Navigating ISO 9001:2015

Understanding why the new ISO 9001 revision matters to everyone

Abstract
This whitepaper takes a concise, yet detailed look at the ISO 9001:2015 revision. Published in September 2015, the standard includes various changes that impact quality management. This white paper can be used as a primer for organisations looking to implement and certify their quality management system, and is a valuable resource for those already certified but want to know how this revision will affect their current system. The fact that over one million certificates[1] for ISO 9001 have now been issued globally according to the ISO Survey of Management System Standard Certifications is a testament to the success and demand of the standard.
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Introduction

Efficiency and profitability are the most important motivations of every organisation. Regardless of size, industry or geographical location, all businesses are constantly looking to improve their efficiency and maximise their profitability.

ISO 9001 was designed as a standard for organisations looking to optimise their operational excellence. The fact that over one million certificates for ISO 9001 have now been issued globally according to the ISO Survey of Management System Standard Certifications is a testament to the success and demand of the standard.

The ISO 9001 standard is becoming especially important as end customers increasingly demand better value. With a certified system, organisations – regardless of size, industry or location – are able to optimise their operational performance and higher profits while saving time, money and resources. It also enables them to be well positioned to organise resources and processes to achieve corporate goals.

The ISO 9001 standard is becoming especially important as end customers increasingly demand better value.
The origins of ISO 9001

The beginnings of ISO 9001 are rooted in two military standards: the UK Government’s BS 5750 standard, driven by the Ministry of Defence, and the MIL-Q-9858, the US Military manufacturing standard. Both focused on the management of manufacturing processes instead of the manufactured end product.

In 1987, the UK Government urged ISO to adopt the BS 5750 as an international standard. ISO 9001, specifically ISO 9001:1987, was born. Essentially a BS 5750 standard at its core, it introduced three models for a quality management system (QMS). The first concerned quality assurance in design, development, production, installation and service for organisations manufacturing new products; the second model looked at production, installation and service; and the third was concerned about final inspection and testing, regardless of how the product was manufactured.

The evolution of ISO 9001

Since its introduction in 1987, ISO 9001 has undergone numerous revisions. Below is a quick summary of its evolution:

**ISO 9001:1987**

First version introduced after the adoption of BS5750 by ISO. It offered three models for QMS which included variants that covered different types of businesses.

**ISO 9001:1994**

Emphasised product assurance using preventive actions, instead of solely checking the final product. The standard focused on managing quality by control rather than assurance, requiring organisations to comply with documented procedures.

**ISO 9001:2000**

Made a radical change by putting quality and process management at its core, focusing on quality management instead of quality control. The standard first analysed the organisation’s requirements before designing processes to deliver on them. In addition, the standard also looked at how to continuously improve processes and track customer satisfaction.

**ISO 9001:2008**

Clarified the specifications of the 2000 revision, making it more consistent with ISO 14001:2004, the environmental management system standard.

**ISO 9001:2015**

Published in September 2015, this version of the standard adopts the high-level structure and format prescribed in Annex SL, extends the scope to include service industries and incorporates a number of important changes.
The 2015 revision

All ISO standards are reviewed every five years to ensure that they remain relevant to the market environment. ISO 9001:2015 is the final result of a multi-year process involving representatives from ISO member countries and stakeholders from around the world.

The revision process originally began in May 2012 when a proposal to revise the 2008 version of the standard was officially introduced. A Committee Draft (CD) of the revised standard was first published in June 2013, which allowed ISO members of participating countries to form national positions on the draft ISO standard and comment on them.

Based on these comments, the Draft International Standard (called ISO/DIS 9001:2015) was distributed for review and comment in May 2014. More than 3000 comments were received and the suggestions were subsequently approved by 80% of ISO member countries in a preliminary vote.

Work on the Final Draft International Standard (FDIS) incorporating the proposed changes began in November 2014. The FDIS was released for a final vote by ISO member countries in July 2015. The revised version of the standard, ISO 9001:2015, was officially published by the ISO in September 2015.

THE EVOLUTION OF THE ISO 9001 STANDARD

1987 Introduction of first version by ISO
1994 1994 version emphasised managing quality by control
2000 2000 version clarified specifications of the 2000 revision
2008 Focused on quality and process management at its core
November 2014 Final Draft International Standard developed
May 2014 Draft International Standard distributed for review and comment
September 2015 Publication of 2015 version
New ISO 9001:2015 structure

Every ISO management system shares common elements. However, unique implementation difficulties still arise because of the diverse shapes and structures used by the systems.

ISO is addressing these by providing identical structures, texts, common terms and definitions for all future management system standards.

Using similar terms and definitions allows future and revised management system standards to be both consistent and easier to integrate.

ISO 9001:2015 replaces the former structure with a new “high-level structure” (also called Annex SL) that will be the blueprint for all future management system development.

The ISO 14001 and BS OHSAS 18001 standards will also be revised accordingly.

The purpose of this new high-level structure is to align format, text, terms and definitions, while offering the flexibility to integrate technical topics and requirements that are specific to the standard.


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Understanding the changes in the new ISO 9001 standard is important as we cover the following points of interest.

**Coverage extended for service industries** - Overall, the new version of the standard makes it more applicable to service industries. The term "product" is now replaced with "product and services" when referring to deliverables for the customer.

**Getting the context right** - The standard adopts a stakeholder approach to quality management and focuses on Stakeholder Relationship Management (SRM) with the addition of two clauses (4.1 Understanding the organisation and its context and 4.2 Understanding the needs and expectations of interested parties) which relates to the context of the organisation.

These new clauses require organisations to determine the issues and requirements that can impact the planning of the QMS, which are used as inputs when developing the system. Such an approach assumes that long-term business success is possible when stakeholder requirements are considered. Although new to ISO 9001, this approach is not new to ISO. ISO 9004:2009, Section 4.4 addresses this in detail.

Addressing SRM goes much further than Customer Relationship Management (CRM) that previous revisions used. While CRM only addresses the relationship between an organisation and its customers, SRM balances the relationship of the organisation with all stakeholders, including customers, suppliers, partners, authorities, etc. To align with this new requirement, the term "interested parties" now also includes owners, staff belonging to that organisation, bankers and even competitors.

One noteworthy feature of the new standard is that it does not require the products and services to fulfil the needs and expectations of all external parties but only for those interested parties that are relevant to the QMS.
Process approach further defined - ISO 9001:2008 promoted the adoption of a process approach to developing, implementing and improving QMS effectiveness. ISO 9001:2015 does it more explicitly in Section 4.4 Quality Management System and its processes. Now, organisations need to define required inputs and expected outputs of each process. The measurement of performance indicators and the assignment of responsibilities is also required.

Focus on risk - The standard emphasises the adoption of a risk-based approach in various places. This approach requires an understanding of risk assessment, found in Section 4.4 Quality Management System and its processes, leadership issues in Section 5.1.1, a separate sub-clause in Section 6.1.2 Actions to Address Risks and Opportunities, and risk-based approaches, found in Chapter 8.1 Operational Planning and Control and Chapter 9.3 Management Review. While organisations are required to identify and act on these risks, no standardised risk management is required.

In addition, there is no specific clause for specific requirements for preventive measures in the high-level structure or core texts. This is already seen as one of the main purposes of QMS.

Flexibility in documentation - Terms “documents” and “records” are now replaced by “documented information.” This offers flexibility on how processes are described. An organisation is now able to determine the amount of documented information on processes based on factors such as process complexity and employees’ competence. In addition, documented procedures required by the previous version of the standard are no longer mandatory in ISO 9001:2015 and is up to the organisation to decide.

More responsibility on management - The new standard expands what the term “management responsibilities” entails. The focus is on leadership and commitment. In future, top management will take on responsibilities of a Quality Management Representative. The standard also requires organisations to assign roles and responsibilities more precisely.

Extension of management review scope - The scope of management review has expanded with the addition of the aspect “strategic direction of the organisation.” Management now needs to consider the interest of “relevant interested parties” and assess risks at a strategic level.
Organisations already holding ISO 9001 certification are advised to begin the transition to the requirements of the new standard as soon as possible. This will help avoid unnecessary delays in achieving certification.

How you can prepare for the new standard?

Organisations currently certified to the requirements of ISO 9001:2008 will have three years to achieve recertification to the requirements found in ISO 9001:2015. However, the differences between the two versions of the standard are extensive. Therefore, organisations are advised to promptly begin the process of reviewing their current QMS and quality processes and documentation in order to identify required changes.

Once this gap analysis has been completed, organisations can then map out a process and timetable for bringing their existing QMS into compliance with the requirements of the revised standard. Considering the scope of potential changes that may be required, postponing these tasks until the end of the transition period can expose an organisation to unnecessary risk.

For organisations seeking ISO 9001 certification for the first time, it is also advisable to begin the planning and implementation process as early as possible to avoid unexpected delays in achieving certification.

How can TÜV SÜD help you?

TÜV SÜD is an internationally-accredited Certification Body for ISO 9001. With its global presence, it can offer certification servicing and auditor engagement services in many locations around the world.

Based on the numerous revisions in ISO 9001:2015, we recommend that organisations begin upgrading their systems early. TÜV SÜD can conduct a regular re-certification audit to highlight areas affected and suggest amendments to the current QMS of the respective organisation.

Negotiating the technical and social complexities of ISO 9001 certification for a wide range of industries is extremely complex and requires industry expertise. TÜV SÜD has a strong track record in helping organisations from various industries in different geographical locations achieve the new standard.

TÜV SÜD also offers a vast array of other management system standards as well and this is a key reason why many leading organisations make use of TÜV SÜD as their sole provider for certification needs and solutions.
Navigating ISO 9001:2015

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