ISO/TC 176/SC 2 Listing of Approved Interpretations against ISO 9001:2008

ISO 9001: 2008 Clause No	Request	Background to the request (when provided)	Interpretation	Rational for the interpretation	RFI	Date
4.2.3 a)	Does documented purchasing information that is part of the quality management system, have to be approved according to 4.2.3 a)?		Yes		104	2011-02-22
4.2.3 a)	Do documented inspection and test procedures that are part of the quality management system, have to be approved according to 4.2.3 a)?		Yes		105	2011-02-22
4.2.3 a)	Does sub-clause 4.2.3 a) require that documents required for the QMS be reviewed as well as approved prior to issue?		**No**	**Rationale:** Clause 4.2.3 a) is applicable to new documents which are being developed. Some degree of checking, examination or assessment by the person or persons approving is inherent in "approval for adequacy". There is no requirement for an additional "review" (as defined in ISO 9000:2000 clause 3.8.7).	106	2011-02-22
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4.2.2 c) and 4.1 b)	Does Clause 4.2.2 c), require that the manual include a description of the processes, in addition to a “description of the interaction between the processes of the QMS ”?	**Background:** Attention is also drawn to the connection between Clause 4.2.2 c) and Clause 4.1 b), where the organization is required to “determine the sequence and interaction” of the processes. On this problem of interpretation there is a divergence of opinion between an organization and a Certification Body.	No	No	107	2011-02-22
5.1a)	Is 5.1 a) in ISO 9001:2008 applicable only to requirements that relate to an organization's products and services?		Yes		102	2011-02-22
5.4.2	Is it a requirement of Clause 5.4.2 to have a document that describes the objectives, timeframe, action and responsibilities? (Note: The description of this document is not the same as the definition of “Quality Plan” in ISO 9000:2000, paragraph 3.7.5)	**Background:** Some users interpret Clause 5.4.2 of the standard to require a document (quality plan) that describes the objectives and the responsibilities etc. This is in addition to the quality manual and procedures document already established to control the relevant processes.	No		108	2011-02-22
5.5.2	In our organization we have a management representative appointed by top management, who works for the company in a managerial capacity. He is not a permanent member of staff, but works full-time on a contract basis. Is it allowable under the standard, for such a person to act as the organization’s management representative?		Yes		109	2011-02-22
5.5.2	Can a person who is independent of the organization’s management (e.g. a consultant) undertake the role of management representative.		No	*For guidance see the ISO handbook: “ISO 9001 for Small Businesses – What to do; Advice from ISO/TC 176”*	101	2011-02-22

ISO 9001: 2008 Clause No	Request	Background to the request (when provided)	Interpretation	Rational for the interpretation	RFI	Date
5.6.3 b)	Outputs from the management review shall include decisions and actions on the "improvement of product related to customer requirements". Outputs from the management review shall include decisions and actions on the "improvement of product related to customer requirements". If an improvement consists in the realization of a new product, does it respond to this specific requirement?	**Background**: This clause is the only place where the improvement deals with the "product". In all other places the improvement concerns the "effectiveness of the QMS". But it's not clear if the sentence "improvement of product *related to customer requirements*" intends to limit the improvement only to the products where the requirements have been already established (e.g. contractually). A clarification on this point will help users and auditors in understanding the extent of application of this requirement.	Yes	**Rationale**: The realization of a new product to improve an old one could be one of the results of the management review (Clause 5.6.3 b).	110	2011-02-22
6.3	Does Clause 6.3 require records of the maintenance of infrastructures?		No		111	2011-02-22
7.1	Does the use of the word "**form**" in the last sentence of this clause, mean that the output of the planning process must be documented?	**Background**: There has been some confusion due to the word "form" being interpreted as meaning "document used to record data".	No	**Rationale:** The word "form" means usual/ suitable format.	112	2011-02-22
7.2.1 a)	Does the word "specify" or "specified" quoted in various clauses require documentation? Clauses 7.2.1 a) and b), 7.3.3 d), 7.3.6 and others.		No	**Rationale:** A relevant example to support the answer is in the definition of procedure (ISO 9000:2005, 3.4.5), "specified way to carry out an activity or process (3.4.1)", with "Note 1 Procedures can be documented or not".	113	2011-02-22

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7.2.1	In some countries, in order to perform professional work, a law requires that a professional be a member of the appropriate Order and that the Order prescribes its own rules. Some of the rules have an impact on the product. Are these rules of the professional Order to be considered requirements related to the product?		Yes		114	2011-02-22
7.4.3	Does Clause 7.4.3 require records of the verification of purchased product?		No		115	2011-02-22
7.5.2	Does the process of an organization, whose results can be verified by means of monitoring or measurement after their realization and prior to delivery to the customer, need to be validated in order to comply with the requirements of clause 7.5.2?	**Background**: The organization provides transportation of orders (goods etc.) involving collection and dispatching services that can be monitored during their respective execution.	No		116	2011-02-22
8.3	When an organization detects, after delivery or after use has started, a product which does not conform to one of the “requirements specified by the customer” (Clause 7.2.1 a)), does the standard require that the organization inform the customer of the nonconforming product?		No		117	2011-02-22

ISO 9001: 2008 Clause No	Request	Background to the request (when provided)	Interpretation	Rational for the interpretation	RFI	Date
8.3	When an organization detects, after delivery or after use has started, a product which does not conform to one of the “statutory and regulatory requirements related to the product” (Clause 7.2.1 c)), does the standard require that the organization inform the competent authority of the nonconforming product?		No		118	2011-02-22
8.5.1	Does the continual improvement of the QMS required by Clause 8.5.1 also cover the improvement of the product related to customer requirements” required by Clause 5.6.3 b) to be included as an output of the management review?	**Background:** Clause 5.6.3 mentions in bullet a), the improvement of the “effectiveness of the quality management system” and adds, in bullet b), the “improvement of the product related to customer requirements”. Clause 8.5.1 requires only the “improvement of the effectiveness of the quality management system”, with no mention to the “improvement of the product related to customer requirements”	No		120	2011-02-22

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7.6	Is it correct that Clause 7.6 requires only the measuring and monitoring devices utilized by persons responsible for release of the product to be calibrated or verified?		**No**	**Rationale**: Clause 7.6 requires calibration or verification of measuring equipment "where necessary to ensure valid results". It could be more than measuring equipment for product release only (i.e.: verification of purchased products; in process inspection, etc.) but does not necessarily mean all measuring equipment. When the organization determines the monitoring and measuring required (as defined **e.g.** in clauses 4.1 a); 4.1 e); 7.1 c) and the first paragraph of 7.6), it shall decide which of them require calibration or verification of the measuring equipment because of the requirement of "valid results".	121	2011-02-22
7.3.1 b)	Does Clause 7.3.1 b) allow the organization to decide on the need, appropriateness and extent of the review, verification and validation to be carried out at each design and development stage?		Yes		122	2011-02-22
7.5.2	Does Clause 7.5.2, Validation of processes for production and service provision, require the validation of the equipment, locations and people involved?	**Background:** The original query implied that the question arose in relation to a hospital.	No	**Rationale:** Clause 7.5.2 does not say what shall be excluded from or included in validation of the process. It is up to the organization to determine which of the arrangements from a) to e) are applicable (refer also to 7.1)	123	2011-02-22

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7.5.2	Does Clause 7.5.2, Validation of processes for production and service provision, require that any applicable statutory and regulatory requirements must be taken into account?	**Background:** The original query implied that the question arose in relation to a hospital	**Yes**	**Rationale:** Clause 7.5.2 makes no reference to statutory and regulatory requirements. However, these statutory and regulatory requirements are general and must be taken into account wherever applicable to the intended product (see the Note in Clause 1.1).	123	2011-02-22