

ISO 9001:2008 updates

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History

- ISO 9001:2008 is the fourth edition of the standard which was first published in 1987. (1987, 1994, 2000 and 2008)
- The draft of new International Standard was approved at the 19-23 May 2008 meeting of ISO technical committee ISO/TC 176, *Quality management and quality assurance*,
- It was adopted by American Society for Quality in Nov. 15, 2008

History

- ISO's rules for the development of standards require their periodic review to decide if they need revising, maintaining or withdrawing

History

- The new revision does not introduce additional requirements compared to the last edition in 2000 and does not change the intent of ISO 9001:2000
- Compared to the 2000 revision, ISO 9001:2008 represents fine-tuning, rather than a thorough overhaul.
- It introduces clarifications to the requirements existing in ISO 9001:2000

Deadline

- 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.

4. Quality management system

- 4.1 General requirements

Added two new notes (2 and 3) for:

- Outsourced process
- Control over outsourced process,

Note 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.

Note3- Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer , statutory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

- a) the potential impact of the outsourced on the organization's capability to provide product that conforms to requirements
- b) the degree to which the control for the process is shared
- c) the capability of achieving the necessary control through the application of 7.4

4. Quality management system

4.2 Documentation requirements

4.2.1 General

- Deleted bullet (c) “documented procedure required by this international Standard”
- Added description for a “single document” and “documented procedure” to the note 1
 - Note 1 -..... A single document may address the requirements for one or more procedure. A requirement for a documented procedure may be covered by more than one document.

4. Quality management system

4.2 Documentation requirements

4.2.3 Control of documents

(f) To ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled.

4. Quality management system

4.2 Documentation Requirements

4.2.4 Control of records

Records **shall be established and maintained** to provide evidence of conformity to requirementsand...of the quality management system. **Records shall remain**

A documented procedure **shall be established** to define the controls needed for the identification, storage,.....

Is changed to:

Records established to provide evidence of conformity to requirements.....and and...of the quality management system shall be controlled.

The organization shall established a documented to define the controls needed for the identification, storage,.....

Records shall remain

5. Management responsibility

5.5 Responsibility, authority and communication
5.5.2 Management representative

- Top management shall appoint a member of management who irrespective of

Is changed to:

- Top management shall appoint a member of organization's management who irrespective of

6. Resource management

6.2 Human resources
6.2.1 General

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

Is changed to:

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

6. Resource management

6.2 Human resources
6.2.1 General

Added a new note

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

6. Resource management

6.2 Human resources

6.2.2 Competence, awareness and training

- Title is rearranged to

“competence, training and awareness”

- a) Determine the necessary competence for personnel performing work affecting **product quality**

Is changed to

- a) Determine the necessary competence for personnel performing work affecting conformity to product requirements

6. Resource management

• 6.2 Human resources

6.2.2 Competence, awareness and training

- b) provide training or take other actions to **satisfy these needs**

Is changed to:

- b) where applicable, provide training or take other actions to achieve the necessary competence

6. Resource management

6.3 Infrastructure

- c) Supporting services (such as transport or communication)

Is changed to

- c) Supporting services (such as transport, communication, or information systems)

6. Resource management

6.4 Work Environment

Added a new note

- Note: The term “ work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

7. Product realization

7.1 planning of product realization

b)the need to establish processes, documents, and provide resources specific to the product

Is changed to:

b)the need to establish processes and documents, and to provide resources specific to the product

7. Product realization

7.1 Planning of product realization

c)Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance

Is changed to

c)Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance

7. Product realization

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product
Minor modification to the requirements in bullets(c) and (d)

c)Statutory and regulatory requirements **related** to the product

Is changed to:

c)Statutory and regulatory requirements applicable to the product

d)any additional requirements **determined** by the organization

Is changed to:

d)any additional requirements considered necessary by the organization

7. Product realization

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Added a note to describe "post delivery" activities

- Note: Post-delivery activities include for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

7. Product realization

7.3 Design and development

7.3.1 Design and development planning

Added a note

- 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.

7. Product realization

7.3 Design and development

7.3.3 Design and development outputs

- “The outputs of design and development shall be **provided in a form that enables** verification.....”

Is changed to:

- “The outputs of design and development shall be in a form suitable for verification.....”

7. Product realization

7.3 Design and development

7.3.3 Design and development outputs

Added a new note:

Note: information for production and service provision can include details for the preservation of product

7. Product realization

7.5 production and service provision

7.5.2 Validation of processes for production and service provision

- The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. **This includes any processes where** deficiencies become apparent only after the product is in use or the service has been delivered.

Is changed to

- The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

7. Product realization

7.5 production and service provision

7.5.3 ID and Traceability

Added:

- The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization

And

- Where traceability is a requirement, the organization shall control **and record** the unique identification of the product.

Is changed to:

- Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records.

7. Product realization

7.5 production and service provision

7.5.4 Customer property

- If any customer property is lost or otherwise found to be unsuitable for use, **this shall be reported to the customer and records maintained**

Is changed to

- If any customer property is lost or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records

7. Product realization

7.5 Production and service provision

7.5.4 Customer property

- Note: Customer property can include intellectual property and personal data.

7. Product realization

7.5 Production and service provision

7.5.5 Preservation of product

- The organization shall preserve the **conformity of** product during the internal processing and delivery to the intended destination. **This** preservation shall.....

Is changed to

- The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall.....

7. Product realization

7.6 Control of monitoring and measuring devices

- Word "devices" is changed to "equipment"
- Added "both" to clause (a)
 - a) Be calibrated or verified, or both.....
- Rephrased clause (c)
 - c) be indentified to enable the calibration status to be determined
 to
 - c) to have identification in order to determine its calibration status

7. Product realization

7.6 Control of monitoring and measuring devices

Replaced the old note

Note: See ISO10012-1 and 10012-2 for guidance with a new note

- Note: 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.

8.Measurement, analysis and improvement

• 8.1 General

- a)to demonstrate conformity of the product
- Is changed to
- a)to demonstrate conformity to product requirement

8.Measurement, analysis and improvement

8.2.1 Customer Satisfaction

Added a new note

- Note: monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

8.Measurement, analysis and improvement

• 8.2.2 Internal audit

- The responsibilities and requirements for planning and conducting audits..... shall be defined in a documented procedure.

Is rephrased to

- A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

8.Measurement, analysis and improvement

8.2.2 Internal audit

Added : "Records of the audits and their results shall be maintained" as a new paragraph

Added

- The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are.....
- Note is revised to: See ISO 19011 for guidance

8.Measurement, analysis and improvement

8.2.3 Monitoring and measurement of processes

Deleted "to ensure conformity of the product" from the end of the paragraph

Added note

- Note: When determining suitable methods, it is advisable that the organization 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

8.Measurement, analysis and improvement

8.2.4 Monitoring and measurement of Product

Removed "Evidence of conformity with the acceptance criteria shall be maintained" from the beginning of the second paragraph and added to the end of the first paragraph.

Added the sentence "for delivery to the customer" to the end of second paragraph:

- Records shall include the person(s) authorizing release of product for delivery to the customer

Rephrased the third paragraph to:

- The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed unless otherwise approved by a relevant authority and where applicable, by the customer.

8.Measurement, analysis and improvement

• 8.3 Control of nonconforming product

Rephrased the sentence

- The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

to:

- A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming products.

- Added “where applicable” to “the organization shall deal with nonconforming product by one or more of the following ways”.

8.Measurement, analysis and improvement

8.3 Control of nonconforming product

- Revised the last paragraph and changed it to a new bullet.

“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.

A new bullet:

- 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.

8.Measurement, analysis and improvement

8.4 Analysis of data

- Changed the reference section in bullet (b)
- Added reference sections to (c) and (d)

8.Measurement, analysis and improvement

- 8.5.2 and 8.5.3 Corrective action and preventive action
- Added “effectiveness” to bullet (e) and (f) in both sections
- e, f) reviewing the effectiveness of the of corrective action or preventive actions taken

Summary

Most of the changes made are really minor and are assistance to understanding open issues.

- Statutory requirements are given scale as any other legal or customer's requirements.
- The statutory requirements are including the suppliers as well.
- A purchased process is just like any other product that the organization purchased. If it's affecting the product it must be under the quality system.
- You may include two quality processes in one document and split one process to two documents.
- The management representative must be a member of the management.
- A requirement to ensure that trainings are suitable for the product in advance and not to check if the training was effective after it was taken.
- Information system in now officially considered as a substructure.

Summary

- Parameters such as humidity, noise and temperatures, concerning the employees' health are considered as working environment.
- Measuring is considered as one of the activities of product realization.
- The product must be identifying not only on the shelves but also throughout the realization process.
- The management is now responsible for preventive and corrective actions regarding nonconformities that were discovered during audit.
- The organization should determine the type of the monitoring and measuring according to the processes and how will this affect the quality management system.
