ISO 9001:2015 – Quality Management System

Demonstrating strategic commitment to continuous improvement

Abstract

ISO 9001 is the world’s most widely adopted quality management system (QMS) standard. It is also the only standard in the 9000 family of standards, published by the International Organization for Standardization (ISO), which can be used for the purpose of conformity assessment.

ISO 9001 also serves as the basis for many other sector-specific standards, including ISO 13485 (medical devices), ISO/TS 16949 (automotive) and AS/EN 9100 (aerospace), as well as widely used management system standards such as OHSAS 18001 and ISO 14001.

To ensure that they remain relevant and reflect the changing needs of the global marketplace, ISO standards are reviewed every five years. Therefore, ISO published a major revision of ISO 9001 on September 15th 2015. This whitepaper outlines the key updates, giving an overview of the various changes that will impact an organization’s quality management approach, as well as the additional organizational benefits it delivers.
As Product Compliance Manager for ISO 9001, Sami Gatz is responsible for assuring that the standard’s requirements are understood and complied with. Prior to joining TÜV SÜD, he worked in various organizations, including NGOs, across diverse industries, covering automotive, elevators, furniture, and insurance. Trained as an auditor, he has conducted management system audits for a broad range of companies, and as a recognised industry expert he has also been actively involved in the creation and establishment of a certification body. His auditing experience with ISO 9001 was complemented by the management of both internal and supplier audits for automotive OEMs. He obtained his work experience while living and studying in different countries, including Germany, Mexico and the USA.
Introduction

ISO 9001 was first introduced in 1987 and is the world’s most popular quality improvement standard, with over one million certified organizations in 180 countries. The origins of ISO 9001 are embedded in the global defense industry’s need for standards that govern quality assurance, and it is based upon two military standards: the UK’s BS 5750 series of standards, driven by the Ministry of Defence; and the MIL-Q-9858, the US Military manufacturing standard.

The first edition of ISO 9001 introduced three QMS models, with several variants of each QMS making an allowance for the working practices of different industry sectors. The first was concerned with quality assurance in design, development, production, installation and service for manufacturing new products. The second model covered production, installation and service, while the third focused on final inspection and testing.

The second edition (ISO 9001:1994) emphasized product assurance using preventive actions, instead of solely checking the final product. Focusing on managing quality by control, rather than assurance, the standard required organizations to comply with documented procedures.

The introduction of ISO 9001:2000 presented a radical change, by placing quality and process management at its core. Focusing on quality management instead of quality control, the standard first analyzed the organization’s requirements before designing processes to deliver them. This third edition also focused on the continuous improvement of processes and the importance of tracking customer satisfaction.

In 2008, updates to ISO 9001 clarified the specifications of the 2000 edition, making it more consistent with ISO 14001:2004, the environmental management system standard.

Why is ISO 9001 important?

To ensure success, businesses must offer products and services that surpass customer expectations, while meeting ongoing competitive pressures to increase efficiency and cut costs. The ISO 9001 QMS was developed as a way for all organizations, regardless of size, industry or location, to take a structured and comprehensive approach to quality management, which resolves the joint challenges of improved quality, increased efficiency and lower costs.

Overview of ISO 9001:2015

A major revision of the ISO 9001 standard was published on September 15, 2015, the final result of a multi-year process involving representatives from ISO member countries and stakeholders from around the world. The new version is now more applicable to service, as well as manufacturing industries, as the term “product” has been replaced with “product and services” throughout the standard.

The main changes since the 2008 fourth edition include:

Revised structure

One of the key changes to the new ISO 9001 standard is the adoption of the High-Level Structure, common to many other standards such as ISO 9001, ISO 14001 and ISO 45001, making it easy to integrate into any existing ISO management system. This means that in the future, ISO member countries and stakeholders, who are responsible for the development of management system standards, will use a consistent structure that shares the same common section headings and core texts.

Risk-based approach

Another major modification to ISO 9001 is the new emphasis on risk-based thinking. This helps you to examine the context of your organization and to choose the most appropriate risk mitigation technique. This systematic approach to risk-based thinking can save significant amounts of management time, and must be embedded within the organization as a continuously evolving process that optimizes knowledge development and preparedness.
A risk-based approach requires an understanding of risk assessment, which can be found in Section 4.4 “Quality Management System and its processes”; as well as the leadership issues outlined in Section 5.1.1; a separate sub-clause in Section 6.1 “Actions to Address Risks and Opportunities”; and risk-based approaches, which can be found in Chapters 8.1 “Operational Planning and Control” and 9.3 “Management Review.”

While organizations are required to identify and act on these risks, there is no statement within the standard which outlines how the risk management should be conducted. In addition, there is no clause containing specific requirements for preventive measures in the High-Level Structure or core texts. This is because it is already considered one of the main purposes of QMS.

**Correct context**

The standard is based on the principle that long-term business success is achieved when relevant stakeholder requirements are considered. It therefore adopts a stakeholder approach to quality management and focuses on Stakeholder Relationship Management (SRM), which goes much further than the Customer Relationship Management (CRM) approach outlined in previous editions of ISO 9001. While the CRM only addresses the relationship between an organization and its customers, SRM balances the relationship of the organization with all relevant stakeholders, including customers, suppliers, partners, owners, employees, authorities, etc.

Two additional clauses therefore include:

- 4.1 Understanding the organization and its context.
- 4.2 Understanding the needs and expectations of interested parties.

These new clauses require organizations to determine the issues and requirements that can impact the planning of the QMS, which are used as inputs when developing the system. Although new to ISO 9001, this approach is addressed in detail in Section 4.4 of ISO 9004:2009.

To align with this new requirement, the term “interested parties” now also includes owners, the organization’s staff, bankers and even competitors. One noteworthy feature of the new edition of ISO 9001 is that it does not require the products and services to fulfil the needs and expectations of all external parties, but only those interested parties that are relevant to the QMS.

**Process definition**

While ISO 9001:2008 adopted a process approach in the
development, implementation and improvement of QMS effectiveness, ISO 9001:2015 does this more explicitly in Section 4.4. Consequently, organizations must now address the risks and opportunities within the QMS processes. The measurement of performance indicators and the assignment of responsibilities of these processes are also required.

**Documentation flexibility**
ISO 9001:2015 replaces the previously used terms “documents” and “records” with “documented information.” This offers greater flexibility on how processes are described, so that an organization is now able to determine the amount of information related to processes that are documented, based on factors such as process complexity and employees’ competence. In addition, documented procedures and management handbooks such as Quality Manual, required by the previous version of the standard, are no longer mandatory and will be at the discretion of the organization.

**Increased responsibility**
The new standard expands what encompasses the term “management responsibilities.” Consequently, leaders at all levels within the organization are now required to demonstrate QMS performance. However, while responsibilities of a Quality Management Representative now rest with top management, they can still be delegated, with the standard simply requiring the more precise assignment of roles and responsibilities.

**Extended scope**
The scope of management review has also been expanded with the addition of the aspect “strategic direction of the organization.” This means that an organization’s management team must now consider the interest of “relevant interested parties” and assess risks at a strategic level.

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**Meeting ISO 9001:2015 requirements**

From 15th September 2015, organizations that are currently certified to ISO 9001:2008 have three years to make the transition to the revised standard. After 15th of September 2018, ISO 9001:2008 certificates will no longer be valid. As the differences between the two versions of the standard are substantial, you are strongly encouraged to begin the process of reviewing your current QMS, quality processes and documentation as soon as possible.

**DELTΔ audits**
If your organization already holds ISO 9001 certification, our DELTΔ audit provides a systematic approach in the transition to the new ISO 9001:2015 standard. Experienced TÜV SÜD auditors analyze your existing QMS to identify any gaps, and the potential need for action, ensuring a smooth path to re-certification.

Advantages of the DELTΔ audit include:
- Supporting a systematic approach in the transition process.
- Avoiding misinterpretations of the new requirements and strengthening the position of employees responsible for the transition within the organization.
- Development of actions needed to adjust your quality management system.
- Faster readiness for certification according to the new standard.
TÜV SÜD identifies six steps in determining a company’s readiness towards achieving ISO 9001 certification.

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<td>Our team can conduct a DELTA Audit to determine if your organization already fulfils ISO 9001 requirements and identify areas for improvement.</td>
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<td>TÜV SÜD auditors verify (Stage 1) the profile submitted during your application and determine your readiness for Stage 2. Stage 1 can be on-site and/or off-site.</td>
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<td>Receive your audit report after the audit and certificate after approval from the certification body with annual surveillance audits conducted thereafter.</td>
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## Working with TÜV SÜD

As an internationally accredited Certification Body for various management systems, TÜV SÜD’s certificates are accepted and recognized globally. Having TÜV SÜD as your certification partner not only allows your company to lean on our experience, but also lends your brand the distinction of the TÜV SÜD certification mark - a powerful demonstration of your commitment to quality management.

TÜV SÜD is accredited by ANAB (U.S.), DAkkS and other European Accreditation Bodies under the European co-operation for Accreditation Multilateral Agreement (EA MLA), and JAS-ANZ (Australia and New Zealand) under the International Accreditation Forum Multilateral Agreement (IAF-MLA) among many others. This ensures that ISO 9001 certification is conducted with the highest degree of professionalism and conformance to international guidelines and standards.

Our international network of subsidiaries on every continent enables us to serve organizations worldwide and certify their compliance to ISO 9001 on a global scale. In addition, our auditors are required to follow a strict code of conduct through Auditor Codex as well as our corporate compliance guidelines that assures both you and your customers of our complete independence and professionalism.
Benefits to your business

While ISO 9001:2015 maintains the benefits inherent from using the previous standard, it also introduces more.

**Increase competitiveness** - ISO 9001:2015 is a globally accepted quality management system, which is applicable to all industries. TÜV SÜD’s certification mark ensures that your systems are reliable and robust, resulting in improved customer satisfaction and lower trade barriers.

**Improve marketability and sales** - significantly improve your bargaining position for public and private procurement tenders.

**Improve efficiency and reduce costs** - the quality management practices inherent in ISO 9001 increase your organizational efficiency, productivity and profitability.

**Minimize risk** - increase your ability to mitigate strategic and operational risks by addressing both risks and opportunities in a structured manner.

**Engage top management** - emphasize leadership engagement through active participation.

**Minimize management time** - the High-Level Structure, simplified language and common terms reduce complexity. ISO 9001:2015’s consistency with other ISO management system standards, makes it particularly easy to implement and maintain, as well as integrate with multiple management systems, such as those for the environment, health & safety, or business continuity.

Conclusion

While accredited certification to ISO 9001 is not a mandatory requirement, organizations can reap many benefits by adopting and implementing the system.

With organizations under increasing scrutiny from stakeholders to optimize business efficiency, ISO 9001 certification demonstrates a strategic commitment to continuous improvement. Certification may also significantly minimize costs, improve staff morale and boost brand reputation.

Third-party certification, where an independent certification body audits your practices against the requirements of the standard, gives a strong signal to your buyers, customers, suppliers and other stakeholders that you have implemented the standard accurately. It also helps organizations to demonstrate that their system complies with regulatory and contractual requirements.
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GLOSSARY OF ACRONYMS

- CRM – customer relationship management
- QMS – quality management system
- SRM – stakeholder relationship management

FOOTNOTES

¹ http://www.iso.org/iso/iso-survey

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