Six Sigma Kaizen

ISO 9001 IMPLEMENTATION HUB

Volume 1 • Guide 1 of 6

# Gap Analysis & Readiness Assessment

*Before You Begin: How to Know Where You Actually Stand*

A Practitioner-Level Implementation Guide for Quality Professionals

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

# How to Use This Guide

This guide is the first in a six-part implementation roadmap for ISO 9001:2015 certification. It is written for quality professionals, operations managers, and management representatives who are accountable for building and certifying a Quality Management System (QMS) and who need practical, realistic guidance — not a recitation of the standard itself.

Each guide in this series follows a consistent format: grounding in the standard's intent, step-by-step implementation guidance, practitioner warnings about common failure points, auditor perspective notes, and a continuous case study following Meridian Precision Components through the same journey your organization is undertaking.

## The Meridian Case Study

Throughout all six guides in Volume 1, you will follow Meridian Precision Components, Inc. (MPC) — a 220-person contract machining and metal fabrication company pursuing ISO 9001:2015 certification for the first time. Meridian's Management Representative is Denise Alvarez, Quality Systems Manager, who is responsible for the implementation from gap analysis through certification. Meridian is a realistic, deliberately typical mid-size manufacturer — not a best-case showcase — and the challenges Denise faces will likely mirror your own.

## A Note on Clauses 1 Through 3

ISO 9001:2015 has ten clauses. This guide and the series that follows focus exclusively on Clauses 4 through 10 — and that is not an oversight. Clauses 1, 2, and 3 are informational:

- Clause 1 defines the scope of the standard (what it applies to)
- Clause 2 identifies normative references (documents incorporated by reference)
- Clause 3 provides terms and definitions (the standard's glossary)

No implementation activity, audit finding, or certification requirement is associated with Clauses 1 through 3. Every requirement your organization must demonstrate conformance to lives in Clauses 4 through 10. This is consistent with how registrars audit, how practitioners implement, and how every credible ISO 9001 resource in existence approaches the standard.

**Kaizen Connection**

ISO 9001:2015 uses the High Level Structure (HLS), also called Annex SL — a common framework shared across all major ISO management system standards including ISO 14001 (environmental), ISO 45001 (occupational health and safety), and ISO 27001 (information security). The clause numbering from 4 through 10 is intentionally identical across all of these standards, making integrated management systems significantly easier to build and audit simultaneously. If your organization is considering ISO 9001 alongside ISO 14001, a combined implementation and audit approach often reduces cost and administrative burden by 20 to 35 percent.

# Introduction: What the Gap Analysis Is Really For

The gap analysis is the first real work of ISO 9001 implementation — and the work that most organizations either rush through or execute too narrowly. Done well, a gap analysis accomplishes four things that nothing else in the implementation can replace:

1. It tells you exactly where you stand relative to the standard's requirements, clause by clause, in measurable terms — not impressions or assumptions.
2. It identifies the critical path items: the gaps that must be closed before certification is achievable, as distinct from improvements that would be nice but are not required.
3. It surfaces the quick wins: areas where your organization is already doing the right things but has not documented or formalized them — representing low-effort, high-value early progress.
4. It provides the factual foundation for the implementation plan that follows — resource requirements, timeline estimates, ownership assignments, and budget.

What the gap analysis is not: it is not an internal audit, it is not a pre-certification mock audit, and it is not a comprehensive evaluation of your quality performance. It is a structured current-state assessment measured against the requirements of ISO 9001:2015. The distinction matters because the mindset and methodology are different.

**⚠ Common Pitfall**

The most common gap analysis failure is confusing regulatory compliance or customer audit conformance with ISO 9001 QMS conformance. An organization can pass every customer audit, meet all applicable regulations, and ship product that consistently meets specifications — and still have significant gaps against ISO 9001:2015 requirements. The standard is not primarily about product quality outcomes. It is about whether you have a systematic, documented, maintained management system for achieving and improving those outcomes. The distinction is crucial and is the source of most first-time certification surprises.

## The Compliance vs. System Thinking Distinction

Understanding this distinction before conducting the gap analysis will fundamentally improve the quality of your assessment. ISO 9001:2015 requires evidence that your organization has established systematic processes — not just that good outcomes are happening. Consider these contrasting scenarios:

| Situation | Compliance Mindset Assessment | System Thinking Assessment |
|---|---|---|
| Products rarely have defects | Likely conforming | Is there a documented process for defining quality requirements? Are acceptance criteria established? Are records of product release maintained? |
| Suppliers are carefully selected | Likely conforming | Is there a documented supplier evaluation procedure? Are evaluation records maintained? Is ongoing supplier performance monitored against defined criteria? |
| Employees are experienced and skilled | Likely conforming | Has required competence been determined for each role? Is |

| Situation | Compliance Mindset Assessment | System Thinking Assessment |
|---|---|---|
| | | competence verified? Are training records maintained? Is training effectiveness evaluated? |
| Customer complaints are handled quickly | Likely conforming | Is there a formal nonconformance process? Are root causes analyzed? Are corrective actions verified effective? Are records retained? |

The gap analysis must apply system thinking throughout. For every clause, the question is not only whether the right things are happening but whether there is a maintained, documented system ensuring they happen consistently — and whether there is evidence of that system functioning.

# Section 1: Understanding What ISO 9001:2015 Actually Requires

Before conducting the gap analysis, every member of the assessment team needs a working understanding of what the standard actually requires. This section provides a high-level orientation to each clause that will be evaluated. The clause-by-clause practitioner guides in Volume 2 of this series provide deeper interpretation — this section gives you enough context to conduct a meaningful gap assessment.

## The Structure of ISO 9001:2015 Requirements

The requirements clauses (4 through 10) follow the Plan-Do-Check-Act (PDCA) cycle that underlies all ISO management system standards:

| PDCA | Clause(s) | What It Covers |
|---|---|---|
| Plan | Clauses 4, 5, 6 | Context, leadership, planning — establishing what the QMS needs to do and how it will be governed |
| Do | Clauses 7, 8 | Support and operation — the resources, people, processes, and controls that deliver quality outcomes |
| Check | Clause 9 | Performance evaluation — monitoring, measurement, internal audit, and management review |
| Act | Clause 10 | Improvement — nonconformance, corrective action, and continual improvement |

## Clause-by-Clause Overview for Gap Assessment Purposes

### Clause 4: Context of the Organization

Clause 4 establishes the foundation for the entire QMS. It requires your organization to understand its external and internal context — the factors and conditions that affect what the QMS must achieve. It requires identification of interested parties (stakeholders) and understanding of their relevant needs and expectations. It requires a defined scope for the QMS — a clear statement of what the QMS covers and what, if anything, is legitimately excluded. And it requires that the organization determine its quality-related processes: what they are, how they interact, and how they will be managed.

| Standard Requirement |
|---|
| ISO 9001:2015, Clause 4.1: "The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system." |
| |
| Clause 4.4.1: "The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions." |

## Clause 5: Leadership

Clause 5 places explicit, non-delegable accountability on top management. The 2015 revision of the standard was deliberately designed to make quality the responsibility of organizational leadership — not a delegated function housed in the quality department. Top management must demonstrate leadership and commitment, not just authorize a policy. The Environmental Policy must be established by and accountable to top management. Organizational roles, responsibilities, and authorities for quality must be defined, assigned, and communicated.

**⚠ Common Pitfall**

The single most common and most consequential gap in Clause 5 is the absence of genuine top management engagement. In many organizations, the quality manual was written by the quality manager, the policy was signed by the CEO without review, and management reviews are conducted by quality staff who present data to leadership rather than leadership genuinely evaluating the QMS. Registrars have learned to probe this directly — they interview top management individually, ask them to describe their specific responsibilities in the QMS, and ask for evidence of their involvement. Generic answers from executives reveal the gap immediately.

## Clause 6: Planning

Clause 6 introduced risk-based thinking as an explicit requirement in the 2015 revision — one of the most significant changes from ISO 9001:2008. Organizations must determine the risks and opportunities relevant to the QMS and plan actions to address them. This does not require a formal risk management system — but it does require a systematic approach to identifying what could go wrong (or right) and what the organization will do about it. Clause 6 also requires quality objectives that are measurable, monitored, communicated, and updated as appropriate, along with plans for how they will be achieved.

## Clause 7: Support

Clause 7 covers the resources required to establish, implement, maintain, and continually improve the QMS. This includes people, infrastructure, the work environment, monitoring and measuring resources (including calibration), and organizational knowledge. It also addresses competence (determining required skills, ensuring people have them, taking action where they do not, and retaining evidence), awareness, internal and external communication, and the control of documented information — the 2015 term for what earlier versions called documents and records.

## Clause 8: Operation

Clause 8 is the most operationally intensive section of the standard. It covers how your organization plans, implements, and controls the processes needed to provide products and services that meet requirements. This includes determining customer requirements and reviewing them before commitment, design and development (where applicable), control of externally provided processes and products (supplier management), production and service provision controls, identification and traceability, control of customer or external provider property, post-delivery activities, release of products and services, and control of nonconforming outputs.

**🔍 Auditor Perspective**

Clause 8 is where most of the evidence-gathering happens during certification audits. Auditors will walk your shop floor, pull work orders, examine inspection records, interview operators, review supplier qualification files, and trace a product from order through release. The question throughout is always the same: is there a documented process, is the process followed, and is there evidence that it was followed? Process without evidence and evidence without process are equally problematic.

## Clause 9: Performance Evaluation

Clause 9 requires your organization to determine what needs to be monitored and measured, how it will be done, and what will be done with the results. Customer satisfaction must be monitored and the methods for doing so must be determined. Internal audits must be conducted at planned intervals to provide information on whether the QMS conforms to requirements and is effectively implemented. Management reviews must be conducted by top management and must address specified inputs and produce specific outputs. The results of analysis and evaluation must feed the management review.

## Clause 10: Improvement

Clause 10 requires that your organization determine and select opportunities for improvement and implement necessary actions to meet customer requirements and enhance customer satisfaction. When nonconformities occur — including those arising from complaints — the organization must react, evaluate the need for corrective action, implement actions, review their effectiveness, and make changes to the QMS if necessary. The organization must also continually improve the suitability, adequacy, and effectiveness of the QMS.

# Section 2: Preparing for the Gap Analysis

A gap analysis executed without adequate preparation produces unreliable results — either overstating conformance because the assessors do not know what to look for, or understating it because existing good practices have not been fully investigated. This section covers the preparation steps that ensure your assessment is both efficient and accurate.

## Step 1: Assemble the Assessment Team

The gap analysis should not be conducted by a single person. Quality management spans every operational function, and a single assessor — however experienced — will have blind spots in areas outside their primary domain. The ideal assessment team includes:

- The Management Representative or Quality Systems Manager (lead assessor and overall coordinator)
- A representative from Operations or Manufacturing (the primary service delivery area)
- A representative from Purchasing or Supply Chain (Clause 8.4 scope)
- A representative from Human Resources (Clause 7.2 competence requirements)
- A senior leader or member of the leadership team (Clause 5 requirements require their direct input)

Each team member assesses their own functional area using the gap analysis worksheet, while the Management Representative coordinates, consolidates, and validates the results. Cross-functional review of findings before scoring is finalized significantly improves accuracy.

**Best Practice**

The most effective gap analysis teams include someone with prior ISO 9001 experience — either as an internal auditor trained to the standard, a former employee from a certified organization, or an external consultant brought in specifically for the assessment phase. The value is not in having someone else do the work — it is in having someone who has seen what conforming evidence actually looks like, so the team does not incorrectly score partial or informal practices as conforming. If no internal experience exists, a one-day ISO 9001 awareness training for the assessment team before beginning the gap analysis is worth the investment.

## Step 2: Obtain and Study the Standard

Every member of the gap analysis team needs access to ISO 9001:2015 — the actual standard, not a summary or paraphrase. The standard is available for purchase from ISO (www.iso.org), from national standards bodies such as ANSI in the United States, and from various authorized distributors. At the time of writing, the standard costs approximately $160 to $200 USD in PDF format.

Each assessor should read the clauses relevant to their assessment area in full before conducting any assessment activities. The normative language of the standard — "the organization shall" — identifies requirements. Language such as "the organization should" or "the organization may" identifies guidance or options, not requirements.

**Standard Requirement**

The word "shall" in ISO 9001:2015 indicates a requirement. Every "shall" statement must be addressed in your QMS. There are no optional requirements — however, there are requirements that may not apply to your organization's scope (such as design and development for organizations that do not perform design

activities, which may be legitimately excluded per Clause 4.3). Understanding this distinction — shall vs. should, applicable vs. excludable — is foundational to conducting an accurate gap analysis.

## Step 3: Define the Assessment Scope

Before conducting the gap analysis, define the scope of the assessment — which facilities, processes, products, services, and organizational units will be included. This assessment scope should match (or inform) the eventual QMS scope that will be defined in Clause 4.3. Common scoping decisions include:

- Single site vs. multi-site: If your organization has multiple facilities, decide whether the QMS will cover all of them or only specific sites
- All products and services vs. specific lines: Some organizations initially scope their QMS to cover only certain product lines or service categories
- Design and development applicability: Organizations that only manufacture to customer-provided specifications, with no internal design activity, may legitimately exclude Clause 8.3 from scope
- Service vs. manufacturing operations: Both are covered by ISO 9001:2015, but the way requirements manifest differs; ensure the assessment team understands how requirements apply to your specific operation type

## Step 4: Gather Existing Documentation

Before beginning any interviews or process observations, collect all existing documentation that may be relevant to the gap assessment. This typically includes:

- Current quality-related procedures, work instructions, and forms
- Existing quality policy or quality-related policy statements
- Organizational charts and role descriptions
- Training records and competency documentation
- Supplier qualification and evaluation records
- Customer complaint and corrective action records
- Inspection and testing records
- Customer audit results and findings from the past three years
- Any previous ISO 9001 certification history or gap assessment results
- Calibration records for measurement equipment

The purpose of document collection is not to assume that documented processes are being followed — it is to understand what formal systems exist as a starting point, so that the assessment can focus on verifying implementation and identifying gaps between documentation and practice.

# Section 3: Conducting the Gap Analysis

The gap analysis is conducted through a combination of document review, process observation, and structured interviews with process owners and employees. This section describes the methodology, the scoring approach, and the assessment activities for each clause.

## The RAG Scoring System

Each requirement element is scored using a three-level RAG (Red, Amber, Green) rating system that provides a clear, consistent, and visually intuitive picture of current conformance. The scoring criteria are:

| Rating | Status | Definition |
|---|---|---|
| 🔴 **Red** | **Not Addressed** | No current activity, system, or documentation addresses this requirement. Significant work required to achieve conformance. |
| 🟡 **Amber** | **Partially Addressed** | Some activity or documentation exists but is incomplete, informal, inconsistently applied, or lacks required evidence. Moderate work required to achieve conformance. |
| 🟢 **Green** | **Conforming** | Requirement is fully addressed by documented processes that are consistently followed and for which evidence exists. Minor enhancements may improve the system but conformance is demonstrable. |

A common and important scoring discipline: when in doubt between Green and Amber, score Amber. The gap analysis serves your implementation — understating gaps produces a misleading picture that leads to under-resourced implementation plans and certification surprises. Conservatism in gap scoring is an asset, not a pessimism.

**⚠ Common Pitfall**

Avoid the "we do this informally" trap. When an interviewee says "we do that, but we do not have it written down," the correct score is Amber — not Green. ISO 9001:2015 requires documented information for many of its requirements, and for requirements where documentation is not explicitly mandated, the standard still requires evidence that the process is systematically applied. "We do it in our heads" is not a QMS — it is individual practice that may or may not be consistent, transferable, or auditable.

## Assessment Methods

Each clause area should be assessed using at least two of the following methods to triangulate findings and reduce the risk of inaccurate scoring:

### Document Review

Examine existing documents related to the clause requirements. Look for: Does the document exist? Is it current and controlled? Does it actually address the requirement, or only tangentially relate to it? Is it consistent with other related documents? Signs that a document exists but is not being used include: revision dates years old, no distribution evidence, content inconsistent with what interviewees describe as current practice.

### Process Observation

Walk the process. Observe how work is actually being done in the areas relevant to the clause being assessed. This is the most reliable assessment method for operational requirements (Clause 8) and often reveals the most significant gaps — cases where a procedure exists but current practice has diverged from it, where controls exist on paper but are not applied consistently, or where requirements are met in some areas but not others.

### Structured Interviews

Interview process owners, supervisors, operators, and support staff. Key questions for any clause area: What is the process for [requirement area]? How do you know if the process is working? What happens when something goes wrong? How were you trained on this? Can you show me an example of how this was done recently? Listen for uncertainty, inconsistency across interviewees, and discrepancies between what is described and what documents or observations show.

## Clause-by-Clause Assessment Guide

The following pages provide assessment guidance for each requirement clause. For each clause, the guidance identifies the key questions to ask, the evidence to look for, and the most common gap patterns. Use this in conjunction with the Gap Analysis Worksheet template included at the end of this guide.

### Assessing Clause 4: Context of the Organization

| Assessment Area | Key Questions and Evidence to Seek |
|---|---|
| 4.1 Understanding the organization and its context | Has the organization identified external issues (market, regulatory, competitive, technology, economic) and internal issues (culture, resources, capabilities) relevant to quality? Is there documented evidence of this analysis? Is it periodically reviewed and updated? |
| 4.2 Interested parties | Has the organization identified who its relevant interested parties are (customers, regulators, suppliers, employees, owners)? Have their relevant needs and expectations been determined? Is there a process for monitoring and reviewing this information? |
| 4.3 QMS scope | Is there a documented scope statement? Does it identify the products and services covered? Does it justify any exclusions? Is the scope appropriate and defensible given the organization's actual activities? |
| 4.4 QMS processes | Has the organization identified its QMS processes and their sequence and interaction? Is there a process map, turtle diagram, or equivalent? Are inputs, outputs, owners, and performance measures defined for key processes? |

**Meridian Case Study**

Meridian's Gap Analysis — Clause 4 Results: Denise found that Meridian had a general sense of its competitive position and regulatory environment but had never formally documented organizational context. The company had identified its key customers but had not systematically identified all relevant interested parties or documented their requirements. No formal scope statement existed. Process maps existed for production operations but not for quality-related management processes. Clause 4 score: Red (4.1, 4.2),

Amber (4.3 — informal scope understood but not documented), Red (4.4 — process maps incomplete for QMS purposes). Estimated remediation effort: 12 to 16 hours of facilitated work sessions to build these foundational elements.

## Assessing Clause 5: Leadership

| Assessment Area | Key Questions and Evidence to Seek |
|---|---|
| 5.1 Leadership and commitment | Can top management describe their specific accountabilities in the QMS? Do they participate in quality-related decision-making? Do they allocate adequate resources? Do they actively promote quality culture? Is there evidence of their direct engagement (signed documents, management review participation, quality metrics review)? |
| 5.2 Quality Policy | Does a documented Quality Policy exist? Does it include a commitment to satisfy applicable requirements and to continual improvement? Is it appropriate to the organization's context? Is it available as documented information? Is it communicated, understood, and applied? Do employees know what it is? |
| 5.3 Roles, responsibilities, authorities | Have quality-related roles and responsibilities been formally defined and communicated? Do employees understand their quality responsibilities? Is there a designated Management Representative or equivalent? Are backup responsibilities defined? |

**Auditor Perspective**

Registrars audit Clause 5 by interviewing top management directly — typically in the opening meeting and separately during the audit. Auditors ask executives: "What is your specific role in the QMS?" "When did you last review quality performance data, and what did you decide as a result?" "How do you ensure quality is considered when business decisions are made?" Executives who answer with "I support the quality team" or "I rely on our quality manager" are revealing a leadership gap. Prepare your executive team for these questions before the certification audit.

## Assessing Clause 6: Planning

| Assessment Area | Key Questions and Evidence to Seek |
|---|---|
| 6.1 Risks and opportunities | Has the organization determined risks and opportunities relevant to the QMS? Is there documented evidence of this analysis? Are there planned actions to address significant risks and opportunities? Are these actions integrated into QMS processes? |
| 6.2 Quality objectives | Are quality objectives established at relevant functions, levels, and processes? Are they measurable? Monitored? Communicated? Updated? Is there a plan for achieving each objective identifying what will be done, by whom, by when, with what resources, and how results will be evaluated? |

| Assessment Area | Key Questions and Evidence to Seek |
|---|---|
| 6.3 Planning of changes | When changes to the QMS are needed, are they planned and implemented in a controlled manner? Is there a process for evaluating change impact before implementation? |

## Assessing Clause 7: Support

| Assessment Area | Key Questions and Evidence to Seek |
|---|---|
| 7.1 Resources | Has the organization determined and provided the resources needed for the QMS? This includes people, infrastructure (buildings, equipment, utilities), work environment (physical, social, psychological factors), and monitoring and measuring resources. |
| 7.1.5 Calibration | Is there a calibration program for measurement equipment? Are calibration records maintained? Is equipment status clearly identified? Are out-of-tolerance actions documented? |
| 7.2 Competence | Has required competence been determined for roles affecting quality? Are employees competent based on education, training, or experience? Has competence been verified (not just training delivered)? Are records maintained? |
| 7.3 Awareness | Are employees aware of the Quality Policy, relevant quality objectives, their contribution to QMS effectiveness, and the implications of not conforming? |
| 7.4 Communication | Has the organization determined what to communicate, when, to whom, and how regarding QMS topics? |
| 7.5 Documented information | Is there a document control process? Are documents approved before use? Are revision histories maintained? Are obsolete documents prevented from unintended use? Are records retained and retrievable? |

**Kaizen Connection**

The calibration requirement in Clause 7.1.5 aligns directly with the Lean/Six Sigma concept of measurement system analysis (MSA). A measurement system that is not calibrated or validated produces data that cannot be trusted — and decisions made on untrustworthy data are at best lucky and at worst systematically wrong. If your organization conducts SPC, Cpk analysis, or attribute inspection, all of those analytical tools are only as reliable as the measurement systems feeding them. Calibration is not bureaucratic compliance; it is the foundation of data integrity.

## Assessing Clause 8: Operation

| Assessment Area | Key Questions and Evidence to Seek |
|---|---|
| 8.1 Operational planning and control | Are quality criteria established for products/services and for accepting them? Are documented processes in place for all key operational activities? Is the control of planned changes documented? |

| Assessment Area | Key Questions and Evidence to Seek |
|---|---|
| 8.2 Customer requirements | Is there a process for determining customer requirements (stated, implied, statutory/regulatory)? Is there a review before commitment to supply? Are changes to requirements controlled and communicated? |
| 8.3 Design and development | (If applicable) Are design inputs defined? Are design controls planned and implemented? Are design outputs verified and validated? Are design changes controlled? |
| 8.4 External providers | Are externally provided products/services controlled? Is there a supplier qualification process? Are supplier performance records maintained? Are purchase requirements adequately specified? |
| 8.5 Production/service provision | Are production processes controlled (procedures, equipment, work environment, personnel, monitoring)? Is identification and traceability maintained where required? Is customer property identified and protected? |
| 8.6 Release of products/services | Are there defined release criteria? Is release authorized by designated personnel? Are release records maintained showing who authorized release and against what criteria? |
| 8.7 Nonconforming outputs | Are nonconforming products/services identified and controlled? Are dispositions documented (rework, scrap, accept on deviation, return)? Is there a process for root cause and corrective action when nonconformances recur? |

## Assessing Clause 9: Performance Evaluation

| Assessment Area | Key Questions and Evidence to Seek |
|---|---|
| 9.1 Monitoring and measurement | Is there a defined approach to monitoring quality performance? Are methods, frequency, and responsibility defined? Is data analyzed and used for decision-making? |
| 9.1.2 Customer satisfaction | Is customer satisfaction monitored? Is the monitoring method defined? Is the resulting information analyzed and used? |
| 9.2 Internal audit | Is there an internal audit program? Are audits planned, conducted, and documented? Are findings reported to relevant management? Are corrective actions taken and verified? |
| 9.3 Management review | Does top management conduct periodic management reviews? Are the required inputs reviewed (audit results, customer feedback, process performance, corrective actions, changes, opportunities for improvement)? Are outputs documented (decisions and actions)? |

## Assessing Clause 10: Improvement

| Assessment Area | Key Questions and Evidence to Seek |
|---|---|
| 10.2 Nonconformity and corrective action | Is there a formal corrective action process? Are nonconformances documented? Is root cause analysis conducted? Are corrective actions implemented, verified for effectiveness, and closed? Are records maintained? |
| 10.3 Continual improvement | Is there evidence of systematic continual improvement activity beyond reactive corrective action? Are improvement opportunities identified and pursued proactively? |

# Section 4: Interpreting and Prioritizing Gap Findings

When the assessment is complete, you will have a clause-by-clause RAG scorecard. The next step is to interpret those findings in terms of what they mean for your implementation plan — not all gaps are equal in their impact on the certification timeline or the resources required to close them.

## Identifying Critical Path Gaps

Critical path gaps are those that, if unresolved, will result in a major nonconformance during the certification audit — meaning certification cannot be granted until they are addressed. Critical path gaps share one or more of these characteristics:

- They represent a complete absence of a required system (Red scores in areas where the standard requires documented processes or maintained evidence)
- They affect the ability of other systems to function (foundational elements like document control, scope definition, and process identification underpin everything else)
- They involve mandatory documented information — areas where ISO 9001:2015 explicitly requires documents or records to exist
- They are systemic — they reflect how work is done across the organization rather than isolated instances

| Mandatory Documented Information | Clause Reference | Critical Path Impact |
|---|---|---|
| QMS scope | 4.3 | Cannot define what the certification covers without it |
| Quality Policy | 5.2 | Required by standard; auditor will request on Day 1 |
| Quality objectives and plans to achieve them | 6.2 | Must be established before implementation can be assessed |
| Competence evidence (training records) | 7.2 | Auditors verify competence for every role sampled |
| Calibration/verification records | 7.1.5 | Required where measuring equipment is used |
| Documented operational processes (where required) | 8.1 | Process-specific; determined by organization's context |
| Customer requirement review records | 8.2.3 | Evidence of review before commitment to supply |
| Externally provided product/service controls | 8.4 | Supplier qualification records required |
| Design and development records (if applicable) | 8.3 | If design is in scope, full design control records required |
| Nonconforming output records | 8.7 | Records of identification and disposition |
| Monitoring and measurement results | 9.1 | Evidence of what was measured and what happened with results |

| Mandatory Documented Information | Clause Reference | Critical Path Impact |
|---|---|---|
| Internal audit program and audit results | 9.2 | Minimum one complete audit cycle before Stage 2 |
| Management review results | 9.3 | At least one complete review before certification |
| Nonconformity and corrective action records | 10.2 | Evidence of the full CAPA cycle |

## Identifying Quick Wins

Quick wins are Amber-scored items where the gap is primarily one of formalization rather than practice — situations where the right things are already happening but the documentation, records, or systematic application needed for conformance are missing. Quick wins can often be addressed within days or weeks and generate momentum and motivation for the broader implementation effort.

Common quick win patterns include:

- An informal quality policy statement in use but not formally approved, documented, or communicated — can be formalized in a single working session
- Calibration being performed but records not retained or equipment not labeled — a records management improvement, not a new program
- Training being conducted but not documented — establishing a training record template and retrofilling recent training history
- Customer requirements being reviewed verbally but not recorded — adding a requirement review step to the existing order entry process
- Supplier qualification criteria existing informally in the purchasing manager's judgment — documenting the existing criteria and applying them to create the first formal approved supplier list

## The Gap Scoring Summary Dashboard

Consolidate your clause-by-clause RAG scores into a summary dashboard that provides leadership with a single-page view of the organization's current readiness state. This dashboard becomes the foundation for the executive presentation that authorizes the implementation investment and timeline.

| Clause | Area | Score | Critical Path? | Priority Action |
|---|---|---|---|---|
| 4.1 | Organizational context | Red | Yes | Conduct context analysis session with leadership |
| 4.2 | Interested parties | Red | Yes | Identify and document interested parties and requirements |
| 4.3 | QMS scope | Amber | Yes | Formalize existing scope understanding |

| Clause | Area | Score | Critical Path? | Priority Action |
|---|---|---|---|---|
| | | | | into documented scope statement |
| 4.4 | QMS processes | Red | Yes | Develop process map and process descriptions for key QMS processes |
| 5.1 | Leadership commitment | Amber | Yes | Brief executive team on ISO 9001 leadership requirements; schedule management review |
| 5.2 | Quality Policy | Amber | Yes | Revise and formally approve quality policy; communicate to all personnel |
| 5.3 | Roles and responsibilities | Amber | No | Document quality roles; formalize Management Representative appointment |
| 6.1 | Risks and opportunities | Red | Yes | Develop risk/opportunity register; link to QMS processes |
| 6.2 | Quality objectives | Amber | Yes | Formalize existing quality metrics as documented objectives with targets and plans |
| 7.1.5 | Calibration | Amber | Yes | Audit calibration records; ensure all equipment labeled; establish recall system |
| 7.2 | Competence | Red | Yes | Develop competence matrix; establish training records retroactively for current staff |
| 7.5 | Document control | Red | Yes | Establish document control procedure and register; number and version-control all QMS documents |

| Clause | Area | Score | Critical Path? | Priority Action |
|---|---|---|---|---|
| 8.2 | Customer requirements | Amber | Yes | Add requirement review step to order process; establish review records |
| 8.4 | External providers | Amber | Yes | Formalize supplier qualification criteria; create approved supplier list |
| 8.7 | Nonconforming outputs | Green | No | Document existing NCR process; verify records are maintained |
| 9.2 | Internal audit | Red | Yes | Develop audit program; train internal auditors; schedule first audit cycle |
| 9.3 | Management review | Red | Yes | Schedule and conduct first management review before Stage 2 audit |
| 10.2 | Corrective action | Amber | Yes | Formalize existing corrective action process; ensure root cause analysis and closure verification |

**Meridian Case Study**

Meridian's Gap Summary Results: After completing the full gap analysis over three weeks (assessment team of five, approximately 80 hours of combined effort), Denise consolidated the findings into the summary dashboard and calculated an overall conformance picture: 22% of assessed requirement elements were Green, 31% were Amber, and 47% were Red. On first impression, this concerned the executive team. Denise's presentation reframed the results: the 31% Amber represented existing good practices that could be formalized relatively quickly, and many of the Red scores were in management system infrastructure (context, documentation, audit program) rather than operational practices — meaning Meridian was making quality product already and the work ahead was primarily about systematizing and evidencing what they already did. Estimated implementation investment: 14 months, one dedicated part-time QMS resource plus 10 to 15% of Denise's time, approximately $45,000 in consulting, training, and registrar fees.

# Section 5: Selecting a Certification Body (Registrar)

The certification body — also called the registrar — is the third-party organization that will audit your QMS and grant (or deny) ISO 9001 certification. Selecting the right registrar is a consequential decision that affects audit quality, cost, scheduling flexibility, industry credibility, and the relationship you will have with your certification partner for three or more years.

## Accreditation: The Non-Negotiable Starting Point

Any registrar you consider must be accredited by a recognized accreditation body. Accreditation means that the accreditation body has verified that the registrar operates in accordance with ISO/IEC 17021 — the international standard for management system certification bodies. Common accreditation bodies include:

- ANAB (ANSI National Accreditation Board) — United States
- UKAS (United Kingdom Accreditation Service) — United Kingdom
- DAkkS (Deutsche Akkreditierungsstelle) — Germany
- RvA (Raad voor Accreditatie) — Netherlands
- JAB (Japan Accreditation Board) — Japan

Do not accept a certificate from a non-accredited registrar, regardless of how it is marketed or priced. Many customers and industry sectors require accredited certification — and a certificate from an unaccredited body is not recognized in most formal qualification processes.

## Key Selection Criteria

| Criterion | What to Evaluate |
|---|---|
| Industry sector experience | Has the registrar certified organizations in your industry? Auditors should understand your processes, terminology, and industry-specific regulatory context. Ask specifically which industry codes (IAF scopes) the registrar is accredited for. |
| Auditor qualifications | Who will be assigned as your lead auditor? What is their industry background and certification auditing experience? You have the right to approve or reject an auditor assignment. |
| Geographic coverage | For single-site organizations, proximity matters less. For multi-site, confirm the registrar can adequately cover all locations. |
| Scheduling flexibility | How far in advance must audit dates be booked? What is their rescheduling policy? What happens if you need to delay your Stage 2? |
| Combined audit capability | If you are pursuing or considering ISO 14001 or ISO 45001, can this registrar conduct combined audits? Combined audits with a single audit team are significantly more efficient. |
| Certificate recognition | Is the registrar's certificate recognized by your key customers and target markets? Some customers or sectors specify approved registrars. |

| Criterion | What to Evaluate |
|---|---|
| Fee structure and transparency | Get a detailed fee proposal covering Stage 1, Stage 2, annual surveillance, and recertification. Understand what is included and what triggers additional charges. |

## The Registrar Engagement Process

Once you have identified two or three accredited registrar candidates, the process typically follows this sequence:

5. Submit a Request for Proposal (RFP) or Application: Provide your scope, number of employees, sites, shift patterns, and complexity factors. Registrars use this to calculate audit day requirements per the IAF MD 5 document.
6. Receive and compare proposals: Compare scope of service, audit day allocation, fees, and auditor qualifications. Be cautious of proposals with significantly fewer audit days than others — this may indicate understaffing of the audit, not efficiency.
7. Check references: Ask for references from certified organizations in your industry sector. Ask specifically about auditor quality, communication, and responsiveness when issues arose.
8. Select and contract: Execute the certification agreement. Understand the terms for the three-year certification cycle including surveillance audit frequency (typically annually) and recertification requirements.
9. Schedule Stage 1: Stage 1 is typically conducted 2 to 4 months before Stage 2. It is primarily a document review and readiness assessment. Plan to have your QMS documentation substantially complete before Stage 1.

**Best Practice**

Engage your chosen registrar early — ideally 6 to 9 months before your target certification date. Registrars schedule audit capacity well in advance, and popular registrars may not have your preferred dates available if you engage late. Early engagement also allows the registrar to conduct an optional pre-assessment visit if you desire one, and ensures you understand the documentation the registrar will want to review at Stage 1.

# Section 6: Building Organizational Readiness

The gap analysis evaluates your systems — but your organization's readiness to implement a QMS is also about its people, culture, and leadership alignment. Technical gaps are easier to close than cultural ones. This section addresses the human dimensions of readiness that the gap analysis worksheet does not fully capture.

## Executive Sponsorship: The Non-Negotiable Prerequisite

ISO 9001 implementation without genuine executive sponsorship fails consistently and predictably. Not because executives do not care about quality — most do — but because implementation requires sustained resource allocation, cross-functional cooperation, and organizational priority that only executive authority can secure and maintain.

The executive sponsor's role in implementation includes:

- Visibly and explicitly authorizing the implementation effort and communicating its organizational priority
- Allocating adequate resources — personnel time, budget, external expertise — without requiring the QMS team to justify every expenditure as the implementation proceeds
- Resolving cross-functional resistance when departments resist process changes or documentation requirements
- Chairing or actively participating in management reviews throughout the implementation, not just at certification
- Modeling the quality culture the standard requires — understanding and referring to the quality policy, asking about quality performance in operational meetings, and treating quality objectives as real organizational commitments

**⚠ Common Pitfall**

Watch for the "quality department project" trap. In many organizations, ISO 9001 implementation begins as a quality department initiative and never becomes an organizational one. The quality manager does all the work, writes all the procedures, conducts all the training, and presents everything to management for signatures. The result is a QMS that exists on paper but has no organizational ownership — and when the registrar interviews operators, supervisors, and executives who cannot speak to the QMS, the certification audit reveals the gap that was always there. From Day 1, ensure that process ownership for QMS elements is assigned to the operational managers who actually run those processes, not to the quality team.

## Department Readiness Assessment

Beyond executive sponsorship, assess the readiness of each functional area that the QMS will cover. Common readiness factors by department:

| Function | Key Readiness Factors | Common Resistance Patterns |
|---|---|---|
| Operations / Manufacturing | Openness to documented procedures; supervisor commitment to training and adherence; tolerance for documentation during production | "We cannot afford the time for paperwork during production." Addressed by designing lean, practical |

| Function | Key Readiness Factors | Common Resistance Patterns |
|---|---|---|
| | | procedures that fit how work actually happens. |
| Purchasing / Supply Chain | Willingness to formalize supplier qualification; supplier relationship management vs. audit mindset | "Our suppliers are long-term partners — we do not need formal evaluations." Addressed by framing supplier qualification as protection of those relationships. |
| Human Resources | Competence records integration; training program documentation; role description currency | "We have hiring processes already." Addressed by connecting ISO requirements to existing HR processes rather than creating parallel systems. |
| Engineering / Design | Design control documentation; change management formalization; specification management | "Our engineers know what they are doing." Addressed by framing design controls as protection against rework and customer returns, not bureaucracy. |
| Sales / Customer Service | Customer requirement review documentation; complaint management formalization | "We know our customers' requirements — we do not need forms." Addressed by showing how documented reviews protect the company legally and operationally. |
| Senior Management | Time commitment to management reviews; willingness to be personally accountable for quality policy and objectives | "The quality team handles quality." Addressed by explicitly reviewing ISO 9001's leadership requirements and the personal accountability they create. |

## Communicating the "Why" to the Organization

One of the most common early-implementation mistakes is announcing ISO 9001 certification as a goal without explaining to the workforce why the organization is pursuing it and what it means for them. This creates anxiety (Will this change how I do my job?), skepticism (Is this just more paperwork?), and disengagement (This is a management project, not mine) — all of which make implementation harder.

Effective internal communication about the ISO 9001 journey addresses:

- Why the organization is pursuing certification — customer requirement, competitive differentiation, operational improvement, or market access
- What certification means in practical terms — what will change, what will not, and what employees will be asked to contribute
- The timeline and major milestones — people want to know when this will affect them
- How employees can contribute — certification is not something done to the workforce but with it
- What the benefit is to them — more systematic processes, clearer roles, reduced rework and frustration are legitimate employee-facing benefits of a well-implemented QMS

# Section 7: From Gap Analysis to Implementation Planning

The gap analysis is not the destination — it is the input to the implementation plan. This section bridges the two, showing how gap findings translate into the planning work that Guide 1.2 covers in depth.

## Estimating Remediation Effort

Each gap requires a realistic estimate of the effort to close it. These estimates will be used to develop the implementation timeline and resource plan. Common effort categories and typical ranges for a mid-size manufacturing organization:

| Gap Remediation Activity | Effort Range | Key Driver | Who Does the Work |
|---|---|---|---|
| Organizational context analysis and documentation | 8 to 16 hours | Leadership availability for facilitated sessions | Quality + Senior Leadership |
| Quality Policy development/revision | 4 to 8 hours | Iteration with executive team | Quality + CEO/President |
| QMS scope statement | 2 to 4 hours | Scope complexity | Quality Manager |
| Process mapping (QMS processes) | 16 to 40 hours | Number and complexity of processes | Quality + Process Owners |
| Risk and opportunity register | 8 to 20 hours | Depth of analysis desired | Quality + Management Team |
| Quality objectives development | 4 to 8 hours | Data availability for baseline setting | Quality + Senior Management |
| Document control system setup | 8 to 24 hours | Electronic vs. paper; existing document volume | Quality (primarily) |
| Competence matrix and training records | 16 to 40 hours | Number of roles; training record history availability | Quality + HR + Supervisors |
| Calibration program formalization | 8 to 20 hours | Number of measuring devices; existing calibration history | Quality + Maintenance |
| Procedure writing (key operational processes) | 4 to 12 hours per procedure | Process complexity; approval cycle | Process Owners + Quality |

| Gap Remediation Activity | Effort Range | Key Driver | Who Does the Work |
|---|---|---|---|
| Supplier qualification system | 12 to 24 hours | Number of suppliers; existing records | Purchasing + Quality |
| Internal audit program and auditor training | 24 to 40 hours | Number of auditors to train; audit scope | Quality + Internal Auditors |
| Management review process | 4 to 8 hours setup; 4 to 6 hours per review | Data availability; leadership engagement | Quality + Senior Leadership |
| CAPA system formalization | 8 to 16 hours | Existing corrective action maturity | Quality |

## The Ten Things Organizations Most Commonly Underestimate

Based on the patterns that emerge in ISO 9001 implementations across manufacturing, service, and mixed organizations, these are the ten items most consistently underestimated in gap analysis planning — underestimated either in the effort required to address them or in the organizational change they require:

10. The management review: Setting up a genuine management review that meets the standard's input and output requirements — and getting senior leadership to engage meaningfully rather than ratify a quality department report — takes far more preparation and organizational change than most implementations plan for.
11. Competence documentation: Many organizations have trained their people but have almost no records to show for it. Reconstructing historical training records, building the competence matrix, and establishing verification processes for all current-role employees is consistently more time-consuming than anticipated.
12. Document control for existing documents: Organizations often have dozens or hundreds of existing quality-related documents — none of them controlled. Inventorying, numbering, versioning, approving, and distributing these before the audit is a substantial project in itself.
13. Risk-based thinking: Many organizations are comfortable with operational risk management but struggle to apply risk thinking to the QMS itself — identifying what could undermine QMS performance and planning actions to address those risks at the system level.
14. Process mapping at the right level of detail: Too detailed and the maps are unusable; too high-level and they are meaningless. Finding the right level of abstraction for QMS process documentation — and building agreement across functions on how processes interact — takes multiple iterations.
15. Supplier qualification retroactivity: Most organizations have established suppliers they have been working with for years without formal qualification records. The standard does not grandfather these relationships — conformance requires documented evaluation of all suppliers of externally provided products or services that affect QMS conformance.
16. Internal audit program maturity: The internal audit program must demonstrate a complete cycle — planning, conducting, reporting, and following up — before the Stage 2 audit. This requires auditor training, scheduling, execution, and CAPA closure, all of which take more calendar time than effort time.

17. Customer satisfaction measurement: Many organizations track complaints and respond to them but do not systematically monitor customer satisfaction. Establishing a method, gathering initial data, and analyzing it takes time — and the results, if unflattering, require further action before the audit.
18. The actual extent of calibrated equipment: Equipment inventories consistently undercount the measuring devices in use. The gap between what is on the calibration list and what is actually being used to make quality decisions is frequently discovered during audit preparation.
19. Change management for operators and supervisors: Getting the workforce to understand why the QMS matters, engage with the new procedures, and consistently apply new documentation requirements takes sustained, repeated communication and supervisor reinforcement — not a single training session.

# Section 8: The Meridian Case Study — Gap Analysis in Full

This section presents the Meridian Precision Components gap analysis experience in narrative form, providing a complete picture of how the process unfolded, what was discovered, and how the results were used. Meridian is a composite of typical mid-size manufacturer experiences and is intended to be representative rather than exceptional.

## About Meridian Precision Components

Meridian Precision Components, Inc. (MPC) is a 220-person contract machining and metal fabrication company founded in 1987. Meridian machines and fabricates precision components for customers in the aerospace, defense, and industrial equipment sectors. Operations include CNC machining, grinding, welding, heat treatment, and light assembly. The company operates from a single 85,000 square-foot facility with two production shifts and an engineering department of twelve.

Meridian has never been ISO 9001 certified. It has, however, passed multiple customer quality audits over the years — including two AS9100 (aerospace quality standard) customer audits that identified areas for improvement but did not result in disqualification. Customer pressure from two major aerospace accounts, who are moving to require ISO 9001 certification of their Tier 2 suppliers, is the primary driver for Meridian's decision to pursue certification.

Denise Alvarez has been Meridian's Quality Systems Manager for four years. She has ISO 9001 awareness training and has participated in customer audits as the quality point of contact, but she has not personally managed an ISO 9001 implementation previously. The CEO, Robert Nolan, has authorized the certification project and assigned Denise as Management Representative, with a $50,000 budget for Year 1 of implementation.

## Assembling the Assessment Team

Denise assembled a five-person assessment team representing the major functional areas the QMS would cover:

- Denise Alvarez — Quality Systems Manager (lead assessor)
- Marco Pedraza — Operations Supervisor (production and manufacturing processes)
- Sarah Kim — Purchasing Manager (external providers and supplier management)
- James Thornton — HR Manager (competence and training requirements)
- Robert Nolan — CEO (leadership and management review requirements — interviewed, not a day-to-day assessor)

Denise engaged an ISO 9001 consultant for two days to provide an orientation session for the assessment team and to review the completed assessment before scoring was finalized. The consultant's orientation covered the intent behind each requirement clause, how auditors evaluate conformance, and the common places where organizations overstate their current conformance. The two-day consulting investment — approximately $3,200 — was, in Denise's assessment, the highest-ROI expenditure of the entire assessment phase.

## The Assessment Process

The assessment took three weeks of calendar time and approximately 80 combined hours of team effort. The first week was document review — Denise gathered all existing quality-related documentation and each assessor reviewed materials relevant to their area. The second week was process observation and interviews — each assessor walked their functional area processes and interviewed supervisors and operators. The third week was consolidation, scoring, and results preparation.

The most significant finding in the document review phase was the sheer informality of Meridian's existing quality practices. Good practices existed — product was being inspected, nonconformances were being segregated and dispositioned, suppliers were being evaluated in a general sense — but almost none of this was documented in a controlled way. Existing documents were un-numbered, un-versioned, and inconsistently distributed. In several cases, the procedure on the quality manager's computer was not the same version being used on the shop floor.

## Key Findings by Clause

| Clause Area | Score | Meridian-Specific Finding |
|---|---|---|
| 4.1 Context | Red | No documented context analysis. Leadership had a strong intuitive sense of competitive position but no formal analysis. SWOT exercises conducted in strategic planning had never been connected to QMS requirements. |
| 4.2 Interested parties | Red | Customers well-identified; regulators (ITAR, OSHA) identified informally. No systematic interested party register. Employee needs and expectations not formally considered in QMS planning. |
| 4.3 Scope | Amber | Scope understood informally (all machining and fabrication operations, single site) but no documented scope statement existed. Design and development exclusion not formally justified despite Meridian operating exclusively to customer specifications. |
| 4.4 QMS processes | Red | Production process maps existed for machining and fabrication. No process maps for quality management processes (nonconformance handling, corrective action, management review, document control). |
| 5.1 Leadership | Amber | CEO genuinely engaged with quality as a business value. However, his engagement was informal and reactive — responding to major quality problems rather than proactively governing the QMS. No evidence of his defined quality accountabilities. |
| 5.2 Quality Policy | Amber | A quality policy existed — three sentences on a framed document in the lobby. It was not formally approved (no signature, no version), not communicated beyond the lobby display, and most employees interviewed could not recall its content. |

| Clause Area | Score | Meridian-Specific Finding |
|---|---|---|
| 6.1 Risks and opportunities | Red | No risk-based thinking formalized for the QMS. Risk assessment existed for safety (OSHA compliance) but had never been applied to quality management system risks. |
| 6.2 Quality objectives | Amber | On-time delivery and first-pass yield were tracked on a production dashboard. Neither was formally documented as a quality objective with a stated target, responsible owner, or achievement plan. |
| 7.1.5 Calibration | Amber | Calibration was performed — most gauges and CMM equipment were on calibration schedules. However, 23% of devices inventoried were overdue. Calibration labels were not consistently applied. One critical CMM had no calibration record for 14 months. |
| 7.2 Competence | Red | Training was conducted regularly. Training records were almost nonexistent — a sign-in sheet existed for some formal training sessions, nothing for on-the-job training. No competence matrix. No formal verification that training produced competence. |
| 7.5 Document control | Red | Approximately 40 quality-related documents existed in various states: un-numbered, un-versioned, inconsistently distributed, with multiple obsolete versions circulating on the shop floor. No document control procedure. |
| 8.2 Customer requirements | Amber | Customer orders were reviewed by the estimating and engineering team before acceptance — a real and functioning process. It was entirely verbal and undocumented. No review records existed. |
| 8.4 External providers | Amber | Supplier selection was based on the purchasing manager's experience and relationship history — sound in practice, entirely informal in documentation. No approved supplier list, no documented evaluation criteria, no ongoing performance monitoring records. |
| 8.5 Production controls | Green | Production processes were well-controlled with documented travelers, inspection criteria, and operator instructions on most machines. This was Meridian's strongest area — customer audit pressure over the years had driven good operational discipline. |
| 8.7 Nonconforming outputs | Green | NCR process functioned well — nonconforming parts were tagged, segregated, and dispositioned through a consistent process. Disposition records were maintained. Root cause analysis quality was variable but the process infrastructure was conforming. |
| 9.1 Monitoring and measurement | Amber | Quality data was collected and reported on a production dashboard. Analysis was primarily descriptive (what happened) rather than trend-based (what is the direction) and did not feed formal management review. |

| Clause Area | Score | Meridian-Specific Finding |
|---|---|---|
| 9.2 Internal audit | Red | No internal audit program existed. Customer audits had served as the primary external quality assessment mechanism. No internal auditors trained to ISO 9001. |
| 9.3 Management review | Red | No formal management review meeting existed. Quality topics were addressed in monthly operations meetings but not in the structured format required by ISO 9001, and no review minutes documented the required inputs or outputs. |
| 10.2 Corrective action | Amber | A corrective action request (CAR) process existed and was used for significant customer-reported issues. Root cause analysis depth was variable — 5-Why used sometimes, immediate symptom correction used others. No effectiveness verification step. Process not extended to internal quality findings consistently. |

## The Gap Analysis Presentation to Leadership

Denise presented the gap analysis results to the Meridian executive team in a one-hour working session. She structured the presentation in three parts: the overall scorecard, the critical path findings with implementation implications, and the recommended implementation approach with timeline and budget.

The executive team's initial reaction to the 47% Red score was concern — several questioned whether certification was realistic. Denise's reframing was effective: she walked through the NCR process (Green) and production controls (Green) findings as evidence that Meridian already operated with quality discipline in its core processes. She positioned the Red scores in management infrastructure as the work of building the QMS around existing good practices — systematizing, documenting, and evidencing what Meridian already did — rather than rebuilding how work was done.

The CEO authorized a 14-month implementation timeline, the $50,000 Year 1 budget, and — critically — committed to personally leading the management review process and attending a half-day ISO 9001 leadership briefing with the full executive team. These commitments, extracted at the gap analysis presentation, would prove to be among the most valuable outcomes of the entire assessment exercise.

# Quick Reference: Gap Analysis Essentials

## The 10 Most Common Gap Analysis Mistakes

| # | Mistake — and What to Do Instead |
|---|---|
| 1 | Scoring current practices as conforming because the right outcomes are occurring, without verifying that a documented system is producing them. Score based on system, not results. |
| 2 | Excluding functions from the assessment because their leaders resist or are unavailable. Every function in QMS scope must be assessed. Resistance is itself a finding. |
| 3 | Accepting verbal assurances without observation or document verification. "We do that" requires evidence. Without evidence, score Amber at best. |
| 4 | Failing to assess top management directly. Clause 5 requirements apply specifically to top management — their conformance cannot be inferred from what the quality team does. |
| 5 | Underestimating the document control gap. Most organizations with no existing document control system underestimate both the volume of documents requiring control and the effort to establish and apply a control system. |
| 6 | Not accounting for the internal audit cycle in the implementation timeline. A complete audit cycle — from program establishment through finding closure — must be complete before Stage 2. This takes 4 to 6 months minimum. |
| 7 | Treating design and development exclusion as automatic for manufacturers. If your organization performs any engineering work to develop product configurations, even if to customer specifications, Clause 8.3 may apply. Get a qualified opinion before excluding it. |
| 8 | Failing to identify the competence gap specifically. "We train our people" does not answer whether required competence has been determined, whether current employees are competent, or whether evidence exists. The gap is almost always larger than initially assessed. |
| 9 | Treating the gap analysis as a one-person task. Single-assessor gap analyses consistently miss functional area specifics and produce less credible results for leadership presentations. Cross-functional teams produce better assessments. |
| 10 | Not using the gap analysis findings to anchor the implementation plan. The gap analysis should directly produce the work breakdown structure and resource estimates for Guide 1.2's implementation planning exercise. If the gap analysis does not drive the plan, its value is lost. |

## RAG Scoring Quick Reference

| To Score Green, you need... | To Score Amber, you have... | To Score Red, you have... |
|---|---|---|
| A documented process that addresses the requirement | An existing practice that partially addresses the requirement but is undocumented or inconsistently applied | No current activity or system addressing this requirement |
| Evidence that the process is consistently followed | Documentation that does not fully address the requirement | Practices that are entirely informal or individual |

| To Score Green, you need... | To Score Amber, you have... | To Score Red, you have... |
|---|---|---|
| Records demonstrating the process has been executed | Records that are incomplete, inconsistently maintained, or not retrievable | No records of the required activity |
| Employees who can describe the process consistently when interviewed | Employees whose descriptions of the process vary significantly from each other or from documentation | Employees who are unaware that a requirement applies to their work |

## Mandatory Documented Information: The Complete ISO 9001:2015 List

These are the specific instances where ISO 9001:2015 requires documented information. Every item must be addressed in your QMS regardless of organization size or complexity (unless the organization can demonstrate the requirement does not apply to its scope).

| Required Documented Information | Type | Clause Reference |
|---|---|---|
| QMS scope | Document | 4.3 |
| Quality Policy | Document | 5.2.2 |
| Quality objectives | Document | 6.2.1 |
| Fitness for purpose of monitoring and measuring resources | Record | 7.1.5.1 |
| Basis used for calibration (when no standards exist) | Record | 7.1.5.2 |
| Evidence of competence | Record | 7.2 |
| Results of review of customer requirements | Record | 8.2.3.2 |
| Inputs for design and development (if applicable) | Record | 8.3.3 |
| Controls applied to design and development (if applicable) | Record | 8.3.4 |
| Design and development outputs (if applicable) | Record | 8.3.5 |
| Design and development changes (if applicable) | Record | 8.3.6 |
| Results of evaluation, monitoring, and re-evaluation of external providers | Record | 8.4.1 |
| Evidence of unique identification for traceability (if applicable) | Record | 8.5.2 |
| Property of customer or external provider lost, damaged, or unsuitable for use | Record | 8.5.3 |
| Review of changes to production or service provisions | Record | 8.5.6 |

| Required Documented Information | Type | Clause Reference |
|---|---|---|
| Release of products and services (who authorized and against what criteria) | Record | 8.6 |
| Nonconforming outputs (nature, actions, concessions) | Record | 8.7.2 |
| Results of monitoring, measurement, analysis, and evaluation | Record | 9.1.1 |
| Internal audit program and audit results | Record | 9.2.2 |
| Results of management reviews | Record | 9.3.3 |
| Nature of nonconformities and actions taken | Record | 10.2.2 |
| Results of any corrective actions | Record | 10.2.2 |

## Registrar Selection Checklist

| | Registrar Evaluation Criterion |
|---|---|
| ☐ | Registrar is accredited by a recognized accreditation body (ANAB, UKAS, DAkkS, or equivalent) |
| ☐ | Registrar is accredited for your IAF scope (industry code) |
| ☐ | Registrar can provide an auditor with demonstrated experience in your industry sector |
| ☐ | Certificate issued will be recognized by your key customers |
| ☐ | Audit day allocation meets IAF MD 5 minimum requirements (not significantly below other proposals) |
| ☐ | References from certified organizations in your sector provided and checked |
| ☐ | Fee structure covers Stage 1, Stage 2, annual surveillance, and recertification clearly |
| ☐ | Rescheduling and delay policy understood and acceptable |
| ☐ | Combined audit capability confirmed (if ISO 14001 or ISO 45001 anticipated) |
| ☐ | Contract terms reviewed and accepted |
| ☐ | Stage 1 date scheduled (minimum 6 to 8 weeks before Stage 2 target) |

*Next in Series: Guide 1.2 — Implementation Planning & Project Management: Building the Implementation Plan That Actually Works. Covering realistic timeline construction, work breakdown structure, resource allocation, change management, and how to translate gap analysis findings into a project plan that survives contact with organizational reality.*