

# The Future of ISO 9001

## What's Changing and How Organizations Should Prepare

### Disclaimer:

The contents herein are based on the presenter's own opinions about what is likely to be changing in the upcoming revision.

**Laura Halleck**

Sr. Quality Systems Consultant | Quality Support Group

## OVERVIEW

# Session objectives

*By the end of this session, quality professionals will be positioned to lead their organizations through the ISO 9001 transition with clarity and confidence.*

### **Understand the direction**

Recognize why ISO/TC 176 is revising the standard now and what it signals about the direction of modern quality management.

### **Identify the substantive changes**

Distinguish editorial updates from requirements that will drive real work — across context, planning, operations, and performance evaluation.

### **Interpret the emerging themes**

Frame the revision through digitalization, opportunity-based thinking, and quality culture and ethical behavior.

### **Plan the transition**

Translate the changes into a practical readiness plan for your organization, its leadership, and its certification scope.

## CONTEXT

# Why a revision now?

*The operating environment has moved on since 2015*

ISO 9001:2015 was drafted against a very different backdrop. A decade later, ISO/TC 176/SC 2 is modernizing the standard to reflect how organizations operate today — and how they need to operate tomorrow.

The revision responds to three converging pressures:

1

### Technology & data

Digital transformation, remote and hybrid work, data-driven decision-making, and emerging technologies have reshaped processes and risks.

2

### Stakeholder expectations

Customers, regulators, and interested parties now expect transparency, ethical conduct, and demonstrable resilience — including climate response.

3

### Harmonized Structure

ISO now mandates a common Harmonized Structure (HS) across all management system standards, superseding the 2012 High Level Structure.

## REVISION TIMELINE

### From 2015 to the sixth edition

- **September 2015** ISO 9001:2015 (5<sup>th</sup> ed.) published
- **February 2024** Climate change amendments issued
- **August 2025** DIS 9001 6<sup>th</sup> Ed. circulated for international vote
- **Late 2025** Voting closes; comment disposition begins
- **Fall 2026 (expected)** FDIS publication and final standard release
- **2026 – 2029** Anticipated three-year transition period

## REVISION SCOPE

# What is on the table

*The two ISO 9000-family documents under revision*

## REQUIREMENTS STANDARD

COMPARED vs ISO 9001:2015

### ISO 9001:2026

- **Replaces ISO 9001:2015**

The certifiable Requirements standard. What auditors will check your organization against.

- **Aligned to Harmonized Structure**

Clauses 4–10 carry common text required across all ISO MSS (9001, 14001, 45001, 27001, etc.).

- **Annex A substantially expanded**

.

## FUNDAMENTALS & VOCABULARY

COMPARED vs ISO 9000:2015

### ISO 9000:2026

- **Title reframed to “Quality management”**

Broader than the former QMS framing — reflects an expanded conceptual scope.

- **New fundamental concepts**

Quality culture, customer experience, emerging technologies, circular economy, change and information management, business continuity.

- **Terms added, modified, reorganized**

Core definitions (e.g., process) refined; many new terms introduced to support the 9001 revision.

# What emerging technologies / digitalization means for your QMS

*Where in the standard to look — and what auditors will expect*

## Context & issues (4.1)

Determine the relevance of emerging technologies to your organization's external and internal issues — treat them as context factors, not afterthoughts.

## Accountability (5.3)

Where algorithms or automation influence QMS decisions, document who is accountable, who is responsible, and how decisions remain traceable.

## People & infrastructure (7.1.2 / 7.1.3)

Evaluate risks when technology replaces people; address hybrid and remote work as part of the environment for the operation of processes.

## Documented information (7.5)

Address new data risks — loss, confidentiality, and integrity of digital information — within your documented information controls.

# Opportunity-based thinking

*Building an opportunity discipline distinct from the risk register*

*A separate requirement calls for separate evidence. Organizations that merely re-label their risk register may attract findings.*

## Look for (or build):

- **An opportunity log** — distinct from the risk register, with source, impact, and owner
- **Opportunity criteria** — proportionate to potential impact on customer satisfaction and conformity
- **Evaluation evidence** — how opportunities were analyzed, prioritized, and selected for action
- **Linkage to improvement** — feed into continual improvement (10.1) and management review (9.3)
- **Reporting line** — new authority to report improvement opportunities to top management (5.3 e)

# Quality culture and ethical behavior

*From unspoken expectation to named leadership requirement*

## LEADERSHIP COMMITMENT

*Top management must demonstrate leadership and commitment by “promoting quality culture and ethical behaviour.”*

*Quality culture “reflected in shared values, attitudes, and established practices.”*

## AWARENESS

*Persons doing work under the organization’s control must be aware of the “organizational quality culture and ethical behaviour.”*

*Awareness training, onboarding, and refreshers will need to address culture explicitly.*

# Formalizing quality culture

*Leadership behaviours, policy, awareness, and measurement*

Culture is intangible — the standard does not prescribe methods, but auditors will expect demonstrable evidence.

## Define

*quality culture*

Articulate values, behaviors, and ethical commitments in the quality policy (5.2) and supporting documents.

Reference ISO 10010 for guidance on quality-culture evaluation.

## Demonstrate

*leadership*

Embed culture-related indicators in management review (9.3). Role-model ethical decisions in resource allocation, change management, and response to nonconformities.

## Develop

*awareness*

Update onboarding and refresher training to cover organizational values and ethical behavior. Move beyond policy posters to scenario-based learning.

## Detect

*signals*

Build mechanisms — surveys, confidential reporting, culture pulse — to detect drift. Treat culture metrics as inputs to risks, opportunities, and continual improvement.

## CROSS-CUTTING AMENDMENT

# Climate change — now a determination

*The 2024 ISO-IAF amendment will be carried into new revision*

*In February 2024, ISO added climate change language to all management system standards. The new revision will retain that text — and organizations certified to ISO 9001:2015 should already have addressed it.*

### CLAUSE 4.1 — new requirement

*“The organization shall determine whether climate change is a relevant issue.”*

### CLAUSE 4.2 — new NOTE

*“Relevant interested parties can have requirements related to climate change.”*

### WHAT IT MEANS

A determination is required — not a specific conclusion. Organizations must consider the question and be able to show their reasoning. Relevance will depend on context (sector, geography, supply chain, customer expectations).

## UNDER-THE-HOOD CHANGES

# Documented information — a language shift worth noting

*Subtle wording, pervasive implications for procedures and audit*

### ISO 9001:2015 wording

*“maintain documented information”*

*“retain documented information as evidence of...”*

### ISO 9001:2026 wording (based on Harmonized Structure)

*“shall be available as documented information”*

*“documented information shall be available as evidence of...”*

## WHY IT MATTERS

The obligation moves from a specific custody and retention arrangement to availability when information is needed. This small shift cascades through procedures, records policies, and audit trails — especially in digital and distributed database environments.

# ISO/FDIS 9000 — new fundamental concepts

*Vocabulary that supports the 9001 revision*

*Beyond terms, FDIS 9000 introduces new fundamental concepts — conceptual scaffolding for the modern QMS. Each is an emerging theme in how organizations operate today.*

## **Quality culture**

*shared values, beliefs, ethics, attitudes, behaviours supporting achievement of quality policy and objectives...*

## **Customer experience**

*emotional, physical and psychological connection customers have with product / service*

## **Change management**

*human, social, cultural aspects along with technological and structure aspects of change*

## **Knowledge management**

*acquire, create, retain, use, maintain, protect, and share knowledge*

## **Information management**

*acquisition, integrity, storage, preservation and protection of data and information*

## **Business continuity**

*Ability to continue delivery of products and services during and following a disruption*

## **Circular economy**

*decoupling economic activity from consumption of finite resources*

## **Integrated management**

*Unified approach to managing functions and processes across QMS, EMS, ISMS, OH&S*

HOW TO PREPARE

# A transition roadmap

*A phased approach for organizations certified to ISO 9001:2015*

**Phase 1**

*NOW — through FDIS*

**Orient & educate**

1

Brief leadership, auditors, and process owners.

**Phase 2**

*FDIS → Publication*

**Gap assessment**

2

Conduct a detailed clause-level gap analysis once the FDIS stabilizes. Focus on new requirements.

**Phase 3**

*Year 1 of transition*

**Implement & integrate**

3

Update the quality policy, objectives, awareness training, opportunity process, change-management procedures, and documented information controls.

**Phase 4**

*Years 2–3*

**Verify & certify**

4

Run internal audits against the new edition; coordinate the transition audit with your certification body. Sustain cultural and continual improvement practices.

# Common pitfalls to avoid

*Where first-wave transitions are likely to stumble*

## Copy-forward manuals

Re-stamping a 2015 quality manual with “revised for 2026” without addressing new clauses is the fastest route to major findings.

## Risk register relabeled as opportunities

Opportunities need their own source, evaluation, and proportionate action — not a column on the risk register.

## Skipping the climate determination

Even when the conclusion is “not relevant,” the determination itself must be made, documented, and reviewed as context evolves.

## Culture reduced to a poster

Culture and ethical behavior must be visible in policy, training, leadership decisions, and measurement — not just a statement on the wall.

## Retention-based records logic

Procedures that just say “retain for X years” may miss the new “available as evidence” framing — audit trails in digital systems must make information retrievable when needed.

## Treating emerging tech as optional

Emerging technologies are a legitimate context factor. If you have deployed automation, AI, or hybrid work, expect auditors to probe accountability and traceability.

## KEY TAKEAWAYS

# Prepare now — in substance, not just paperwork

## The shape is familiar

Clauses 4 – 10 remain. The Harmonized Structure keeps the top-level framework stable.

## The substance is not

Digitalization, opportunity-based thinking, culture and ethics, and climate change reshape what conformity looks like.

---

## Questions & discussion

Quality Support Group | Always Keep Improving

Laura Halleck

[laura.halleck@qualitysupportgroup.com](mailto:laura.halleck@qualitysupportgroup.com)