



## Swiss Association for Quality and Management Systems

### SQS position paper of ISO 9001:2008

The changes of the ISO 9001:2008 do not contain new requirements. There are specifications and clarifications in the text of the new standard. The following statements are an overview of these changes in keywords. The official publication of ISO 9001:2008 was published in November 2008.

#### **Principles**

- Process approach unchanged
- 8 management principles unchanged
- No major changes

#### **Main modifications**

- Outsourcing process defined
- Training to achieve competence
- Work environment includes physical and environmental factors
- Process measurement focussed to effectiveness

#### **Certification process after release official version**

- New certificates at next re-certification audit
- New certificates at first certification audit
- New certificates at annual audit at request

#### **4.1 General requirement outsourcing**

- Type and nature of control to the outsourced processes shall ensure the conformity to requirement
- Outsourcing has to be a well managed part of the QMS

#### **5.5.2 Management representative**

- Top management shall appoint a member of the organization's management.
- Outsourcing of the Management representative not conform!

### **6.2.2 Competence, training and awareness**

- Provide training to achieve the necessary competence
  - Ensure that the necessary competence has been achieved
- From product quality to competence

### **6.4 Work environment**

- „Work environment“ includes physical, environmental and other factors
- Broader scope and not limited to product quality only

### **7.2.1 Determination of requirements related to the product**

- Note: Post-delivery activities (e.g. maintenance services) are included
- Product requirements include post-delivery activities

### **7.3.1 Design and development planning**

- Note: Design and development review, verification and validation have distinct purposes
- clarification

### **7.3.3 Design and development outputs**

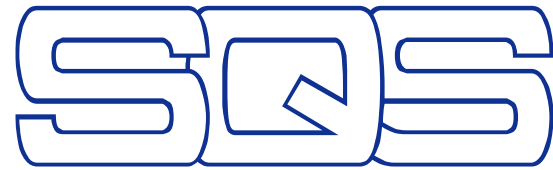
- Note: Information for production and service provision include preservation of product
- clarification

### **7.5.4 Customer property**

- Note: Customer property can include intellectual property and personal data
- Intellectual property and personal data as useful part of customer property

### **8.2.3 Monitoring and measurement of process**

- Note: Monitoring and measurement of process in relation to their impact on the conformity (product) and effectiveness (QMS)
- Focus changed from product conformity to the impact on the conformity and effectiveness



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