

ISO 9001 IMPLEMENTATION HUB

Volume 1 • Guide 4 of 6

Training & Competence Building

Getting Your People Ready for the QMS

A Practitioner-Level Implementation Guide for Quality Professionals

ISO 9001:2015 • Step-by-Step Roadmap Series

How to Use This Guide

This is Guide 1.4 in the six-part ISO 9001:2015 implementation roadmap. It covers the training and competence phase of implementation — the work that converts a QMS documented on paper into a QMS that 220 employees understand, can describe, and actively apply in their daily work. Documentation without training produces conforming paperwork and nonconforming behavior. Training without documentation produces inconsistent behavior that cannot be audited or improved systematically. Both together are what certification actually requires.

This guide covers Clause 7.2 (Competence) and Clause 7.3 (Awareness) in practitioner depth — not as a clause summary but as an implementation guide for building a competence management system, executing effective QMS awareness training, verifying that training transferred to on-the-job behavior, and maintaining the training records that will satisfy a registrar auditor. It concludes with Meridian's three-phase training rollout across all 220 employees and the competence infrastructure built to sustain the QMS beyond certification.

Where We Are in the Meridian Journey

Denise Alvarez is at the end of Month 5. Phase 1 is complete. Phase 3 documentation development is well underway — 14 of 23 procedures have been approved and issued. Phase 2 support system work on competence and calibration has been running in parallel. The competence matrix framework has been built; the hard work of populating it for all 220 employees, reconstructing historical training records, identifying and closing gaps, and rolling out QMS awareness training to the full workforce is the task of this phase.

Section 1: The Competence Imperative — Why This Phase Is Harder Than It Looks

Of all the implementation phases, the competence and training phase is the one most consistently underestimated in planning and most consequential in audits. Organizations that have excellent documented procedures and well-designed management systems routinely receive major nonconformances in Clause 7.2 because they cannot demonstrate that the people performing quality-affecting work have been determined to be competent to do so.

The reason is almost always the same: training was delivered — sometimes extensively — but competence was not verified, or the evidence that either training or verification occurred is insufficient or missing entirely. The auditor does not doubt that training happened. The auditor simply cannot accept "we trained everyone" as a substitute for records that show who was trained on what, when, by whom, and with what demonstrated result.

The Three Failures of Training in QMS Implementations

Failure 1: Training Delivered, Competence Not Verified

An employee attends a training session, watches a presentation, and signs an attendance sheet. The organization records this as trained and competent. The problem: attendance at training is not evidence of competence. A person can sit through eight hours of machining instruction and still be incapable of producing a conforming part. ISO 9001:2015 requires the organization to determine competence — a present-tense judgment that the person is actually capable of performing their role to the required standard — not merely that training was provided.

Failure 2: Competence Assumed from Experience

Many organizations have long-tenured employees whose competence is genuinely unquestionable. The machinist with 22 years of experience running the CMM does not need to be taught how to use it. But ISO 9001:2015 still requires that the organization has determined and documented what competence is required for that role, has established that this individual meets that requirement (even if the basis is demonstrated experience rather than formal training), and has retained evidence of that determination. "We know he is competent — he has been here for 22 years" is a credible statement. It is not a conforming record.

Failure 3: Training Records That Exist But Cannot Be Found

Some organizations have conducted training religiously for years and have records to prove it — somewhere. The training records are in a binder in the HR office from 2018, on a hard drive that no longer works, or in a filing system that no one currently employed understands. ISO 9001:2015 requires that records of competence be retained as documented information. Retained means retrievable — an auditor who asks to see training records for a specific employee in a specific role should be able to receive them within minutes, not after a two-hour archive search.

Common Pitfall

The most damaging Clause 7.2 finding is not "no training records exist" — it is "training records exist but the organization cannot demonstrate that the training produced competence." An organization that spent \$50,000 on training over three years and has sign-in sheets to prove every session can still receive a major nonconformance if it cannot show that the training content matched the determined competence

requirements for each role, that competence was verified after training was delivered, and that employees found deficient after training were given additional development and re-evaluated. The standard requires a complete cycle: determine requirements, ensure employees meet them, take action where they do not, retain evidence. A training attendance log addresses only the middle element.

Section 2: Clause 7.2 — What the Standard Actually Requires

Clause 7.2 is four sentences. Reading them carefully — not as a compliance checklist but as a system design specification — reveals exactly what must be built. Each sentence is a step in a cycle that the organization must be able to demonstrate has been executed.

Standard Requirement

ISO 9001:2015, Clause 7.2 — Competence: "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 1: "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."

Dissecting the Four Requirements

Requirement A: Determine Necessary Competence

The word "determine" is active and deliberate — it means the organization must make an explicit judgment about what competence each quality-affecting role requires. This determination cannot be implied or informal. It must result in documented competence requirements for each role that are specific enough to be verifiable. Competence requirements typically include a combination of:

- Education: minimum formal educational qualifications, where relevant (engineering roles, quality positions with technical requirements, positions requiring professional credentials)
- Training: specific courses, certifications, or programs that must be completed; internal qualification processes; regulatory or customer-mandated training
- Experience: minimum time in role or in similar roles; demonstrated ability with specific processes, materials, or equipment; prior industry exposure
- Skills: specific technical abilities, physical capabilities, or judgment capacities that can be assessed and verified independently of training credentials

The competence determination must be role-specific — not generic. A "machine operator" competence requirement that applies identically to a CNC machining center operator and a welding operator provides no meaningful guidance. Competence requirements must reflect what each specific role actually needs to perform quality-affecting work effectively.

Requirement B: Ensure Persons Are Competent

Having determined what competence is required, the organization must ensure that the persons performing each role actually possess it. This is a verification step, not a training delivery step. The basis of competence — the

standard explicitly offers education, training, or experience as alternatives, not a hierarchy — must be documented for each individual.

Practical verification methods include: review of education credentials and certifications, observation of the employee performing the work, written or practical skills assessments, supervisor attestation based on direct observation, review of work output samples, and qualification testing for technically demanding roles. The method must be appropriate to the nature of the competence being verified — a supervisor signature on a training record is sufficient verification for some competencies; a documented practical assessment with pass/fail criteria is required for others.

Requirement C: Take Actions Where Competence Is Lacking

When a gap exists between required competence and an individual's current competence, the organization must take action to close it. The standard offers a practical list of options: training, mentoring, reassignment, or hiring/contracting someone who already possesses the required competence. Critically, the standard requires not only that action be taken but that its effectiveness be evaluated — confirming that the action actually produced the required competence.

This effectiveness evaluation requirement is where most organizations fall short. Training is delivered and the case is considered closed. The standard requires more: after the action (training, mentoring, reassignment), the organization must verify that the gap was actually closed. Was the person's competence re-assessed? Did they demonstrate the required capability? The record must show not just what action was taken but what result it produced.

Requirement D: Retain Evidence of Competence

The word "retain" in ISO 9001:2015 terminology means records — evidence of what was done. For Clause 7.2, this means maintaining records that demonstrate all three preceding steps: what competence was determined to be required, that the individual's competence was verified against those requirements, and what actions were taken where gaps were found and with what result. These records must be retrievable, legible, and protected from accidental loss or alteration.

Auditor Perspective

The Clause 7.2 audit follows a specific pattern that every implementation team should anticipate. The auditor selects a role — typically one identified during the shop floor tour as quality-affecting. They ask for the competence requirements for that role. They then select an employee in that role and ask for evidence that the employee meets those requirements. They examine the training records, look for verification of competence beyond attendance, ask the employee directly about their training and qualifications, and observe whether the employee's actual behavior aligns with the documented competence requirements. This sequence — role requirements to individual verification to behavioral observation — is what the competence management system must be able to support for every quality-affecting role in the organization.

Section 3: Building the Competence Matrix

The competence matrix is the organizing document that makes the Clause 7.2 cycle manageable at scale. It is a structured tool that maps every quality-affecting role in the organization against the competence requirements for that role, and then maps every individual employee against those requirements — showing at a glance who is currently competent, who has gaps, and what actions are planned or underway to close those gaps.

The competence matrix is not a mandatory document under ISO 9001:2015 — but it is the most effective single tool available for satisfying Clause 7.2 at an organizational scale. An organization with 50 employees and five quality-affecting roles might manage Clause 7.2 without a formal matrix; an organization with 220 employees across 18 quality-affecting roles cannot.

Step 1: Identify Quality-Affecting Roles

The first step in building the competence matrix is identifying which roles in the organization affect QMS performance and effectiveness. This is broader than "quality roles" — it encompasses anyone whose work influences whether products and services meet requirements. In most manufacturing organizations this includes:

Function	Quality-Affecting Roles to Include
Production / Operations	All operators, setup technicians, and machine operators who perform production steps. Production supervisors and leads who make quality decisions. Material handlers whose work affects product identification and preservation.
Quality	Quality inspectors, quality engineers, calibration technicians, Quality Manager. All quality roles are by definition quality-affecting.
Engineering	Process engineers, design engineers (if D&D in scope), manufacturing engineers who develop and maintain work instructions and control plans.
Purchasing / Supply Chain	Purchasing agents and managers who select and evaluate suppliers, approve purchase requisitions, and manage supplier relationships affecting product quality.
Receiving and Shipping	Receiving inspectors who verify incoming materials. Shipping personnel who pack and handle finished goods.
Maintenance	Maintenance technicians who perform preventive and corrective maintenance on production and measurement equipment.
Sales / Customer Service	Account managers who determine and communicate customer requirements. Customer service personnel who handle complaints and returns.
Management	Department managers who own QMS processes. The Management Representative. Top management with QMS accountability.

Roles that do not affect QMS performance and effectiveness — administrative support, janitorial services, non-production-facing IT — do not need to be included in the competence matrix, though all employees must receive QMS awareness training per Clause 7.3.

Step 2: Define Competence Requirements Per Role

For each quality-affecting role, document the specific competence requirements across the four dimensions: education, training, experience, and skills. The level of specificity should be sufficient for a supervisor to make a yes/no determination of whether a given individual meets the requirement — vague requirements produce vague assessments.

Example competence requirement specifications for three Meridian roles:

Role	Competence Requirements
CNC Machining Operator	<p>Education: High school diploma or equivalent. Training: Completed MPC new-employee orientation; completed MPC-WI-001 (CMM Operation) qualification; completed MPC-PRO-008 (Machining Process) training with supervisor sign-off; completed measurement equipment use training for all gages assigned to role. Experience: Minimum 6 months supervised operation of CNC machining equipment prior to unsupervised operation. Skills: Ability to read and interpret engineering drawings and GD&T; ability to operate assigned measurement equipment and record results accurately; ability to identify nonconforming conditions and initiate NCR process per MPC-PRO-002.</p>
Quality Inspector	<p>Education: High school diploma or equivalent; technical coursework in metrology, inspection, or quality preferred. Training: Completed MPC QMS awareness training; completed training on all applicable inspection procedures and work instructions; completed measurement systems training for all assigned equipment; completed MPC-PRO-016 (Inspection and Release) training with demonstrated proficiency assessment. Experience: Minimum 2 years inspection experience in precision manufacturing environment. Skills: Ability to interpret engineering drawings, GD&T, and customer specifications; proficiency with assigned measurement equipment (CMM, surface plate, optical comparator, precision hand tools); ability to make independent accept/reject decisions and document them accurately; ability to complete First Article Inspection reports.</p>
Purchasing Manager	<p>Education: Bachelor's degree in business, supply chain, or related field, or equivalent experience. Training: Completed MPC QMS awareness training; completed MPC-PRO-006 (Supplier Qualification and Evaluation) training; completed MPC-PRO-007 (Purchasing Controls) training; completed ISO 9001 supplier management awareness (internal or external training). Experience: Minimum 5 years purchasing or supply chain experience; minimum 2 years in manufacturing environment with quality system requirements. Skills: Ability to evaluate supplier quality systems and performance data; ability to communicate quality requirements in purchase documents; ability to manage supplier relationships while maintaining quality requirements.</p>

Step 3: Assess Current Competence for Each Employee

With competence requirements defined for each role, the next step is assessing each employee in that role against those requirements. This assessment should be conducted by the employee's direct supervisor — the

person with daily visibility into the employee's work — with input from HR for education and credential verification and from Quality for technical skill assessment where applicable.

The assessment produces one of three findings for each competence requirement:

- Meets requirement: The employee demonstrably meets this competence requirement based on verified education, documented training, demonstrated experience, or observed skill proficiency. Evidence exists to support this finding.
- Partially meets requirement: The employee meets some elements of the requirement but has identified gaps. A development action is needed and the timeframe for resolution is defined.
- Does not meet requirement: The employee does not currently meet this requirement. Immediate action is required: additional supervision, reassignment, or restricted duties until competence is achieved.

Step 4: Build the Competence Matrix Document

The competence matrix document consolidates role requirements and individual assessments into a single navigable format. The most common formats:

- Role-by-competence matrix: Rows are competence requirements; columns are employees in that role. Each cell shows assessment status (Met / Partial / Gap) and evidence reference. Best for small teams where all employees share the same role requirements.
- Employee-by-role matrix: Rows are employees; columns are the roles they hold or are qualified for. Useful for organizations where employees perform multiple roles or cross-qualification is tracked.
- Skill inventory grid: A heat-map style matrix showing all quality-affecting competencies across the organization — useful for identifying single points of failure where only one employee holds a critical competency.

Best Practice

The single-point-of-failure analysis is one of the most valuable outputs of a well-built competence matrix. When the matrix reveals that only one employee is qualified to perform a critical quality function — operate the CMM, conduct First Article Inspections, evaluate incoming material against material certifications — the organization has identified a business continuity risk, not just a training gap. Cross-training plans triggered by single-point-of-failure identification are both a Clause 7.2 conformance action and a genuine operational resilience investment. This is where the competence matrix pays dividends far beyond QMS compliance.

Step 5: Build and Execute the Gap Training Plan

Every identified competence gap requires a documented action plan: what training or development will be provided, by when, who is responsible, and how competence will be verified after the action is complete. The gap training plan is a living document — it should be reviewed monthly during the implementation and updated as gaps are closed and new employees join or change roles.

Gap Description	Employee(s)	Action Required	Completion Date	Verification Method
CMM qualification not documented for role	J. Torres, R. Singh	Complete MPC-WI-001 qualification	Month 6, Week 2	Supervisor sign-off on practical

Gap Description	Employee(s)	Action Required	Completion Date	Verification Method
		assessment with supervisor observation		assessment form MPC-FRM-014
GD&T interpretation skills — not assessed	All 14 machining operators	Schedule GD&T fundamentals training (internal: 4-hour session)	Month 7	Written assessment: minimum 80% pass score
First Article Inspection procedure — new procedure, all inspectors	All 4 quality inspectors	Procedure awareness training + supervised FAI on live job	Month 8	Supervised FAI completed with quality manager sign-off
Supplier qualification procedure — new to purchasing team	S. Kim (PM), 2 purchasing agents	MPC-PRO-006 procedure training + walkthrough of first 5 supplier evaluations	Month 6	Supervisor observation during first independent supplier evaluation
ISO 9001 QMS awareness — all employees	All 220 employees	Three-session rollout per Phase 3 plan (see Section 6)	Month 7	Session attendance record; spot-check awareness questions by supervisors

Section 4: Training Records — What Auditors Actually Need to See

Training records are the evidence that Clause 7.2's first three requirements have been executed. They are not bureaucratic artifacts — they are the proof that the organization has taken its competence obligations seriously enough to document them. An auditor who cannot find adequate training records will issue a nonconformance regardless of how confident supervisors are in their employees' abilities.

The Minimum Record Requirements

For each employee in a quality-affecting role, the competence record set must be able to answer five questions:

#	Question	Evidence Required
1	What competence is required for this role?	The competence requirements document or competence matrix for the role — not an individual record but a role-level document that establishes the standard against which individuals are assessed
2	What is this employee's educational background?	Education verification: diploma or degree copies, certification copies, license records, or employer-verified credential review records
3	What training has this employee received?	Training records: session attendance records, online completion certificates, internal training sign-off sheets — showing the training topic, delivery date, format, and trainer or provider
4	Has this employee's competence been verified?	Competence verification records: supervisor assessment forms, practical test results, qualification sign-offs, performance observation checklists — showing that the employee was observed or tested against the competence requirements
5	What actions were taken for any identified gaps, and did they work?	Gap training records plus effectiveness verification records: documentation of the additional training provided, re-assessment results, and supervisor determination that the gap was closed

The Historical Records Problem — and How to Solve It

The most common training record challenge in first-time ISO 9001 implementations is the historical gap: experienced employees have been competently performing their roles for years with minimal or no documentation of how they acquired that competence. A machinist hired in 2015 who has been producing quality product for nine years may have no training records from their onboarding or subsequent skill development.

ISO 9001:2015 does not require the organization to reconstruct the entire training history of its workforce. What it requires is that current competence is documented. For experienced employees with established performance records, the solution is a competence attestation process: a structured supervisor review that documents the basis for determining the employee competent — typically a combination of employment history, education credentials, observed job performance, and supervisor professional judgment.

The competence attestation record should include:

- Employee name, role, and department
- The competence requirements for the role (by reference to the competence matrix)
- For each requirement: the basis of competence (education credential, prior experience, employer verification, direct observation) and a pass/partial/fail determination
- Identified gaps and planned actions
- Supervisor signature and date of assessment
- Management Representative or HR countersignature

Once the attestation is complete and on file, the organization has a documented determination of current competence that satisfies Clause 7.2(b) and (d). Gaps identified through the attestation become items in the gap training plan that satisfies 7.2(c).

Record Format and Storage

Training records must be retained as documented information — which means they must be organized, retrievable, and protected from alteration or loss. The practical requirements:

- An individual training file or record set for each employee in a quality-affecting role, either electronic or paper, organized so that all relevant records for any individual can be retrieved in a single access
- A training record index or log that provides a summary view — who has been trained on what, when, and with what verification result — without requiring the full record set to be opened for every inquiry
- A defined retention period for training records; ISO 9001:2015 does not specify a retention period, but most quality systems retain training records for the duration of employment plus a defined period afterward (commonly three to seven years); customer and regulatory requirements may impose longer retention
- Access controls preventing unauthorized modification while allowing authorized personnel to retrieve and review records without obstruction

Meridian Case Study

Meridian Training Record Reconstruction: The competence records reconstruction work package (2.3 from the implementation WBS) consumed 52 hours of combined HR and supervisor time over six weeks — the most labor-intensive support system task in the implementation. James Thornton (HR Manager) coordinated the work: he created an individual competence file folder in SharePoint for each of the 178 employees in quality-affecting roles, populated each file with the education records already in the HR system, and then distributed role-specific competence attestation forms to each department supervisor. Supervisors completed attestation assessments for each employee in their area over a three-week period, working through the competence matrix requirements systematically. The process identified 34 employees with documented gaps requiring training action — a number that would not have been visible without the matrix. The gap training plan that resulted became the driver of Meridian's structured training calendar for Months 6 through 8.

Section 5: Clause 7.3 — Awareness vs. Competence

Clause 7.2 addresses competence: the ability to perform quality-affecting work to the required standard. Clause 7.3 addresses awareness: the understanding of how one's work connects to the QMS and its quality outcomes. These are distinct requirements, and the distinction matters for training design. A CNC machinist needs both — competence to operate the machine and produce conforming parts, and awareness of why the QMS exists, what the Quality Policy commits the organization to, and how their work contributes to or undermines those commitments.

Standard Requirement

ISO 9001:2015, Clause 7.3 — Awareness: "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."

The Four Awareness Elements — In Plain Language

Awareness Requirement	What Employees Should Be Able to Say
"The quality policy"	"Our Quality Policy commits us to [key commitments in plain language]. I know where to find it if I need to reference it." Note: employees do not need to recite the policy verbatim. They need to understand its general meaning and commitments.
"Relevant quality objectives"	"The quality goals most relevant to my work are [specific objectives]. I know what we are trying to achieve and how my work affects whether we get there." Note: not all employees need to know all objectives — those relevant to their function are sufficient.
"Contribution to QMS effectiveness and benefits of quality improvement"	"When I [specific quality behavior], it contributes to [specific quality outcome]. When we improve quality performance, the benefit is [real, tangible outcome for the business and for me personally]."
"Implications of not conforming"	"If I do not follow [specific procedure or requirement], the consequence is [specific quality or business outcome — customer return, rework, potential injury, loss of certification, customer loss]."

Why Awareness Training Typically Fails

QMS awareness training delivered as a compliance exercise produces compliance-level awareness: employees who know they went to a QMS training session but cannot describe what the Quality Policy says or how their work connects to quality outcomes. This failure is caused by three predictable design mistakes:

- Abstract language disconnected from daily work: Training that presents ISO clause numbers, quality management theory, and organizational policy language without connecting to what employees actually do every day produces awareness of the training event, not awareness of the QMS. Effective training speaks the language of the employees being trained.
- One-size-fits-all content: A machining operator and a purchasing manager have different quality-affecting roles, different relevant objectives, and different implications of nonconformance. Training that is identical

for both fails both. Effective awareness training has a common core and role-specific content that makes the connection between this specific job and QMS effectiveness explicit.

- Training as an event rather than a practice: A single ninety-minute awareness session at QMS launch satisfies the training record requirement but rarely produces sustained awareness. Employees who heard about the Quality Policy once eighteen months ago and have not encountered it since cannot be said to be meaningfully aware of it. Effective awareness builds it into ongoing operations: supervisors reference quality objectives in team meetings, quality metrics are visible in the work area, the policy is referenced in performance discussions.

Kaizen Connection

The Kirkpatrick Four-Level evaluation model — originally developed for corporate training effectiveness assessment — maps directly onto ISO 9001's awareness and competence requirements. Level 1 (Reaction): Did employees find the training relevant and useful? Level 2 (Learning): Did training produce the understanding and knowledge required? Level 3 (Behavior): Are employees demonstrating the required behaviors on the job after training? Level 4 (Results): Is the training producing measurable quality outcomes? ISO 9001:2015 Clause 7.2(c) requires evaluation of effectiveness — which is a Kirkpatrick Level 3 or 4 evaluation. Organizations that evaluate training effectiveness only at Level 1 (smile sheets) are meeting the spirit of the requirement at the lowest possible threshold. Organizations that track Level 3 behavior change — through supervisor observation, quality metric trending, and audit findings — are demonstrating genuine commitment to training effectiveness.

Section 6: Designing QMS Training That Changes Behavior

This section provides a practical framework for designing and delivering QMS training that satisfies both the letter of the standard's requirements and the spirit of its intent — training that actually changes how employees think about and perform quality-affecting work, not training that produces a signature on an attendance sheet.

The Three-Tier QMS Training Architecture

An effective QMS training program operates at three tiers, each with a distinct purpose, audience, and content design:

Tier	Audience	Purpose	Typical Format and Duration
Tier 1: QMS Awareness	All employees — including non-quality-affecting roles	Satisfy Clause 7.3; build organizational understanding of why the QMS exists and how it connects to each person's work	60 to 90 minutes; group session; delivered by Management Representative or senior manager
Tier 2: Role-Specific Procedure Training	All employees in quality-affecting roles	Satisfy Clause 7.2; train employees on the specific procedures, work instructions, and controls governing their role	Variable: 30 minutes to 4 hours per procedure; delivered by supervisor or process owner; includes hands-on demonstration
Tier 3: Technical Competence Development	Employees with identified competence gaps; new employees in technical roles	Close specific competence gaps identified through the competence matrix assessment; build new capabilities for role qualification	Variable: hours to weeks depending on competence required; may include formal coursework, on-the-job training, mentoring, or external certification

Tier 1: Designing the QMS Awareness Session

The QMS awareness session is the organization-wide training that introduces the QMS to all employees. It must cover all four Clause 7.3 elements and do so in language that is meaningful to employees across all functions and levels. The following session design has proven effective in manufacturing environments:

Session Element	Content and Delivery Guidance
Opening: Why This Matters (15 minutes)	The business context for certification: customer requirements, competitive position, what ISO 9001 certification means to the company's future. Delivered by the CEO or senior executive — not the Quality Manager. This signals organizational priority. If leadership does not show up to explain why this matters, employees correctly conclude that it does not.

Session Element	Content and Delivery Guidance
The Quality Policy (10 minutes)	Read and explain the Quality Policy in plain language. Connect each commitment to daily work examples. Ask employees what they think the policy means for their specific job. Distribute a laminated card or wallet-sized version. Post the policy in work areas.
Quality Objectives Relevant to This Group (10 minutes)	Present the two to three quality objectives most relevant to this audience. Show current performance against target. Explain how this group's work affects those numbers. Use real data from the past 90 days.
How Your Work Connects (15 minutes)	The most critical segment. Use specific, role-appropriate examples: "When a machinist catches a setup error during first-piece inspection instead of running 50 bad parts, here is what that prevents — and here is the cost when it is not caught." Connect individual behavior to quality outcomes in concrete terms employees recognize.
Implications of Not Conforming (10 minutes)	Real examples — from within the organization or from the industry — of what happens when quality requirements are not followed. Customer returns, rework costs, certification risks, customer loss. Not to create fear but to create understanding of why procedures and controls exist.
The QMS Structure (10 minutes)	Brief overview of the QMS: what procedures govern their work, how to find them, who to ask when they have questions, how to report a quality problem or suggest an improvement. The goal is navigation, not comprehension of the full system.
Questions and Discussion (10 to 15 minutes)	Open Q&A. The questions employees ask reveal both what landed in the session and what the organization should reinforce through follow-up communications.

Tier 2: Role-Specific Procedure Training

Procedure training is the competence-building training that employees in quality-affecting roles receive on the specific procedures and work instructions governing their work. This training is distinct from QMS awareness — it is not about understanding the QMS in general but about being able to perform specific quality-critical tasks per the documented process.

Effective procedure training follows a consistent four-step model:

1. **Explain the why:** Before teaching the steps, explain why this procedure exists — what quality problem or risk it prevents, what happens if it is not followed. Employees who understand the purpose of a procedure follow it more reliably than employees who were simply told the steps.
2. **Walk through the procedure:** Review the procedure document together, step by step. Explain any decision points or judgment calls. Identify the records that must be created and show where they are filed. Answer questions about specific steps before anyone attempts to follow them independently.
3. **Demonstrate:** The trainer or a competent peer performs the process in the actual work environment while the employee observes. Narrate the decision points. Show what conforming and nonconforming situations look like.
4. **Supervised practice with sign-off:** The employee performs the process under supervision. The supervisor or trainer observes for procedural adherence, correct decision-making, and accurate record completion.

Sign-off on the training record confirms that the employee demonstrated the required competence — not merely that they were present for the training.

Common Pitfall

The most common Tier 2 training failure is conducting step 1 and 2 without steps 3 and 4 — reviewing the procedure with employees but not observing them perform it. This produces employees who have read the procedure but whose on-the-job behavior has not been verified against it. ISO 9001:2015 requires that competence be ensured, not that training be delivered. A procedure walkthrough session followed by a supervisor sign-off saying "trained" — without the employee ever having demonstrated the procedure under observation — will not satisfy an auditor who asks to see evidence of competence verification. The supervised practice and observation step is not optional.

Tier 3: Technical Competence Development

Technical competence development addresses specific skill gaps identified through the competence matrix assessment. Unlike awareness training (one-to-many) and procedure training (process-specific), technical competence development is often tailored to specific individuals or small groups with identified gaps. Common forms include:

- Formal external training: Industry courses, certification programs, technical seminars. Appropriate for foundational technical skills (GD&T, metrology, welding, SPC) where the organization cannot develop adequate internal training content.
- Structured on-the-job training with a mentoring plan: A defined period of working alongside a competent peer or supervisor, with specific competence milestones to be demonstrated at defined intervals. Most effective for complex technical roles where mastery develops through practice over time.
- Internal expert-led training: Designed and delivered by an internal subject matter expert. Cost-effective for role-specific technical skills where internal expertise exists. Requires that the trainer's own competence is documented.
- Job rotation or cross-training: Temporary assignment to a different role or process to develop competence through direct experience. Used both for gap closure and for building organizational redundancy in critical competencies.
- External certification programs: Industry-recognized qualifications (AWS welding certifications, ASNT inspection certifications, ASQ quality certifications) that provide independent verification of competence against an external standard. Particularly valuable in regulated industries.

Section 7: New Employee Onboarding — Building Competence from Day One

The competence management system must extend beyond existing employees to cover new hires. Every employee who joins the organization in a quality-affecting role must go through the competence determination and training cycle — regardless of their prior experience. ISO 9001:2015's Clause 7.2 applies to persons doing work under the organization's control, which includes new employees from their first day.

The new employee QMS onboarding program should be designed at the start of the implementation and documented as a standard onboarding process — not improvised for each new hire. It typically consists of three elements delivered in the first 30 to 90 days of employment:

Element 1: Day-One QMS Orientation (First Day)

On the first day, every new employee receives an orientation that covers: the organization's Quality Policy and what it means, the employee's role in the QMS and their quality-affecting responsibilities, how to find and use QMS documents, how to report a quality problem or nonconformance, and who to contact with quality questions. This orientation is separate from general HR onboarding — it specifically addresses QMS awareness and is documented in the training record.

Element 2: Role-Specific Procedure Training (Days 2 to 30)

Within the first 30 days, the new employee completes training on all procedures and work instructions governing their quality-affecting role. This training follows the four-step model described in Section 6: explain the why, walk through the procedure, demonstrate, and supervised practice with sign-off. The training is delivered by the employee's supervisor or a designated competent peer, not by the quality department.

The employee is not considered independently competent to perform quality-affecting work without supervision until the procedure training and supervised practice for that specific process is complete and signed off. For complex technical roles, this supervised period may extend well beyond 30 days.

Element 3: Competence Verification and Matrix Entry (Days 30 to 90)

By the end of the first 90 days, a formal competence assessment for the new employee is completed and the competence matrix is updated. The assessment evaluates competence against all requirements for the role, identifies any remaining gaps, and documents the basis of current competence determination. The completed assessment is added to the employee's competence record file.

Best Practice

Design the new employee QMS onboarding checklist as a controlled document with a tracking version that becomes the training record for each new employee. The checklist lists every onboarding training step with columns for: training topic, delivery method, trainer name, date completed, and supervisor sign-off confirming competence. When the checklist is complete, it becomes the primary training record for the new employee's first 90 days — a single document that demonstrates the full onboarding training cycle was completed. This approach is both operationally efficient and highly auditor-friendly: one document tells the complete story of how this employee was onboarded into quality-affecting work.

Section 8: Training Records — The Complete System

This section provides a complete blueprint for the training records system that will satisfy Clause 7.2(d) and survive registrar auditor scrutiny. The system must be simple enough to maintain consistently and comprehensive enough to answer any audit question about any quality-affecting employee's training and competence history.

The Five Essential Record Types

Record Type	Purpose and Content
Competence Requirements Document (per role)	Documents what competence is required for each quality-affecting role. Maintained as a controlled document. Updated when roles change. Referenced by individual training records as the standard against which individuals are assessed.
Individual Training Record / Competence File	The master record for each employee — contains or references all evidence of that employee's competence: education credentials, training certificates, internal training sign-offs, competence attestations, assessment results, gap actions and their outcomes. Organized so any element can be retrieved in minutes.
Training Attendance / Completion Record	Documents group training sessions: date, topic, trainer, attendees, duration, and any assessment conducted. Signed by trainer. Filed in the training records system and cross-referenced from individual employee records.
Competence Assessment / Verification Form	Documents the outcome of a competence verification event: who was assessed, against what requirements, by whom, using what method, on what date, with what result. Essential for demonstrating that 7.2(b) was met for each employee — that competence was ensured, not merely assumed.
Gap Training Action and Effectiveness Record	Documents identified competence gaps, the actions taken to close them, and the effectiveness verification results. Demonstrates that 7.2(c) was fully executed — action taken and effectiveness evaluated.

The Training Records Audit Trail

For any quality-affecting employee selected by an auditor for review, the training records system should support the following complete audit trail within ten minutes:

5. Retrieve the competence requirements for the employee's role from the competence matrix or role competence document
6. Retrieve the employee's individual training record showing education credentials on file
7. Retrieve all internal training records showing procedure and work instruction training received, with dates and trainer signatures
8. Retrieve the competence assessment record showing that the employee's competence was verified against role requirements
9. Retrieve any gap training records showing identified gaps, actions taken, and effectiveness verification results
10. Confirm the competence matrix entry for this employee reflects current competence status

An organization whose training records system can deliver this complete trail for any employee within ten minutes has a genuinely conforming Clause 7.2 record system. An organization that must search multiple filing systems, ask multiple people, and still cannot produce all elements has a records management problem that will produce audit findings.

Retention Periods for Training Records

ISO 9001:2015 does not specify minimum retention periods for training records. The organization must determine appropriate retention based on: the nature of the quality-affecting role (safety-critical and regulated roles warrant longer retention), customer and contractual requirements (many aerospace and defense customers require training records to be retained for the life of the product or program), applicable regulations, and the organization's own liability management considerations.

Record Type	Recommended Minimum Retention
Employee competence files (all training and assessment records)	Duration of employment + 5 years minimum; longer where customer or regulatory requirements apply
Training attendance records for group sessions	5 years from session date, or duration of employment of youngest attendee + 3 years
Competence assessment records	Duration of employment + 5 years
Gap training action and effectiveness records	Duration of employment + 5 years; cross-reference to associated CAPA record if applicable
Competence requirements documents (role specifications)	Current version controlled; all prior versions retained for minimum 5 years from supersession date
New employee onboarding checklists	Duration of employment + 5 years

Section 9: Clause 7.4 — Communication

Clause 7.4 requires the organization to determine the internal and external communications relevant to the QMS — what to communicate, when to communicate, to whom, how, and who does the communicating. While simpler than Clause 7.2, the communication requirement is frequently under-documented: organizations communicate about quality constantly but rarely have a planned, systematic communication approach that can be demonstrated to an auditor.

Standard Requirement

ISO 9001:2015, Clause 7.4 — Communication: "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."

Internal QMS Communication Requirements

The most important internal communication requirements in a functioning QMS include:

What to Communicate	How and When	Who Communicates
Quality Policy — initial rollout and ongoing reinforcement	Awareness training session; posted in work areas; referenced in performance discussions; new employee orientation	Management Representative and supervisors
Quality Objectives — current performance and trends	Monthly team meetings; visible performance boards in work areas; management review outputs shared with relevant functions	Management Representative; department managers
New or revised QMS procedures	Procedure awareness sessions before effective date; supervisor briefings; change notices in controlled document system	Process owners and supervisors
Internal audit findings and corrective actions	Audit closing meeting; corrective action assignments to responsible parties; follow-up verification status updates	Lead internal auditor; Management Representative
Quality performance data — metrics, trends, issues	Regular quality meetings; visual management boards; management review	Quality Manager; department managers
Management review decisions and actions	Management review minutes distributed to relevant functions; actions assigned with owners and due dates	Management Representative; CEO

What to Communicate	How and When	Who Communicates
Customer quality feedback — complaints, returns, satisfaction data	Shared with relevant operational functions as appropriate; included in management review inputs	Quality Manager; Sales Manager

External QMS Communication

External communication requirements under Clause 7.4 are less prescriptive — the standard requires the organization to determine what external communication is relevant to its QMS. Common external QMS communications include: customer notification of quality issues affecting delivered product, supplier communication of quality requirements (addressed more fully in Clause 8.4), responses to customer quality questionnaires or audit requests, and communication of certification status to customers and other interested parties.

The communication plan document does not need to be elaborate. A one-page table identifying each type of QMS communication, its audience, frequency, method, and owner satisfies the documented information requirements and provides auditors with clear evidence that the organization has thought through its communication approach systematically.

Section 10: Meridian's Three-Phase Training Rollout

This section describes Meridian's complete training and competence implementation across all 220 employees — from the competence matrix framework built in Phase 2 through the full training rollout in Phase 3 and the sustaining competence management system established for ongoing operations. The Meridian approach is presented as a complete worked example that can be adapted to any mid-size manufacturing organization.

Training Program Overview

Phase	Audience	Timing	Content and Objectives
Phase A: Leadership and Management Training	22 people: CEO, 8 senior managers, 13 department supervisors and team leads	Months 4 to 5	ISO 9001:2015 requirements for their specific roles; personal audit preparation; QMS leadership behavior expectations; management review process; their role in competence management; their role in procedure training delivery for their teams
Phase B: Quality-Affecting Employee Training	156 people: all operators, inspectors, engineers, purchasing, sales, receiving, shipping, and maintenance roles	Months 6 to 7	QMS awareness session; role-specific procedure training for all applicable procedures; competence assessment completion; gap training for identified deficiencies
Phase C: Organization-Wide Awareness Completion	42 remaining employees: administrative, IT, non-quality-affecting support functions	Month 7	QMS awareness session only (Clause 7.3); no procedure training required for non-quality-affecting roles

Phase A: Leadership and Management Training

Phase A began in Month 4 — before the main procedure training rollout — for a deliberate reason: supervisors needed to understand the QMS and their role in it before they could train their teams on procedures. A supervisor who does not understand why a procedure exists cannot credibly train their team on it, and cannot reinforce it in daily operations. Building leadership competence first created the internal training capacity that Phase B depended on.

The Phase A program was delivered over three sessions:

- Session A1 — Executive Leadership Briefing (Half day; CEO and 8 senior managers): Delivered by an external ISO 9001 consultant. Content: the standard's leadership requirements (Clause 5); what top management must personally demonstrate; management review requirements and how to chair an effective review; how registrars audit leadership; how to respond to auditor questions about quality accountability. Robert Nolan found this session clarifying — he arrived with a general sense of his QMS

responsibilities and left with specific, actionable understanding of what the registrar would expect from him personally at Stage 2.

- Session A2 — Supervisor and Team Lead Training (Full day; 13 supervisors and leads): Delivered by Denise Alvarez with external consultant support. Content: QMS structure and their process ownership responsibilities; how to conduct procedure training using the four-step model; competence attestation and the competence matrix; how to complete training records; what to expect from internal auditors; how to answer auditor questions during Stage 2 shop floor walkthroughs.
- Session A3 — Procedure Owner Training (Half day; procedure owners not already covered in A2): Training specific to the procedure review and approval responsibilities of process owners who would be authoring or approving Phase 3 procedures.

Phase B: Quality-Affecting Employee Training

Phase B was the largest training effort — 156 employees receiving both QMS awareness training and role-specific procedure training over a six-week period. Denise coordinated the schedule; delivery was almost entirely by department supervisors who had been trained and equipped in Phase A.

QMS Awareness Sessions

Denise designed a single 75-minute QMS awareness session and delivered it eight times across two weeks — running four sessions per week across both shifts to ensure all quality-affecting employees could attend without disrupting production scheduling. Each session was capped at 25 employees to preserve the discussion and Q&A character of the session.

Robert Nolan attended and opened two of the eight sessions personally — both in high-visibility production areas. The effect on employee perception of the QMS's organizational priority was, by Denise's and supervisors' consistent reports, immediate and significant. Employees who saw the CEO attending a quality training session took the message differently than employees who received the session as a quality-department initiative.

Role-Specific Procedure Training

Procedure training was conducted by department supervisors, not by the quality department. Denise provided each supervisor with a procedure training kit for each applicable procedure: the procedure document itself, a one-page trainer guide summarizing the key points and common misunderstandings, the applicable form or record template, and a training record sign-off sheet. Supervisors conducted the training in their work areas — at the machine, at the inspection station, at the receiving dock — not in a conference room.

The on-the-job training location was a deliberate design decision. Training conducted at the point of use is more relevant, more memorable, and more directly transferable to behavior than training conducted away from the work environment. When a machinist learns the nonconforming material procedure standing next to the red-tagged quarantine area where nonconforming parts are physically held, the connection between the procedure and daily reality is immediate and tangible.

Phase B Results

By the end of Month 7, Denise had achieved the following against the Phase B training targets:

- 156 employees completed the QMS awareness session (100% of Phase B target)

- 148 employees completed all required procedure training for their role (95% of Phase B target; 8 employees on approved leave)
- 138 employees had completed competence assessments with supervisor sign-off (88% of target; remainder in process)
- 34 identified competence gaps reduced to 11 still in remediation, with all 11 having active training plans in progress
- 0 employees identified as performing quality-affecting work without any competence documentation — a baseline of zero that would not have been achievable without the competence matrix framework

Meridian Case Study

The Surprise Finding from Phase B: During Phase B supervisor-led procedure training, Meridian's Production Supervisor Marco Pedraza discovered that four of his machining operators had been using an undocumented shortcut in the first-piece inspection process — skipping the check of two dimensions on the inspection plan for a specific part family because "they always come out fine." The skip had been informal practice for at least two years. Marco documented the finding as a potential nonconformance and brought it to Denise, who opened a corrective action. The root cause analysis revealed that the inspection criteria for this part family had been verbally communicated as "priority dimensions only" by a former quality manager who had since left — a case of undocumented process change creating unauthorized practice variation. The corrective action updated the inspection procedure, retrained the four operators, and verified that the skipped dimensions were in fact consistently within specification (they were). The nonconformance was internal and addressed before Stage 2. This is exactly what a well-designed training program should produce: revealing what is actually happening in the work, not just confirming that employees can recite what should happen.

Phase C: Organization-Wide Awareness Completion

The 42 employees in non-quality-affecting roles received the same 75-minute QMS awareness session as Phase B employees. While their work does not directly affect QMS performance and effectiveness, organizational coherence and morale are served by including all employees in understanding why the organization is pursuing certification and what the QMS means for the business they work for. All 42 completed the session in Month 7 and their attendance was documented in a group training record.

The Sustaining Competence System

The training rollout completed, Meridian established three mechanisms to sustain the competence management system beyond certification:

- Annual competence review: Each department supervisor conducts an annual review of the competence matrix for their function, updating assessments for any employees who changed roles, acquired new qualifications, or had performance observations indicating competence concerns. The review is documented and submitted to HR and the Management Representative.
- New employee standard onboarding: The QMS onboarding checklist (see Section 7) was incorporated into Meridian's standard HR onboarding process. Every new employee in a quality-affecting role now enters the competence cycle automatically, without requiring quality department coordination for each new hire.
- Procedure change training triggers: The document control procedure was updated to require that any procedure revision triggers a re-training notification to the procedure's process owner, who is then responsible for communicating the change to affected employees and documenting the communication. Changes to documented procedures that are not communicated to the people who follow them are a common post-certification quality system degradation mechanism — the trigger discipline prevents it.

Quick Reference: Training and Competence Essentials

The Clause 7.2 Compliance Checklist

	Requirement
<input type="checkbox"/>	Competence requirements determined and documented for every quality-affecting role (not just "quality" roles — all roles that affect QMS performance and effectiveness)
<input type="checkbox"/>	Every employee in a quality-affecting role assessed against the competence requirements for their role
<input type="checkbox"/>	Assessment basis documented for each employee: education credentials on file, training records on file, experience verified, skills assessed
<input type="checkbox"/>	Historical competence attestation completed for long-tenured employees without formal training records
<input type="checkbox"/>	All identified competence gaps have documented action plans with owners, timelines, and verification methods
<input type="checkbox"/>	All completed gap training actions have effectiveness verification records showing the gap was closed
<input type="checkbox"/>	No employee performing quality-affecting work without documented competence determination
<input type="checkbox"/>	Competence matrix current and accessible to auditors
<input type="checkbox"/>	Individual training records for all quality-affecting employees organized and retrievable within minutes
<input type="checkbox"/>	Training record retention policy defined and implemented
<input type="checkbox"/>	New employee onboarding process documents the complete first-90-day competence cycle
<input type="checkbox"/>	Procedure change training trigger mechanism in place — new procedure revisions automatically trigger re-training communications

The Clause 7.3 Awareness Compliance Checklist

	Requirement
<input type="checkbox"/>	All employees (not just quality-affecting roles) made aware of the Quality Policy and its meaning
<input type="checkbox"/>	Employees aware of quality objectives relevant to their function — not all objectives for all employees, but the objectives their work affects
<input type="checkbox"/>	Employees can describe how their specific work contributes to QMS effectiveness
<input type="checkbox"/>	Employees understand the implications of not conforming with QMS requirements as they apply to their role

	Requirement
<input type="checkbox"/>	Awareness training documented for all employees with dates and attendance records
<input type="checkbox"/>	QMS awareness is reinforced through ongoing mechanisms beyond the initial training session (posted policy, quality boards, supervisor references in team meetings)
<input type="checkbox"/>	Supervisor spot-checks confirm employees can describe their QMS awareness in their own words

Competence Verification Methods by Role Type

Role Type	Appropriate Verification Methods	What the Record Should Show
Technical / precision work roles (operators, inspectors, technicians)	Supervised practical demonstration; direct observation by qualified supervisor or peer; assessment of work output samples; formal skills test with pass criteria	Who observed the demonstration, what was observed, specific competence requirements verified, date, and supervisor determination of competent vs. requires additional development
Process management roles (supervisors, purchasing, sales)	Supervisor assessment of role performance; review of work product samples (purchase orders, order reviews, supplier evaluations); discussion-based assessment of process knowledge and decision-making	Assessment criteria used, work samples reviewed (with reference), supervisor determination of competence level, date
Technical / professional roles (engineers, quality professionals)	Credential verification; review of work product; professional judgment assessment by qualified peer or manager; demonstrated application of specific technical skills in work context	Credentials on file and verified; work product reviewed; peer or manager professional assessment documented
Management roles with QMS accountability	Management review participation records; quality objective review evidence; direct interview with Management Representative or auditor; observed quality decision-making in management meetings	Participation records; demonstrated QMS knowledge in documented interactions; Management Representative assessment
Long-tenured employees with experiential competence	Structured supervisor competence attestation; review of performance history; sampling of work output quality; direct observation of key judgment calls	Attestation form with supervisor signature; basis of competence determination explicitly stated (X years of demonstrated performance in role); any specific observations documented

Next in Series: Guide 1.5 — Internal Audit Program Development: Your Early Warning System. Covering internal audit program planning, auditor selection and training, writing audit plans and clause-by-clause checklists, conducting the audit, writing findings, managing corrective actions from audit results, and building an audit program that adds real value — with Meridian's first complete internal audit cycle in detail.
