

Annex B (informative)

Changes between ISO 9001:2000 and ISO 9001:2008

Table B.1 — 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
Foreword	Para 2	D + A	International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3 Part 2.
Foreword	Para 3, Sentence 1	A	The main task of technical committees is to prepare International Standards.
Foreword	Para 4, Sentence 1	D + A	Attention is drawn to the possibility that some of the elements of this International Standard document may be the subject of patent rights.
Foreword	Para 5	D	International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC 2, Quality systems.
Foreword	Para 6	D	This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.
		A	This fourth edition cancels and replaces the third edition (ISO 9001:2000), which has been technically revised.
Foreword	Para 7	D	The title of ISO 9001 has been revised in this edition and no longer includes the term "Quality assurance". This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.
Foreword	Para 8	D	Annexes A and B of this International Standard are for information only.
Foreword	New para 7	A	Details of the changes between the third edition and this fourth edition are given in Annex B.
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.
		A	The design and implementation of an organization's quality management system is influenced by its business environment, changes in that environment or risks associated with that environment, its varying needs, its particular objectives, the products it provides, the processes it employs, its size and organizational structure.
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.
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 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.
0.3	Note	A	NOTE At the time of the publication of this International Standard, ISO 9004 is under revision.

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (continued)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text
0.4	Para 1	D + A	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. <u>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.</u>
1.1	Bullet a)	A	a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
	Bullet b)	A	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	D	NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.
		A	<u>NOTE 1 In this International Standard, the term "product" only applied to</u> <u>— a product intended for, or required by, a customer.</u> <u>— any intended output resulting from the product realization processes.</u>
	New Note 2	A	<u>NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.</u>
1.2	Para 3	A	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.
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 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.
		A	<u>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.</u>
		D + A	<u>ISO 9000:20052005, Quality management systems — Fundamentals and vocabulary</u>
3	Paras 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".
4.1	Bullet a)	D + A	a) identify <u>determine</u> 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 management system referred to above should include processes for management activities, provision of resources, product realization and measurement, analysis and improvement.

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (continued)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text
4.1	New Notes 2 & 3	A	<p>NOTE 2 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.</p> <p>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</p> <p>a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,</p> <p>b) the degree to which the control for the process is shared,</p> <p>c) the capability of achieving the necessary control through the application of Clause 7.4.</p>
4.2.1	Bullet c)	A	c) documented procedures and records required by this International Standard, and
4.2.1	Bullet d)	A + D	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)	D	e) records required by this International Standard (see 4.2.4).
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.
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
6.2.1	Para 1 New Note	A + D A	Personnel performing work affecting conformity to product quality requirements shall be competent on the basis of appropriate education, training, skills and experience. 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
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 conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting, or weather).
7.1	Bullet b)	A + D	b) the need to establish processes and documents , and to provide resources specific to the product;
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;

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (continued)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text
7.2.1	Bullet c) Bullet d), New Note	D + A D + A A	c) statutory and regulatory requirements related applicable to the product, and d) any additional requirements determined considered necessary by the organization. <u>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.</u>
7.3.1	New Note	A	<u>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.</u>
7.3.2	Para 2	D + A	These The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.
7.3.3	Para 1	D + A	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	New Note	A	<u>NOTE Information for production and service provision can include details for the preservation of product.</u>
7.5.1	Bullet d)	D + A	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	D + A	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	D + A	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 Note	D + A A	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). <u>NOTE Customer property can include intellectual property and personal data.</u>
7.5.5	Para 1	D + A	The organization shall preserve the conformity of 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	D + A	Control of monitoring and measuring devices equipment
7.6	Para 1	D + A	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 7.2.4).
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)	D + A	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).
7.6	Note	D + A	Note See ISO 10012-1 and ISO 10012-2 for guidance <u>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.</u>

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (continued)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text
8.1	Bullet a)	D + A	a) to demonstrate conformity of the product to product requirements.
8.2.1	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, dealer reports.
8.2.2	New Para 2	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	D + A	The responsibilities and requirements for planning 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	A	The management responsible for the area being audited shall ensure that <u>any necessary corrections and corrective actions</u> are taken without undue delay to eliminate detected nonconformities and their causes.
8.2.2	Note	D + A	NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3. See ISO 19011 for guidance.
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	Note	A	<u>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.</u>
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). <u>Evidence of conformity with the acceptance criteria shall be maintained.</u>
	Para 2	D + A	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).
	Para 3	D + A	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	D + A	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.
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	<u>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.</u>
	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)
	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).
	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.
8.4	Bullet b)	D + A	b) conformity to product requirements (see 7.2.1) <u>(see 8.2.4).</u>
	Bullet c)	A	c) characteristics and trends of processes and products, including opportunities for preventive action <u>(see 8.2.3 and 8.2.4), and</u>
	Bullet d)	A	d) suppliers <u>(see 7.4).</u>

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (continued)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or Deletion (D)	Amended text
8.5.2	Para 1	D + A	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	D + A	Updated to reflect ISO 9001:2008 versus ISO 14001:2004
Annex B	All	D + A	Updated to reflect ISO 9001:2008 versus ISO 9001:2000
Bibliography	New and amended references	D + A	Updated to reflect new standards (including ISO 9004, currently under revision), new editions of standards, or withdrawn standards.