

ISO 9001: 2008 Checklist

The 2008 version of the standard has no requirements additional from the 2000 edition it replaces. It merely provides clarification to the existing requirements.



Here is a summary of the changes we have identified:

Clause	Clarification	Addressed? Yes / No
	Does the company have a copy or access to a copy of ISO 9001: 2008?	
	Have all references been amended to reflect an upgrade to ISO 9001: 2008?	
4.1	Confirm that any outsourced process is fully controlled where there is potential for an impact on the product or service provided. This should be controlled through clause 7.4. The type and extent of control should be defined.	
5.5.2	Confirm that the Management Representative is a member of the organisations own management.	
6.2.1	Ensure that any person performing work affecting “conformity of the product/service” is competent.	
6.3	Include information systems as a supporting service.	
6.4	Confirm that all applicable work environment conditions have been considered.	
7.2.1	Ensure any post delivery activity is covered (e.g. warranty, recycling, disposal obligation).	
7.3.1	Design review, verification and validation have distinct purposes. Confirm that they have been conducted and recorded as suitable for the product or the organisation.	
7.3.3	Ensure that the preservation of the product has been considered as applicable.	
7.5.4	Personal data and intellectual property (e.g. software) may now be considered as customer property and reported if unsuitable, lost or damaged.	
7.6	Title amended. “Control of monitoring and measuring equipment.” Confirmation that computer software may not be subject to traditional calibration. May be focused on verification and configuration management. Calibration status identification does not have to be physically on the equipment, provided that the identification employed can determine the calibration status.	
8.2.2	Ensure that the Management of the “units” audited have implemented correction and corrective actions.	
8.2.3	Confirm that appropriate monitoring and measurement processes have been implemented, dependant on the impact of the product/service and the effectiveness of the management system.	
8.2.4	The standard specifies that when products are released to the customer the company must maintain records of who is responsible to sign off the product for delivery.	
8.3	Corrective action taken should be appropriate to the effects, or the potential effects of the nonconformity when nonconforming product is detected AFTER delivery or use has started.	
8.5.2	Review of the effectiveness of corrective actions taken.	
8.5.3	Review of the effectiveness of preventative actions taken.	