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ISO 9001:2008 Internal Auditor Checklist

4 Quality Management System	Observation/Comments	Results
4.1 General Requirements		
Has your organization established a management system (QMS) giving consideration to: a) Identifying the processes needed and the application of the processes throughout the organization: b) Determining the sequence and interaction of the processes? c) Determining the criteria and methods for operation and control of the processes? d) Ensuring the availability of resources and information to support the processes? e) Monitoring, measuring and analyzing these processes? f) Implementing actions to achieve planned results and the continual improvement? If your organization out sources any processes that affects product conformity, are the outsourced process controlled and identified? **Additional questions**		
4.2 Documentation Requirements		
4.2.2 Quality Manual		
Does your organization have a quality manual? Does it include the following: a) The scope of your QMS and justifications and details of any exclusions b) The documented procedures for the QMS or reference them? c) A description of interactions between the processes of the QMS? **Additional questions**		

4.2.3 Control of Documents		
Does your organization have a formal procedure regarding the control of documents for your organization: Does this procedure address the following items: a) Are documents approved prior to issue? b) Are documents reviewed and updated as necessary and then re-approved? c) Are changes and the current revision status of documents identified? d) Are relevant versions of applicable documents available at points of use? e) Are documents legible and readily identifiable? f) Are documents of external origin identified and their distribution controlled? g) Is a mechanism in place to prevent unintended use of obsolete documents: Are old documents identified if retained? **Additional questions**		
4.2.4 Control of Quality Records		
Does your organization have a formal procedure for the control of quality records? Are quality records legible, readily identifiable and retrievable? Does the procedure describe identification, storage, protection, retrieval, retention time, and disposition of records? **Additional questions**		

6.3 Infrastructure	**Observations/Comments**	**Results**
Has your organization maintained the facilities needed to achieve the conformity to product requirements including? a) Buildings, workspace, and utilities? b) Process equipment, hardware and software c) Supporting services, such as transportation, communication or information systems? **Additional questions**		
6.4 Work Environment		
Has your organization determined and is it managing the work environment needed to achieve conformity to product requirements? **Additional questions**		
7 Product Realization		
7.1 Planning of Product Realization		
In planning and developing processes needed for product realization, has your organization determined: **a)** The quality objectives and requirements of the product **b)** If established processes, documents and specific product resources are needed? **c)** The required verification, validation, monitoring, and inspection and test activity specific to the product, and the product acceptance criteria? **d)** Records needed to provide evidence that the realization processes and the resulting product meet requirements?		

Is the output of the planning process in a form suitable for your method of operation? **Additional questions**		
7.2 Customer-Related Processes		
7.2.1 Determination of Requirements Related to the Product		
Has your organization determined: a) Customer requirements including delivery and post-delivery activities? b) Product requirements not stated by the customer but necessary for use of the product? c) Statutory and regulatory requirements related to the product? d) Any additional requirements determined by your organization? **Additional questions**		
7.2.2 Review of Requirements Related to the Product		
Does your organization review customer requirements prior to commitment to supply the product? Has a process of review (submission of a tender, acceptance of contract or order) been established? Does the review process: a) Define product requirements? b) Resolve contract or order requirements differing from previously expressed? c) Determine the ability to meet the defined requirements? Are records of the review and subsequent action maintained? Are the customer requirements confirmed by your organization before acceptance when the customer provides no documented requirements?		

8.2 Monitoring and Measurement	Observations/Comments	Results
8.2.1 Customer Satisfaction		
Does your organization monitor information on customer perception regarding fulfilling customer requirements? Are there records to show this is being done? **Additional questions**		
8.2.2 Internal Audits		
Are internal audits conducted at planned intervals to determine if the QMS: a) Conforms to the planned arrangements for product realization, requirements of the ISO 9001 standard and to the QMS established by your organization? b) Is effectively implemented and maintained? Has your audit program and audit schedule taken into account: a) The status and importance of the processes and areas to be audited? b) The results of previous audits? Have the audit criteria, scope, frequency and methods been defined? Are auditors selected to ensure the audits and auditors are objective and impartial in the audit process? Is there a documented procedure? Does it define the responsibilities and requirements for planning and conducting audits, including audit reports and maintaining records? Does the management responsible for the area audited take timely action to eliminate nonconformities and their causes? Do follow up activities include verification of the corrective action and the reporting of those results? **Additional questions**		