

SUMMARY OF CHANGES IN ISO 9001:2008 (DRAFT INTERNATIONAL STANDARD)

Disclaimer

- This update on the ISO 9001:2008 amendment is based on the Draft International Standard (DIS) published in September 2007.
- While minimal changes are expected during the next comment phase, the contents are subject to change and should not be used in any contractual or legally binding agreements.

CLAUSE	SUMMARY OF CHANGE
0.1 Introduction – General	<ul style="list-style-type: none"> • Added the phrase “by business environment and its changes, its associated risks,” to the first paragraph to the first paragraph
0.2 Process Approach	<ul style="list-style-type: none"> • Added the phrase “to produce the desired outcome” to the third paragraph to emphasize that output matters.
0.4 Compatibility with other management systems	<ul style="list-style-type: none"> • Revised the first paragraph to indicate that the provisions of the most recent version of ISO 14001 were taken into consideration during the revision.
1.1 Scope – General	<ul style="list-style-type: none"> • Revised this section to include statutory requirements. • Revised NOTE in ISO 9001:2000 to clarify what is meant by product. Product includes output resulting from product realization processes and purchasing. • Note 2 was added to provide an explanation that statutory and regulatory requirements can also be called legal requirements.
1.2 Application	<ul style="list-style-type: none"> • Revised Paragraph 3 to include statutory requirements.
2.0 Normative Reference	<ul style="list-style-type: none"> • Revised this section to show that when a document is referenced in the standard (e.g. 19011), it is referring to the most current version

	<p>of the document unless otherwise specified.</p> <ul style="list-style-type: none"> • ISO 9000 • ISO 9000:2005
3.0 Terms and Definitions	<ul style="list-style-type: none"> • Deleted the text of this clause relating to the transition of the supply chain from 1994 to 2000. This includes the explanation of supplier, organization, and customer, • The text related to the fact that product can also remain service remains.
4.1 General Requirements	<ul style="list-style-type: none"> • a) replaced identify with determine • e) adding (where applicable) after measure. • In the last paragraph revised controls to type and extent of control to be applied. Deleted the word “should” in the note and added “analysis and improvement.” • Added Note 2 to explain that outsourced processes are those needed by the organization but that the organization chooses to be performed by an external party. • Added Note 3 to explain that the amount of control that the organization is applying to the outsourced process is influenced by details such as what is the impact of the outsourced process on overall product realization in the organization, any shared control with the organization and the external party, controlling the process through clause 7.4. • Note 3 also addresses the fact that outsourcing does not remove any responsibility of the organization to conform to customer, statutory and regulatory requirements.
4.2.1 Documentation Requirements – General	<ul style="list-style-type: none"> • Added records to paragraphs c) and d) and deleted e) which specifically addressed records. • Added records to paragraph d). • Revised to include words to show that the documents and records to be controlled are those that the organization determines to be necessary. • Revised Note 1 to provide guidance that procedures can be combined into a single document or covered by more than one document.
4.2.3 Control of Documents	<ul style="list-style-type: none"> • Revised f) to indicate that the documents of the external original are those determined by the organization to be necessary.

4.2.4 Control of Records	<ul style="list-style-type: none"> • Editorial changes including restructuring the clause. • Changed records shall be maintained to records shall be controlled.
5.5.2 Management Representative	<ul style="list-style-type: none"> • Added the words “the organization’s” to management in the first paragraph.
6.2 Human Resources 6.2.1 General	<ul style="list-style-type: none"> • Changed product quality to conformity to product requirements. • Added note that indicates conformity to product requirements may be affected by personnel who are indirectly or directly with tasks within the quality management system.
6.2.2 Competence, Training and Awareness	<ul style="list-style-type: none"> • Clause a) was revised to delete the words product quality. • Clause b) was revised to add “where applicable” and revised the sentence to address necessary competence versus the satisfaction of needs. • Clause c) was revised to emphasize that the necessary competence has been achieved.
6.3 Infrastructure	<ul style="list-style-type: none"> • Added information systems as an example in clause c).
6.4 Work Environment	<ul style="list-style-type: none"> • Added note to provide examples of what work environment relates to. Examples include physical, noise, temperature, humidity, and weather.
7.1 Planning of Product Realization	<ul style="list-style-type: none"> • Editorial change to clause b). • Added measurement in clause c).
7.2.1 Determination of Requirements Related to Product	<ul style="list-style-type: none"> • a) Added a common and the word for in front of post-delivery. • c) revised related to applicable. • d) revised determined to considered necessary/ • Added note that describes what are considered post-delivery activities. These include warranty provisions, contractual obligations, and maintenance services.
7.3.1 Design and Development Planning	<ul style="list-style-type: none"> • Added note that explains that review, verification, and validation are activities with a unique purpose. These activities and records can be conducted separately or at the same time.

7.3.2 Design and Development Inputs	<ul style="list-style-type: none"> • In the last paragraph changed “These inputs” to “The inputs.”
7.3.3 Design and Development Outputs	<ul style="list-style-type: none"> • Revised the first paragraph with an editorial change. • Added a note to indicate that preservation of product needs to be considered in the design and development outputs.
7.5.1 Control of Production and Service Provision	<ul style="list-style-type: none"> • Revised devices to equipment in clause d). • Revised clause f) by adding the word product to release.
7.5.2 Validation of Production and Service Provision	<ul style="list-style-type: none"> • Revised first paragraph by making editorial changes to emphasize what processes this clause is referring to. The words “as a consequence” were added to when the deficiencies are identified only after the product is in use.
7.5.3 Identification and Traceability	<ul style="list-style-type: none"> • Paragraph two was revised to add the phrase “throughout product realization” at the end of the sentence. • Paragraph 3 was revised to use “maintain records.”
7.5.4 Customer Property	<ul style="list-style-type: none"> • Revised the last sentence of the clause, which addresses records, with an editorial change. • The note was revised to address personal data.
7.5.5 Preservation of Product	<ul style="list-style-type: none"> • In the first sentence deleted “conformity of” in front of product. • In the second sentence replaced this with “as applicable.”
7.6 Control of Monitoring and Measuring Equipment Devices	<ul style="list-style-type: none"> • Revised devices to equipment in the first paragraph • In clause a) added or both after calibrated or verified. • In clause c) changed be identified to have identification. • Deleted Note referring to 10012 • Added Note that explains that confirmation of software includes verification and configuration to maintain its suitability for use.
8.1 General	<ul style="list-style-type: none"> • Revised clause a) from product to product requirements.

8.2.1 Customer Satisfaction	<ul style="list-style-type: none"> Added a note that identifies that sources of information for customer perception can be surveys, data on products delivered to customers, and compliments.
8.2.2 Internal Audit	<ul style="list-style-type: none"> This clause was restructured. The last paragraph was revised to include necessary corrections and corrective with any actions taken. The reference to 10011 was revised to 19011.
8.2.3 Monitoring and Measuring of Processes	<ul style="list-style-type: none"> The clause was revised to delete the phrase “to ensure conformity of the product.” A note was added to emphasize that the type and extent of monitoring and measurements is dependent on the product’s impact to the quality management system.
8.2.4 Monitoring and Measuring of Product	<ul style="list-style-type: none"> Restructured the paragraph to more clearly show that the records that are to me maintained are those that are authorizing release of the product or deliver to the customer.
8.3 Control of Nonconforming Product	<ul style="list-style-type: none"> Restructured clause. Added the words “where practicable” to paragraph 2. Moved the last paragraph of the clause to the list making it item d)
8.5.2 Corrective Action	<ul style="list-style-type: none"> Revised the first paragraph from cause to “causes.”