Draft

Quality System Assessment

For

ISO 9000:2000
(CIS)

By
David Taylor

3/15/00

other words, don’t sell it! Please give credit to the author when passing it along to others. Thank you!

Quality System Assessment

Date_____

Auditee Company _____

Address _____

City, State, Zip_____

Aisitor(s) _____ _____
Print Name Sign

Aisitor(s) _____ _____
Print Name Sign

Aisitor(s) _____ _____
Print Name Sign

Aisitor(s) _____ _____
Print Name Sign

Opening Meeting	Closing Meeting

Quality System Assessment

Management Commitment
PARAGRAPH 5

	Questions	Assessor Notes	Result
1.	Has management communicated to the organization the importance of meeting customer as well as regulatory and legal requirements? (5.1a)		
2.	Is management aware of: establishing the quality policy and quality objectives; conducting management reviews; ensuring the availability of necessary resources. (5.1b, 5.1c, 5.1d)		
3.	Are there records showing how customer needs and expectations are determined, converted into requirements and fulfilled with the aim of achieving customer satisfaction, including legal requirements? (5.2)		
4.	Review the quality policy: a) is it appropriate to the purpose of the organization? b) does it include a commitment to meeting requirements and to continual improvement? c) does it provides a framework for establishing and reviewing quality objectives? d) is it communicated and understood at appropriate levels in the organization? e) is it reviewed for continuing suitability? By whom? a) is it a controlled document? (5.3)		

Quality System Assessment

5.	Are quality objectives established at relevant functions and levels within the organization? Are they measurable? Are they consistent with the quality policy? Do they use continual improvement?. Do they include objectives needed to meet requirements for product? (5.4.1)		
6.	What resources are identified and planned to achieve the quality objectives? How is this quality planning documented? Does quality planning include: a) the processes of the quality management system, considering permissible exclusions ; b) the resources needed; c) continual improvement of the quality management system? Is change conducted in a controlled manner? (5.4.2)		
7	Are functions and their interrelations within the organization, including responsibilities and authorities, defined and communicated to enhance quality management? (5.5.2)		
8.	What management member has been appointed to have responsibility and authority that includes: a) ensuring that processes of the quality management system are established and maintained; b) reporting to top management on the performance of the quality management system, including needs for improvement; c) promoting awareness of customer requirements throughout the organization? (5.5.3)		
9.	How does the organization communicate the quality management system and their effectiveness between its various levels and functions? (5.5.4)		

Quality System Assessment

10.	Is a quality manual established and maintained and controlled that includes: a) the scope of the quality management system, including details of, and justification for, any exclusions b) documented procedures or reference to them; c) a description of the sequence and interaction of the processes included in the quality management system. (5.5.5)		
11	Is there a written procedure for controlling the system documents? Does it provide for: a) approval of documents for adequacy prior to issue; b) review and updating as necessary and re-approve documents; c) identification of the current revision status of documents; d) are relevant versions of applicable documents are available at points of use; e) are the documents legible, readily identifiable and retrievable; f) are documents of external origin identified and their distribution controlled; g) are obsolete documents prevented from unintended use and suitable identification applied if they are retained for any purpose? (5.5.6)		
12.	Is there a written procedure for the identification, storage, retrieval, protection, retention time and disposition of quality records? (5.5.7)		

Quality System Assessment

13	Are there records of a review the quality management system by top management? Are these reviews held at planned intervals? Does the review address the continuing suitability, adequacy and effectiveness of the quality system? Does the review evaluate the need for changes to the organization's quality management system, including quality policy and quality objectives? (5.6.1)		
14	Do management review inputs include current performance and improvement opportunities related to the following: a) results of audits; b) customer feedback; c) process performance and product conformance; d) status of preventive and corrective actions; e) follow-up actions from earlier management reviews; f) changes that could affect the quality management system? (5.6.2)		
15	Do the outputs from the management review include actions related to: a) improvement of the quality management system and its processes; b) improvement of product related to customer requirements; c) resource needs? (5.6.3) Are there records of the results of management reviews? (5.5.7)		

Quality System Assessment

Resource Management
PARAGRAPH 6

1	Are there records that show the organization has determined and provided, in a timely manner, the resources needed: a) to implement and improve the processes of the quality management system, and b) to address customer satisfaction? (6.1)		
2	Are there records that show personnel who are assigned responsibilities defined in the quality management system are competent on the basis of education, training, skills and experience? Does any evidence exist that shows non-competency? (6.2.1)		
3	Is there evidence that the organization has: a) identified competency needs for personnel performing activities affecting quality; b) provided training to satisfy these needs; c) evaluated the effectiveness of the training provided; d) ensured that its employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; (6.2.2) e) maintained appropriate records of education, experience, training and qualifications? (5.5.7).		
4	Has the organization identified, provided and maintained the facilities it needs to achieve the conformity of product, including: a) workspace and associated facilities; b) equipment, hardware and software; c) supporting services? (6.3)		

5	Are the human and physical factors of the work environment identified and managed as needed to achieve conformity of product? (6.4)		

Quality System Assessment

Product Realization
PARAGRAPH 7

1	Is the planning of processes consistent with the other requirements of the organization's quality management system? Is this planning (which may be referred to as the quality plan) documented in a suitable form? Does the quality plan include the following as appropriate? a) quality objectives for the product, project or contract; b) the need to establish processes and documentation, and provide resources and facilities specific to the product; c) verification and validation activities, and the criteria for acceptability; d) the records that are necessary to provide confidence of conformity of the processes and resulting product? (7.1)		
2	Where evidence is there that the organization has determined customer requirements including: a) product requirements specified by the customer, including the requirements for availability, delivery and support; b) product requirements not specified by the customer but necessary for intended or specified use; c) obligations related to product, including regulatory and legal requirements? (7.2.1)		

3	Show records that prior to the commitment to supply a product to the customer the organization has reviewed customer requirements along with requirements determined by the organization? Does this review ensure that: a) product requirements are defined; b) where the customer provides no written requirements, these are confirmed before acceptance; c) requirements differing from those previously expressed are resolved; d) the organization has the ability to meet defined requirements? (7.2.2) Are the results of the review and subsequent follow-up actions recorded? (5.5.7). If the requirements are changed, does the organization have evidence that documentation was amended? Is there evidence that relevant personnel are made aware of the changed requirements? (7.2.2)		
4	How does the organization communicate customers relating to: a) product information; b) enquiries, contracts or order handling, including amendments; c) customer feedback, including customer complaints? (7.2.3)		

5	Does the organization have evidence of planing and controlling design and/or development of the product? Does this planning include the determination of: a) stages of design and/or development processes; b) review, verification and validation activities appropriate to each design and/or development stage; c) responsibilities and authorities for design and/or development activities. Are interfaces between different groups involved in design and/or development managed to ensure effective communication and clarity of responsibilities? Are planning outputs updated, as appropriate, as the design and/or development progresses? (7.3.1)		
6	Are Inputs relating to product requirements defined and documented? Do they include: a) functional and performance requirements; b) applicable regulatory and legal requirements; c) applicable information derived from previous similar designs; and d) any other requirements essential for design and/or development. Is there evidence these inputs are reviewed for adequacy. Incomplete, ambiguous or conflicting requirements? Are these conflicts resolved? (7.3.2)		

7	Are the outputs of the design and/or development process in a manner that enables verification against the inputs? Does the design and/or development output include: a) meet the design and/or development input requirements; b) provide appropriate information for production and service operations (7.5) c) contain or reference product acceptance criteria; d) define the characteristics of the product that are essential to its safe and proper use? Are the design and/or development output documents approved prior to release? (7.3.3)		
8	Are there records that systematic reviews of design and/or development are conducted, suitable stages to: a) evaluate the ability to fulfil requirements; b) identify problems and propose follow-up actions? Do participants in such reviews include representatives of functions concerned with the design and/or development stage(s) being reviewed? (7.3.4) Are the results of the reviews and subsequent follow-up actions recorded? (5.5.7).		
9	Are there records that design and/or development verification is performed to ensure the output meets the design and/or development inputs? (7.3.5) Are the results of the verification and subsequent follow-up actions recorded? (5.5.7).		

10	Are there records showing design and/or development validation is performed to confirm that resulting product is capable of meeting the requirements for the intended use. If it is impractical to perform full validation prior to delivery or implementation are partial validation shall be performed to the extent applicable. (7.3.6) Are the results of the validation and subsequent follow-up actions recorded? (5.5.7).		
11	Are there records that design and/or development changes are identified, documented and controlled? Does this review include evaluation of the effect of the changes on constituent parts and delivered products? Are the changes verified and validated, as appropriate, and approved before implementation? (7.3.7) Are the results of the review of changes and subsequent follow up actions documented? (5.5.7).		
12	Is there evidence that the organization has evaluated and selected suppliers based on their ability to supply product in accordance with the organization's requirements? Are criteria for selection and periodic evaluation defined. (7.4.1) Are the results of evaluations and follow-up actions shall be recorded (5.5.7).		

13	Do purchasing documents contain information describing the product to be purchased, including where appropriate? a) requirements for approval or qualification of: product, procedures, processes, equipment, and personnel; b) quality management system requirements? Does the organization ensure the adequacy of specified requirements contained in the purchasing documents prior to their release? (7.4.2)		
14	Has the organization identified and implemented the activities necessary for verification of purchased product? If the organization or its customer proposes to perform verification activities at the supplier's premises, did the organization specify the intended verification arrangements and method of product release in the purchasing information? (7.4.3)		
15	In order to control production and service operations, does the organization have: a) the availability of information that specifies the characteristics of the product; b) where necessary, the availability of work instructions; c) the use and maintenance of suitable equipment for production and service operations; d) the availability and use of measuring and monitoring devices; e) the implementation of monitoring activities; f) the implementation of defined processes for release, delivery and applicable post-delivery activities? (7.5.1)		

Quality System Assessment

16	Where appropriate, is the product identified by suitable means throughout production and service operations? Is the status of the product with respect to measurement and monitoring requirements identified? (7.5.2) Where traceability is a requirement, Is the unique identification of the product controlled and recorded? (5.5.7).		
17	If customer property is used or incorporated into the product, is it. identified, verified, protected and maintained? If any customer property is lost, damaged or otherwise found to be unsuitable for use is there evidence it was recorded and reported to the customer. (7.5.3) NOTE Customer property may include intellectual property (e.g. information provided in confidence).		
18	Is conformity of the product and/or parts with customer requirements preserved during internal processing and delivery ? Does this include identification, handling, packaging, storage and protection? (7.5.4)		

19	If there are any processes where deficiencies may become apparent only after the product is in use or the service has been delivered, are production and service processes validated to demonstrate the ability of the processes to achieve planned results? Does the records of the validation include the following, as applicable: a) qualification of processes; b) qualification of equipment and personnel; c) use of defined methodologies and procedures; d) requirements for records; e) re-validation? (7.5.5)		

20	Are there documents identifying measurements to be made and the measuring and monitoring devices required to assure conformity of product to specified requirements? Are measuring and monitoring devices used and controlled to ensure that measurement capability is consistent with the measurement requirements? Where applicable, are measuring and monitoring devices: a) calibrated and adjusted periodically or prior to use, against devices traceable to international or national standards; where no such standards exist, is the basis used for calibration recorded; b) safeguarded from adjustments that would invalidate the calibration; c) protected from damage and deterioration during handling, maintenance and storage; d) have the results of their calibration recorded (5.5.7); e) have the validity of previous results re-assessed if they are subsequently found to be out of calibration, and corrective action taken? If applicable, is software used for measuring and monitoring of specified requirements validated prior to use?. (7.6)		

Quality System Assessment

Measurement, Analysis, And Improvement
PARAGRAPH 8

1	Are plans available that define and plan the measurement and monitoring activities needed to assure conformity and achieve improvement? Are these plans implemented? Do they include the determination of the need for, and use of, applicable methodologies including statistical techniques? (8.1)		
2	Are there records of monitoring information on customer satisfaction and/or dissatisfaction as one of the measurements of performance of the quality management system? Are the methods for obtaining and using this information determined? (8.2.1)		

3	Are there records of periodic internal audits being conducted to determine whether the quality management system: a) conforms to the requirements of this International Standard; b) has been effectively implemented and maintained? Is the internal audit program planned taking into consideration the status and importance of the activities and areas to be audited as well as the results of previous audits? In the audit plans, are the audit scope, frequency and methodologies defined? Do audit records show that audits are conducted by personnel other than those who perform the activity being audited? Is there a documented procedure that includes the responsibilities and requirements for conducting audits, ensuring their independence, recording results and reporting to management? Are there records showing that management has taken timely corrective action on deficiencies found during the audit? Do records of follow-up actions include the verification of the implementation of corrective action, and the reporting of verification results? (8.2.2)		
4	Are suitable methods used for measurement and monitoring of processes necessary to meet customer requirements? Do these methods confirm the continuing ability of each process to satisfy its intended purpose? (8.2.3)		

5	Are their records of measurement and monitoring the characteristics of the product to verify that requirements for the product are met?. Is this carried out at appropriate stages of the process? Is evidence of conformity with the acceptance criteria documented? Does product release and service delivery wait all the specified activities have been satisfactorily completed, unless otherwise approved by the customer? (8.2.4) Do records indicate the authority responsible for release of product? (5.5.7).		
6	Are all products which do not conform to requirements identified and controlled to prevent unintended use or delivery? Ifs there a documented procedure defining these activities? Are there records showing that nonconforming product is corrected and subject to re-verification after correction to demonstrate conformity? When nonconforming product is detected after delivery or use has started, is appropriate action taken regarding the consequences of the nonconformity?. (8.3)		

Quality System Assessment

7	Is appropriate data collected and analyzed to determine the suitability and effectiveness of the quality management system and to identify improvements that can be made.? Are there records to show data is analyzed to provide information on: a) customer satisfaction and/or dissatisfaction; b) conformance to customer requirements; c) characteristics of processes, product and their trends; d) suppliers? (8.4)		
8	Is there evidence that the organization facilitates the continual improvement of the quality management system through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive action and management review. (8.5.1)		

9	Are there records showing the taking of corrective action to eliminate the cause of nonconformities in order to prevent recurrence? Are the corrective actions appropriate to the impact of the problems encountered? Is there a documented procedure for corrective action that defines requirements for: a) identifying nonconformities (including customer complaints); b) determining the causes of nonconformity; c) evaluating the need for actions to ensure that nonconformities do not recur; d) determining and implementing the corrective action needed; e) recording results of action taken; f) reviewing of corrective action taken? (8.5.2)		
10	Are there records showing the identification of preventive actions to eliminate the causes of potential nonconformities to prevent occurrence? Do these cords show that preventive actions taken are appropriate to the impact of the potential problems? Does the documented procedure for preventive action define requirements for: b) identifying potential nonconformities and their causes; c) determining and ensuring the implementation of preventive action needed; d) recording results of action taken; e) reviewing of preventive action taken? (8.5.3)		