Six Sigma Kaizen

ISO 9001 IMPLEMENTATION HUB

Volume 1 • Guide 5 of 6

Internal Audit Program Development

Your Early Warning System: Building an Internal Audit Program That Adds Value

A Practitioner-Level Implementation Guide for Quality Professionals

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

How to Use This Guide

This is Guide 1.5 in the six-part ISO 9001:2015 implementation roadmap. It covers everything required to build, operate, and sustain an internal audit program that genuinely serves the QMS — not merely satisfies Clause 9.2. By this point in the Meridian implementation, Phase 3 documentation development is complete, Phase B and C training has been delivered, and the QMS is operational. The internal audit program is the mechanism that now verifies whether the QMS is actually working as designed.

This guide covers the full internal audit lifecycle: what Clause 9.2 actually requires, the difference between a compliance audit and a value-adding audit, building the annual audit program, selecting and training internal auditors, writing audit plans and checklists, conducting the audit from opening meeting through closing meeting, writing findings that produce real improvement, managing corrective actions from audit findings through verification, and feeding the management review. It concludes with Meridian's complete first internal audit cycle — every finding, every corrective action, and the surprises that made the audit worth conducting.

Where We Are in the Meridian Journey

It is Month 8. Denise Alvarez has just confirmed that all 23 procedures are approved and operational, all Phase B training is complete, and the competence matrix is current. The quality dashboard is live and producing the first two months of performance data. Stage 2 is scheduled for Month 13. Between now and Stage 2, a complete internal audit cycle must be planned, executed, reported, acted upon, and verified — with all corrective actions closed and documented before the registrar arrives. The clock is running, and the internal audit is the most calendar-constrained remaining element of the implementation.

Section 1: Why Internal Audits Fail — and What a Good One Actually Does

The internal audit is the most frequently conducted and most consistently underperformed element of the ISO 9001 QMS. In organizations that treat it as a compliance exercise, the internal audit consumes significant time and produces audit reports full of minor observations that no one acts on — confirming conformance that everyone already assumed existed and missing the systemic issues that will surface as major nonconformances when the registrar arrives.

In organizations that conduct their internal audits with genuine rigor and professional skepticism, the audit functions exactly as the standard intends: as an early warning system that identifies process gaps, documentation failures, and behavioral nonconformances before they become customer escapes, certification findings, or operational crises. The difference between these two outcomes is not the audit checklist or the audit schedule — it is the mindset, skill, and organizational independence of the auditors, and the genuine commitment of leadership to acting on what the audit finds.

The Five Most Common Internal Audit Failures

Failure 1: The Friendship Audit

Internal auditors who have strong collegial relationships with the people they are auditing — which in a mid-size organization is virtually everyone — face a natural social pressure to avoid findings that create discomfort or conflict. The result is an audit that confirms what people want to hear, misses what is actually happening, and provides no real information about QMS effectiveness. The auditor does not consciously decide to avoid findings; the social dynamic produces softer questioning, easier acceptance of partial answers, and a tendency to score ambiguous situations as conforming rather than investigating further.

Failure 2: The Paper Audit

An internal audit that reviews documents and records without observing processes in operation can confirm that documentation exists and is controlled but cannot verify that documented processes are being followed. A procedure can be impeccably written, current, approved, and available — and completely ignored on the shop floor. The paper audit misses this disconnect entirely. Effective internal audits combine document review with process observation and personnel interviews to triangulate evidence from all three sources.

Failure 3: The Checklist Audit

A checklist designed as a series of yes/no questions — "Do you have a calibration procedure? Yes. Does the procedure describe the calibration frequency? Yes. Are calibration records maintained? Yes." — produces a checklist full of checkmarks and an audit report that says everything is fine. The checklist audit asks whether systems exist but not whether they are effective, consistently applied, or producing the quality outcomes they were designed to produce. The best internal audit checklists are prompts for investigation, not questionnaires for completion.

Failure 4: The Zero-Finding Audit

An internal audit in a first-time-certified organization with a recently implemented QMS that produces zero nonconformance findings is not a success — it is a failure of audit rigor. Newly implemented quality

management systems always have implementation gaps, procedural inconsistencies, and behavioral nonconformances. An audit that finds none of them did not look hard enough. The purpose of the internal audit is to find what is not working before the registrar does. Zero findings before a first certification audit should be treated as a red flag, not a celebration.

Failure 5: The No-Action Audit

An internal audit that produces findings that are acknowledged, recorded, and then left unaddressed has accomplished nothing beyond generating paperwork. The value of the audit is realized entirely through the corrective actions it triggers and the improvements those actions produce. Organizations that open corrective action requests from audit findings and then allow them to age indefinitely without resolution are running an audit program that satisfies the letter of Clause 9.2 while failing its intent completely.

Kaizen Connection

The internal audit is the QMS equivalent of a Gemba walk with a compliance lens. In Lean thinking, the Gemba walk takes managers to where value is created — the shop floor, the service counter, the warehouse — to see actual conditions rather than rely on reports and assumptions. The internal audit does the same thing for the quality management system: it goes where the processes actually operate, observes what is actually happening, and compares reality to the documented standard. Organizations that have mastered Lean Gemba walks often find the internal audit mindset immediately familiar — because both tools share the same fundamental discipline: go see, ask why, show respect, and be willing to find what you did not want to find.

Section 2: What Clause 9.2 Actually Requires

Clause 9.2 is the internal audit requirement. Read carefully, it is both more specific and more flexible than many practitioners realize — specific about what the audit must determine, flexible about how the audit program is structured and conducted.

Standard Requirement

ISO 9001:2015, Clause 9.2.1: "The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system: a) conforms to: 1) the organization's own requirements for its quality management system; 2) the requirements of this International Standard; b) is effectively implemented and maintained."

Clause 9.2.2: "The organization shall: a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned and the changes affecting the organization, and the results of previous audits; b) define the audit criteria and scope for each audit; c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; d) ensure that the results of the audits are reported to relevant management; e) take appropriate correction and corrective action without undue delay; f) retain documented information as evidence of the implementation of the audit programme and the audit results."

Decoding the Requirements

Requirement Element	What It Means in Practice
"At planned intervals"	Audits must be scheduled in advance and occur on a regular cadence. The standard does not require annual audits — the frequency must be appropriate to the importance of the process and the results of previous audits. High-risk processes may be audited more frequently; stable, well-performing processes may be audited less frequently.
"Conforms to own requirements and to this Standard"	The audit evaluates two things simultaneously: whether the QMS meets the organization's own documented requirements (its procedures, work instructions, and policies) and whether the QMS meets ISO 9001:2015's requirements. Both must be covered.
"Effectively implemented and maintained"	Conformance to requirements is necessary but not sufficient. The audit must also assess whether the QMS actually works — whether it is producing the quality outcomes it was designed to produce, and whether it is being maintained as an active system rather than a paper artifact.
"Objectivity and impartiality"	Auditors must not audit their own work. A purchasing manager cannot audit the purchasing process. The quality manager should not be the only auditor if it means auditing their own procedures. Independence is required for audit results to be credible.
"Reported to relevant management"	Audit findings must reach the managers responsible for the audited processes — not merely be filed in the quality department.

Requirement Element	What It Means in Practice
	The management review process then draws on these reports as a required input.
"Correction and corrective action without undue delay"	When the audit finds nonconformances, action must follow promptly. Findings aged for months without response represent a failure of the corrective action system, not just a scheduling problem.
"Retain documented information"	The audit program, individual audit plans, audit reports, and corrective action records are all required documented information that must be retained and retrievable.

What Clause 9.2 Does Not Require

Several common misconceptions about internal audit requirements lead organizations to either over-engineer their programs or approach them with excessive formality that reduces their effectiveness:

- It does not require annual audits of every clause. The audit frequency must be appropriate to process importance and prior audit results — meaning some processes may be audited quarterly while others are audited every 18 months in a mature QMS.
- It does not require certified or formally credentialed auditors. Internal auditors must be competent — trained in audit methods and the standard — but ISO 9001:2015 does not require ISO 9001 Lead Auditor certification or any specific external credential.
- It does not require a physical audit checklist, though checklists are the most reliable tool for ensuring coverage. The audit plan and approach must be defined, but the specific format is determined by the organization.
- It does not require that every process be covered in a single audit event. The audit program — the planned series of audits over a defined period — must cover all QMS processes. Individual audit events can cover one process, one department, or one clause area.

Section 3: Building the Annual Audit Program

The audit program is the planned series of internal audits that, collectively, provide the required information about QMS conformance and effectiveness over a defined period — typically a calendar year. Building the audit program requires decisions about scope, frequency, scheduling, auditor assignment, and coverage to ensure that all QMS processes and all ISO 9001:2015 requirements are addressed within the program cycle.

Step 1: Define the Audit Program Scope and Cycle

The audit program must cover all QMS processes — every process that affects quality, every clause of ISO 9001:2015, every organizational function in scope. For most mid-size manufacturing organizations in the first certification year, completing this coverage in a single 12-month program cycle is the target. In subsequent years, the program may be structured differently based on risk assessment and prior audit results.

The program scope decision should specify: which sites are covered (for multi-site organizations), which QMS processes are included, which ISO 9001:2015 clauses will be evaluated across the program cycle, the planned timeframe for completing the full cycle, and how coverage will be confirmed at program close.

Step 2: Determine Audit Frequency by Process Risk

ISO 9001:2015 requires that the audit program take into consideration the importance of the processes concerned and the results of previous audits. In practical terms, this means higher-frequency auditing for processes that are higher-risk, more complex, more critical to product conformance, or have historically produced nonconformances — and lower-frequency auditing for stable, well-controlled processes with clean histories.

Process / Clause Area	Recommended Initial Frequency	Rationale
Core production processes (Clause 8.5)	Twice per cycle in Year 1	Highest volume of quality-affecting activity; most common source of nonconformances; new procedures need early verification of implementation
Customer requirement review (Clause 8.2)	Once per cycle	Important but typically limited variation; process is straightforward once documented
Design and development (Clause 8.3)	Once per cycle (more if design activity is high)	Complex requirements with significant documentation burden; new process for most organizations; risk is high
Supplier management (Clause 8.4)	Once per cycle	Important but process is well-defined once supplier evaluation records are established
Nonconforming output control (Clause 8.7)	Twice per cycle in Year 1	Frequent activity with direct customer impact; compliance rate is easily observed in records
Corrective action / CAPA (Clause 10.2)	Twice per cycle in Year 1	Systemic health indicator; open CAPA aging and root cause depth are common weaknesses in Year 1

Process / Clause Area	Recommended Initial Frequency	Rationale
Calibration (Clause 7.1.5)	Once per cycle	Records-based; verifiable against calibration schedule and equipment status labels
Competence and training (Clause 7.2)	Once per cycle	Records-based; sampling of employee training files against competence matrix
Document control (Clause 7.5)	Once per cycle	Infrastructure process; verifiable through document register and obsolete document controls
Internal audit program (Clause 9.2)	Once per cycle	Self-referential; audited once to verify the program itself is being executed as planned
Management review (Clause 9.3)	Once per cycle (after first review has been conducted)	Can only be audited after the management review has occurred; verify inputs, outputs, and action follow-up
Customer satisfaction monitoring (Clause 9.1.2)	Once per cycle	Verify the measurement method is implemented and results are being used
Leadership / context / planning (Clauses 4, 5, 6)	Once per cycle	Foundational clauses; verify organizational context is current, policy is communicated, objectives are monitored

Step 3: Structure Individual Audit Events

Once the overall coverage requirements and frequency decisions are made, structure the individual audit events that will collectively deliver the program. Each audit event should be scoped to a manageable, cohesive subject area that can be meaningfully covered in one to two audit days. Common structuring approaches for manufacturing organizations:

- Department-based auditing: Each audit covers all QMS processes within one functional area — a production department audit, a purchasing and supplier management audit, an engineering and design audit. Advantage: auditor interviews and process observations stay within one area, reducing scheduling complexity. Disadvantage: clause coverage is indirect and must be tracked across the program to ensure all requirements are addressed.
- Process-based auditing: Each audit follows a quality-critical process from input to output across departmental boundaries — a "customer order to product release" audit, a "nonconformance detection to corrective action closure" audit. Advantage: reveals handoff breakdowns between functions that department-based auditing misses. Disadvantage: requires coordination across multiple departments and is more complex to schedule.
- Clause-based auditing: Each audit focuses on one or more ISO 9001:2015 clauses across the organization. Advantage: directly tracks clause coverage; ensures nothing is missed. Disadvantage: may feel artificial to auditees who think in process and functional terms rather than clause terms.

Most organizations use a combination of these approaches — department-based for operational areas, process-based for cross-functional processes like CAPA and supplier management, and clause-based verification for management system infrastructure requirements.

Step 4: Assign Auditors to Events

The objectivity and impartiality requirement (Clause 9.2.2c) is the primary constraint on auditor assignment. Auditors must not audit their own work. In practice, this means:

- The Quality Manager or Management Representative should not be the sole auditor for processes they own or that fall primarily within the quality function — though they may audit other functional areas
- Department supervisors and managers may serve as auditors for areas outside their own department — a production supervisor auditing the purchasing process, a purchasing manager auditing the production documentation process
- A minimum of two trained internal auditors allows cross-auditing within the organization; three or more provides scheduling flexibility and backup
- For organizations with very small staff where independence is difficult to achieve, using an external consultant as an internal auditor on a contracted basis is explicitly permitted and may be the most practical solution

Step 5: Build the Audit Program Schedule

The audit program schedule is the documented plan showing each audit event, its scope, planned dates, assigned auditors, and completion status. The schedule should be approved by the Management Representative, made available as a controlled document, and updated when changes to timing or scope are needed.

Critical scheduling constraints that must be respected:

- The management review audit event cannot occur until the management review itself has been conducted — schedule the management review audit after the management review is complete
- The design and development audit cannot occur until sufficient design records exist to provide evidence of the process operating — schedule at least 60 days after D&D procedures are issued and in active use
- All audit events must be complete and all corrective actions from findings must be closed (or formally in process with documented status) before Stage 2 — build the schedule with a minimum 6-week buffer before the Stage 2 date
- Avoid scheduling audits during the organization's highest-demand production periods — auditees who are managing a production crisis cannot give an internal audit their adequate attention

Meridian Case Study

Meridian Audit Program Design: Denise structured the first-year audit program as eight audit events scheduled across Months 8 through 11 — giving all corrective actions from audit findings a minimum of two months to be addressed before Stage 2 in Month 13. She selected three internal auditors: Marco Pedraza (Production Supervisor, auditing Purchasing, Engineering, and QMS infrastructure), Sarah Kim (Purchasing Manager, auditing Production and Quality inspection processes), and Lisa Nakamura (Quality Engineer, auditing Production documentation, customer requirements, and CAPA). Denise retained Lead Auditor responsibility for the management review and leadership/planning clauses audits — areas where her role as Management Representative provided independence from operational process ownership. The eight events were: Production Operations (twice), Purchasing and Supplier Management, Engineering and Design Development, Quality Inspection and Release, Corrective Action and Nonconformance (twice), and QMS

Infrastructure (document control, calibration, training, customer satisfaction, and management review combined). Total planned audit time: approximately 28 auditor-days across the 4-month window.

Section 4: Selecting and Training Internal Auditors

The quality of an internal audit program is determined almost entirely by the quality of the auditors who conduct it. Auditor selection and training are the highest-leverage investments in the entire audit program — more important than the checklist design, the schedule, or the reporting format. A skilled, prepared auditor with a mediocre checklist will consistently produce more valuable findings than an unprepared auditor with a comprehensive one.

Auditor Selection Criteria

Internal auditors are typically selected from among existing employees who bring a combination of the following attributes. No single individual will score perfectly on all dimensions — the selection goal is finding people whose strengths and limitations balance each other across the auditor team:

Attribute	Why It Matters and What to Look For
Analytical thinking	Auditors must identify systemic patterns from specific evidence, distinguish conforming from nonconforming conditions, and evaluate whether the intent of requirements is being met — not just the letter. Look for people who ask "why" naturally and who are not satisfied with surface-level answers.
Communication skills	Auditors conduct interviews, communicate findings diplomatically, and write reports that are clear and unambiguous. Poor communicators produce adversarial audit experiences and unclear findings. Look for people who can ask direct questions respectfully and explain a finding without provoking defensiveness.
Organizational credibility	Auditees are more cooperative with auditors they respect. An auditor who is not credible in the eyes of the people being audited will encounter resistance that limits the depth of evidence they can gather. Look for people whose professional judgment is trusted by their peers.
Objectivity and professional courage	Auditors must be willing to document and report findings even when the auditee is a peer, a supervisor, or a popular colleague. This requires professional courage that not everyone possesses. Look for people who are consistent and principled in their professional judgments.
Sufficient process knowledge	Auditors must understand enough about the processes they are auditing to evaluate whether what they observe is conforming. A complete novice cannot audit a complex technical process effectively. Look for people with enough cross-functional exposure to ask meaningful questions outside their primary area.
Time availability	Internal auditing requires protected time — the auditor must be present and focused during the audit, not multitasking or managing operational crises. Look for people whose supervisors will genuinely support releasing them for audit activities.

Internal Auditor Training — What Is Required

ISO 9001:2015 requires that auditors be competent (Clause 7.2 applies to all quality-affecting roles, including internal auditors) but does not specify a particular training program or credential. In practice, effective internal auditor training covers:

- ISO 9001:2015 requirements in depth: auditors must understand what each clause requires, how conformance is demonstrated, and what common nonconformances look like — not just a high-level overview
- Audit principles and methods: planning an audit, developing and using checklists, gathering objective evidence, conducting interviews, documenting observations, writing clear and actionable findings
- Audit communication: opening meetings, interviewing techniques, managing auditee reactions, closing meetings, presenting findings diplomatically but clearly
- The finding classification system: understanding the distinction between major nonconformances, minor nonconformances, and observations — and how each is handled differently in the corrective action process
- Practical application: simulated audit exercises, worked examples of conforming and nonconforming evidence, practice writing findings from observation scenarios

Training Options and Their Trade-offs

Training Option	Typical Investment	Best For
Two-day internal auditor course (external provider, classroom or virtual)	$500 to $1,500 per person; typically 2 to 3 candidates trained simultaneously	Most common approach; covers all required competency areas; provides interaction with other practitioners; training credential from accredited provider adds credibility; courses available from ASQ, Exemplar Global, BSI, DNV, and others
Five-day lead auditor course (external provider)	$1,500 to $3,000 per person	Appropriate for the Management Representative or senior auditor who will serve as audit program manager and lead complex audits; provides deeper competency and internationally recognized credential; generally more than needed for internal-auditor-only roles
Internal training by a qualified consultant	$2,000 to $5,000 for a group session	Cost-effective for training 4 or more internal auditors simultaneously; can be customized to the organization's specific processes and QMS; requires a competent external trainer with audit experience in your industry
Self-study plus mentor-supported first audit	$200 to $500 in materials; plus consultant time for mentored audit	Suitable for small organizations with budget constraints; requires a mentor (external consultant or registrar contact) to supervise the first audit and provide feedback; higher risk of developing habits that are difficult to correct later

Best Practice

Schedule the first internal audit to occur within 4 to 6 weeks of auditor training completion — while the training content is fresh and the auditors' motivation is high. Internal auditors who are trained in Month 5 but do not conduct their first audit until Month 9 have lost the momentum and much of the specific technique. The first audit is also where the most learning occurs — auditors discover the gap between classroom audit technique and the real experience of interviewing a defensive supervisor, tracing a record through an inconsistent filing system, and writing a finding that is diplomatically worded but technically precise. This learning cannot happen in training; it can only happen in the audit itself. Get auditors into the field quickly after training.

Section 5: Planning the Individual Audit

Each audit event within the audit program requires individual planning — a specific audit plan that defines the scope, criteria, schedule, team, and approach for that particular audit. The audit plan is the document that transforms the audit from a general intention to a structured professional activity. It is also required documented information under Clause 9.2.2.

The Audit Plan — Elements and Purpose

A practical audit plan contains the following elements:

Audit Plan Element	Purpose and Content
Audit scope	Which processes, departments, products, or ISO 9001:2015 clauses will be covered in this specific audit event. Be specific enough that auditees know what to prepare and that coverage can be confirmed at audit close.
Audit criteria	The standards against which conformance will be evaluated: the specific ISO 9001:2015 clauses, the organization's procedures and work instructions, customer requirements, and any other applicable standards within scope.
Audit objectives	What the audit is designed to determine: typically, whether the processes in scope conform to requirements and are effectively implemented and maintained. Objectives may also include specific focus areas based on prior findings or risk assessment.
Audit team	The lead auditor and any supporting auditors assigned to this event. Note which auditor is responsible for which process areas where multiple auditors are used.
Audit schedule	The date or date range for the audit, the timeline of activities (document review, process observation, interviews, opening meeting, closing meeting), and the names and roles of auditees for scheduled interview slots.
Audit methods	How evidence will be gathered: document review, records sampling, process observation, personnel interviews. Note any specific sampling plans for records-intensive processes.
Resources required	Any equipment, access, or arrangements needed to conduct the audit (access to specific work areas, computer system access, advance provision of records for review).
Reporting plan	When the audit report will be issued, to whom, and the process for auditee review before final issuance.

The Audit Checklist — Prompts for Investigation, Not Questionnaires

The audit checklist is the auditor's primary working tool during the evidence-gathering phase of the audit. Its quality directly determines the quality of the audit. The critical design principle: a checklist item should be a prompt for investigation, not a question to be answered yes or no.

The difference in practice:

Weak Checklist Item (Yes/No Question)	Strong Checklist Item (Investigation Prompt)
Is there a procedure for document control?	Select 5 controlled documents at random. Verify current revision in the system matches the effective date in the document register. Verify no superseded versions are accessible in the current folder. Request evidence of the approval record for the most recent revision of each document.
Are training records maintained for employees?	Request the competence matrix. Select 3 employees from different roles whose work affects product quality. Retrieve training records for each. Verify records address all competence requirements for their role. Verify competence was assessed, not only training delivered. Identify any gaps and verify they have documented action plans.
Are nonconforming materials identified and segregated?	Walk the production floor and receiving area. Identify any material in the nonconforming hold area. Verify each item has a Nonconforming Material Report. Verify the report is complete and disposition has been authorized by an authorized person. Ask an operator: what do you do when you find a part that does not meet the drawing?
Is customer satisfaction monitored?	Request the customer satisfaction data for the past 12 months. Verify the monitoring method matches what is documented in the QMS procedure. Verify results were reviewed at the most recent management review. Ask: what action was taken based on the customer satisfaction data?

Clause-by-Clause Audit Prompts — Key Investigation Areas

The following table provides the core investigation prompts for each major clause area. These are not exhaustive checklists — they are the most productive lines of inquiry for each clause, representing the areas where nonconformances are most commonly found in first-year QMS audits.

Clause	Key Audit Investigation Prompts
4.1 / 4.2 Context and Interested Parties	Is the context analysis documented and current? Can leadership describe the key external issues affecting the QMS? Is the interested party register current? How were interested party requirements identified, and how are they monitored for change?
4.3 / 4.4 Scope and Processes	Is the scope statement documented and available? Can the Management Representative explain the basis for any exclusions? Is there a process map or equivalent showing QMS process interactions? Are process owners identified for each key process?
5.1 / 5.2 Leadership and Policy	Ask a senior manager: describe your specific role in the QMS. What quality decisions have you made in the past 90 days? Can you show me how you were

Clause	Key Audit Investigation Prompts
	involved in the last management review? Can an operator describe what the Quality Policy means for their work?
6.1 / 6.2 Risk and Objectives	Is the risk register current? Has it been reviewed in the past 12 months? Can a process owner describe a risk relevant to their process and what action is planned? Are quality objectives being monitored — request the trend data. Are any objectives off-track and if so what is the response?
7.1.5 Calibration	Select 10 measuring devices from the production floor at random. Verify each is on the calibration equipment list. Verify calibration status label is current for each. Request calibration records for 3 of them. Verify any out-of-tolerance findings were acted on. Are there any devices in use that are not on the calibration list?
7.2 Competence	Select 3 employees in quality-affecting roles. Request the competence requirements for their role. Verify they have documentation of all required education, training, and competence verification. Ask a supervisor: how do you determine whether a new employee is competent to perform a quality-affecting task without supervision?
7.5 Document Control	Select a procedure at random and verify it is current in the controlled document system. Go to the shop floor and find the same procedure in use — is it the current revision? Ask an operator where they find procedures when they need them. Are blank form templates controlled and current?
8.2 Customer Requirements	Select 3 recent customer orders. Verify there is a review record for each before commitment to supply. What happens when a customer requirement changes after an order is accepted? Show me how the change is controlled and communicated.
8.3 Design and Development	Select a recently completed or active design project. Verify design inputs are documented. Verify design reviews have been conducted and recorded. Verify design outputs are released against the inputs. How are changes to approved designs controlled?
8.4 External Providers	Request the approved supplier list. Select 3 suppliers. Verify initial qualification records exist. Verify ongoing performance monitoring records exist. Select a purchase order — verify it includes the required quality requirements. What happens when a supplier's performance falls below standard?
8.5 Production Controls	Observe a production operation in progress. Is the operator following the work instruction? Are first-piece inspection requirements being met? Is identification and traceability being maintained? Ask an operator: what do you do if you are unsure whether a part meets the drawing requirement?
8.7 Nonconforming Outputs	Walk the quarantine / hold area. Verify each item has an NCR. Select 5 closed NCRs — verify disposition was authorized. Are nonconforming items physically segregated from conforming? What happens if a nonconforming part is accidentally released?
9.2 Internal Audit	Is the audit program documented and current? Were all planned audits conducted on schedule? Were findings reported to the relevant manager? Were corrective actions opened and closed? Is audit program effectiveness being evaluated?
9.3 Management Review	Has a management review been conducted in the past 12 months? Were all required inputs addressed? Is there a documented output (minutes or equivalent) showing decisions and actions? Were actions from the review assigned, tracked, and completed?

Clause	Key Audit Investigation Prompts
10.2 Corrective Action	Request a list of all open and recently closed corrective action requests. Select 5 CARs — verify root cause analysis was conducted and documented. Verify the corrective action addressed the root cause, not just the symptom. Verify effectiveness was verified after implementation. How old is the oldest open CAR?

Section 6: Conducting the Audit — From Opening Meeting to Closing Meeting

The audit execution phase — the day or days when the auditor is actually in the organization gathering evidence — is where audit skill is most visibly demonstrated and where the difference between a compliance exercise and a genuine evaluation is most apparent. This section provides a complete guide to audit execution from the opening meeting through to the closing meeting.

The Opening Meeting

Every formal internal audit event begins with an opening meeting attended by the audit team and the managers responsible for the processes being audited. The opening meeting establishes the context, confirms the scope, and sets expectations for both parties. It should take no more than 15 to 20 minutes.

Standard opening meeting agenda:

1. Introduce the audit team and confirm the auditee representatives present
2. State the purpose of the audit: to provide information on whether the QMS conforms to requirements and is effectively implemented — emphasize that the purpose is improvement, not fault-finding
3. Confirm the scope: which processes, departments, and clauses will be covered in this audit event
4. Confirm the audit criteria: which standards, procedures, and requirements will be used to evaluate conformance
5. Review the schedule: who will be interviewed, when, and in which areas the auditor will be observing
6. Explain the finding classification system: what constitutes a major nonconformance, a minor nonconformance, and an observation
7. Confirm the closing meeting time and attendees
8. Ask if there are any questions or issues that the auditee team would like to raise before the audit begins

Evidence Gathering — The Three Sources

During the evidence-gathering phase, auditors collect evidence from three sources that, together, provide a triangulated picture of QMS conformance and effectiveness. Relying on only one or two sources produces an incomplete and potentially misleading assessment.

Source 1: Document and Records Review

The auditor reviews documented procedures, work instructions, policies, forms, and records. The review evaluates whether documented information exists as required, whether it is current and controlled, and whether records show that processes are being executed as documented. Key technique: do not simply check that a record exists — read it. A corrective action record that lists "retrain employee" as the root cause of a recurring nonconformance tells an experienced auditor that root cause analysis was not conducted adequately. A calibration record with a gap of 14 months between the last two calibrations tells a story regardless of whether the equipment is currently in-tolerance.

Source 2: Process Observation

The auditor observes work being performed in its normal environment. Observations answer the questions that documents cannot: Is the procedure being followed? Is the operator aware of the procedure and its requirements? Is the nonconforming material quarantine area actually segregated, or just labeled? Is identification and traceability being maintained consistently, or only when someone is watching? Process observation is the most powerful evidence source for operational clauses (Clause 8) and is the source most commonly skipped in inadequate audit programs.

Observation technique: be unobtrusive and ask questions that do not telegraph the expected answer. "Can you show me what you do when you complete a first-piece inspection?" is better than "Do you fill out the first-piece inspection form?" The first question produces a demonstration; the second produces a yes or no that reveals nothing about actual behavior.

Source 3: Personnel Interviews

Interviews with process owners, supervisors, operators, and managers provide evidence about understanding, awareness, and practice that neither documents nor observation alone can reveal. Effective interview technique in internal audits:

- Ask open-ended questions that require explanation, not yes/no answers: "Walk me through what happens when a customer makes a change to a specification after we have accepted the order."
- Follow the thread: when an answer raises a question, pursue it. "You mentioned the supervisor has to approve the NCR — what happens when the supervisor is not available?"
- Ask for examples: "Can you show me a recent example of how this process worked?" moves from assertion to evidence
- Interview people at multiple levels: the manager describes the process as designed; the operator reveals the process as executed. The gap between those two descriptions is where findings live
- Avoid leading questions that suggest the correct answer and allow the interviewee to simply agree

Classifying What You Find

As evidence is gathered, auditors make real-time assessments of what the evidence indicates. Findings fall into one of three classification levels that determine how they are reported and how the corrective action process responds to them:

Classification	Definition	Examples
Major Nonconformance	The absence of, or total breakdown of, a system to meet a requirement. A major nonconformance puts QMS effectiveness — and therefore certification — at risk. Multiple related minor nonconformances in the same area may be elevated to a major.	No internal audit program exists or has been executed. No corrective action process exists. No calibration records for critical measuring equipment. Complete absence of required documented information (no Quality Policy, no training records for any employee, no NCR records).
Minor Nonconformance	A single lapse in implementation, or a partial failure to meet a requirement. The system exists and generally	Two of fifteen reviewed employee training files are missing required competence verification records. One

Classification	Definition	Examples
	functions, but specific evidence of nonconformance was found. Does not put overall system effectiveness at risk but requires corrective action.	of three reviewed NCRs has no documented root cause. One procedure references an obsolete form version. Calibration label missing on one measuring device.
Observation / Opportunity for Improvement	A situation that is currently conforming but where the auditor identifies a risk of future nonconformance, or an opportunity to improve QMS effectiveness beyond the minimum requirements. No corrective action required — but recording observations provides value.	Approved supplier list is current but no trending analysis of supplier performance is conducted to enable proactive identification of declining performance. Management review minutes exist but action items from the review have no assigned completion dates. Calibration is on schedule but no out-of-tolerance trend analysis is being performed.

The Closing Meeting

The closing meeting is attended by the audit team and the managers of audited areas. It provides the auditee team with a verbal summary of findings before the written report is issued and gives them the opportunity to clarify any factual errors in the auditor's understanding before findings are formally recorded. The closing meeting should take 20 to 40 minutes depending on the number of findings.

Standard closing meeting structure:

9. Thank the auditee team for their time and cooperation
10. Restate the audit scope and confirm all planned areas were covered; if any were not, explain why
11. Summarize positive observations — conforming practices and areas of strength identified during the audit
12. Present each finding in turn: the classification, the specific requirement that was not met, the objective evidence observed, and the finding statement. Give auditees the opportunity to clarify factual errors — not to argue classification, but to correct misunderstandings of fact
13. Review the corrective action process: timelines for responding to nonconformances, the corrective action form, and who is responsible for opening CARs
14. Confirm the audit report issuance timeline and distribution
15. Close the meeting formally

Section 7: Writing Findings That Drive Real Improvement

The audit finding is the primary output of the audit evidence-gathering process. A well-written finding contains everything the corrective action team needs to understand exactly what was observed, why it constitutes a nonconformance, and where to look when investigating root cause. A poorly written finding is vague, ambiguous, or factually incomplete — and produces corrective actions that address the wrong problem.

The Anatomy of a Well-Written Finding

Every finding, regardless of classification, should contain four elements:

- The requirement: Which specific ISO 9001:2015 clause and/or organizational procedure was not met. State the clause number and the specific requirement element: "ISO 9001:2015 Clause 7.2(b) requires that persons are competent on the basis of appropriate education, training, or experience."
- The objective evidence: The specific, factual observation that demonstrates the requirement was not met. This must be evidence — not opinion, not impression, not inference. "Review of training files for employees J. Torres (Machining Operator, Line 3) and R. Singh (Machining Operator, Line 3) found that competence assessments have not been completed for either employee. Both employees have training attendance records but no documentation of competence verification was found."
- The finding statement: A clear, unambiguous statement of the nonconformance that synthesizes the requirement and the evidence into a single declarative sentence. "The organization has not ensured that employees in quality-affecting machining operator roles are competent, as evidenced by the absence of competence verification records for two of three machining operators sampled."
- The classification: Major, Minor, or Observation — with a brief rationale for major classifications or when the boundary with minor is close.

Finding Writing Examples — Before and After

Weak Finding (What Not to Write)	Strong Finding (What to Write Instead)
Finding: Training records are incomplete. Clause: 7.2. Classification: Minor.	Finding: ISO 9001:2015 Clause 7.2(d) requires that documented information be retained as evidence of competence. Review of training records for machining operators revealed that competence verification records are absent for employees J. Torres and R. Singh. Training attendance records exist for both employees (courses attended June and July of the current year), but no competence assessment form, supervisor sign-off, or equivalent verification document was found in either employee's training file. Classification: Minor Nonconformance.
Finding: Calibration is not being done properly. Clause: 7.1.5. Classification: Minor.	Finding: ISO 9001:2015 Clause 7.1.5.1 requires that the organization retain appropriate

Weak Finding (What Not to Write)	Strong Finding (What to Write Instead)
	documented information as evidence of fitness for purpose of the monitoring and measuring resources. During production floor walkthrough, micrometer MPC-CAL-0047 (serial number 7749-B) was observed in active use on Line 2. The calibration label shows a calibration due date of 14 March of the current year — 4 months overdue at the time of audit. No calibration record for this device since the expiration date was found in the calibration log. Classification: Minor Nonconformance.
Finding: The corrective action process is not working well. Clause: 10.2. Classification: Minor.	Finding: ISO 9001:2015 Clause 10.2.1(e) requires that the organization review the effectiveness of any corrective action taken. Review of 8 closed corrective action requests from the past 12 months found that 6 of 8 (75%) contain no documented effectiveness verification — the CAR form's "Effectiveness Verification" section is blank in each case. In the remaining 2 CARs, the verification entry states "action implemented" without providing evidence of verified effectiveness. Classification: Minor Nonconformance (pattern across 75% of sampled records warrants escalation consideration if similar finding recurs in next audit cycle).

⚠ Common Pitfall

Two specific finding-writing failures that consistently undermine audit program value: The personality finding — "the operator did not seem to know the procedure" or "the supervisor appeared unfamiliar with the requirements." Findings must be based on objective evidence, not impressions of attitude or apparent knowledge. If the operator cannot describe the procedure when asked, the finding is "the operator was unable to describe [specific procedure requirement] when asked" — not a characterization of their apparent knowledge level. The vague systemic finding — "training records are generally incomplete across the organization." Findings must be specific and evidenced. How many records were reviewed? How many were found deficient? What specifically was missing? Vague findings produce vague corrective actions that address the symptom in the aggregate without fixing the specific causes.

Section 8: The Audit Report

The audit report is the formal document that records the audit event, its findings, and its conclusions. It is required documented information under Clause 9.2.2(f) and is a primary input to the management review under Clause 9.3. A well-constructed audit report serves multiple purposes: it communicates findings to management, it provides the basis for corrective action, it becomes part of the organization's QMS performance history, and it demonstrates to registrar auditors that the internal audit program is being executed with appropriate rigor.

Audit Report Structure

Report Section	Content
Report header / identification	Audit reference number, date of report, audit event name, audit scope, audit criteria, audit team (lead auditor and supporting auditors), auditees by name and role, date(s) of audit execution.
Audit summary	A brief (one to two paragraph) summary of the audit: what was covered, the overall impression of QMS effectiveness in the audited area, the number and classification of findings, and any noteworthy positive observations. This is what a senior manager reads when they receive the report without time to read the full document.
Positive observations / areas of strength	Specific examples of conforming practice or exceptional quality management observed during the audit. This section serves two purposes: it provides a balanced picture of actual QMS performance, and it reinforces good practices by formally recognizing them. Audits that record only nonconformances fail to communicate the full picture of QMS health.
Findings — Nonconformances	Each nonconformance listed separately with: finding number, classification (Major/Minor), the requirement referenced, the objective evidence, and the finding statement. Each nonconformance should have a unique identifier that will be used to track the associated corrective action.
Findings — Observations	Each observation listed separately with: the area of potential risk or improvement opportunity, the relevant process or clause, and the specific observation. Observations do not require corrective action but should be tracked to assess whether they become nonconformances in future audit cycles.
Conclusion	The auditor's overall conclusion on QMS conformance and effectiveness in the audited area. May include a general recommendation on areas requiring priority attention in the corrective action response.
Corrective action response section	A table or form section where the auditee documents the corrective actions planned or taken in response to each nonconformance. May be included in the original report as a response section or issued as a separate corrective action request form. Due dates for response should be stated.
Distribution list	Who receives the audit report: the auditee managers, the Management Representative, and the executive sponsor at minimum. Management review records should show that audit reports were reviewed at the management review.

Audit Report Issuance Timeline

The audit report should be issued within five to ten business days of the audit closing meeting. Reports issued weeks or months after the audit are less useful — management attention has moved on, memories of the audit discussion have faded, and the corrective action response is delayed. Build the report issuance timeline into the audit plan and hold to it as a professional standard.

For nonconformances, set a response due date for the corrective action plan — typically 15 to 30 days from report issuance for minor nonconformances. This is not the completion date for the corrective action; it is the date by which the auditee must submit a documented corrective action plan showing root cause analysis, planned actions, and target completion date.

Section 9: From Audit Finding to Verified Corrective Action

The corrective action process triggered by audit findings is addressed in depth in Guide 1.3 (through the CAPA procedure) and in Volume 2's Guide 2.7 (Clause 10). This section focuses specifically on the corrective action cycle as it applies to internal audit findings — the particular considerations, timelines, and verification requirements that distinguish audit-triggered CARs from customer-complaint-triggered or production-nonconformance-triggered CARs.

The Audit Finding Corrective Action Cycle

Step	Action Required	Timing and Responsibility
1. Open the CAR	Create a corrective action request referencing the audit finding number and classification. Assign to the process owner for the audited area.	Within 5 business days of audit report issuance. Assigned by: Management Representative.
2. Immediate containment (if applicable)	For findings that represent an active quality risk — a nonconforming condition that may be producing or releasing defective product — containment action must be documented before root cause analysis begins.	Immediately upon CAR opening. Responsibility: Process Owner.
3. Root cause analysis	Analyze the specific evidence from the finding to determine the systemic cause of the nonconformance. The root cause is why the system allowed the nonconformance to occur — not what the nonconformance was. Use 5-Why, Ishikawa, or equivalent method appropriate to the finding's complexity.	Within 15 days of CAR opening (minor NC) or 10 days (major NC). Responsibility: Process Owner with Quality support.
4. Corrective action plan	Document the specific actions that will address the root cause — changes to procedures, training actions, system controls, or management oversight. Actions must address the root cause, not merely correct the specific instance found. Target dates and responsible parties for each action.	Submitted within 20 days of CAR opening (minor) or 15 days (major). Responsibility: Process Owner.
5. Implementation	Execute the planned corrective actions. Document	Per the corrective action plan target dates. Responsibility: Action assignees.

Step	Action Required	Timing and Responsibility
	implementation as each action is completed.	
6. Effectiveness verification	After corrective actions are implemented, verify that the root cause was actually addressed and the nonconformance will not recur. Effectiveness verification must be evidenced — a supervisor statement that "it is fixed" is not evidence. Return to the process and verify the corrected condition directly.	Typically 30 to 60 days after implementation. Responsibility: Internal Auditor or Management Representative.
7. CAR closure	When effectiveness verification confirms the root cause is addressed and the system is conforming, close the CAR with documented closure rationale and date. Filed in the corrective action records system.	After effectiveness verification is complete. Responsibility: Management Representative.

Tracking Open Audit CARs

The Management Representative must maintain a tracking log of all open corrective action requests from internal audits. The log provides visibility into the corrective action backlog and supports management review reporting. Key metrics to track:

- Total number of open CARs from the current audit cycle
- Age of each open CAR from the date it was opened
- CARs past their target completion date — these require escalation
- CARs awaiting effectiveness verification (implementation complete but not yet verified)
- Percentage of CARs closed within the defined target timeframe — a quality objective candidate

Auditor Perspective

Registrar auditors examine the internal audit corrective action record with particular attention to two patterns. First, the aging CAR: a CAR that has been open for more than 90 days without documented progress indicates either a failure of follow-through or a corrective action that is more complex than initially planned — either way, it should be documented and explained. Second, the shallow root cause: a CAR where the root cause is stated as "employee error" or "failure to follow procedure" without asking why the error occurred or why the procedure was not followed. These root causes produce corrective actions (retrain the employee, remind the team about the procedure) that do not address the systemic conditions that made the error possible. Auditors have seen this pattern thousands of times; they will probe it directly.

Section 10: Feeding the Management Review

The internal audit program does not exist in isolation — it is one element of the QMS performance evaluation cycle that culminates in the management review. Understanding how audit results feed the management review ensures that the information generated by the audit actually reaches the people with the authority and responsibility to act on it at the organizational level.

Standard Requirement
ISO 9001:2015, Clause 9.3.2 — Management Review Inputs: The management review shall be planned and carried out taking into account: "e) information on the performance and effectiveness of the quality management system, including trends in: 1) customer satisfaction and feedback from relevant interested parties; 2) the extent to which quality objectives have been met; 3) process performance and conformity of products and services; 4) nonconformities and corrective actions; 5) monitoring and measurement results; 6) audit results; 7) the performance of external providers."
The internal audit results — findings, corrective action status, and trend data across audit cycles — are an explicit and mandatory input to the management review.

Preparing Audit Information for the Management Review

To make audit results actionable at the management review, the Management Representative should prepare a structured audit performance summary covering:

- Audit program completion status: Which audit events were planned and which were completed on schedule
- Finding summary: Total findings by classification across the cycle, with trend comparison if a prior cycle exists
- Finding distribution by clause and process area: Where are nonconformances concentrated? Patterns across clauses or departments indicate systemic issues
- Corrective action status: How many CARs are open, closed, and overdue. The percentage closed on time against the target.
- Repeat findings: Are any nonconformances recurring from prior audit cycles? Repeat findings indicate corrective actions that did not address root cause effectively
- Audit program effectiveness: Are the audits producing useful findings? Are corrective actions leading to genuine improvement? Is the audit program itself improving?

Management Review Outputs Related to the Audit Program

The management review must produce decisions and actions in response to the audit information presented. Appropriate management review outputs related to internal audit include:

- Resource allocation decisions where audit findings reveal systemic under-resourcing of a QMS process
- Priority assignments where multiple open CARs compete for limited process owner time
- Audit program adjustments — increasing audit frequency for processes with persistent findings, expanding audit scope to cover newly identified risk areas

- Escalation of specific finding patterns to executive attention where department-level corrective action has been insufficient
- Recognition of effective corrective actions that have demonstrably improved QMS performance

Meridian Case Study

Meridian's First Internal Audit Cycle — Complete Results: The eight-audit program conducted between Month 8 and Month 11 produced a total of 22 findings: 0 major nonconformances, 14 minor nonconformances, and 8 observations. The finding distribution revealed three significant patterns. First: the design and development audit produced 4 of the 14 minors — design inputs were documented but design review records were incomplete for 3 of 5 projects reviewed, and the design change control process had not been followed for 2 recent specification revisions. Second: the corrective action audit confirmed the pattern that Denise had suspected from monitoring — effectiveness verification was missing or inadequate in 5 of 8 CARs reviewed, consistent with the finding Marco had uncovered during procedure training. Third: document control was largely conforming with one minor exception — the calibration procedure referenced a form version number that had been superseded. The production operations audits produced 3 minors related to identification and traceability record completeness, and the purchasing audit produced 2 minors on supplier performance monitoring records. By Month 12, 19 of 22 CARs were closed with verified effectiveness. The 3 remaining open CARs — all related to design change control, which required a more extensive procedure revision and re-training cycle — had documented status updates and projected completion dates within the Stage 2 buffer period. Denise presented the audit summary at the Month 11 management review. Robert Nolan's response to the design change control findings was to authorize a half-day design process workshop with the engineering team — the first executive-initiated quality improvement action in Meridian's history. The internal audit had done exactly what it was designed to do.

Section 11: The 20 Most Common First-Year Internal Audit Findings

The following findings appear with high frequency in internal audits of first-time ISO 9001:2015 implementations across manufacturing industries. Reviewing these before the audit program begins serves two purposes: it helps auditors know where to look most productively, and it helps process owners address likely gaps proactively before they are found during the audit.

#	Clause Area	Finding Pattern
1	Clause 7.2 — Competence	Training records exist (attendance) but competence verification records are absent — no evidence that competence was assessed, only that training was delivered
2	Clause 10.2 — Corrective Action	Root cause analysis states "employee error" or "failure to follow procedure" without asking why — corrective action is retraining rather than systemic correction
3	Clause 10.2 — Corrective Action	Effectiveness verification section of CAPA form is blank or contains only "action implemented" with no evidence of verified effectiveness
4	Clause 7.1.5 — Calibration	Measuring devices in active use on the production floor not on the calibration equipment list, or on the list but overdue for calibration
5	Clause 9.3 — Management Review	Management review minutes do not address all required inputs — commonly missing: customer satisfaction data, audit results summary, or performance of external providers
6	Clause 8.3 — Design and Development	Design review records exist but do not capture the review outcome, attendees, issues identified, or disposition of open issues — records are minutes of a meeting, not evidence of a controlled review
7	Clause 8.4 — External Providers	Approved supplier list exists but ongoing supplier performance monitoring records are absent or not linked to re-evaluation decisions
8	Clause 7.5 — Document Control	Obsolete procedure versions found accessible in shared drive folders alongside current versions — no clear separation of current from superseded
9	Clause 8.6 — Product Release	Release records do not identify who authorized release or against what specific criteria — signature exists but role and criteria reference are missing
10	Clause 8.5.2 — Identification and Traceability	Identification maintained through production but breaks at an intermediate step — work-in-process is identifiable at the start and end of a process but not during transport between operations
11	Clause 6.2 — Quality Objectives	Objectives are documented but monitoring data is not being collected — the metric exists on paper but the measurement is not occurring in practice
12	Clause 5.1 — Leadership Commitment	Senior managers cannot describe their specific QMS responsibilities when asked by the auditor — they understand

#	Clause Area	Finding Pattern
		they support quality but cannot articulate their defined accountability
13	Clause 8.2 — Customer Requirements	Customer requirement review is conducted but records do not consistently capture what was reviewed, what the review conclusion was, and who conducted the review
14	Clause 4.2 — Interested Parties	Interested party register was built at implementation and has not been reviewed since — does not reflect changes in regulatory environment, customer base, or organizational context
15	Clause 8.7 — Nonconforming Outputs	Nonconforming material quarantine area is labeled but physical segregation is incomplete — conforming and nonconforming material commingled or quarantine boundary is ambiguous
16	Clause 7.3 — Awareness	Employees in quality-affecting roles cannot describe the relevant quality objectives for their function or explain how their work contributes to QMS effectiveness
17	Clause 9.1.2 — Customer Satisfaction	Customer satisfaction monitoring method is documented but first data collection has not been completed — method exists, measurement has not yet occurred
18	Clause 8.5.6 — Control of Changes	Process changes were implemented in production without documented review and authorization — informal changes made by operators or supervisors without going through the change control process
19	Clause 6.1 — Risks and Opportunities	Risk register was populated at implementation but has not been reviewed or updated since — does not reflect new processes, products, customers, or operational changes
20	Clause 7.5.3 — Document Control	External documents (customer drawings, industry standards, supplier specifications) in use but not listed in the document register or subject to revision monitoring — organization does not know when the external document was revised

Quick Reference: Internal Audit Program Essentials

Audit Program Readiness Checklist

	Item
☐	Internal audit procedure (MPC-PRO-019 or equivalent) approved and issued
☐	Minimum two internal auditors trained to ISO 9001:2015 and audit methods
☐	Auditor competence records on file (training completion, course provider, date)
☐	Annual audit program document approved — all processes and clauses covered, frequencies determined by risk
☐	Auditor assignments confirmed — objectivity and impartiality verified for each assignment
☐	Audit plans prepared for each scheduled audit event with scope, criteria, team, and schedule
☐	Audit checklists prepared as investigation prompts, not yes/no questionnaires
☐	All planned audit events scheduled to complete at least 6 weeks before Stage 2
☐	Corrective action process defined for audit findings — timelines, ownership, tracking
☐	Audit report template prepared and approved as a controlled document
☐	CAR tracking log established for open audit-generated corrective actions
☐	Management review planned to occur after at least one complete audit cycle, with audit results as an agenda input

Audit Finding Quality Self-Check

Before finalizing any finding, the auditor should confirm all of the following are true:

	Self-Check Question
☐	Does the finding state the specific requirement that was not met — ISO clause and/or procedure reference?
☐	Is the objective evidence specific and factual — actual document numbers, employee names, dates, quantities observed?
☐	Could anyone reading this finding understand exactly what was observed without having been present at the audit?
☐	Is the finding based on what was observed — not on what the auditor believes or suspects?
☐	Is the classification justified — is this truly a major, or would a competent peer auditor classify it as minor?

	Self-Check Question
☐	Does the finding provide enough information for the corrective action team to investigate root cause without requiring an additional information-gathering visit?
☐	Is the finding free of personality language, characterizations of employee attitude, and subjective impressions?
☐	Has the finding been checked for factual accuracy before the closing meeting — so the auditee is not correcting facts for the first time at the closing meeting?

Next in Series: Guide 1.6 — Certification Audit Preparation and Life After Certification: Crossing the Finish Line and Starting the Real Work. Covering Stage 1 preparation and what the registrar evaluates, Stage 2 audit day by day, handling findings under pressure, managing post-certification surveillance audits, and integrating the QMS with Lean/Six Sigma for continuous improvement — with Meridian's complete certification experience from Stage 1 through Year 1 surveillance.
