

Is That Clear?

by Don Brecken

How should auditors audit against subjective standard requirements?

ISO 9001's requirements became a little clearer and a little less subjective with its 2008 revision. However, several subjective elements survived the revision. This is not necessarily a bad thing; it's just an observation. The standard includes such phrases as "where appropriate," "where applicable," and "where necessary." It requires organizations to determine the effectiveness and suitability of their processes, and to evaluate the documentation, records and policies, and procedures they deploy—all subjective measurements.

Check Points

- ✓ ISO 9001:2008 was written to clarify some of the more confusing requirements in its 2000 version, but a few subjective requirements survived the update.
- ✓ These include requirements that indicate "where applicable," "where necessary," and "where appropriate," which have tripped up many auditors.
- ✓ When auditing these subjective requirements, don't hesitate to ask the auditee organization for supporting evidence. Use open-ended questions to provoke open-ended answers.
- ✓ The ISO 9001 Auditing Practices Group provides additional guidance on how to audit against subjective requirements on its Web site.

All of this subjective language has a purpose: to provide an international standard that can apply to different types of organizations, be they large or small. This subjective language, however, can pose a challenge to quality management system (QMS) auditors. How does an auditor deal with such subjectivity when auditing an organization?

"Where applicable," "where necessary," and "where appropriate"

ISO 9001:2008 includes several "where applicable," "where necessary," and "where appropriate" requirements designed to ensure that it can be implemented in a wide array of organizations. Some requirements may not be appropriate or may not be applicable to some organizations, so it has to include some flexibility to users. This is the reason for the subjectivity in some of its requirements.

Subclause 4.1, General requirements, states "[t]he organization shall a) determine the processes needed for the quality management system." In this example, determining the processes needed for a QMS can be subjective in nature. Clearly, this is a decision each organization needs to make. There is no one-size-fits-all model that specifies a standard list of processes you need for an effective QMS. So how does the auditor know whether the organization determined all the processes necessary for its QMS or not? Why, for example, did the organization determine it needed only six processes instead of eight or nine?

Subclause 4.1, General require-

ments, also states "[t]he organization shall e) monitor, measure where applicable, and analyze processes..." In this example, the "measure, where applicable" requirement is subjective. The organization must determine whether measurement applies to one process or another within its system of interrelated processes. There are situations where measurement does not apply and monitoring alone is acceptable; it's left up to the organization to determine if it needs to measure a process or not. Whether it's applicable or not is for the auditor to assess.

Subclause 5.3, Internal communications, states that "Top management shall ensure that appropriate communication processes are established within the organization." In this example, the "appropriate communication processes" requirement is subjective. Top management must establish communication processes within the organization and these processes need to be "appropriate." In this case, the auditor is tasked with the challenge of proving those methods appropriate or not.

Subclause 7.5.1, Control of production and service provision, states "Controlled conditions shall include, as applicable b) the availability of work instructions, as necessary." In this example, it would seem that the "as applicable" and the "as necessary" statements would cancel themselves out in the way a double negative in a sentence turns the sentence into a positive statement. The organization must determine whether its work instructions are "applicable and necessary."

INTERPRETING SUBJECTIVE REQUIREMENTS

These are only a few examples of the “where applicable, necessary, and appropriate” requirements found in ISO 9001. How does the auditor audit these requirements?

“Suitable,” “adequate,” and “effective” requirements

ISO 9001:2008 also includes several “suitable, adequate, and effective” requirements. These requirements help ensure that an organization’s solution is its best option. As the old saying goes, “There’s more than one way to skin a cat!” Consider the following examples, which in no way represents a complete listing of the subjective requirements in the standard:

- Subclause 7.1, Planning of product realization, which states: “The output of this planning shall be in a form suitable for the organization’s method of operations.” In this example, the planning output must be in a particular form, but what is telling about this requirement is what it does *not* say. It doesn’t say the output of this planning shall be in one form or another, which allows the organization to choose the right solutions for its particular needs. This also is a challenge for the auditor.
- Subclause 7.2.3, Customer communication, which states: “The organization shall determine and implement effective arrangements for communication with customers.” In this example, the arrangements implemented for communicating with customers must be effective. Whether the organization has effective arrangements for communicating with customers can be subjective and challenging for an auditor to assess.

- Subclause 7.4.2, Purchasing information, which states: “The organization shall ensure the adequacy of specified purchase requirements prior to its communication to the supplier.” In this case, the organization must decide and the auditor must assess what’s “adequate.” This is a little more cut and dried than many of the other subjective requirements, because what’s “adequate” is usually defined in a purchasing procedure.
- Subclause 5.6, Management review (5.6.1 General), which states: “Top management shall review the organization’s management system at planned intervals to ensure its continuing suitability, adequacy, and effectiveness.” In this example, top management must ensure suitability, adequacy, and effectiveness of the QMS. The challenge the auditor faces is determining if an organization’s management system is sufficiently suitable, adequate, and effective.

Guidelines for auditors

The ISO 9001 Auditing Practices Group (www.iso.org/tc176/ISO9001auditingpracticesgroup.com) provides guidance on auditing “where appropriate” standard requirements. This guidance suggests that the organization determine whether the “where appropriate” requirements of ISO 9001 are applicable or not. It also suggests that the auditor “should ensure that the ‘where appropriate’ requirements are really ‘appropriate’” to the organization and necessary to meet its customer and applicable regulatory requirements.

The above guidance helps clarify how the auditor can assess these subjective and open-ended require-

ments. The auditor can ask him or herself, “Would the absence of the “where appropriate, applicable, or necessary” requirements put the organization at risk of not meeting its customer or regulatory requirements?” The example in subclause 7.5.1 shared on page 13 may help demonstrate this concept. Consider this question, “Has the absence of work instructions for a particular operation put the organization at risk of not meeting its customer requirements?” Or, “Has the absence of a work instruction ever disrupted downstream operations or the next shift?” If the answer is “Yes,” then work instructions do apply and are necessary for that operation. The auditor should look for objective evidence of any such disruption.

Another way auditors can assess these subjective requirements is by asking “how” questions. For example, “How did you determine that work instructions are not necessary or applicable for this operation?” Or, “How did you determine the processes for your quality management system?” Subclause 7.1, Planning of product realization, describes how processes needed for the organization are determined. Asking “how” begs a response that describes a process. Strategically placed “how” questions will prompt the auditee to describe how it made its decisions.

Conclusion

Auditors must maintain their objectivity while auditing, especially when auditing subjective requirements. Audit evidence needs to be verifiable, and audit findings and conclusions must be based only on objective evidence. Collecting objective evidence of compliance to subjective requirements can be a

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challenge. In a pinch, don't hesitate to ask the auditee organization how it complies with this or that requirement or how it determined this or that requirement was not applicable or necessary. Some say it's up to the auditor to prove compliance, but I say disclosure is important as well. Asking the right open-ended question can prompt an auditee to disclose if and how the organization complies.

About the author

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