version must be established in affected personnel. Communication of procedure changes (Clause 7.4) triggers the training and verification cycle (Clause 7.2) that maintains competence in the evolving QMS. Without systematic change communication, competence gaps develop silently as the QMS evolves away from employee knowledge.
7.1.4 Environment affects 7.2 Competence expression	A psychologically unsafe environment — one where employees fear reprisal for raising quality concerns — suppresses the expression of competence even where competence exists. Operators who know they should stop a suspect run but do not because they fear production pressure will override their concern are demonstrating competence failure driven by environment failure.

Quick Reference: Clause 7 Audit Readiness

Clause 7 Comprehensive Conformance Checklist

	Clause	Conformance Item
<input type="checkbox"/>	7.1.1	Resources needed for the QMS are determined, provided, and documented — people, equipment, infrastructure, and external support
<input type="checkbox"/>	7.1.2	Sufficient personnel with appropriate competencies are provided for QMS implementation and process operation and control
<input type="checkbox"/>	7.1.3	Infrastructure required for quality-affecting processes is identified, provided, and maintained — including maintenance programs for critical equipment
<input type="checkbox"/>	7.1.4	Work environment factors affecting product conformance are determined and controlled — physical and human/social factors both addressed
<input type="checkbox"/>	7.1.5	Complete calibration equipment register exists and is current — no measuring devices in active use missing from register
<input type="checkbox"/>	7.1.5	All calibrated devices have current calibration status labels with due date and device ID visible
<input type="checkbox"/>	7.1.5	Calibration records retained for all calibrated devices showing results, traceability, and pass/fail status
<input type="checkbox"/>	7.1.5	Out-of-tolerance response procedure exists and is followed — previous measurement results assessed when device found out of tolerance
<input type="checkbox"/>	7.1.6	Critical organizational knowledge identified and documented — processes where knowledge loss would materially affect quality outcomes
<input type="checkbox"/>	7.1.6	Knowledge capture mechanisms embedded in operations — not just a standalone system that no one uses
<input type="checkbox"/>	7.2	Competence requirements documented for all quality-affecting roles — specific to the role, not generic
<input type="checkbox"/>	7.2	Competence verified for all employees in quality-affecting roles — including contractors and agency staff
<input type="checkbox"/>	7.2	Gap training actions include effectiveness verification — not just training delivery
<input type="checkbox"/>	7.2	Competence records retrievable within minutes for any quality-affecting employee
<input type="checkbox"/>	7.3	All employees can describe Quality Policy commitments in own words when interviewed at random
<input type="checkbox"/>	7.3	Employees are aware of quality objectives relevant to their function — verified through supervisor spot-checks
<input type="checkbox"/>	7.3	Visual management of quality performance data maintains ongoing awareness — not only at training sessions

	Clause	Conformance Item
<input type="checkbox"/>	7.4	Communication plan documents what is communicated, when, to whom, how, and by whom for all QMS-relevant communications
<input type="checkbox"/>	7.4	External communication approach defined — what quality information is shared with customers and suppliers and how
<input type="checkbox"/>	7.5	Document register current and complete — all controlled documents listed with current revision and effective date
<input type="checkbox"/>	7.5	External documents in the document register — customer drawings, referenced standards, regulatory documents
<input type="checkbox"/>	7.5	No obsolete documents accessible as current — superseded versions archived and inaccessible to operational personnel
<input type="checkbox"/>	7.5	Record retention periods defined for all record types and enforced in the records management system

Most Common Clause 7 Audit Findings

Finding Area	Clause	Typical Finding Statement
Calibration register incomplete	7.1.5	Physical verification of production floor measuring devices identified 3 devices in active use that are not listed in the calibration equipment register. No calibration records exist for these devices, and their measurement adequacy for their intended use cannot be confirmed.
Overdue calibration device in use	7.1.5	Micrometer MPC-CAL-0047 (serial number 7749-B) was found in active use on Line 2 with a calibration due date of 14 March — 4 months overdue. No out-of-tolerance investigation was initiated for inspection results made using this device since the expiration date.
Organizational knowledge not captured	7.1.6	Competence matrix identifies two senior quality engineers as holders of critical process knowledge for CMM programming and customer-specific dimensional verification methods. No documented knowledge capture, cross-training records, or succession plan exists for either individual, despite one having notified the organization of intent to retire within 18 months.
Competence not verified	7.2	Training records for CNC machining operators on Line 3 confirm training delivery for MPC-PRO-008 (Machining Process) but contain no competence verification records. Attendance is documented; competence assessed against role requirements is not documented for 4 of 6 operators sampled.
Contractor competence not addressed	7.2	Two contract quality inspectors have been performing inspection and release activities for 4 months. No competence determination or verification records exist for either individual. The staffing agency contract specifies "qualified inspectors" without defining qualification criteria or requiring evidence.

Finding Area	Clause	Typical Finding Statement
Policy awareness failure	7.3	Of 6 employees interviewed at random during production floor walkthrough, 4 were unable to describe the Quality Policy content or connect it to their work. One employee stated they had attended the QMS awareness session at launch but could not recall the Policy content.
External documents not controlled	7.5	MPC-PRO-015 (First Article Inspection) references ASME Y14.5 (Dimensioning and Tolerancing) and AS9102 (First Article Inspection Requirements). Neither document is listed in the document register, and there is no evidence that the organization monitors these standards for revisions or knows whether the current versions are in use.
Obsolete document in use	7.5	MPC-PRO-002 (Nonconforming Material Control), Revision 2, was found posted on a bulletin board in the production area. The document register shows MPC-PRO-002, Revision 3, as the current version. Revision 2 was superseded 4 months ago but was not removed from the production area posting.

Next in Volume 2: Guide 2.4 — Clause 8, Part 1: Operational Planning and Customer Focus. Deep-dive coverage of operational planning and control (8.1), customer communication and requirements determination (8.2.1 and 8.2.2), review of customer requirements before commitment (8.2.3), and design and development (8.3) — with full guidance on when design and development applies, how to design the controls, and how to manage design changes.
