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ISO 9001:2008



An Orientation into the latest modifications

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Amendment Not Revision

- Emphasizes no MAJOR changes to ISO 9001
 - No new requirements
- No formal ISO distinction between a “revision” and an “amendment”
- Amendment Focus is on:
 - Changes that improve clarity
 - Translatability
 - Ease of use
 - Consistency with the ISO 9000 Family
 - Compatibility with ISO 14001:2004

Rationale For Revision



- ISO Review process:
 - Requires continual review to keep standards up to date.
 - At least every 5 years.
- User inputs:
 - User questionnaire
 - Suggestions arising from the interpretation process.
 - Opportunities for increased compatibility with ISO 14001
- Current trends:
 - Keeping up with recent developments in management system practices.

Key Inputs for the Amendment

- ISO/TC 176 approved interpretations (33)
 - See www.tc176.org/ for details
- The ISO 9001:2000 Introduction & Support Package set of documents.
- Systematic Reviews conducted on ISO 9001:2000 and ISO 9004:2000
- Web based User Feedback Survey conducted by ISO/TC 176/SC2
- ISO 14001:2004

Impacts and benefits



- Amendment to ISO 9001 focuses **ONLY** on high benefit / low impact cases.

Main changes



- Clause 0.1 (General)
 - Introduces concept of organization's business environment and associated risks.
 - Inclusion of statutory requirements

Main Changes

- Clause 0.2 (Process Approach)
 - More emphasis on output from processes
 - Emphasis on the concept of “output matters”

(<http://www.anab.org/HTMLFiles/docs/HeadUp/HU61.pdf>)

Main Changes

- Clause 1.1 (Scope)
 - Clarification that “product” also includes intermediate product
 - Explanation regarding statutory, regulatory and legal requirements –
Added a new note (Note 2)

Main changes

- Clause 4.1 (General requirements)
 - Recognition that it might not always be possible to measure processes (clause 4.1 e), - addition of “*measure, where applicable*”
 - Notes added to explain more about outsourcing, based on the ISO 9001:2000 Guidance Documents.
 - Types of control that may be applied
 - Relationship to clause 7.4 (Purchasing)
 - Clarification that outsourced processes are still responsibility of the organization and must be included in the QMS

Main changes



- Clause 4.1 (General requirements)
 - 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

Main changes



- Clause 4.1 (General requirements)
 - Note 3: The type and nature 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 produce product that conforms to requirements

Main changes



- Clause 4.1 (General requirements)
 - The extent to which the control of the process is shared
 - The capability of achieving the necessary control through the application of clause 4.1
 - Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory, and regulatory requirements

Main changes



- Clause 4.2.1 (Documentation)
 - Clarification that QMS documentation also includes records
 - Documents required by the standard may be combined
 - ISO 9001 requirements may be covered by more than one documented procedure
 - Organization decides on which documents / records are necessary

Main changes

- Clause 4.2.3 (Document Control)
 - Clarification that only external documents relevant to the QMS need to be controlled – Organization decides on the required external documents that are necessary for effective planning and operation of its quality management system.

Main changes



- Clause 4.2.4 (Records Control)
 - Editorial changes only
(better alignment with ISO 14001)
- Clause 5.5.2 (Management Rep)
 - Clarifies that this must be a member of the organization's own management

Main changes



- Clause 6.2.1 (Human resources)
 - Clarification that competence requirements are relevant for any personnel who are involved in the operation of the quality management system
 - Added Note: Conformity to product requirements may be affected directly or indirectly by personnel performing any task within the quality management system.

Main changes



- Clause 6.2.2 (Competence, training and awareness)
 - Clause title changed for better alignment with ISO 14001
 - Clause 6.2.2 (c) changed to read *“The organization shall... ensure that the necessary competence has been achieved”*

Main Changes

- Clause 6.3 (Infrastructure)
 - Includes information systems as example
- Clause 6.4 (Work environment)
 - Clarifies through a note that work environment includes conditions under which work is performed and includes, for example physical, environmental and other factors such as noise, temperature, humidity, lighting, or weather.

Main changes



- Clause 7.2.1 (Customer related processes)
 - Clarifies through a note that post-delivery activities may include:
 - actions under warranty provisions
 - contractual obligations such as maintenance services
 - supplementary services such as recycling or final disposal

Main changes



- Clause 7.3.1 (Design & development planning)
 - Clarifies through a note that design and development review, verification and validation have distinct purposes.
 - These may be conducted and recorded separately or in any combination as suitable for the product and the organization

Main Changes

- Clause 7.3.2 (Design & development inputs)
 - Clarifies by changing the word “these” to “the list of inputs” are not limited to the items a-d.
- Clause 7.3.3 (Design & development outputs)
 - Clarifies that information needed for production and service provision includes preservation of the product.

Main changes



- Clause 7.5.4 (Customer property)
 - Explains that both intellectual property and personal data should be considered as customer property

Main changes



- Clause 7.6 (Re-titled Control of Monitoring and Measuring *Equipment*)
 - New explanatory note added:
 - “Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.”

Main changes



- Clause 8.2.1 (Customer Satisfaction)
 - Note added to explain that monitoring of customer perception may include input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, dealer reports

Main Changes

- Clause 8.2.2 (Internal audit)
 - The standard now requires the area being audited to ensure that “any necessary corrections and corrective actions” are taken without undue delay.....

Main changes



- Clause 8.2.3 (Monitoring / Measurement of process)
 - Note added to clarify that when deciding on appropriate methods, the organization should consider impact on the conformity to product requirements and on the effectiveness of the quality management system.

Transition to ISO 9001:2008

- Basic premises:
 - Review the standard to check if clarified requirements necessitate changes by your organization
 - For companies that had correctly understood ISO 9001:2000 requirements, there should be no changes needed
 - No additional audits required
 - “Co-existence” period for ISO 9001:2000 and ISO 9001:2008. Both will have same “prestige”.

Transition to ISO 9001:2008 - Timeline

- No ISO 9001:2008 Certifications until formal publication
 - Now slated for November 2008
- Co-use for 12 months (either certificate may be issued)
 - Tentatively ends November 2009
 - Thereafter no new ISO 9001:2000 certifications
- All ISO 9001:2000 certifications must transition to “:2008” within 24 months
 - Tentatively November 2010.

Summary

- No increased or reduced requirements
- No change in intent of requirements
- Use of notes to clarify text
- No impact on most users
- No need for additional training for users
- Only need for minimal changes to an organization's documentation

Credits/References

- International Organization for Standardization (ISO), Geneva, Switzerland
- Technical Advisory Group (TAG) 176 to ISO
- American Society For Quality (ASQ)
- American National Accreditation Board (ANAB)
- QP (formerly Quality Progress), published by ASQ, October 2008
- ABS Quality Evaluations, Nigel Croft
 - Presentation, January 2008

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