



ISO 9001:2008 Published

Rev A: January, 2009

Transitioning from ISO 9001:2000 to ISO 9001:2008

Effective November 15, 2008, the long awaited revision to ISO 9001 is available at www.iso.org, www.webstore.ansi.org or www.asq.org and can be downloaded in a .pdf format. The International Accreditation Forum www.iaf.nu has set the following rules for transition:

- Transition can occur anytime within 2 years from the date of publication - up to November 15, 2010. At that time any ISO 9001:2000 certifications will expire, regardless of the expiration date on your current certificate.
- Transition must occur concurrent with a regularly scheduled surveillance or re-registration audit (including ISO 9001:2008 requirements) followed by a registration decision by Advantage.
- Any NEW registrations to ISO 9001:2000 are permitted for one year – up to November 15, 2009
- Any NEW registrations after November 15, 2009, must be to ISO 9001:2008.

Advantage international Registrar, Inc. recommends organizations seeking transition to do the following:

- Obtain a copy of ISO 9001:2008 (See above)
- Review the changes and any impacts to your organization (Annex B of ISO 9001:2008 lists all of the changes (Text Additions and Deletions) AND changes are also attached to this Bulletin.
- Incorporate the changes into Quality Manuals and any procedures (as appropriate to your organization)
- Document any significant impacts in your Management Review process and ensure that changes are implemented.

Notification to Advantage

- In order to support a smooth transition, please notify us prior to your next regularly scheduled surveillance or re-registration audit whether you will be transitioning during that particular audit. **Our auditors will not arrive prepared for transition without prior notification.**

Training

- Industry consensus is that the changes are just clarifications and improvements to the standard. As such, no training is currently required to be “qualified” with these changes. However, if you are interested in some transition training, please visit www.advantageregistrar.info for available times and locations. We will try to accommodate all of our clients with training in your area.

Changes between ISO 9001:2000 and ISO 9001:2008

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text	Impact
0.1	Para 1, Sentence 2	D	The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization.	None
0.1	Para 1, Sentence 2	A	The design and implementation of an organization's quality management system is influenced by a) its organizational environment, change 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.	Initial system planning. Introduction of "risk analysis"
0.1	Sentence 3	Now a new para.	It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.	None
0.1	Para 4,	A	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.	More emphasis on statutory requirements.
0.2	Para 2	D + A	For an organization to function effectively, it has to identify 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.	
0.2	Para 3	A	The application of a system 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".	
0.3	Para 1	D + A	The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of are quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.	None
0.3	Para 3	D + A	ISO 9004 gives a guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a	None Reference to ISO 9004 only

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			<p>guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.</p> <p>At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.</p>	
0.4	Para 1	D + A	<p>This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.</p> <p>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. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004.</p>	None Alignment with ISO 14001 only
1.1		D + A	<p>a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and</p> <p>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.</p> <p>NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.</p> <p>NOTE 1 In this International Standard, the term "product" only applies to</p> <p>a) a product intended for, or required by, a customer,</p> <p>b) any intended output resulting from the product realization processes.</p> <p>NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.</p>	More emphasis on statutory requirements.
1.2	Para 3	A	<p>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,</p>	More emphasis on statutory requirements.

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			or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.	
2	Para 1	D + A	The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards. The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.	None Reference to ISO 9000:2005
2	Para 1	D + A	ISO 9000:2000 2005 , Quality management systems — Fundamentals and vocabulary	None Reference to ISO 9000:2005
3	Para 1	D + A	For the purposes of this document International Standard, the terms and definitions given in ISO 9000 apply.	None
3	Para 2,3	D	The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used: supplier — organization — customer The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “subcontractor”.	None

4.0 Quality Management System

4.1	Bullet a	D + A	a) identify determine the processes needed for the quality management system and their application throughout the organization (see 1.2),	
4.1	Bullet e	A	e) monitor, measure where applicable , and analyse these processes, and	
4.1	Para 4	D + A	Where an organization chooses to outsource any process that affects product conformity with 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.	
4.1	Note 1	D + A	NOTE 1 Processes needed for the quality	

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			management system referred to above should include processes for management activities, provision of resources, product realization, and measurement, analysis and improvement.	
4.1	New Note 2	A	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.	
4.1	New Note 3	A	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.	
4.2.1	Bullet c)	A	c) documented procedures and records required by this International Standard, and	
4.2.1	Bullet d)	D + A	d) documents, including records, needed determined by the organization to be necessary to ensure the effective planning, operation and control of its processes. and	
4.2.1	Bullet e)	A	e) records required by this International Standard (see 4.2.4):	None
4.2.1	Note 1	A	NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. 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.	
4.2.3	Bullet f)	A	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 their distribution controlled, and	
4.2.4	Para 1	D + A	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled . Records shall remain legible, readily identifiable and retrievable. The organization shall establish a documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. Records shall remain legible, readily identifiable and retrievable.	

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5.0 Management Responsibility

5.5.2	Para 1	A	Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes	

6.0 Resource Management

6.2.1	Para 1	A + D	Personnel performing work affecting conformity to product quality requirements shall be competent on the basis of appropriate education, training, skills and experience.	
6.2.1	New Note	A	NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.	
6.2.2	Clause title	A + D	Competence, training and awareness and training	None
6.2.2	Bullets a) & b)	A + D	a) determine the necessary competence for personnel performing work affecting conformity to product quality requirements , b) where applicable , provide training or take other actions to satisfy these needs achieve the necessary competence .	
6.3	Bullet c)	A	c) supporting services (such as transport, communication or information systems).	
6.4	New note	A	NOTE 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).	

7.0 Product Realization

7.1	Bullet b)	A + D	b) the need to establish processes and documents, and to provide resources specific to the product;	None
7.1	Bullet c)	A	c) required verification, validation, monitoring, measurement , inspection and test activities specific to the product and the criteria for product acceptance;	
7.2.1	Bullet c)	A + D	c) statutory and regulatory requirements related applicable to the product, and	None
7.2.1	Bullet d)	A + D	d) any additional requirements determined considered necessary by the organization.	
7.2.1	New note	A	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	

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			disposal.	
7.3.1	New note	A	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	Para 2	A + D	These The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	None
7.3.3	Para 1	A + D	The outputs of design and development shall be provided in a form that enables in a form suitable for verification against the design and development input and shall be approved prior to release.	
7.3.3	Bullet b)	D	b) provide appropriate information for purchasing, production and for service provision,	None
7.3.3	New note	A	NOTE Information for production and service provision can include details for the preservation of product.	
7.3.7	Para 1 & 2	No text change. Paras now merged	Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).	None
7.5.1	Bullet d)	A + D	d) the availability and use of monitoring and measuring devices equipment,	
7.5.1	Bullet f)	A	f) the implementation of product release, delivery and post-delivery activities.	
7.5.2	Para 1	A + D	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement This includes any processes where and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.	
7.5.3	Para 2	A	The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.	
7.5.3	Para 3	A + D	Where traceability is a requirement, the organization shall control and record the unique identification of the product and maintain records (see 4.2.4).	
7.5.4	Para 1, Sentence 3	A + D	If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained the organization shall report this to the customer and maintain records (see 4.2.4).	
7.5.4	Note	A	NOTE Customer property can include intellectual property and personal data.	
7.5.5	Para 1	A + D	The organization shall preserve the conformity of	

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			product during internal processing and delivery to the intended destination in order to maintain conformity to requirements . This As applicable , preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	
7.6	Title	A + D	Control of monitoring and measuring devices equipment	
7.6	Para 1	A + D	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices equipment needed to provide evidence of conformity of product to determined requirements (see 7.2.1).	
7.6	Bullet a)	A	a) be calibrated or verified, or both , at specified intervals, or prior to use, against measurement 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);	
7.6	Bullet c)	A + D	e) be identified to enable the calibration status to be determined ; c) have identification in order to determine its calibration status ;	
7.6	Para 4, Sentence 3	Now new para 5, without change.	Records of the results of calibration and verification shall be maintained (see 4.2.4).	None
7.6	Note	A + D	NOTE See ISO 10012-1 and ISO 10012-2 for guidance 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.	

8.0 Measurement, Analysis and Improvement

8.1	Bullet a)	A + D	a) to demonstrate conformity of the product to product requirements ,	
8.2.1	New note	A	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 and dealer reports.	
8.2.2	Para 2 Sentence 3	A	The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.	None
8.2.2	New para 3	A	A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.	
8.2.2	Para 3	Now	The responsibilities and requirements for planning	

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		Para 4 D + A	and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. Records of the audits and their results shall be maintained (see 4.2.4).	
8.2.2	Para 4, Sentence 1	Now Para 5 A	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.	
8.2.2	Note	A + D	NOTE See ISO 10011-1, ISO 10011-1 and ISO 10011-3. See ISO 19011 for guidance.	None
8.2.3	Para 1, Sentence 3	D	When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.	
8.2.3	New note	A	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	Para 1	A	The organization shall monitor and measure the characteristics of the 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.	
8.2.4	Para 2	A + D	Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).	
8.2.4	Para 3	A + D	Product release and service delivery 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	Para 1, Sentence 2	A + D	The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.	None
8.3	Para 2	A	Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:	
8.3	New Bullet d)	A	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.	

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8.3	Para 3	Moved to Be Para 4	Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4)	
8.3	Para 4	Moved to Be Para 3	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).	
8.3	Para 5	Now new bullet d)	When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.	None
8.4	Bullet b)	A + D	b) conformity to product requirements (see 7.2.4) (see 8.2.4).	None
8.4	Bullet c)	A	c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and	None
8.4	Bullet d)	A	d) suppliers (see 7.4).	None
8.5.2	Para 1	A + D	The organization shall take action to eliminate the cause causes of nonconformities in order to prevent recurrence.	
8.5.2	Bullet f)	A	f) reviewing the effectiveness of the corrective action taken.	
8.5.3	Bullet e)	A	e) reviewing the effectiveness of the preventive action taken.	

Annex A	All	A + D	Updated to reflect ISO 9001:2008 versus ISO 14001:2004
Annex B	All	A + D	Updated to reflect ISO 9001:2008 versus ISO 9001:2000