

# INTERNAL AUDIT CHECKLIST

ISO 9001-2000

4 Quality Management System	Observation/Comments	Results
<b>4.1 General Requirements</b>		
<p>Has your organization established a management system (QMS) giving consideration to:</p> <ul style="list-style-type: none"> <li>a) Identifying the processes needed and the application of the processes throughout the organization:</li> <li>b) Determining the sequence and interaction of the processes?</li> <li>c) Determining the criteria and methods for operation and control of the processes?</li> <li>d) Ensuring the availability of resources and information to support the processes?</li> <li>e) Monitoring, measuring and analyzing these processes?</li> <li>f) Implementing actions to achieve planned results and the continual improvement?</li> </ul> <p>If your organization out sources any processes that affects product conformity, are the outsourced process controlled and identified?</p> <p><b>Additional questions</b></p>		
<b>4.2 Documentation Requirements</b>		
<b>4.2.2 Quality Manual</b>		
<p>Does your organization have a quality manual? Does it include the following:</p> <ul style="list-style-type: none"> <li>a) The scope of your QMS and justifications and details of any exclusions</li> <li>b) The documented procedures for the QMS or reference them?</li> <li>c) A description of interactions between the processes of the QMS?</li> </ul> <p><b>Additional questions</b></p>		

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<b>4.2.3 Control of Documents</b>		
<p>Does your organization have a formal procedure regarding the control of documents for your organization: Does this procedure address the following items:</p> <ul style="list-style-type: none"><li>a) Are documents approved prior to issue?</li><li>b) Are documents reviewed and updated as necessary and then re-approved?</li><li>c) Are changes and the current revision status of documents identified?</li><li>d) Are relevant versions of applicable documents available at points of use?</li><li>e) Are documents legible and readily identifiable?</li><li>f) Are documents of external origin identified and their distribution controlled?</li><li>g) Is a mechanism in place to prevent unintended use of obsolete documents: Are old documents identified if retained?</li></ul> <p><b>Additional questions</b></p>		
<b>4.2.4 Control of Quality Records</b>		
<p>Does your organization have a formal procedure for the control of quality records?</p> <p>Are quality records legible, readily identifiable and retrievable?</p> <p>Does the procedure describe identification, storage, protection, retrieval, retention time, and disposition of records?</p> <p><b>Additional questions</b></p>		

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5 Management Responsibility	Observation/Comments	Results
<b>5.1 Management Commitment</b>		
<p>Has top management demonstrated commitment to both the development and implementation of the QMS and to continual QMS improvement by:</p> <ul style="list-style-type: none"> <li>a) Communication the importance of meeting customer requirements and statutory/regulatory requirements:</li> <li>b) Establishing a written quality policy?</li> <li>c) Identifying quality objectives</li> <li>d) Conducting management reviews?</li> <li>e) Ensuring resources are available?</li> </ul> <p><b>Additional questions</b></p>		
<b>5.2 Customer Focus</b>		
<p>Does your organization have a process in place to identify your customer requirements?</p> <p>Are your customer needs and requirements identified on a continual basis?</p> <p>Is you organization aimed at achieving customer satisfaction?</p> <p><b>Additional questions</b></p>		
<b>5.3 Quality Policy</b>		
<p>Has top management established a quality policy that:</p> <ul style="list-style-type: none"> <li>a) Is appropriate to the purpose of your organization?</li> <li>b) Includes a statement of commitment to meet requirements and continually improve?</li> <li>c) Provides a framework for establishing and reviewing quality objectives?</li> </ul>		