Q#	ISO 9001:2015 Clause	Audit Question	Audit Evidence
	4 Context of the Organization		
	4.1 Understanding the organization and its context		
4.1q1	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.	How has the organization determined external and internal issues relevant to its purpose and strategic direction? How do these affect the ability to achieve the intended result of the QMS?	
4.1q2	The organization shall monitor and review the information about these external and internal issues.	How do you monitor and review information about these internal and external issues?	
	NOTE 1 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, regional or local. NOTE 2 Understanding the internal context can be facilitated by considering issues related to values, culture knowledge and performance of the organization.		
	4.2 Understanding the needs and expectations of interested parties		
4.2q1	Due to their impact or potential impact 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.	How have you determined what interested parties are relevant to the QMS? How have you determined what requirements those parties have that are relevant to the QMS? How has impact or potential impact been determined?	
4.2q2	The organization shall monitor and review the information about these interested parties and their relevant requirements.	How do you monitor and review the information about interested parties and their relevant requirements?	
	4.3 Determining the scope of the quality management system		
4.3q1	The organization shall determine the boundaries and applicability of the quality management system to establish its scope.	How have the boundaries and applicability of the QMS been used to establish the scope of the organization?	
4.3q2	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.	How have: The external and internal issues; The requirements of relevant interested parties and; The products and services of the organization been considered when determining the scope of the organization?	
4.3q3	Where a requirement of this International Standard within the determined scope can be applied, then it shall be applied by the organization.	How has the application of the International Standard within the scope been determined, and how has it been applied by the organization?	

Internal Quality Management System Audit Checklist

Sabine Zange

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