

QUALITY MANAGEMENT SYSTEM QUESTIONNAIRE

Applicable to

I.S. EN ISO 9001:2015



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GENERAL INFO	RMATION	1					
Company Name:							
Address:							
Contact Name:							
Telephone No.:							
Email Address:							
Website URL:							
Sites relevant to this	s application):					
☐ Single Site			Multiple Locatio	ns as listed below			
Address				Employee Numbers	Contact	Email	
Major products / se	rvices provid	led at th	is location(s):				



	CONTEXT OF THE ORGANISATION (CLAU	ISE 4)		
A	Requirement	Response/Evidence	Auditor verification For office use only	Compliant (Y/N)
1	What are the external and internal issues that are relevant to your organisation's purpose and the achievement of customer satisfaction and the organisation's strategic direction?			
2	How frequently, where and in what context are these issues reviewed and monitored?			
3	In the context of the QMS:			
	Who are the relevant interested parties?			
	In the context of the QMS:			
	What are their needs and expectations?			
4	What is the scope of the QMS, taking into account the external and internal issues, interested parties and your products and services?			
5	Is there any requirement of the standard that cannot be applied?			
	If so state the justification.			
6	List the QMS processes, their inputs, outputs, metrics, targets, risks, opportunities, and their sequence and interaction?			



	LEADERSHIP (CLAUSE 5)				
В	Requirement	Response/Evidence	Auditor verification For office use only	Compliant (Y/N)	
1	Who are the top management within the organisation?			(1,11,	
2	What role do top management take in monitoring the effectiveness of the QMS?				
3	Provide examples of how the organisations QMS policy and objectives are compatible with its strategic direction of the organisation?				
4	How have the QMS policy and objectives been established and communicated?				
5	Provide examples of the organisations objectives and how these have been established at relevant departmental and individual levels within the organisation?				
6	Have the requirements for the QMS been integrated into the business processes and how have management promoted awareness of the process approach?				
7	How are customer requirements and applicable statutory and regulatory requirements determined, met and communicated throughout the organisation?				
8	How have top management assigned and communicated responsibilities and authority for relevant roles within the organisation?				
9	How has the organisation established and communicated the responsibilities and authorities for the effective operation of the QMS				



	PLANNING (CLAUSE 6)					
C	Requirement	Response/Evidence	Auditor verification For office use only	Compliant (Y/N)		
1	What are the risks and opportunities that need to be addressed to ensure the QMS system can achieve its intended results?					
2	List the actions planned to address these risks and opportunities					
3	How are the above planned actions integrated into the QMS processes?					
4	What is the process for determining the need for changes to the QMS, and managing their implementation?					
5	Define what quality objectives have been established, and how is achievement of objectives assured?					



File Number:

	SUPPORT (CLAUSE 7)				
D	Requirement	Response/Evidence	Auditor verification For office use only	Compliant (Y/N)	
1	What key resources, processes and infrastructural requirements have been established to ensure the delivery of conforming product and/or services? E.g. People, environmental and infrastructure requirements?			(1),11)	
2	What resources has the organisation determined are required to ensure the validity and reliability of the results of monitoring and measurements activities? E.g. Calibration, Equipment, Test methods, etc.				
3	What knowledge has the organisation determined is required for the operation of its processes and achievement of conformity of products and services?				
4	What roles in the organisation have an effect on the implementation and maintenance of the QMS?				
5	What are the key competency criteria for those roles (appropriate knowledge, education, training, or experience)?				
6	How are deficiencies in competency identified and the required requirements fulfilled? Provide examples.				
7	How has the organisation ensured that those persons doing work under their control are aware of the quality policy and objectives, their contribution to these and the implications of not conforming?				
8	What internal and external communications are relevant to the QMS? What? When? With whom? How?				
9	What documented information is required for the effective implementation and operation of the QMS?				

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	SUPPORT (CLAUSE 7)				
D	Requirement	Response/Evidence	Auditor verification For office use only	Compliant (Y/N)	
10	How is documented information controlled, maintained and retained?				





	OPERATION (CLAUSE 8)				
E	Requirement	Response/Evidence	Auditor verification For office use only	Compliant (Y/N)	
1	What processes have been defined to ensure the provision of products and services that meet requirements defined by the customer?			(3,33)	
2	How does the organisation manage the risks associated with change?				
3	What processes are involved in reviewing and communicating with customers in relation to its products and services, enquiries, contracts or order handling?				
4	When does this review take place?				
5	Where relevant, how are design and development processes established and implemented?				
6	How do you ensure that externally provided processes, products, and services are evaluated, selected, and monitored to ensure conformance to specified requirements?				
7	How does the organisation control the conditions necessary for providing conforming products and services? E.g. a) What documented information is necessary? b) What monitoring and measurement activities are required to verify that products and services meet acceptance criteria? c) How do you ensure that people are competent to perform their required tasks?				
8	Define the methods of ensuring identification and traceability of products and services?				



	OPERATION (CLAUSE 8)				
E	Requirement	Response/Evidence	Auditor verification For office use only	Compliant (Y/N)	
9	Where property belonging to customers or external providers is used in the provision of the product or service, how is this effectively controlled?				
10	Where required, how are post-delivery activities associated with the products and services defined and managed? N.B. Post delivery services include warranty, maintenance services, recycling or final disposal?				
11	Define the processes involved in controlling nonconforming products and services so as to prevent their unintended use?				





	PERFORMANCE EVALUATION (CLAUSE 9)		
	Requirement	Response/Evidence	Auditor verification For office use only	Compliant (Y/N)
1	What process/product/service parameters need to be monitored and measured?			
2	What methods have been established for monitoring, measurement, analysis and evaluation, to ensure valid results?			
3	Define the frequency for the analysis and evaluation of monitoring and measurement results?			
4	How does the organisation monitor customer perceptions of the provision of products and services?			
5	How are needs and opportunities for improvements identified?			
6	Define the organisations internal audit processes?			
7	Define the organisations management review process.	A		



	IMPROVEMENT (CLAUSE 10)				
G	Requirement	Response/Evidence	Auditor verification For office use only	Compliant (Y/N)	
1	How does the organisation determine and select opportunities for improvement?				
2	How are opportunities for improvement implemented and the necessary actions taken to meet customer requirements and enhance customer satisfaction?				
3	Define the organisations processes for managing nonconformities and the related corrective actions?				
4	How does the organisation continually improve the suitability, adequacy, and effectiveness of the QMS?				





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IF YOU ARE UPGRADING TO ISO 9001:2015, PLEASE COMPLETE SECTION H. NOT APPLICABLE TO NEW REGISTRATIONS.

н	IMPROVEMENT (CLAUSE 10)					
	Requirement	Response/Evidence	Auditor verification For office use only	Compliant (Y/N)		
1	Are you maintaining the ISO 9001:2008 QMS					
2	Is there any change to scope					
3	Quality Manual					
4	Management Rep.					
5	Are you maintaining the following procedures: Document Control - Record Control - Internal audit - Non-conforming control - Corrective action - Preventive action					
6	Are you maintaining the required records 4.2.3, 5.6, 6.2, 7.1, 7.2, 7.3, 7.4, 7.5.2, 7.5.3, 7.5.4, 7.6, 8.2.2, 8.2.4, 8.3, 8.5.2, 8.5.3.					

SIGNATURES:									
Client – Top Management:			Auditor:						
Signature:		Date:		Signature:		Date:			