

Clause No.	Main Clause	ISO 9001 Question	Findings	Evidence	Score	Gap	Max	% Implm
4	4. Context	Context of the Organization			24.5	0.5	25	98
4.1	4. Context	Understanding the organization and its context			0.5	1.5	2	25
4.1a1	4. Context	Has your organization determined the external and internal issues relevant to the Purpose & strategic direction of its QMS and that can affect its ability to achieve the intended results?	Partially		0.5	0.5	1	50
4.1a2	4. Context	Does the organization monitor and review information about these external and internal issues?	No		0	2	2	0%
4.2	4. Context	Understanding the needs and expectations of workers and other interested parties			1	2	3	33
4.2a1a	4. Context	Has the organization determined the interested parties that are relevant to the QMS?	No		0	2	2	0%
4.2a1b	4. Context	Has the organization determined the requirements of these interested parties relevant to the QMS?	No		0	2	2	0%
4.2a1	4. Context	Does the organization monitor and review the information about these interested parties and their relevant requirements?	Yes		1	0	2	50%
4.3	4. Context	Determining the scope of the quality management system			10	0	10	100
4.3a1	4. Context	Has the organization established the scope of its QMS?	Yes		1	0	2	50%
4.3a2	4. Context	Has the organization determined the boundaries and applicability of the QMS?	Yes		1	0	2	50%
4.3a2a	4. Context	When establishing the scope has the organization taken into consideration the external and internal issues referred to in 4.1?	Yes		1	0	2	50%
4.3a2b	4. Context	When establishing the scope has the organization taken into consideration the requirements of relevant interested parties referred to in 4.2?	Yes		1	0	2	50%
4.3a2c	4. Context	When establishing the scope has the organization taken into consideration the products and services of the organization?	Yes		1	0	2	50%
4.3a2	4. Context	Has the organization applied all of the requirements of the ISO 9001:2015 International Standard (if applicable) within the determined scope of its quality management system?	Yes		1	0	2	50%
4.3a3	4. Context	Is the scope of the organization's quality management system available and maintained as documented information?	Yes		1	0	2	50%
4.3a3a	4. Context	Does the scope state the types of products and services covered?	Yes		1	0	2	50%
4.3a3b	4. Context	Does the scope provide any justification for any requirement of the ISO 9001:2015 International Standard that the organization determines is not applicable to the scope of its quality management system?	Yes		1	0	2	50%
4.3a3c	4. Context	Can the organization claim conformity to the ISO 9001:2015 International Standard by ensuring that requirements determined as not applicable do not affect the organization's ability or responsibility to ensure the conformity of its products, services and enhancement of customer satisfaction?	Yes		1	0	2	50%
4.4	4. Context	Quality management system and its processes			11	0	13	85

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Sabine Zange



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