Six Sigma Kaizen

ISO 9001 IMPLEMENTATION HUB

Volume 1 • Guide 3 of 6

Documentation Development

Writing a QMS That People Will Actually Use

A Practitioner-Level Implementation Guide for Quality Professionals

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

How to Use This Guide

This is Guide 1.3 in the six-part ISO 9001:2015 implementation roadmap. It covers Phase 3 of the implementation — the documentation development phase — in full. By the time you reach this guide, Phase 1 (Foundation) should be substantially complete: your document control system should be operational, your scope statement approved, your Quality Policy issued, and your process owners assigned and briefed. If those elements are not in place, complete Guide 1.2's Phase 1 checklist before proceeding.

This guide covers every aspect of QMS documentation: the document hierarchy, what the standard actually mandates versus what is optional, how to write procedures that function in the real world, document control systems and their practical operation, the Quality Policy and Quality Objectives as living documents, process mapping for the QMS, and control plans. It concludes with Meridian's complete documentation journey — from the document inventory on Day 1 to 23 controlled procedures at Stage 2.

Where We Are in the Meridian Journey

Denise Alvarez has completed Phase 1. The document control procedure is approved and the numbering system is live. The Quality Policy has been approved by Robert Nolan and posted on the intranet. The scope statement is finalized. Process owners have been briefed on their procedure writing responsibilities. The competence matrix work is underway in parallel. Now the largest single work phase of the implementation begins: building the documented information that will govern how quality-affecting work is performed, controlled, and evidenced at Meridian.

Section 1: The Right Documentation Philosophy

The single most consequential decision in QMS documentation development is not which software system to use, which template format to adopt, or how many procedures to write. It is whether the documentation will describe how work actually happens or how someone thinks work should happen. The gap between those two is where QMS implementations live or die.

A QMS built on aspirational documentation — procedures that describe ideal practice rather than current practice — fails in two predictable ways. First, employees do not follow it because it does not match their reality. Second, auditors discover the gap between the documented process and observed practice and issue nonconformances. Neither outcome serves anyone. The correct starting point is always the current state: document what is actually done, then improve it through the normal continuous improvement cycle of the QMS.

The ISO 9001:2015 Documentation Philosophy

The 2015 revision of ISO 9001 made a deliberate, significant shift in its documentation requirements relative to the 2008 version. The 2008 standard required six specific documented procedures regardless of organizational context. The 2015 revision replaced prescriptive documentation requirements with a principle: the organization shall maintain documented information to the extent necessary to support the operation of its processes and retain documented information to the extent necessary to have confidence that the processes are being carried out as planned.

Standard Requirement
ISO 9001:2015, Clause 7.5.1: "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."
The critical phrase is "determined by the organization as being necessary." ISO 9001:2015 trusts organizations to determine what documentation their QMS needs to function effectively — and holds them accountable for that judgment during audits. Over-documentation wastes resources and produces maintenance burden. Under-documentation produces inconsistent processes and audit findings. Calibrated documentation — the right amount for the complexity and risk of each process — is the objective.

What "Documented Information" Means in 2015 Terminology

ISO 9001:2015 uses the single term "documented information" to cover what the 2008 version called both "documents" (instructions, procedures, policies — what to do) and "records" (evidence that something was done). The standard requires organizations to both maintain documented information (keeping instructional documents current and controlled) and retain documented information (preserving evidence records). Understanding this distinction matters for document control system design:

Maintain (Instructional Documents)	Retain (Evidence Records)
Written to describe how processes work	Created as evidence that processes were executed
Controlled — must be current, approved, and revision-managed	Retained — must be retrievable, legible, and protected from alteration

Maintain (Instructional Documents)	Retain (Evidence Records)
Examples: procedures, work instructions, forms, the Quality Policy, process maps, the Quality Manual	Examples: training records, calibration certificates, inspection results, NCR forms, corrective action records, management review minutes
Requires approval before use and version control	Requires defined retention periods and access controls
Updated when processes change; obsolete versions controlled	Not updated — records capture what happened at a point in time

Kaizen Connection

The Lean principle of "minimum necessary" applies directly to QMS documentation. A procedure that is longer than it needs to be to ensure consistent, quality-achieving execution is waste — it takes longer to write, longer to train on, harder to update, and less likely to be followed. The ideal procedure is the shortest document that reliably produces the intended result in the hands of a competent, trained employee. Document the decisions and judgment points that vary between individuals; do not document what any competent person in that role would automatically know to do.

Section 2: The QMS Document Hierarchy

Most QMS documentation systems use a three- or four-tier hierarchy that moves from high-level organizational intent at the top to specific operational detail at the bottom. Understanding the hierarchy prevents a common mistake: writing work instruction-level detail into policy-level documents, or leaving procedure-level processes undocumented because they are addressed at a higher level without enough specificity to guide execution.

Tier 1: Policy Level

The highest tier of the document hierarchy establishes organizational intent, commitments, and the overall framework of the QMS. Tier 1 documents are typically brief, signed by senior leadership, and rarely changed.

- Quality Policy: The organization's formal commitment to quality — its purpose, direction, and pledges to satisfy requirements and pursue continual improvement. Required by Clause 5.2. Typically one to two pages.
- Quality Manual (optional but common): An overview document describing the QMS scope, the process approach, how major clauses are addressed, and the interaction between QMS elements. Not required by the 2015 standard but provides a useful orientation framework for new employees, customers, and auditors.
- Scope Statement: The formal declaration of what the QMS covers — which sites, products, services, and processes — and what if any exclusions apply and why. Required by Clause 4.3.

Tier 2: Process Level — Procedures

Procedures are the operational core of most QMS documentation systems. A procedure describes a process: what is done, in what sequence, by whom, under what conditions, and with what records created. Procedures operate at the process level — they describe how a category of work is managed across multiple instances, not how a specific job is executed step by step.

The key characteristics of a well-written procedure:

- It describes the process as it actually operates, not as it ideally would operate
- It is written for a competent, trained employee in that role — not for a complete novice and not for an expert who already knows everything
- It defines the decision points and judgment calls that vary between individuals and must be standardized
- It identifies who is responsible for each step and what records are generated
- It is short enough to be read and referenced during actual work — not a shelf document consulted only at audit time

Tier 3: Task Level — Work Instructions

Work instructions provide step-by-step operational detail for specific tasks within a process. Where a procedure answers "how does this process work?", a work instruction answers "how do I perform this specific operation, on this specific equipment, for this specific product type?" Work instructions are most valuable in high-risk, high-complexity, or high-variability operations where step-by-step guidance prevents errors.

Not every process requires work instructions. Procedures that fully describe how work is done for experienced, competent employees do not need to be supplemented by work instructions. Work instructions are appropriate when: the operation involves a specific sequence that must not deviate, when different personnel produce meaningfully different results without step-by-step guidance, or when the consequences of error are severe enough to warrant detailed controls.

Tier 4: Evidence Level — Forms and Records

Forms are the structured templates used to create records — the evidence that processes were executed. A blank inspection checklist is a form (maintained document); a completed, signed inspection checklist for a specific job is a record (retained document). Forms are controlled documents: they must be approved before use, version-controlled, and updated when processes change. Records generated from outdated form versions must still be retained; the form itself must be updated.

⚠ Common Pitfall

The most common document hierarchy mistake is writing everything as a procedure regardless of its appropriate tier. Quality Policies written with step-by-step instructions become unmanageably long and require executive re-approval every time a process detail changes. Work-instruction-level detail embedded in procedures makes procedures too long to be practically useful as operational references. Calibrating documents to their appropriate tier — brief at the top, detailed at the bottom — produces a hierarchy that is both auditable and genuinely functional.

The Hierarchy in Practice — Meridian's Document Architecture

Tier	Document Type	Meridian Examples	Approximate Count
1 — Policy	Quality Policy, Quality Manual, Scope Statement	MPC-POL-001 Quality Policy, MPC-QM-001 Quality Manual, MPC-SCO-001 QMS Scope Statement	3 documents
2 — Process	Procedures (how a category of work is managed)	MPC-PRO-001 Document Control, MPC-PRO-002 Corrective Action, MPC-PRO-003 Customer Requirement Review, MPC-PRO-004 Supplier Qualification... (23 procedures total)	23 procedures
3 — Task	Work Instructions (how a specific operation is performed)	MPC-WI-001 CMM Operation, MPC-WI-002 First Article Inspection, MPC-WI-003 Weld Inspection, MPC-WI-004 Surface Finish Measurement... (11 work instructions)	11 work instructions
4 — Evidence	Forms and Records	MPC-FRM-001 Nonconforming Material	31 forms

Tier	Document Type	Meridian Examples	Approximate Count
	(templates and completed evidence)	Report, MPC-FRM-002 Training Record, MPC-FRM-003 Corrective Action Request, MPC-FRM-004 Supplier Evaluation... (31 active forms)	

Section 3: Document Control — The System That Makes Everything Else Work

Document control is the operational infrastructure of the QMS. A document control system that works prevents the single most damaging documentation failure mode: multiple versions of the same document in circulation simultaneously, with employees using different versions of the same procedure and producing different results. This failure mode is invisible until the audit reveals it — and it reveals it every time.

What ISO 9001:2015 Requires for Document Control

Standard Requirement
ISO 9001:2015, Clause 7.5.2 (Creating and Updating): "When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number); b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); c) review and approval for suitability and adequacy."
Clause 7.5.3 (Control): "Documented information required by the QMS 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 (e.g. from loss of confidentiality, improper use, or loss of integrity). For the control of documented information, the organization shall address the following activities as applicable: distribution, access, retrieval and use; storage and preservation, including preservation of legibility; control of changes (version control); retention and disposition."

The Six Elements of an Effective Document Control System

Element 1: Document Identification

Every controlled document must be uniquely identified. A document numbering system assigns each document an identifier that makes it unambiguous — there can be no confusion about which document is being referenced, which version is current, or what category of document it is. The numbering system should be designed at the start of Phase 1 and applied consistently to every document created thereafter.

A practical numbering convention: [Organization Abbreviation]-[Document Type Code]-[Sequential Number]. For Meridian: MPC-PRO-001 (first procedure), MPC-WI-003 (third work instruction), MPC-FRM-012 (twelfth form). Document type codes should be defined and consistently applied: POL (Policy), QM (Quality Manual), SCO (Scope), PRO (Procedure), WI (Work Instruction), FRM (Form), PLA (Plan).

Element 2: Version Control

Every controlled document must carry its current revision designation — a number or letter that identifies which version of the document is in effect. When a document is revised, the revision designation changes, providing immediate visual identification of whether a given copy is current. The most common revision conventions: sequential numbers (Rev. 0, Rev. 1, Rev. 2) or sequential letters (Rev. A, Rev. B, Rev. C). Either works; consistency matters more than convention choice.

Every document should display its document number, revision, effective date, and page count (Page X of Y) as a minimum header. Some organizations also include the document title, the author, and the approver on each page. Electronic documents managed in a controlled system may carry this information in the system metadata rather than in page headers — acceptable provided the information is always accessible to the user.

Element 3: Approval Before Use

No document enters the QMS without being reviewed and approved by authorized personnel. The approval authority should be defined in the document control procedure and should reflect the document's scope and organizational impact. A work instruction may require the approval of the relevant supervisor and the Management Representative. A procedure may require the relevant department manager and the Management Representative. The Quality Policy requires the CEO or equivalent.

Electronic approval systems that capture approver identity, date, and approval action are strongly preferred over wet-ink signatures for two reasons: they are searchable and auditable, and they prevent the practical problem of routing physical documents through multiple approvers — a process that routinely takes weeks longer than the electronic equivalent.

Element 4: Controlled Distribution and Access

Documents must be available where they are needed and protected from unauthorized modification. The two primary approaches:

- Electronic controlled distribution (preferred): All controlled documents stored in a single authoritative electronic location — a shared drive, document management system, or intranet portal. The current revision is always the version in the system. Employees access documents from the system rather than maintaining local copies. Superseded documents are automatically archived and prevented from being accessed as current.
- Paper controlled distribution: Current revision documents are stamped "CONTROLLED COPY" and distributed to specific locations. A distribution list is maintained. When documents are revised, the old copies are retrieved and destroyed or archived as superseded. Paper systems are significantly more labor-intensive and error-prone than electronic systems and are appropriate only in environments where electronic access is not feasible.

Element 5: Management of Obsolete Documents

When a document is superseded by a new revision, the old revision must be prevented from unintended use. In electronic systems, this typically means moving the old version to an archived folder that is read-only and clearly labeled as obsolete. In paper systems, this means physically retrieving controlled copies from all distribution points before or simultaneously with distributing the new revision.

Some organizations must retain obsolete documents for legal, regulatory, or historical reference purposes — for example, to reconstruct what procedure was in effect when a specific product was manufactured. This is acceptable: obsolete documents retained for reference purposes must be clearly marked as obsolete and prevented from being used as current instructions.

Element 6: The Document Register

The document register is the master inventory of all controlled documents in the QMS. It lists every document by number, title, current revision, effective date, owner, and location. The document register is itself a controlled document. It provides immediate visibility into the state of the QMS documentation and serves as the auditor's primary navigation tool during a document review audit.

Best Practice

Maintain the document register as a living document updated every time a document is issued, revised, or retired. A document register that is updated only at audit preparation time is a document register that regularly contains errors. The effort of updating the register at the time of each document transaction is minimal; the effort of reconstructing accuracy from a stale register at audit time is substantial. Build the update habit from Day 1 of Phase 1.

Electronic vs. Paper Document Control

For any organization with computer access at the point of use, electronic document control is the strongly preferred approach. The administrative burden of paper document control — printing, stamping, distributing, retrieving, and destroying controlled copies — is disproportionate to the value it provides compared to a well-organized electronic system. The threshold for choosing a dedicated document management software system over a controlled shared folder approach depends on document volume and the need for workflow automation:

Approach	Best For	Key Advantages
Controlled shared drive folder structure (SharePoint, Google Drive, etc.)	Organizations with under 100 controlled documents and limited IT resources	Low cost, familiar technology, easy to implement. Requires discipline in folder structure and access permissions. Version control managed through naming conventions and folder organization.
Document management system (DMS) — purpose-built QMS software	Organizations with 100+ controlled documents, multi-user review/approval workflows, or integration with other quality management tools	Automated version control, approval workflows, distribution lists, audit trails. Higher initial cost and setup effort but significantly lower ongoing administrative burden at scale.
Paper controlled distribution	Environments with no or limited computer access at point of use — some factory floor environments, field operations	Viable but highest administrative burden. Requires strict discipline in copy retrieval and destruction. High risk of obsolete documents remaining in use if retrieval is not systematically managed.

Meridian Case Study

Meridian Document Control Decision: Denise chose a controlled SharePoint folder structure as Meridian's document control platform. The IT department created a "QMS Documents" site with three top-level folders: Current (active controlled documents, read-write for MR only, read access for all employees), Superseded

(archived prior revisions, read-only for MR only), and Forms-Blank (current blank form templates, read access for all employees). Each folder was organized by document type and numbered document. Denise created a Document Register (MPC-FRM-001) as a controlled Excel file in the Current folder, updated every time a document was issued or revised. The system cost zero beyond existing IT infrastructure and took two days to configure. At Stage 2, the registrar auditor described it as "well-organized and clearly functional" — confirmation that simplicity of implementation does not compromise conformance.

Section 4: Writing a Quality Policy That Means Something

The Quality Policy is the most frequently written and least frequently understood document in the QMS. Every ISO 9001-certified organization has one. Far too many of them are identical interchangeable statements that communicate nothing about what the specific organization actually commits to — statements so generic they could apply to any organization in any industry on any continent.

The Quality Policy exists to communicate the organization's intent about quality — to customers, employees, suppliers, and regulators. When it fails to do that, it fails at its only purpose. An auditor who has reviewed Quality Policies for twenty years can identify an empty one in thirty seconds. More importantly, an employee who reads it and cannot connect it to their daily work will not use it as the guiding framework it is intended to be.

The ISO 9001:2015 Requirements for the Quality Policy

Standard Requirement
ISO 9001:2015, Clause 5.2.1: The top management shall establish, implement and maintain a quality policy that: a) is appropriate to the purpose and context of the organization and supports its strategic direction; b) provides a framework for setting quality objectives; c) includes a commitment to satisfy applicable requirements; d) includes a commitment to continual improvement of the quality management system.
Clause 5.2.2: The quality policy shall: a) be available and maintained as documented information; b) be communicated, understood and applied within the organization; c) be available to relevant interested parties, as appropriate.

The Four Requirements — What They Actually Mean

Requirement	What It Means in Practice
"Appropriate to context and supports strategic direction"	The policy should reflect what your organization actually does and aspires to be — not generic quality aspirations. A precision machining company's policy should reference precision. A food service company's policy should reference food safety. A company pursuing market leadership on delivery performance should reference delivery. Auditors look for specificity that demonstrates the policy was written for this organization.
"Framework for setting quality objectives"	Quality objectives must logically flow from the policy. If the policy commits to customer satisfaction, there should be an objective measuring it. If it commits to continual improvement, improvement objectives should exist. The policy and objectives must be coherent as a set.
"Commitment to satisfy applicable requirements"	This is the non-negotiable statement that the organization will meet customer requirements and applicable statutory/regulatory requirements. It must appear in the policy, though the wording can vary.

Requirement	What It Means in Practice
"Commitment to continual improvement of the QMS"	Also non-negotiable. The policy must include a commitment to improve the QMS itself — not just product quality, but the management system that governs quality management. This is a 2015 revision requirement that some older-style policies miss.

The Quality Policy Anatomy — What to Include

An effective Quality Policy typically contains three to five paragraphs covering: the organization's core purpose and quality commitment, specific commitments that reflect the organization's strategic priorities, the two mandatory commitments (requirements satisfaction and QMS improvement), and a statement of communication and accountability. Total length: one page. Longer policies are rarely more effective and are harder to communicate and remember.

Quality Policy Examples — The Spectrum from Empty to Effective

Example A: The Empty Policy (What to Avoid)

"XYZ Company is committed to providing quality products and services that meet customer expectations. We strive for continuous improvement in all we do. Our goal is total customer satisfaction."

Problems: No organizational context (could be anyone). No specific commitments. Vague language ("strive for," "total satisfaction") that is unmeasurable. Missing the required commitment to satisfy requirements. Missing the required commitment to continual improvement of the QMS. An auditor will identify this as nonconforming to Clause 5.2.1.

Example B: The Conforming but Generic Policy (Minimum Threshold)

"ABC Manufacturing is committed to delivering products that consistently meet customer specifications and applicable regulatory requirements. We maintain a Quality Management System certified to ISO 9001:2015 and are committed to its continual improvement. Quality objectives are established and reviewed regularly to drive performance improvement."

Assessment: Technically conforming — all four requirements are addressed. But it communicates nothing distinctive about ABC Manufacturing. It could be copied verbatim by any manufacturer and remain equally meaningful (or meaningless). Employees cannot connect it to their specific work.

Example C: An Effective, Context-Specific Policy

"Meridian Precision Components delivers precision machined and fabricated metal components that perform to specification in the demanding applications our aerospace and defense customers depend on. We understand that our components are not interchangeable commodities — they are critical parts in systems where failure is not an option.

Our commitment to quality means: meeting every customer specification and drawing requirement; delivering on time so our customers can deliver on time; identifying and resolving quality problems at their

root so they do not recur; and continuously improving our processes, our capabilities, and our Quality Management System.

Every Meridian employee owns a part of this commitment. Quality is not the responsibility of the quality department alone — it is the standard to which we hold every job, every shift, every day. We satisfy applicable requirements, support regulatory compliance in our customers' industries, and pursue the continual improvement of our QMS as a core organizational discipline."

Assessment: Specific to Meridian's industry and customer base. Makes the stakes of quality concrete (critical components in systems where failure is not an option). Includes all four required commitments. Assigns quality responsibility broadly, not only to the quality department. Employees can connect this to their daily work.

The Mandatory Communication Requirement

ISO 9001:2015 requires that the Quality Policy be communicated, understood, and applied within the organization. "Communicated" means employees have been exposed to it through deliberate organizational communication — not that it is posted in the lobby. "Understood" means employees can describe in general terms what it commits the organization to. "Applied" means the policy's commitments are reflected in how work is actually done.

Auditors test the understanding requirement directly: they ask employees at random what the Quality Policy says. The expected answer is not verbatim recitation — it is a general description of the organization's quality commitments. Employees who respond with "I do not know" or "something about quality and customers" indicate that communication has been inadequate. Build the Quality Policy into onboarding, post it prominently, reference it in quality meetings, and include it in the QMS awareness training.

Section 5: Quality Objectives — From Platitude to Performance Driver

Quality Objectives are the bridge between the Quality Policy's commitments and the organization's actual measurement and improvement activity. They should tell any informed observer what the organization is specifically trying to achieve in quality performance, how it will know when it has achieved it, and who is responsible for making it happen.

In too many implementations, Quality Objectives are a list of aspirations attached to a policy as a compliance exercise: "We will improve customer satisfaction. We will reduce defects. We will improve on-time delivery." These statements fail both the standard's requirements and the organization's actual needs. An objective without a target, a measurement method, a responsible owner, and a plan for achievement is a wish, not an objective.

The ISO 9001:2015 Requirements for Quality Objectives

Standard Requirement
ISO 9001:2015, Clause 6.2.1: Quality objectives shall: a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) be relevant to conformity of products and services and to enhancement of customer satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate.
Clause 6.2.2: When planning how to achieve its quality objectives, the organization shall determine: what will be done; what resources will be required; who will be responsible; when it will be completed; how the results will be evaluated.

SMART Quality Objectives in Practice

The SMART framework (Specific, Measurable, Achievable, Relevant, Time-bound) is the appropriate lens for quality objective development. Applied to ISO 9001 requirements, each objective needs five elements:

Element	ISO 9001 Requirement	What It Means Concretely
What is the goal?	Consistent with policy, relevant to product conformity or customer satisfaction	State the specific quality performance dimension being improved. Not "improve quality" but "reduce customer-reported nonconformance rate."
How is it measured?	Be measurable, be monitored	Define the metric, the data source, the measurement frequency, and the baseline current performance. Without a baseline, improvement cannot be demonstrated.
What is the target?	Be measurable	Set a specific numeric or percentage target with a timeframe. "Reduce customer returns from 1.8% to under 1.0% by Q4." Vague targets cannot be evaluated.
Who is responsible?	Determine who will be responsible	Name the role or individual accountable for achieving the objective. Objectives without owners are nobody's priority.

Element	ISO 9001 Requirement	What It Means Concretely
What is the plan?	Determine what will be done, what resources will be required, when it will be completed, how results will be evaluated	Identify the specific actions that will drive improvement toward the target. The plan must be realistic and resourced — not "try harder."

Setting Objectives at Relevant Functions and Levels

ISO 9001:2015 requires quality objectives to be established at relevant functions, levels, and processes — not just at the organizational level. This means objectives should cascade from the overall organizational quality objectives down to department or process-level objectives that support them. An organizational objective to reduce customer complaints should connect to a production objective to reduce first-pass rejection rate, which connects to a machining process objective to reduce dimensional nonconformances on specific product families.

In practice, most organizations establish three to seven organizational-level quality objectives plus supporting objectives at the department or process level. The number matters less than the coherence: objectives at every level should logically connect to and support the organizational-level commitments.

Meridian's Quality Objectives — A Complete Example

Objective	Current Baseline	Target	By When	Owner and Plan Summary
Reduce customer-reported nonconformance rate (parts per million returned)	2,200 PPM	Under 1,000 PPM	Month 12	Quality Manager. Actions: First article inspection for all new jobs, root cause analysis on all customer returns, monthly PPM review with Operations.
Achieve on-time delivery rate (shipped complete on or before customer requested date)	87%	95% or higher	Month 9	Operations Manager. Actions: Capacity planning review weekly, order backlog visibility dashboard, early warning trigger at 80% schedule attainment.
Reduce internal first-pass yield failure rate (parts requiring rework before release)	8.3%	Under 5%	Month 12	Production Supervisor. Actions: Setup verification checklist, first-piece inspection on all critical dimensions, machine

Objective	Current Baseline	Target	By When	Owner and Plan Summary
				capability tracking for repeat jobs.
Achieve 100% on-time completion of corrective actions (closed within defined timeframe)	Not currently tracked	90% on-time closure	Month 6 (establish baseline), Month 12 (achieve target)	Quality Manager. Actions: CAPA tracking system, weekly open CAR review, escalation protocol for overdue actions.
Maintain supplier on-time delivery rate for critical suppliers	91%	96% or higher	Month 12	Purchasing Manager. Actions: Monthly supplier scorecards, quarterly supplier reviews, approved supplier list with performance ratings.
Complete all ISO 9001 implementation milestones on or before scheduled dates	0% (implementation beginning)	100% of Phase 1-5 milestones on or before schedule	Month 13 (certification)	MR (Denise Alvarez). Actions: Weekly implementation check-ins, monthly milestone reviews with CEO, escalation protocol for at-risk tasks.

Auditor Perspective

When auditors evaluate Quality Objectives, they look for four things in sequence: Do the objectives exist and are they documented? Are they measurable with defined targets? Is there evidence they are being monitored (data records, trend charts, review meeting minutes)? And are the results being used — do management review records show that objective performance was reviewed and that decisions or actions resulted from under-performing objectives? An organization that can show documented objectives, monitoring data, and management review discussion of that data demonstrates a functioning performance evaluation system. An organization that has beautifully written objectives but no monitoring data demonstrates a documentation exercise.

Section 6: Writing Procedures That Actually Get Used

Procedure writing is a craft. A well-written procedure that people will actually read, reference, and follow looks very different from a compliance document written to satisfy an auditor. The difference is not length, formatting, or terminology — it is whether the document was written for the people who will use it or for the people who will audit it. Procedures written for auditors are technically complete and practically useless. Procedures written for users are both used and auditable.

The Standard Procedure Architecture

While ISO 9001:2015 does not mandate a specific procedure format, a consistent structure across all QMS procedures reduces training burden, simplifies navigation, and improves the document control process. The following architecture has proven effective across a wide range of manufacturing and service organizations:

Section	Content
1. Purpose	One to three sentences: why this procedure exists and what quality outcome it is designed to ensure. Not a restatement of the ISO clause requirement — a plain statement of the business purpose.
2. Scope	What this procedure applies to (products, services, locations, job types) and what it explicitly does not cover if the boundary needs clarification.
3. Responsibilities	Who does what in this process — by role, not by name. Identifying responsibilities by name creates a maintenance burden every time personnel change.
4. Definitions	Terms used in this procedure that have a specific meaning not obvious from common usage. Do not define commonly understood terms — only those that could be misunderstood or that have a specific QMS meaning.
5. Procedure	The process itself: what steps occur, in what sequence, under what conditions, with what decision points. This is the core of the document. Use numbered steps for sequential processes and flowcharts or decision trees for complex branching processes.
6. Records	What records are generated by this process, which form template is used for each, where records are stored, who is responsible for creating and filing them, and how long they are retained.
7. Related Documents	Cross-references to other QMS documents that interact with this procedure — upstream procedures that trigger this one, downstream procedures that this one triggers, work instructions or forms referenced in the body.
8. Document History	Revision table: revision number, effective date, description of change, author, approver. Provides a traceable revision history without requiring access to previous versions.

Writing the Procedure Section — Practical Guidance

The process description in Section 5 of the procedure is where most writing effort should be concentrated and where most writing errors occur. The following principles produce procedure sections that are both compliant and functional:

Use Active Voice with a Clear Subject

Passive voice procedures obscure accountability. "Nonconforming parts shall be identified and segregated" tells no one who is responsible. "The operator identifies and segregates nonconforming parts immediately upon detection" is specific, actionable, and auditable. Every step in the procedure should have a clear subject — a role — performing a specific action.

Write Steps at the Right Level of Specificity

Steps should be specific enough that different employees performing the step will produce consistent results, but not so specific that they micromanage judgment calls that competent employees handle automatically. A step that says "the inspector verifies dimensions against the drawing" is appropriately specific. A step that says "the inspector picks up the micrometer with the right hand and places it against the workpiece" has descended into absurd specificity that adds no quality value and insults the reader.

Document Judgment Calls, Not Just Actions

The most valuable procedures document the decision points where different employees make different choices — the places where individual variation produces inconsistent quality outcomes. If an operator finds a dimension slightly outside tolerance, what are the options? Who decides which option applies? Under what criteria? These are the judgment calls that produce defects when undocumented and that auditors will specifically ask about.

Use Flowcharts for Complex or Branching Processes

Narrative step-by-step descriptions work well for linear sequential processes. For processes with significant branching — different paths depending on conditions — a flowchart communicates the process logic more clearly than any narrative can. The corrective action procedure, the nonconforming output procedure, and the customer complaint procedure are classic candidates for flowchart representation. Include both a flowchart and narrative descriptions of decision criteria for complex branching.

Limit Procedure Length

A procedure that cannot be read in five to ten minutes will not be read in practice. Most QMS procedures for well-understood processes should be two to four pages. If a procedure is growing beyond six to eight pages, consider whether it is trying to cover too much scope (split into two procedures) or whether work instruction-level detail is being included that belongs in a separate document.

⚠ Common Pitfall

The two most common procedure writing failures are opposite extremes. The "regulatory" procedure: written in passive voice, abstract language, and ISO clause terminology, technically covering every requirement but providing no operational guidance anyone would actually follow. The "training manual" procedure: so detailed it covers every conceivable scenario step by step, requiring forty pages to describe a process that takes ten minutes to execute. Neither extreme produces a document people use. The target is a procedure that a competent employee in that role would reach for when they encounter an unfamiliar situation or disagreement about how a process works — because it answers the question clearly and in their language.

Section 7: Process Mapping for the QMS

ISO 9001:2015 requires the organization to determine the processes needed for the QMS and their sequence and interaction (Clause 4.4). Process mapping is the tool that makes this requirement visible — turning the abstract statement "we have a process for X" into a documented, communicable picture of how work flows through the organization. Process maps are required at two levels: a high-level QMS process interaction map and more detailed individual process maps for key operational processes.

The High-Level QMS Process Interaction Map

The high-level map — sometimes called the Process Landscape or Turtle Diagram overview — shows the major processes of the QMS, their sequence, and their interactions. It is typically displayed as a visual diagram in the Quality Manual or as a standalone controlled document. Its purpose is orientation: an auditor, new employee, or customer reviewing the QMS should be able to understand how the system is structured from this single view.

A typical manufacturing QMS process landscape organizes processes into three categories:

- Management processes: those that govern and direct the QMS (context determination, planning, management review, continual improvement)
- Core operational processes: the value-creating processes through which products and services are produced (order receipt, design/development, purchasing, production, inspection, delivery)
- Support processes: those that enable operational processes to function (document control, training, calibration, corrective action, internal audit)

The Turtle Diagram — Process-Level Mapping

For individual key processes, the Turtle Diagram is a widely used process mapping tool in ISO 9001 implementations. Named for its visual resemblance to a turtle when drawn, it maps a single process across six dimensions that together define what the process needs and produces:

Turtle Diagram Element	What It Documents
With What? (Inputs)	What information, materials, components, or conditions enter this process? Where do they come from?
With Whom? (Competence)	What roles perform this process? What competence, training, or certification is required?
How? (Methods and Procedures)	What documented procedures, work instructions, standards, or specifications govern how this process is performed?
With What? (Equipment and Tools)	What equipment, tools, software, or infrastructure is required for this process? What calibration or maintenance is required?
What? (Process Activities)	The core activities of the process — the transformation that occurs between input and output. This is the center of the turtle.
Outputs and Measures (How Well?)	What does this process produce? What records? What KPIs measure whether the process is performing as intended?

Turtle Diagrams are particularly valuable during the gap analysis and process documentation phases because they force a comprehensive view of what each process requires — not just the steps, but the people, tools, methods, inputs, and measures that make it function. Gaps revealed in any dimension (for example, a process with no defined performance measures, or a process where competence requirements have never been specified) become documentation and implementation priorities.

SIPOC Diagrams for Operational Process Clarity

The SIPOC (Suppliers, Inputs, Process, Outputs, Customers) diagram is the Six Sigma process mapping tool that pairs naturally with ISO 9001's process approach. Where the Turtle Diagram provides a comprehensive internal view of a process, the SIPOC situates it in its supply chain context — making explicit who provides inputs, what those inputs are, what the process produces, and who receives the output. This view is particularly useful for Clause 8.4 (external providers) and Clause 8.2 (customer requirements) documentation.

Kaizen Connection

Process mapping is a Kaizen act before it is a documentation act. When a cross-functional team sits down to map a process they all work within, disagreements about how the process actually works are almost universally revealed — the purchasing manager describes the supplier qualification process one way, the quality technician who executes it describes it differently, and the receiving inspector who interfaces with its outputs describes it differently again. These disagreements are not problems; they are the discovery of process variation that the QMS will standardize. The mapping session is the most valuable output, not the finished map.

Section 8: Control Plans — Where ISO 9001 Meets Production Reality

A Control Plan is a structured document that identifies the key process steps, the critical quality characteristics to be controlled at each step, the control method used, the sampling plan, the measurement system, the reaction plan when controls indicate a problem, and the responsible party. Control Plans are the most operationally specific form of documented process control in a manufacturing QMS — and they are the documents that shop-floor employees actually use to execute quality-critical work.

ISO 9001:2015 does not use the term "control plan" — but Clause 8.1 requires the organization to plan, implement, control, and maintain processes for the realization of products and services, including the establishment of criteria for the processes and the acceptance of products and services. Control Plans are the natural documentation vehicle for meeting this requirement in a manufacturing context.

The Elements of an Effective Control Plan

Control Plan Element	ISO 9001 Connection	What to Document
Process step	Clause 8.1: control of operational processes	Each significant step in the production or service delivery process where quality characteristics can be influenced or must be verified
Product or process characteristic	Clause 8.6: criteria for release	The specific quality attribute being controlled at this step — a dimension, surface finish, material property, functional requirement, or visual attribute
Specification / acceptance criterion	Clause 8.2: customer requirements	The numeric or descriptive standard the characteristic must meet — drawing requirement, customer specification, or internal standard
Control method	Clause 8.1: operational control	How the characteristic is controlled — 100% inspection, statistical sampling, process parameter control, Poka-Yoke device, SPC chart
Measurement system	Clause 7.1.5: monitoring and measuring resources	The specific equipment or method used to verify the characteristic, including gage number and calibration frequency
Sample size and frequency	Clause 9.1: monitoring and measurement	How many pieces are measured and at what frequency — every piece, first and last of each lot, hourly samples, etc.
Reaction plan	Clause 8.7: control of nonconforming outputs	What actions are taken when the measurement indicates the characteristic is out of specification — who is notified, what is done with the affected product, how root cause is initiated
Responsible party	Clause 5.3: roles and responsibilities	Which role performs the control activity at this step — operator, inspector, setup technician, quality engineer

When Are Control Plans Required?

ISO 9001:2015 does not mandate control plans as a specific document type for all organizations. However, for manufacturing organizations — and especially those supplying aerospace, defense, automotive, or medical device customers — control plans are widely expected by customers and by auditors as evidence of documented process control. Organizations that cannot demonstrate how specific quality characteristics are controlled at specific process steps will struggle to satisfy Clause 8.1 audit questions regardless of what other documentation exists.

Recommended control plan deployment:

- All new product launches and first article situations: mandatory
- All products with customer-specified critical or significant characteristics: mandatory
- Products with recurring quality escapes or customer complaints: mandatory as part of corrective action
- Routine repeat products with established process history and clean quality record: based on risk assessment — a simplified control plan or process routing with inspection criteria may suffice

Best Practice

Control Plans and First Article Inspection (FAI) are natural partners. FAI verifies that a new or revised process produces product that meets all drawing requirements; the Control Plan documents how that conformance will be maintained in production. Organizations that conduct FAI without a Control Plan verify conformance once and then leave ongoing control to individual judgment. Organizations that have a Control Plan but no FAI may have defined their controls incorrectly from the start. Both together constitute a complete new-part-launch quality process — and together they demonstrate exactly the kind of systematic approach to production control that Clause 8.1 is designed to ensure.

Section 9: Mandatory Documented Information — Clause by Clause

ISO 9001:2015 explicitly requires specific documented information at identified points in the standard. These are the non-negotiable documentation requirements that every certified organization must satisfy. Understanding exactly what each one requires — and what form acceptable evidence takes — prevents both over-documentation (building elaborate systems for requirements that need simple solutions) and under-documentation (missing requirements that auditors will definitely verify).

The following table provides practical guidance on each mandatory documented information requirement: what is required, what acceptable evidence looks like, and the most common audit finding associated with each.

Required Documented Information	Clause	Acceptable Evidence Forms	Most Common Audit Finding
QMS scope	4.3	Scope statement in Quality Manual, standalone scope document, or clearly documented in the document register	Design and development exclusion not justified; scope not reviewed after organizational changes
Quality Policy	5.2	Signed and dated policy document, available on intranet or posted, distributed and communicated	Not communicated to all employees; employees cannot describe its content; not signed by top management
Quality objectives and plans to achieve them	6.2	Objectives register or table with metric, baseline, target, owner, timeframe, and action plan for each objective	Objectives not measurable; no action plans; objectives not monitored or reviewed at management review
Evidence of fitness for purpose of monitoring and measuring resources	7.1.5	Calibration records, calibration certificates, equipment identification labels showing calibration status	Overdue calibrations; equipment in use without calibration records; out-of-tolerance not documented
Evidence of competence	7.2	Training records, competence matrices, certifications, qualification records, on-the-job verification sign-offs	Training conducted but not recorded; competence not verified beyond training completion; records not retrievable
Results of the review of requirements related to products and services	8.2.3	Order review records, contract review checklists, email confirmations with customers, signed quotes	Reviews conducted verbally with no records; reviews not conducted before commitment to supply

Required Documented Information	Clause	Acceptable Evidence Forms	Most Common Audit Finding
Design and development inputs (if applicable)	8.3.3	Design input register, drawing/spec review records, regulatory requirement list, interface requirement documentation	Inputs not documented at design start; inputs not reviewed and approved; incomplete inputs used
Design and development controls (if applicable)	8.3.4	Design review records, verification records, validation records, design review meeting minutes	Design reviews not held or not documented; verification not distinguished from validation
Design and development outputs (if applicable)	8.3.5	Released drawings, specifications, manufacturing instructions, approved models or prototypes	Outputs not formally released against inputs; output adequacy not reviewed before release
Design and development changes (if applicable)	8.3.6	Engineering change notices, change request records, re-verification/re-validation records	Changes implemented without formal review or re-verification; no change record traceability
Results of evaluation of external providers	8.4.1	Supplier evaluation records, scorecards, audit reports, approved supplier list with evaluation dates	Supplier evaluations not documented; no ongoing monitoring; approved supplier list not maintained
Traceability records (if traceability is required)	8.5.2	Lot records, serial number logs, material certifications linked to specific product, heat/lot traceability records	Traceability breaks in the record chain; records not retained for the required period
Customer property records (lost, damaged, or unsuitable)	8.5.3	Incident reports for customer-owned property; customer notification records	No process for identifying customer property; incidents not documented or reported to customer
Records of review of changes to production provisions	8.5.6	Engineering change review records, process change authorization records	Changes implemented without documented review; impact on in-process product not assessed
Evidence of product/service release (who authorized, against what criteria)	8.6	Inspection reports, certificate of conformance, traveler with inspector signature, release stamps or electronic approvals	Release not documented; releasing authority not identified; release criteria not defined
Nonconforming output records (nature, actions, concessions obtained)	8.7	Nonconforming Material Reports (NMRs), NCR forms, customer	No NCR records for known nonconformances; disposition not

Required Documented Information	Clause	Acceptable Evidence Forms	Most Common Audit Finding
		concession records, scrap/rework records	documented; customer waivers not retained
Monitoring, measurement, analysis, and evaluation results	9.1	Quality metrics dashboard data, trend charts, KPI tracking records	Data collected but not analyzed; analysis not reviewed at management review; no trend analysis
Internal audit program and audit results	9.2	Audit program schedule, audit plans, audit reports, finding logs, corrective action records from audit findings	Audit program not complete before Stage 2; findings not formally reported; CARs from findings not closed
Management review results	9.3	Management review meeting minutes or summary document covering all required inputs and all required outputs	Required inputs not all addressed; no documented decisions or action items; review not held by top management
Nonconformity and corrective action records	10.2	CAPA forms, root cause analysis documentation, corrective action plans, effectiveness verification records	Root cause superficial; corrective actions not verified effective; CARs left open without resolution

Section 10: The Meridian Documentation Journey

This section traces Meridian's complete documentation development journey from the document inventory on Day 1 of Phase 1 through the 23 controlled procedures, 11 work instructions, 31 forms, and supporting documents in place at Stage 2. The Meridian experience illustrates both the predictable challenges of Phase 3 documentation development and the practical solutions that kept the implementation on schedule.

The Day 1 Document Inventory

Before any new documentation was created, Denise conducted a complete inventory of existing quality-related documents. The purpose was twofold: to identify what could be formalized rather than written from scratch (quick wins), and to identify what existed in multiple competing versions and needed to be reconciled before the document control system went live.

The inventory revealed 43 documents across various locations — quality manager's computer, shared network drives in various states of organization, binders on the shop floor, and email attachments from customer audits. Of these 43:

- 12 were current, relevant, and could be numbered, version-controlled, and formally approved with modest revision
- 9 were outdated versions of procedures that had been informally revised without document control — both the current and prior versions were in circulation simultaneously
- 14 were forms and inspection records that needed standardization and formal approval
- 8 were customer-provided specifications, standards, and reference documents that needed to be listed in the document register as external documents under control

Denise's first Phase 3 action was to archive all documents not in the "current and formalizable" category to a designated "Pre-QMS Archive" folder with a clear "DO NOT USE AS CURRENT INSTRUCTION" label. This removed the ambiguity about which version of any document was current — a single action that immediately reduced the risk of quality problems caused by document confusion.

The Procedure Development Sequence

Denise sequenced procedure development in a deliberate order: highest-risk processes first, foundational infrastructure second, lower-risk supporting processes third. The rationale: procedures for high-risk processes needed the most review iterations and the most time to accumulate operational records before Stage 2. Starting them first built that buffer.

Order	Procedure	Owner	Key Challenge
1	MPC-PRO-001 Document Control	Denise Alvarez (MR)	None — foundational enabler for all others, written first
2	MPC-PRO-002 Nonconforming Material Control	Denise Alvarez + Production Supervisor	Existing informal process needed significant formalization of the disposition authority matrix

Order	Procedure	Owner	Key Challenge
3	MPC-PRO-003 Corrective Action (CAPA)	Denise Alvarez (MR)	Root cause analysis method needed to be standardized; effectiveness verification step was new to the organization
4	MPC-PRO-004 Customer Requirement Review	Sales Manager (authored), Denise (reviewed)	Sales manager initially resisted written records for verbal customer discussions; resolution was a lightweight email confirmation template
5	MPC-PRO-005 Design and Development	Engineering Manager Mike Chen (authored), Denise (reviewed), External Consultant (reviewed)	Most complex procedure in the system; required three revision cycles and external consultant input on D&D control requirements
6	MPC-PRO-006 Supplier Qualification and Evaluation	Purchasing Manager Sarah Kim	Approved Supplier List had to be built from scratch — 34 suppliers evaluated and documented over 6 weeks
7	MPC-PRO-007 Purchasing Controls	Sarah Kim (Purchasing Manager)	Purchase order template revision required to include quality requirements; IT involvement for ERP system updates
8-14	Production Process Procedures (7 procedures covering machining, grinding, welding, heat treatment, assembly, preservation, and delivery)	Operations Manager + individual supervisors	Fastest-written group — existing informal practices were good and formalizing them was straightforward; supervisor engagement was high
15	MPC-PRO-015 First Article Inspection	Quality Engineer	FAI procedure required simultaneous development of the FAI form and linkage to the Design and Development procedure
16	MPC-PRO-016 Product Inspection and Release	Quality Manager	Release authority matrix needed executive approval; multi-level release criteria for

Order	Procedure	Owner	Key Challenge
			different product risk levels
17	MPC-PRO-017 Identification and Traceability	Production Supervisor + Quality	Traceability gap discovered: lot records for heat treatment were maintained by the subcontractor, not Meridian — new controls required
18	MPC-PRO-018 Customer Property	Operations Manager	Straightforward — Meridian rarely receives customer-owned tooling but needed a written process for when it occurs
19	MPC-PRO-019 Internal Audit	Denise Alvarez (MR)	Written in parallel with internal auditor training; auditors reviewed draft procedure as part of their training
20	MPC-PRO-020 Management Review	Denise Alvarez (MR)	Procedure required CEO review and explicit commitment to the review cadence and agenda; Robert reviewed personally
21	MPC-PRO-021 Calibration	Quality Technician + Maintenance	Calibration equipment census had revealed 23% overdue devices; procedure could not be issued until remediation was substantially complete
22	MPC-PRO-022 Training and Competence	HR Manager James Thornton	Competence matrix was built simultaneously; procedure had to describe the matrix system and the records it generated
23	MPC-PRO-023 Risk and Opportunity Management	Denise Alvarez (MR)	Written last as the risk register was refined through the implementation; procedure describes the review and update cadence

The Documentation Timeline Reality

Denise's original plan called for all 23 procedures to be approved and in active use by the end of Month 8. The actual completion date was Month 9 — one month behind plan. The slippage had two primary causes:

First, the Design and Development procedure (MPC-PRO-005) required three revision cycles and external consultant involvement, consuming six weeks more than planned. Mike Chen discovered during drafting that Meridian's informal design review process — which he had estimated would take two weeks to document — was actually more complex and less consistent than his initial description suggested. The procedure that emerged from the six-week process was significantly more robust than what a two-week effort would have produced, but the schedule impact was real.

Second, the traceability gap discovered during Procedure 17 development — the discovery that heat treatment lot traceability records resided with the subcontractor, not Meridian — required a six-week remediation effort to establish new controls and verify that traceability could be reconstructed for recent production history. This was an unplanned but essential quality system improvement that would almost certainly have been a Stage 2 nonconformance if not discovered and addressed during the implementation.

The one-month slippage was surfaced immediately at the Month 8 milestone review. Robert Nolan approved a one-month extension to Phase 3, accepting a corresponding one-month shift in Phase 4 completion. The Stage 2 certification date was preserved by compressing the Stage 1 to Stage 2 gap from twelve weeks to eight — still within the registrar's minimum requirement. This is exactly the purpose of implementation governance: surfacing slippage early enough that recovery options exist.

Meridian Case Study

Meridian Documentation Lessons Learned: Three insights Denise documented in the implementation file for future reference. First: the processes that are most confidently described by their owners at the start of procedure development are not always the ones that prove easiest to document — confidence sometimes reflects familiarity with a process that is actually inconsistent, not mastery of a process that is actually controlled. Second: procedure review cycles are faster and better when reviewers are given a specific, focused review question ("Does this procedure ensure that customer specifications are captured completely before we commit to delivery?") rather than an open-ended review invitation ("Please review and comment"). Third: the document register is the single most valuable QMS navigation tool for auditors — maintaining it meticulously, with accurate revision and effective dates, made the Stage 1 document review faster and the Stage 2 audit opening meeting significantly more confident.

Quick Reference: Documentation Development Essentials

The Procedure Writing Checklist

Apply this checklist to every procedure before it enters the approval cycle:

	Checklist Item
☐	Written by or in close collaboration with the process owner — not by quality on behalf of the process owner
☐	Describes how the process actually operates, not how it ideally would operate
☐	Uses active voice with a clear role as the subject of each step
☐	Documents decision points and judgment calls, not just sequential actions
☐	Identifies the responsible role for each step (by role title, not individual name)
☐	Specifies what records are generated, what form is used, where records are filed, and how long they are retained
☐	Is short enough to be read in five to ten minutes by the intended audience
☐	Uses a flowchart for any branching or conditional logic that is difficult to follow in narrative form
☐	Cross-references related procedures, work instructions, and forms by document number
☐	Addresses all ISO 9001:2015 requirements for this process area (verified against the applicable clause)
☐	Has been assigned a document number and revision per the document control procedure
☐	Has been approved by authorized personnel before being issued for use
☐	Has been communicated to all personnel who perform this process before the effective date

Quality Policy Compliance Checklist

	Requirement
☐	Appropriate to the purpose and context of the organization (specific to what your organization does and aspires to, not generic)
☐	Provides a framework for setting quality objectives (objectives can logically be derived from the policy commitments)
☐	Includes a commitment to satisfy applicable requirements
☐	Includes a commitment to continual improvement of the quality management system

	Requirement
☐	Available as documented information (written, controlled, in the document register)
☐	Communicated within the organization (active communication to all employees, not just posted)
☐	Understood within the organization (employees can describe its commitments in general terms when asked)
☐	Applied within the organization (quality decisions are made in alignment with its commitments)
☐	Available to relevant interested parties as appropriate (customers, regulators, as needed)
☐	Signed and dated by top management

Document Control System Quick Reference

Document Control Element	Minimum Requirements
Document identification	Unique document number, title, current revision designation, effective date, page numbering (page X of Y)
Approval before use	Defined approval authority for each document type; approval recorded (electronic or signature); no document issued for use before approval
Version control	Revision history maintained; prior revisions archived and inaccessible as current; revision description documents what changed and why
Distribution and access	Employees can access current controlled documents at point of use; only current revisions accessible for operational use; access controlled to prevent unauthorized modification
Obsolete document control	Superseded documents archived or destroyed; cannot be accessed as current instructions; retained copies clearly marked "OBSOLETE" if retained for reference
Document register	Complete inventory of all controlled documents with number, title, revision, effective date, owner, and location; updated at every document transaction
External document control	Customer specifications, standards, and regulatory documents listed in the document register with revision control; updated when external documents are revised
Record retention	Defined retention periods for each record type; records stored in retrievable, legible format; protected from accidental alteration or loss

Next in Series: Guide 1.4 — Training and Competence Building: Getting Your People Ready for the QMS. Covering Clause 7.2 competence requirements in depth, the competence matrix, QMS awareness

training that actually changes behavior, on-the-job verification, training records that satisfy auditors, and Meridian's three-phase training rollout covering all 220 employees.
