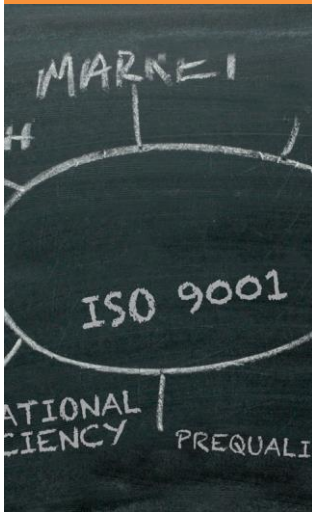


ISO 9001:2015 TRANSITION CHECKLIST



Use the checklist below, along with your internal audit of the ISO 9001:2015 requirements followed by a management review to evaluate the changes prior to your organization's transition audit.

If you are not able to complete this document, it is a strong indicator that your organization may not be ready to complete the transition to ISO 9001:2015.

New Concepts & Themes: These concepts will bridge multiple processes, clauses and functional areas. Ensure that these new concepts have been deployed in a manner that supports the process approach and risk based thinking.

If you have any questions, feel free to email us at usainfo@nqa.com or call us at 800-649-5289.

New Concepts	Instructions	Organization Response
<p>Are there any requirements of ISO 9001:2015 that the organization is considering not applicable?</p>	<p>If "Yes", please list all non-applicable requirements and justifications of why they do not affect your organization's ability or responsibility to ensure the conformity of your products and services and the enhancement of customer satisfaction (ref. ISO 9001:2015, 4.3)</p> <p>If "No", mark response column as "N/A" and proceed to next question</p>	
<p>Is the organization still maintaining a documented Quality Manual?</p>	<p>If "Yes", mark response column as "N/A" and proceed to next question</p> <p>If "No", please detail how your organization has determined the processes needed, and their interactions in accordance with ISO 9001:2015 (ref. ISO 9001:2015, 4.4.1)</p>	
<p>Is the organization still maintaining Documented Procedures?</p>	<p>If "Yes", mark response column as "N/A" and proceed to next question</p> <p>If "No", please describe on what basis your organization has determined that documented information (i.e. procedures) are not necessary for the effectiveness of the quality management system (ref. ISO 9001:2015, 7.5.1)</p>	
<p>Has the approach changed with regard to the appointment of a Management Representative?</p>	<p>If "Yes", please detail how top management demonstrates leadership and commitment with respect to the quality management system (ref. ISO 9001:2015, 5.1.1)</p> <p>If "No", mark response column as "N/A" and proceed to next question</p>	

New Themes	Phase	Clauses	Activity	Evidence to Support Conformance
Business planning and strategic direction	Plan	4.1, 4.2	Has the organization identified both internal and external issues and interested parties that are relevant to and/or support the strategic direction of the organization?	
	Do	5.2.1	Is the strategic direction being utilized as an input to the Quality Policy/Quality Objectives/Risk Management/Management Review processes?	
	Check	4.1, 4.2, 5.1.1, 9.3.2	Is the quality system being assessed and reviewed in accordance with the strategic direction?	
	Act	10.3	Is the quality system being updated as necessary in response to changes in any of the above?	
Process Risk	Plan	4.4.1, 6.1, 6.2, 6.3, 8.5.6	When establishing the QMS and planning for change, have risks to achieving process objectives been identified?	
	Do	8.1	Have the identified process risks been addressed?	
	Check	6.1.2, 9.1.3, 9.3.2	Is the organization analyzing the effectiveness of actions taken to address process risks?	
	Act	10.2.1, 10.3	Following analysis and corrective action is there evidence that process risks have been updated?	
Product and Service Risk	Plan	5.1.2, 6.1, 6.2, 8.1, 8.2.2, 8.2.3, 8.3.2	Have risks to achieving product or service conformity been: <ul style="list-style-type: none"> • considered as part of the planning for operational control? • considered when determining and reviewing customer requirements? • identified and has product complexity been considered during design planning? 	
	Do	8.1, 8.2.3.1, 8.3.3	Have design and operational controls to address the identified product and service risks been implemented?	
	Check	9.1.3, 9.3.2	Is the organization analyzing the effectiveness of actions taken to address product risks?	
	Act	10.1	Has the organization determined and selected opportunities for improvement on product and service?	
Risk associated with the control of externally provided product and service	Plan	6.1	Have risks associated with externally provided product, process (i.e. formerly named outsourced) or service been identified?	
	Do	8.4.1, 8.4.2	Are the identified risks utilized as an input into the: <ul style="list-style-type: none"> • potential impact of externally provided product, process or service • type and extent of controls • selection and evaluation of external providers • degree of information provided to these resources? 	
	Check	8.4.1, 9.3.2	Has the organization applied criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers?	
	Act	9.3.3	Has the organization modified the controls applied to external providers based upon the results of evaluation?	

ISO 9001:2015 enhanced emphasis: Please complete the table below to demonstrate that each of the following requirements have been addressed within the quality management system.

ISO 9001:2015

Evidence to support conformance

5.1 Leadership and commitment (ref. ISO 9001:2008, 5.1)	
6.3 Planning of changes (ref. ISO 9001:2008, 5.4.2)	
7.1.5 Monitoring and measuring resources (ref. ISO 9001:2008, 7.6)	
7.3 Awareness (ref. ISO 9001:2008, 6.2.2)	
7.4 Communication (ref. ISO 9001:2008, 5.5.3)	
8.2 Determination of requirements for products and services (ref. ISO 9001:2008, 7.2)	
8.3 Design and development of products and services (ref. ISO 9001:2008, 7.3)	
8.5.5 Control of production and service Provision (ref. ISO 9001:2008, 7.5.1)	
8.5.6 Control of changes (ref. ISO 9001:2008, 5.4.2)	
8.6 Release of products and services (ref. ISO 9001:2008, 8.2.4)	
8.7 Control of nonconforming process outputs, products and services (ref. ISO 9001:2008, 8.3)	
9.3 Management review (ref. ISO 9001:2008, 5.6)	
10.2 Nonconformity and corrective action (ref. ISO 9001:2008, 8.5.2)	

Areas for further investigation



Contact us

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