

ISO Standard Approval Process

6 Stage Process

- 1: Proposal
- 2: Preparatory - Working Draft (WD)
- 3: Committee – Committee Draft (CD)
- 4: Enquiry – Draft International Standard (DIS)
- 5: Approval – Final Draft International Standard (FDIS)
- 6: Publication – Standard Revision

Who is responsible for Updates

TC 176/SC 2 Committee Members (Quality Systems)

- David Zimmerman – CSA TC176 Secretary
- Trevor Smith – Kodak – TC 176 Chairperson
- Charles Corrie – BSI - SC2 Secretary
- Dr. John Davies – UK – SC2 Chairperson
- 65 Participating Countries
- 10 Observing Countries
- SCC, ANSI & DGN representatives

Recommendation

- No specific reaction required
- Review for improvement
- DIS comments by 02/01/08
- Issue date tentatively October 31, 2008

Information Links

- ISO/TC 176 SC2 Home Page within ISO
<http://isotc.iso.org/livelink/livelink/fetch/2000/2122/138402/755901/1069636/customview.html?func=ll&objId=1069636&objAction=browse&sort=name>
- ISO TC 176 Home Page
www.tc176.org
- ISO Main Page
www.iso.org

ISO-9001:2008 Revision Summary Description

- Minor in nature - clarification & editorial
- Analysis - 78 Proposed changes
 - 12 General
 - 2 "Enhanced Requirements"
 - 10 new "Notes"
 - 3 revised "Notes"
 - 29 "Clarifications"
 - 4 "Deletions"
 - 18 "Editorial changes"
 - Clause numbering essentially maintained.

General Statutory

Several additional references (examples)

- General - 0.1- use of the standard to assess organizations ability to meet customer and statutory and regulatory requirements
- General 0.3 – focus of the standard on the effectiveness of the management system in meeting customer and applicable statutory and regulatory requirements.
- Scope – 1.1.a - standard specifies requirements for a management system where an organization needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements.
- None of the changes are in the requirements
- Increased compatibility with ISO 14001

ISO 9004 Relationship

Analysis

- 2000 release emphasized consistent pair.
- TC176 SC2 tasked with revision
- Managing for sustained success - A quality management system approach,"
- Sustainable Success
- June 2007 Communiqué

Relationship with ISO 9004 (2 proposed changes)

1. Current

- ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards, . designed to complement each other..." and "... have similar structures in order to assist their application as a consistent

Proposed

- The present edition of ISO 9004 has been developed to maintain consistency with ISO 9001. Both standards complement each other, but can also be used independently.

2. Current

- ISO 9004 gives guidance on a wider range of objectives, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide ...to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance.

Proposed

- ISO 9004 gives guidance on a wider range of objectives _particularly in managing for the sustainable success of an organization. ISO 9004 is recommended as a guide, ,.to extend the benefits of ISO 9001 in pursuit of systematic and continual improvement of the organization's overall performance,

Enhanced Requirements

5.5.2 — Management Representative

Current

- "...Top management shall appoint a member of management who..."

Proposed

- "...Top management shall appoint a member of the organization's management who

Analysis

- Management representative duties and responsibilities are significant
- Needs to be a member of the organization
- Outsourcing responsibility not appropriate

6.2.2. a, b & c—Conformity & Competency

Current

- 6.2.2.a - determine the necessary competence for personnel performing work affecting product quality
- 6.2.2,1 - provide training or take other actions to satisfy these needs
- 6.2.2,c - evaluate the effectiveness of the actions taken,

Proposed

- 6.2.2.a - ...conformity to product requirements.
- 6.2.2.b - where applicable, provide training or take other actions to achieve the necessary competence
- 6.2.2.c - ensure that the necessary competence has been achieved

Analysis

- Conformity to product requirements. competency and achievement

New Notes

1.1 Note 2

Proposed

- Statutory and regulatory requirements may be expressed as legal requirements

Analysis

- Compatibility with ISO 14001

4.1 - Note1 & 2 Analysis

- Debate on what is "outsourcing"
- ISO Guidance N630
- Current requirements
- Appropriate controls
- ISO, customer & statutory & regulatory

4.1 – 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.

4.1 Note 3

- The type and nature of control to be applied to the outsourced process may 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 extent to which the control for the process is shared;
 - c) the capability of achieving the necessary control through the application of clause 7.4.

- Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customers, statutory and regulatory requirements

6.2.1 - General

Proposed

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

Analysis

- Enforces "New enhancement" regarding competency
- Not limited to personnel performing product realization activities,

6A – Work Environment

Proposed

- The term work environment relates to conditions under which work is performed including physical, environmental and other factors {such as noise, temperature, humidity, lighting, or weather)

Analysis

- No significant additional information

7.2.1 – Review of requirements related to the product

Proposed

- 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.

Analysis

- Clarification only
- Should consider during design input, REQ. contract review, customer interface/meetings
- Consider review for recycling f& final disposal

7.3.1 — Design and Development Planning

Proposed

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

Analysis

- Recognize one design activity may satisfy another
- Greater degree of flexibility for design process

New Notes

7.3.3 Design and development outputs

Proposed

- information for production and service provision may include details for the preservation of product

Analysis

- Relates directly to 7.3.3.b
- RF1043
- Clause 7.5.5 also revised to reflect this note guidance.

8.2.1 Customer satisfaction

Proposed

- Monitoring customer perception may 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, dealer reports.

Analysis

- Current requirement had no guidance
- ISO 9004 did include direction
- Note provides direction with flexibility

8.2.3 Monitoring and measurement of processes

Proposed

- 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.

Analysis

- Clause 8.2.3 requires organization "...apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.," to "...demonstrate the ability of the processes to achieve planned results..." - new guidance appears to be risk based
- Correlation to 8.2.2. internal audits based on status and importance of processes.

Revised Notes

1.1 General Note 1

Current

- In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.

Revision

- Adds or the product realization processes. This applies to any intended output resulting from product realization processes. Including purchasing.

Analysis

- Requested additional information
- Notes are informative and guidance only

4.1 General Requirements Note 1

Current

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

Revision

- Adds "analysis and improvement..." at the end of the paragraph.

Analysis

- Recognize that analysis and improvement processes should be part of the management system.
- Examples are processes for customer satisfaction, internal audits, etc.

4.2.1 General Note 1

Current

- Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

Revision

- The proposed revision adds "...A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document."

Analysis

- Recognizes a degree of flexibility for documentation

Clarification Examples

4.2.1.d QMS General Requirements

Current

- Documents needed by the organization to ensure the effective planning, operation and control of its processes.

Proposed

- Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

Analysis

- Re-iterates 4.2.3 requirements on records
- Clarifies flexibility in documentation requirements

4.2.3.f Control of Documents external origin

Current

- "...to ensure that documents of external origin are identified and their distribution controlled..."

Proposed

- "...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..."

Analysis

- Emphasis on determined by the organization
- Includes identification with respect to revision/edition, etc.
- Process still needs to be in a documented procedure.

7.5.3 — Identification and traceability

Current

- "...the organization shall identify the product status with respect to monitoring and measurement requirements..."

Proposed

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

Analysis

- New or clarification?
- Consistent with other sections of the standard
- Organization determines method of such status identification

8.2.2 Internal Audits

Current

- The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes

Proposed

- The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

Analysis

- ISO 9000:2005 Fundamentals and vocabulary
- Correction eliminate detected nonconformity
- Corrective Action eliminates cause for the detected nonconformity.
- Clarification of standard intent and alignment with ISO 9000 definitions

8.2.3 Monitoring and measurement of processes

Current

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

Proposed

- When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

Analysis

- In context with preceding sentences and "New Note"

8.5.2 Corrective action

Current

- The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence.

Proposed

- The organization shall take action to eliminate the causes. of nonconformities in order to prevent recurrence.

Analysis

- Alignment with ISO 9001:2005 Section 3.6.5. Note 1