



# ISO 9001:2008

## Summary of Changes

The 2008 revision of ISO 9001 was officially released on November 13, 2008. This guidance document highlights additions, deletions and clarifications. Additions are shown in bold, italicized text. Where appropriate, this presentation will also provide insight as to what the changes mean to you, the certified client or applicant client.

### Section 0.1 General

- Added as a factor that influences the design and implementation of an organization's quality management system is "its organizational environment, changes in that environment and the risks associated with that environment."
- All influencing factors are now arranged in a bulleted list.

*The design and implementation of an organization's quality management system is influenced by*

- a) **its organizational environment, changes in that environment, and the risks associated with that environment,***
- b) its varying needs,*
- c) its particular objectives,*
- d) the products it provides,*
- e) the processes it employs,*
- f) its size and organizational structure*

**What does this mean to you? This forces the organization to consider its unique organizational environment and its dynamic nature and risks associated with this environment. This consideration is especially important in today's economic times.**

- Also revised was "regulatory" to "statutory and regulatory." A clarification was made that the customer, statutory and regulatory requirements are those applicable to product.

*This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, **statutory and regulatory requirements applicable to the product**, and the organization's own requirements.*

### Section 0.2 Process Approach

- "Identify" was changed to "determine" in this section.
- Furthermore, clarification was provided that a process can be an activity or set of activities.

*For an organization to function effectively, it has to **determine** and manage numerous linked activities. An activity **or set of activities** using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process.*

- Finally, the definition of a process approach has been augmented by addition of the text “to produce the desired outcome.”

*The application of a set of processes within an organization, together with the identification and interactions of these processes, and their management **to produce the desired outcome**, can be referred to as the “process approach.”*

### **Section 0.3 Relationship with ISO 9004**

- ISO 9004 is currently under revision, with an anticipated release date of 2009. The revisions will be such that it will no longer parallel ISO 9001 in its organizational structure. As such, the following text was deleted: “*Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.*”

### **Section 0.4 Compatibility with Other Management Systems**

- ISO 14001:1996 has been updated to ISO 14001:2004:

*During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community.*

### **Section 1.1 General**

- Again, “regulatory” has been changed to “statutory and regulatory.”

- a) *needs to demonstrate its ability to consistently provide product that meets customer and applicable **statutory** and regulatory requirements, and*
- b) *aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable **statutory** and regulatory requirements.*

- Note 1 has been expanded, and a Note 2 has been added:

*Note 1 In this International Standard, the term “product” only applies to*

- a) *product intended for, or required by, a customer,*
- b) ***any intended output resulting from the product realization process.***

*Note 2 **Statutory and regulatory requirements can be expressed as legal requirements.***

### **Section 1.2 Application**

- Again, “regulatory” has been changed to “statutory and regulatory.”

*Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization’s ability, or responsibility to provide product that meets customer and applicable **statutory** and regulatory requirements.*

### **Section 2 Normative References**

- ISO 9000:2000 has been changed to ISO 9000:2005, *Quality Management Systems – Fundamentals and vocabulary.*

### **Section 3 Terms and Definitions**

- Explanation of the terms “supplier” and “organization” have been deleted.

## Section 4.1 General Requirements

- In 4.1a, the word “identify” has been replaced with “determine.”

*a) **Determine** the processes needed for the quality management system and their application throughout the organization (see 1.2),*

- In 4.1e, “where applicable” has been added.

*e) monitor, measure (where applicable), and analyze these processes, and...*

**What does this mean to you? It may not be possible or make sound business sense to measure all processes. The outputs of some processes, especially support processes, may best be measured in a downstream process. However, all processes still need to be monitored.**

- Also, in clause 4.1, controls over outsourced processes now must be defined and not simply identified:

*Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be **defined** within the quality management system.*

**What does this mean to you? Somewhere in the management system, e.g. part of your documentation, these controls shall be defined.**

- There are now three notes. In Note 1, there has been an addition of “analysis and improvement,” and the word “should” has been deleted, making it mandatory for all of these types of processes to be included. Note 2 and 3 are new.

*Note 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement, **analysis and improvement**.*

*Note 2: An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.*

*Note 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can 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 degree to which the control for the process is shared,*
- c) the capability of achieving the necessary control through the application of 7.4.*

**What does this mean to you? An outsourced process needs to be treated as any other purchased commodity and subjected to the requirements of 7.4.**

### Section 4.2.1 General

- Subclause (e) has been deleted, as “records” has been added to clauses (c) and (d).

*c) documented procedures **and records** required by this International Standard, and  
d) documents, **including records, determined** by the organization **to be necessary** to ensure the effective planning, operation and control of its processes.*

- Note 1 has been expanded:

*... 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.*

**What does this mean to you? An example of the first sentence would be a single procedure for Document and Record Control. An example of the second sentence would be the requirements for corrective action being addressed in a procedure for Corrective Action and a procedure for Internal Audits.**

### Section 4.2.3 Control of Documents

- Clause (f) has been revised to clarify the types of external documents that need to be identified and controlled.

*f) 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 controlled, and*

### Section 4.2.4 Control of Records

- This section has been re-organized into three paragraphs. The requirement for a documented procedure has been moved in front of the requirement for records to remain legible, readily identifiable and retrievable.

*Records established to provide conformity to requirements and of the effective operation of the quality management system shall be controlled.*

*The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.*

*Records shall remain legible, readily identifiable and retrievable.*

### Section 5.5.2 Management Representative

- The addition of two words here creates a very significant change:

*Top management shall appoint a member of **the organization's** management who, irrespective of other responsibilities, shall have responsibility and authority that includes:*

**What does this mean to you? Some organizations have chosen to outsource the role of the Management Representative to a consultant or other third party. This revision is clear in that the Management Representative must be a member of the organization's management who has been granted the necessary authority to perform his/her responsibilities.**

### Section 6.2.1 General

- In this section work affecting “product quality” has been amended to work affecting “conformity to product requirements.” In addition, a new note has been added to explain this change.

*Personnel performing work affecting **conformity to product requirements** shall be competent on the basis of appropriate education, training, skills and experience.*

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

**What does this mean to you? An organization would have a difficult time justifying that personnel within the management system would not be subject to this requirement.**

### Section 6.2.2 Competence, Training and Awareness

- Here, the title of this section of requirements has been changed from “Competence, Awareness and Training.” Also, the same change made in 6.2.1 (“product quality” to “conformity to product requirements”) has been made in clause (a):

*a) determine the necessary competence for personnel performing work affecting **conformity to product requirements**,*

- In clause (b), addition of the words “where applicable” clarifies that provision of training may not be required to achieve the necessary competence. Individuals may already have the necessary competencies and not require training.

*b) **where applicable**, provide training or take other actions to achieve the necessary competence,*

### Section 6.3 Infrastructure

- Information systems was added as an example of a supporting service:

*c) supporting services (such as transport, or communication, or **information systems**).*

### Section 6.4 Work Environment

- Examples have now been provided of conditions that could affect conformity to product requirements:

*Note: 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).*

### Section 7.1 Planning of Product Realization

- There has been a small change in subclause (b) and the addition of the word measurement in subclause (c).

*In planning product realization, the organization shall determine the following, as appropriate:  
b) the need to establish processes, **and** documents, and **to** provide resources specific to the product;  
c) required verification, validation, monitoring, **measurement**, inspection and test activities specific to the product and the criteria for product acceptance;*

### Section 7.2.1 Determination of Requirements Related to the Product

- There has been small changes in subclauses (c) and (d), and a new note has been added.

*The organization shall determine:*

- c) *statutory and regulatory requirements **applicable** to the product, and*
- d) *any additional requirements **considered necessary** by the organization.*

**Note:** *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.*

**What does this mean to you?** This note provides much needed clarification on the extent of post delivery activities. Of special note is the inclusion of “green services” such as recycling and final disposal.

### 7.3.1 Design and Development Planning

- A new note has been added.

**Note:** *Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.*

### 7.3.2 Design and Development Inputs

- Again, a small change: the word “these” has been changed to “the.”

*The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.*

### 7.3.3 Design and Development Outputs

- The word “provided” has been deleted. “A form that enables verification” has been changed to “a form suitable for verification.”

*The outputs of design and development shall be in a form **suitable for** verification against the design and development input and shall be approved prior to release.*

- A new note has been added to explain that design output should consider product preservation issues.

**Note:** *Information for production and service provision can include details for the preservation of product.*

### 7.5.1 Control of Production and Service Provision

- Changes have been made to subclauses (d) and (f).

d) *the availability of monitoring and measuring **equipment**,*  
f) *the implementation of **product** release, delivery, and post-delivery activities.*

### 7.5.2 Validation of Processes for Production and Service Provision

- There has been a small change in the first paragraph.

*The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring and measurement **and, as a consequence,** deficiencies become apparent only after the product is in use or the service has been delivered.*

### 7.5.3 Identification and Traceability

- This clause has been expanded to clarify that the product must be identified by suitable means “throughout product realization.” This applies to received product and in-process product, as well as final product.

*The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization.*

- The small change of moving the record keeping requirement to the end of the following sentence has changed the intent from recording the product identification to maintaining all records associated with product traceability.

*Where traceability is a requirement, the organization shall control the unique identification of the product **and maintain records** (see 4.2.4).*

### 7.5.4 Customer Property

- The wording has been changed for clarification and the note has been expanded to include personal data.

*If any customer property is lost, damaged, or otherwise found to be unsuitable for use, **the organization shall report this** to the customer and **maintain records** (see 4.2.4).*

*Note: Customer property can include intellectual property **and personal data**.*

### 7.5.5 Preservation of Product

- The wording has been changed for clarification.

*The organization shall preserve the product during internal processing and delivery to the intended destination **in order to maintain conformity to requirements**. As **applicable**, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to constituent parts of a product.*

### 7.6 Control of Monitoring and Measuring Equipment

- The word “device” has been replaced by “equipment” in the title and throughout this section of requirements. The reference to clause 7.2.1 at the end of the first sentence of this clause has been removed.

*The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring **equipment** needed to provide evidence of conformity of product to determined requirements.*

- In subclause (a), “calibrated or verified” has been changed to “calibrated or verified, or both.”

*Where necessary to ensure valid results, measuring **equipment** shall:*  
*a) be calibrated or verified, **or both**, at specified intervals, or prior to use, against measurable standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);*

- Subclause (c) has been reworded to clarify that it may not be necessary to physically identify some measuring equipment, as some types may already be identified.

***c) have identification in order to determine its calibration status;***

- The record keeping requirement is now its own paragraph:

***Records of the results of calibration and verification shall be maintained (see 4.2.4).***

- The last paragraph of clause 7.6 was deleted. A new note was added to clarify that confirmation of software includes verification and configuration management activities. In addition, the note referencing ISO 10012-1 and ISO 10012-2 has been deleted.

***Note: 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.***

## **8.1 General**

- Clause 8.1(a) has been reworded for clarification.

***The organization shall plan and implement the monitoring, measurement, analysis, and improvement processes needed  
a) to demonstrate conformity to product requirements,***

### **8.2.1 Customer Satisfaction**

- A new note has been added to provide examples of how customer satisfaction can be monitored.

***Note: Monitoring customer perception can 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.***

### **8.2.2 Internal Audit**

- The requirements in this section have been re-ordered. The requirement for a documented procedure is now first, and “establishing records” is before “reporting results” to emphasize that records should be captured throughout the audit.

***A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.***

- A new paragraph regarding records was added.

***Records of the audits and their results shall be maintained (see 4.2.4).***

- The word “actions” has been changed to “any necessary corrections and corrective actions.” In some cases, an immediate correction or containment action might be required before the root cause analysis and implementation of corrective actions.

***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.***



- References to ISO 10011-1, ISO 10011-2 and ISO 10011-3 in the note have been changed to ISO 19011, *Guidelines for Quality and/or Environmental Management Systems Auditing*.

*Note: See ISO 19011 for guidance.*

### **8.2.3 Monitoring and Measurement of Processes**

- This clause contains requirements for monitoring and measuring processes to ensure desired results are achieved. In the 2008 version, the words “to ensure conformity of product” have been deleted. Not all processes directly relate to conformity of product.

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

- A new note has been added to clarify what are suitable methods for monitoring and measuring processes.

***Note: When determining suitable methods, it is advisable that the organization 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.***

### **8.2.4 Monitoring and Measurement of Product**

- “Evidence of conformity with the acceptance criteria shall be maintained” has been moved to the preceding paragraph from its original location.

*The organization shall monitor and measure the characteristics of product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). **Evidence of conformity with the acceptance criteria shall be maintained.***

- Release of product is now defined as not to the next in-process stage, but to the customer.

*Records shall indicate the person(s) authorizing release of product **for delivery to the customer** (see 4.2.4).*

***The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.***

### **8.3 Control of Nonconforming Product**

- The requirement for a documented procedure has been moved to the beginning of the paragraph.

***A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.***

- The words “where applicable” have been added to the sentence below:

***Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:***

- An option (d), which is text from later in clause 8.3 of the 2000 version, has been added to the list of ways to deal with nonconforming product:

***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.***

- The following paragraphs have been re-ordered as follows:

*When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.*

*Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).*

#### **8.4 Analysis of Data**

- Additions and deletions of clause number references were made:

*The analysis of data shall provide information relating to*

- a) customer satisfaction (see 8.2.1)*
- b) conformity to product requirements (see 8.2.4)*
- c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and*
- d) suppliers (see 7.4).*

#### **8.5.2 Corrective Action**

- “Cause” is now plural to match with the plural “nonconformities.”

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

- Subclause (f) has been revised as follows:

- e) reviewing **the effectiveness** of the corrective action taken.*

**What does this mean to you? This is to clarify that subclause (f) relates to not just ensuring that corrective actions have been taken, but that they are indeed effective.**

#### **8.5.3 Preventive Action**

- The same change has been made to preventive action:

*e) reviewing **the effectiveness** of the preventive action taken.*

**Clause numbers not detailed above have no changes.**