

ISO 9001:2008

Changes to the New Revision vs. ISO 9001:2000

ASQ Nebraska Section 1302 Workshop

Presented by Jon Ridgway

ISO Lead Auditor, CSSBB, CQE, CQA

Overview of ISO 9001:2008

- An **Amendment**, not a revision – mainly “*editorial changes*”
- Intention:
 - To remove ambiguity
 - To provide clearer text
 - To improve compatibility with ISO 14001
 - To improve its ability to be translated
 - To incorporate TC176 website interpretations

Transition Plan

- Published November 15, 2008
 - Can begin auditing to ISO 9001:2008
- Effective November 15, 2009:
 - *ISO 9001:2008* certificates will be issued
- Effective November 15, 2010:
 - *ISO 9001:2000* certificates will be **invalid**
 - **Impact:** Must transition to ISO 9001:2008 or lose your certification

In General:

- Many minor editorial changes:
 - Referring to statutory / regulatory requirements:
 - From “*statutory*” to “*statutory and regulatory*”
 - Rewording sentences without changing meaning
 - From “*and / or*” to “*or*”
 - From “*cause*” to “*causes*”
- **Bottomline:** No “*shalls*” removed or added

0.1 General

- Split out factors from 1st paragraph into stand-alones
- Added a new factor:
 - *a) its organizational environment, changes in that environment, and the risks associated with that environment*

0.2 Process Approach

- Focus on *determining* processes, rather than *identifying* processes – see 4.1
- Highlights importance of processes being capable of achieving desired outputs

0.3 Relationship with ISO 9004

- Reference to upcoming revision to *ISO 9004:2000*:
 - Next *ISO 9004* **will not** have a clause structure similar to *ISO 9001:2008*
 - Therefore, no longer a “*consistent pair*”

0.4 Compatibility with Other Management Systems

- Updates the *ISO 14001* version:
 - From *ISO 14001:1996*
 - To *ISO 14001:2004*

1.1 Scope

- Clarifies the meaning of “*product*”
 - Revised *Note 1* to include a product is “*any intended output of the process*”
 - Added *Note 2*
 - Explains that statutory & regulatory requirements can include legal requirements
 - Intended to help non-English speakers understand

1.2 Application

- Added to 3rd paragraph, “*statutory and*” to “*regulatory requirements*”
- Now reads, “*statutory and regulatory requirements*”

2.0 Normative References

- Updates the *ISO 9000* version:
 - From *ISO 9000:2000*
 - To *ISO 9000:2005*

3.0 Terms and Definitions

- Removed supply chain definitions
- Removed organization and supplier definitions

4.1 General Requirements

- Replaced *a)* “*identify...*” with “*determine...*”
– see 0.2
- Added to *e)* “*as applicable*” to *measure*
- Outsourcing:
 - Rewrote last sentence of last paragraph
 - Added *Note 2*: Explains an “outsourced” process
 - Added *Note 3*: Must control outsourced processes

4.2 Documentation

- 4.2.1 General:
 - Added *records* to *c)* and dropped *e) records required*
 - Clarified: Can be single or more documents to meet a requirement
- 4.2.3 Control of Documents:
 - Added verbiage to *f)*
 - Meaning: Not all external documents need to be controlled; only those **needed** for the planning and operation of the quality management system

4.2 Documentation, Cont.

- 4.2.4 Control of Records:
 - From “*maintained*” (warehousing of records) to “*controlled*” (regulating the use of records)
 - Broke 1 paragraph into 3
 - Moved documented procedure requirement up to emphasize it

5.5.2 Management Representative

- From “*member of management*”
- To “*member of organization’s management*”
- **Meaning:** Outsiders cannot be the Mgt Rep

6.2 Human Resources

- 6.2.1 General:
 - From “*product quality*” to “*work affecting conformity to product requirements*”
 - Added *Note* on how employees can impact quality, directly and indirectly
- 6.2.2 Competence, Training & Awareness:
 - From “*product quality*” to “*work affecting conformity to product requirements*”

6.2 Human Resources, Cont.

- 6.3 Infrastructure:
 - Added to *c)*, “*or information services*”
- 6.4 Work Environment:
 - Added a *Note* defining work environment

7.1 Planning of Product Realization

- Added to *c)*, “*measurement*”
- Now reads: “*c) required verification, validation, monitoring, **measurement**, inspection and test activities specific to the product and the criteria for product acceptance;*”

7.2.1 Determination of Requirements related to the Product

- Changed c):
 - From “*related to the product*”
 - To “*as applicable to the product*”
- Changed d):
 - From “*requirements determined*”
 - To “*any additional requirements considered necessary*”
- Added a *Note* with post-delivery activity examples

7.3.1 Design and Delivery Planning

- Added a *Note*:
 - Explaining distinct purposes of review, verification and validation.
 - They can be conducted and recorded separately or in any combination.

7.3.3 Design and Delivery Output

- Change to 1st sentence:
 - From a form that “*enables verification*”
 - To a form “*suitable for verification*”
- Added a *Note* about how information for product / service provision can explain preservation of the product.

7.5.1 Control of Production and Service Provision

- Change to c):
 - From “*monitoring & measuring devices*”
 - To “*monitoring & measuring equipment*”
 - See 7.6
- Added to f): product – now reads “*f) the implementation of **product** release, delivery and post-delivery activities.*”

7.5.2 Validation of Processes for Product and Service Provision

- 1st paragraph: From 2 sentences into 1 long sentence
- No real change in meaning

7.5.3 Identification and Traceability

- Added to the end of the second sentence on product status:
 - “*throughout product realization*”
- Dropped “*and record*” from last sentence:
 - Now reads: “*shall control unique identification of the product and maintain records.*”

7.5.4 Customer Property

- Change to third sentence,
 - From, “*this shall be reported...*”
 - To “*the organization shall report this...*”
- Change to *Note*: added “*and personal data*”

7.5.5 Preservation of Product

- Added to end of 1st sentence:
 - From: “...*shall preserve the conformity of product...*”
 - To “...*in order to maintain conformity to requirements*”
- Added to beginning of 2nd sentence: “*As applicable...*”

7.6 Control of Monitoring and Measuring *Equipment*

- From “*devices*” to “*equipment*” – see 7.5.1
- Changed a):
 - From “...*calibrated or verified*...”
 - To “...*calibrated or verified, or both*...”

7.6 Control of Monitoring and Measuring *Equipment*, Cont.

- Changed c):
 - From “*be identified to enable the calibration status to be determined*”
 - To “*have identification in order to determine its calibration status*”
- *Note* removed: Reference to *ISO 10011*
- Added *Note*: software confirmation to include verification / configuration management

8.2.1 Customer Satisfaction

- Added a *Note* with examples of how to obtain this information

8.2.2 Internal Audit

- Rewrote last 2 paragraphs into 3 paragraphs
- Added: “*Records of the audits and their results shall be maintained.*”
- Changed *Note* reference from *ISO 10011* to *ISO 19011*

8.2.3 Monitoring and Measurement of the Process

- Removed from end of last sentence, “*to ensure conformity of the product*”
 - Now reads: “*When planned results are not achieved, correction and corrective action shall be taken, as appropriate.*”
- Added a *Note* with suggestions

8.2.4 Monitoring and Measurement of the Product

- Added release of product “*to the customer*”
- Rewrote last sentence with no change in meaning

8.3 Control of Nonconforming Product

- Added, “*Where applicable*” to 2nd paragraph
- Rewrote several sentences with no change in meaning
- Moved the last sentence up to 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.*”

8.4 Analysis of Data

- Changed reference in *b)* from 7.2.1 to 8.2.4
- Added references to *c)* 8.2.3 *and* 8.2.4 and *d)* 7.4

8.5.2 / 8.5.3 Corrective & Preventive Action

- Added “*effectiveness*” to the last sentence in each:
 - “*reviewing the effectiveness of the corrective / preventive action taken.*”
- Not a new requirement, added for emphasis

Questions?

- *Thank You!*