

Quality assurance

# ISO 9001:2026 WHAT'S CHANGING AND WHAT YOU NEED TO DO

A guide to understanding the proposed updates to ISO 9001

# QUALITY **ASSURED**



Your Risk Management  
Advantage



# INTRODUCTION

The Draft International Standard (DIS) of ISO 9001:2026 signals the next evolution of quality management. While the structure remains consistent with Annex SL, the DIS introduces clearer expectations around risk-based thinking, leadership, quality culture and continual improvement.

This guide walks through the proposed changes clause by clause and offers practical advice to help you prepare your quality management system (QMS) ahead of the final publication.

## Why it matters

Global expectations for resilient, strategically aligned quality systems are increasing. Acting now will help you meet stakeholder demands, protect certification and gain competitive advantage.



# CLAUSE-BY-CLAUSE BREAKDOWN OF KEY CHANGES

## CLAUSE 1 TO 3

### SCOPE, REFERENCES AND DEFINITIONS

The opening clauses are non-certifiable but have been refined to improve readability and consistency across ISO management system standards.

#### KEY CHANGES



- “Maintain documented information” is replaced with “available as documented information” throughout
- Definitions have been clarified and aligned with the combined concept of risks and opportunities

#### WHAT YOU NEED TO DO



- ✓ Review QMS documentation and terminology for consistency with the updated language
- ✓ Confirm that all required documented information is accessible and auditable

#### TIP



Update procedure templates and training materials early so your team uses the new terms from day one.

CLAUSE 4

CONTEXT OF THE ORGANISATION

Clause 4 has been sharpened to ensure external and internal issues are fully understood and documented, with a specific prompt to consider climate change where relevant.

INSIGHT



Embedding climate-related risks and opportunities now will help future-proof your QMS against regulatory and market shifts.

KEY CHANGES



- **External and internal issues (4.1):** now explicitly require you to determine whether climate change is a relevant factor
- **Interested parties (4.2):** expectations may include climate-related or new market requirements
- **Scope of the QMS (4.3):** scope must be justified and documented
- **Processes (4.4):** editorial updates to clarify process interactions

WHAT YOU NEED TO DO



- ✓ Expand context analysis to include climate change and other emerging factors
- ✓ Revisit stakeholder analyses to capture evolving expectations
- ✓ Ensure the QMS scope statement is evidence-based and available as documented information

CLAUSE 5

LEADERSHIP

Clause 5 reinforces the central role of top management in shaping quality culture and integrating the QMS with strategic objectives.

LEADERSHIP SPOTLIGHT



The DIS expects leaders to create and live a quality culture, moving beyond compliance oversight.

KEY CHANGES



- **Leadership and commitment (5.1.1):** requires active demonstration of quality culture and ethical behaviour, not just policy approval
- **Customer focus (5.1.2):** reaffirms the need to make customer satisfaction a core driver
- **Quality policy (5.2):** simplified wording with documentation to be “available” rather than merely “maintained”

WHAT YOU NEED TO DO



- ✓ Engage senior leaders in visibly championing the QMS and modelling ethical behaviour
- ✓ Refresh your quality policy and ensure it is accessible to employees and external stakeholders
- ✓ Link QMS objectives to corporate strategy to demonstrate alignment during audits

CLAUSE 6

PLANNING

Planning requirements see the most structural change, making risk and opportunity management more explicit and auditable.

NEW CLAUSE ALERT



Clause 6.3 introduces an auditable requirement to plan and control QMS-related changes – a major shift from the 2015 edition.

KEY CHANGES



- **6.1.2 Determining risks and opportunities** and **6.1.3 Planning actions** are now distinct, clarifying the difference between identifying and acting on risks
- **6.3 Planning of changes** is a new clause requiring formal evaluation of purpose, impact, resources and effectiveness before implementing changes

WHAT YOU NEED TO DO



- ✓ Separate risk identification from action planning in your QMS processes
- ✓ Introduce a structured change management process to meet the new 6.3 requirement
- ✓ Ensure risk assessments and related plans are proportionate and integrated into business objectives

CLAUSE 7

SUPPORT

Changes to Clause 7 standardise language and strengthen expectations for communication and awareness.

TIP



Involve HR and training teams early so competence and awareness programmes reflect the new expectations.

KEY CHANGES



- All references to “maintain documented information” now read “**available as documented information**”
- **Awareness (7.3):** explicitly calls for promoting quality culture and ethical behaviour

WHAT YOU NEED TO DO



- ✓ Ensure competence evidence and controlled documents are accessible and up to date
- ✓ Enhance internal communication to reinforce quality culture and ethical practices
- ✓ Update records and procedures to reflect the revised terminology

CLAUSE 8

OPERATION

Clause 8 clarifies how operational controls and external providers are managed and links customer requirements more tightly to contingency planning.

INSIGHT



Clearer supplier controls reduce risk exposure across global supply chains and strengthen customer confidence.

KEY CHANGES



- **Operational planning and control (8.1):** stronger emphasis on managing planned and unplanned changes
- **Requirements for products and services (8.2):** customer communication must cover disruptions and contingency actions
- **Externally provided processes, products and services (8.4):** terminology simplified and expectations clarified

WHAT YOU NEED TO DO



- ✓ Reassess supplier and contractor controls to ensure they fall fully within QMS oversight
- ✓ Strengthen change and contingency management in operational procedures
- ✓ Verify that customer requirements are fully defined, reviewed and documented

# PERFORMANCE EVALUATION

Performance evaluation now requires more structured management reviews and purpose-driven audits.

TIP



Link management review outputs directly to your continual improvement log to demonstrate evidence of action.

## KEY CHANGES



- **Monitoring and measurement (9.1.1):** improved link between performance evaluation and improvement outputs
- **Internal audit (9.2):** split into 9.2.1 (general) and 9.2.2 (programme) to sharpen focus on objectives and effectiveness
- **Management review (9.3):** now divided into 9.3.1 to 9.3.3 for inputs, process and outputs

## WHAT YOU NEED TO DO



- ✓ Define clear audit objectives and ensure audits assess system effectiveness, not just compliance
- ✓ Restructure management reviews to follow the three-part format and record measurable outcomes
- ✓ Use performance data to drive continual improvement decisions

## CLAUSE 10

# IMPROVEMENT

Clause 10 integrates continual improvement more tightly with monitoring and management review outputs.

## KEY CHANGES



- **Continual improvement (10.1):** explicitly linked to data and QMS outputs
- **Corrective action (10.2):** clarifies the need to assess recurrence potential and verify action effectiveness

## WHAT YOU NEED TO DO



- ✓ Demonstrate how improvement actions are triggered by audits, data analysis and management review
- ✓ Strengthen root cause analysis and follow-up to prevent recurrence
- ✓ Align procedures and records with updated clause numbering

# CONCLUSION

The ISO 9001:2026 Draft International Standard strengthens the relationship between risk-based thinking, leadership and continual improvement. While many updates are editorial, several introduce new or clearer requirements that must be addressed to maintain compliance and keep your QMS fit for the future.



## NEXT STEPS WITH LRQA

### To support your transition:

- [Join LRQA's Transition Club](#) for regular updates on ISO 9001, ISO 14001 and ISO 45001, and gain early insights, tools and practical guidance to support your QMS updates
- Use LRQA's [ISO 9001:2026 gap analysis checklist](#) to pinpoint where action is required
- Explore LRQA's ISO 9001:2026 transition training to help your team understand and implement the changes
- Speak to LRQA experts for tailored guidance and support

# ABOUT LRQA

LRQA is a leading global risk management partner.

Through our connected risk management solutions, we help you navigate an evolving global landscape to keep you one step ahead.

From certification and cybersecurity, to safety, sustainability and supply chain resilience, we work with you to identify risks across your business. We then create smart, scalable solutions, tailored to help you prepare, prevent and protect against risk.

Through relentless client focus, backed by decades of sector-specific expertise, data-driven insight and on-the-ground specialists across assurance, certification, inspection, advisory and training, we support over 61,000 organisations in more than 150 countries.

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