



**ISO/TC 176/SC 2 Listing of Approved Interpretations against ISO 9001:2015**

ISO 9001: 2015 Clause No(s)	Request	Background to the request (when provided)	Interpretation	Rational for the interpretation	RFI	Date
10.2.1	Does ISO 9001:2015 allow in 10.2.1 bullet b) that an organization that evaluates the need for action to eliminate the cause(s) of a nonconformity concludes after reviewing and analyzing the nonconformity (according to bullet b1) only that further action is not needed and therefore the activities specified in bullets b2) and b3) do not need to be conducted?	This interpretation question arose during the development of a national NEN Code of Practice on Corrective Actions. A discussion took place whether an organization needs to carry out all the activities specified in bullet b1), b2) and b3) of 10.2.1 before being able to decide upon the need for corrective action. It was considered feasible that the organization after reviewing and analyzing the nonconformity concludes that the frequency of occurrence and any impacts are such that the nonconformity does not pose any substantial risk to the organization or its stakeholders and that any further investigation on determining causes (bullet b2) or similar conformities potentially occurring elsewhere (bullet b3) is not necessary.	No	The actions required in sub-clauses, 10.2.1 b)2), 10.2.1 b)3) shall be carried out, since they are part of the clause 10.2.1 b). Therefore, their fulfilment is necessary for the clause 10.2.1 b) to be fulfilled	140	2023-03-22

8.4.3	Are all requirements of 8.4.3 listed in bullets (a) through (f) required to be communicated to all suppliers for all purchases?		No	Each requirement listed in bullets a) through f) of ISO 9001.2015 clause 8.4.3 shall be applied when it is applicable	139	2023-01-26
8.2.3.1	According to 8.2.3.1 e), is it necessary to check any differences regarding the offer and order?	Thus, both product and service relevant differences (specification, delivery time, price, etc.) as well as any differences in terms of commercial-legal conditions (eg warranty, disclaimers, legal status, etc.), which are not directly related to the product / service and their characteristics, but have a clear connection to the objective of the order and in the event of a malfunction come into play?	Yes	According to 8.2.3.1(e), it is necessary to check the differences between the requirements that have been expressed and defined. This includes any differences in terms of expressed and defined conditions that are not directly related to the product/service, but that are related to the requirements.	138	2022-02-08
8.4.3	Is it mandatory for the organization to maintain or retain documented information as evidence of communication to outside suppliers of their requirements for control and monitoring of those requirements to be applied by the organization?	It has been common for certification bodies to require that the organization retain documented evidence that it has made such a communication, not only accepting verbal communication.	No	Clause 8.4.3 (Information for external providers) does not include any requirement to maintain or retain documented information.	136	2019-08-29
1, 4.2, 5.1.2, 8.2.2, 8.3.3, 8.4.2, 8.5.5	Does ISO 9001:2015 require an organization to take into account in its QMS a statutory and regulatory requirement (e.g. on gender equality) which has been assessed by the organization as being peripheral and not directly linked or relevant to the services and products it offers, or to its customer satisfaction?	To fulfil fire safety regulation is of course relevant for a hotel, but is non-compliance against for example regulation in the field of equality between genders to be considered a nonconformity against the requirements of ISO 9001:2015?  If the organization has identified that its customer consider equality between genders being important and the organization therefore has decided that the lack of equality between genders is a relevant risk, then it's easy. But in the question above, this is not the case. That risk is not identified or considered relevant.	No		135	2018-06-02
8.5.1a)	Does clause no. 8.5.1a) of ISO 9001:2015 "availability of documented information" mean "maintain documented information"	The 2015 standard provides meanings for words like "Retain" , "Maintain", "Keep" for documented information, but does not have any meaning for "Availability of	No	The terms "available" and "maintain" are not synonyms, and the use of "availability" was deliberate. "Available" means "able to be used or obtained, or	133	2017-08-01

		documented information”		accessible”, whereas “maintain” means “cause or enable to continue”. The “maintenance” of documented information is not explicitly required by Clause 8.5.1(a), but is addressed by other parts of ISO 9001:2015. Clause 8.5.1 (a) requires the documented information to be “available” so that it can be used, not just “maintained” (i.e. preserved). The documented information that needs to be available under Clause 8.5.1(a) is part of the quality management system documentation, and therefore has to be managed in accordance with Clause 7.5.		
10.2.1	Is it a requirement of ISO 9001:2015, Subclause 10.2, to document the root cause analysis?	<p>According to ISO9001:2015 Sub-clause 10.2 “Nonconformity and corrective action” (10.2.1) the organization shall react to a nonconformity and take action to control and correct it. In addition, the organization must evaluate the need for action to eliminate the causes of the nonconformity so it does not recur elsewhere by reviewing the nonconformity, determining the causes etc.</p> <p>Chapter 10.2.2 describes that the organization shall retain documented information as evidence of the nature of the nonconformities and any subsequent actions taken, as well as, evidence of the results of any corrective action.</p> <p>It is not quite clear if also the root cause analysis shall be documented or if it is enough to document only the cause.</p>	No	<p>This is because ISO 9001 does not address “root cause analysis”.</p> <p>Note: If the organization conducts a root cause analysis subsequently to a nonconformity, subclause 10.2.2 a) applies</p>	134	2018-08-17