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ISO 9001:2015 Revision Factsheet

A quick guide to the new
ISO 9001:2015 standard

What is ISO 9001?

The ISO 9001 Quality Management System is the world's most popular quality improvement standard, with over one million certified organisations in 180 countries around the globe. It is the only standard in the 9000 family of standards published by the International Organization for Standardization (ISO) that can be used for the purpose of conformity assessment. ISO 9001 also serves as the basis for many other important sector-specific standards, as well as widely used management system standards such as OHSAS 18001 and ISO 14001.

ISO 9001 revision

The International Organization for Standardization (ISO) published a major revision of the ISO 9001 standard in September 2015. The last revision dates back to 2008 and introduced only a small number of new requirements. By contrast, the new version, characterised by its focus on risk-based thinking and its process approach, has given rise to high expectations.

New structure

One new feature is the "High Level Structure (HLS)". The new version is structured in accordance with the requirement of the ISO Directive, Annex SL 2013. In the future, the parties developing management system standards will use a consistent structure and outline, identical core texts and common terms and core definitions. This is to ensure that all sections of management system standards (for example, ISO 20121:2012 "Event sustainability management systems") share the same section headings and core texts. The ISO 9001 and 14001 standards already use this HLS.

Further standards (such as ISO 45001 which will replace BS OHSAS 18001) will follow in the future.

This ISO 9001:2015 follows the new structure and comprises ten sections:

STRUCTURE COMPARISON	
ISO 9001:2015	ISO 9001:2008
1. Scope	1. Scope
2. Normative references	2. Normative references
3. Terms and definitions	3. Terms and definitions
4. Context of the organisation	4. Quality management system
5. Leadership	5. Management responsibility
6. Planning	6. Resource management
7. Support	7. Product realisation
8. Operation	8. Measurement, analysis and improvement
9. Performance evaluation	
10. Improvement	

Summary of the key changes

ISO 9001:2015 is designed to make the standard more generic and more easily applicable by service industries. Therefore, the term “product” has been replaced by “products and services” when specifically referring to the deliverables for the customer.

Context of the organisation

The high-level structure and the core text established in Annex SL, Appendix 2, have introduced two new clauses related to the context of the organisation:

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

These two clauses require the organisation to determine the issues and requirements that can impact the planning of the quality management system (QMS) and can be used as input for the development of the QMS.

The stakeholder approach, considered one of the most modern corporate governance principles, is new. This approach is based on the assumption that long-term business success can only be ensured by considering the requirements of company stakeholders.

The approach has been described for many years in ISO 9004:2009, Section 4.4 “Interested parties, needs and expectations”, and has been introduced in the draft standard. In comparison to “Customer Relationship Management” (CRM), which only addresses the relationship between an organisation and its customers, the principle of Stakeholder Relationship Management (SRM) goes significantly further. It tries to balance the relationship of the organisation with all, or with the most important, stakeholders/interested parties. These could include direct consumers, suppliers and retailers and other parties along the supply chain, authorities and other relevant interested parties. As a new feature, the term “interested parties” now also includes owners, people in an organisation, bankers and even competitors.

Although ISO 9001:2015 now points out that organisations must determine the requirements of the relevant interested parties, there is no new requirement to ensure goods and services meet the needs and expectations of these parties (with the exception of customers and authorities). Such a requirement would necessitate a change to the scope of the standard that is not permitted by the design specification for the final draft.

Process approach

The ISO 9001:2008 standard promoted the adoption of a process approach when developing, implementing and improving QMS effectiveness. The new standard does so even more explicitly in Section 4.4 Quality management system and its processes. This sub-chapter lists the essential requirements of a process-focused management approach. Inputs and outputs of each process must be defined. In the future, the standard will require the measurement of performance indicators and the assignment of responsibilities.



Risk and preventive actions

The high-level structure and core texts specified in Annex SL, Appendix 2, does not include a clause stating specific requirements for “preventive action”. The reason is because acting as a “preventive tool” is one of the key purposes of a formal management system. The emphasis on a risk-based approach is referenced in many places in the draft standard, from risk assessment in sub-clause 4.4 “Quality management system and its processes”, leadership issues in sub-clause 5.1.1 and a separate sub-clause in Section 6.1.2 “Actions to address risks and opportunities” to risk-based approaches in “Operational planning and control” (clause 8.1) and “Management review” (clause 9.3). While ISO 9001:2015 demands that risks are identified and acted upon, there is no requirement for standardised risk management.

Documented information

The term “documented information” replaces the previous terms “document” and “record”. The intention was to give users more flexibility. This also applies to process descriptions. The organisation determines the extent of documented information on processes, depending on factors such as process complexity or employee competence. Documented procedures previously required by the standard are no longer necessary.

Management responsibility

ISO 9001:2015 increases “management responsibilities”. The responsibilities of a Quality Management Representative now rest with top management but can still be delegated.

Management review

The scope of the management review is extended by the addition of the aspects “strategic direction of the organisation”, consideration of the “relevant interested parties” and “assessment of risks and opportunities” at a strategic level.

How can you prepare?

Users of management systems should familiarise themselves with the changes, align their QM systems accordingly and have their QM systems certified within three years of the publication of ISO 9001:2015 in September 2015.

How can we help you?

TÜV SÜD recommends that organisations upgrade their systems to the new standard at an early stage within the scope of a regular re-certification audit. We also offer gap analysis to identify the differences between the old and the new standard within the scope of a Delta audit. For more information, please visit www.tuev-sued.de/ms/delta-audit.



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- ISO/TS 16949 – Quality management system certification for automotive
- OHSAS 18001 – Occupational health and safety management system certification
- IRIS – International Railway Industry Standard (IRIS) certification
- ISO/IEC 27001 – Information security management system certification
- ISO/IEC 20000-1 – IT service management system certification