Approachable Certification Ltd ISO 9001:2015 Client Transition Checklist

Instructions for Client: Please complete this checklist prior to your organisations transition audit and forward it to Rachel Maxwell and Lead auditor and complete one full internal audit against the requirements ISO 9001:2015. Please ensure that the completed checklist and internal audit records are available to your auditor at the commencement of your transition visit.

If you are not able to complete this document, it is a strong indicator that your organisation may not be ready to complete the transition to ISO 9001:2015. In this case, please inform the office that you need additional time to prepare for the transition and they will work with you to select a mutually agreeable date to complete the transition.

New Concepts & Themes: Please complete the tables below which highlights some of the new concepts and themes present in ISO 9001:2015. 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.

New Concepts	Instruction	Organisation Response
Are there any requirements of ISO 9001:2015 that the organisation is considering to be not applicable?	If "Yes", please list all non-applicable requirements and justifications of why they do not affect your organisation'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)	
	If "No", mark response column as "N/A" and proceed to next question	
Is the organisation still maintaining a documented Quality Manual?	If "Yes", mark response column as "N/A" and proceed to next question	
	If "No", please detail how your organisation has determined the processes needed, and their interactions in accordance with ISO 9001:2015 (ref. ISO 9001:2015, 4.4.1)	
Is the organisation still maintaining Documented Procedures?	If "Yes", mark response column as "N/A" and proceed to next question	
	If "No", please describe on what basis your organisation 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)	
Has the approach changed with regard to the appointment of a Management Representative?	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)	
	If "No", mark response column as "N/A" and proceed to next question	

New Themes	Phase	Clauses)	Activity	Evidence to support compliance
Business Planning and Strategic Direction	Plan	4.1, 4.2	Has the organisation identified both internal and external issues and interested parties that are relevant to and/or support the strategic direction of the organisation?	
	Do	5.2.1	Is the strategic direction being utilised 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 organisation analysing 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 • 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 organisation analysing the effectiveness of actions taken to address product risks?	
	Act	10.1	Has the organisation determined and selected opportunities for improvement on product and service?	

New Themes	Phase	Clauses)	Activity	Evidence to support compliance
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 • 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 organisation applied criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers?	
	Act	9.3.3	Has the organisation 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 has been addressed within the quality management system.

ISO 9001:2015	Evidence to support compliance
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)	
7.1.6 Organisational knowledge	
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)	

ISO 9001:2015	Evidence to support compliance
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
