



□ Release of ISO 9001:2015

Since ISO 9001:2015 has been published on 1 November 2015, both basic standards of the ISO 9000 family

- ISO 9000 covering the basic concepts and language of quality management systems and
- ISO 9001 setting out the requirements of a quality management system

became a single EN ISO standard. In the run-up to the publication, we have already learned about various new contents, especially new requirements of a quality management system. We are familiar with at least some keywords describing the following topics:

- Context of the organization
- How to address risks and opportunities
- Role of management representative for quality management systems disappeared
- Quality manual no longer mandatory
- Knowledge as a resource

It is also known that the new standard keeps the process-oriented approach of a quality management system – an approach which has been favoured since 2000. However, it has been extended and tightened beyond doubt by adding issues such as “performance indicators to measure the effectiveness of processes“ and “how to address risks and opportunities“.

What most of us are not acquainted with are the many little changes in the ISO 9001 structure of requirements; they only become apparent in a detailed analysis of the text. As the following examples show (list is not intended to be exhaustive), you will immediately start considering how to translate these small changes into and implement them in an available quality management system.

1

The topic of “control of measuring and monitoring devices“ (1994/2000) now becomes “monitoring and measuring resources“ (2015) dedicating an entire subsection to “measurement traceability“ for measuring equipment. Since the activity of “controlling“ has a precise meaning now, you have to analyse and assess the fitness for purpose of measuring and technical equipment observing and monitoring the process.

2

There are four text passages demanding controlled and documented operations to address changes in the quality management system, products, contract requirements and in the processes producing a product or providing a service.

3

ISO 9001:2015 finally includes the long overdue demand to determine and control requirements for a development process.

4

It is important to establish specific requirements for contingency actions together with the customer immediately after order completion or while preparing a contract. These requirements are part of the communication with customers.

5

A note recommends the application of statistical techniques in order to meet the numerous requirements to evaluate process results, verify products and to use available data for performance and effectiveness evaluation of the quality management system.

6

Parts of the standard are hard to read and difficult to understand because ISO changed some terms. Even though ISO explains why they changed them, these reasons are barely comprehensible. All attempts to search for terms such as “customer-related processes” (now: determination of requirements), “purchasing process” (now: products and services from external providers) and “production and service provision” (now: operation) are in vain, even though this terminology was quite common and daily routine. Most of us were even familiar with “documents and records” but ISO 9001:2015 combines these two categories and expresses them as documented information. At least, it seems like it. However, it is logical that the new ISO standard distinguishes between documents and records when it comes to the verbs “maintaining” and “retaining”.



TEQ® Training & Consulting GmbH
Eisleber Str. 2
69469 Weinheim
+ 49 6201 3941-15

Interested in this topic?
www.teq.de
Contact the author
gunter.effenberger@teq.de