

**Mastering ISO 9001:2015**  
**Exercise - True/False Statements**

The following statements relate to various ISO 9001 concepts, principles and requirements. Indicate whether these are true or false in the adjacent column. Please note that some statements are deliberately vague. Here is an approach to answering these questions:

1. For each statement provide two reasons why you think it is true.
2. Next, provide two reasons why you think it is false.
3. Next make a decision whether the statement is true or false.
4. Next go to your ISO 9001:2015 eBook and find the clause or sub-clause where this statement is discussed and determine whether you were right or wrong.
5. Only check the answer sheet, after you have taken the first four steps listed above.
6. If you have a differing opinion, send me an email supporting your position.
7. When you complete this 717 question exercise following the process listed above, you will be guaranteed to be an ISO 9001:2015 expert!
8. Send me your completed exercise sheet and I will award you a **“Certificate of Achievement”** for successfully completing this eCourse.

	Statement	True/ False
1	You don't need to adopt the process approach and the PDCA cycle if you use other equally or more effective methods to develop an effective QMS	
2	Risk based thinking requires that you address QMS and strategic risks related to your business	
3	Use of specifications guarantee that a customer's requirements will be met consistently.	
4	Quality system standards can substitute for relevant product requirements provided in technical specifications.	
5	Preventive action has been consolidated into corrective action as c/a must prevent the root cause of a n/c from recurring	
6	It is expected that organizations with similar products or services to have similar quality management systems.	
7	By implementing a QMS based on this standard, you can provide assurance of conformity of products and services to customer requirements	
8	The ISO 9001 standard provides guidance for quality management and general requirements for quality control	
9	If you had a QMS that effectively met customer requirements, before implementing ISO 9001, you must change your controls to meet ISO requirements.	
10	Ensuring product quality meets customer needs also ensures that internal management, employees and other stakeholders needs are met	
11	An organization's stakeholders have the same needs and expectations as its customers	

12	Because of varying stakeholder needs such as quality, health & safety, environment protection and security, it is not required that management systems (to address these needs), be compatible.	
13	The ISO 9001 QMS standard addresses quality system requirements as well as provide technical standards for product quality.	
14	The ISO 9001 QMS standard provides quality system objectives to be met and guidance on controls to achieve them.	
15	If you had a QMS that effectively met customer requirements, before implementing ISO 9001, you must change your controls to meet ISO requirements.	
16	Besides meeting requirements, a product must also provide value to customers and other stakeholders.	
	<b>Statement</b>	<b>True/ False</b>
17	A process must have inputs and outputs which may only exist in tangible form	
18	Product value involves both quality and price and as such price is a facet of quality.	
19	For an interested party to be relevant to your organization, they must provide value relevant to your QMS	
20	Inputs, outputs and activities within the process are all capable of being measured and improved	
21	A process serves no purpose if it does not add value to the output or organization	
22	You must take action on interested party requirements if it can affect customer satisfaction	
23	Quality system management is accomplished by managing the structure and operation of processes as well as the quality of product and information flowing through them.	
24	Every organization exists to accomplish value-adding work through a network of processes. The structure of the network is usually a simple sequential structure.	
25	A QMS process cannot be effective if it does not have any improvement objectives.	
26	Every process should have an owner to clarify interfaces, responsibilities and authorities	
27	To be effective, a QMS needs coordination and compatibility of its component processes and definition of their interfaces.	
28	For your relationship with an interested party to be effective, you must provide value for each organization	
29	Documented standard operating procedures are essential for maintaining the gains from quality improvement activities	

30	The best time to implement a QMS is in response to demands by customers and other interested parties	
31	This standard requires the use of risk based thinking instead of preventive action to address potential problems in QMS processes	
32	Organizations implementing a QMS based on ISO 9001 are required to be certified by a Registrar.	
33	Organizations using ISO 9001 based QMS must demonstrate adequacy and effectiveness of the QMS as well as capability to achieve product conformity to specified requirements	

	<b>Statement</b>	<b>True/ False</b>
34	As per ISO 9001 customers cannot allow an organization to delete certain quality system clauses and sub-clauses from its QMS.	
35	Customers may not specify supplementary QMS requirements beyond those specified by ISO 9001	
36	A service can have tangible as well as intangible components to it.	
37	An opportunity for improvement is not the same as a positive outcome of risk, according to the ISO 9000 definition of risk	
38	Quality control is defined as the planned and systematic activities implemented within the QMS and demonstrated as needed to provide confidence that the organization will fulfill requirements for quality	
39	Positive outcomes from addressing a risk may not always result in an opportunity that can be exploited	
40	Materials used in a process could include liquids and gases transported through pipelines and containers	
41	The purpose of applying risk based thinking to QMS processes is to identify opportunities for improvement	
42	Product characteristics and/or quality characteristics are absolute and cannot be changed	
43	To be relevant, contextual issues must pose risks and opportunities to your organization and QMS	
44	As required by ISO 9001 qualification of certain processes may refer to demonstrating that specific personnel are competent to perform those processes	
45	According to ISO 9001 the terms nonconformity and defect can be used interchangeably	
46	Verification refers to checking conformance of product design and validation refers to checking conformance of the product design process – both to specified requirements	
47	An organizations quality policy may be stated in qualitative and/or quantitative terms	

48	Risk arise from uncertainties in QMS processes, whereas opportunities arise from situations favorable to achieving an intended result	
49	According to ISO 9001, the terms quality planning and quality plans can be used interchangeably	
	<b>Statement</b>	<b>True/ False</b>
50	A quality plan may be combined with a production plan to facilitate control of processes	