

AB. OUR ISO 9001 CONFORMANCE AUDIT QUESTIONNAIRES

6. ASSESS HOW WELL YOU CONFORM TO ISO'S PLANNING REQUIREMENTS

6.1 DEFINE ACTIONS TO MANAGE RISKS AND ADDRESS OPPORTUNITIES

6.1.1 CONSIDER RISKS AND OPPORTUNITIES WHEN YOU PLAN YOUR QMS

1	Did you plan the development of your organization's QMS?		
2	Did you identify the risks and opportunities that could influence the performance of your organization's QMS or disrupt its operation?		
3	Did you consider how your organization's context could affect how well its QMS is able to achieve intended results?		Since section 6.1.1 asks us to "consider the issues referred to in 4.1", that's what we've done. We've used the main points from section 4.1 to explain what section 6.1.1 expects you to do.
4	Did you consider how <i>external issues</i> could affect your QMS?		
5	Did you consider how your <i>legal</i> environment could affect your QMS?		
6	Did you consider how your <i>social</i> environment could affect your QMS?		
7	Did you consider how your <i>cultural</i> environment could affect your QMS?		
8	Did you consider how your <i>market</i> environment could affect your QMS?		
9	Did you consider how your <i>economic</i> environment could affect your QMS?		
10	Did you consider how your <i>competitive</i> environment could affect your QMS?		
11	Did you consider how your <i>technological</i> environment could affect your QMS?		
12	Did you consider how <i>internal issues</i> could affect your QMS?		
13	Did you consider how your organization's <i>values</i> could affect your QMS?		
14	Did you consider how your organization's <i>culture</i> could affect your QMS?		
15	Did you consider how your organization's <i>knowledge</i> could affect your QMS?		
16	Did you consider how your organization's <i>performance</i> could affect your QMS?		
17	Did you consider how your organization's interested parties could affect how well its QMS is able to achieve intended results?		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	Did you consider how interested parties could affect your ability to provide products and services that meet customer requirements?		

ORGANIZATION:

YOUR LOCATION:

COMPLETED BY:

DATE COMPLETED:

REVIEWED BY:

DATE REVIEWED:

FEB 2016

A. ISO 9001 2015 CONFORMANCE AUDIT TOOL

EDITION 1.0

PART 6

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6. ASSESS HOW WELL YOU CONFORM TO ISO'S PLANNING REQUIREMENTS

19	Did you consider how interested parties could affect your ability to provide products and services that meet statutory and regulatory requirements?		
20	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?		
21	Did you figure out what you need to do to ensure that your QMS will achieve intended results?		
22	Did you figure out what you need to do to prevent or reduce any undesired effects that your QMS could cause?		
23	Did you figure out how to enhance desirable effects?		
24	Did you figure out what you need to do to ensure that your QMS is improved?		

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

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

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6. ASSESS HOW WELL YOU CONFORM TO ISO'S PLANNING REQUIREMENTS

6.2 SET QUALITY OBJECTIVES AND DEVELOP PLANS TO ACHIEVE THEM

6.2.1 ESTABLISH QUALITY OBJECTIVES FOR ALL RELEVANT AREAS

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

6.2.2 DEVELOP PLANS TO ACHIEVE OBJECTIVES AND EVALUATE RESULTS

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

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6. ASSESS HOW WELL YOU CONFORM TO ISO'S PLANNING REQUIREMENTS

6.3 PLAN CHANGES TO YOUR QUALITY MANAGEMENT SYSTEM

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

For each question, three answers are possible: YES, NO, or N/A. A YES answer means you're in compliance with the standard, a NO answer means you're not in compliance, while an N/A answer means that a question is not applicable in your situation. NO answers identify gaps that exist between the standard and your organization's practices while N/A answers point to items that aren't applicable in your case. All gaps must be filled and all N/A answers must be justified and explained before you can say that your organization's quality management system (QMS) complies with the ISO 9001 2015 standard.

Please answer each question by recording one of these three answers in the cell to the right of each question. To the right of your answers you will also find a column that you can use to record any comments or observations you might have. 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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