



Revision of the Quality Management System ISO 9001:2015

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The revised ISO 9001 offers more flexibility regarding process documentation as a part of the management system. This applies to the documentation of management, strategy and core processes as well as support processes such as maintenance and qualification of persons. For example, for very simple processes, clear verbal instructions in conjunction with training material may be sufficient. However, traceable documentation in forms such as a checklist or an electronic workflow will generally be required to provide guidance for various work steps.

To safeguard a high level of process quality, the new ISO 9001 includes an ambitious definition of the expected degree of process maturity. The relevant quality characteristics should be available and effective to ensure that organisations implement the standard successfully and realise the benefits offered by the new standard.

With reference to *Panel 1*, eight steps are involved:

1. Organisations define the inputs required and the outputs expected from their processes.
2. The sequence and interactions of these processes can be expressed in a form such as a process map or individual process sheets.
3. The organisation also reviews the responsibilities and those who authorise these processes, using tools such as responsibility matrices.
4. Once this is completed, organisations are expected to identify the technological and human resources needed. Here, the important aspects in this context include personnel and investment planning to respond appropriately to cases such as evident fluctuations or planned market expansion.
5. Here, the focus is on risk-based thinking. To this end, organisations verify that they have identified all risks relevant for the key processes. Beyond

Panel 1: The degree of process maturity required according to ISO 9001:2015

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PDCA-cycle



Requirements / criteria

Possibilities for documentation in practice

1 Improvement of the process + QMS	CIP workshop, process analysis, internal audit
2 Monitoring and measurement	ERP system, SPC, Process-KPI's
3 Effective operation + control	Workflow system, ERP system, instructions
4 Risks + opportunities	Process sheet, risk matrix, turtle diagram
5 Availability + resources	Personnel planning / staffing, investment planning
6 Responsibilities + authorities	Workflow system, ERP system, responsibility matrix
7 Inputs + outputs	Workflow, ERP system, documented procedures
8 Sequence + interactions	Process map, workflow, ERP system

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the financial risks already analysed by many companies, there are other risks including the availability of expertise among knowledge owners and specialists, or market risks caused by innovative competitors.

A quality management system according to the new ISO standard identifies these risks in direct association with the processes established by an organisation. While the old ISO 9001 focused predominantly on the avoidance of risks through appropriate preventive actions, the revised version also considers chances.

To identify these chances, the detail-oriented process focus should be expanded to view the whole picture, particularly including customers' expectations and the context of the organisation.

6. Effective process operation and control are ensured. This requires organisations to have either clear instructions for simple tasks in the service sector or process-integrated solutions, e.g. an ERP (Enterprise-Resource-Planning) system for complex production operations. Depending on the complexity involved,

this step requires fast feedback or control loops and adequate communication.

7. The processes are evaluated with the help of appropriate monitoring and measurement methods. These are required in cases in which technical or personnel risks or instabilities were identified and, in particular, in cases involving risks related to customer requirements. Checking at an early stage for possible signs of non-conformities with the target is recommended. After all, a high level of accuracy in measurement results is of little use if the results are available too late.
8. The data gained from process evaluation enables management to make a robust decision regarding the necessary improvement actions. As outlined above, the process approach of the new ISO 9001 ensures a high level of transparency and thus supports organisations in the targeted triggering and driving of the improvement process. ●

Further information can be found at www.tuev-sued.de/management-systemeliso-9001.