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

The international quality management standard ISO 9001, under revision since 2012, was published in September 2015 and replaces the 2008 version. Quality management according to ISO 9001 is an issue of relevance for companies of all sizes across the world and across all industries, and therefore companies are bound to have questions about the standard. What changes are coming? What do I need to consider?

What changes does the new standard bring with it?
With the revision, the scope of the standard does not change; it will continue to apply to all companies. One substantial change affects the structure of ISO 9001. The revision follows the so-called "high-level" structure.

This guarantees 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 improves standards comprehension and facilitates the implementation and certification of integrated management systems (i.e. the integration of quality and environment).

In addition to the customer, the new ISO 9001 takes into account other "interested parties" as well. Nowadays, companies often find themselves in a complex, dynamic environment which presents new challenges. This change is also reflected in ISO 9001:2015, with such topics as risk management, change management and knowledge management playing an important role. The process-oriented approach is maintained and "risk-based thinking" is required. Furthermore, there is a guide to ISO 9001:2015 which will be published as ISO/TS 9002.

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 conformity 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.

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Transition period for ISO 9001

The first official draft of ISO/DIS 9001:2015 was published in mid-May 2014 and the final draft (ISO/FDIS 9001) in July 2015. The standard was then published in September 2015. The transition period will last three years. This means that for most certified companies the rescheduling of the re-certification audit can be planned.

The ten sections of ISO 9001:2015

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

Examples of requirements

- Identification of internal and external topics (pt. 4.1.)
- Understanding expectations and needs of interested parties. (pt. 4.2)
- Process-oriented approach: explicit naming of input, output and those responsible for processes is required.(pt. 4.4)
- Handbook: no formal requests for a handbook; requests with regard to content remain unchanged. (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 about what, when, with whom and how communication should take place. (Chap. 7.4)
- Development: a development process must be introduced that is capable of ensuring the availability of products and services. (Chap. 8.3.1)
- Outsourcing: "Externally provided goods" are now treated the same as "externally provided services." (Chap. 8.4)

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