Revision of the DIN EN ISO 9001:2015 – Changes and Their Impact

Since 2012, the international quality management standard ISO 9001 has been under revision. The update, which would replace the current version from 2008, is expected to be published at the end of 2015. As quality management according to ISO 9001 is an issue of relevance for companies of all sizes across the world and across all industries, companies are bound to have questions about the standard. What changes are coming? What do I need to consider?

What changes are on the horizon?

With the publication of ISO/DIS 9001, changes are emerging in terms of the revision of ISO 9001. With the revision, the scope of the standard will not change, but some particular, formal changes in the standard can be expected. An essential change will, however, affect the structure of ISO 9001. Additionally, the revision will follow the so-called "high-level" structure.

This is intended to bring about an identical definition and structure for all management systems as well as the uniform use of core texts and terms. Having a uniform structure as the basis of certification for management systems will improve the comprehensibility of standards and make combined certification more efficient.

The new ISO 9001 is expected to be more focused on the customer and „interested parties". Nowadays, companies often find themselves in a complex, dynamic environment which presents new challenges. This change is also taken into account by ISO 9001:2015, with such topics as risk management, change management and knowledge management playing an important role. On the basis of ISO/DIS 9001 published in May 2014, the process-oriented approach is maintained within the standard and includes „risk-based thinking". Furthermore, there will be a guide to the ISO 9001:2015 which is announced as ISO/NP TS 9002 in 2015 together with the ISO 9001.

Objectives of the new ISO 9001:2015

- Provide a stable framework of requirements for the next ten years.
- Be sufficiently generic, yet still relevant to all types and sizes of organizations, regardless of their industry or sector.
- Maintain the present focus on effective process management in order to achieve the desired results.
- Take into account changes to QM practice and technology since the last major revision in 2000.
- Reflect changes in the increasingly complex and dynamic working environment in which organizations operate.
- Apply the uniform structure, core texts and definitions (high-level structure) laid down in Annex SL of the ISO directives in order to ensure compatibility and adjustment with other ISO management systems (e.g. ISO 14001).
- Simplify effective implementation in organizations and effective compliance reviews.
- Use simple phrasing to ensure common understanding and consistent interpretation of the requirements.

www.tuv.com/iso-9001-2015

TÜVRheinland®
Precisely Right.

Draft and transition period

The first, official draft of ISO/DIS 9001:2015 was published in mid-May 2014 with a final draft of the standard expected by the end of 2014. According to publication on the ISO website, the transition period should be three years. This means that for most certified companies, the transfer can be planned for the time of the re-certification audit.

The ten clauses of ISO 9001:2015

1. Scope
2. Normative references
3. Terms and definitions
4. Environment of the organization
5. Management
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

Examples of requirements (based on ISO/DIS 9001, published 05/2014)

- Process-oriented approach: The naming of input, output and process owners is explicitly required. (Pt. 4.4.)
- Manual: No formal requirement for a manual; the content requirements remain. (Pts. 4.4 & 7.5)
- Quality management representatives: Functional requirements exist but not regarding their position within the company. The requirement „member of management" does not exist. (Pt. 5.3)
- Implementation of quality goals: When planning the achievement of quality goals, the organization must determine who is responsible, when the procedure should be completed and how the results should be evaluated. (Chap. 6.2)

- Dealing with risks: Organizations must identify risks which could affect the achievement of product and process goals. The company must plan measures to counter these risks and evaluate their effectiveness. (Chap. 6.1)
- Communication: The organization must determine on what, when, with whom and how it shall be communicated. (Chap. 7.4)
- Development: If detailed requirements by customers and interested parties are not defined in a way to be suitable for the subsequent production or delivery of services, the organization shall establish a development process. (Chap. 8.3.1)
- Outsourcing: "Externally provided goods" are now treated the same as "externally provided services". (Chap. 8.4)

Our recommendation to certified companies

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 that influence how your company performs.
- Inform all the participants in the quality management process of the ISO 9001 revision.
- Update your current quality management system to meet the new requirements and to ensure that the performance of the system is verified.

Timeline of the ISO 9001 revision

June 2012	Dec. 2012	April 2013 *(actual: June 2013)*	March 2014 *(actual: May 2014)*	November 2014	May 2015	September 2015
Initial draft of specifications and working document (WDO)	Approved specifications and working draft (WD1)	Committee draft for comment and agreement (CD)	Draft international standard for agreement (DIS)	Proposal for the final draft	Final draft international standard for agreement (FDIS)	Publication

TÜVRheinland®
Precisely Right.