FAQs – Revision of the ISO 9001

Quality Management – Revision of the ISO 9001 Standard

What you should know about the new version of ISO 9001.

1. Why is the Management Representative no longer mentioned in the new version?

The Quality Management System is a tool utilized by top management to implement concepts and ideas. It is a clear management tool and its responsibility remains with the management, and the new version of ISO 9001 reflects this approach even more than before. The tasks and activities of Management Representatives, however, continue to exist and must be fulfilled. In this respect, the QMA can continue to be entrusted with the tasks so that the „quality management“ project can be promoted and improved from a central location within the company.

2. Does the QM manual in the new version really disappear?

Many companies that use a QM system in accordance with ISO 9001 have already presented their manual electronically in the form of various documents. They can retain this as long as it is suitable and properly documented in this form. For companies that are just starting with the new version, it is recommended to follow the new version. In other words, the manual as such is not required, but the content is. Whether a company stores these documents combined or not is at their discretion. It is simply useful to handle the documents in a manner that is most suitable for that respective company.

3. What is the timeline for companies that already have an accredited certification but would like to be certified according to the new version?

After publication of the new ISO 9001:2015 version in September 2015, according to the current status, companies have a three-year transition period to become audited and certified according to the new version. Afterwards, all accredited certificates according to the old version are no longer valid.

4. After which version – ISO 9001:2008 or ISO 9001:2015 – should companies become certified or have to recertify in 2015?

We recommend companies whose recertification was due until September 2015, to perform the audit based on the current version, ISO 9001:2008. In subsequent control audits or repeat audits, a certification according to ISO 9001:2015 can then be targeted.

5. What can companies, which are certified according to ISO 9001:2008, currently do?

They can identify the differences with the new ISO 9001:2015 standard, for example, in the form of a gap analysis. On this basis, an implementation plan can be developed to gradually convert the system to the requirements of the new standard. It is also important to ensure appropriate training and awareness among all parties that have influence on the performance of the organization. TÜV Rheinland can support you by performing a gap analysis audit.

Risk Management in the Revision of the ISO 9001 Standard

What you should know about risk management.

6. What is understood by risk and risk management in ISO 9001:2015?

The standard defines „risk“ as the outcome of uncertainty on an expected result. Essentially, the new version calls for more risk awareness. Companies should identify and evaluate potential risks. After a company has identified, assessed and prioritized risks, it may decide, for example, to accept the risk, avoid it or develop appropriate measures to minimize its impact.

7. Does the standard determine how and by what method businesses should proceed in the area of risk assessment?

No, the standard does not specify which methods can be applied for risk analysis and assessment. Companies are free to choose an appropriate method.

8. What methods exist to control risk management?

A common method for risk management is FMEA (Failure Mode and Effects Analysis). Based on this method, processes can be analyzed and evaluated with regard to possible risks. For production / service delivery and their processes, methods are often already in use in companies, such as HACCP in the food industry. For all other processes, such as management processes, FMEA provides suitable possibilities. However, other methods and tools such as an Ishikawa diagram, the “5 Why‘s” or brainstorming are imaginable.

9. Is it ok to use aTurtle diagram for the presentation of risk?

As the standard does not specify the form of presentation, a turtle diagram is also possible. The Turtle Diagram is suitable for the representation and analysis of processes. The individual processes with their various influencing factors can be mapped on the basis of the Turtle diagram, and possible risk factors can be derived on the basis of this.

10. Is there a specific number of risks that a company must list?

No. Risks that can occur are endless, but companies should ask themselves what risks are likely and severe. The aim of the ISO 9001 standard is to make companies aware of the risks, to evaluate and prioritize them and develop appropriate policies. For example, water shortages in Germany compared to some southern European areas does not play a significant role. In some areas of southern Europe, this risk is much higher and companies whose production processes are dependent on water, must consider the risk of a drought and its associated water shortages and make decisions on possible measures, for example pre-production, building a water reservoir, etc.

11. What does it mean to consider risk management in terms of quality?

Companies illustrate an average of 15 to 25 processes in the process map. The standard does not specify how much risk a company must list per process or in total. An auditor who reviews these processes in terms of risk management would ask questions such as: Where are the risks in the respective process? State the identified risks for me? On what basis have you identified these risks? How do you assess the probability of occurrence of these risks? How do you handle these risks? If the answers are plausible and are verified with corresponding documents, the requirement of the standard is met.

**not legally binding (status: September 2015)*