

Analysis of changes in requirements

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
4.1	The standard requires the organization to establish a quality management system in accordance with the requirements of ISO 9001.	4.2.1	The standard required the supplier to establish a quality system as a means of ensuring that product conforms to specified requirements.	There is no change in intent but the new wording loses the reasons for doing it.	NCI
4.1	The standard requires the organization to document a quality management system in accordance with the requirements of ISO 9001.	4.2.1	The standard required the supplier to document a quality system as a means of ensuring that product conforms to specified requirements.	There is no change in intent but the new wording loses the reasons for doing it.	NCI
4.1	The standard requires the organization to implement a quality management system in accordance with the requirements of ISO 9001.	4.2.2b	The standard required the supplier to effectively implement the quality system and its documented procedures.	There is no change in intent but the new wording loses the reasons for doing it. Internal audits now have to verify that the system has been effectively implemented therefore; the intent of the previous wording is retained.	NCI
4.1	The standard requires the organization to maintain a quality management system in accordance with the requirements of ISO 9001.	4.2.1	The standard required the supplier to maintain a quality system as a means of ensuring that product conforms to specified requirements.	There is no change in intent but the new wording loses the reasons for doing it.	NCI
4.1	The standard requires the organization to continually improve a quality management system in accordance with the requirements of ISO 9001.		No equivalent requirement.	This new requirement means that the organisation will need to demonstrate that it has a policy or value of continuous improvement and is implementing that policy.	NR
4.1a	The standard requires the organization to identify the processes needed for the quality management system.	4.9	The standard required the supplier to identify the production, installation and servicing processes which directly affect quality.	The difference is an extension of the requirement to all processes needed for the management of the organisation's objectives.	NR
4.1b	The standard requires the organization to determine the sequence and interaction of the identified processes.		No equivalent requirement.	This new requirement means that the organisation will need to have an understanding and description of the processes and how they relate and interface.	NR
4.1c	The standard requires the organization to determine criteria and methods required to ensure the effective operation and control of the identified processes.		No equivalent requirement.	This new requirement means that the organisation will need to establish measurement and review mechanisms to manage the performance of their processes.	NR