

# ISO/FDIS 9001:2008 Overview

Sept. 22, 2008

ISO/FDIS 9001, the final draft of the upcoming ISO 9001:2008 standard, has been published and is available for purchase from both ANSI and the American Society for Quality (ASQ). Pending formal approval of the draft by the ISO membership, publication of the ISO 9001:2008 standard is expected in October or November of this year. According to a June 17<sup>th</sup> press release from the International Organization for Standardization (ISO), “The proposed ISO 9001:2008 does not introduce additional requirements compared to the last edition in 2000 and does not change the intent of ISO 9001:2000.” ISO’s process does not allow for changes to documents in the FDIS stage. The ISO membership either votes to approve and publish it, or votes against publication, so no further changes are expected between the FDIS and the ISO 9001:2008 standard.

While the clause numbering has not changed, and no new requirements have been added, there are numerous clarifications to the requirements. While many of the clarifications are only rearrangements of existing text and punctuation, others involve additional notes and text. It is possible that a previous misunderstanding of a requirement, or a partial fulfillment of a requirement, will be identified during an audit to the new standard. Companies’ management and/or management representatives should review ISO 9001:2008, and ensure that their quality management system effectively addresses the clarified requirements. In addition, internal audits should be conducted to ISO 9001:2008.

In mid-August of 2008, ISO stated that it “is now working on implementation guidance for ISO 9001:2008, a reference table comparing and contrasting ISO 9001:2000 and ISO 9001:2008 and answers to Frequently Asked Questions.”

## Changes in ISO/FDIS 9001

This document addresses the changes in ISO/FDIS 9001 that Orion Registrar feels are most likely to impact our clients. It is not a comprehensive list of all of the text and punctuation changes to ISO/FDIS 9001. A comprehensive list of the changes is available within ISO/FDIS 9001, in Appendix B.

### Vocabulary Changes

There are several words and phrases that have been changed throughout ISO/FDIS 9001.

- References to “regulatory requirements” have been changed to “statutory and regulatory requirements.” This can be seen in sections .0.1, 1.1 a) and b) and 1.2. In addition, a note was added to section 1.1 explaining that statutory and regulatory requirements can also be called legal requirements. Companies should keep in mind that statutory and regulatory requirements may come from the

location in which the product is created or from the country in which it is sold, or both

- References to “measuring devices” have been changed to “measuring equipment.” This can be seen in sections 7.5.1 d) and 7.6.
- References to “product quality” have been changed to “conformity to product requirements” in section 6.2.1 and 6.2.2 a). In addition, a note has been added to 6.2.1 stating that this new phrase can be affected “by personnel performing any task within the quality management system.”
- The word “identify” has been replaced with “determine” in sections 0.2 and 4.1.

### **Other Changes by Section**

#### Section 0.1

New text has been added stating that a business environment, or risks associated with that environment, influences a quality management system. Section 0.4 still states that this standard does not include requirements specific to risk management. It is left to each organization to determine the best approach for their management system. When addressing statutory and regulatory requirements, the words “applicable to the product” have been added.

#### Section 0.2

When defining a process, text has been changed to include a “set of activities” instead of just a single activity.

The words “to produce the desired outcome” have been added to the explanation of the process approach. This is part of an on-going effort to stress the importance of meeting an expected outcome or goal. More information on this can be found in an ISO/IAF Auditing Practices Group paper entitled “Output Matters.” It can be found on the following webpage: <http://isotc.iso.org/livelink/livelink/6024189/APG-OutputMatters.doc?func=doc.Fetch&nodeid=6024189>

#### Section 1.1

The note defining “product” has been enlarged. It now also includes “any intended output resulting from the product realization processes.” According to the committee drafting this document, this change was meant to help with outsourcing and to clarify that “Output Matters.”

When performing a process audit, auditors review the outputs of the steps within the integrated processes that produce the final product or service. They look at how the individual processes provide acceptable ‘product’ to internal customers for the next process in the product realization process. It is also important to remember that data and other information can also be “output”.

## Section 2.0

The section was revised to show that when a document is referenced in the standard (e.g. 19011), it is referring to the most current version of the document unless otherwise specified.

## Section 4.1

In e), the words “where applicable” have been added to the requirement to measure.

ISO FDIS 9001 has a lot of new text regarding outsourced processes. Companies should carefully review it and determine if they conform to the clarified requirements.

The last sentence in the last paragraph prior to the notes has been revised. It now says “The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.” This clarification may require some companies to expand on their documentation of their outsourced processes. Note 3 contains more information on this requirement.

Note 1 has been revised. The word “should” has been removed, and new processes have been added. It now says “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.” This clarifies the extensive scope of processes covered by these requirements.

Two new notes have been added. Note 2 says “An outsourced process is identified as one needed for the organization's quality management system but chosen to be performed by a party external to the organization.”

Note 3 says “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.”

The notes make clear that a process cannot be excluded from an organization's management system simply because it is an outsourced process. ISO previously published “Introduction and Support Package Guidance on 'Outsourced Processes” (Document: ISO/TC 176/SC 2/N 630R2). This document contains further information on outsourced processes and can be found at this webpage:

*[http://www.iso.org/iso/iso\\_catalogue/management\\_standards/iso\\_9000\\_iso\\_14000/more\\_resources\\_9000/guidance\\_on\\_outsourced\\_processes.htm](http://www.iso.org/iso/iso_catalogue/management_standards/iso_9000_iso_14000/more_resources_9000/guidance_on_outsourced_processes.htm)*

ISO/TC 176/SC 2/N 630R2 contains very useful information, including this statement “An outsourced process can be performed by a supplier that is totally independent from the organization, or which is part of the same parent organization (e.g. a separate department or division that is not subject to the same quality management system). It may be provided within the physical premises or work environment of the organization, at an independent site, or in some other manner.”

Many companies outsource one or more of their processes (i.e. calibration). Note 3 c) connects these requirements for outsourced processes with those of 7.4. These clarifications should cause organizations to carefully review the scope of their supplier management programs, and to look for areas for improvement.

#### Section 4.2.1

A change in wording has been made to clarify that records are needed both as required by ISO 9001, and as “determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.”

Sentences were also added to Note 1 to state that “a single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.”

#### Section 4.2.3 f)

The phrase “documents of external origin” has been modified to include “determined by the organization to be necessary for the planning and operation of the quality management system.” This clarifies which external documents must be controlled within the quality management system.

#### Section 4.2.4

The text in this section has been rearranged, and it now states that records shall be controlled.

#### Section 5.5.2

The requirements for the management representative have been clarified. The words “the organization’s” have been added to the first sentence which now says “Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes...”

According to the deputy task group leader of the international team responsible for amending the current version of ISO 9001, this requirement does not necessarily mean that this role must be filled by a full time employee. A contracted person is acceptable if they are involved in on-going management of the system. It would not be acceptable if the management representative was just involved during the management review.

## Section 6.2

The order of the words in the title of 6.2.2 has been changed to “Competence, training and awareness.”

6.2.2 b) has been changed to “where applicable, provide training or take other actions to achieve the necessary competence.”

## Section 6.3

Examples of supporting services, described in c), have been expanded to include information systems. Companies which have not considered all of their supporting services within the context of the requirements of 6.3 Infrastructure need to review how they meet these requirements.

## Section 6.4

A note has been added to clarify what is meant by work environment. It says “The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).” Companies which have taken a more narrow approach to this requirement need to revisit how they address the requirements of 6.4.

## Section 7.1

The word “measurement” has been added to c). Companies which have excluded measurement from their planning processes need to include it.

### Section 7.2.1

The word “related” has been changed to “applicable” in c). This was meant to remove ambiguity relating to non-product requirements which can be termed “related to the product.”

The word “determined” has been changed to “considered necessary” in d).

A note has been added which states “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.” Companies which have not considered all of their post-delivery activities within the context of the requirements of 7.2.1 need to review how they meet these requirements.

### Section 7.3.1

A note has been added to clarify that although design and development review, verification and validation have distinct purposes, they may be conducted and recorded separately or in any combination, as suitable for the product and the organization.

### Section 7.3.3

A note has been added saying “Information for production and service provision can include details for the preservation of product.” Companies which have not considered this aspect of design and development outputs may wish to include it.

### Section 7.5.1

The requirement in f) was changed to clarify that this requirement is related to the product.

### Section 7.5.2

The first paragraph of 7.5.2 has been reworded. The meaning has not been revised.

### Section 7.5.3

The second paragraph has been revised to clarify that this requirement applies “throughout product realization.” If a company previously believed that this requirement was more limited, for example to final product, then its process for identifying product status would need to be expanded.

The third paragraph has been revised to include the phrase “maintain records.”

### Section 7.5.4

The last sentence has been revised to clarify that it is the organization’s responsibility to report to the customer “if any customer property is lost, damaged or otherwise found to be unsuitable for use.”

The note giving examples of customer property has been expanded to include “personal data.” Organizations dealing with customer’s personal data should seriously consider how they apply the requirements in 7.5.4.

### Section 7.5.5

This section has been modified to clarify that preserving the conformity of the product means preserving conformity to requirements.

The words “as applicable” have been added to the second sentence.

### Section 7.6

“In a), the words “be calibrated or verified” have been changed to “be calibrated or verified or both.”

“See 4.2.4” was added to a) to clarify that the information that is being recorded is to be maintained as a record.

The text in c) now states “have identification in order to determine its calibration status.”

The records requirement is now a separate paragraph and clarifies that the requirement applies to more than a single paragraph within 7.6.

The note has been revised to say “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.” If a company has not considered configuration management in this context before, it should investigate this application.

### Section 8.1

The text in a) has been changed to say “to demonstrate conformity to product requirements.” It previously said “conformity of the product.”

### Section 8.2.1

A note has been added which gives examples of sources of customer perception. It says “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.” Organizations may wish to expand their sources of customer perception in order to gain better accuracy.

### Section 8.2.2

The requirement for records of the audits and their results has been split out and made into its own paragraph.

The first sentence of the last paragraph has been changed to “...ensure that any necessary correction and corrective actions are taken...” Previously, the text just said “...ensure that actions are taken...” This approach may be new to many organizations. These terms are defined in ISO 9000.

- Correction is “Action to eliminate a detected nonconformity.” It is also called commonly called “containment.”
- Corrective action is “Action to eliminate the cause of a detected nonconformity or other undesirable situation.”

The note in this section now references ISO 19011 instead of the outdated ISO 10011 documents.

### Section 8.2.3

The last sentence was revised, which results in an expanded scope for this requirement. It previously said “When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.” The clause was revised to delete the phrase “to ensure conformity of the product.” It now says “...correction and corrective action shall be taken, as appropriate.” Since the requirement is no longer tied solely to product conformity, appropriate actions may include those regarding the monitoring or measurement of the processes, or regarding the processes themselves.

A note has been added saying “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.”

#### Section 8.2.4

Two changes have been made in this section to clarify that when this section refers to release of product, it means release of product (or service) for delivery to the customer.

#### Section 8.3

The words “as applicable” have been added to the beginning of the sentence “The organization shall deal with nonconforming product by one or more of the following ways:”

#### Section 8.4

“See 7.2.1” has been changed to “see 8.2.4” in b).

“See 8.2.3 and 8.2.4” has been added to c).

“See 7.4” has been added to d).

#### Section 8.5.2

The word “cause” has been replaced by “causes” in the first sentence. It may be a change for some companies to take appropriate actions when multiple causes are identified.

The text in f) has been revised to say “reviewing the effectiveness of the corrective action taken.”

#### Section 8.5.3

The text in e) has been revised to say “reviewing the effectiveness of the preventive action taken.”

#### Appendix B

It lists all of the changes to ISO/FDIS 9001.

#### Bibliography

It has been updated with appropriate documents and revisions. It contains a wealth of resources of which your company may be unaware.