The 9000 Advisers

Transitioning to ISO 2001:2008

The International Organization of Standards formally announced the publication of the ISO 9001:2008 standard on November 15, 2008. It is an amendment – not a revision – of the current ISO 2001:2000 standard. The new standard modifies and clarifies but doesn't change any of the regulations within the current standard, nor are there any additional requirements. Its primary purpose is to clarify existing requirements and make the standard more compatible with the environmental standard, ISO 14001:2004.

The conditions for transitioning to the new standard include:

- ✓ Systems will continue to be certified to the old standard until November 2009 after which time all new systems will be certified to the new standard.
- ✓ Organizations currently certified to ISO 9001:2000 must transition to the amended standard by November 2010.

The following is a clause-by-clause review of the changes.

0.1 – General
Clarification: You must meet all the statutory as well as the regulatory requirement that apply to the products or services you provide.

0.2 – Process approach
Clarification: A process is identified as "an activity or set of activities."

0.3 – Relationship with ISO 9004
Clarification: Specifies that ISO 9001:2000 can be used "to move beyond the requirements of ISO 9001."

0.4 – Compatibility with other management systems
Clarification: Added a reference to Annex A that compares ISO 9001:2008 and ISO 14001:2004.

1.1 and 1.2 – Scope
Added: "product can be any intended output from the product realization process."
Added: "a statutory requirement can also be a legal requirement."

2 – Normative references
Change: ISO 9000:2000 is now replaced by ISO 9000:2005.

3 – Terms and definitions
Deletion: The meaning of "customer," "organization" and "supplier" have been removed.

4.1 – General requirements
Clarification: Clause a - The word "determine" replaces the word "identify" for processes.
Clarification: The notes now cover the definition of outsourced process and types of controls that may be applied to these processes.
Addition: A reference to clause 7.4 has been added.

4.2.1 – Documentation requirements, general
Clarification: The QMS documentation also includes records.
Clarification: A single document may address the requirements for one or more procedures, and a requirement for a documented procedure may be covered by more than one document.

4.2.3 – Control of documents
Clarification: Clause f) – Only those external documents that are determined by the organization to be necessary for the planning and operation of the QMS need to be identified and have their distribution controlled.

4.2.4 – Control of records
Addition: Editorial comments were added to describe the alignment of ISO 14001 to ISO 9001.

5.5.2 – Management representative
Clarification: The ISO Representative must be a part of the organization's management team.

6.2.2 – Competence, training and awareness
Clarification: Clause b) – "provide training or take other actions to satisfy these needs" was changed to read "where applicable, provide training or take other action to achieve the necessary competence"

6.3 – Infrastructure
Addition: Clause c) – "information systems" are included as part of the infrastructure.

6.4 – Work environment
Clarification: "work environment" includes noise, temperature, humidity, lighting, and weather.

7.1 (c) – Planning of product realization
Addition: "measurement" was added to the planning activities.

7.2.1 – Determination of requirements related to the product
Addition: "post delivery activities" is part of the product requirements.

7.3.1 – Design and development planning
Clarification: Design and development review, verification and validation have distinct purposes, however, they can be conducted and recorded separately or in any combination.

7.3.3 – Design and development outputs
Clarification: The documents that describe the production and service provisions must include details for product preservation.

7.5.3 – Identification and traceability
Clarification: The organization shall identify the product status with respect to the monitoring and measuring requirements throughout the product realization processes.

7.5.4 – Customer property

Clarification: Personal data is considered part of "customer property."

7.5.5 – Preservation of product

Clarification: Preservation means "in order to maintain conformity to requirements."

Clarification: "As applicable," preservation shall include …"

7.6 – Control of monitoring and measuring equipment

Clarification: The regulation was changed from monitoring and measuring "devices" to read monitoring and measuring "equipment."

Deletion: The reference to paragraph 7.2.1 was removed.

Clarification: Clause a) was changed from "and/or" to "or." It now reads "be calibrated or verified, or both."

Clarification: Clause c) was changed from "be identified to enable the" to "have identification in order to"

Deletion: The references to ISO 10012-1 and ISO 10012-2 were removed.

Clarification: You must provide a means for verifying that your software is suitable for its intended application.

8.2.1 – Customer satisfaction

Clarification: The monitoring of customer perception can include 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.

8.2.2 – Internal audit

Clarification: 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.

Clarification: Records of audits include audit results.

Clarification: All references to ISO 10011-1, ISO 10011-2, and ISO 10011-3 were changed to ISO 19011.

8.2.3 – Monitoring and measurement of processes

Deletion: "to ensure conformity of the product" was removed.

Added: "When determining suitable methods, it is advisable that the organization should consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to [how they impact] the conformity to product requirements and on the effectiveness of the quality management system."

8.3 – Control of nonconforming product

Clarification: The paragraphs were rearranged.

8.4 – Analysis of data

Clarification: References to other clauses included in items b), c), and d) were updated.

8.5.2 – Corrective action

Clarification: Clause f) was changed to read "reviewing the effectiveness of the corrective action taken."

8.5.3 – Preventive action

Clarification: Clause e) was changed to read "reviewing the effectiveness of the preventative action taken."

