Questions and Answers about the Revision of ISO 9001

Our experts have answered the most frequently asked questions about the ISO 9001 Revision. Would you like to learn more? Get in touch with our experts!

1. HOW TO TRANSITION FROM THE FORMER VERSION OF ISO 9001 TO THE NEW VERSION?
For certificates and audits under accreditation, the following transitional arrangements and deadlines apply:

- A transitional period of three years was granted after the publication of ISO 9001:2015 (September 15, 2015). After September 14, 2018, all accredited certificates according to ISO 9001:2008 will become invalid.
- Certificates may only be issued after an audit and after the accreditation of the certifier.
- Audits in conjunction with monitoring or recertification are expected to require additional time.
2. HOW CAN A COMPANY THAT IS ALREADY CERTIFIED OPTIMALLY PREPARE ITSELF FOR ISO 9001:2015?
Companies certified according to the new version of ISO 9001 can take the following measures:

- Identify gaps in the new standard. Use the standard as a checklist and check requirements for their fulfillment. We would like to support you as a first step towards the secure conversion to the new ISO 9001:2015 with a GAP analysis.
- Develop an implementation plan.
- Ensure proper training and awareness of all parties that influence the performance of your organization.
- Inform all parties involved in the quality management process in time for the conversion to the new ISO 9001:2015 and the resulting changes and effects.
- Update your current quality management system to meet the additional or changed requirements and verify the performance of the system.

3. IS THERE AN IMPLEMENTATION GUIDE?
Currently, there is an ISO/TS 9002 English-language guide for the implementation of ISO 9001:2015. The guide from the International Organization for Standardization (ISO) provides examples that are intended to illustrate the application of the new ISO 9001.

4. WHAT GOALS DOES THE ISO 9001 REVISION PURSUE?
The revision of ISO 9001 aims at adapting itself better to the dynamic, complex market conditions in which many companies are moving today, with content enhancements and structural changes. The ISO 9001 Revision also has the following goals:

- Creation of a stable requirement framework for the next ten years.
- Consideration of changes in quality management practice, technology and the increasingly complex and dynamic work environment for more practical proximity.
- Pursue a generic approach on the condition that relevance is given to all company sizes and types of organization, regardless of industry or sector.
- Focus on effective process management.
- Implementation of the „High Level Structure“ (uniform structure, text blocks and definitions). This ensures structural compatibility with other management standards such as ISO 14001 for environmental management or ISO 50001 for energy management.
- Simplify the implementation in organizations and the conformity assessment.
- Simplification of the formulations to ensure the same understanding and consistent interpretation of requirements.

5. WHY ARE MANAGEMENT REPRESENTATIVES (MR) NOT MENTIONED IN THE NEW VERSION?
The quality management system is a tool for the executive management to implement concepts and ideas. It is a clear management tool and the responsibility for it remains with management. The new version of ISO 9001 reflects this approach even more strongly than before. However, the tasks and duties of the MR remain and must be fulfilled. In this respect, the MR can continue to be entrusted with tasks so that the project „Quality Management“ can be advanced and improved by a central office in the company.

6. IS THE QM MANUAL IN THE NEW VERSION ACTUALLY OMITTED?
Many companies that use a QM system according to ISO 9001 have already provided their manual electronically in the form of various documents. You can keep this as long as this is, for you, purposive and properly documented in this form. For companies that start with the new ISO 9001:2015, it is recommended to follow the new version. That is, the manual as such is not required, but the content is. It is only optional as to how a company collects and consolidates these documents or not. Again, it is sensible to deal with the documents in such a way that it is appropriate for the respective company.

7. WHAT DOES RISK AND RISK MANAGEMENT MEAN ACCORDING TO ISO 9001:2015?
The standard defines „risk“ as the effect of uncertainty on an expected outcome. Basically, the new version requires more risk awareness. Companies should identify and assess possible risks. Once the company identifies, evaluates and prioritizes risks, it can decide, for example, whether the risk is tolerated or avoided or whether appropriate measures should be developed to minimize the impact of this risk.

8. WHAT DOES IT MEAN TO VIEW RISK MANAGEMENT QUALITATIVELY?
Companies have an average of 15 to 25 processes represented in the process map. The standard does not specify the number of risks a company must have per process or total. An auditor who examines these processes in terms of risk management would ask questions such as: Where are risks in the respective processes? Can you name the identified risks? On what basis did you identify these risks? How do you assess the probability of these risks? How do you deal with these risks? If the answers are plausible and corresponding documentation is provided, this requirement of the standard is fulfilled.
9. HOW CAN A GAP ANALYSIS HELP WITH THE NEW ISO 9001:2015?

GAP analysis for ISO 9001:2015
The International Accreditation Forum (IAF) recommends a GAP analysis as a first step towards the conversion to the new ISO 9001 standard. With a GAP analysis of your existing quality management system, you are taking the first step towards the successful conversion to ISO 9001:2015.

The analysis helps you to confirm the conformity of already implemented procedures as well as to recognize systems, processes and documentations that need improvement.

In the form of an audit, we will examine your company. On the basis of questions from various fields of action, a first impression is gained about the extent to which your management system meets the essential requirements of ISO 9001:2015. We will provide you with the results of the GAP analysis in a final discussion.

OUR EXPERTS WILL BE HAPPY WITH ANY FURTHER QUESTIONS. PLEASE GET IN TOUCH WITH US!

ONLINE CONTACT