

Transitioning to ISO 9001:2008

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Topics

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Reason for the Amendment

- **ISO Review process:**
 - Requires continual review to keep standards up to date. Must be initiated within 5 years of publication of the standard.
- **User inputs:**
 - Global user questionnaire/survey
 - Market Justification Study
 - Suggestions arising from the interpretation process
 - Opportunities for increased compatibility with ISO 14001
- **Current trends:**
 - Keeping up with recent developments in management system practices.

Scope of Amendment

- An ISO definition does not exist for “amendment.”
- Criteria established to focus amendment on high benefit/low impact changes.
- Provide greater clarity and ease of use.
- Incorporate improvements to address the interpretations and clarifications requested through the official interpretations process.
- Improve compatibility with ISO 14001:2004.

High Benefit

- Addresses a widely expressed specific user need by improving clarity.
- Corrects an error in the standard.
- Eliminates inconsistencies within the ISO 9000 family.
- Eliminates major problems of translation.

Low Impact

- No increased or reduced requirement.
- No change in intent of requirement.
- No need for additional education or training for users.
- Only need for minimal or marginal changes to an organization’s documentation.

User Feedback on Amendment

- Users wanted minimal change
- Balance minimal change with needed changes to eliminate the need for interpretations.
- Several changes accomplished this without changing requirements in the standard.

ISO 9000 Quality Management Systems- Fundamentals and Vocabulary

- Many comments submitted to clarify requirements are associated with defined terms.
 - Measuring Equipment
 - Verification
 - Validation
- Editing team determined ISO 9000:2005 adequately defined terms.
 - ISO 9000 is doing its job - users need to remember it.

Notes

- 1.1 Explains that statutory and regulatory requirements can be expressed as legal requirements.
- 4.1 Explains what type of controls are to be applied to Outsourcing.
- 6.2.1 Explains that conformity to product requirements may be affected directly or indirectly.
- 6.4 Provides examples of work environment.
- 7.2.1 Provides examples of post-delivery activities.
- 7.3.1 Explains that review, verification, and validation can be conducted at the same time.
- 7.3.3 Explains preservation of product is to be considered an output.
- 7.6 Explains what confirmation of software means.
- 8.2.1 Explains what monitoring of customer perception can include.
- 8.2.3 Note to clarify relationship with 8.2.4.



Actual Changes in ISO
9001:2008

Statutory and Regulatory

Introduction

0.1 General

- This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, [statutory and](#) regulatory requirements [applicable to the product](#), and the organization's own requirements.

Scope

1.1 General

- Needs to demonstrate its ability to consistently provide product that meets customer and applicable [statutory and](#) regulatory requirements, and
- [NOTE 2 Statutory and regulatory requirements may be expressed as legal requirements](#)

1.2 Application

- Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such

CONSISTENCY

- Consistency with “statutory and regulatory” which is existing text in clause 7.2.1.
- Clarified with a note and explanation of statutory and regulatory requirements.

“Devices” to “Equipment”

7.5.1 Production and Service Provision

- d) the availability and use of monitoring and measuring ~~devices~~ [equipment](#)

7.6 Control of monitoring and measuring ~~devices~~ [equipment](#)

- The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring ~~devices~~ [equipment](#) needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

CONSISTENCY/CLARIFICATION

- “Devices” has been changed to “equipment” throughout the standard.
- “Equipment” is defined in ISO 9000:2005 to include devices.
- Eliminates the need for the word “device” to be defined.

4.1 General Requirements

The organization shall

- a) Identify determine the processes needed for the quality management system and their application throughout the organization (see 1.2),
- e) monitor, measure (where applicable) and analyse these processes, and

Where an organization chooses to outsource any process that affects product conformity with to requirements, the organization shall ensure control over such processes. ~~Control of such~~ The type and extent of control to be applied to these outsourced processes shall be defined ~~identified~~ within the quality management system.

CLARIFICATION/CONSISTENCY

- Clarify with the note “the processes needed.”
- Explain outsourced processes without adding a definition to ISO 9000.
- Clarify that monitoring and measuring may not be applicable in all cases.
- The use of the phrase “type and extent of control” improves consistency within 9001 - clause 7.4.

4.1 General Requirements (cont.)

NOTE 1 Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement, analysis and improvement.

NOTE 2 An outsourced process is identified as one being needed for the organization's quality management system but chosen to be performed by a party external to the organization.

NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process may be influenced by factors such as:

- 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 clause 7.4.

CONSISTENCY/CLARIFICATION

- Revised notes only to provide additional information.
- Consistency with the name of Clause 8.0.
- Leveraged information in guidance document on Outsourced Processes.
- Clarify what is meant by the type and extent of control.

5.5.2 Management Representative

- Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes...

CLARIFICATION/INTERPRETATION

- **The Management Representative shall be a person of the organization's management.**
- **Organizations have the option of using a consultant or subcontractor as long as that person is a member of management.**

6.2 Human Resources

6.2.1 General

Personnel performing work affecting product quality conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

Note: Conformity to product requirements may be affected directly or indirectly by personnel performing any task within the quality management system.

CLARIFICATION

- Clarify that conformity to product requirements may be affected directly or indirectly.
- This is no change, but could be perceived as a new requirement by organizations who have had a minimal approach to implementation on this requirement.

8.2.3 Monitoring and Measuring of Processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, ~~to ensure conformity of the product.~~

NOTE When determining suitable methods, the organization should consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

CLARIFICATION

- Differentiate between this clause and 8.2.4 Monitoring and Measuring of Product.
- Clarify the confusion around the phrase “to ensure conformity of the product.”
- Note was added to retain the link to product without focusing it as a requirement.

8.3 Control of Nonconforming Product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the The controls and related responsibilities and authorities for dealing with nonconforming product ~~shall be defined in a documented procedure.~~

Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) by taking action to preclude its original intended use or application;
- d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to requirements.

~~When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.~~

CLARIFICATION/CONSISTENCY

- **Restructure clause for consistency within the standard.**
- **“As Applicable” was added to improve application of this clause for all types of organizations.**

8.5.2 Corrective Action

The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

- f) reviewing effectiveness of the corrective action taken.

CLARIFICATION

- **Nonconformities can have more than one cause.**
- **Clarify that not only should corrective actions be reviewed, but that review needs to consider the effectiveness of the actions taken.**

8.5.3 Preventive Action

8.5.3 Preventive Action

- f) reviewing effectiveness of the preventive action taken.

CLARIFICATION

- Clarify that not only should preventive actions be reviewed, but that review needs to consider the effectiveness of the actions taken.

Certification Audit/ Transition Timeline

- Certification to ISO 9001:2008 will only be issued after publication of ISO 9001:2008 and after a routine surveillance audit or re-certification audit against ISO 9001:2008.
- The transition can be planned with the certification extension audit to eliminate the need for updated certificates.
- The registrars will then use the ISO 9001:2008 Standard to conduct their surveillance audits.
- **One year** after publication of ISO 9001:2008, all certifications issued (new certifications and re-certifications) must be to ISO 9001:2008.
- **Two years** after publication of ISO 9001:2008, existing ISO 9001:2000 certifications will not be valid.
- ISO 9001:2000 and ISO 9001:2008 will be considered equal in the marketplace during the transition time.

Conclusion

Impact to Your Organization

- The impact of this amendment may vary based on the maturity of an organization's quality management system.
- Intent of the Amendment:
 - No increased or reduced requirements;
 - No change in intent of requirements;
 - No impact on most users;
 - No need for additional education or training for users;
 - Only need for minimal or marginal changes to an organization's documentation.

Become knowledgeable and proactively manage the change within your organization and with your registrar.

For further information:

- QMS Solutions, LLC website www.qmssolutions.com
- ISO website www.iso.org
- ASQ Standards Group website standardsgroup.asq.org/about/overview.html
- ASQ Quality Press website www.asq.org/quality-press
- ISO Liaison Member websites
- ISO/TC176/SC2 website www.iso.org/tc176/sc2
- ISO Management Systems magazine
- ISO Press Releases

Questions?

Credit for this presentation is given to Ms. Lori Hunt, a member of the U.S. Technical Advisory Group to ISO Technical Committee 176. Ms. Hunt was the International Deputy Task Group Leader for the amendment of ISO 9001:2000 to ISO 9001:2008