Interpretations Of The ISO 9000 Series

So you think you know ISO 9001:2000? Various users have formally requested interpretations of the ISO 9000 series. You decide, then email us at jh@jaegerholland.com or call us at 630-428-2709 and receive a no-obligation, hassle-free direction on where to go to get ISO/TC 176's official interpretation and the rationale.

1) ISO 9001:2000 Clause(s): 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? ..... ☐ yes ☐ no

2) ISO 9001:2000 Clause(s): 4.1a)

Does the expression "needed for the QMS" in Clause 4.1a) require the organization to identify the QMS processes related to product realization only? ..... ☐ yes ☐ no

3) ISO 9001:2000 Clause(s): 4.2.1

Clause 4.2.1 states that the organization's quality management system documentation shall include "a quality manual" (item b) and "documented procedures required by this International Standard" (item c). 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? ..... ☐ yes ☐ no

4) ISO 9001:2000 Clause(s): 4.2.2c) and 4.2b)

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"? ..... ☐ yes ☐ no

5) ISO 9001:3000 Clause(s): 4.2.3a)

Does documented purchasing information that is part of the quality management system, have to be approved according to 4.2.3a)? ..... ☐ yes ☐ no

6) ISO 9001:2000 Clause(s): 4.2.3a)

Do documented inspection and test procedures that are part of the quality management system, have to be approved according to 4.2.3a)? ..... ☐ yes ☐ no

7) ISO 9001:2000 Clause(s): 4.2.3a)

Does sub-clause 4.2.3 a) require that documents required for the QMS be reviewed as well as approved prior to issue? ..... ☐ yes ☐ no

8) ISO 9001:2000 Clause(s): 5.4.1

Does clause 5.4.1 of ISO 9001:2000 consider quality objectives defined by "YES/NO" criteria to be measurable? ..... ☐ yes ☐ no

Background: 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".

9) ISO 9001:2000 Clause(s): 5.4.2

Is it a requirement of Clause 5.4.2 to have a document that describes the objectives, timeframe, action and responsibilities? ..... ☐ yes ☐ no

(Note: the description of this document is not the same as the definition of "Quality Plan" in ISO 9000:2000, paragraph 3.7.5)

10) ISO 9001:2000 Clause(s): 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 ☐ no

11) ISO 9001:2000 Clause(s): 5.6.3 b)

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?..... ☐ yes ☐ no

12) ISO 9001:2000 Clause(s): 6.3

Does Clause 6.3 require records of the maintenance of infrastructures?..... ☐ yes ☐ no

13) ISO 9001:2000 Clause(s): 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". ☐ yes ☐ no

14) ISO 9001:2000 Clause(s): 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 ☐ no

15) ISO 9001:2000 Clause(s): 7.2.1 a)

Does the word "specify" or "specified" quoted in various clauses require documentation?. ☐ yes ☐ no

Reference clauses 7.2.1 a) and b), 7.3.3 d), 7.3.6 and others.

16) ISO 9001:2000 Clause(s): 7.3

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?..... ☐ yes ☐ no

Background: This request for interpretation does not address the packaging process, but the package that is necessary to protect and product.

17) ISO 9001:2000 Clause(s): 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 ☐ no

18) ISO 9001:2000 Clause(s): 7.4.1

Does Clause 7.4.1 require that records of evaluations of suppliers and any necessary actions arising from these evaluations be maintained by all organizations, irrespective of their size?..... ☐ yes ☐ no

19) ISO 9001:2000 Clause(s): 7.4.3

Does Clause 7.4.3 require records of the verification of purchased products?..... ☐ yes ☐ no

20) ISO 9001:2000 Clause(s): 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? .... ☐ yes ☐ no

21) ISO 9001:2000 Clause(s): 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?..... ☐ yes ☐ no

22) ISO 9001:2000 Clause(s): 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? ..... ☐ yes ☐ no

23) ISO 9001:2000 Clause(s): 7.6

Is it correct that Clause 7.6 requires only the measuring and monitoring devices utili9zed by persons responsible for release of the product to be calibrated or verified?..... ☐ yes ☐ no

24) ISO 9001:2000 Clause(s): 7.6 a)

Clause 7.6 a) states: "Where necessary to ensure valid results, measuring equipment shall a) be calibrated **or** 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 **or** verified at specified intervals …" be interpreted as meaning that these two activities are always mutually exclusive?..... ☐ yes ☐ no

25) ISO 9001:2000 Clause(s): 8.2.1

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. In the situation described, does the standard require an organization to consider **also** the end user as a customer for monitoring satisfaction?..... ☐ yes ☐ no

26) ISO 9001:2000 Clause(s): 8.2.2

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? ..... ☐ yes ☐ no

27) ISO 9001:2000 Clause(s): 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 7.2.1a)), does the standard require that the organization inform the customer of the nonconforming product?..... ☐ yes ☐ no

28) ISO 9001:2000 Clause(s): 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?..... ☐ yes ☐ no

29) ISO 9001:2000 Clause(s): 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 7.2.1a). The organization believes that the best solution is to accept and delivery 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 if of the product?..... ☐ yes ☐ no

30) ISO 9001:2000 Clauses(s): 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?..... ☐ yes ☐ no