Revision of EN ISO 9001: 2015 – Changes and Effects

In September 2015 ISO published ISO 9001:2015 which replaced the older 2008 edition. The purpose of this change was to adopt greater commonality between management system standards, which includes a common risk based approach, as well as ensuring the standards relevancy to companies of all sizes and in all industries. Therefore, some companies may have questions regarding the standard. What changes have been made? What do I have to consider?

WHAT DOES THE STANDARD CHANGE?

The scope of the standard remains unchanged and should continue to apply to all companies. A major change affects the structure of ISO 9001. The revision follows the so-called High Level Structure.

This is intended to ensure an identical definition and structure for all management systems as well as an uniform use of core texts and terms. This uniform structure, as a basis for certification for management systems, helps to understand the standard and facilitates the establishment and certification of integrated management systems (e.g. integration of quality and environment).

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GOALS OF THE NEW ISO 9001:2015

- Provide a stable framework for requirements for the next 10 years.
- Be sufficiently generic – but still relevant to all organizational variables and types, regardless of industry or sector.
- Maintain the current focus on effective process management to achieve the desired results.
- Current changes in QM practice and technology since the last major revision in 2000.
- Changes in the increasingly complex and dynamic work environment in which organizations operate.

- Use the uniform structure, text modules and definitions („High Level Structure") prescribed in Appendix SL of the ISO Directives to ensure compatibility and adaptation with other ISO management systems (such as ISO 14001).
- Effective implementation in organizations and effective compliance assessments.
- Simplifying the formulations to ensure the same understanding and consistent interpretation of requirements.

In addition to customers, the new ISO 9001 also covers other „interested parties". Today, companies are often in a complex, dynamic environment that presents them with new challenges. This change also takes into account ISO 9001:2015. Topics such as risk management, change management and knowledge management play an important role here. The process-oriented approach is maintained and „risk-based thinking" is called for. Furthermore, there is a guide to ISO 9001:2015, which was published as ISO/TS 9002.
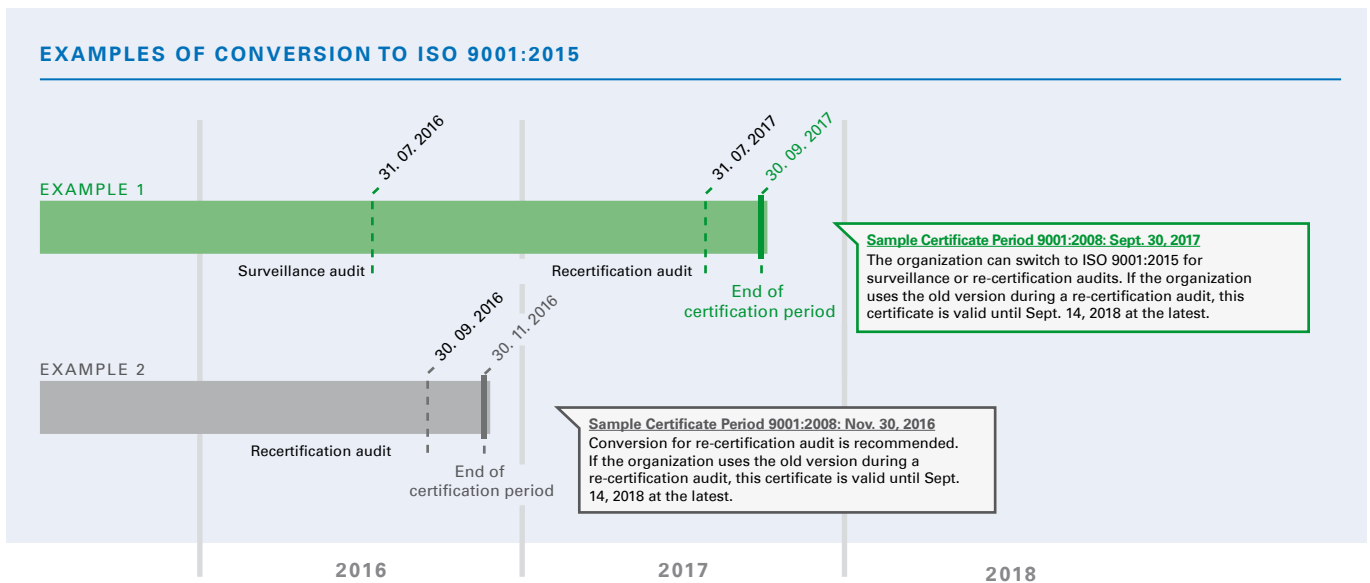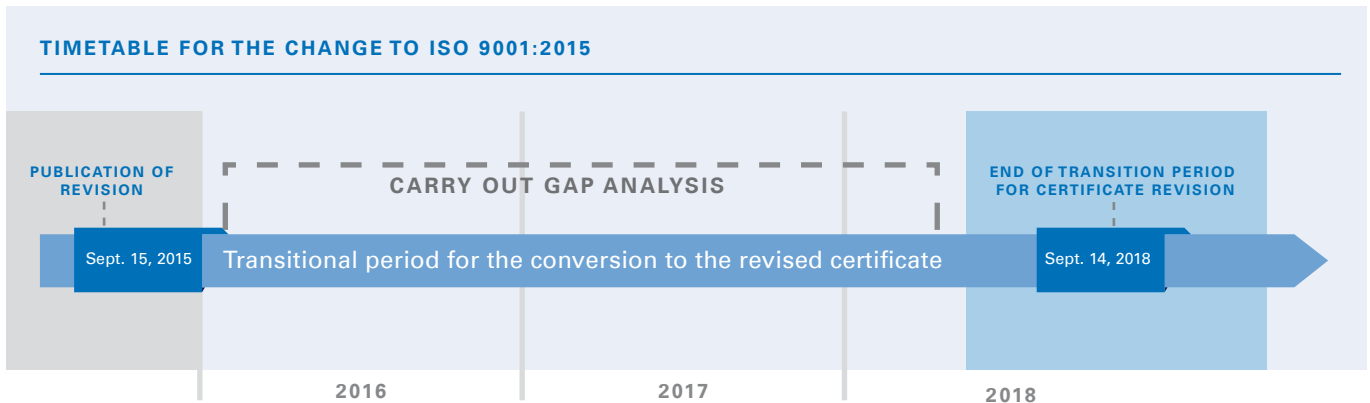
THE TEN CLAUSES OF ISO 9001:2015

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

TRANSITION PERIOD FOR ISO 9001

The first official draft of ISO 9001:2015 (ISO/DIS 9001) was published in mid-May 2014 and the final draft (ISO/FDIS 9001) was published in July 2015. The standard was issued in September 2015. The transition period is 3 years. Depending on the duration of the certificate, different procedures are possible to switch to the new standard. The following figure shows, by means of two examples, when a good time for the changeover is for companies. We recommend that you carry out a GAP analysis in order to be optimally prepared for the conversion.

TIMETABLE FOR THE CHANGE TO ISO 9001:2015

PUBLICATION OF REVISION

CARRY OUT GAP ANALYSIS

END OF TRANSITION PERIOD FOR CERTIFICATE REVISION

Sept. 15, 2015 Transitional period for the conversion to the revised certificate Sept. 14, 2018

2016 2017 2018

EXAMPLES OF CONVERSION TO ISO 9001:2015

EXAMPLE 1

31. 07. 2016 31. 07. 2017 30. 09. 2017

Surveillance audit Recertification audit End of certification period

Sample Certificate Period 9001:2008: Sept. 30, 2017
The organization can switch to ISO 9001:2015 for surveillance or re-certification audits. If the organization uses the old version during a re-certification audit, this certificate is valid until Sept. 14, 2018 at the latest.

EXAMPLE 2

30. 09. 2016 30. 11. 2016

Recertification audit End of certification period

Sample Certificate Period 9001:2008: Nov. 30, 2016
Conversion for re-certification audit is recommended. If the organization uses the old version during a re-certification audit, this certificate is valid until Sept. 14, 2018 at the latest.

2016 2017 2018

EXAMPLES OF REQUIREMENTS

- Determination of internal and external topics (Point 4.1)
- Understanding of the expectations and needs of interested parties (Point 4.2)
- Process-oriented approach: The designation of input, output and process managers is explicitly required. (Point 4.4)
- Manual: No formal requirement for a manual. The content requirements remain the same. (Point 4.4; Point 7.5)
- QMO: Functional requirements, but no requirements regarding the position within the company. The requirement to be a „member of the management" does not exist. (Point 5.3)
- Implementation of quality objectives: In planning this, the organization must determine, among other things, when the action should be completed and how the results should be assessed. (Chap. 6.2)
- Dealing with risks: Organizations must identify risks that may affect the attainment of product and process objectives. The company must plan measures to mitigate these risks and assess their effectiveness. (Chap. 6.1)
- Communication: The organization must determine who should communicate with whom, through what channel, how, and when. (Chap. 7.4)
- Development: A development process must be introduced to ensure the provision of products and services. (Chap. 8.3.1)
- Outsourcing: Equal treatment of „external provided goods" and „external provided services". (Chap. 8.4)

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