



Audit Checklist for ISO 9001

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	Requirements	Conformity		
		Y	N	N/A
1.1	General Requirements			
	a) Processes needed for QMS and their application throughout the organization are determined b) Sequence and interaction of these processes is determined c) Criteria and methods needed to ensure that operation and control of these processes are effective is determined d) Availability of resources and information necessary to support operation of these processes is ensured e) Monitoring, measuring (where applicable) and analysis of these processes are done f) Actions to achieve planned results and continual improvement of processes are implemented Type & extent of controls defined for the outsourced processes which affect product conformity to requirements			
1.2	Documentation Requirements			
1.2.1	QMS documentation includes a) Statements of quality policy and quality objectives b) Quality Manual c) Procedures and records required by IS/ISO 9001 d) Documents, including records, determined by organization to ensure effective planning, operation and control of its processes			
1.2.2	Quality Manual – Quality Manual includes Scope of QMS including details of and justification for any exclusions a) Procedures established for QMS, or reference to them b) Description of interaction between the processes of QMS			
1.2.3	Control of documents – Controls defined under the established procedure implemented for a) approval of documents for adequacy prior to issue b) review and updation as necessary and re-approval of documents c) identifying changes and current revision status of documents d) ensuring availability of relevant versions of applicable documents at points of use e) ensuring that documents remain legible and readily accessible f) ensuring identification of necessary documents of external origin and control of their distribution g) preventing unintended use of obsolete documents and suitably identifying them if any for any purpose.			
1.2.4	Control of Records – Control defined under the established procedure implemented for records with respect to Identification, Storage, Protection, Retrieval, Retention and Disposition - Records to be legible, readily identifiable and retrievable.			
2	Management Responsibility			
2.1	Management's commitment for development & implementation QMS and continually improving its effectiveness by a) Communication of importance of meeting customer, statutory and regulatory requirements b) Establishing the quality policy c) Ensuring establishment of quality objectives d) Conducting Management review Ensuring availability of resources			
2.2	Customer Focus Top Management has ensured that customer requirements are determined and met with aim of enhancing customer satisfaction			
2.3	Quality Policy a) Appropriate to the purpose of the organization b) Includes commitment to comply with the requirements and continual improvement of effectiveness of QMS c) Provides framework for establishing and reviewing quality objectives d) Communicated and understood within the organization e) Reviewed for continuing suitability			

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Robert R. Redfield



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