ISO 9001:2015 Master Internal Audit Checklist

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Before you begin auditing, review and edit the process name list in Cell B313. This will populate the drop-down menus in Column E and various axes within the audit result charts. Use the drop-down menu in Column F to select one of four audit findings defined by the audit criteria. Column G will automatically display a recommendation based on the audit finding. The response is then automatically represented as an 'x' in either Column H, I, J, or K. These columns are hidden. The indicator in Column L will update according to the perceived level of risk, e.g., minor or major. (Ref. Clause 6.4.8, ISO 19011:2018). Use the drop-down menus in Col M to select an appropriate root-cause. You can change this list by editing the root-cause list in Cell M313. Describe how to correct a nonconformance or adopt an opportunity in Col N. Record audit evidence, such as document numbers and revisions in Col O.

					Audit Findings & Actions					
Ref No.	**Clause Title**	**Q-No**	**Requirements/Questions**	**Process Name**	**Audit Result**	**Recommendations**	**Score**	**Possible Root-cause**	**Action Plan**	**Audit Evidence & Notes**
4.1	Organizational Context	1	Has your organization determined external and internal issues (Incl. whether climate change is a relevant issue) are applicable to its purpose and its strategic direction that affect its ability to achieve the intended result(s) of its quality management system?	Business Planning	Minor NC	Identify and discuss the root-cause within 4 weeks and correct.	75	Human - Poor employee involvement	Reinforce training	
4.1	Organizational Context	2	Does your organization monitor and review information about these external and internal issues?	Business Planning	Major NC	Contain the problem imediately. Identify the root-cause within one week and correct.	25	Process - Procedures or work-instructions were inadequate/non-existent	Review and rewrite WI	
4.2	Relevant Interested Parties	3	Does your organization determine the interested parties that are relevant to the quality management system?	Business Planning	Minor NC	Identify and discuss the root-cause within 4 weeks and correct.	75	Human - Lack of skill, training or experience	Reinforce training	
4.2	Relevant Interested Parties	4	Does your organization determine the requirements (Incl. those relating to climate change) of the interested parties that are relevant to the quality management system?	Design & Development	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Relevant Interested Parties	5	Does your organization monitor and review information about these interested parties and their relevant requirements?	Business Review	Major NC	Contain the problem imediately. Identify the root-cause within one week and correct.	25	Process - Procedure was contradictory or confusing	Review and rewrite procedure	
4.3	Management System Scope	6	Does your organization determine the boundaries and applicability of the quality management system to establish its scope?	Management System	Major NC	Contain the problem imediately. Identify the root-cause within one week and correct.	25	Human - Inadequate management involvement	Reinforce training	
4.3	Management System Scope	7	When determining this scope, has your organization considered the external and internal issues referred to in 4.1?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.3	Management System Scope	8	When determining this scope, has your organization considered the requirements of relevant interested parties referred to in 4.2?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.3	Management System Scope	9	When determining this scope, has your organization considered all relevant products, services and work-related activities, functions and physical boundaries to the quality management system?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.3	Management System Scope	10	Has your organization applied all the requirements of ISO 9001:2015 if they are applicable within the determined scope of the quality management system?	Management System	Minor NC	Identify and discuss the root-cause within 4 weeks and correct.	75	Human - Poor employee involvement	Review training procedure	
4.3	Management System Scope	11	Does the scope state the types of products and services covered, and provide justification for any requirement of ISO 9001:2015 that your organization determines is not applicable to the scope of its quality management system?	Management System	Opportunity	Review and implement actions to deploy the opportunity to improve the process(s).	100	Opportunity for improvement	Review scope	
4.3	Management System Scope	12	Is the scope of your organization's quality management system available and maintained as documented information and available to interested parties and workers? (See 7.5.1a)	Management System	Major NC	Contain the problem imediately. Identify the root-cause within one week and correct.	25	Human - Human error	Reinforce training	
4.4	Management System Processes	13	Has your organization established, implemented, maintained and continually improved its quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001:2015?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.4	Management System Processes	14	Has your organization determined the process required for the quality management system, including their interactions, in accordance with requirements and their application throughout the organization?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.4	Management System Processes	15	Has your organization determined the inputs required and the outputs expected from these processes?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.4	Management System Processes	16	Has your organization determined the sequence and interaction of these processes?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.4	Management System Processes	17	Has your organization determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.4	Management System Processes	18	Has your organization determined the resources needed for these processes and ensure their availability?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.4	Management System Processes	19	Has your organization assigned responsibilities and authorities for these processes?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.4	Management System Processes	20	Has your organization addressed the risks and opportunities as determined in accordance with the requirements of 6.1?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.4	Management System Processes	21	Has your organization evaluated these processes and implement any changes needed to ensure that these processes achieve their intended results?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.4	Management System Processes	22	Does your organization improve the processes and the quality management system?	Management System	Major NC	Contain the problem imediately. Identify the root-cause within one week and correct.	25	Human - Did not follow procedures, a one-time lapse	Review training procedure	
4.4	Management System Processes	23	To the extent necessary, does your organization maintain documented information to support the operation of its processes?	Management System	Major NC	Contain the problem imediately. Identify the root-cause within one week and correct.	25	Human - Physically unable perform the task	Reassign duties	
4.4	Management System Processes	24	To the extent necessary, does your organization retain documented information to have confidence that the processes are being carried out as planned?	Management System	Opportunity	Review and implement actions to deploy the opportunity to improve the process(s).	100	Opportunity for improvement	Review previous management review minutes	
5.1.1	Leadership & Commitment - General	25	Has Top Management demonstrated leadership and commitment to the quality management system by taking accountability for the effectiveness of your organization's quality management system?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
5.1.1	Leadership & Commitment - General	26	Has Top Management demonstrated leadership and commitment to the quality management system by ensuring that your organization's quality policy and objectives are established, are documented; and are compatible your organization's goals (See 6.2) and its context (See 4.0)?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
5.1.1	Leadership & Commitment - General	27	Has Top Management demonstrated leadership and commitment to the quality management system by ensuring that quality requirements are integrated into your organization's business processes?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
5.1.1	Leadership & Commitment - General	28	Does Top management demonstrate leadership and commitment with respect to the quality management system by promoting the use of the process approach and risk-based thinking?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
5.1.1	Leadership & Commitment - General	29	Has Top Management demonstrated leadership and commitment to the quality management system by ensuring that your organization has the required resources to implement it?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
5.1.1	Leadership & Commitment - General	30	Does Top management demonstrate leadership and commitment with respect to effective quality management system by communicating the importance of effective quality management and of conforming to quality management requirements?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			