ISO 9001:2026 Transition Guide

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Helping manufacturers strengthen quality systems, prepare for audits, and successfully navigate ISO 9001 transitions.

ISO 9001:2026

ISO 9001:2026 has been published, bringing several minor updates while maintaining key concepts such as customer focus, performance evaluation, leadership and continuous improvement. In addition, since the last revision organizations have experienced significant changes in technology, supply chain, work arrangements and stakeholder expectations and ISO 9001:2026 includes updates to reflect this evolving business environment.

Here's a brief overview of the revisions and how to prepare.

What Changed?

Requirement Changes

There are three main additions and changes to requirements.

- *Quality Culture and Ethical Behavior*

  These concepts have been added throughout the standard, appearing in the Leadership, Environment for the operation of processes and Awareness clauses. Leadership is now expected to actively promote and ensure employees are aware of the organization's quality culture and ethical expectations.

- *Risks and Opportunities*

  Risks and opportunities are now addressed separately, highlighting the differences and recognizing that organizations may use different approaches to evaluate and manage them. The change does ***not*** introduce a formal risk management system, but rather is an approach involving risk-based thinking and opportunity-based thinking.

- *Planning of Changes*

  Additional considerations have been added to strengthen planning of changes and to improve the effectiveness of implementing changes. There is still room for the approach to vary depending on the change being implemented.

Changes That Don't Add New Requirements

A few things look different, but don't actually add new requirements.

- *Alignment with the Harmonized Structure*

  ISO 9001 follows the Harmonized Structure. This is a common clause structure and wording that is shared with the other Management System Standards (such as ISO 14001). Having a common structure makes it easier for organizations that follow multiple standards to have one set of requirements for common elements.

  As part of the revision, words were changed to match this shared structure. In some clauses, lists were reordered to align with this shared structure.

- *Inclusion of the Climate Change Amendment*

  The climate change amendment was published in February 2024 and became a requirement at that time. The amendment text has now been included in the standard.

Informational Changes

Some additional changes were made to provide enhanced explanations and clarification. They are provided as informative content and are ***not*** additional requirements.

- *Terms and Definitions*

  23 core management system standard terms and definitions have been added. There are also links for online search platforms. The terms and definitions in ISO 9000 do still apply.

- *Annex A*

  Annex A was completely rewritten. It is formatted to match the clause structure and provides additional content for each of the clauses.

- Annex B

  Annex B has been removed. There is still a bibliography of other related standards.

Preparing for the Transition

Organizations have 3 years to make the transition; however, there's no need to wait! There are simple steps you can take today:

- Obtain and review the new standard
- Understand which changes affect your organization
- Conduct a gap assessment against the new requirements
- Evaluate whether additional Quality Management System improvements would benefit the organization
- Develop and implement an action plan to address gaps and needed changes
- Start early to complete the transition before the deadline

Need Help Preparing for ISO 9001:2026?

The changes in ISO 9001:2026 may be modest, but understanding how to apply them to your organization and determining the most effective path forward can still feel overwhelming. The Quality Maven provides practical support for manufactures preparing for certification audits, maintaining ISO 9001 systems, conducting internal audits and transitioning to the revised standard.

Schedule a conversation:

www.thequalitymavenllc.com/contact

Appendix A: Detailed ISO 9001:2026 Clause Changes

(Clauses 3-10)

Clause	Change
Forward	Included summary of main changes
Throughout	Changed “this International Standard” to “this document”
	Added “continual” before improvement
	For documented information, changed “maintain” to “be available”
	For documented information, changed “retain” as evidence to “be available” as evidence
3	Added core management system standard terms and definitions
4.1	Added climate change amendment text to determine whether climate change is a relevant issue
4.2 Note	Added climate change amendment note regarding potential requirements related to climate change
4.3b	Removed “of relevant interested parties”
5.1.1f	Removed “engaging”
5.1.1i	Added promoting quality culture and ethical behavior
5.1.1k	Added opportunity-based thinking
5.1.1 Note 2	Added note regarding quality culture and ethical behavior
6.1.2/6.1.3	Separated risks and opportunities
6.1.2 Note 1	Added note regarding risks during and after disruptions
6.3c	Added availability of information
6.3e, f, g	Added communication of changes, how effectiveness will be monitored and evaluated, and how results will be reviewed
7.1.3 Note	Added note about types of work (on-site, remote, hybrid)
7.1.4	Added that some factors may be influenced by quality culture and ethical behavior

7.1.5.2b	Added “calibration or verification” before status
7.1.6 Note	Modified note regarding different forms of organizational knowledge
7.2a	Removed effectiveness
7.3e	Added awareness of quality culture and ethical behavior
8.1	Extended outsourced processes to externally provided processes, products or services relevant to the QMS
8.2.1e	Added requirement to provide information about contingency actions, including disruptions
8.2.1 Note	Added note regarding forms of customer communication
8.3.1 Note	Added note regarding stages of the design and development process
8.3.2g	Changed “users” to “relevant interested parties”
8.3.3 Note	Added note regarding the evolving nature of design and development inputs
8.3.5d	Added specifying information, not just characteristics
8.4.3d	Added customers and relevant interested parties
9.1.2 Note	Added social media as a source of information
9.1.3 e, f	Separated risks and opportunities
9.2.2a	Added audit objectives
9.3.2	Clarified inputs as “shall include”
9.3.2c	Added changes in needs and expectations of interested parties
9.3.2g, h	Separated risks and opportunities
10.1	Combined 10.1 and 10.3

Questions About ISO 9001:2026?

Visit www.thequalitymavenllc.com for additional transition resources and support.