Six Sigma Kaizen

ISO 9001 IMPLEMENTATION HUB

Volume 3 • Guide 2 of 3

Planning and Control Templates

Ready-to-Use Templates with Completion Instructions, Meridian Examples, and Auditor Guidance

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Ready-to-Use Template Library • ISO 9001:2015

Risk & Opportunity Register • Quality Objectives Tracker • Competence Matrix • Training Record • Calibration Log • Document Control Register

How to Use This Guide

This is Guide 3.2 in Volume 3 of the ISO 9001 Implementation Hub. It provides six ready-to-use planning and control templates covering the Clause 6 and 7 requirements that most directly determine whether the QMS functions as a managed system or a collection of procedures. Each template includes step-by-step completion instructions, a filled Meridian Precision Components example, common mistakes that generate audit findings, and auditor perspective on what each document must demonstrate.

The six templates in this guide represent the operational backbone of the QMS planning and support infrastructure: the Risk and Opportunity Register translates context analysis into managed risk; the Quality Objectives Tracker converts policy commitments into measured improvement targets; the Competence Matrix defines who must know what and documents that they know it; the Training Record creates the evidence chain between training delivery and competence assurance; the Calibration Log ensures measurement integrity across the instrument fleet; and the Document Control Register maintains the living inventory of all controlled QMS documents.

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TEMPLATE 1: Risk and Opportunity Register

ISO 9001:2015 Clause 6.1

Document Type	Maintained record — reviewed and updated at each management review and when significant organizational or environmental changes occur
Clause Reference	Clause 6.1: Actions to address risks and opportunities; also connects to Clauses 4.1, 4.2, and 10.2
Document Control	Controlled document — numbered, versioned; changes require Management Representative approval
Retention	Current version plus all prior versions for the certification life; prior versions demonstrate risk evolution over time

Completion Instructions

Column 1 — ID: Assign a unique identifier to each entry. Use R-xx for risks and O-xx for opportunities. Sequential numbering within each category. Never reuse a retired ID — this allows historical traceability.

Column 2 — Risk/Opportunity Description: Write a specific, organizational-context description. Avoid generic language. Include: what condition exists, what could happen as a result, and what the quality management impact would be. Specific descriptions enable specific actions.

Column 3 — Category: Classify using a consistent taxonomy. Suggested categories: Process, Supply Chain, Regulatory/Compliance, Technology, Human Resources/Knowledge, Customer/Market, Infrastructure. Consistent categories enable trend analysis across audit cycles.

Column 4 — Source: Where was this identified? Context analysis (Clause 4.1), interested party review (Clause 4.2), internal audit finding, management review discussion, corrective action trend, customer feedback, or external event.

Column 5 — Likelihood (1-3): 1 = Unlikely (would be surprised if it occurred in the next 12 months); 2 = Possible (could reasonably occur); 3 = Likely (expected to occur or already showing early indicators).

Column 6 — Impact (1-3): 1 = Minor (limited effect on QMS performance, no customer impact); 2 = Moderate (affects quality objectives or specific process performance, potential customer impact); 3 = Major (significant threat to QMS effectiveness, confirmed or likely customer impact, regulatory exposure).

Column 7 — Priority Score: Likelihood x Impact. Range 1-9. Color code: 7-9 = Red (High priority — requires substantive planned action); 4-6 = Amber (Medium priority — requires monitoring and may require action); 1-3 = Green (Low priority — monitor; retain with informed decision).

Column 8 — Planned Action: For High and Medium priority items, specify the action(s) to address the risk or capitalize on the opportunity. Each action should be specific — what will be done. Reference a CAPA number if a formal corrective action was opened.
Column 9 — Owner: Named role (not individual name) responsible for executing the planned action and monitoring the risk or opportunity.
Column 10 — Target Date: Specific date by which the planned action should be completed. For monitoring-only entries, specify the next scheduled review date.
Column 11 — Status / Effectiveness: Current status (Open, In Progress, Action Complete, Closed) and, for completed actions, the effectiveness assessment — did the action reduce the likelihood or impact as intended?

MERIDIAN RISK AND OPPORTUNITY REGISTER (MPC-ROR-001, Rev. 3) — Selected Entries

ID	Description	Category	Likelihood	Impact	Score	Owner	Planned Action / Status
R-01	Senior quality engineer (22 years) intends retirement in 18 months — critical CMM programming and customer-specific dimensional verification knowledge at risk of loss	HR / Knowledge	3 — Likely	3 — Major	**9 — HIGH**	MR + HR Manager	Org. knowledge documentation complete (Month 12); cross-training of backup in progress; structured transfer plan Q2. Status: In Progress — effectiveness to be assessed at Month 24 review
R-02	Single-source titanium bar stock supplier serving defense customers — financial instability noted; no qualified alternative source in supply chain	Supply Chain	2 — Possible	3 — Major	**6 — MED**	Purchasing Manager	Alternative supplier qualification underway — target approval by Month 20. Maintain 90-day safety stock of critical sizes. Status: In Progress

ID	Description	Category	Likelihood	Impact	Score	Owner	Planned Action / Status
R-03	Customer MBD adoption replacing 2D drawings — inspection procedure competency gap for 4 of 5 quality inspectors; 2 customers actively transitioning	Technology	3 — Likely	2 — Moderate	**6 — MED**	Quality Manager	MBD training completed Month 17 — 4 of 4 inspectors assessed competent. Risk score reduced to 2 (Likelihood reduced to 1). Status: Action Complete — monitoring
R-04	Production incentive structure rewards throughput over quality — operator behavior risk during peak production periods when first-pass yield pressure conflicts with schedule pressure	Process / Culture	2 — Possible	2 — Moderate	**4 — LOW**	Operations Manager	First-pass yield added to operational KPIs alongside throughput; supervisor quality-stop authority reinforced in QMS awareness training. Status: Action Complete — monitoring monthly
O-01	Aerospace Tier 1 customer (Northfield Systems) has opened new Tier 2 program access to ISO 9001 certified suppliers — previously closed to Meridian; estimated $2.1M annual revenue potential	Customer / Market	3 — Confirmed	3 — Major	**9 — HIGH**	MR + Sales	Certification achieved Month 12. First bid submitted Month 14. Award received Month 17 — $480K initial program. Status: REALIZED — continuing to pursue additional programs

⚠ Common Mistakes to Avoid

Mistake 1: Generic risk descriptions. "Customer requirements may change" or "regulatory environment may evolve" contribute nothing. Every risk must be specific to this organization's actual situation — naming the customer, the regulation, the supplier, or the process.

Mistake 2: No opportunities — only risks. The register is called a risk AND opportunity register for a reason. Organizations that list only risks have missed the Clause 6.1 requirement to identify and plan actions for opportunities. Opportunities often emerge from the same analysis that identifies risks.

Mistake 3: A static register. A register created during implementation and never reviewed or updated is a compliance artifact. The management review minutes must show that the register was reviewed, scores were updated based on action effectiveness, and new entries were added as organizational conditions changed.

Mistake 4: Actions that are monitoring plans for high-priority risks. A Risk Score of 9 (Likelihood 3, Impact 3) requires a substantive planned action to reduce likelihood or impact — not a note to "continue monitoring." Monitoring is appropriate for low-priority risks; high-priority risks require intervention.

Auditor Perspective

The auditor's risk register evaluation follows three steps. First: is the register current? What is the last review date, and are any significant organizational changes since that date reflected? Second: are the risks specific and authentic? The auditor selects two or three entries and asks: "Tell me about this risk — is it still current, and what has changed since you identified it?" Third: can you trace from a risk to a QMS control? "For Risk R-02, show me where in your QMS the control for single-source supplier dependency lives." This connectivity test reveals whether the register drives QMS decisions or exists as a parallel document. Auditors also check whether Risk R-01's knowledge transfer plan is linked to the organizational knowledge procedure and whether O-01's realization is documented anywhere in the system as a closed-loop.

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TEMPLATE 2: Quality Objectives Tracker

ISO 9001:2015 Clause 6.2

Document Type	Maintained record — updated monthly with current performance data; reviewed at each management review
Clause Reference	Clause 6.2.1 (objective requirements), Clause 6.2.2 (achievement planning); also connects to Clause 9.3.2 (management review input)
Document Control	Controlled document — base document versioned annually when objectives are reset; monthly data updates are not version-change events
Retention	Current tracker plus 3 years of prior trackers retained to demonstrate performance trend over time

Completion Instructions

Section A — Objective Definition Fields (completed once per planning cycle, reviewed annually):

Policy Commitment: Which specific Quality Policy statement does this objective support? Quote the relevant policy language. This creates the traceable link between policy and objective that auditors verify.

Objective Statement: The specific, measurable outcome to be achieved. Written as "[Metric] will achieve [target] by [date] as measured by [method]." Not "improve quality" — that is a direction. "Reduce customer PPM from 2,200 to below 1,000 by December 31, as measured by customer return records" is an objective.

Metric and Baseline: The specific numeric measure and the documented starting point from which improvement is measured. The baseline must be from real data — not estimated. If baseline data does not yet exist, document the plan to establish it.

Target: The specific value to be achieved by the target date. SMART — Specific, Measurable, Achievable, Relevant, Time-bound.

Achievement Plan: What will be done, by whom, with what resources, by when, and how results will be evaluated — the five Clause 6.2.2 elements.

Section B — Monthly Monitoring Data (added monthly):

Record the current metric value each month. Calculate percent of target achieved. Assign RAG (Red/Amber/Green) status: Green = at or above target or trend line; Amber = within 10% of target trajectory; Red = more than 10% below target trajectory. Note any significant events that affected the metric.

Section C — Management Review Fields (completed at each management review):
Review Conclusion: Is the objective on track, off track, or achieved? What decision was made — continue current approach, modify action plan, revise target, or close as achieved? Document the specific management review decision, not just the performance data.

MERIDIAN QUALITY OBJECTIVES TRACKER — Objective QO-01 (MPC-OBJ-001, Rev. 2)

OBJECTIVE QO-01: Customer PPM Reduction	
Policy Commitment Supported	"Meeting every customer specification and drawing requirement; identifying and resolving quality problems at their root so they do not recur." (MPC-POL-001)
Objective Statement	Reduce the customer-reported nonconformance rate from 2,200 PPM to below 1,000 PPM by December 31 of the certification year, as measured by customer quality notification records and return material authorizations.
Metric	Customer-reported PPM (parts per million nonconforming as reported by customers against delivered quantities)
Baseline	2,200 PPM (12-month average prior to certification; data from customer quality notifications and RMAs, verified against customer scorecard data from Northfield Systems and Allied Manufacturing)
Annual Target	Below 1,000 PPM by December 31 (Year 1 post-certification)
Achievement Plan	WHAT: Implement first-piece inspection protocol for all new jobs; complete CAPA for top 3 recurring defect types; initiate supplier corrective action for supplier-caused returns. WHO: Quality Manager (inspection protocol); Quality Engineer (CAPAs); Purchasing Manager (supplier CARs). RESOURCES: No additional budget required; Quality Engineer time reallocation to CAPA activity estimated 4 hrs/week. WHEN: Inspection protocol by Month 3; CAPAs complete by Month 6; supplier CARs closed by Month 8. EVALUATION: Monthly PPM tracking against linear improvement trajectory from 2,200 to 1,000; reported at management review.

Monthly Monitoring Data:

Month	1	2	3	4	5	6
PPM	2,180	2,050	1,890	1,720	1,580	1,410
RAG	GREEN	GREEN	GREEN	GREEN	GREEN	GREEN

Month	7	8	9	10	11	12
PPM	1,380	1,290	1,240	1,210	1,190	1,240
RAG	GREEN	GREEN	AMBER	AMBER	AMBER	AMBER

Management Review Decision (Month 18):	Objective not achieved at 1,000 PPM target — Year-end result: 1,240 PPM. However, 44% improvement from baseline (2,200 to 1,240). Root cause analysis confirms remaining gap attributable to supplier-caused defects from heat treatment process; supplier corrective action in progress. Decision: Revise Year 2 target to 1,100 PPM (achievable given current trend, with heat treatment CAPA expected to close in Q1 Year 2). New target entered in Year 2 tracker QO-01-Y2.

⚠ Common Mistakes to Avoid

Mistake 1: Objective statements without specific numeric targets. "Improve customer satisfaction" is not an objective. "Achieve a customer satisfaction survey score of 4.2 out of 5.0 on the annual survey" is. Every objective must have a number that anyone can use to determine at any moment whether it has been achieved.

Mistake 2: Monitoring data that exists only in a spreadsheet the quality manager consults. Objectives must be communicated to the people whose work affects them. If the first-pass yield objective only lives in the quality office, it cannot influence operator behavior.

Mistake 3: Off-track objectives with no management review decision. An objective in RED status at management review that receives no action — not a revised plan, not a root cause discussion, not a decision to revise the target — is evidence that the management review is passive rather than governing.

Mistake 4: Achieved objectives left unchanged indefinitely. Once an objective is achieved, the organization should either set a more ambitious target or redirect the objective to a different quality dimension. Permanent objectives at which the organization has been consistently achieving 100% for two years are not driving improvement.

Auditor Perspective

Quality objectives receive detailed scrutiny at every audit. The auditors standard approach: select two objectives (typically one that appears on track and one that appears off-track), and verify three things for each. First: does the objective have a measurable, specific target with a documented baseline? Second: is monitoring data available for every month since the last review? Gaps in the data record suggest monitoring was not occurring consistently. Third: for any off-track objective, what management review decision was made and has it been acted on? A management review that noted an objective was off-track and took no action is a governance failure visible in the minutes. The objective policy-linkage is also checked: auditors ask to see the Quality Policy and then ask to be shown how objective QO-X connects to a specific policy commitment.

TEMPLATE 3: Competence Matrix

ISO 9001:2015 Clause 7.2

Document Type	Maintained record — updated when roles change, new employees join, competence requirements change, or gap training is completed
Clause Reference	Clause 7.2: Competence (determining requirements, ensuring competence, evaluating training effectiveness)
Document Control	Controlled document — numbered, versioned; updated within 30 days of any role or personnel change
Retention	Current version maintained; prior versions retained for duration of employment plus 5 years

Completion Instructions

Structure: The competence matrix is organized with roles (job titles, not individual names) as column headers across the top, and competence requirements as row headers down the left side. Each cell shows whether the competence is Required (R) for this role and whether the current role-holder is Competent (C), In Training (T), or has a Gap (G).

Step 1 — Define all quality-affecting roles: List every role that could affect QMS performance — not just quality roles. Include: operators, inspectors, setup technicians, engineers, supervisors, purchasing, management. Use role titles, not names. Where the same role exists in multiple departments (e.g., Production Supervisor across multiple lines), list each distinct role.

Step 2 — Define competence requirements for each role: For each role, determine what knowledge, skills, and qualifications are required. Be specific: not "quality knowledge" but "Ability to interpret GD&T tolerances including profile tolerances per ASME Y14.5." Sources for requirements: job descriptions, procedure requirements, customer quality flow-down, regulatory requirements, and process risk assessment.

Step 3 — Define competence basis for each requirement: How will competence be verified? Acceptable bases: education (degree or certification), training (attended a defined course and passed an assessment), experience (documented observation of competent performance), or combination. Document the basis alongside the requirement.

Step 4 — Assess current competence of each role-holder: For each Required (R) cell, determine whether the current person in that role is Competent (C), In Training (T — on a training plan with a target completion date), or has a Gap (G — competence required but not yet addressed). Document the evidence of competence (training record reference, certification number, supervisor assessment date).

Step 5 — Develop gap closure plans: For every Gap (G) cell, a training or qualification action must be planned — with a method, a target date, and an identified resource. Gap cells without action plans are open Clause 7.2 nonconformances.

Refresh cycle: Review the full matrix at minimum annually. Update immediately when: a new employee joins (add to existing roles); an existing employee changes roles; a role's competence requirements change; training is completed; or a gap is identified through an audit, nonconformance, or management review.

MERIDIAN COMPETENCE MATRIX — Sample Extract (MPC-CMP-001, Rev. 4)

Competence Requirement	QC Inspector	CNC Machinist	Purchasing Agent	Basis / Evidence
ISO 9001:2015 awareness (Quality Policy, objectives, individual contribution)	R / C	R / C	R / C	Training: MPC-TRN-AWR-001; attendance record
Read and interpret engineering drawings (GD&T per ASME Y14.5)	R / C	R / C	R / G*	Training + assessment: MPC-TRN-GDT-001; skills test score on file
CMM operation and programming (Zeiss Contura)	R / C	R / T**	Not Required	Training + OJT sign-off: MPC-TRN-CMM-001; supervisor competence sign-off
Model-based definition (MBD) interpretation	R / C	Not Required	Not Required	External training (MBD Solutions Inc., Month 17); competence assessment by QM
Nonconforming material identification and segregation	R / C	R / C	Not Required	Training: MPC-TRN-NCR-001; annual refresher during QMS awareness update
Corrective action initiation and root cause participation	R / C	R / C	R / C	Training: MPC-TRN-CAP-001; demonstrated in at least one documented CAPA participation
Supplier qualification evaluation criteria	Not Required	Not Required	R / C	Training: MPC-TRN-SUP-001; signed

Competence Requirement	QC Inspector	CNC Machinist	Purchasing Agent	Basis / Evidence
				acknowledgment on file
Calibration status verification before use	R / C	R / C	Not Required	Training: MPC-TRN-CAL-001; included in new employee orientation for production roles

** G = Gap: Purchasing Agent requires GD&T literacy for purchase order specification verification. Gap action: Enroll in MPC-TRN-GDT-001 by Month 19. Interim control: Quality Engineer reviews all POs for GD&T-specified characteristics before issue. Gap owner: Purchasing Manager. Target close: Month 20.*

*** T = In Training: CNC Machinist is currently completing CMM training — estimated completion Month 19. Training record MPC-TRN-CMM-2024-007 tracks progress. Supervisor assessment target: Month 20.*

⚠ Common Mistakes to Avoid

Mistake 1: Using individual names instead of role titles. The matrix must be role-based. When individuals change, the matrix content (competence requirements and evidence basis) remains stable — only the personnel assignment column needs updating.

Mistake 2: "Training attended" accepted as evidence of competence without an assessment. Attendance at training is a training record, not competence evidence. Competence is the ability to perform the task correctly — which requires either assessment results, demonstrated performance, or qualified experience documentation.

Mistake 3: Gap cells without action plans. Every gap requires a closure plan. An assessor who finds a gap cell with no action plan, no target date, and no interim control has found a Clause 7.2 nonconformance.

Mistake 4: Omitting support and management roles. The matrix is frequently populated only for production and quality roles. The standard applies to all roles that affect QMS performance — including engineering, purchasing, supervisory, and executive roles.

🔍 Auditor Perspective

The competence matrix audit has two components. First, completeness: does the matrix cover all quality-affecting roles? Auditors look for role categories that appear to be missing — typically support roles (purchasing, engineering) and management roles. Second, verification: auditors select 3 to 5 employees at random and ask for the competence records that support their "C" (Competent) designations. A competence matrix that shows C in every cell but produces only training attendance records (not assessments) as evidence has confused training with competence. The gap closure plan audit — verifying that every G cell has an action plan with a target date — is typically conducted at the same time.

TEMPLATE 4: Training Record

ISO 9001:2015 Clauses 7.2 and 7.3

Document Type	Retained record — evidence of training delivery and, where applicable, competence assessment
Clause Reference	Clause 7.2(b): Ensuring competence on basis of training; Clause 7.3: Awareness; Clause 7.2(d): Retained documented information as evidence of competence
Document Control	Records retention: duration of employment plus 5 years; stored in personnel quality file or QMS records system
Retention	Permanent records — retained for duration of employment plus 5 years minimum; longer for roles with regulatory implications

Completion Instructions

Header Fields: Record the training event details — unique training record number, training title, date conducted, trainer name and qualification, training method (classroom, OJT, e-learning, external course), duration, and document number of the procedure or work instruction that this training addresses.

Content Summary: Briefly describe what was covered. This does not need to be a full curriculum outline — a 2 to 3 sentence summary of topics sufficient to demonstrate that the training content is relevant to the competence being developed. Reference any training materials by document number.

Attendee and Assessment Section: For each attendee: name, role title, date of attendance, assessment method (written test, practical demonstration, supervisor observation, no formal assessment for awareness-only training), and assessment result (Pass/score, or N/A for awareness training where no formal assessment is required).

Competence Confirmation: For training intended to establish operational competence (not just awareness), include a supervisor or qualified assessor sign-off confirming that the individual demonstrated the required competence during or following the training. This is the element most frequently missing — and the element that distinguishes competence evidence from attendance evidence.

Effectiveness Evaluation: For significant training events (new procedure training, gap closure training, qualification training), include a field or Competence Matrix to document how training effectiveness was evaluated — not just that training occurred, but that it produced the intended competence.

Key distinction: Training records serve two purposes: Clause 7.3 awareness records require only attendance documentation. Clause 7.2 competence records require both attendance AND a form of competence verification — assessment results, demonstrated performance record, or supervisor sign-off on observed competent performance.

MERIDIAN TRAINING RECORD (MPC-TRN-2024-043)

Training Record Number	MPC-TRN-2024-043
Training Title	Model-Based Definition (MBD) Interpretation for Quality Inspection
Date Conducted	[Month 17, Year 1 post-certification] — 2-day external course
Trainer / Provider	MBD Solutions, Inc. — ASME-certified MBD instruction; provider qualification on file as MPC-EXT-TRN-003
Training Method	External classroom (Day 1) + Practical lab exercise on Meridian CMM equipment (Day 2)
Procedure / Document Addressed	MPC-PRO-014 (Dimensional Inspection) — competence requirement updated in Competence Matrix Rev. 4 to include MBD interpretation
Content Summary	Day 1: ASME Y14.41 standard introduction; model annotation types; PMI (Product and Manufacturing Information) reading; annotation query workflow. Day 2: Practical interpretation of Northfield Systems NC-884 MBD dataset on Zeiss Contura CMM; verification of 14 critical annotations; documentation of measurement plan from MBD dataset without 2D drawing.

Attendee Name	Role Title	Assessment Result	Competence Sign-off
[Name 1]	QC Inspector	Written test: 91% (Pass). Practical: CMM measurement plan for 14 features completed correctly — all within specification	Quality Manager sign-off [date]: Competent to perform MBD-based dimensional inspection without 2D drawing support
[Name 2]	QC Inspector	Written test: 88% (Pass). Practical: Completed correctly with one annotation interpretation error corrected after review	Quality Manager sign-off [date]: Competent with note — first 5 MBD jobs to be reviewed by lead inspector before independent release
[Name 3]	QC Inspector	Written test: 79% (Pass). Practical: Completed correctly	Quality Manager sign-off [date]: Competent to perform MBD-based inspection
[Name 4]	Senior QC Inspector	Written test: 95% (Pass). Practical: All features correct — fastest completion, offered to assist new starters	Quality Manager sign-off [date]: Competent; nominated as MBD SME for peer support

Effectiveness Evaluation	Competence Matrix updated (Rev. 4): all four inspectors moved from G (Gap) to C (Competent) for MBD interpretation. Risk register R-03 score updated: Likelihood reduced from 3 to 1

	(actions complete); combined score reduced from 6 to 2. First MBD-only job from Northfield Systems (NC-891) processed without 2D drawing by [Name 4] Month 18 — no inspection discrepancies reported by customer. Effectiveness confirmed.

⚠ Common Mistakes to Avoid

Mistake 1: Attendance record only, no assessment. A sign-in sheet confirms attendance, not competence. For any training intended to establish role-critical competence, an assessment of some form is required — written test, practical demonstration, or supervisor observation and sign-off.

Mistake 2: Training records that do not connect to the competence matrix. Training records are evidence; the competence matrix is the status document. After a training event closes a gap, both the training record (retained as evidence) and the competence matrix (updated to show C) must be updated to maintain system coherence.

Mistake 3: No effectiveness evaluation for significant training. Training effectiveness evaluation (was the training effective in developing the required competence?) is required by Clause 7.2(c). For operational competence training, the effectiveness evaluation should confirm whether the trained individual can now perform the task correctly — not just that they attended a course.

Auditor Perspective

Training records are sampled during every audit. Auditors typically select 3 to 5 employees visible on the shop floor, note their roles, and request the training records that demonstrate their competence for the quality-critical aspects of those roles. The most revealing gap: records that show training attendance but no competence assessment for roles where the standard (or the organization's own procedure) requires demonstrated competence. Auditors also check whether training records for procedures that have been revised since the last audit exist — revised procedures require training of affected personnel, and a procedure with a revision date more recent than the training record date for the people using it signals a change management gap.

TEMPLATE 5: Calibration Equipment Register and Log

ISO 9001:2015 Clause 7.1.5

Document Type	Maintained record (register) + Retained records (calibration results log) — master list of all calibrated equipment and history of all calibration events
Clause Reference	Clause 7.1.5.1 (fitness for purpose of monitoring and measuring resources) and Clause 7.1.5.2 (measurement traceability)
Document Control	Register is a controlled document; calibration history records retained for minimum 5 years or device retirement plus 2 years
Retention	Equipment register: current version maintained. Calibration records: minimum 5 years from calibration date

Completion Instructions

PART A — EQUIPMENT REGISTER (master inventory):

Equipment ID: Assign a unique identifier to every measuring device. Use a consistent format: prefix + sequential number (e.g., MPC-CAL-0001). This ID must match the physical label on the device.

Description and Model: Sufficient detail to identify the device unambiguously — make, model, serial number, and range. Two identical micrometers in the same range require separate IDs and entries.

Location: Where is the device normally kept? This must be specific enough for the auditor to physically locate the device — "Line 1 inspection station" not "production area."

Calibration Method: Internal (specify the internal procedure reference) or External (specify accredited laboratory name and lab accreditation number). For external calibration, attach the current calibration certificate to the register entry.

Calibration Interval: How frequently must this device be calibrated? State in months. The interval must be based on the device type, use frequency, and calibration history — not arbitrarily assigned.

Last Calibration Date and Next Due Date: Actual dates, not planned dates. Update immediately after each calibration event.

Calibration Status: In Calibration (current), Overdue (past due date), Out for Calibration (at external lab), Quarantined (found out of tolerance), Retired (no longer in service).

PART B — CALIBRATION RESULTS LOG (history record):

For each calibration event, record: the device ID, calibration date, calibration provider, results (as-found and as-left measurements for key reference points), pass/fail determination, and certificate number for external calibrations. For out-of-tolerance findings, record the out-of-tolerance investigation outcome — what product was affected, what action was taken.

MERIDIAN CALIBRATION EQUIPMENT REGISTER — Sample Entries (MPC-CAL-REG-001, Rev. 6)

Device ID	Description / Model / Serial No.	Location	Interval (mo.)	Last Cal.	Next Due
MPC-CAL-0001	Outside Micrometer 0-1 in. / Mitutoyo 103-177 / SN 4421087	Line 1 Inspection Station	12 months	[Month/Year]	[Month/Year]
MPC-CAL-0002	Outside Micrometer 1-2 in. / Mitutoyo 103-178 / SN 4421088	Line 1 Inspection Station	12 months	[Month/Year]	[Month/Year]
MPC-CAL-0011	Digital Caliper 0-6 in. / Mitutoyo 500-197 / SN 3092114	Quality Lab	12 months	[Month/Year]	[Month/Year]
MPC-CAL-0021	CMM — Zeiss Contura 7/10/6 / SN CONTURA-MPC-001	Quality Lab	12 months (ext.)	[Month/Year]	[Month/Year]
MPC-CAL-0022	CMM — Zeiss Contura 7/10/6 (Unit 2) / SN CONTURA-MPC-002	Quality Lab	12 months (ext.)	[Month/Year]	[Month/Year]
MPC-CAL-0035	Hardness Tester — Rockwell C / Wilson 600 MRK / SN W600-4412	Receiving Inspection	6 months	[Month/Year]	[Month/Year]
MPC-CAL-0047	Surface Roughness Tester / Mitutoyo SJ-210 / SN 5091234	Quality Lab	12 months	[Month/Year] — QUARANTINED: Out of tolerance found at calibration — investigation in progress	N/A pending investigation

Calibration Results Log — Recent Events (MPC-CAL-LOG-001):

Device ID	Cal. Date	Provider	As-Found Result	Pass/Fail	Certificate No.
MPC-CAL-0047	[Month/Year]	Precision Measurement Labs (ISO 17025 Accredited)	Measurement deviation: +0.8 microinch at 32 microinch reference standard; +1.2 microinch at 63 microinch reference standard. Both readings exceed the 0.5 microinch accuracy specification.	FAIL — Out of Tolerance	PML-2024-1847
MPC-CAL-0047	OOT Investigation	QC Department	Device quarantined. Jobs using Ra measurement since last in-tolerance calibration ([Month/Year]) reviewed: 3 jobs with Ra specified. All 3 had Ra results within specification by sufficient margin (all measured 28-35 microinch against 63 microinch limit) that 1.2 microinch OOT error would not have affected conformance decisions. No product recall required. Device submitted for repair and recalibration.	N/A — Investigation	See MPC-NCR-2024-019

⚠ Common Mistakes to Avoid

Mistake 1: Incomplete equipment register — devices in use not on the list. The most common and consequential calibration finding. Conduct a physical census of all measuring devices in use, not just those already in the calibration system. Walk every production and inspection area.

Mistake 2: No out-of-tolerance investigation when a device is found OOT. Finding a device out of tolerance and simply sending it for recalibration without investigating what product was measured since the last good calibration is a Clause 7.1.5.2 nonconformance. The investigation must be documented even when the conclusion is that no product was affected.

Mistake 3: Devices used without checking calibration label. The physical label serves no quality function if it is not checked before use. Calibration status verification before use must be part of the inspection procedure, not an afterthought.

Mistake 4: No certificate of traceability from external calibration provider. "Calibrated" without documented traceability to national or international measurement standards is not compliant measurement. External calibration certificates must state the traceability chain.

Auditor Perspective

Calibration is a physically verifiable audit area. After reviewing the equipment register, auditors walk the production floor and inspection areas comparing what they find to what the register shows. Any device found in use that is not on the register, that has no calibration label, or that has an overdue label is an immediate finding. The auditor will also select a sample of recently calibrated devices and trace from the physical device to the register entry to the calibration certificate, verifying that the certificate includes a traceability statement and that the next due date on the label matches the register. The out-of-tolerance record for MPC-CAL-0047 will be examined specifically: was the investigation documented, and was the conclusion reasonable?

TEMPLATE 6: Document Control Register

ISO 9001:2015 Clause 7.5

Document Type	Maintained record — the authoritative master list of all controlled QMS documents; updated whenever documents are issued, revised, or retired
Clause Reference	Clause 7.5.3: Control of documented information — ensuring documents are available, suitable for use, and adequately protected
Document Control	This document IS the document control register — it controls itself; maintained by the Management Representative or designated Document Controller
Retention	Current version maintained; prior register versions retained to enable reconstruction of historical document status

Completion Instructions

Column 1 — Document Number: A unique alphanumeric identifier for each controlled document. Use a consistent numbering system that reflects document type: MPC-POL (policies), MPC-PRO (procedures), MPC-WI (work instructions), MPC-FRM (forms/templates), MPC-EXT (external documents).

Column 2 — Document Title: The document's official title exactly as it appears in the document header. Abbreviated or informal titles create confusion during audits.

Column 3 — Document Type: Policy, Procedure, Work Instruction, Form/Template, External Document, or Record Template.

Column 4 — Current Revision: The revision level currently in effect. Use a simple, consistent revision scheme: Rev. 0 (initial issue), Rev. 1, Rev. 2, etc. or alphabetical (Rev. A, B, C).

Column 5 — Effective Date: When the current revision was placed in effect — not when it was written, but when it was approved for use.

Column 6 — Process Owner / Responsible Role: Who is responsible for maintaining and updating this document? Named by role title.

Column 7 — Document Location: Where is the controlled copy stored? For electronic document control systems: the folder path or document system URL. For physical documents: the physical location.

Column 8 — External Document Source (for external documents only): The originating body, standard number, and current revision level as tracked by the organization.

Column 9 — Status: Active (current and in use), Superseded (replaced by a newer revision — retained as historical record), Retired (no longer needed — archived), or Under Review (being revised — current version remains in effect until new version is approved).

Monthly maintenance check: Review the register for any documents due for periodic review (many organizations set a maximum document life of 3 years before mandatory review), any external documents where a new revision may have been issued, and any documents referenced in procedures that do not appear in the register.

MERIDIAN DOCUMENT CONTROL REGISTER — Sample Entries (MPC-DCR-001, Rev. 8)

Doc. No.	Title	Type	Rev.	Effective Date	Owner Role	Status
MPC-POL-001	Quality Policy	Policy	Rev. 2	[Month/Year]	CEO	Active
MPC-QM-001	Quality Manual	Quality Manual	Rev. 1	[Month/Year]	Management Rep.	Active
MPC-SCO-001	QMS Scope Statement	Policy	Rev. 1	[Month/Year]	Management Rep.	Active
MPC-PRO-001	Document and Records Control Procedure	Procedure	Rev. 3	[Month/Year]	Management Rep.	Active
MPC-PRO-002	Nonconforming Material Control	Procedure	Rev. 3	[Month/Year]	Quality Manager	Active
MPC-PRO-002	Nonconforming Material Control	Procedure	Rev. 2	[Month/Year - 8 months prior]	Quality Manager	Superseded
MPC-PRO-004	Customer Requirement Review	Procedure	Rev. 2	[Month/Year]	Operations Manager	Active
MPC-PRO-005	Design and Development Control	Procedure	Rev. 2	[Month/Year]	Engineering Manager	Active
MPC-FRM-030	Roles and Responsibilities Matrix	Form/Record	Rev. 4	[Month/Year]	Management Rep.	Active
MPC-CAL-	Calibration Equipment Register	Record Template	Rev. 6	[Month/Year]	Quality Engineer	Active

Doc. No.	Title	Type	Rev.	Effective Date	Owner Role	Status
REG-001						
MPC-EXT-001	ASME Y14.5-2018 Dimensioning and Tolerancing	External Standard	Y14.5-2018	[Year acquired]	Engineering Manager	Active
MPC-EXT-002	AMS 2759 Heat Treatment of Steel Parts (General)	External Standard	Rev. F	[Year acquired]	Quality Manager	Active
MPC-EXT-003	AS9102B First Article Inspection Requirement	External Standard	Rev. B	[Year acquired]	Quality Manager	Active

Best Practice

The most effective document control systems for small to mid-size manufacturing organizations are SharePoint-based or equivalent cloud document management platforms. A well-configured SharePoint library with: version control enabled (all prior versions retained automatically); check-out/check-in for editing; role-based read permissions (all employees) and edit permissions (process owners only); automatic notification to subscribers when a document is updated; and a master document list view filtered to show only Active documents — satisfies all Clause 7.5 requirements with minimal administrative overhead. The document register can be maintained as a SharePoint list that auto-populates from document metadata. Physical paper document control systems require significantly more administrative effort to maintain and are more prone to the obsolete-document-in-use finding.

Common Mistakes to Avoid

Mistake 1: External documents not in the register. Customer drawings, industry standards (ASME, AMS, AWS, MIL-SPEC), and regulatory documents referenced in procedures are controlled documents. If they are not in the register, there is no mechanism for detecting when they are revised.

Mistake 2: Superseded documents accessible alongside current documents. If employees can find and use Rev. 2 of a procedure when Rev. 3 is the current version, the document control system has failed its primary function. Superseded documents must be archived and inaccessible to operational personnel.

Mistake 3: Register not updated when documents are revised. A register that shows Rev. 2 as current when Rev. 3 has been issued is a document control finding. The register update must occur simultaneously with the document issuance — not as a follow-up task.

Mistake 4: No process for monitoring external document revisions. Knowing the current revision of an external standard at one point in time is not sufficient. The organization needs a process for detecting when a standard is revised — standards body subscription, industry association notifications, or periodic review schedule.

Auditor Perspective

Document control is audited through a combination of register review and physical verification. The auditor reviews the register and selects 5 to 8 documents across types — a policy, two procedures, a form, and two external documents. For each, they verify: (1) the current revision in the register matches the document itself; (2) the document is physically accessible in the designated location; (3) any superseded version is not accessible in the same location. For external documents, they check the current revision in the register and ask: "How would you know if ASME Y14.5 was revised?" If the answer is "we would not" — there is no monitoring mechanism — the external document control is inadequate. One of the most efficient audit approaches for document control: ask the auditor to point to a procedure being followed on the floor, then ask to see that procedure version in the controlled system, and verify they match.

Quick Reference: Planning and Control Templates Summary

Template	Clause	Critical Fields	Update Trigger	Frequency
Risk and Opportunity Register	6.1	Specific descriptions; likelihood/impact scores; substantive actions for high-priority items; effectiveness status	Context changes; new risks identified; action completion; management review	Review at every management review; update within 30 days of triggering event
Quality Objectives Tracker	6.2	Measurable target; documented baseline; achievement plan with 5 elements; monthly data; management review decision	New planning cycle; achieved objective reset; off-track objective action plan change	Monthly data entry; management review evaluation at each review cycle
Competence Matrix	7.2	All quality-affecting roles; specific competence requirements; basis of competence evidence; gap closure plans with dates	New hire; role change; new competence requirement; gap closure; competence assessment update	Review annually; update within 30 days of personnel or role change
Training Record	7.2, 7.3	Content summary; attendee names and roles; assessment results; supervisor competence sign-off; effectiveness evaluation	Each training event; procedure revisions affecting trained personnel	Created at each training event; filed within 5 business days
Calibration Log	7.1.5	Complete equipment register; calibration results with as-found data; OOT investigation records; certificate traceability statement	Each calibration event; new equipment acquired; equipment retired; OOT finding	Register updated at each calibration event; census conducted annually

Template	Clause	Critical Fields	Update Trigger	Frequency
Document Control Register	7.5	All controlled documents including external; current revision; superseded versions archived; external revision tracking	Document issuance; document revision; document retirement; external standard revision	Updated immediately upon any document change; monthly review for external document currency

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Next in Volume 3: Guide 3.3 — Operational and Improvement Templates. The final guide in the series: Internal Audit Checklist (full clause-by-clause), Audit Report, Nonconformance Report, CAPA Form, Management Review Agenda and Minutes, Customer Satisfaction Survey, Supplier Evaluation Form, Control Plan Template, and Process Map Template — with completion instructions, Meridian examples, and auditor guidance for each.
