

ISO 9001:2008

ASQ

February 10, 2009





Summary of Changes

- No new requirements
- Clarification of existing “shalls”



Section 4.1

- Notes added:
- #2: An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.




Section 4.1

- Notes added:
- #3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conforming to all customer , statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as:




Section 4.1 General QMS Requirements

- #3 continued:
 - The potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements;
 - The degree to which the control for the process is shared;
 - The capability of achieving the necessary control through the application of 7.4 (purchasing).



Section 4.2 Documentation Requirements

- Note 1: ...A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document



Section 5.5.2 Mgmt Rep

- Management rep as a member of the organization's management (i.e. can be a contracted person as long as that person is considered a part of management).



Section 6.2.1 HR General

- Changes “product quality” to “conformity of product requirements”.
- Added note: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.



Section 7.3.1 D&D Planning

- Added note: Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination as suitable for the product and the organization.



Section 7.6 Control of M&M Equipment

- Changed the word from devices back to equipment



8.2.3 M&M of Processes

- When planned results are not achieved, correction and corrective action shall be taken, as appropriate. (Removed the wording “to ensure conformity of product.”)



8.3 Control of Non-conforming Product

- Word-smithing to aid service industries.



General

- Changed “statutory” to “statutory and regulatory” to assist those organizations to comply with ISO 14001 and/or OHSAS 18001.



AS 9100C

- Section 3 Terms and Definitions
 - Risk
 - Special Requirements
 - Critical Items
 - Key Characteristics (revised)



AS 9100C

- Section 4 Requirements

- 4.1 the organization's qms shall also address customer and applicable statutory and regulatory qms requirements
- 4.2.1 combined c & d
- 4.2.4 removed requirement for customers and suppliers to have access to records



AS 9100C


- 4.3 Configuration Management has been moved to 7.1.3.



AS 9100

■ Section 5

- Product conformity and on-time delivery must be measured
- Management Rep has organizational freedom “and unrestricted access” to top management to resolve quality issues.



AS 9100

- Section 6
 - No changes



AS 9100C

- Section 7.1
 - Revised quality objectives and requirements for the product
 - 7.1.1 Project Management
 - 7.1.2 Risk management
 - 7.1.3 Configuration management
 - 7.1.4 Work transfer (Note: was 7.5.1.4)



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- 7.2.2 Special requirements of the product are determined.



AS 9100C

- 7.3 Design

- 7.3.1 Clarifications

- 7.3.3 Critical items, data requirements

- 7.3.5 Verification Simplified

- 7.3.6 Design verification and validation

- Clarification language

- 7.3.7 Changes



AS 9100C

■ 7.4 Purchasing

- 7.4.1 Using data from outside sources to qualify suppliers; also risk management
- 7.4.2 Clarifying language including the need for revision control with suppliers
- 7.4.3 Clarifying notes including the need to validate test results done by the supplier



AS 9100C

- 7.5.1 Definitions
- 8.2.1 defines some data to be used for customer satisfaction
- 4.3 Configuration Management has been moved to 7.1.3