

AB. OUR AS9100D CONFORMANCE AUDIT QUESTIONNAIRES

6. ASSESS HOW WELL YOU CONFORM TO PLANNING EXPECTATIONS

6.1 DEFINE ACTIONS TO MANAGE RISKS AND ADDRESS OPPORTUNITIES

6.1.1 CONSIDER RISKS AND OPPORTUNITIES WHEN YOU PLAN YOUR QMS

1	SHL	Did you plan the development of your organization's QMS?	Y	N	X	
2	SHL	Did you identify the risks and opportunities that could influence the performance of your organization's QMS or disrupt its operation?	Y	N	X	
3	SHL	Did you consider how your organization's context could affect how well its QMS is able to achieve intended results?	Y	N	X	
4	SHL	Did you consider how external issues could affect your QMS?	Y	N	X	
5	SHL	Did you consider how your legal environment could affect the QMS?	Y	N	X	
6	SHL	Did you consider how your social environment could affect the QMS?	Y	N	X	
7	SHL	Did you consider how your cultural environment could affect the QMS?	Y	N	X	
8	SHL	Did you consider how your market environment could affect the QMS?	Y	N	X	
9	SHL	Did you consider how your economic environment could affect the QMS?	Y	N	X	
10	SHL	Did you consider how your competitive environment could affect the QMS?	Y	N	X	
11	SHL	Did you consider how your technological environment could affect the QMS?	Y	N	X	
12	SHL	Did you consider how internal issues could affect your QMS?	Y	N	X	
13	SHL	Did you consider how your organization's values could affect the QMS?	Y	N	X	
14	SHL	Did you consider how your organization's culture could affect the QMS?	Y	N	X	
15	SHL	Did you consider how your organization's knowledge could affect the QMS?	Y	N	X	
16	SHL	Did you consider how your organization's performance could affect the QMS?	Y	N	X	
17	SHL	Did you consider how your organization's interested parties could affect how well your QMS is able to achieve intended results?	Y	N	X	Since section 6.1.1 asks us to consider "the requirements referred to in 4.2", that's what we've done. We've used material from section 4.2 to explain what section 6.1.1 expects you to do.
18	SHL	Did you consider how interested parties could affect your ability to provide products and services that meet customer requirements?	Y	N	X	

ORGANIZATION:

YOUR LOCATION:

COMPLETED BY:

DATE COMPLETED:

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6. ASSESS HOW WELL YOU CONFORM TO PLANNING EXPECTATIONS

19	SHL	Did you consider how interested parties could affect your ability to provide products and services that meet statutory and regulatory requirements?	Y	N	X	
20	SHL	Did you figure out what you need to do to address the risks and opportunities that could influence the performance of your QMS or disrupt its operation?	Y	N	X	
21	SHL	Did you figure out what you need to do to ensure that your QMS will achieve intended results?	Y	N	X	
22	SHL	Did you figure out what you need to do to prevent or reduce any undesired effects that your QMS could cause?	Y	N	X	
23	SHL	Have you figured out how to enhance desirable effects?	Y	N	X	
24	SHL	Have you figured out what needs to be done to ensure that QMS is improved?	Y	N	X	

6.1.2 PLAN HOW YOU'RE GOING TO MANAGE RISKS AND OPPORTUNITIES

25	SHL	Do you consider your organization's risk treatment options?	Y	N	X	
26	SHL	Do you consider your options when you define actions to address QMS risks and opportunities?	Y	N	X	
27	CAN	Do you consider avoiding or reducing your risk?	Y	N	X	
28	CAN	Do you consider eliminating the source of your risk?	Y	N	X	
29	CAN	Do you consider retaining the risk or sharing it with others?	Y	N	X	
30	CAN	Do you consider modifying the probabilities or consequences?	Y	N	X	
31	CAN	Do you consider increasing your risk in order to pursue an opportunity?	Y	N	X	
32	SHL	Do you define actions to address risks and opportunities?	Y	N	X	
33	SHL	Do you define actions that you can take to address the risks and opportunities that could influence the performance of your QMS or disrupt or damage its operation?	Y	N	X	
34	SHL	Do you consider the potential impact on products and services when you define the actions you plan to take to address QMS risks and opportunities?	Y	N	X	
35	SHL	Do you figure out how you're going to implement these actions and how you're going to make them part of your QMS processes?	Y	N	X	
36	SHL	Do you figure out how you're going to evaluate the effectiveness of the actions you take to address QMS risks and opportunities?	Y	N	X	

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6. ASSESS HOW WELL YOU CONFORM TO PLANNING EXPECTATIONS

6.2 SET QUALITY OBJECTIVES AND DEVELOP PLANS TO ACHIEVE THEM

6.2.1 ESTABLISH QUALITY OBJECTIVES FOR ALL RELEVANT AREAS

37	SHL	Have you clarified criteria for setting quality objectives?	Y	N	X	
38	SHL	Do you ensure that quality objectives are measurable?	Y	N	X	
39	SHL	Do you ensure that quality objectives consider requirements?	Y	N	X	
40	SHL	Do you ensure that quality objectives comply with quality policy?	Y	N	X	
41	SHL	Do you set quality objectives in all relevant areas?	Y	N	X	
42	SHL	Do you set objectives at relevant levels and for relevant functions and processes?	Y	N	X	
43	SHL	Do you set objectives that address the need for compliant products and services?	Y	N	X	
44	SHL	Do you set objectives that encourage the need to enhance customer satisfaction?	Y	N	X	
45	SHL	Do you document your quality objectives?	Y	N	X	
46	SHL	Do you control documents that list quality objectives?	Y	N	X	
47	SHL	Do you retain documents that list quality objectives?	Y	N	X	
48	SHL	Do you communicate your quality objectives?	Y	N	X	
49	SHL	Do you monitor your quality objectives?	Y	N	X	
50	SHL	Do you update your quality objectives?	Y	N	X	

6.2.2 DEVELOP PLANS TO ACHIEVE OBJECTIVES AND EVALUATE RESULTS

51	SHL	Do you establish plans to achieve quality objectives?	Y	N	X	
52	SHL	Do you figure out what must be done to achieve objectives?	Y	N	X	
53	SHL	Do you figure out who will be responsible for achieving objectives?	Y	N	X	
54	SHL	Do you figure out what resources will be needed to achieve objectives?	Y	N	X	
55	SHL	Do you figure out when quality objectives must be achieved?	Y	N	X	
56	SHL	Do you plan how you're going to evaluate your results?	Y	N	X	

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6. ASSESS HOW WELL YOU CONFORM TO PLANNING EXPECTATIONS

6.3 PLAN CHANGES TO YOUR QUALITY MANAGEMENT SYSTEM

57	SHL	Do you plan changes to your quality management system?	Y	N	X	
58	SHL	Do you consider the purpose of the changes you intend to make?	Y	N	X	
59	SHL	Do you consider responsibilities and authorities whenever you make changes?	Y	N	X	
60	SHL	Do you consider allocating or reallocating responsibilities and authorities?	Y	N	X	
61	SHL	Do you consider the consequences that changes could potentially produce?	Y	N	X	
62	SHL	Do you consider the availability of resources whenever you make changes?	Y	N	X	
63	SHL	Do you consider the integrity of your QMS whenever you make changes?	Y	N	X	

For each question, three answers are possible: YES, NO, or N/A. A YES (Y) answer means you're in compliance with the standard, a NO (N) answer means you're not in compliance, while an N/A (X) answer means that a question is not applicable in your situation. NO (N) answers identify gaps that exist between the standard and your organization's practices and processes while N/A (X) answers point to items that may be eXcluded.

In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates.

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