

Update on ISO 9001:2008

Current status

Following a recent meeting of ISO's Technical Committee TC176 in Helsinki, Finland, from June 11 – 15, 2007, publication of the new version of **ISO 9001** has been brought forward from 2009 and is now scheduled to be published in October 2008. Experts representing over 70 **ISO** member bodies, met to discuss the comments received during circulation of the Committee **Draft** ("CD") of the new standard, and concluded that in view of the very limited changes being proposed, the **draft** is now sufficiently mature to progress directly to the **DIS** (**Draft International Standard**).

The main changes being introduced into the new standard are as follows:

Clause 0.2 (Process approach)

Text added to emphasize the importance of processes being capable of achieving desired outputs

Clause 1.1 (Scope)

Clarification that "product" also includes intermediate product
Explanation regarding statutory, regulatory and legal requirements

Clause 4.1 (General requirements)

Notes added to explain more about outsourcing
Types of control that may be applied to outsourced processes
Relationship to clause 7.4 (Purchasing)
Clarification that outsourced processes are still responsibility of the organization and must be included in the quality management system

Clause 4.2.1 (Documentation)

Clarification that QMS documentation also includes records
Documents required by the standard may be combined
ISO 9001 requirements may be covered by more than one documented procedure

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)

Editorial changes only (better alignment with **ISO 14001**)

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 example

Clause 6.4 (Work environment)

Clarifies that this includes conditions under which work is performed and includes, for example physical, environmental and other factors such as 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
- 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

These 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 (Now retitled Control of Monitoring and Measuring *equipment*)

Explanatory notes added regarding the use of computer software: “Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.”

Clause 8.2.1 (Customer satisfaction)

Note added to explain that monitoring of customer perception may include input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, and dealer reports

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.