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US #	Clause	Date Rec'd	Request	Answer	Notes
2016-01	8..3, 4.3	2016-02-02	Is it the intent of the new ISO9001:2015 standard that we now apply 8.3, Design and development of products and services to our internal QMS processes?	--	Unanswerable. Deals with application of clauses. (exclusions)
2017-01	9.2.2.c	2017-06-03	When a consultant who helped to design an organization's management system audits that system from year to year, is the requirement of 9.2.2.c for objectivity and impartiality of the audit process being met?	Yes	See revised request #2018-01. Moderate consensus was reached on this RFI. The use of the word "consultant" in this RFI proved controversial. Interesting that consensus was easily reached in RFI #2018-01 when Consultant was replaced by Quality Manager in the request which seemed to expose a prejudice that the Standard is applied one way for one person and differently for another which should not be.
2017-02	9.2	2017-05-16	Does ISO 9001:2015 require internal audits to be process-based vs. clause/element-based?	Yes (Originally No*	Best practice given in ISO19011 and 17021 recommend Process-based audits although there ois no direct "SHALL" requirement for process based audits. Being changed to "Yes" as a result of the revision and release of ISO 19011:2018 which is referenced by ISO 9001:2015-9.2.2
2017-03	4.2.a	2017-07-28	Does subclause 4.2.a require that organization determine the interested parties relevant to the quality management system for every business function and business process?	Yes	
2017-04	7.4	2017-07-28	Does subclause 7.4 require that organization determine the internal and external communications relevant to the quality management system at all functions, levels and processes?	Yes	
2017-05	8.7.1	2017-07-28	Does subclause 8.7.1 refers to products and services in the requirement "outputs that do not conform to requirements"?	Yes	
2018-01	9.2.2	2018-01-02	If an individual (e.g. the quality manager for a company) who may have helped to design & document the company's management system performs the internal audits of the company's QMS from year to year, is the requirement of 9.2.2.c for "objectivity and impartiality of the audit process" being met?	Yes	
2018-02	6.1	2018-06-01	Does ISO 9001:2015, Clause 6.1 require an organization to provide documented information as evidence that the organization has determined the risks and opportunities that need to be addressed?	No	ISO 9001:2015 does not require an organization to provide documented information as evidence of determining risk or opportunities. Annex A.4 of ISO 9001:2015 states: …the organization is responsible for its application of risk based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks. (emphasis added)
2018-03	6.2.1	2018-06-14	Does clause 6.2.1 require objectives to be changed to different objectives from time-to-time?	Yes	YES. (6.2.1.g …objectives shall be updated "as appropriate"). It may NOT be appropriate to update an objective.
2018-04	6.2.1	2018-06-14	Is every process established by an organization required to have at least one quality objective?	No	NO. (6.2.1 …shall establish objectives at "relevant" processes…) It may NOT be relevant to set an objective for some processes.

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2018-05	4.4.1	2018-06-14	Do clauses 4.4.1h and 10.3 require an organization to demonstrate continual improvement to every process in an organization? (ref. item h)	Yes	YES. 4.4.1 The organization shall establish, implement, maintain and "continually improve" a quality management system, "including the processes" needed and their interactions, in accordance with the requirements of this International Standard. (4.4.1h …"improve the processes"…) and (10.3 …shall "continually improve"…the system). Therefore, "Continual Improvement of processes" is a requirement per the previous references from ISO 9001:2015. This does NOT mean that processes must be "continuously" or "constantly" improved. There is a difference between the words continuous and continual (see ISO 9000:2015 references above). 10.3 does NOT say to "continuously" improve. With "continual" improvement, there may be NO improvement for many years, then there is an improvement. ISO 9002:2016 states in Clause 10.3: The intent of this subclause is to ensure that the organization "continually improves" the suitability, adequacy and effectiveness of its (QMS).
2018-06	8.3	2018-08-10	Does an organization that designs a service to be used by only internal customers need to apply 8.3?	Yes	Experts consulted arrived at the consensus opinion of "Yes" and cited the following arguments from published Standards and guidance documents: ISO 9001:2015 Clause 1 "Scope" states in Note 1 that this Standard (including Clause 8.3) applies to "products and services intended for, or required by, a customer". By definition, ISO 9000:2015, 3.2.4 – Customer is defined as a "person or organization (3.2.1) that could or does receive a product (3.7.6) or a service (3.7.7) that is intended for or required by this person or organization" and further states in "Note 1 to entry: A customer can be internal or external to the organization." (So, 9001 applies not only to products or services intended for external customers but to internal customers as well.) Therefore, an organization that designs a service to be used by internal customers' needs to apply 8.3. In addition, the following is considered from ISO/TS 9002:2016, Clause 8.3.1, "In some cases, an organization could decide to apply the requirements for design and development to its operational processes, either based on the scope of the quality management system, customer or statutory and regulatory requirements, or best business practices."

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2018-07	8.3	2018-08-10	Does an organization that designs a service need to include 8.3 (Design) in their QMS?	Yes	Comment: Experts consulted cite several references from established Standards and Guidance Documents in support of the response. It is very clear that services are included in Clause 8.3. The title of Clause 8.3 is "Design and development of products and services". It is also clear that services are included (here and) in Section 8.3.1 "General". From ISO 9001:2015, 8.3.1 General – The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. Further, ISO/TS 9002:2016 states in 8.3.1 General, "The intent of this subclause is to ensure that the organization establishes, implements, and maintains a design and development process, in order to ensure that its products and services meet requirements."
2018-08	4.4.1 and 6.1.1	2018-12-18	Do clauses 4.4.1 and 6.1.1 require the organization to determine and address the risks and opportunities of all the organization's processes?	Declined	RFI declined. Nonconformance during ISO 9001:2015 CB audit. Resolving disputes between a CB and their client is not allowed.
2019-01	10.2.1	2018-12-18	If action is taken under section 10.2.1, c) that addresses a cause, but not the "root" cause (e.g., 1 why vs. 5 whys), is a review of the effectiveness of corrective action (part d) required?	Yes	Experts agree that the intent of 10.2.1d (review the effectiveness of any corrective action taken) is to ensure that the organization manages nonconformities, and implements corrective action, appropriately. ISO/TS 9002:2016 states in Clause 10.2.1, "The organization should review the effectiveness of any corrective actions by confirming (through evidence) that the actions have been implemented or correction taken and as a result the nonconformities have not recurred."
2019-02	10.2.1	2018-12-18	ISO 9001:2015, 10.2.1, "When a nonconformity occurs...". I interpret this wording to mean that parts a-f (c-f only if it is concluded that action is needed in part b) are required for every nonconformity. Is the intent that a-f be completed for every nonconformity or are other methods acceptable, such as: 1. completing b-f on an aggregate of NCs, such as a week or month of production, etc. 2. defining b-f, in advance, so that b-f is not completed for every nonconformity 3. defining what "nonconformity" means for my company, or those nonconformities requiring 10.2.1, b-f, to limit the cases where b-f are completed?		
2019-03	7.5.2	2019-02-24	When creating procedures (SOP's), is there one medium (e.g. software program) that ISO 9001 requires over another?		