

ISO 9001 Experts



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The Tools You Need to Achieve and Maintain ISO 9001

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# **ISO 9001:2008 Internal Auditor Checklist**



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# INTERNAL AUDIT CHECKLIST

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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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<b>6.3 Infrastructure</b>	<b>Observations/Comments</b>	<b>Results</b>
<p>Has your organization maintained the facilities needed to achieve the conformity to product requirements including?</p> <ul style="list-style-type: none"> <li>a) Buildings, workspace, and utilities?</li> <li>b) Process equipment, hardware and software</li> <li>c) Supporting services, such as transportation, communication or information systems?</li> </ul> <p><b>Additional questions</b></p>		
<b>6.4 Work Environment</b>		
<p>Has your organization determined and is it managing the work environment needed to achieve conformity to product requirements?</p> <p><b>Additional questions</b></p>		
<b>7 Product Realization</b>		
<b>7.1 Planning of Product Realization</b>		
<p>In planning and developing processes needed for product realization, has your organization determined:</p> <ul style="list-style-type: none"> <li>a) The quality objectives and requirements of the product</li> <li>b) If established processes, documents and specific product resources are needed?</li> <li>c) The required verification, validation, monitoring, and inspection and test activity specific to the product, and the product acceptance criteria?</li> <li>d) Records needed to provide evidence that the realization processes and the resulting product meet requirements?</li> </ul>		

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<p>Is the output of the planning process in a form suitable for your method of operation?</p> <p><b>Additional questions</b></p>		
<b>7.2 Customer-Related Processes</b>		
<b>7.2.1 Determination of Requirements Related to the Product</b>		
<p>Has your organization determined:</p> <ul style="list-style-type: none"> <li>a) Customer requirements including delivery and post-delivery activities?</li> <li>b) Product requirements not stated by the customer but necessary for use of the product?</li> <li>c) Statutory and regulatory requirements related to the product?</li> <li>d) Any additional requirements determined by your organization?</li> </ul> <p><b>Additional questions</b></p>		
<b>7.2.2 Review of Requirements Related to the Product</b>		
<p>Does your organization review customer requirements prior to commitment to supply the product?</p> <p>Has a process of review (submission of a tender, acceptance of contract or order) been established?</p> <p>Does the review process:</p> <ul style="list-style-type: none"> <li>a) Define product requirements?</li> <li>b) Resolve contract or order requirements differing from previously expressed?</li> <li>c) Determine the ability to meet the defined requirements?</li> </ul> <p>Are records of the review and subsequent action maintained?</p> <p>Are the customer requirements confirmed by your organization before acceptance when the customer provides no documented requirements?</p>		

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8.2 Monitoring and Measurement	Observations/Comments	Results
<b>8.2.1 Customer Satisfaction</b>		
<p>Does your organization monitor information on customer perception regarding fulfilling customer requirements? Are there records to show this is being done?</p> <p><b>Additional questions</b></p>		
<b>8.2.2 Internal Audits</b>		
<p>Are internal audits conducted at planned intervals to determine if the QMS:</p> <ul style="list-style-type: none"> <li>a) Conforms to the planned arrangements for product realization, requirements of the ISO 9001 standard and to the QMS established by your organization?</li> <li>b) Is effectively implemented and maintained?</li> </ul> <p>Has your audit program and audit schedule taken into account:</p> <ul style="list-style-type: none"> <li>a) The status and importance of the processes and areas to be audited?</li> <li>b) The results of previous audits?</li> </ul> <p>Have the audit criteria, scope, frequency and methods been defined?</p> <p>Are auditors selected to ensure the audits and auditors are objective and impartial in the audit process?</p> <p>Is there a documented procedure?</p> <p>Does it define the responsibilities and requirements for planning and conducting audits, including audit reports and maintaining records?</p> <p>Does the management responsible for the area audited take timely action to eliminate nonconformities and their causes?</p> <p>Do follow up activities include verification of the corrective action and the reporting of those results?</p> <p><b>Additional questions</b></p>		