

VA Checklist Tool for AB Auditor Guidance

VA Report Template #	Element	Questions	Look For:	Evidence
				In order to evaluate effectiveness, intent and implementation have to be evaluated first to assure that a plan or a document exists and is executed, and then effectiveness can be evaluated. Per ISO 9000:2005, effectiveness is defined as the extent to which planned activities are realized and planned results achieved. Therefore to assess results, we will have to sample records, so clause 4.2.3 and 4.2.4 will apply and this will support item 8 of the Validation Audit Process document, section 10 B, #8 which states "Ensure that current practices within scope of the Validation Audit are accurately reflected in the documented procedures".
All Items	4.2.4 Record Control	Records must comply with record requirements.	Identification, storage, protection, retrieval, retention and disposition	
11	4.2.2 Quality manual (ISO 9001:2008)	Does the quality manual comply with the requirements as outlined under 4.2.2?	Scope statement for QMS and details/justification for any exclusions, list of documented procedures for QMS or reference to them, and description of interaction between QMS processes.	
11	4.2.3 Control of Documents (ISO 9001:2008)	For the functions reviewed, those which require process documentation, did the documentation reflect current business practices?	Documentation is current and controlled for all process documentation reviewed vs. minor discrepancies. Procedures exist for all required ISO elements and TL adders.	
10	5.4.1 Quality Objectives Planning (ISO 9001:2008)	What are the quality objectives that apply in this function that align with the organization's targets? Where are actions tracked from measurement indicators? Were actions taken effective?	Look at measurements and actions taken based on measurements. Are TL 9000 measurements included in the targets? Reference Measurement Elements: 5.4.1, 5.4.1.C.1, 5.4.2.C.1, 7.3.1.HS.2, 8.1, 8.2.1, 8.2.1.C.1, 8.2.3, 8.2.3.C.1, 8.2.4	
10	5.6.1 General (ISO 9001:2008) QMS Review of Top Mgt	How does mgt ensure valid input info is available for the mgt review?	Look for management reviews that are conducted at planned intervals.	
10	5.6.2 Review Input (ISO 9001:2008)	Does mgt review results of audits, customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up action items from previous reviews, changes that can affect the QMS and recommendations for improvement?	Audit results may also include customer, 3rd-Party. Also Ref 5.2.C.2 + 5.4.1 and Adders. For QMS changes: [example, when an organization goes from 200 employees down to 50, what plans are in place for continued support of systems such as corrective action, internal audit, customer satisfaction, process performance and continual improvement?]	
10	5.6.3 Review Output (ISO 9001:2009)	What evidence is there to show evidence of outputs resulting in decisions and actions to improve the effectiveness of the QMS and its processes? Improvement of product related to customer reqs.? Resource needs? Consider whether there are 1) performance objectives for products and processes, 2) performance improvement objectives, 3) strategies and initiatives for marketing, products, and satisfaction of customers or other interested parties, 4) loss prevention and mitigation plans for identified risks, and 5) info on strategic planning for organization's future needs.	Required evidence here is for output of management review to include any decisions and actions related to a) improvement of the effectiveness of the QMS and its processes, b) improvement of product related to customer requirements, and c) resource needs.	

10	5.6 Management Review (TL 9000)	<p>How does top management demonstrate its leadership, commitment and involvement in the QMS?</p> <p>Does top management review the QMS at planned intervals to ensure effectiveness?</p> <p>In conducting the review, does top management review the QMS to evaluate whether the established vision, policies and strategic objectives are consistent?</p> <p>Are records of the management review kept maintained as quality records?</p> <p>Does the company have records to provide evidence that the QMS is effective (examples include management review records, corrective and preventive actions logs, customer satisfaction or feedback records)?</p> <p>What records are available to demonstrate effectiveness of the use of customer satisfaction results?</p> <p>What actions are taken with regard to the management reviews – including corrective action and preventive action? Are the results of the reviews and any actions recorded?</p> <p>Does the management review include a review of the TL 9000 measurements performance against the targets?</p> <p>Are the TL 9000 measurements used internally for continual improvement?</p> <p>Sample the management review records to demonstrate evidence of the above.</p>		
12	5.4.1 Quality Objectives (ISO 9001:2008) and 5.4.1.C.2 (TL 9000)	<p>Are the Quality objectives consistent with the quality policy?</p> <p>Are the quality objectives measurable?</p> <p>Are quality objective set for appropriate levels of the organization?</p> <p>Are targets for the TL 9000 Measurements defined?</p> <p>How are the targets established – based upon what?</p> <p>What occurs if the targets are not met?</p>		
9	8.2.1 Customer Satisfaction (ISO 9001:2008)	<p>Is information relating to customer perception monitored by the organization as to whether customer requirements have been met?</p> <p>Have the methodologies for obtaining and using information related to customer perception been determined?</p>	<p>NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports</p>	
9	8.2.1.C.1 Customer Satisfaction Data (TL 9000)	<p>Has the organization established and maintained a method to collect data directly from customers concerning their satisfaction with provided products?</p> <p>Does the organization collect customer data on how well the organization meets commitments?</p> <p>Does the organization collect customer data on its responsiveness to customer feedback and needs?</p> <p>Is this data collected and analyzed?</p> <p>Are the trends of this data being kept?</p>		

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5, 6, 8	8.5.2 Corrective Action (TL 9000)	If any are available within the most recent (12) month period, a sample of customer TL 9000 audit findings (2nd party audit) should be included. In the review, include a sample of corrective actions that are overdue or still open after nine months. Review the status of any nonconformities from the previous CB assessment(s).	Consider adding these notes in Column B or C-- NOTES related to reviewing CA taken for effectiveness: 1) Review of corrective action is intended to ensure that the action taken was effective. Review activities may include ensuring that root cause was properly identified and addressed, appropriate containment action was taken, and corrective actions have not introduced additional problems. 2) Consideration should be given to include training as part of implementing corrective and preventive actions.	
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