

ISO 9001:2015 – Self Assessment Transition Checklist

This questionnaire is developed as a guide to give you an indication of your readiness for audit against ISO 9001:2015. Use this self-assessment checklist to determine how close you are to compliance with the new ISO 9001:2015 requirements.

**For support regarding your transition, please contact us:
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ISO 9001:2015 Clause	New requirement	Complies (Yes/No)	Evidence
<p><u>4 Context of the organization</u> <u>4.1 Understanding the organization and its context</u> The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. The organization shall monitor and review the information about these external and internal issues</p>	Yes		
<p><u>4.2 Understanding the needs and expectations of interested parties</u> Due to their impact or potential impact on the organizations ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: The interested parties that are relevant to the quality management system The requirements of these interested parties that are relevant to the quality management system; the organization shall monitor and review the information about these interested parties and their relevant requirements</p>	Yes		
<p><u>4.3 Determining the scope of the quality management system</u> The organization shall determine the boundaries and applicability of the quality management system to establish its scope and consider requirements as defined in clause 4.1 & 4.2 and its products & services.</p>	Yes		
<p><u>4.4 Quality management system</u> The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions.</p>	Yes		

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<p>5 Leadership 5.1 Leadership and commitment</p> <p>5.1.1 General Top management shall demonstrate leadership and commitment with respect to the quality management system by: Taking accountability of the effectiveness of the QMS Ensuring that the quality policy and objectives are established for the QMS and are compatible with the context and strategic direction of organization Ensuring the integration of the QMS requirements into the organization's business processes Promoting the use of the process approach and risk based thinking Ensuring that the resources needed for the QMS are available Communicating the importance of effective quality management and of conforming to the QMS requirements Ensuring that the QMS achieves its intended results Engaging, directing and supporting persons to contribute to the effectiveness of the QMS Promoting continual improvement Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility</p> <p>5.1.2 Customer Focus Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring:</p> <ul style="list-style-type: none"> a) Customer and applicable statutory and regulatory requirements are determined, understood and consistently met b) The risks and opportunities that can effect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed c) The focus on enhancing customer satisfaction is maintained 	Yes		
<p>5.2 – Policy 5.2.1 Developing the Quality Policy Top management shall establish, review and maintain a quality policy that: Is appropriate to the purpose and context of the organization.</p>	Yes		

<p>Provides a framework for setting and reviewing quality objectives Includes a commitment to satisfy applicable requirements</p> <p>It should communicated and understood and be available to relevant interested parties as appropriate</p> <p>5.2.2 Communicating the Quality Policy The quality policy shall:</p> <ul style="list-style-type: none"> a) Be available and be maintained as documented information b) Be communicated, understood and applied within the organisation c) Be available to relevant interested parties, as appropriate 			
<p>5.3 Organizational roles, responsibilities and authorities Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization</p>	No		
<p>6 Planning 6.1 Actions to address risk and opportunities When planning for the QMS the organization shall consider the issues referred to 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:</p> <ul style="list-style-type: none"> a) give assurance that the QMS can achieve the intended results b) enhance desirable effects c) prevent or reduce, undesired effects d) achieve improvement 	Yes		
<p>6.1.2 The organization shall plan:</p> <ul style="list-style-type: none"> a) actions to address these risks and opportunities b) how to: <ul style="list-style-type: none"> 1) Integrate and implement the actions into its QMS 2) Evaluate the effectiveness of these actions 	Yes		
<p>6.2 Quality objectives and planning to achieve them 6.2.1 The organisation shall establish quality objectives at relevant functions,</p>	Yes		

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<p>6.2.2 When planning actions to achieve quality objectives the organization shall determine:</p> <p>What will be done, what resources will be required, who will be responsible, when will it be completed, how will the results be evaluated</p>	Yes		
<p>6.3 Planning of changes When the organisation determines the need for changes to the QMS, the changes shall be carried out in a planned manner: The purpose of the change and any potential consequences, the integrity of the QMS, the availability of resources, the allocation or re-allocation of responsibilities and authorities</p>	No		
<p>7 Support 7.1 Resources The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system</p>	No		
<p>7.2 Competence The organisation shall:</p> <p>Determine the necessary competence of persons doing work under its control that affects the performance and effectiveness of the QMS</p> <p>Ensure that these persons are competent on the basis of appropriate education, training or experience</p> <p>Where applicable take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken</p> <p>Retain appropriate documented information as evidence of competence</p>	No		
<p>7.3 Awareness Persons doing work under the organization's control shall be aware of: The quality policy and relevant quality objectives</p> <p>Their contribution to the effectiveness of the QMS, including the benefits of improved performance</p>	Yes		

The implications of not conforming with the QMS requirements			
ISO 9001:2015 Clause	New requirement	Complies (Yes/No)	Evidence
<p>7.4 Communication The organization shall determine internal and external communications relevant to the QMS What it will communicate? When to communicate? With whom to communicate? How to communicate?</p>	Yes		
<p>7.5 Documented information 7.5.1 General The organizations QMS shall include: Documented information required by this international standard and determined by the organization as being necessary for the effectiveness of the QMS 7.5.2 Creating and updating When creating and updating documented information the organization shall ensure appropriate: Identification and description (e.g. a title, date, author, or reference number); format (e.g. language, software version, graphics) and media (e.g. paper, electronic); review and approval for suitability and adequacy.</p>	No		
<p>7.5.3 Control of documented information Documented information required by the QMS and by this International Standard shall be controlled to ensure: it is available and suitable for use, where and when it is needed it is adequately protected</p>	No		
<p>7.5.3.2 For control of documented information the organization shall address the following activities where applicable: Distribution, access, retrieval and use Storage and preservation Control of changes Retention and disposition Documented information of external origin shall be identified as appropriate and controlled</p>			

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<p>8 Operation 8.1 Operational planning and control The organization shall plan, implement and control the processes needed to meet requirements for the provision of products and services, and to implement the actions determined in 6.0 by:</p> <p>Determining requirements for the products and services</p> <p>Establishing criteria for the processes and for the acceptance of products and services</p> <p>Determining the resources needed to achieve conformity to product and service requirements</p> <p>Implementing control of the processes in accordance with the criteria</p> <p>Determining and keeping documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate conformity of products and services to requirements</p> <p>The organisation shall control planned changes and review the consequences of unintended changes taking action to mitigate any adverse effects as necessary</p> <p>The organisation shall ensure that outsourced processes are controlled in accordance with 8.4</p>	Yes		
<p>8.2 Requirements for products and services</p>			
<p>8.2.1 Customer communication Communication with customers shall include:</p> <p>Providing information relating to products and services</p> <p>Handling enquiries, contracts or orders including changes</p> <p>Obtaining customer feedback, including customer complaints</p> <p>The handling or controlling customer property</p>	No		

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Establishing specific requirements for contingency actions when relevant			
8.2.2 Determining requirements related to products or services	No		
8.2.3 Review of requirements related to products and services	No		
8.2.4 Changes to requirements for products and services No	No		
8.3 Design and development	No		
8.3.1 General The organisation shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services	No		
8.3.2 Design and development planning	No		
8.3.3 Design and development inputs	No		
8.3.4 Design and development controls	No		
8.3.5 Design and development outputs	No		
8.3.6 Design and development changes	No		
8.4 Control of externally provided services	No		
8.5 Production and service provision	No		
8.6 Release of products and services	No		
8.7 Control of nonconforming process outputs	No		
9 Performance evaluation 9.1 Monitoring, measurement, analysis and evaluation 9.1.1 General The organization shall determine: what needs to be monitored and measured, the methods of monitoring measurement, analysis and evaluation as applicable to ensure valid results when monitoring and measuring will be performed and when results from monitoring and measurement shall be analysed and evaluated The organisation shall evaluate the quality performance and effectiveness of the QMS	No		
9.1.2 Customer Satisfaction	No		
9.1.3 Analysis and evaluation	No		
9.2 Internal Audit 9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the QMS conforms to the organisations own	New clause but not really any new requirements		

requirements for its QMS and to this international standard and is effectively implemented and maintained			
ISO 9001:2015 Clause	New requirement	Complies (Yes/No)	Evidence
9.3 Management Review Top management shall review the organization's QMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness	New clause but not really any new requirements		
10 Improvement 10.1 General 10.2 Nonconformity and corrective action When a nonconformity occurs, including those arising from complaints, the organization shall react to the nonconformity	New clause but not really any new requirements		
10.3 Continual improvement The organization shall continually improve the suitability, adequacy and effectiveness of the QMS	New clause but not really any new requirements		