

The 10 Most Impactful Changes in ISO 9001:2015

What Sets the Current Standard Apart from ISO 9001:2008

ISO 9001:2015 remains the current edition of the world's most widely used quality management standard. Whether you are certifying for the first time or modernizing a system originally built under the 2008 edition, these are the ten changes that matter most in day-to-day practice.

1. A New 10-Clause Structure

The standard was completely renumbered from an 8-element structure to a 10-clause structure. You do NOT have to renumber your quality management system, but if it doesn't put too much strain on your resources, renumbering is recommended so your personnel can better relate your system to the standard.

2. Context of the Organization

You must be able to demonstrate that management has a deep understanding of the company's internal and external issues, such as strengths, weaknesses, opportunities, and threats. Organizations are expected to monitor these issues on an ongoing basis, not just document them once.

3. The QMS and Its Processes

Organizations must demonstrate they fully understand their processes, including inputs, outputs, and performance indicators or metrics. Process diagrams (turtle diagrams or process maps) are one effective way of achieving this.

4. Interested Parties

You need to document a general description of your external interested parties. Examples include customers, regulatory authorities, parent corporations, and shareholders.

5. Objective Programs

Instead of only defining an action plan when an objective is missed, you must now have a plan for each objective describing what will be done, what resources will be required, who will be responsible, when it will be completed, and how the results will be evaluated. We commonly refer to this as a documented objective program.

6. Risk-Based Thinking

Organizations must show they are assessing risks and opportunities and taking action to mitigate risk, which can include accepting risk to pursue an opportunity. The results of these activities must be discussed in management review.

7. Management Review

Management review gained several new required inputs, including the performance of external providers, the adequacy of resources, and the effectiveness of actions taken to address risks and opportunities. Action items from management review must also be considered for the continual improvement process.

8. Organizational Knowledge

The new wording lends itself toward a matrix or database showing the organization has determined what knowledge and training its personnel need, and it pushes organizations further toward maintaining job descriptions.

9. Communication

Organizations must determine their requirements for internal and external communication: what to communicate, when to communicate, with whom to communicate, how to communicate, and who communicates.

10. Change Management

There is a stronger emphasis throughout the standard on controlling changes to the QMS, its processes, planning, production, and contracts.

KEEPING CURRENT: AMENDMENT 1:2024

In February 2024, ISO amended ISO 9001:2015 (Amendment 1) to require organizations to determine whether climate change is a relevant issue when evaluating their context (clause 4.1), and to note that interested parties can have climate-related requirements (clause 4.2). If your context and interested-party documentation hasn't been revisited since 2024, add climate change to the review agenda.

Modernizing your quality system?

Let's start with a conversation - no jargon, no pressure. We'll assess your current system against ISO 9001:2015, close the gaps, and get your team certification-ready. Call (844) MY-ISO-PRO or email Sales@MyISOFamily.com.

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