



Comparison of ISO 9001:2000 and ISO 9001:2008

Clause	ISO 9001:2000	ISO 9001:2008
General Requirement 4.1	'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.'	Although outsourcing of processes is still an integral Part of the new standard it emphasizes that the Processes should comply with both legal and customer requirement. Although an organization is outsourcing, it is still organization's responsibility to ensure all the necessary processes are in place to meet all regulatory, mandatory and customer requirements. The clause defines the responsibilities of the organization more to help organization determine any impacts or problems that may occur between it and its supplier, and to ensure they are effectively managed in your core processes.
Documentation Requirements 4.2.1	'Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.'	This note now includes reference to situations where a single document can contain one or more procedures. Documented procedures can also be covered by one or more documents. More flexibility in creation of documented procedures
Documentation Requirements 4.2.3 (f)	'To ensure that documents of external origin are identified and their distribution controlled, and...'	The organization is now required to determine the extent of the external documentation that requires controlling to maintain and operate the management system.
Management Representative 5.5.2	'Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes...'	The standard determines that the member of management must be a member of the organization's management team and not an external member of management.
Human Resources - General 6.2.1	'Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.'	Competence is a key issue, and more so in the new standard. It specifies the competence of personnel affecting the performance of conformity to product requirements directly or indirectly is to be controlled by the organization.
Infrastructure 6.3 (c)	'Supporting services (such as transport or communication)'	Within the examples in brackets this now includes 'information systems' .
Work environment 6.4	'The organization shall determine and manage the work environment needed to achieve conformity to product requirements.'	The definition of work environment is now more defined to include physical, environments and other factors like weather, lighting, sound and

		temperature to ensure product requirements are being met.
Design and Development planning 7.3.1	'The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility Planning output shall be updated, as appropriate, as the design and development progresses'	An additional guidance note has been included to expand on the definition of this clause. The standard informs users that the activities listed in this clause can be done as one activity or separately, whichever is best to meet product realization.
Design and development outputs 7.3.3	'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. Design and development outputs shall a) Meet the input requirements for design and development, b) Provide appropriate information for purchasing, production and for service provision, c) Contain or reference product acceptance criteria, and d) Specify the characteristics of the product that are essential for its safe and proper use	An additional description has been added to identify the meaning of service provision to include details of product preservation.
Control of monitoring and measuring devices 7.6	When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and re-confirmed as necessary.'	Additional guidance has been added for extra guidance to cover the ability to constantly monitor the effectiveness of the software being used, and determine its suitability for its purpose.
Customer satisfaction 8.2.1	'As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.'	Additional guidance has been added to explain the different methods on measuring and monitoring customer satisfaction through data analysis, surveys, claims, warranties, dealer reports.
Internal Audit 8.2.2	'The old standard does not state that internal audit records must be maintained.'	The standard specifies the requirement for internal audit records to be maintained.
Monitoring and measurement of processes 8.2.3	'The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.'	Additional guidance has been added to explain "suitable methods", to specify that the organization needs to consider the type and extent of monitoring and measuring for each process to determine the impact on the conformity for product requirements and its effectiveness within QMS.
Monitoring and measurement of product 8.2.4	'Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, the customer.'	The standard is clearer in specifying that products are released for delivery to the customer. The organization must maintain records of who is responsible to sign off the product for delivery.