

ISO 9001:2015 Example of Audit Checklist

Clause	Requirements (ver. 2015)	Points To Look For	Documented Information / Audit Evidence
4.0	4 Context of the organization		
4.1	Organization context		
	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.	Has company identified their external & internal issues affecting the operation process. What is the strategic plan to achieve the quality objectives?	
4.2	Needs and expectations of interest parties		
	Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: a) the interested parties that are relevant to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system.	Who are other stakeholders and what is their topic of interests?	
4.3	Determining the Scope		
	The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider: a) the external and internal issues referred to in 4.1; b) the requirements of relevant interested parties referred to in 4.2; c) the products and services of the organization. The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.	Certification Scope	
4.4	Quality Management System and its process		
	The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall: a) determine the inputs required and the outputs expected from these processes; b) determine the sequence and interaction of these processes; c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes; d) determine the resources needed for these processes and ensure their availability; e) assign the responsibilities and authorities for these processes; f) address the risks and opportunities as determined in accordance with the requirements of 6.1; g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results; h) improve the processes and the quality management system.	- observe the processes - Interview personnel involved - check documents	
4.4.1			
4.4.2	To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes; b) retain documented information to have confidence that the processes are being carried out as planned.	Check retention of record	
5.0	Leadership		
5.1	Leadership and commitment		
	General Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the process approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.	Check: - Check organization chart for support - Check any resource planning? Expansion planning? Any improvement planning? - Interview the top management - Check how management ensure communication deliver - Check how is external communication channel	
5.1.1			
5.1.2	Customer focus - Determine the customer and legal requirement- Risk & Opportunity which can affect the conformity of product and enhance customer satisfaction level to be determined. - Customer satisfaction.	- method of customer feedback - any analysis and improvement plan - discuss with management?	
5.2	Policy - Developing Quality Policy. - Communication of QP. - Be available for relevant interest party, if applicable.	- Check the policy - communication of policy to interested parties	
5.3	Organization roles, responsibilities and authorities - Assign, communication and understood the responsibilities and authorities for relevant roles - Assign resp. and authorities to QMS implementation, reporting the performance etc.	- Check the job descriptions of each roles - Check Authorities	
6.0	Planning		
6.1	Actions to address risks and opportunities		
6.1.1	Planning for QMS QMS →intended result - Enhance desired effect - Prevent and reduce undesired effect - Improvement.	- Check the Risk and Opp. Assessment Record to include the strategic to achieve desired result, the effectiveness of action taken and improvement.	
6.1.2	Action to: - Address the risk & opportunity - Evaluate the effectiveness of the action taken		
6.2	Quality Objectives and Planning to achieve them	- Check Quality Objective statement if any resource planning / was objective measurable and realistic, how objectives is measured and evaluate.	
6.2.1	Quality Objective (no change)		
6.2.2	Planning to achieve Quality Objective (like EMP)		
6.3	Planning for Change	- Traceable of change including reason of change and plan	
7.0	Support		
7.1	Resources		
7.1.1	General		
7.1.2	People	-Infrastructure maintenance records	
7.1.3	Infrastructure		
7.1.4	Environment for the operation processes		
7.1.5	Monitoring and measuring resources	-Check calibration planning and record	
7.2	Competence	- Training need analysis, training plan, record	
7.3	Awareness - Quality Policy/Objective - Contribution of QMS effectiveness	- Interview staffs to check understanding	
7.4	Communication - Internal and external communication	- communication channel - example of communication internal & external. -QMS document and record control	
7.5	Documented Information		
8.0	Operation		
8.1	Operation Planning & Control		
8.2	Requirement for product/service		
8.2.1	Customer Communication	-Check if any contingency plan	
8.2.2	Determine the requirement related to product/service		
8.2.3	Review requirement related to product/service		
8.2.4	Changes to requirement related to product/service		
8.3	Design & development of product/service		
8.4	Control of externally provided processes, products and services		
8.4.1	General	- Check documented evidence and interview how to ensure the control	
8.4.2	Type of extent of control		
8.4.3	Information for external providers		
8.5	Production & Service Provision		
8.5.1	Control of Production & Service provision	- check any implementation of action to prevent human error? through audit process and also some document tracing as evidence	
8.5.2	Identification & Traceability		
8.5.3	Properties belonging to external provider and customer		
8.5.4	Preservation		
8.5.5	Post-delivery activity	- Check legal requirement of post-delivery activities such as disposal/recycle etc. - Check undesired consequence of product/service. - Check post-delivery maintenance service and product warranty.	
8.5.6	Control of Changes	- Review & control of changes for production/service provision. - Check proper process in placed& record and understanding of person in-charge	
8.6	Release of product/service		
8.7	Control of nonconforming products		
8.7.1			
8.7.2			
9.0	Performance Evaluation		
9.1	Monitoring, measurement, analysis and evaluation		

9.1.1	General		
9.1.2	Customer Satisfaction		
9.1.3	Analysis and Evaluation	<ul style="list-style-type: none"> - Conformity of product/service values from clients, any improvement? - Degree of customer satisfaction - check effectiveness of corrective action and whether evaluation is done - any identification of risk versus opportunities 	
9.2	Internal Audit		
9.3	Management Review		
9.3.1	General		
9.3.2	Management Review Input	Check management review record what was discussed	
	Management Review Output		
10.0	Improvement		
10.1	General		
10.2	Nonconformity and corrective action	Chech whether non-conformities was closed	
10.3	Continous Improvement		