

ISO 9001:2015 Compliance Checklist Simplified Version by QualityGurus.com

Question	Evidence	Status	Comments
4.0 Context of the Organization			
4.1 Understanding the Organization and Its Context			
Can you please explain how the organization identifies relevant internal and external issues?			
How often do you review and update these issues? Can you provide examples of recent changes?			
4.2 Understanding the Needs and Expectations of Interested Parties			
How does the organization go about identifying relevant interested parties?			
Can you describe the process of determining the requirements and expectations of these interested parties?			
How often do you review and update the requirements and expectations of interested parties? Can you share any recent updates or changes?			
4.3 Determining the Scope of the Quality Management System			
Can you walk me through how the organization defined the scope of its QMS?			
How did you ensure that the scope includes all relevant products, services, and processes covered by the QMS?			
How were the organization's context and the requirements of interested parties considered while determining the scope?			
Is the scope documented and easily accessible to relevant personnel? Can you show me where it is available?			
4.4 Quality Management System and Its Processes			
How has the organization established, implemented, maintained, and continually improved its QMS?			
Can you explain how the QMS processes are identified and their interactions determined?			
How do you document process inputs, outputs, sequences, and interactions?			
How were responsibilities and authorities assigned to personnel for QMS processes?			
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Question	Evidence	Status	Comments
Can you provide examples of how process performance criteria, resources, and risks are identified and managed?			
How does the organization establish methods for monitoring, measuring, and controlling QMS processes?			
Can you share any recent evaluations of QMS processes and improvements made as a result?			
5.0 Leadership			
5.1 Leadership and Commitment			
<i>5.1.1 General</i>			
Can you provide examples of how top management demonstrates leadership and commitment to the QMS?			
How does top management ensure that quality policy and objectives are established and compatible with the organization's strategic direction?			
Can you explain how top management ensures the integration of the QMS into the organization's processes?			
How does top management promote the use of a process approach and risk-based thinking within the organization?			
<i>5.1.2 Customer Focus</i>			
How does top management ensure that customer requirements are understood and met?			
Can you share any examples of how top management emphasizes the importance of enhancing customer satisfaction?			
5.2 Policy			
<i>5.2.1 Establishing the Quality Policy</i>			
Can you explain how the quality policy was established, documented, and communicated within the organization?			
How does the quality policy align with the organization's purpose and context?			
Can you provide examples of how the quality policy supports the organization's strategic direction and provides a framework for setting quality objectives?			
<i>5.2.2 Communicating the Quality Policy</i>			

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Question	Evidence	Status	Comments
How do you ensure the quality policy is available to relevant interested parties?			
Can you provide examples of how top management ensures the quality policy is understood, implemented, and maintained at all levels of the organization?			
5.3 Organizational Roles, Responsibilities, and Authorities			
Can you explain how roles, responsibilities, and authorities have been assigned, communicated, and understood within the organization?			
How does top management ensure the QMS conforms to the ISO 9001 requirements?			
Can you provide examples of how top management ensures processes deliver intended outputs?			
How do top management review and report on QMS performance, resource needs, and opportunities for improvement?			
6.0 Planning			
6.1 Actions to Address Risks and Opportunities			
How does the organization identify risks and opportunities associated with the QMS?			
Can you explain the process for assessing and prioritizing these risks and opportunities?			
How does the organization determine appropriate actions to address identified risks and opportunities?			
Can you provide examples of recent actions taken to address risks and opportunities?			
6.2 Quality Objectives and Planning to Achieve Them			
Can you explain how the organization sets and documents quality objectives?			
How do you ensure the quality objectives are specific, measurable, achievable, relevant, and time-bound (SMART)?			
Can you describe the process for determining the necessary resources and actions to achieve the quality objectives?			
How does the organization evaluate progress toward meeting the quality objectives?			
6.3 Planning of Changes			

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Question	Evidence	Status	Comments
Can you explain the process for planning and implementing changes to the QMS?			
How does the organization ensure that the purpose and potential consequences of changes are considered before implementation?			
Can you provide examples of recent changes made to the QMS and the planning process followed?			
7.0 Support			
7.1 Resources			
<i>7.1.1 General</i>			
How does the organization determine and provide the necessary resources for the QMS?			
Can you share examples of how the organization ensures that resources are available, maintained, and monitored for effectiveness?			
<i>7.1.2 People</i>			
How does the organization ensure that it has the required personnel to effectively implement the QMS and maintain its processes?			
Can you provide examples of how the organization manages personnel resources to meet its quality objectives?			
<i>7.1.3 Infrastructure</i>			
How does the organization identify and provide the necessary infrastructure for the QMS?			
Can you provide examples of how the organization maintains and improves its infrastructure to support its processes and achieve its quality objectives?			
<i>7.1.4 Environment for the Operation of Processes</i>			
How does the organization determine and manage the work environment needed for its processes?			
Can you share examples of how the organization ensures that the work environment supports the achievement of its quality objectives?			
<i>7.1.5 Monitoring and Measuring Resources</i>			
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Question	Evidence	Status	Comments
How does the organization identify and provide the necessary monitoring and measuring resources to ensure valid results?			
Can you provide examples of how the organization ensures that monitoring and measuring resources are calibrated and maintained?			
<i>7.1.6 Organizational Knowledge</i>			
How does the organization identify, maintain, and manage the necessary organizational knowledge for its processes?			
Can you share examples of how the organization acquires and shares new knowledge within the organization?			
7.2 Competence			
How does the organization determine the necessary competence for personnel affecting the QMS performance?			
Can you explain how the organization ensures that personnel are competent and, if necessary, provide training or other actions to acquire the required competence?			
How does the organization evaluate the effectiveness of the actions taken to address competence requirements?			
7.3 Awareness			
How does the organization ensure that personnel are aware of the quality policy, quality objectives, and their contribution to the QMS?			
Can you provide examples of how the organization promotes awareness of the importance of conforming to QMS requirements and enhancing customer satisfaction?			
7.4 Communication			
How does the organization determine and implement internal and external communication relevant to the QMS?			
Can you explain how the organization ensures the effectiveness of its communication processes?			
7.5 Documented Information			
<i>7.5.1 General</i>			
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Question	Evidence	Status	Comments
How does the organization create, update, and control documented information required by the QMS?			
Can you provide examples of how the organization ensures the availability and suitability of documented information?			
<i>7.5.2 Creating and Updating</i>			
How does the organization ensure that documented information is properly identified, described, reviewed, and approved before use?			
Can you provide examples of recent updates to documented information and the process followed?			
<i>7.5.3 Control of Documented Information</i>			
Can you explain how the organization controls access, distribution, and retrieval of documented information?			
How does the organization ensure the proper storage, preservation, and disposal of documented information?			
8.0 Operation			
8.1 Operational Planning and Control			
How does the organization plan, implement, and control its processes to meet requirements and enhance customer satisfaction?			
Can you provide examples of how the organization ensures effective control over outsourced processes?			
8.2 Requirements for Products and Services			
<i>8.2.1 Customer Communication</i>			
How does the organization communicate with customers regarding product and service information, inquiries, contracts, and handling customer feedback?			
Can you share examples of effective customer communication processes?			
<i>8.2.2 Determining Requirements for Products and Services</i>			
How does the organization determine and review the requirements for its products and services?			
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Question	Evidence	Status	Comments
Can you provide examples of how the organization ensures that it can meet the requirements for products and services before committing to customers?			
<i>8.2.3 Review of Requirements for Products and Services</i>			
Can you explain the process for reviewing and confirming customer requirements before accepting an order?			
How does the organization handle changes in requirements and communicate them internally?			
<i>8.2.4 Changes to Requirements for Products and Services</i>			
How does the organization manage changes to requirements for products and services?			
Can you provide examples of recent changes to requirements and the process followed to ensure proper implementation?			
8.3 Design and Development of Products and Services			
How does the organization plan and control the design and development process for its products and services?			
Can you provide examples of design and development activities, including inputs, controls, outputs, and validation?			
8.4 Control of Externally Provided Processes, Products, and Services			
How does the organization ensure that externally provided processes, products, and services conform to its requirements?			
Can you provide examples of how the organization evaluates, selects, and monitors external providers and their performance?			
8.5 Production and Service Provision			
8.5.1 Control of Production and Service Provision			
Are production and service provision processes planned and carried out under controlled conditions?			
Are criteria for workmanship established and communicated?			
Are suitable equipment and infrastructure available for production and service provision?			
8.5.2 Identification and Traceability			
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Are products and services identified throughout the production process?			
Is traceability maintained, as necessary, to ensure conformity to requirements?			
Are the status of products and services monitored throughout the production process?			
8.5.3 Property Belonging to Customers or External Providers			
Is customer or external provider property identified, verified, protected, and safeguarded?			
Are necessary actions taken if the customer or external provider property is lost, damaged, or found to be unsuitable for use?			
8.5.4 Preservation			
Are products and services preserved during production and service provision to maintain conformity to requirements?			
Is preservation also applied to the constituent parts of products?			
8.5.5 Post-Delivery Activities			
Are post-delivery activities, such as warranty provisions, maintenance services, and disposal, determined and controlled?			
Are post-delivery activities considered in the risk assessment process?			
8.5.6 Control of Changes			
Are changes to production and service provision processes properly controlled and documented?			
Are changes reviewed, verified, and validated as appropriate?			
Are changes approved by the responsible person before implementation?			
Are the consequences of changes evaluated, and necessary actions taken to mitigate any potential adverse effects?			
8.6 Release of Products and Services			
How does the organization ensure that products and services meet the specified requirements before releasing them to customers?			
Can you provide examples of release criteria and the process for verifying conformity to requirements?			

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Question	Evidence	Status	Comments
8.7 Control of Nonconforming Outputs			
How does the organization control nonconforming outputs to prevent unintended use or delivery?			
Can you provide examples of how the organization identifies, evaluates, and takes appropriate actions on nonconforming outputs?			
9.0 Performance Evaluation			
9.1 Monitoring, Measurement, Analysis, and Evaluation			
<i>9.1.1 General</i>			
How does the organization determine what needs to be monitored and measured and the methods, criteria, and timing for monitoring and measurement?			
Can you provide examples of the organization's approach to maintaining documented information as evidence of the results?			
<i>9.1.2 Customer Satisfaction</i>			
How does the organization monitor and measure customer satisfaction?			
Can you provide examples of methods used to obtain and analyze customer feedback?			
<i>9.1.3 Analysis and Evaluation</i>			
How does the organization analyze and evaluate the data and information from its monitoring and measurement activities?			
Can you provide examples of how the organization uses the analysis results to improve its QMS?			
9.2 Internal Audit			
Can you explain the organization's internal audit process, including planning, conducting, reporting, and follow-up activities?			
How does the organization ensure that internal audits are objective and impartial?			
9.3 Management Review			
How does the organization conduct management reviews to ensure the continuing suitability, adequacy, and effectiveness of the QMS?			
Can you provide examples of inputs, outputs, and actions taken as a result of management reviews?			

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Question	Evidence	Status	Comments
10.0 Improvement			
10.1 General			
How does the organization identify and implement opportunities for improvement in its QMS?			
Can you provide examples of recent improvements and the processes used to identify and implement them?			
10.2 Nonconformity and Corrective Action			
How does the organization handle nonconformities and take corrective actions to prevent recurrence?			
Can you provide examples of recent nonconformities, the root cause analysis performed, and the corrective actions taken?			
10.3 Continual Improvement			
How does the organization continually improve the suitability, adequacy, and effectiveness of its QMS?			
Can you provide examples of how the organization uses data and information from monitoring, measurement, analysis, and evaluation to drive continual improvement?			