

ISO 9001:2000 AUDIT CHECKLIST

No.	Question	Proc. Ref.	Comments
	4 Quality Management System		
	4.1 General Requirements		
1	Has the organization established, documented, implemented and maintained a quality management system in accordance with the requirements of ISO 9001?		
2	Is the effectiveness of the quality management system <u>continually improved</u> ?		
3	Has the organization:		
	a) Identified the processes needed for the quality management system including their applications throughout the organization?		
	b) Determined the sequence and interaction of these processes?		
	c) Determined the criteria and methods needed to ensure that both the operation and control of these processes are effective?		
	d) Ensured the availability of resources and information necessary to support the operation and monitoring of these processes?		
	e) <u>Measured, monitored and analyzed these processes?</u>		
	f) <u>Implemented actions needed to achieve planned results and continual improvement of these processes?</u>		
4	Does the organization manage these processes in accordance with the requirements of ISO 9001?		
5	<u>Where processes that affect product conformity with requirements are outsourced, are the controls for these processes identified within the quality management system?</u>		
	4.2 Documentation Requirements		
	4.2.1 General		
6	Does the quality management system documentation include:		
	a) Documented statement of a quality policy <u>and quality objectives</u> ?		
	b) Quality Manual?		
	c) Documented procedures required by ISO 9001?		
	d) Documents needed by the organization to ensure the effective planning, operation and control of its processes?		
	e) Records required by ISO 9001?		
	4.2.2 Quality Manual		
7	Has a quality manual been established and maintained that includes:		
	a) The scope of the quality management system, <u>including details of, and justification for any exclusions?</u>		

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