



4.2.3 Control of Documents		
<p>Does your organization have a documented procedure regarding the control of documents for your organization: Does this procedure address the following items:</p> <ul style="list-style-type: none"> a) Are documents reviewed and approved for adequacy 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? When documents are obsolete, do you have a defined length of time that they must be retained? <p>Additional questions</p>		
4.2.4 Control of Quality Records		



5 Management Responsibility	Observation/Comments	Results
5.1 Management Commitment		
<p>Has top management demonstrated commitment to both the development and implementation of the QMS and maintaining its effectiveness:</p> <ul style="list-style-type: none"> a) Communication the importance of meeting customer requirements and statutory/regulatory requirements: b) Establishing a written quality policy? c) Identifying quality objectives d) Conducting management reviews? e) Ensuring resources are available? <p>Additional questions</p>		
5.2 Customer Focus		
<p>Does your organization have a process in place to identify your customer requirements?</p> <p>Are your customer needs and requirements identified and met on a continual basis?</p> <p>?</p> <p>Additional questions</p>		
5.3 Quality Policy		
<p>Has top management established a quality policy that:</p> <ul style="list-style-type: none"> a) Is appropriate to the purpose of your organization? b) Includes a statement of commitment to meet requirements and to maintain the effectiveness of the QMS? c) Provides a framework for establishing and reviewing quality objectives? 		



5.5.1 Responsibility and Authority		
<p>Are responsibilities, authorities and their interrelation defined and communicated within you organization? Is it understood who has the authority to check and verify the quality of workmanship?</p> <p>Additional questions</p>		
5.5.2 Management Representative		
<p>Has top management appointed a member of management that has responsibility and authority to:</p> <ul style="list-style-type: none"> a) Establish, implement, and maintain the processes needed for the QMS? b) Report to top management on the QMS and the need for improvement? c) Communicate and promote awareness of regulatory and customer requirements throughout your organization? <p>Additional questions</p>		
5.5.3 Internal communication		
<p>Has a communication process been established within your organization?</p> <p>Do the communications include the effectiveness of the QMS?</p> <p>Additional questions</p>		



<p>assess and record the validity of previous measuring results? Does your organization take appropriate action on the equipment and any product affected above? Where are the results of calibration and verification being recorded? Is software used for measuring and monitoring verified prior to use and reconfirmed as necessary? Additional questions</p>		
8 Measurement, Analysis and Improvement		
8.1 General		
<p>Has your organization planned and implemented the monitoring, measurement, analysis and improvement processes to:</p> <ul style="list-style-type: none"> a) Demonstrate conformity of the product? b) Confirm conformity of the QMS? c) Maintain the effectiveness of the QMS? <p>Does this include the determination of the need for, and use of applicable methods, including statistical techniques? Additional questions</p>		