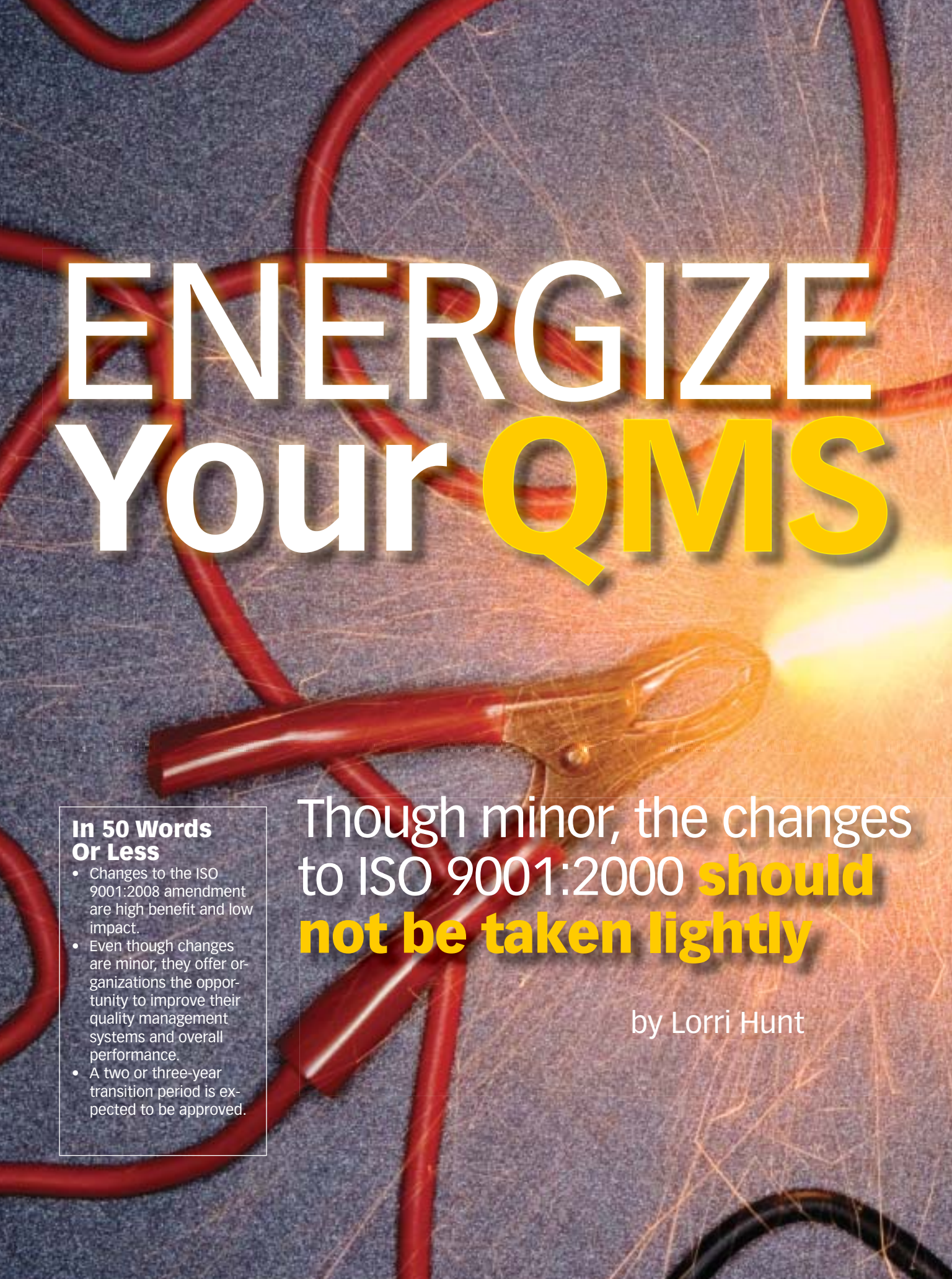

ENERGIZE Your QMS

Though minor, the changes to ISO 9001:2000 **should not be taken lightly**

by Lorri Hunt

In 50 Words Or Less

- Changes to the ISO 9001:2008 amendment are high benefit and low impact.
- Even though changes are minor, they offer organizations the opportunity to improve their quality management systems and overall performance.
- A two or three-year transition period is expected to be approved.

ANTICIPATION SURROUNDING the ISO 9001:2008 amendment is growing as the standard nears publication. But, if you are in a panic because of this, take a deep breath and relax.

Members of ISO technical committee 176 (TC 176) realize it is difficult not to flash back and remember the transition to ISO 9001:2000. It was a tedious process for many organizations and required that significant resources be applied to the effort. Requirements included providing training to employees, updating documents and, in some cases, making significant changes to the overall structure of quality management systems (QMS).

Fast forward to 2008. The ISO 9001:2008 amendment process has been 180 degrees different from its 2000 predecessor. First and foremost, it is an amendment and not a revision. That does not mean it should be taken lightly. Instead, it should be welcomed as an opportunity to improve your QMS through a better understanding of requirements. It can also be used to work with your registrar to review any inconsistencies in interpretations of requirements.

The process

Because the International Organization for Standardization (ISO) directives do not differentiate between an amendment and a revision, it was important for the technical experts on TC 176 to clarify what an amendment was.

These technical experts determined an amendment would be something used to address known issues, but not to create new or delete existing requirements. When drafting started, however, that determination became a difficult task.

For that reason, the technical experts developed a design specification for the amendment to ensure they exercised care and stayed on track for what the user community was demanding: no significant change. The design specification that was developed clearly identified the parameters of what could be considered part of the amendment.

The technical experts also developed a risk matrix. Each change was reviewed against this matrix to ensure the modification was of high benefit and low impact.

High-benefit changes included those things identified in the design specification as goals of the amendment. Low-impact ones included types that would require minimal change to an organization's existing QMS. Table 1 shows characteristics that are high benefit and low impact.

As you can see by the list of the characteristics of a high-benefit/low-impact change, the technical experts had a sharp focus on the types of changes that would be made for this amendment. Additionally, not only could a specific change not modify requirements, but it also could not give the perception a requirement had been changed.

For that reason, the technical experts decided they would lean toward no change if consensus could not be reached on whether a change added or deleted a requirement.

What to expect

With these controls in place, what types of enhancements can users expect to see? First, changes will not be wholesale text ones, as with previous revisions. In fact, some of the changes are so subtle that they will not be noticeable when users review the document.

Because it is important for users to be able to identify changes quickly, and because even the most subtle change offers improvement to the standard, ISO 9001:2008 includes Annex B, which outlines the text changes that have been made to specific clauses.

This annex will include the clause number and text from ISO 9001:2000, with strike-throughs and added text. But, having the annex at hand will not eliminate the need for organizations to consider each change and its potential impact. The annex also does not eliminate the need to review the change in context with the other requirements in a specific clause.

Keeping to the spirit of the amendment, which was to make modifications without changing requirements, the technical experts had to be creative in how they incorporated the improvements.

One way clarifications were made was to restructure a clause, as was done with clause 8.3, control of nonconforming product. The clause was restructured to improve its ability to apply to all types of organizations, specifically service ones.

Additionally, clause 4.2.4, control of records, was

High-benefit and low-impact changes / TABLE 1

High benefit	Low impact
Addresses a widely expressed specific user need by improving clarity and eliminating confusion (for example, improve compatibility with ISO 14001, reduce the need for official interpretations)	No increased or reduced requirement
Corrects an error in the existing standard	No change in intent of requirement
Is consistent within the ISO 9000 family of standards, including ISO 9001	No impact on most users
Improves translation into other languages	No need for additional education or training for users
	Only minimal or marginal changes of an organization's documentation needed

restructured to improve compatibility with ISO 14001, the environmental management standard. Changing the sequence of the requirements clarified the clause without changing words—the latter being something that could have given the perception of a bigger change than the one made.

Another method of determining whether a change was needed when reviewing various concepts was to refer to ISO 9000:2005. Many of the requests for clarification that had been originally identified were determined not to be necessary because existing terms were adequately defined.

For instance, one of the considerations of the design specification was to clarify the term "device," as used in clause 7.6. When the technical experts discussed this issue, they determined that the term "equipment," which was already defined in ISO 9000:2005, addressed devices. The more logical change, therefore, would be to change "device" to "equipment."

This change will cause alarm for some users and could give the impression of a requirement change. For that reason, this change, and any others that relate to terms used in the standard, should not be considered standalone but in conjunction with ISO 9000:2005.

The technical experts also leveraged the use of notes. Clause 0.1, general in the introduction, says, "Information marked 'NOTE' is for guidance in understanding or clarifying the associated requirement." Notes provide a mechanism for clarifying requirements and minimizing the need to change the text in the actual clauses. Table 2 shows the clauses in which notes were added, deleted or revised.

Some of the changes to notes are what we call no-brainers. For instance, changing the reference in clause 8.2.2, internal audit, from 10011 to 19011 was a change required to reflect the current number of ISO's auditing standard. Other notes were added to address sanctioned interpretations, such as in clause 7.3.1, design and development planning, and 7.3.3, design and development outputs.

Additionally, some changes were made to notes simply due to the amount of feedback received on an issue during the development of ISO 9001:2008. Specifically, two notes in clause 4.1 were added to address the requirement for outsourcing.

One of the most common questions about notes is, "If they are not requirements and not subject to audit, then how can they provide clarification?" Notes, specifically those added or revised for this amendment, can help organizations and auditors or registrars broaden their understanding of a specific requirement that previously was unclear to them.

For example, clause 8.2.1, customer satisfaction, was revised to include methods beyond the traditional customer survey an organization can use to monitor customer perception and show compliance to this

Changes made to standard using notes / TABLE 2

Clause	New/deleted/revised
4.1	Two new notes
4.2.1	Revised
6.2.1	New
6.4	New
7.2.1	New
7.3.1	New
7.3.3	New
7.5.4	Revised
7.6	Deleted 2000 note; added new note
8.2.1	New
8.2.2	Revised
8.2.3	New

MAKING THE TRANSITION

What should an organization do to transition to ISO 9001:2008? There are some basic steps that each organization should go through regardless of the maturity of its QMS:

- Obtain a copy of ISO 9001:2008.
- Review Annex B, and become familiar with the changes in the standard.
- Discuss transition requirements, including scheduling and expectations, with your registrar.
- Analyze whether the changes impact your organization. Some organizations might find it beneficial to attend training or obtain further information to ensure they clearly understand and don't misinterpret a change.
- Develop an implementation plan for changes the organization needs to make.
- Make adjustments or improvements to the QMS according to the implementation plan.

Organizations will see this as an **opportunity** to improve **their QMSs.**

requirement. After reviewing this note in ISO 9001:2008, an organization might have a better understanding of the customer service requirement. This knowledge could lead to enhancement of a QMS and might also provide enlightenment to an auditor who previously had too narrow of a view of the requirement.

Driving analogy

As you can see, many of these changes appear very basic. Many might perceive this to mean the amendment doesn't change anything for their organizations. This view of the amendment is comparable to driving in inclement weather during winter.

Many people who live in areas with bad winter weather say, "I can drive on snow and ice. It's everyone else who is causing problems." In reality, it is very rare to hear someone admit to being a terrible driver in bad weather. The statistics on accidents in inclement weather, however, show that the number of people who can't drive in it are higher than the numbers who admit it.

Implementing ISO 9001 is similar. You never hear anyone say, "I don't clearly understand all of the requirements." But, if you look at the requests for interpretation or simply at the questions asked, it is clear some organizations have either taken a minimal approach to a requirement or clearly just don't understand it.

As the amendment has taken shape, the conversation around some water coolers has been, "We understood ISO 9001:2000. We won't need to do anything." In reality, this could be the case for some, but organizations won't know this to be true unless they review the ISO 9001:2008 amendment and determine its specific impact.

Transition process

As with any changed standard, however, the thought on most users' minds is not the impact of the changed requirements to their organizations, but what the transition to the new standard is going to look like.

Two specific steps were taken at the most recent TC 176 meeting to ensure the transition process is as simple as possible.

First, the Conformity Advisory Liaison Group (CALG), which provides feedback to TC 176 on issues relating to conformity assessments, developed a position for the International Accreditation Forum (IAF), the group ultimately responsible for specifying the transition plan for this amendment.

This position stated the following: "ISO 9001:2008 has been developed to introduce clarifications to the existing requirements of ISO 9001:2000 and changes that are intended to improve compatibility with ISO 14001:2004. ISO 9001:2008 does not introduce additional requirements nor does it change the intent of the ISO 9001:2000 standard. Certification to ISO 9001:2008 is not an upgrade, and organizations that are certified to ISO 9001:2000 should be afforded the same status as those who have already received a new certificate to ISO 9001:2008."

Second, to support the position of CALG and to reaffirm the design specification, TC 176 approved a formal resolution that stated the position of CALG.

The International Accreditation Forum recently published the transition plan for ISO 9001:2008. The highlights of the transition plan include:

- No organization can be certified to ISO 9001:2008 until its formal publication as an international standard.
- Twelve months after publication of ISO 9001:2008, there will be no new certifications issued to ISO 9001:2000. That means if your organization is currently seeking certification to ISO 9001:2000, it can proceed on its current path.
- All organizations currently certified to ISO 9001:2000 must transition to the amended standard 24 months after publication.

In addition, the IAF confirmed the position taken by ISO TC 176 that ISO 9001:2000 and ISO 9001:2008 are to be considered equal during their co-existence.

The question then becomes, why the need for a transition period if this is only an amendment? A transi-

MORE ON ISO 9001:2008

For a discussion of how ISO 9001:2008 can help leadership improve organizational performance, read Jack West's Standards Outlook column on p. 67 of this issue.

tion period is needed to help maintain the integrity of the standard. Without a formal transition period, some registrars might issue certificates without an audit to confirm the requirements in ISO 9001:2008.

Keep in mind that this is a topic organizations need to discuss with their registrars. While each registrar will be responsible for following the position of the IAF, it is important for organizations to work with their registrars to determine the timetable of the transition to ISO 9001:2008 and how the registrars will work with the organization to ensure the timetable is followed.

Not so simple for some

Now that you understand there are no new requirements in ISO 9001 and that the 2000 and 2008 versions are considered to be equal, you might think it is as simple as checking a box (see "Making the Transition," p. 23). For many organizations with mature QMSs and a clear understanding of requirements, there might be no changes needed.

But, organizations with a history of audit findings that are based solely on their lack of understanding of requirements will see this as an opportunity to improve their QMSs.

It is important that organizations not put themselves into the no-change category too quickly. Not only can this amendment be used by organizations that have not fully understood all of the requirements, but it can also be used for ones that have become lackadaisical in their QMS implementations. This amendment is an excellent opportunity for such organizations to reinvigorate their QMSs.

The 2008 amendment brings to the forefront the fact that ISO 9001 is still relevant to the marketplace. What is so great about this version is that it can be used as an opportunity to review a QMS and reinforce the value it adds to an organization.

The key will be to find the balance between potentially overinterpreting the standard and making no change. You will be missing a great opportunity if you simply check the box. QP

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PUBLICATION OF STANDARD
ISO 9001:2008 will be available for purchase from ASQ by the end of the year.