ISO 9001:2015 Revision

Understanding Changes and Preparing for Transition

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ISO 9001:2015 Revision

The new ISO 9001:2015 standard is expected to be published in September. Companies across the world are anticipating the upcoming changes and wondering how the revision will affect their business. TÜV Rheinland has summarized the most significant changes in order to assist companies preparing for the transition.

ISO 9001 At a Glance

More than 1 million companies around the world are certified according to the ISO 9001 standard. Germany alone boasts more than 55,000 certifications. Since its introduction in 1987, the certification has grown in popularity and continuously evolved in order to address business needs. Every year, new industries adopt ISO 9001 as the standard for their suppliers. Today, it is applied in the health and social work sectors as well as the chemical, electrical and machinery industries.

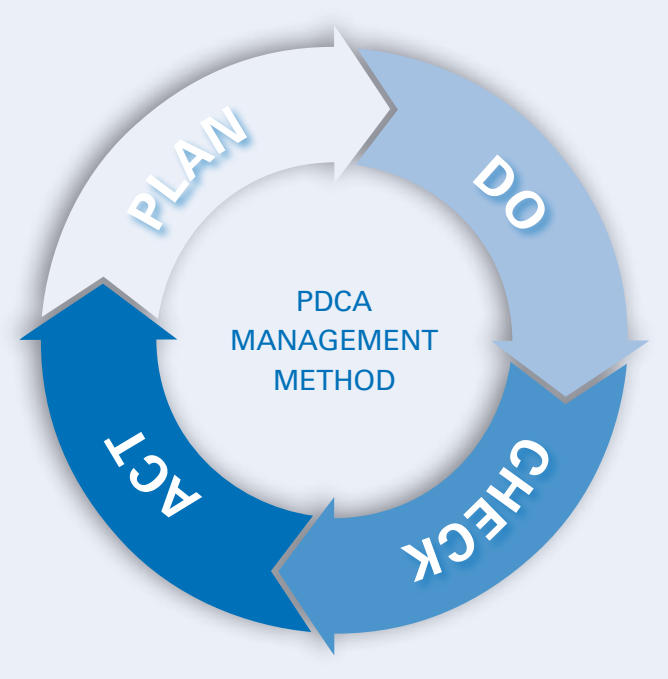
ISO 9001 regulates requirements for quality management systems. The standard requires a control circuit providing on-going further development in terms of a continuous improvement process.

Particularly focused on process orientation, the ISO 9001 standard takes a process-oriented approach to demonstrate potential for improvement in all businesses, even those who are currently healthy and successful.

In order to continue the push to continually improve quality management, the standard has once again been revised.

PDCA Ensures Constant Improvement

The ISO 9001 standard is built on the operating principle of all ISO management standards known as the Plan-Do-Check-Act (PDCA) approach. It works as follows:



Plan:
Analysis of the business environment and customer needs and their influence on the organization. Define company targets, objectives and processes to meet customer expectations.

Do:
Implementation of management and quality action plans and collection of data for analysis in subsequent steps.

Check:
Monitoring and measuring processes and actual results for comparison with expected results and targets.

Act:
Improving quality and customer satisfaction by responding to previously collected information.

Benefits of an ISO 9001 Certification

TÜV Rheinland certification of your quality management system in accordance with ISO 9001 will:

- Improve market access opportunities and gain a competitive advantage.
- Increase organizational efficiency.
- Reduce errors and complaints.
- Generate trust with your customers.
- Increase customer orientation.
- Achieve significant cost savings.
- Improve processes and structures.
- Motivate employees with better communication and readily available information.

Why ISO 9001 Is Changing

ISO standards are reviewed every five years by the standards committee responsible for their relevance, suitability and effectiveness. At a review in 2012, the majority of ISO committee members decided that the current ISO 9001 standard for quality management needed revision. The new version, expected to come out in September 2015, will replace the 2008 standard.

Objectives of the ISO 9001 Revision

The new ISO 9001:2015 is designed to:

- Provide a stable requirements framework for the next ten years.
- Address recent changes in technology, quality management practice and the increasingly complex and dynamic work environment in order to improve practical relevance.
- Be sufficiently generic, yet remain relevant to all types and sizes of organizations, regardless of their industry or sector.
- Maintain the present focus on an effective process management.
- Apply the "high level structure" (uniform structure, core texts and definitions) to ensure structural compatibility with other management standards, such as the environmental management standard ISO 14001 and the energy management standard ISO 50001.
- Simplify implementation and the conformity assessment.
- Simplify phrasing to ensure common understanding and consistent interpretation of the requirements.

WD0	WD1	CD	DIS	FDIS	Publication
June 2012	**December 2012**	**June 2013**	**May 2014**	**May 2015**	**September 2015**
Initial draft of specifications and Working Document (WDO)	Approved specifications and Working Draft (WD1)	Committee Draft for comments and agreement (CD)	Draft international standard for agreement (DIS)	Final draft international standard for agreement (FDIS)	Publication of the new ISO 9001 version

ISO 9001 Revision Timeline

Following the 2012 decision to revise the ISO 9001 standard, the first draft for the requirements and a working document (WD0) emerged in June of the same year. Six months later, the working draft (WD1) with approved specifications was released. The committee draft (CD) followed in June 2013 and the draft of the international harmonization standard (DIS) came out one year later.

With some delay, the proposal for the final draft of the ISO 9001 revision (FDIS) is expected to be ready for harmonization in May 2015. The new version of the ISO 9001 standard for quality management systems is expected to be published in September 2015.

What Are the Significant Proposed Changes?

The revised ISO 9001:2015 will affect content as well as structure as illustrated by the changes listed below:

Process-oriented Approach:
The naming of input, output and process owners is explicitly required.

Manual:
No formal requirement for a manual; the content requirements remain.

Quality Management Representatives:
Functional requirements exist but are not dependent upon position within the company. The "member of management" requirement no longer exists.

Implementation of Quality Goals:
When planning the achievement of quality goals, the organization must determine who is responsible, when procedures should be completed and how results should be evaluated.

Dealing with Risks:
Organizations must identify risks which could affect the achievement of product and process goals. The company must plan actions to counter these risks and evaluate the effectiveness of those actions.

Communication:
The organization must determine what, when, with whom and how information shall be shared and communicated.

Development:
If detailed requirements by customers and interested parties are not suitably defined for the subsequent production or delivery of services, the organization shall establish a development process.

Outsourcing:
"Externally provided goods" are now treated the same as "externally provided services".

Concentration on Risk Management

The standard defines "risk" as the uncertain outcome of an expected result.

Essentially, the new version calls for more risk awareness. Businesses should recognize and evaluate potential risks. After identifying, assessing and prioritizing each risk, a company may decide to accept the risk, avoid it or develop appropriate actions to minimize its impact.

Upgrade to High Level Structure

The essential change affecting the ISO 9001 structure is its following of the so-called “high level” structure designed to promote common definition and uniformed structure among certified management systems as well as assign core texts and terminology in order to make standards easier to understand and streamline combined certification.

ISO 9001:2008		ISO 9001:2015	
1 Scope	Introduction	1 Scope	Introduction
2 Normative Reference		2 Normative Reference	
3 Terms and Definitions		3 Terms and Definitions	
4 Quality Management System	Plan	4 Context of the Organization	Plan
5 Management Responsibility		5 Leadership	
6 Resource Management		6 Planning	
		7 Support	
7 Product Realization	Do	8 Operation	Do
8 Measurement, Analysis and Improvement	Check, Act	9 Performance Evaluation	Check
		10 Improvement	Act

Paving the Way for Combined Certifications

A cross-industry standard, ISO 9001 is suitable for the certification of quality management systems in any company. ISO 9001 audits can be easily combined with industry-specific audits related to quality management and other management systems.
Standards with which ISO 9001 certification is commonly combined include the ISO/TS 16949 quality standard for the automotive industry, the EMAS and ISO 14001 standards for environmental management, the ISO 50001 standard for energy management and others. Educational and vocational institutions might wish to combine ISO 9001 certification with an AZAV certification. And learning service providers with ISO 29990 certified quality management can also benefit from an ISO 9001 certification.

What Does the Transition Period Look Like?

For certificates and audits subject to accreditation, the following transition arrangements apply:

- A three-year transition period is granted from the publication of ISO 9001:2015. After those three years, all previous accredited certificates will be invalid.
- Certificates may be issued only after an audit conducted by an accredited certification body.
- It is to be expected that more time will be needed for those audits held in conjunction with supervision or recertification.

What Certified Companies Can Do in Preparation for ISO 9001:2015

Certified companies wishing to prepare for the new version of ISO 9001 can:

- Identify gaps for the new standard. Use the standard as the basis of a checklist and check what needs to be done to meet that standard.
- Develop an implementation plan.
- Ensure adequate training and awareness among all parties influencing how your company performs.
- Promptly inform all participants in the quality management process about the ISO 9001 revision and the changes and impacts arising from it.
- Update your current quality management system to meet the additional or modified requirements and ensure that system performance is verified.

How TÜV Rheinland Can Help

TÜV Rheinland provides you with professional quality management training courses to ensure the continuous maintenance of your quality management system. Furthermore, our GAP analysis will help you prepare for a smooth transition to ISO 9001:2015.

GAP analysis

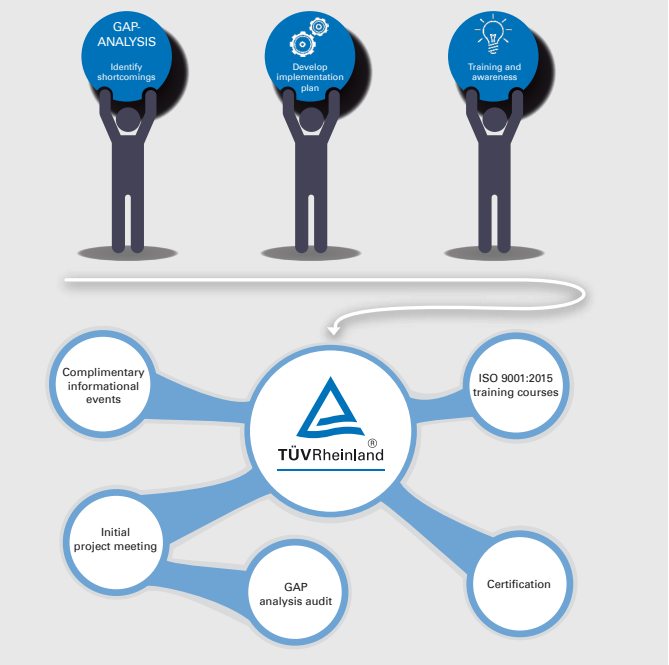
The International Accreditation Forum (IAF) recommends a GAP analysis of your existing quality management system as the first step in a successful transition to the new ISO 9001 standard. The analysis will help you confirm that procedures already implemented are in compliance with the new ISO 9001:2015 standard, and it will also help pinpoint systems, processes and documentation in need of improvement.

Our expert auditor will examine your company, ask questions about various fields your company is active in and gain a first impression of how closely (or not) your management system meets the basic requirements of DIN EN ISO 9001:2015. In conclusion, the results of the expert GAP analysis will be presented and discussed with you.

Training

TÜV Rheinland offers various training opportunities such as praxis dialoges, webinares and training seminars to improve your skills and competences in quality management and prepare you for the ISO 9001:2015.

Further information:
www.tuv.com/Praxisdialog-Qualitaetsmanagement
and www.tuv.com/qm-training



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