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Amazon Consulting, Inc.

ISO9001:2008 UPDATES



OBJECTIVES

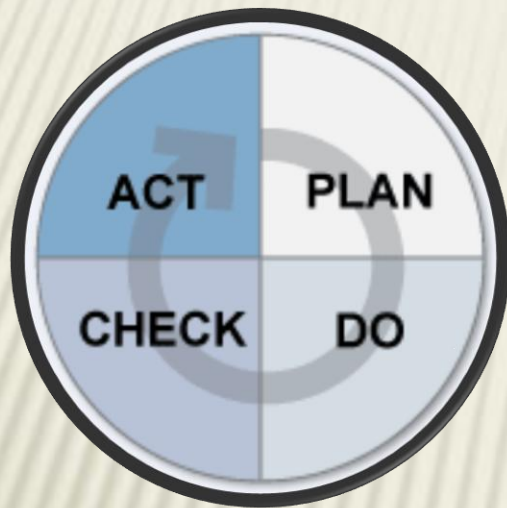
- × ISO9000 Quality Management Series Objectives
- × How changes are made to standards
- × Why the changes were made
- × How to roll to ISO9001:2008
- × Implementation details
- × What changed?
- × Where to find information

ISO9001:2008
Released
11/17/2008

STANDARD OBJECTIVES

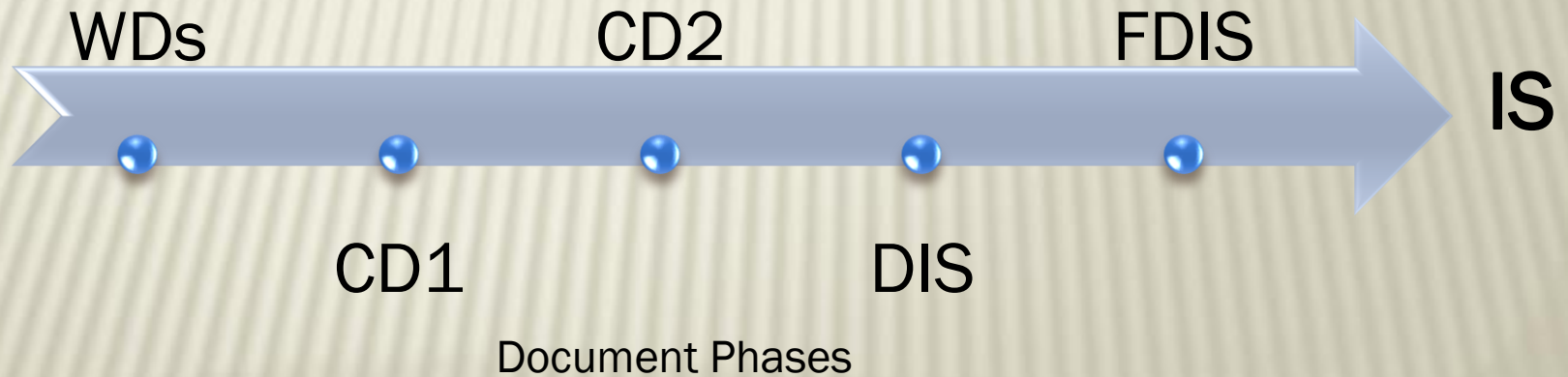
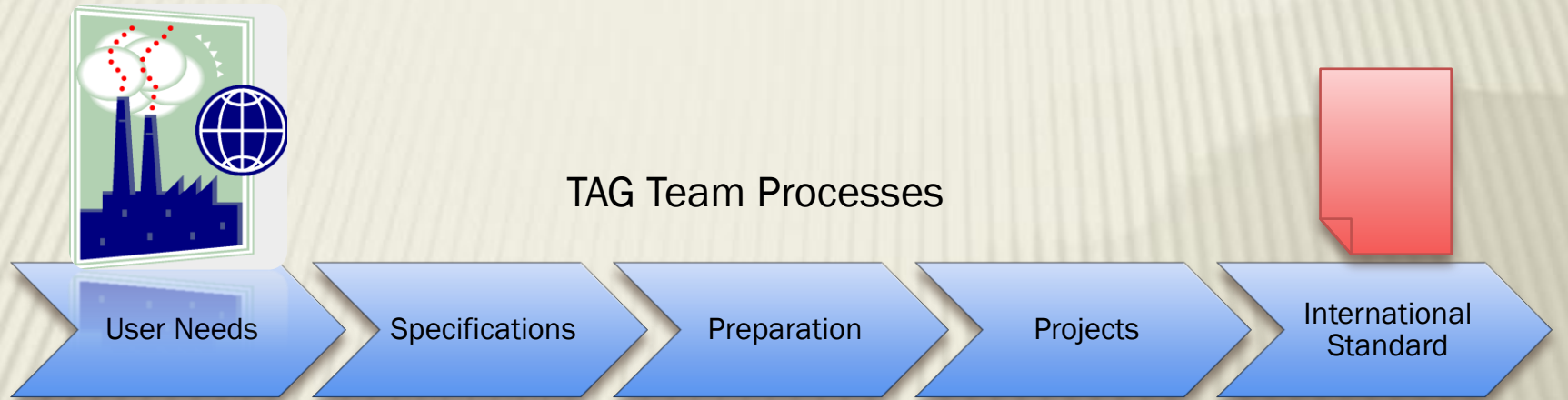
- × The **ISO 9000** family addresses "**quality management**". This means what the organization does to fulfill:
 - + the customer's quality requirements, and
 - + applicable regulatory requirements, while aiming to
 - + enhance customer satisfaction, and
 - + achieve continual improvement of its performance in pursuit of these objectives.

PLAN – DO – CHECK – ACT



- × The Plan – Do – Check – Act (PDCA) cycle is the **operating principle** of ISO's management system standards.
 - + **Plan** – establish objectives and make plans (analyze your organization's situation, establish your overall objectives and set your interim targets, and develop plans to achieve them).
 - + **Do** – implement your plans (do what you planned to).
 - + **Check** – measure your results (measure/monitor how far your actual achievements meet your planned objectives).
 - + **Act** – correct and improve your plans and how you put them into practice (correct and learn from your mistakes to improve your plans in order to achieve better results next time).

HOW CHANGES ARE MADE TO STANDARDS



ISO Publishes on 1st / 15th

WHY THE CHANGES

- × ISO 9001:2008 only introduces clarifications to the existing requirements of ISO 9001:2000 based on eight years of experience of implementing the standard world wide with about one million certificates issued in 170 countries to date.
 - + **Product Realization > English to Japanese> Japanese to English = Stage Show**
- × Introduces changes intended to improve consistency with ISO14001:2004
 - + Full rewrite of ISO9001 will coincide with ISO14001's rewrite.

FACTS ABOUT THE CHANGES

- × **ISO 9001:2008 does not contain any new requirements**
 - + Technically called an amendment
- × **Certification of conformity to ISO 9001:2008 and/or national equivalents shall only be issued after official publication of ISO 9001:2008 and after a routine surveillance or recertification audit against ISO 9001:2008.**

VALIDITY OF CERTIFICATIONS TO ISO 9001:2000

- × One year after publication of ISO 9001:2008 all accredited certifications issued (new certifications or recertifications) shall be to ISO 9001:2008.
- × Twenty four months after publication by ISO of ISO 9001:2008, any existing certification issued to ISO 9001:2000 shall not be valid.

MINOR IMPACT TO EXISTING CERTIFICATIONS

- × No increased or reduced requirements
- × No change in the intent of the requirements
- × No impact to most users
- × No additional training or education required
- × Minimal changes to the organization's documentation

CHANGES IN A NUT SHELL

- × **Terminology changes** intended to clarify ideas or make documentation more consistent - e.g. "devices" is changed to "equipment".
- × **The Notes:**
 - + Previous “Notes” may now be part of the requirements.
 - + Revised "Notes" within the standard.
 - + Additional Notes, however, notes are not considered auditable requirements, but are used for clarification.
- × **“Where applicable”** is used more extensively to help more organizations in various industries to apply the standard to their particular business.
- × A number of sentences and paragraphs have been re-worded for clarification and application to other languages.

NOTES ADDED

- × 1.1 Statutory and regulatory requirements may be expressed as legal requirements.
- × 4.1 Defines Outsourcing control criteria.
- × 6.2.1 Conformity to product requirement may be affected directly or indirectly.
- × 6.4 Defines work environment, provides examples
- × 7.2.1 Defines examples of post-delivery activities

NOTES ADDED

- × 7.3.1 Notes stating the review, verification, and validation stages can be conducted concurrently.
- × 7.3.3 Preservation of product should be considered as a design output.
- × 7.6 Defines software confirmation.
- × 8.2.1 Provides examples of monitoring for customer perceptions.
- × 8.2.3 Clarification note on relationship to 8.2.4

DEFINITIONS

- × **Shall** – Whenever this word occurs in the standard, it is used to indicate a requirement that must be fulfilled.
- × **Appropriate** – This word means that you need to decide how the requirements apply to your business, and in some cases they may not.
- × **Should/may** – These words are used to suggest a course of action, not a requirement that must be fulfilled.
- × **Identify** – To establish the set of characteristics by which something is known.
- × **Determine** – To decide or settle conclusively and authoritatively.

Note: Section 1.1

Note 1 has been amended to include comments regarding purchased product as well as product from realization processes.

Note 2 has been added explaining that statutory and regulatory requirements may be expressed as legal requirements

1.1 GENERAL

~~✘ Note: In this International Standard, the term “product” applies only to the product intended for or required by a customer.~~

Note: In this International Standard, the term “product” applies only to

- a) A product intended for, or required by a customer
- b) Any intended output resulting from the product realization processes

Note: Statutory and regulatory requirements can be expressed as legal requirements.

- a) a) The word 'identify' has been replaced with 'determine'
- e) Where applicable has been added to measure
- b) The statement regarding outsourced processes has been slightly re-worded and emphasizes that the outsourced controls shall be defined in the quality management system. This is a new 'shall'
- c) **Note 1** 'analysis and improvement' added to list of process inclusions
Note 2 has been added giving a definition of an outsourced process

4.1 GENERAL REQUIREMENTS

The Organization shall

- a) ~~Identify~~ **Determine** the processes needed for the QMS and their application throughout the organization
- e) Monitor, measure **where applicable**, and analyze these processes.

Note 2: When an organization chooses to outsource any process that affects product conformity ~~with~~ **to** requirements, the organization shall control over such processes. **The type and extent of control to be applied to these outsourced processes shall be defined within the QMS.**

Note 3 expands on the type of control that may be applied to outsourced processes in order to ensure control over them including a link to clause 7.4 Purchasing

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 can be influenced by factors such as

- a) The potential impact of the outsourced process 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

4.1 GENERAL REQUIREMENTS

Editorial changes including restructuring the clause.

Changed from

records shall be maintained to records shall be controlled

- × Records ~~shall be established and maintained to provide~~ evidence of conformity to requirements and of the effective operation of the QMS **shall be controlled**.
- × The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.
- × Records shall remain legible, readily identifiable and retrievable.

4.2.4 CONTROL OF RECORDS

No change to this section.

Clarification that conformity to product requirements could be affected directly and indirectly.

Could be perceived as a new requirement by companies that have minimal approaches. (i.e., direct relationships)

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**

6.2 HUMAN RESOURCES

Change in title to
'Competence, training and
awareness' but keeps same
words (change in their order)

a) Where the current version
mentions '... affecting
product quality', it now states
'... affecting conformity to
product requirements'.

b) Now states that 'where
applicable' training needs to
be provided 'to achieve the
necessary competence'

6.2.2 Competence, training, and awareness (changed the order)

- × The organization shall
 - a) Determine the necessary competence for personnel performing work affecting ~~product quality~~ **conformity to product requirements**,
 - b) **Where applicable**, provide training or take other actions to ~~satisfy these needs~~ **achieve the necessary competence**
 - ~~e) Ensure the effectiveness of the actions taken,~~ Ensure that the necessary competence has been achieved

6.2 HUMAN RESOURCES

Devices changed to equipment throughout the standard.

Equipment includes devices according to ISO9000 and eliminates the need for a device definition.

See 7.2.1 deleted based on revisions made to 7.1

- × 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~~).

7.5.1 PRODUCTION AND SERVICE PROVISION

The phrase 'to ensure conformity of the product' has been removed

A Note has been added to explain that the organization should consider the type of monitoring and measuring of processes and the extent to which they affect quality and the QMS

- × 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.

8.2.3 MONITORING AND MEASUREMENT OF PROCESSES

1) The requirement for a documented procedure has been re-worded but remains unchanged

2) The phrase 'where applicable' has been added to the methods for dealing with nonconforming product

d) New bullet, was paragraph 4 concerning action to be taken after delivery has been made. This section was move up from the last paragraph

~~1. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.~~

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

3. d) by taking action appropriate to the effects, or potential effects, of the....

8.3 CONTROL OF NONCONFORMING PRODUCTS

8.5.2

1) 'cause' becomes
'causes'

f) Insertion of 'the
effectiveness of the' to
Corrective Action

8.5.3

e) Insertion of 'the
effectiveness of the' to
Preventive Action

- × The organization shall take action to eliminate the ~~cause~~ **causes** of nonconformities in order to prevent reoccurrence.
- × F) reviewing **the effectiveness of** the corrective action taken
- × E) reviewing **the effectiveness of** preventive action taken

8.5.2 CORRECTIVE ACTION / 8.5.3 PREVENTIVE ACTION

HOW TO PROCEED

- × As the primary resource in the United States for purchase of the U.S. adoption of the ISO 9001:2008 standard, ASQ is offering the new standard at a cost of \$76 for members and \$95 for nonmembers. The standard can be purchased via the ASQ Web site www.asq.org/iso9001 or by calling ASQ at 800-248-1946.

HOW TO PROCEED

- ✘ With the publication of the revision, companies certified to ISO 9001:2000 will have **24 months** to transition to ISO 9001:2008. This transition period provides an opportunity for organizations to review their quality management systems and identify key requirements. While the ISO 9001:2008 is considered a refined version of the 2000 standard, companies can find value in reviewing the 2008 version.

RESOURCES

- × www.asq.org/iso9001 online or hard copy
 - + Online copies do not print
- × www.iso.org
- × www.ansi.org
- × Paton Professional: *The Auditor* Newsletter
 - + www.theauditoronline.com

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