Preparing for ISO 9001:2008

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As a professional in the Quality Management field, I try to keep up with the latest news regarding ISO 9001 and related industry-specific standards. One of the most notable developments recently is the planned release of ISO 9001:2008, scheduled for later this year.

In June of 2007, ISO's Technical Committee TC-176, which is the committee responsible for ISO 9001, concluded that the document was now sufficiently mature to move from a Committee Draft (CD) to the Draft International Standard (DIS) and Final Draft International Standard (FDIS) phases. Upon balloting by ISO members during these phases, the official publication would then be released as an International Standard (IS).

Copies of the FDIS version of ISO 9 001:2008 document have been in circulation for months now, and out of the changes proposed, it appears that the majority of changes are clarifications, modifications or examples relating to existing requirements. In most cases, these changes should have only a limited impact on an established system that was properly implemented and maintained.

Examples of these changes include:

Clause 0.2 (Process approach)
- Emphasis on the importance of processes being capable of achieving desired outputs

Clause 1.1 (Scope)
- Clarification that "product" also includes intermediate product
- Replaces uses of "regulatory" with "statutory and regulatory"

Clause 4.1 (General requirements)
- Clarification that specific controls are to be defined and applied, not just identified

Clause 4.2.1 (Documentation)
- Clarification that QMS documentation also includes records
- Documents required by the standard may be combined

Clause 4.2.3 (Document control)
- Clarification that only external documents relevant to the QMS need to be controlled

Clause 4.2.4 (Records control)
- Expanded from records being "maintained" to having them "controlled". "Retention time" has been reduced to "retention".

Clause 5.5.2 (Management rep)
- Clarifies that this must be a member of the organization's own management

Clause 6.2.1 (Human resources)

- Clarification that competence requirements are relevant for any personnel who are involved in the operation of the quality management system

Clause 6.3 (Infrastructure)
- Includes information systems as an additional example

Clause 6.4 (Work environment)
- Clarifies that this includes conditions under which work is performed (e.g., noise, temperature, humidity, lighting, or weather).

Clause 7.2.1 (Customer related processes)
- Clarifies that post-delivery activities may include: Actions under warranty provisions; Contractual obligations such as maintenance services; and/or Supplementary services such as recycling or final disposal

Clause 7.3.1 (Design & development planning)
- Clarifies that design and development review, verification and validation have distinct purposes, and may be conducted and recorded separately or in any combination as suitable for the product and the organization

Clause 7.3.3(Design & development outputs)
- Clarifies that information needed for production and service provision includes preservation of the product

Clause 7.5.4 (Customer property)
- Explains that both intellectual property and personal data should be considered as customer property

Clause 7.6 (Control of Monitoring and Measuring *Equipment*)
- Replaces the use of "Devices" with "Equipment".
- Explanatory notes added regarding the use of computer software

Clause 8.2.1 (Customer satisfaction)
- Note added regarding the monitoring of customer perception

Clause 8.2.3 (Monitoring / Measurement of process)
- Note added to clarify that when deciding on appropriate methods, the organization should consider impact on the conformity to product requirements and on the effectiveness of the quality management system.

As for ISO 9004, significant changes are expected, and as a result, 9004 will not be updated at the same time as ISO 9001. The proposed title of this revision is "Managing for sustainable success – a quality management approach." Until its revision, the 9004 standard will remain alongside 9001 until at least 2009.

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