	Additional Questions		
4.4	**Quality management system and its processes**		
4.4.1	As required by the standard, do you establish, document, implement, maintain and continually improve the QMS?		
	Does the QMS also address customer and applicable statutory and regulatory quality management system requirements?		
	Does your company determine the processes needed for the QMS, their interactions and applications throughout your company?		
	That is, for the QMS processes do you determine the:		
	• Inputs required and the outputs expected from the processes?		
	• Sequence and interaction of the processes?		
	• Criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of the processes?		
	• Resources needed and ensure they are available?		
	• Assignment of the responsibilities and authorities for		

	these processes?		
	• Risks and opportunities (per 6.1), and plans to implement the appropriate actions to address them?		
	• Methods for monitoring, measuring, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results?		
	• Opportunities for improvement of the processes and the QMS?		
	Does your company maintain the necessary documented information to support the operation of processes?		
4.4.2	Does your company maintain and retain the necessary documented information to provide the confidence that the processes are being carried out as planned?		
	Does the documented information include:		
	• General description of relevant interested parties (see above clause 4.2 a)?		
	• Scope of the QMS, including boundaries and applicability (see above clause 4.3)?		
	• Description of the processes needed for the QMS and their application throughout the organization?		
	• Sequence and interaction of the processes?		

7.1.5.2	**Measurement traceability**		
	When measurement traceability is a requirement, such as with a statutory or regulatory requirement, a customer or relevant interested party expectation, or considered by your company to be an essential part of providing confidence in the validity of measurement results, do you manage the measuring instruments as follows:		
	• Verified or calibrated at specified intervals or prior to use against measurement standards traceable to international or national measurement standards.		
	• Where no such standards exist, do you retain documented information for the basis used for calibration or verification?		
	• Identified to determine their calibration status?		
	• Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results?		
	Have you established, implemented, and maintained a process for the recall of monitoring and measuring equipment requiring calibration or verification?		
	Is a register of the monitoring and measuring equipment maintained?		