

Audit Checklist	Evidence Sighted
Context of the Organisation	
Have you determined the external and internal issues that are relevant to your organization's purpose and the achievement of customer satisfaction and the organization's strategic direction?	
Do you have a way of reviewing and monitoring these on a regular basis?	
Have you determined the needs and expectations of interested parties that are relevant to the Quality Management System (QMS)?	
Has the scope of the QMS been determined taking into account the external and internal issues, interested parties and your products and services?	
Has your QMS been established including the processes needed and their sequence and interaction?	
Have the criteria for managing these been established together with responsibilities, methods, measurements and related performance indicators needed to ensure the effective operation and control?	
Leadership	
Has top management taken accountability for the effectiveness of the QMS?	
Have the policy and objectives for the QMS, which are compatible with the strategic direction of the organization, been established and communicated?	
Have the objectives been established at relevant departmental and individual levels with the business?	
Have the requirements for the QMS been integrated into the business processes and have management promoted awareness of the process approach?	

Have customer requirements and applicable statutory and regulatory requirements been determined, met and communicated throughout the organization?	
Have the risks and opportunities that are relevant to the QMS been established?	
Has the organization established and communicated the responsibilities and authorities for the effective operation of the QMS?	
Planning	
Have the risks and opportunities that need to be addressed to give assurance that the QMS can achieve its intended result(s) been established?	
Has the organization planned actions to address these risks and opportunities and integrated them into the system processes?	
Is there a defined process for the determining the need for changes to the QMS and managing their implementation?	
Support	
Has the organization determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS (including people, environmental and infrastructure requirements)?	
If monitoring or measuring is used for evidence of conformity of products and services to specified requirements, has the organization determined the resources needed to ensure valid and reliable monitoring and measuring of results?	
Has the organization determined the knowledge necessary for the operation of its processes and achievement of conformity of products and services and implemented a lessons learnt process?	

Has the organization ensured that those persons who can affect the performance of the QMS are competent on the basis of appropriate education, training, or experience or taken action to ensure that those persons can acquire the necessary competence?	
Has the documented information required by the standard and necessary for the effective implementation and operation of the QMS been established?	
Operation	
Is there a defined process for the provision of products and services that meet requirements defined by the customer?	
When changes are planned are they carried out in a controlled way and actions taken to mitigate any adverse effects?	
Are any outsourced processes managed and controlled?	
Is there a defined process for reviewing and communicating with customers in relation to information relating to products and services, enquiries, contracts or order handling?	
Is this review conducted prior to the organization's commitment to supply products and services?	
If you design and develop products or services, are these processes established and implemented in line with the requirements of the standard?	
Do you ensure that externally provided processes, products, and services conform to specified requirements?	
Do you have criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers?	
Is the provision of products and services carried out in controlled conditions which include: <ul style="list-style-type: none"> • the availability of documented information that defines the characteristics of the products and services; 	

<ul style="list-style-type: none"> • the availability of documented information that defines the activities to be performed and the results to be achieved? • monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met? • the people carrying out the tasks are competent? 	
Do you have effective methods of ensuring traceability during the operation process?	
Where property belonging to customers or external providers is used in the provision of the product or service, is this controlled effectively?	
If there is a requirement for post-delivery activities associated with the products and services such as warranty, maintenance services, recycling or final disposal, are these defined and managed?	
Are any nonconforming process outputs managed so as to prevent their unintended use?	
Performance Evaluation	
Has the organization determined • what needs to be monitored and measured and • the methods for monitoring , measurement , analysis and evaluation, to ensure valid results?	
Has it established when the results from monitoring and measurement shall be analyzed and evaluated?	
Have methods of monitoring customer perceptions of the provision of products and services been established?	
Has it determined the need or opportunities for improvements within the QMS and how these will be fed into management reviews?	
Has the organization established a process for an internal audit of the QMS?	
Has an approach to perform management reviews been established and implemented?	
Improvement	

Has the organization determined and selected opportunities for improvement and implemented the necessary actions to meet customer requirements and enhance customer satisfaction?	
Has the organization appropriate processes for managing nonconformities and the related corrective actions?	
Has the organization decided on how it will address the requirement to continually improve the suitability, adequacy, and effectiveness of the QMS?	