

# ISO 9001 2015 TRANSLATED INTO PLAIN ENGLISH

## 4. CONTEXT

### 4.1 UNDERSTAND YOUR ORGANIZATION AND ITS UNIQUE CONTEXT

1	Identify and understand your organization's context.		An organization's <i>context</i> is its business environment. It includes all of the internal and external factors and conditions that affect its products and services, have an influence on its QMS, and are relevant to its purpose and strategic direction.
2	Identify and understand your organization's context before you establish its quality management system (QMS).		
3	Consider the <i>external issues</i> that are relevant to your organization's purpose and strategic direction and think about the influence these issues could have on its QMS and the results it intends to achieve.		An organization's <i>external context</i> includes the needs and expectations of its interested parties, as well as its social, cultural, legal, technological, regulatory, and competitive environment.
4	Consider your organization's external environment and think about how it could influence its QMS.		An organization's <i>internal context</i> includes its values, culture, knowledge, and performance.
5	Consider your <i>legal</i> environment and think about the impact it could have on QMS performance.		"Issues can include positive and negative factors or conditions".
6	Consider your <i>social</i> environment and think about the impact it could have on QMS performance.		The new standard expects you to consider your organization's internal and external context when you define the scope of its QMS and when you plan its design and development.
7	Consider your <i>cultural</i> environment and think about the impact it could have on QMS performance.		A <i>quality management system (QMS)</i> is a set of interrelated or interacting elements that organizations use to formulate quality policies and quality objectives and to establish the processes that are needed to ensure that policies are followed and objectives are achieved. These elements include structures, programs, procedures, practices, plans, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, tools, techniques, technologies, and resources.
8	Consider your <i>market</i> environment and think about the impact it could have on QMS performance.		
9	Consider your <i>economic</i> environment and think about the impact it could have on QMS performance.		
10	Consider your <i>competitive</i> environment and think about the impact it could have on QMS performance.		
11	Consider your <i>technological</i> environment and think about the impact it could have on QMS performance.		
12	Consider the <i>internal issues</i> that are relevant to your organization's purpose and strategic direction and think about the influence these issues could have on its QMS and the results it intends to achieve.		
13	Consider your organization's <i>values</i> and think about their impact.		
14	Consider your organization's <i>culture</i> and think about its impact.		
15	Consider your organization's <i>knowledge</i> and think about its impact.		

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# ISO 9001 2015 TRANSLATED INTO PLAIN ENGLISH

## 4. CONTEXT

16	Consider your organization's <i>performance</i> and think about its impact.		
17	Monitor information about your organization's context.		
18	Consider the impact changes in context could have on your organization's quality management system (QMS).		
19	Monitor and review the <i>external</i> issues that could influence your QMS.		
20	Monitor and review the <i>internal</i> issues that could influence your QMS.		

### 4.2 CLARIFY THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

21	Identify the parties who affect or could affect your QMS.		
22	Consider how these interested parties affect or could affect your ability to provide products and services that meet customer requirements.		An <i>interested party</i> is anyone who can affect, be affected by, or believe that they are affected by a decision or activity. An <i>interested party</i> is a person, group, or organization that has an interest or a stake in a decision or activity.
23	Consider how these interested parties affect or could affect your ability to provide products and services that meet all relevant statutory and regulatory requirements.		
24	Clarify and understand their unique needs and expectations.		
25	Figure out how their needs, expectations, and requirements could influence the performance of your organization's QMS.		
26	Monitor and review information about your interested parties.		
27	Monitor their changing needs, expectations, and requirements.		
28	Review their changing needs, expectations, and requirements.		

### 4.3 DEFINE THE SCOPE OF YOUR QUALITY MANAGEMENT SYSTEM

29	Clarify boundaries and think about what your QMS should apply to.		When we use the word <i>section</i> or <i>clause</i> , we're referring to the original standard; and when we use the word <i>part</i> , we're referring to our plain English publication.
30	Use boundary and applicability information to define the scope of your QMS.		
31	Consider your organization's context when you define your scope.		Your <i>context</i> was discussed in part 4.1.
32	Consider how <i>external</i> issues could influence your QMS.		
33	Consider the impact your external environment could have.		

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PLAIN ENGLISH QUALITY MANAGEMENT STANDARD

EDITION 1.0

PART 4

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PAGE 39

# ISO 9001 2015 TRANSLATED INTO PLAIN ENGLISH

## 4. CONTEXT

34	Consider the impact your <i>legal</i> environment could have.		
35	Consider the impact your <i>social</i> environment could have.		
36	Consider the impact your <i>cultural</i> environment could have.		
37	Consider the impact your <i>market</i> environment could have.		
38	Consider the impact your <i>economic</i> environment could have.		
39	Consider the impact your <i>competitive</i> environment could have.		
40	Consider the impact your <i>technological</i> environment could have.		
41	Consider how <i>internal</i> issues could influence your QMS.		
42	Consider the impact your organization's <i>values</i> could have.		
43	Consider the impact your organization's <i>culture</i> could have.		
44	Consider the impact your organization's <i>knowledge</i> could have.		
45	Consider the impact your organization's <i>performance</i> could have.		
46	Consider interested party requirements when you define your scope.		Interested parties were discussed in 4.2.
47	Consider your products and services when you define your scope.		
48	Document the scope of your quality management system (QMS).		
49	Use your scope document to describe the boundaries of your organization's QMS and to explain what it applies to.		
50	Consider your products and services when you document your scope.		
51	Consider your organization's context when you document your scope.		
52	Consider interested party requirements when you document your scope.		
53	Use your scope document to identify the types of products and services that will be included in your organization's QMS.		
54	Use your scope document to specify that every ISO 9001 requirement must be applied unless you can justify and explain why it is not applicable in your case.		

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EDITION 1.0

PART 4

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PAGE 40

# ISO 9001 2015 TRANSLATED INTO PLAIN ENGLISH

## 4. CONTEXT

55	Use your scope document to explain that a requirement may be ignored only if doing so does not compromise your organization's ability or responsibility to provide compliant products and services that enhance customer satisfaction.		ISO 9001 2015 <i>Annex A.5 Applicability</i> says that organizations may consider things like size and complexity, risks and opportunities, and activities and management methods when they decide which requirements could be safely classified as "not applicable".
56	Explain why specified requirements aren't applicable in your case.		
57	Maintain the document that defines the scope of your QMS.		
58	Control the document that defines the scope of your QMS.		This is "documented information". It must be controlled and retained or maintained.

### 4.4 DEVELOP A QMS AND ESTABLISH DOCUMENTED INFORMATION

#### 4.4.1 ESTABLISH A QMS THAT COMPLIES WITH THIS STANDARD

59	Develop a <i>process-based quality management system (QMS)</i> .		ISO 9001 section 0.3 makes it clear that an ISO 9001 QMS must be a <i>process-based QMS</i> .
60	Determine the processes that your QMS needs.		A <i>process-based QMS</i> uses a process approach to manage and control how its quality policy is implemented and how its quality objectives are achieved. A <i>process-based QMS</i> is a network of interrelated and interconnected processes. Each process uses resources to transform inputs into outputs and since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input-output relationships. These process interactions create a single integrated <i>process-based QMS</i> .
61	Determine process sequences and interactions.		
62	Identify required inputs for each process.		
63	Identify expected outputs for each process.		
64	Determine methods needed to manage processes.		
65	Identify the criteria and methods needed to <i>operate</i> processes.		
66	Identify methods needed to ensure process effectiveness.		
67	Identify appropriate process monitoring methods.		
68	Identify measurements needed to operate processes.		
69	Identify all necessary process performance indicators.		
70	Identify the criteria and methods needed to <i>control</i> processes.		
71	Identify methods needed to ensure that control is effective.		
72	Identify measurements needed to control processes.		

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# ISO 9001 2015 TRANSLATED INTO PLAIN ENGLISH

## 4. CONTEXT

73	Identify all necessary process control indicators.		
74	Determine resources needed to support processes.		
75	Provide the resources needed to support processes.		
76	Determine process responsibilities and authorities.		
77	Assign responsibilities and authorities for each process.		
78	Determine risks and opportunities for each process.		
79	Address your organization's risks and opportunities.		Actions to address risks and opportunities will be developed in part 6.1.2, below.
80	Determine methods needed to evaluate your processes.		
81	Make sure that processes achieve intended results.		
82	Implement your process-based quality management system.		
83	Apply criteria needed to operate and control your processes.		
84	Apply monitoring criteria needed to operate and control your processes.		
85	Apply measurement criteria needed to operate and control your processes.		
86	Apply methods needed to operate and control your processes.		
87	Apply monitoring methods needed to operate and control your processes.		
88	Apply measurement methods needed to operate and control your processes.		
89	Maintain your process-based quality management system.		
90	Evaluate the processes that make up your organization's QMS.		
91	Implement changes needed to ensure that they achieve intended results.		Section 6.3 asks you to plan QMS changes.
92	Improve your process-based quality management system.		Improvements are discussed in part 10.
93	Identify opportunities to improve your organization's QMS.		
94	Determine opportunities to improve your QMS processes.		

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PART 4

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PAGE 42

# ISO 9001 2015 TRANSLATED INTO PLAIN ENGLISH

## 4. CONTEXT

### 4.4.2 MAINTAIN QMS DOCUMENTS AND RETAIN QMS RECORDS

95	Maintain documents needed to support process operations.		This is "documented information". It must be controlled and retained or maintained.
96	Control documents which support process operations.		
97	Retain records which show that plans are being followed.		This is "documented information". It must be controlled and retained or maintained.
98	Control records which show that plans are being followed.		

For those who wish to use our publication as a checklist, we have provided a column to the right of each task that you can use to record your response. You could record a *DONE, TO DO, or N/A* in this column, or you could simply place a **✓** to indicate that the task has been or is being performed or you could record an *O/S* to indicate that an item is outstanding.

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

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PAGE 43