# Guide to ISO 9001:2008 Changes

## Objective:

This document identifies the changes between 9001:2000 and 9001:2008. In essence, there are no new requirements or major changes. Amendments have been made to bring more clarity to the clauses.

Words *in italics* and highlighted in yellow are the changes in ISO 9001:2008.

**Red** & **bold** text in the 'Remarks' column identify changes that need a little more attention.

*Disclaimer: Whilst this document endeavours to identify and describe all the changes definitive reference should always be made to the Standard ISO 9001:2008.*

| Clause Number | ISO 9001:2000 | ISO 9001:2008 | Remarks |
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| Foreword | | *Details of the changes between the third edition and this fourth edition are given in Annex B* | This statement has been mentioned in the last line of the foreword on page iv. Annex B is very useful in quickly identifying the changes. |
| 0.1 General | 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. | The design and implementation of an organization's quality management system is influenced by<br>a. *Its organizational environment, changes in that environment, or risks associated with that environment,*<br>b. Its varying needs,<br>c. particular objectives,<br>d. the products it provides,<br>e. the processes it employs,<br>f. its size and organizational structure | The standard now identifies organizational environment & changes therein along with risks associated' as a key factor influencing the design of a QMS. |
| 0.1 General | ..... meet customer, regulatory and the organization's own requirements. | .....meet customer, *statutory and* regulatory *requirements applicable to the product*, and the organization's own requirements. | The word ''statutory'' has been added to requirements that are applicable to the product. |

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| 0.2 Process approach | 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..... | For an organization to function effectively, it has to *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. | The word 'identify' has been replaced with the word 'determine'.<br><br>Further clarity has been provided to the definition of the word ''process'' as process might have more than one activity. |
| 0.2 Process approach | And their management, can be referred to as the ''process approach''. | .....and their management *to produce the desired outcome,* can be referred to as "the process approach". | Further clarity on the process approach has been provided. |
| 0.3 Relationship with ISO 9004 | | *Note At the time of publication of this International Standard, ISO 9004 is under revision.* | ISO 9004 is planned to be published in 2009. |
| 0.4 Compatibility with other management systems | This International Standard has been aligned with ISO 14001:1996..... | *....., due consideration was given to provisions of ISO 14001:2004 to enhance the compatibility.....* | ISO 9001:2008 has been written to make it more compatible with ISO 14001:2004. |
| 1 Scope<br>1.1 General | This International Standard specifies requirements for a quality management system where an organization<br>a. needs to demonstrate its ability to consistently provide product that meets customer and regulatory requirements …. | This International Standard specifies requirements for a quality management system where an organization<br>a. needs to demonstrate its ability to consistently provide product that meets customer and *applicable statutory* and regulatory requirements …. | **Wherever the term 'applicable regulatory requirements' appears, word 'statutory' has been added to read 'and applicable statutory and regulatory requirements'.** |

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| 1 Scope<br>1.1 General | NOTE: In this international standard, the term product applies only to the product intended for, or required by, a customer. | *NOTE 1 In this International Standard, the term product only applies to*<br>*a. product intended for, or required by, a customer,*<br>*b. any intended output resulting from the product realization processes.* | The standard clarifies that by definition ''product'' is not just the end product but the intended output resulting from the product realisation processes. |
| 1 Scope<br>1.1 General | | *NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.* | This wording has been added to clarify the meaning. |
| 2 Normative references | The following normative.....<br>.....<br>ISO 9000:2000, Quality management systems – Fundamentals and vocabulary. | *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.*<br><br>*ISO 9000:2005, Quality management system s - Fundamentals and vocabulary* | This clause has been reworded to clarify the meaning.<br><br>**ISO 9000:2005 has superseded ISO 9000:2000.** |
| 4.1 General requirements Para 4 | Control of such outsourced processes shall be identified with in the quality management system. | *The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.* | This new statement is stronger in its intent. Organizations are required to define the type and extent of control of outsourced processes. |
| 4.1 General requirements 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 | 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*. | Analysis and improvement has been added in NOTE 1**.** |
| 4.1 General requirements NOTE 2 | | *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.* | NOTE 2 has been added to provide guidance and definition of outsourced process. |

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| 4.1 General requirements NOTE 3 | | *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*<br><br>*a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,*<br>*b) the degree to which the control for the process is shared,*<br>*c) the capability of achieving the necessary control through the application of 7.4.*<br>*d)* | This NOTE has been added to clarify the meaning.<br><br>It also identifies factors that may influence the type and extent of control over outsourced processes. |
| 4.2.1 Documentation requirements c) and d)<br><br>Note 1 | c) documented procedures required by this International Standard,<br>d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and<br>e) records required by this International Standard (see 4.2.4). | c) documented procedures *and records* required by this International Standard,<br>d) documents, *including records, determined* by the organization *to be necessary* to ensure the effective planning, operation and control of its processes. | e) is now included in c) |
| 4.2.1 Documentation requirements NOTE 1 | | *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.* | **Each procedure does not necessarily have to be written on a separate document. Organizations can document procedures as they choose, as long as they are clearly understood and meet the standard requirements.** |

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| **Clause Number** | **ISO 9001:2000** | **ISO 9001:2008** | **Remarks** |
| 4.2.3 Control of documents f) | To ensure that documents of external origin are identified and their distribution controlled, and... | 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, … | Clarity has been provided on which external documents organizations need to control. |
| 4.2.4 Control of records | Records shall be established and maintained to provide evidence of conformity to requirements and ..... | *Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.*<br>*The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.*<br>*Records shall remain legible, readily identifiable and retrievable.* | This clause has been re-worded to clarify the meaning. |
| 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.... | **The Management Representative must be a part of the organization's management. The organization may not outsource this responsibility. However this does not prevent the delegation of day to day responsibilities to other individuals (including sub contractors) reporting to the Management Representative.** |
| 6.2.1 General | Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience | Personnel performing work affecting *conformity to product requirements* shall be competent on the basis of appropriate education, training, skills and experience. | **ISO 9001:2008 emphasises conformity to overall product requirements and does not limit it to product quality only.** |

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| 6.2.1 General NOTE | | *NOTE Conformity to product requirements may be affected directly or indirectly by personnel performing any task within the quality management system.* | **A new note has been added to further explain that personnel performing any task which may directly (e.g. in production) or indirectly (e.g. processing relevant information) affect conformity to product requirements shall be competent.** |
| 6.2.2 Competence *training and awareness* | a) determine the necessary competence for personnel performing work affecting product quality, | The organization shall<br>a) determine the necessary competence for personnel performing work affecting *conformity to product requirements,* | **This clause is linked to clause 6.2.1 (Please refer to NOTE in 6.2.1).**<br>**The Organization shall determine the necessary competence for all personnel working within the management system who may directly or indirectly affect conformity to product requirements**. |
| 6.2.2 Competence *training and awareness* | b) provide training or take other actions to satisfy these needs, | The organization shall<br>*b) where applicable*, provide training or take other actions *to achieve necessary competence,* | The phrase 'where applicable' allows organizations to determine their own approach. |
| 6.3 Infrastructure | c) supporting services (such as transport or communication) | c) supporting services (such as transport, communication *or information systems*). | Information systems have been added to the list of supporting services that are needed to be determined and maintained by organizations. |
| 6.4 Work Environment | | *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, lightning, or weather).* | A NOTE has been added to clarify the meaning. |
| 7.1 Planning of product realization c) | c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product | c) required verification, validation, monitoring, *measurement,* inspection and test activities specific to the product and the criteria for product acceptance; | The word 'measurement' has been added to the previous statement. |

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| | acceptance; | | |
| **Clause Number** | **ISO 9001:2000** | **ISO 9001:2008** | **Remarks** |
| 7.2 Customer-related processes<br>7.2.1 Determination of requirements related to the product | c) Statutory and regulatory requirements related to the product, and<br>d) any additional requirements determined by the organization. | c) Statutory and regulatory requirements *applicable* to the product, and<br>d) any additional requirements *considered necessary* by the organization. | This clause has been re-worded to clarify the meaning |
| 7.2 Customer-related processes<br>7.2.1 Determination of requirements related to the product | | *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.* | This NOTE gives examples of post delivery activities. |
| 7.3.1 Design and development planning | | *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.* | This NOTE assists with understanding and use of this design clause as a whole. |
| 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 .... | The outputs of design and development shall be *in a form suitable for* verification against the design and development input and shall be approved prior to release. | This clause has been re-worded to clarify the meaning. |

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| 7.3.3 Design and development outputs | | *NOTE Information for production and service provision can include details for the preservation of product.* | This NOTE gives an example as to how the clause could be used. |
| 7.5.1 Control of production and service provision | d) the availability and use of monitoring and measuring devices, | d) the availability and use of monitoring and measuring *equipment,* | This clause has been re-worded to clarify the meaning. |
| 7.5.1 Control of production and service provision | f) the implementation of release, delivery and post delivery activities. | f) the implementation of *product* release, delivery and post delivery activities. | This clause has been re-worded to clarify the meaning. |
| 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. | This clause has been re-worded to clarify the meaning. |
| 7.5.3 Identification and traceability | 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 the product realization.* | **Clarification has been provided that the product status shall be identified throughout the whole product realization process.** |

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| 7.5.3 Identification and traceability | 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 the unique identification of the product *and maintain records* (see 4.2.4). | This clause has been re-worded to emphasise maintenance of records related to identification and traceability of product. |
| 7.5.4 Customer property | .....otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4). | .....otherwise found to be unsuitable for use, *the organization shall report this to the customer and maintain records* (see 4.2.4). | This clause has been re-worded to clarify the meaning. |
| 7.5.4 Customer property | NOTE Customer property can include intellectual property. | NOTE Customer property can include intellectual property *and personal data*. | **'Personal data' has been added to the NOTE.** |
| 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…. | 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.... | This clause has been re-worded to clarify the meaning. |
| 7.6 Control of monitoring and measuring *equipment* | 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. | The word 'device' has been substituted with the word 'equipment'. |

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| 7.6 Control of monitoring and measuring *equipment* | a) Be calibrated or verified at specified intervals, or..... | a) Be calibrated or verified *or both*, at specified intervals, or..... | This amendment has the option to use both methods. |
| 7.6 Control of monitoring and measuring *equipment* | c) be identified to enable the calibration status to be determined; | *c) have identification in order to determine its calibration status;* | This has been re-worded to clarify the meaning. |
| 7.6 Control of monitoring and measuring *equipment* | 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.* | NOTE from ISO 9001:2000 has been removed and a new NOTE introduced to give an indication of how computer software is fit to meet its intended application. |
| 8.1 General | a) to demonstrate conformity of the product, | a) to demonstrate conformity *to product requirements,* | This clause has been re-worded to clarify the meaning. |
| 8.2.1 Customer satisfaction | | *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*. | A NOTE introduced which should help organizations to understand the different ways in which customer perception could be captured. |
| 8.2.2 Internal audit | 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.*<br><br>Records of the *audits and* their results shall be maintained (see 4.2.4). | This clause has been re-worded to clarify the meaning.<br><br>The requirement for audit records and their results has been separated out to emphasise their importance. |

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| 8.2.2 Internal audit | The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected non conformities 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 to eliminate detected non conformities and their causes. | This clause has been re-worded to clarify the meaning. |
| 8.2.2 Internal audit | NOTE See ISO 10011-1, ISO 10011-1 and ISO 10011-3 for guidance. | NOTE See ISO 19011 for guidance. | Please refer to ISO 19011 Guidelines for quality and environmental management systems auditing |
| 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.<br><br>*NOTE When determining suitable methods, it is advisable that 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 management system.* | A new NOTE has been introduced explaining the factors that should be considered when determining suitable methods for monitoring and measurement. |
| 8.2.4 Monitoring and measurement of product | This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).<br><br>Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorising release of product (see 4.2.4). | 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*.<br><br>Records shall indicate the person(s) authorizing release of product for *delivery to the customer (see 4.2.4).* | Paragraphs have been re-arranged to give separate emphasis to:<br><br>• evidence of conformity<br>• record requirement |

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| 8.2.4 Monitoring and measurement of product | Product release and service delivery shall not proceed until the planned arrangements (see 7.1).... | *The release* of product *and delivery* of service *to the customer* shall not proceed until the planned arrangements (see 7.1)….. | This clause has been re-worded to clarify the meaning. |
| 8.3 Control of nonconforming product | 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.* | This clause has been re-worded to clarify the meaning. |
| 8.3 Control of nonconforming product | 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 applicable,* the organization shall deal with nonconforming product by one or more of the following ways:<br>*e) by taking action appropriate to the effects, or potential effects, of nonconformity when nonconforming product is detected after delivery or use has started.*<br>*f)* | The words 'where applicable' have been added.<br><br>This clauses has been re-worded and re-numbered. The intent remains the same. |
| 8.4 Analysis of data | Analysis of data shall provide information relating to<br>a) customer satisfaction (see 8.2.1),<br>b) conformity to product requirements (see 7.2.1),<br>c) characteristics and trends of processes and products including opportunities for preventive action, and<br>d) suppliers. | a) customer satisfaction (see 8.2.1),<br>b) conformity to product requirements (*see 8.2.4),*<br>c) characteristics and trends of processes and products including opportunities for preventive action (*see 8.2.3 and 8.2.4*), and<br>d) suppliers *(see 7.4).* | The clause numbers now provide clear reference with respect to the kind of data to be analysed. |

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| Clause Number | ISO 9001:2000 | ISO 9001:2008 | Remarks |
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| 8.5.2 Corrective action | The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. | The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. | ISO 9001:2008 now refers to causes rather than cause since there could be more than one cause of noncomformity. |
| 8.5.2 Corrective action | f) reviewing corrective action taken. | f) reviewing *the effectiveness of* corrective action taken. | **The word 'effectiveness' has been added. This strengthens this clause and clarifies the intent. Organizations need to review that the action taken has been effective.** |
| 8.5.3 Preventive action | e) reviewing preventive action taken. | e) reviewing *the effectiveness of* preventive action taken. | **The word 'effectiveness' has been added. This strengthens this clause and clarifies the intent. Organizations need to review that the action taken has been effective.** |
| Annex A | | | Annex A has been updated to reflect ISO 9001:2008 v ISO 14001:2004. |
| Annex B | | | Annex B has been updated to reflect changes between ISO 9001:2000 v ISO 9001:2008. |
| Bibliography | | As applicable | Includes new and amended references. |