

Comparison between ISO/FDIS 9001:2008 and ISO 9001:2000

Clause	Old Text (ISO 9001:2000)	New text (ISO/FDIS 9001:2008)
0.1 General 1 st paragraph	The design and implementation of an organization's quality management system is influenced by varying needs,.....	The design and implementation of an organization's quality management system is influenced by: <i>its business environment, changes in that environment, or risks associated with that environment</i> ; its varying needs;.....
0.1 General 3 rd paragraph	This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.	This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, <i>statutory and regulatory requirements applicable to the product</i> , and the organization's own requirements.
0.2 Process Approach 2 nd paragraph	For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.	For an organization to function effectively, it has to <i>determine</i> and manage numerous linked activities. An activity <i>or set of activities</i> using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.
0.2 Process Approach 3 rd paragraph	The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".	The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management <i>to produce the desired outcome</i> , can be referred to as the "process approach".
0.3 Relationship with ISO 9004 (1st Para)	The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently.....	ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other, but can also be used independently.
0.4 Compatibility with other management systems 1 st paragraph	During the development of this International Standard, due consideration has been taken of the provisions of ISO 14001:1996 to enhance the compatibility of the two standards for the benefit of the user community.	During the development of this International Standard, due consideration <i>was given to</i> the provisions of <i>ISO 14001:2004</i> to enhance the compatibility of the two standards for the benefit of the user community.

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1.1 General	a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements	a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements
1.1 General	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 regulatory requirements.	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.
1.1 General	NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.	In this International Standard, the term "product" only applies to: <ul style="list-style-type: none"> • product intended for or required by a customer • any intended output resulting from the product realisation processes
1.1 General	-	NOTE 2 Statutory and regulatory requirements may be expressed as legal requirements.
1.2 Application 3 rd paragraph	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 regulatory requirements.	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 Normative reference	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.	<i>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.</i>
2 Normative reference 2 nd paragraph	ISO 9000:2000, Quality management systems — Fundamentals and vocabulary	ISO 9000: 2005 <i>Quality management systems — Fundamentals and vocabulary</i>

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3 Terms and definitions 2 nd & 3 rd paragraphs	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”.	<i>Deleted</i>
4.1 General requirements 2 nd paragraph	a) identify the processes needed for the quality management system	a) determine the processes needed for the quality management system
4.1 General requirements 2 nd paragraph	e) monitor, measure and analyse these processes	e) monitor, measure (where applicable), and analyse these processes
4.1 General requirements 4 th paragraph	Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.	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.
4.1 General requirements	NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.	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 .
4.1 General requirements	-	NOTE 2 <i>An outsourced process is identified as one being needed for the organization’s quality management system but chosen to be performed by a party external to the organization.</i>

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4.1 General requirements	-	<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.</p> <p>The type and extent of control to be applied to the outsourced process may 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 Documentati on requirements – General	c) documented procedures required by this International Standard	c) documented procedures and records required by this International Standard, and
4.2.1 Documentati on requirements - General	<p>d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and</p> <p>e) records required by this International Standard (see 4.2.4).</p>	d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.
4.2.1 Documentati on requirements - General	NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.	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.

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4.2.3 Control of documents	f) to ensure that documents of external origin are identified and their distribution 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 their distribution controlled,
4.2.4 Control of records	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.	<p>Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.</p> <p>The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.</p> <p>Records shall remain legible, readily identifiable and retrievable.</p>
5.5.2 Management representative	Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes	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 Human resources - General	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.	<p>Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.</p> <p>NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.</p>
6.2.2 Competence, training and awareness	Title - Competence, awareness and training	Title - Competence, training and awareness
6.2.2 Competence, training and awareness	The organization shall a) determine the necessary competence for personnel performing work affecting product quality,	The organization shall a) determine the necessary competence for personnel performing work affecting conformity to product requirements

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6.2.2 Competence, training and awareness	b) provide training or take other actions to satisfy these needs	b) where applicable , provide training or take other actions to achieve the necessary competence ,
6.3 Infrastructure	c) supporting services (such as transport or communication).	c) supporting services (such as transport, communication or information systems).
6.4 Work environment	The organization shall determine and manage the work environment needed to achieve conformity to product requirements.	The organization shall determine and manage the work environment needed to achieve 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).
7.1 Planning of product realization	b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance	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;
7.2.1 Determination of requirements related to the product	The organization shall determine:..... c) statutory and regulatory requirements related to the product	The organization shall determine:..... c) statutory and regulatory requirements applicable to the product
7.2.1 Determination of requirements related to the product	The organization shall determine..... d) any additional requirements determined by the organization	The organization shall determine..... d) any additional requirements considered necessary by the organization.

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7.2.1 Determination of requirements related to the product	-	<i>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.</i>
7.3.1 Design and development planning	-	<i>NOTE 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.</i>
7.3.2 Design and development inputs 2 nd paragraph	These inputs shall be reviewed for adequacy.	<i>The</i> inputs shall be reviewed for adequacy.
7.3.3 Design and development outputs	The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.	The outputs of design and development shall be provided in a form suitable for verification against the design and development input and shall be approved prior to release. <i>NOTE Information for production and service provision can include details for the preservation of product.</i>
7.5.1 Control of production and service provision	d) the availability and use of monitoring and measuring devices, f) the implementation of release, delivery and post-delivery activities.	d) the availability and use of monitoring and measuring devices equipment , f) the implementation of product release, delivery and post-delivery activities.
7.5.2 Validation of processes for production and service provision	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 deficiencies become apparent only after the product is in use or the service has been delivered.	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement, and as a consequence , deficiencies become apparent only after the product is in use or the service has been delivered.

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7.5.3 Identification and traceability 2 nd paragraph	The organization shall identify the product status with respect to monitoring and measurement requirements.	The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.
7.5.3 Identification and traceability 3 rd paragraph	Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).	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 Customer property	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 (see 4.2.4).	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).
7.5.4 Customer property	NOTE Customer property can include intellectual property	NOTE Customer property can include intellectual property and personal data.
7.5.5 Preservation of product	The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection.	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
7.6 Control of monitoring and measuring equipment 1 st paragraph	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).	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 (see 7.2.1).

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7.6 Control of monitoring and measuring equipment 3 rd paragraph	Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified at specified intervals,	Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified, or both , at specified intervals,
7.6 Control of monitoring and measuring equipment 3 rd paragraph	Where necessary to ensure valid results, measuring equipment shall..... c) be identified to enable the calibration status to be determined	Where necessary to ensure valid results, measuring equipment shall..... c) have identification in order to determine its calibration status;
7.6 Control of monitoring and measuring equipment Note	NOTE See ISO 10012-1 and ISO 10012-2 for guidance.	Deleted
7.6 Control of monitoring and measuring equipment	In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).	In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected . Records of the results of calibration and verification shall be maintained (see 4.2.4).
7.6 Control of monitoring and measuring equipment	-	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.

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8.1 Measurement, analysis and improvement – General 1 st paragraph	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity of the product	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	-	NOTE <i>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</i>
8.2.2 Internal audit New 3 rd paragraph	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.	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 Internal audit New 4 th paragraph	-	Records of the audits and their results shall be maintained (see 4.2.4).
8.2.2 Internal audit 4 th paragraph (becomes 5 th paragraph)	The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.	The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay
8.2.2 Internal audit	NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.	NOTE See ISO 19011 for guidance.
8.2.3 Monitoring and measurement of processes	When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.	When planned results are not achieved, correction and corrective action shall be taken, as appropriate

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8.2.3 Monitoring and measurement of processes	-	NOTE When determining suitable methods, the organization should 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 1 st paragraph	-	Text added after 2 nd sentence Evidence of conformity with the acceptance criteria shall be maintained.
8.2.4 Monitoring and measurement of product 2 nd Paragraph	Records shall indicate the person(s) authorizing release of product (see 4.2.4).	Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).
8.2.4 Monitoring and measurement of product 3 rd paragraph	Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed.....	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.....
8.3 Control of nonconforming product 1 st paragraph	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 Control of nonconforming product 2 nd paragraph	The organization shall deal with nonconforming product by one or more of the following ways.....	Where applicable , the organization shall deal with nonconforming product by one or more of the following ways

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8.3 Control of nonconforming product (2 nd & 5 th paragraphs)	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.	Where practicable, the organization shall deal with nonconforming product by one or more of the following ways:..... <i>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.</i>
8.3 Control of nonconforming product 3rd & 4 th paragraphs	Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4). When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. .	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	The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers.	The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1), b) conformity to product requirements (<i>see 8.2.4</i>), c) characteristics and trends of processes and products including opportunities for preventive action (<i>see 8.2.3 and 8.2.4</i>), and d) suppliers (<i>see 7.4</i>).
8.5.2 Corrective action 1 st paragraph	The organization shall take action to eliminate the cause of nonconformities	The organization shall take action to eliminate the <i>causes</i> of nonconformities
8.5.2 Corrective action	A documented procedure shall be established to define requirements for..... f) reviewing corrective action taken.	A documented procedure shall be established to define requirements for..... f) reviewing <i>effectiveness of the</i> corrective action taken.
8.5.3 Preventive action	A documented procedure shall be established to define requirements for..... f) reviewing preventive action taken.	A documented procedure shall be established to define requirements for..... f) reviewing <i>effectiveness of the</i> preventive action taken.

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Bibliography	Various bibliographical references	All references updated, plus reference added to <ul style="list-style-type: none">• ISO Handbook, ISO 9001:2000 for Small Businesses – What to do; Advice from ISO/TC 176• ISO/IAF Auditing Practices Group website http://www.iso.org/tc176/ISO9001AuditingPracticesGroup