

## Posted Interpretations Table

RFI#	Date NDocument Posted on the website	Ndoc. #	ISO 9001:2000 Clause(s):	Request	Interpretation
001	2004-03-30	N638r	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)?	<b>Yes</b>
002	2003-12-24	N639r	7.4.3	Does Clause 7.4.3 require records of the verification of purchased product?	<b>No</b>
003	2003-12-24	N640r	6.3	Does Clause 6.3 require records of the maintenance of infrastructures?	<b>No</b>
004	2004-03-30	N641r	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)?	<b>Yes</b>
009	2003-12-24	N647r	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.	<b>No</b> <b>Rationale:</b> A relevant example to support the answer is in the definition of procedure (ISO 9000:2000, 3.4.5), “specified way to carry out an activity or process (3.4.1)”, with “Note 1 Procedures can be documented or not”.
011	2004-02-09	N649r	2	Do only terms and definitions of ISO 9000:2000 constitute provisions of ISO 9001:2000 through the reference in the text of Clause 2 of ISO 9001:2000?	<b>Yes</b>
016	2004-02-09	N698.1r	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	<b>No</b> <b>Rationale:</b> The last paragraph of Clause 8.3 specifies that it is the organization’s

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				7.2.1 a)), does the standard require that the organization inform the customer of the nonconforming product?	responsibility to take appropriate action regarding the nonconforming product.
017	2004-04-09	N698.2r	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?	<b>No</b> <b>Rationale:</b> The last paragraph of Clause 8.3 specifies that it is the organization’s responsibility to take appropriate action regarding nonconforming product.
018	2003-11-24	N742r	8.3	A product is at the final stage of realization and a nonconformity is found on a product related requirement which had been specified by the customer (ISO 9001:2000 7.2.1 a)). The organization believes that the best solution is to accept and deliver the product as is, i.e. with a nonconforming characteristic. The customer has not issued instructions on the reporting of nonconformities. Does Clause 8.3 require a concession by the customer for the use, release or acceptance as is of the product?	<b>Yes</b> <b>Rationale:</b> Clause 8.3 identifies three different ways to deal with nonconforming products. Clauses 8.3 a) and c) do not apply in this case. Clause 8.3 b) specifies that the use, release or acceptance shall be authorized. In this case authorization involves a concession by the customer. Furthermore, Clause 5.2 requires that customer requirements are determined and are met.
020	2003-11-24	N743	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?	<b>Yes</b>
021	2004-5-14	N708r	5.4.2	Is it a requirement of Clause 5.4.2 to have a document that	<b>No</b>

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				<p>describes the objectives, timeframe, action and responsibilities?</p> <p>(Note: The description of this document is not the same as the definition of “Quality Plan” in ISO 9000:2000, paragraph 3.7.5)</p> <p><b>Background:</b> 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.</p>	
022	2004-02-09	N716r	7.1	<p>Does the use of the word “<b>form</b>” in the last sentence of this clause, mean that the output of the planning process must be documented?</p> <p><b>Background:</b> There has been some confusion due to the word “form” being interpreted as meaning “document used to record data”.</p>	<p><b>No</b></p> <p><b>Rationale:</b> The word “form” means usual/suitable format.</p>
023	2003-01-31	N761R	7.5.2	<p>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?</p> <p><b>Background:</b> The organization provides transportation of orders (goods etc.) involving collection and dispatching services that can be monitored during their respective execution.</p>	<b>No</b>
024	2004-05-14	N717	8.5.1	Does the continual improvement of the QMS required by Clause 8.5.1 also cover the “improvement of the product	<b>No</b>

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				<p>related to customer requirements” required by Clause 5.6.3 b) to be included as an output of the management review?</p> <p><b>Background:</b> 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”.</p> <p>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”.</p>	
025	2003-01-31	N761R	5.6.3 b)	<p>Outputs from the management review shall include decisions and actions on the "improvement of product related to customer requirements".</p> <p>If an improvement consists in the realization of a new product, does it respond to this specific requirement?</p> <p><b>Background:</b> 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 <i>related to customer requirements</i>" 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.</p>	<p><b>Yes</b></p> <p><b>Rationale:</b> 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).</p>
026	2004-05-14	N718	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	<b>No</b>

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				<p>of the interaction between the processes of the QMS ”?</p> <p><b>Background:</b> 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.</p> <p>On this problem of interpretation there is a divergence of opinion between an organization and a Certification Body.</p>	
027	2003-01-31	N761R	5.5.2	<p>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?</p>	<b>Yes</b>
028	2003-03-10	N766R	7.6	<p>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?</p> <p><b>Background:</b> The Client understands that <b>all</b> of the workers need to have <b>all</b> measuring devices calibrated or verified. The contract just requires compliance with ISO 9001:2000 in this case.</p>	<p><b>No</b></p> <p><b>Rationale:</b> 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 <b>e.g.</b> 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</p>

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					verification of the measuring equipment because of the requirement of “valid results”.
029	2003-01-31	N761R	4.1 a)	Does the expression “needed for the QMS” in Clause 4.1 a) require the organization to identify the QMS processes related to product realization only?	<p><b>No</b></p> <p><b>Rationale:</b> The processes needed for the QMS include those related to product realization as well as the other processes related to the implementation of the QMS, as per the NOTE in clause 4.1.</p>
030	2003-06-06	N774	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?	<p><b>No</b></p> <p><b>Rationale:</b> 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).</p>
031	2003-01-31	N761R	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?	<p><b>Yes</b></p> <p><b>Rationale:</b> Review, verification and validation at each stage of design and development shall be determined by the organization according to 7.3.1.b and shall be performed according to 7.3.4, 7.3.5 and</p>

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					7.3.6.
032	2003-06-09	N776	7.5.2	<p>Does Clause 7.5.2, Validation of processes for production and service provision, require the validation of the equipment, locations and people involved?</p> <p><b>Background:</b> The original query implied that the question arose in relation to a hospital.</p>	<p><b>No</b></p> <p><b>Rationale:</b> 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).</p>
033	2003-06-09	N777	7.5.2	<p>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?</p> <p><b>Background:</b> The original query implied that the question arose in relation to a hospital.</p>	<p><b>Yes</b></p> <p><b>Rationale:</b> 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).</p>
034	2004-03-30	N804r	8.2.1	<p>In the situation described in the background information, does the standard require an organization to consider <b>also</b> the end user as a customer for monitoring satisfaction?</p> <p><b>Background:</b> An organization designs and manufactures a product to its own specifications and sells it to end users through a distribution chain. It is not technically modified between the organization and the end user. The end user can identify the organization through the use of a brand name or a trademark. The organization has contracts with distributors, which in turn sell to stores where end users buy the product.</p>	<b>Yes</b>

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035	2003-03-28	N765	5.4.1	<p>Does Clause 5.4.1 of ISO 9001:2000 consider quality objectives defined by “YES/NO” criteria to be measurable?</p> <p><b>Background:</b> Several companies that we audit have established some (but not all) of their quality objectives based on “YES/NO” criteria. Example “Achieve product certification for “xxxxxxx” product by November 2002”; or “Develop a new product to meet the requirements of the “YYYYY” market by March 2003”. In order to provide a consistent and technically accurate audit, we would like to know if these are considered to be “measurable objectives”.</p>	<b>Yes</b>
036	2003-06-06	N780R	8.2.2	<p>In clause 8.2.2 it is stated that: “An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, ...”. Is it a requirement of this clause that the criteria to determine the status and the importance of the processes and areas to be audited have to be documented?</p> <p><b>Background:</b> There is divergence with the auditor regarding a requirement for documentation of “status and importance criteria” despite the fact that evidence was provided that the planning of the audit programme has taken the status and importance of the processes and areas to be audited into consideration.</p>	<b>No</b>
037	2003-06-09	N778	4.2.1	<p>Clause 4.2.1 states that the organization’s quality management system documentation shall include “a</p>	<b>Yes</b>



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				<p>quality manual” (item b) and “documented procedures required by this International Standard” (item c).</p> <p>Is it in compliance with the standard to include the “documented procedures required by the standard” in the quality manual instead of having two separate sets of documents?</p> <p><b>Background:</b></p> <p>Some advisors recommend that organizations which are implementing their quality management system develop one manual, in addition to all the six documented procedures, because of clause 4.2.1.</p> <p>Yet clause 4.2.2 says:</p> <p>“The organization shall establish and maintain a quality manual that INCLUDES:</p> <p>b) documented procedures established for the quality management system or reference to them</p>	
039	2004-05-14	N805r	7.6 a)	<p>Clause 7.6 a) states: “Where necessary to ensure valid results, measuring equipment shall a) be calibrated <b>or</b> verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.” Can the word “OR” in the phrase “be calibrated <b>or</b> verified at specified intervals....” be</p>	<p><b>No</b></p> <p><b>Rationale:</b> Calibration and verification <b>can both be</b> applicable depending on the situation.</p>

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				<p>interpreted as meaning that these two activities are always mutually exclusive?</p> <p><b>Background:</b> According to the concept of metrological confirmation established in ISO 10012:2003 (e.g. Figure 2 Metrological confirmation process for measuring equipment) for carrying out verification activities, it is indispensable to define the measuring equipment metrological requirements, and the latter are compared against the results of calibration activities.</p>	
042	2005-05-06	N812r	Clause 7.4	Do the requirements of Clause 7.4, Purchasing, also apply to products that are acquired without any payment being made?	<b>Yes</b>
043	2004-07-13	N815r	7.3	<p>Does ISO 9001:2000 require Clause 7.3 to be applied to the design and development of the package necessary to preserve the conformity of the product during delivery?</p> <p><b>Background:</b> This request for interpretation does not address the packaging process, but the package that is necessary to protect the product.</p>	<p><b>Yes</b></p> <p><b>Rationale:</b> The organization is, per sub-clause 7.5.5, responsible for preserving the conformity of the product. Preservation includes packaging. In cases where design and development of the package is necessary to preserve conformity, this has to be performed in accordance with Clause 7.3 of the standard.</p>
044	2005-01-24	N825r	Clause 6.2.2)	Does Clause 6.2.2 e) require the organization to maintain records to demonstrate “the evaluation of the effectiveness of actions taken” to address competence needs, according	<p><b>Proposed Interpretation: NO</b></p> <p><b>Rationale:</b> It is up to the organization to decide what records should be maintained.</p>

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