

# BERND JANSON PROZESSMANAGEMENT

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## ISO 9001:2015 - Frequently Asked Questions

ISO 9001, the world's leading quality management standard, is under revision, with an updated version due by the end of 2015.



ISO 9001:2015 - Release process; source: www.iso.org

### ■ WHY IS ISO 9001 BEING REVISED?

All ISO standards are reviewed every 5 years to update the standard to relevant technical changes and to keep it current and relevant for the marketplace. The future ISO 9001:2015 will respond to the latest trends and be compatible with other management systems such as ISO 14001.

ISO 9001:2008	ISO 9001:2015
<ol style="list-style-type: none"> <li>1. Scope</li> <li>2. Normative Reference</li> <li>3. Terms and Definitions</li> <li>4. Quality Management System</li> <li>5. Management Responsibility</li> <li>6. Resource Management</li> <li>7. Product Realization</li> <li>8. Measurement, Analysis &amp; Improvement</li> </ol>	<ol style="list-style-type: none"> <li>1. Scope</li> <li>2. Normative reference</li> <li>3. Terms and definitions</li> <li>4. Context of the organisation</li> <li>5. Leadership</li> <li>6. Planning</li> <li>7. Support</li> <li>8. Operation</li> <li>9. Performance evaluation</li> <li>10. Improvement</li> </ol>

Comparison between ISO 9001:2008 and ISO 9001:2015. Changes in red

Weitere Informationen finden Sie unter: [www.bernd-janson-prozessmanagement.de](http://www.bernd-janson-prozessmanagement.de)

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## ■ HIGH LEVEL STRUCTURE

The new version of ISO 9001:2015 will follow a new, High-Level Structure to make it easier to use in conjunction with other management system standards (f.e. ISO 14001). The main advantage of the ISO9001:2015 version is that the structure of the Standard follows the processes within organisations. This means that the Standard is easier to use. The Standard has a new structure. All clauses from Clause 4 to Clause 10, with the exception of justified concessions, must be covered.

## ■ NEW REQUIREMENTS

- requirements for risk-based thinking
- documented information
- the context of an organisation
- handling of outsourced processes
- stronger emphasis on management responsibility and commitment
- quality controlling and other requirements

## ■ RESULT ORIENTATION

The main focus of ISO9001:2015 is on results. The most important thing is not where something is described, but if the process is effective.

## ■ CONTEXT OF THE ORGANIZATION

A new requirement in ISO 9001:2015 is the Context of the organization. The organization must consider both the internal and external issues that can impact its strategic objectives and the planning of the QMS. This issues can be government regulations and changes in the law, trading partners, economic shifts in the organization's market, the organization's competition, events that may affect corporate image or changes in technology.

## ■ RISC BASED APPROACH

New in ISO9001:2015 is the requirement of risc-based management in each level of operation between customer and quality system.

## ■ MORE PROCESSMANAGEMENT ORIENTATION

ISO9001:2015 extend the process orientation: The process owner must be clearly assigned. The organisation has to define performance indicators for control of the processes and has to evaluate how this performance indicators relate to the control of these processes.

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## ■ SERVICE PROVIDER AND OUTSOURCED PROCESSES INCLUDED

ISO 9001:2015 can be used across all sectors. In particular, service providers are now explicitly mentioned and it is therefore easier for them to implement the new standard. Organisations whose business is based on a large number of outsourced processes will also find that handling of outsourced processes is now included in the standard. When outsourced processes are present, the interfaces and the monitoring of these processes have to be described and evidenced by means of key indicators

## ■ INDIVIDUAL DOCUMENTATION PROCESS

A further major advantage in the 2015 version is the reduced requirement for documented procedures. This means that the organisation can develop its own individually documented QM system.

### *WHY IS THERE NO LONGER A QUALITY MANUAL?*

*System documentation continues to be required. The standard requires documented information, which also has to be controlled. However, because strict documentation of a certain kind is no longer required, the documentation can be more individually designed and adapted to the sequences and processes in the organisation. The new requirements offer greater freedom for implementation, and the opportunity to define processes more clearly.*

### *NO MORE QUALITY MANAGEMENT REPRESENTATIVE?*

*It is true that the term "Management Representative" no longer exists as such. However, the responsibility of the management is generally increased. In addition, clear responsibility regarding processes is required.*

## ■ WHEN WILL THE NEW STANDARD APPEAR?

September 2015

## ■ TRANSITION PERIOD FOR ISO 9001:2008.

Organisations are granted a three-year transition period after the revision has been published to migrate their quality management system to the new edition of the standard.

**BERND JANSON PROZESSMANAGEMENT  
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