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 ***continually improved?***		
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) ***Measured, monitored and analyzed these processes?***		
	f) ***Implemented actions needed to achieve planned results and continual improvement of these processes?***		
4	Does the organization manage these processes in accordance with the requirements of ISO 9001?		
5	***Where processes that affect product conformity with requirements are outsourced, are the controls for these processes identified within the quality management system?***		
	4.2 Documentation Requirements		
	4.3 4.2.1 General		
6	Does the quality management system documentation include:		
	a) Documented statement of a quality policy ***and quality objectives?***		
	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, ***including details of, and justification for any exclusions***?		

No.	Question	Proc. Ref.	Comments
	b) Documented procedures established for the quality management system, or reference to them?		
	c) ***Description of the interaction between the processes of the quality management system***?		
	4.2.3 Control of Documents		
8	Are documents required for the quality management system controlled?		
9	Has a documented procedure been established identifying the following controls needed?		
	a) Approval of documents for adequacy prior to issue?		
	b) Review, update as necessary and re-approval of documents?		
	c) Ensure that changes and the current revision status of documents are identified?		
	d) Ensure that relevant versions of applicable documents are available at points of use?		
	e) ***Ensure that documents remain legible and readily identifiable.***		
	f) Ensure that documents of external origin are identified and their distribution controlled?		
	g) Preventing the unintended use of obsolete documents, and to apply suitable identification to them if they are retained?		
	4.2.4 Control of Records		
10	Have records been established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system?		
11	Has a documented procedure been established to define the following controls needed?		
	a) Identification?		
	b) Storage?		
	c) Retrieval?		
	d) Protection?		
	e) Retention time?		
	f) Disposition?		
	5 Management Responsibility		
	5.1 Management Commitment		
1	Has top management provided evidence of its commitment to the development and implementation of the quality management system ***and for the continual improvement of its effectiveness by:***		
	a) ***Communicating to the organization the importance of meeting customer as well as regulatory and legal requirements***?		
	b) Establishing the quality policy?		
	c) ***Ensuring that quality objectives are established?***		
	d) Conducting management reviews?		

No.	Question	Proc. Ref.	Comments
	e) Ensuring the availability of resources?		
2	**5.2 Customer Focus** ***Has top management ensured that customer requirements are determined and met with the aim of enhancing customer satisfaction***?		
3	**5.3 Quality Policy** Has top management ensured that the quality policy: a) Is appropriate to the purpose of the organization?		
	b) Includes a commitment to comply with requirements and ***to continually improve the effectiveness of the quality management system***?		
	c) ***Provides a framework for establishing and reviewing quality objectives?***		
	d) Is communicated and understood within the organization?		
	e) ***Is reviewed for continuing suitability***?		
	5.4 Planning **5.4.1 Quality Objectives**		
4	***Has top management ensured that quality objectives are established at relevant functions and levels within the organization?***		
5	***Have quality objectives needed to meet the requirements of the product been established?***		
6	***Are quality objectives measurable and consistent with the quality policy?***		
	5.4.2 Quality Management System Planning		
7	Has top management ensured that the resources needed to ***achieve the quality objectives*** are identified and planned?		
8	Is the output of the planning documented? (e.g., quality manual, procedures, work instructions, quality plans, etc.)		
9	***Does top management ensure that the integrity of the quality management system is maintained when changes are planned and implemented?***		
	5.5 Responsibility, Authority and Communication **5.5.1 Responsibility and Authority**		
10	Has top management ensured that responsibilities, authorities are defined and ***communicated*** within the organization?		
	5.5.2 Management Representative		
11	Has top management appointed member(s) of management who have responsibility and authority for: a) Ensuring that processes are established, implemented and maintained?		
	b) Reporting to top management on the performance of the quality management system, ***including***		

No.	Question	Proc. Ref.	Comments
	needs for improvement?		
	c) ***Promoting awareness of customer requirements throughout the organization***?		
	5.5.3 Internal Communication		
12	***Has top management ensured that appropriate communication processes have been established within the organization?***		
13	***Does communication take place regarding the effectiveness of the quality management system?***		
	5.6 Management Review		
	5.6.1 General		
14	Does the top management review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?		
15	***Are opportunities for improvement and the need for changes to the quality management system, including quality policy and objectives, reviewed during the review?***		
16	Are records of management reviews maintained as quality records?		
	5.6.2 Review Input		
17	Do the inputs to management review include information on:		
	a) ***Results of audits?***		
	b) ***Customer feedback?***		
	c) ***Process performance and product conformity?***		
	d) ***Status of preventive and corrective actions?***		
	e) ***Follow-up actions from previous management reviews?***		
	f) ***Planned changes that could affect the quality management system?***		
	g) ***Recommendations for improvement?***		
	5.6.3 Review Output		
18	***Do the outputs from the management review include the decisions and actions related to***:		
	a) ***Improvement of the effectiveness of the quality management system and its processes?***		
	b) ***Improvement of the product related to customer requirements?***		
	c) ***Resources needed?***		
	6 Resource Management		
	6 Resource Management		
	6.1 Provision of Resources		
1	***Have the resources been determined and provided for:***		

No.	Question	Proc. Ref.	Comments
	a) Implementing and maintaining quality management system and continually improving its effectiveness?		
	b) Enhancing customer satisfaction by meeting customer requirements?		
	6.2 Human Resources		
	6.2.1 General		
2	Is ***competency for personnel who perform work affecting product quality*** based on appropriate education, training, ***skills***, and experience?		
	6.2.2 Competency, awareness and training		
3	Has the organization:		
	a) ***Determined the necessary competency for personnel performing work affecting product quality?***		
	b) Provided training or take other actions to satisfy these needs?		
	c) ***Evaluated the effectiveness of the actions taken?***		
	d) ***Ensured that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives?***		
	e) Maintained appropriate records of education, training, ***skills*** and experience		
	6.3 Infrastructure		
4	To achieve conformity of product, does the organization identify, provide, and maintain the facilities including:		
	a) Buildings, Workspace and associated utilities?		
	b) Process Equipment, hardware ***and software***?		
	c) ***Supporting services?***		
	6.4 Work Environment		
5	***Has the environment needed to achieve conformity of product requirements been determined and managed?***		
	7 Product Realization		
	7 Product Realization		
	7.1 Planning of Realization Process		
1	Is planning of the organization's product realization consistent with the requirements of the other processes of the quality management system?		
2	Are the following being determined when planning the product realization:		
	a) Quality objectives and requirements for the product?		
	b) The need to establish processes, documents, and provide resources specific to the product?		

No.	Question	Proc. Ref.	Comments
	c) Required verification, validation, monitoring, inspection and test activities specific to the product and criteria for product acceptance?		
	d) Records needed to provide evidence that the realization processes and resulting product fulfill requirements?		
3	Is the planning output in a form that is suitable for the organization's method of operation?		
	7.2 Customer-Related Processes		
	7.2.1 Determination of Requirements Related to the Product		
4	***Has the organization determined:***		
	a) Requirements specified by the customer***, including the requirements for delivery and post-delivery activities?***		
	b) Requirements not stated by the customer but necessary for specified or intended use, where known?		
	c) Statutory and regulatory requirements related to the product?		
	d) Any additional requirements determined by the organization?		
	7.2.2 Review of Requirements Related to the Product		
5	Prior to the commitment to the customer (e.g. submission of tenders, acceptance of contracts or orders or acceptance of change orders) are requirements reviewed to ensure that:		
	a) Product requirements are defined?		
	b) Contract or order requirements differing from those previously expressed are resolved?		
	c) The organization has the ability to meet defined requirements?		
6	Are results of reviews and actions arising from these reviews recorded and maintained as records?		
7	Where the customer has not provided a documented statement of requirements, are customer requirements confirmed by the organization before acceptance?		
8	Where product requirements are changed, does the organization ensure that relevant documentation is amended and relevant personnel are made aware of the changed requirements?		
	7.2.3 Customer Communication		
9	***Has the organization determined and implemented effective arrangements for communicating with customers relating to:***		
	a) Product information?		
	b) Inquiries, contracts, amendments or order handling?		
	c) Customer feedback, including customer complaints?		
	7.3 Design and Development		

No.	Question	Proc. Ref.	Comments
	7.3.1 Design and Development Planning		
10	Are product design and development activities planned and controlled?		
11	During design and development planning has the organization determined:		
	a) Stages of design and development?		
	b) Review, verification and validation that are appropriate to each design and development stage?		
	c) Responsibilities and authorities for design and development?		
12	Are interfaces between different groups involved in design and development managed to ensure effective communication and clear assignment of responsibilities?		
13	Is planning output updated as the design and development progresses?		
	7.3.2 Design and Development Inputs		
14	Are inputs relating to product requirements defined, documented and maintained as a record?		
15	Does design and development input include:		
	a) Functional and performance requirements?		
	b) Applicable statutory and regulatory requirements?		
	c) ***Applicable information derived from previous similar designs?***		
	d) Other requirements essential for designs and development?		
16	Are design and development inputs reviewed for adequacy?		
17	Are incomplete, unambiguous or conflicting requirements resolved?		
	7.3.3 Design and Development Outputs		
18	Are outputs of the design and development provided in a form that enables verification against the design and development inputs?		
19	Are design outputs ***approved*** prior to release?		
20	Does the design and development output:		
	a) Meet the design and development input requirements?		
	b) ***Provide appropriate information for purchasing, production and for service provision?***		
	c) Contain or reference product acceptance criteria?		
	d) Specify the product characteristics that are essential to its safe and proper use?		
	7.3.4 Design and Development Review		
21	Are systematic reviews performed in accordance with planned arrangements at suitable stages of the design and development?		
22	Do design and development reviews:		

No.	Question	Proc. Ref.	Comments
	a) Evaluate the ability of the results of design and development to meet requirements?		
	b) ***Identify problems and propose necessary actions?***		
23	Do review participants include representatives of functions concerned with the design and development stage(s) being reviewed?		
24	Are results of reviews and any actions necessary maintained as records?		
	7.3.5 Design and Development Verification		
25	Is design and development verification performed in accordance with planned arrangements to ensure that the design outputs have met the design and development input requirements?		
26	Are results of the verification and actions maintained as records?		
	7.3.6 Design and Development Validation		
27	Is design and development validation performed in accordance with planned arrangements?		
28	Is design and development validation performed to confirm that the product is ***capable of meeting the requirements for the specified application or intended use, where known?***		
29	Is validation completed prior to delivery or implementation of the product wherever applicable?		
30	***Are results of the validation and actions maintained as records?***		
	7.3.7 Control of Design and Development Changes		
31	Are design and/or development changes identified and recorded?		
32	***Do reviews of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered?***		
33	Are design and development changes reviewed, ***verified, validated*** as appropriate and approved before implementation?		
34	***Are results of the review of changes and necessary actions maintained as records?***		
	7.4 Purchasing		
	7.4.1 Purchasing Control		
35	Are the purchasing processes controlled to ensure purchased product (or service) conforms to requirements?		
36	Is the type and extent of control applied to the supplier and purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product?		
37	Are suppliers selected and evaluated based on their ability to supply product in accordance with the organization's requirements?		
38	Has the organization established criteria for select- ion, ***evaluation & re-evaluation*** of suppliers?		
39	Are results of the evaluations and any necessary actions maintained as records?		

No.	Question	Proc. Ref.	Comments
	7.4.2 Purchasing Information		
40	Does purchasing information describe the product to be purchased?		
	Including where appropriate:		
	a) Requirements for approval of product, procedures, processes and equipment?		
	b) Requirements for qualification of personnel?		
	c) Quality management system requirements?		
41	Is the adequacy of specified purchased requirements ensured prior to their communication to the supplier?		
	7.4.3 Verification of Purchased Product		
42	Have the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements been established and implemented?		
43	Are verification arrangements and method of product release specified in the purchasing information where the organization or its customer intends to perform verification at the supplier's premises?		
	7.5 Production and Service Provision		
	7.5.1 Control of Production and Service Provision		
44	Are the production and service provision planned and carried out under controlled conditions including:		
	a) Availability of information that describes the product characteristics?		
	b) Availability of work instructions, as necessary?		
	c) Use of suitable equipment?		
	d) Availability and use of monitoring and measuring devices?		
	e) Implementation of monitoring and measurement?		
	f) Implementation of release, delivery and post-delivery activities?		
	7.5.2 Validation of Processes for Production and Service Provision		
45	Have processes where deficiencies may become apparent only after the product is in use or the service has been delivered been validated?		
46	Do the results of validation demonstrate the ability of the processes to achieve planned results?		
47	Where applicable, have the arrangements been established for:		
	a) Defining criteria for review and approval of processes?		
	b) Approval of equipment and qualification of personnel?		
	c) Use of specific methods and procedures?		
	d) Requirements for records?		

No.	Question	Proc. Ref.	Comments
	e) ***Re-validation?***		
	7.5.3 Identification and Traceability		
48	Is the product identified by suitable means throughout product realization?		
49	Is the product status identified with respect to monitoring and measurement requirements?		
50	When traceability is a requirement, is the product uniquely identified and controlled?		
51	Is the unique identification maintained as a record?		
	7.5.4 Customer Property		
52	Does the organization exercise care with customer property while it is under the organization's control or being used by the organization?		
53	Is customer property identified, verified, protected, and safeguarded?		
54	If lost, damaged or otherwise found to be unsuitable for use, is condition recorded, reported to the customer and maintained as a record?		
	7.5.5 Preservation of Product		
55	Is conformity of product preserved during internal processing and delivery to the intended destination?		
56	Does preservation activities include:		
	a) Identification?		
	b) Handling?		
	c) Packaging?		
	d) Storage?		
	e) Protection?		
57	***Are preservation activities applied to constituent parts of a product?***		
	7.6 Control of Measuring and Monitoring Devices		
58	Has the organization determined the monitoring and measurement to be undertaken and the monitoring and measurement devices needed to provide evidence of conformity of product to determined requirements?		
59	Have processes been established to ensure that monitoring and measurement can be carried out in a manner consistent with the monitoring and measurement requirements?		
60	Where necessary to ensure valid results, are measuring equipment: a) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, is the basis used for calibration or verification recorded?		
	b) Adjusted or re-adjusted as necessary?		
	c) Identified to enable the calibration status to be		

No.	Question	Proc. Ref.	Comments
	determined?		
	d) Safeguarded from adjustments that would invalidate the measurement result?		
	e) Protected from damage and deterioration during handling, maintenance and storage?		
61	Has the organization assessed and recorded the validity of the previous measuring results when the equipment is found not to conform to requirements?, and taken the appropriate action on the equipment and any product affected?		
62	Are records of the calibration ***and verification*** results maintained?		
63	Where computer software is used in the monitoring and measurement of specified requirements, is the ability of the computer software to satisfy the intended application confirmed prior to initial use?		
64	***Is the ability of computer software to satisfy the intended application reconfirmed as necessary?***		
	8 Measurement, Analysis and Improvement		
	8 Measurement, analysis and improvement		
	8.1 General		
1	Have the monitoring, measurement , ***analysis and improvement processes*** been planned, and implemented to:		
	a) Demonstrate conformity of the product?		
	b) Ensure conformity of the quality management system?		
	c) ***Continually improve the effectiveness of the quality management system?***		
2	Have the applicable methods including statistical techniques and their extent of use been determined?		
	8.2 Monitoring and Measurement		
	8.2.1 Customer Satisfaction		
3	***Is information relating to customer perception monitored by the organization as to whether customer requirements have been met?***		
4	***Have the methodologies for obtaining and using information related to customer perception been determined?***		
	8.2.2 Internal Audit		
5	Are internal audits conducted at planned intervals to determine whether the quality management system:		
	a) Conforms to planned arrangements, requirements of ISO 9001 and the quality management system?		
	b) Is effectively implemented and maintained?		
6	Are the audit programs planned taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?		

No.	Question	Proc. Ref.	Comments
7	Is the audit criteria, scope, frequency and method defined?		
8	Do auditor selection and conduct of audits ensure objectivity and impartiality of the audit process?		
9	Is it ensured that auditors do not audit their own work?		
10	Has a documented procedure been established to define responsibilities and requirements for planning and conducting audits, reporting results, and maintaining records?		
11	Have management responsible for the area being audited ensured that actions have been taken without undue delay to ***eliminate detected nonconformities and their causes***?		
12	Do follow-up activities include the verification of the actions taken, and the reporting of the verification results?		
	8.2.3 Monitoring and Measurement of Processes		
13	***Are suitable methods applied for monitoring and where applicable, measurement of the quality management system processes necessary to meet customer requirements?***		
14	***Do these methods demonstrate the ability of the processes to achieve planned results?***		
15	***Are correction and corrective actions taken when planned results are not achieved?***		
	8.2.4 Monitoring and Measurement of Product		
16	Are product characteristics monitored and measured to verify that product requirements are met?		
17	Is monitoring and measurement of product characteristics carried out at appropriate stages of the product realization process in accordance with the planned arrangements?		
18	Is evidence of conformity with the acceptance criteria documented and maintained?		
19	Are records maintained to indicate the person(s) authorizing release of product?		
20	Unless otherwise approved by a relevant authority or where applicable, the customer, are all planned arrangements satisfactorily completed prior to proceeding with release?		
	8.3 Control of Nonconforming Product		
21	Is nonconforming product identified and controlled to prevent unintended use or delivery?		
22	Has a documented procedure been established to define controls and related responsibilities and authorities for dealing with nonconforming product?		
23	Are nonconforming product dealt with by one or more of the following ways: a) Action taken to eliminate the detected nonconformity?		
	b) Authorized use, release or acceptance under concession by a relevant authority and, where applicable, by the customer		

No.	Question	Proc. Ref.	Comments
	c) Action taken to preclude its original intended use or application		
24	Are records maintained identifying the nature of nonconformities and any subsequent actions taken, including any concessions?		
25	When nonconforming product is corrected, is it subject to re-verification to demonstrate conformity to the requirements?		
26	***When nonconforming product is detected after delivery, or use has started, is appropriate action taken by the organization to the effect or potential effect?***		
	8.4 Analysis of Data		
27	***Is appropriate data determined, collected and analyzed to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made?***		
28	***Does this data included data generated from monitoring, measurement and other relevant sources?***		
29	***Does the analysis of this data provide information related to:***		
	a) ***Customer satisfaction?***		
	b) ***Conformance to product requirements?***		
	c) ***Characteristics and trends of processes and products including, opportunities for preventive action?***		
	d) ***Suppliers?***		
	8.5 Improvement		
	8.5.1 Continual Improvement		
30	***Does the organization continually improve the effectiveness of the quality management system?***		
31	***Are results of audits, analysis of data, corrective and preventive actions, management reviews, quality Policy and quality objectives used for continual improvement?***		
	8.5.2 Corrective Action		
32	Are corrective actions taken to eliminate the cause of nonconformities and to prevent recurrence?		
33	Are corrective actions appropriate to the effects of the nonconformities encountered?		
34	Has a documented procedure been established to define the requirements for:		
	a) Reviewing nonconformities, including customer complaints?		
	b) Determining the causes of nonconformity?		
	c) Evaluating the need for action to ensure that nonconformities do not recur?		
	d) Determining and implementing action needed?		

No.	Question	Proc. Ref.	Comments
	e) Recording and maintaining the results of action taken?		
	f) Reviewing corrective action taken?		
	8.5.3 Preventive Action		
35	Has the organization determined actions to eliminate the causes of potential nonconformities in order to prevent occurrence?		
36	Are preventive actions appropriate to the effects of the potential problems?		
37	Has a documented procedure been established to define the requirements for:		
	a) Determining potential nonconformities and their causes?		
	b) Evaluating the need for action to prevent occurrence of nonconformities?		
	c) Determining and implementing actions needed?		
	d) Recording and maintaining the results of action taken?		
	e) Reviewing of preventive action taken?		

Notes
