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SPECIAL REPRINT

Implementing and Auditing an ISO 9001:2000 QMS

Dealing With ISO 9001:2000's Open-Ended Requirements

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Traditionally, conformity standards such as ISO 9001/2:1994 have contained very prescriptive, closed-ended requirements. The use of some open-ended (descriptive) requirements in *ISO 9001:2000, Quality management systems—Requirements*, has caused auditors and organizations to be more cognizant of the need for alternate methods of implementing quality management system (QMS) processes and verifying their conformance to requirements.

For the auditor, it is important that QMS conformance to all requirements is verifiable and traceable. For the implementing organization, it is important that there is a solid approach for addressing the requirements its QMS will be audited against.

One auditor has complained to me that the standards writers "messed up" when they issued the 2000 version of ISO 9001 because of the difficulties of auditing against some of its requirements. Another perspective is that the standards writers were finally on target by writing a standard for the users, not the auditors. With ISO 9001:2000, the members of ISO Technical Committee (TC) 176 are practicing what TC 176 has been preaching. They listened to the users of the QMS standard, reviewed user complaints and then established goals to address user needs.

Standards writers shouldn't write standards just for auditors. Instead, auditors need to develop techniques for auditing against a standard's requirements. Auditors are responsible for verifying that an organization conforms to requirements and, if they are unable to apply techniques to verify requirements, then they should decline to conduct the audit.

Whether you will be implementing or revising a QMS to conform with ISO 9001:2000 or you will be auditing QMSs against ISO 9001:2000's requirements, it is important to understand the distinction between closed- and open-ended requirements, and what audit techniques may be used to verify conformance.

Dealing With Closed-Ended Requirements

Most ISO 9001:2000 requirements are very specific and traceable. For the implementing organization, these closed-ended (prescriptive) requirements are readily apparent. For auditors, most closed-ended requirements can be put on a list and checked off with a yes or no during an audit. The user creates the procedures, records and/or approvals and the auditor evaluates these and checks off his/her corresponding observations.

For example, Clause 8.2.2, Monitoring and Measurement—Internal Audit, of ISO 9001:2000 requires the following:

- A documented procedure
- Reporting of audit results
- Maintenance of records
- Action to address detected nonconformances
- Verifying of action taken
- Reporting of verification results.

Auditors can use various techniques to verify that the QMS addresses specific audit program requirements. Auditors can:

- Evaluate documents
- Verify records
- Interview personnel using the QMS process
- Trace the process forward or backward to verify activities are being performed.

Verification of specified requirements is fast, efficient, reliable and traceable.

Use of the *requirements technique* is suitable in verifying conformance with more than 80% of ISO 9001:2000's

requirements. The *requirements technique* can be represented by the statement: "Show me the specified document, record, procedure, plan, criteria, schedule, material or activity."

Dealing With Open-Ended Requirements

During ISO 9001:2000's drafting, one of the standard writers wrote a memo identifying some clauses as *not being auditable*. "Not being auditable" is when a requirement is so general or vague that an auditor may not be able to obtain objective evidence to prove a QMS adheres to the specified requirement.

Declaring that some requirements are inauditable is very subjective and may not be true. There are alternate techniques that may be used to verify conformance to requirements; however, using these techniques requires auditors to do more than a check of yes and no questions.

Some descriptive requirements are needed to ensure the generic and universal nature of ISO 9001:2000. When requirements are too prescriptive, a standard inadvertently becomes more sector- or product-specific. For users, descriptive requirements provide more flexibility and can result in a more effective QMS.

The common denominator for all types of requirements that might be classified as "not being auditable" or open-ended is that they are subject to broader interpretation than prescriptive requirements. Standard users and auditors will find 4 main types of open-ended requirements in many conformance standards, as shown in Table 1.

Someone eventually determines the intent or meaning of the open-ended requirements. Requirements may be interpreted by the organization implementing the standard, the audit function/organization (whether internal or external), the auditor conducting the audit or an independent board or committee convened for the purpose of making interpretations. Interpretations by organizations other than the one implementing the QMS may be viewed as either helpful guidance or regressive (circumventing the original intent of an ISO 9001 requirement).

Many Type I requirements (open-ended phrases) are clarified by the audit organization, as in the form of registrar or audit department guidelines. For example, registrars may require periodic management reviews to occur annually or timely corrective action to be done within 30 days. The planning of audits based on the importance of a process may be taken to mean auditing all elements annually.

When interpretations are agreed upon (contract between the audit organization and auditee), auditors are bound to audit against the interpretations. Official interpretations may have both positive and negative consequences for the organization being audited, since interpretations may restrict the use of open-ended phrases that are designed to ensure that requirements are appropriate for many situations.

Type II requirements (generalized

Table 1. Types of Open-Ended Requirements[1]

Type I: Open-Ended Phrases/Words	Type II: Generalized Statements
Use of open-ended words subject to wide interpretation. Words such as "periodic", "timely", "readily", "promptly", "without undue delay" and "based on importance" are not definitive. "Periodic" indicates repeatability but no frequency. "Timely" is relative to other undefined factors occurring concurrently or in the recent past or future. "Importance" is relative to the units being compared against.	Phrasing a requirement at a generalized or abstract level (e.g., as to manage or control a function or process). For example: The organization shall ensure *control* over such processes. The organization shall carry out production under *controlled* conditions. The organization shall *manage* the work environment.
Type III: Unclear or Undefined Words	**Type IV: No Tangibles Specified**
Use of words that are not defined or are subject to multiple definitions, which can leave the auditor with no basis for issuing a nonconformance. For example: Top management must ensure the QMS is *suitable*. The organization shall make personnel aware of the *relevance* of their activities. *Exercise care* with customer property.	A requirement lacking specified verifiable actions or outputs (i.e., there is no requirement to define, document, record, schedule, review, etc.). When there are no prescriptive requirements to audit against, audit findings could be perceived as subjective. For example: The organization *shall preserve conformity* of the product. There is no requirement for a procedure, record or for management to control the process.

statements) are operation-level requirements used to manage and control processes and are very powerful. However, if organizations don't know how to implement a Type II requirement and auditors don't know how to audit against it, it may be ignored as fluff or treated as unauditable.

These type of requirement statements make perfect sense, but guidance issues tend to surface when an auditor must prove the negative. The following questions may be difficult for an auditor to answer in issuing a nonconformity:

- When is there lack of control?
- When is a process not being adequately managed?
- If a nonconformity is appealed or questioned, what evidence will withstand the scrutiny of the exit meeting and a subsequent review?

Auditors want to be right the first time and avoid withdrawing a nonconformity once they have determined one is justified. It is in everyone's best interest that the basis for a nonconformity be clear and not appear to be a subjective option.

The word *control* is used 24 times in ISO 9001:2000. For example, ISO 9001:2000 requires organizations to control outsourced processes and nonconforming product and controls of processes must be effective. Organizations must implement controls, which auditors must audit even when there is no specified procedure, record or other tangibles. Auditors and users must know what constitutes adequate control of a process or activity.

Auditors have at least two approaches that they can use to audit generalized requirements to control a process or activity:

- Process techniques (Plan-Do-Check-Act or PDCA), as defined in Table 2.
- Requirement techniques referencing the standard. Subclause 7.5.1, Control of Production and Service Provision, of ISO 9001 has a handy list of specific things to consider for controlling an operation/process. Auditors and the QMS organization can make up a checklist of the specific requirements from Clause 7.5.1 and determine which control conditions do and do not exist.

Simply speaking, there needs to be a method, it should be followed and monitored and there should be a means to adjust the process. That is control.

On one occasion, I audited an operational unit that required adherence to a centrifuge cleaning schedule. The unit recorded the cleaning times and management adjusted the schedule based on the unit's performance.

However, I ran into a problem when, after a 30-minute search, neither I nor management could find a record of the cleaning times that were somewhere in the computer log, much less compare it to the schedule. There was no convenient method for verifying that the schedule was being followed, yet management made adjustments based on apparent adherence to the schedule. There was no control because an element of control was missing. The process could not be verified against a predetermined plan or set of outcomes.

Use of Type III requirements (unclear or undefined terms) is becoming less of an issue. Standard users are more familiar with QMS terminology and standard writers are publishing definitions and being more consistent with word usage. ISO 9000:2000, the new vocabulary standard, can be very helpful to users and auditors alike.

However, if definitions are a problem, auditors and QMS organizations can seek guidance from management of the audit organization (audit department, registrar, oversight group).

Type IV requirements (no tangibles specified) are more flexible and adaptable to a wide range of organizations (e.g., manufacturing, service, large, small). Arguably, these requirements can be much more effective because the organization is free to implement optimal controls rather than prescribed controls.

However, verification of conformance to Type IV requirements is more challenging for auditors and the organizations that employ the auditors. This is particularly true for traditional compliance assessments where supplemental guidance from the audit organization may be appropriate.

For example, Subclause 7.5.5, Production and Service Provision—Preservation of Product, states that an organization "shall preserve the conformity of product". There is no requirement to plan, establish, determine, specify, document, maintain, schedule, review, assess or record. The requirement is more like a goal for which the organization has to come up with an approach to achieving.

Due to the open-ended nature of some ISO 9001:2000 requirements (such as Subclause 7.5.5), an organization may believe it can simply declare conformance to a requirement and challenge the auditor to prove otherwise. Because that can be like looking for a needle in a haystack (to find a defect or a field failure), the auditor must take the opposite approach by challenging the auditee to show why there is no needle in the haystack. In the case of "preserving product," the auditee organization could show the auditor it has a plan, it is being followed, that the organization monitors product preservation and act on the results.[2]

To audit open-ended requirements, an auditor must verify that the organization conforms to the intent of the requirements by using process techniques.

Table 2. Process Technique (PDCA) for Auditing

Adequate control exists when an organization does the following:

- Plan—A plan, procedure or method is developed (establish what needs to be done)
- Do—The plan, procedure or method is being followed (do what was planned)
- Check—The plan, procedure or method is monitored and/or measured against criteria
- Act—Action is taken to resolve the differences between expected and planned results (e.g., analyze and adjust to process).

The auditor must seek to determine the existence of a process, how it was planned and implemented and what its outcomes are—remember the PDCA approach discussed earlier.

Clarification/Research Techniques

For Type I and III open-ended requirements, auditors should seek additional guidance. Such guidance could be obtained from other standards and guidelines or from auditing organization documents. The application or meaning of some words also may vary from industry to industry. For example, a requirement to be prompt in the medical devices sector may mean something different and be applied differently than for a soap manufacturer. Indeed, for this reason, the writers of generic requirements standards may prefer the use of open-ended requirements in certain situations to assure applicability.

In the absence of other guidance or regulatory requirements, an auditor should ask the auditee for its interpretation of a requirement and audit the organization against it. For example: What does "timely" mean? What is "without undue delay"? What is "an acceptable planned interval"?

Process Techniques

For Type II and IV interpretive requirements, process techniques such as PDCA can be used to verify conformity and establish traceability. The key to auditing is to follow the plan for the QMS process. In all things that you do that requires orderliness as opposed to being haphazard, there must be a decision (predetermination) on how work will be preformed or how goals will be accomplished.

The plan for how a task or process is performed may be called a method, procedure, technique or other term. The plan may be verbal or documented in some manner. The key to process techniques is to follow the PDCA cycle for the process under investigation.

An auditor might ask the following questions for the less prescriptive Type II and IV clauses in assessing QMS conformance:

- *Is there a plan or method for conforming to the requirements? What is it? Has it been established?* Evidence may include an outline, flowchart, markings in a work area, a procedure, work instructions, specifications or criteria. Clause 7.1, Planning for Product Realization, contains requirements to be considered in planning.
- *Has it been implemented?* Evidence may be the existence of records, corroboration by multiple interviews, observations, etc.
- *Are there planned results (criteria)? Have they been achieved?* Evidence may consist of trend diagrams, records, bar charts, matrices, comparisons, etc. Data collected to satisfy requirements of Clause 8.4, Analysis of Data, may be useful (e.g., data summaries, analyses, metrics and performance indicators).
- *Is there improvement (adjustments)? Has the system/process been changed?* Evidence may be changes to processes, documents, designs or the ways business is conducted.

It would be very helpful if the organization being audited described how the descriptive requirements are addressed in its quality manual as an overview or executive briefing or in procedures.

No matter what audit techniques are used, the auditor should keep a record or log of the evidence found showing conformance and nonconformance for traceability purposes and to provide consistency from audit to audit. Examples of evidence and perhaps log entries could be included as part of the audit report. The organization being audited should be prepared to answer questions and provide documents or records as evidence of conformance to the requirements.

In each situation the auditor must determine the appropriate data collection plan to ensure the information is free from bias. A worksheet is an ideal tool for listing the clause or requirement on the left and recording the evidence provided in a space to the right.

The process (PDCA) technique for verification of a requirement comes down to: "Show me how you conform to this requirement. Is there a plan (method)? Is it being followed (implemented)? Are planned results (criteria) achieved? Is there ongoing improvement?"

Determining Conformance or Nonconformance

Once the organization has had an opportunity to provide evidence and the auditor has completed his/her investigation, it is time to determine conformance or nonconformance. Good audit practices also require the auditor to indicate the importance of the nonconformance(s) detected.

Some nonconformances represent high risk to the organization's QMS and/or operations, while others represent low risk. One of the simplest methods for gauging importance is to classify nonconformances as major or minor. Each organization should establish its own classification system.

The auditor must make a judgment based on the data presented and his/her audit program guidelines in determining if the QMS is in conformance, has a minor nonconformance or is plagued by a major nonconformance. The credibility of the audit will be questioned unless there is consistency between auditors and audits, whether internal, second-party or registrar audits.

The measurement system should be fair, unbiased, consistent and standardized. One method is to first assess the planning and implementation and then the results (outcomes) of the process. For example, an auditor's guideline for assessing the "planning and implementation" may state:

- *Major nonconformance*—No method is evident or there is partial implementation but significant gaps still exist.
- *Minor nonconformance*—There are sound methods but some minor gaps in deployment.
- *Conformance*—Sound methods are fully implemented.

A similar format can be used to assess continual improvement (results) of the process. For example, if there is no data there may be a major nonconformance or if there is data to verify continual improvement (positive trends), the organization is in conformance.

New Roles for Auditors and Managers

To audit open-ended requirements, auditors will need to be ready to use a diverse set of audit techniques to verify

conformance and provide traceability. Even before the audit, an auditor may request management of the area to be audited to complete a survey that spells out how open-ended requirements are addressed. At the opening meeting, the auditor should share the methods and techniques that will be used during the audit.

In the interest of improvement and gaining added value, management should be prepared to support the design of the organization's QMS for conformance to open-ended requirements. The relationship between the auditor and auditee should be one of mutual benefit and respect rather than "you can't make me" or "I got you" combative attitudes. It is in everyone's best interest for auditors to get the facts and for organizations to address nonconformances and thereby ensure the effectiveness of the QMS.

Most QMS users will agree that ISO 9001:2000 is a very good standard for organizational improvement. Although not perfect, it is very powerful in that it is the output of a highly regarded consensus process.

This article about open-ended requirements does not cover all the auditing and implementation issues surrounding ISO 9001:2000 nor all the techniques available. Instead, its purpose is to provide ISO 9001:2000 auditors and users with some additional strategies and techniques for addressing the open-ended types of requirements found in conformity standards.

What you must keep in mind: If a standard does not prescribe an approach, your organization must establish an approach to be in conformance with the requirements. And auditors must be prepared to audit the QMS against that approach. ###

[1] Accessed from ISO 9001 Transition web-based training by JP Russell & Associates.
[2] Russell, JP, "Auditing to ISO 9001:2000", Quality Progress, *July 2001.*

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