

Change Ahead

Revision of ISO 9001:2008 brings opportunities and challenges

BY THE TIME the upcoming revision to ISO 9001 is developed and issued, the standard will have remained essentially the same for at least 15 years—and a lot has happened in that time.

The use of ISO 9001 is rapidly expanding into many unanticipated areas, including healthcare, service, government and agriculture, just to name a few. Even in the traditional sectors, there has been increasing attention to this standard by small and medium-sized organizations, the service sector and software organizations.

In addition, organizations have become more sophisticated in their application of quality methods, and customers have become better informed and more demanding.

Feedback indicates ISO 9001:2008 must be adjusted to make it more user-friendly for these new users. While a great deal of effort went into making ISO 9001:2008 usable by all sectors, service providers continue to advocate for more service-friendly text.

There also has been a great increase in the development and use of management standards for disciplines other than quality. Again, much work has gone into ensuring these management systems standards (MSS) are compatible and can be used together with minimum or no duplication of effort or conflict. Organizations that use multiple MSSs are increasingly seeking a common format and language that is aligned among different standards.

Complex process

The revision process for an international standard is illustrated in Figure 1. About every five years, a standard is reviewed to determine whether it should be reaffirmed, amended, revised or withdrawn based on user needs. For ISO 9001:2008, it was decided a revision was appropriate. International Organization for Standardization Technical Committee 176 Subcommittee 2 (ISO/TC 176/SC 2) is in the midst of several years of work to develop the changes.

As indicated in Figure 1, each ISO standard goes through a series of drafts before it becomes an international standard. Early working drafts (WD) are developed and edited by a relatively small working group (WG). In the case of ISO 9001, the WG is actually quite large because of the relative importance of the standard.

At the next stage, one or more committee drafts (CD) are provided by the subcommittee to each SC 2 member body for comments and vote. In the case of this revision to ISO 9001, SC 2 recently completed the disposition of comments on a CD.

The result of the vote on a balloted CD was positive and as of January 2014, an interim WD of the DIS has been developed and a final decision to advance the document to DIS will be made in March 2014.

If the DIS process is successful, the document will get a final editing and be reissued for a last check by the member bodies as a final draft international standard (FDIS in Figure 1).

If this all sounds tedious and difficult, it is; but this is the sort of control that is exercised to ensure all points of view are taken into account in the development of international standards.



Anticipated themes

So, for ISO 9001, what is likely to change? As participants in the workings of ISO/TC 176/SC 2, and because we are early in the process, we can provide you with our best projections. This goes with the caveat that there are many uncertainties. There will certainly be additions, deletions and modifications to the currently published DIS document as it proceeds through the revision process in the coming months and years in its journey to becoming a published international standard.

First, the new version will be based on a common structure and will use a common, high-level text mandated by ISO for all MSSs. This new high-level structure and text is contained in a document called “Annex SL,” which is part of the document *ISO/IEC Directives, Part 1, Consolidated ISO Supplement—Procedures Specific to ISO*, which is available on the ISO website.¹

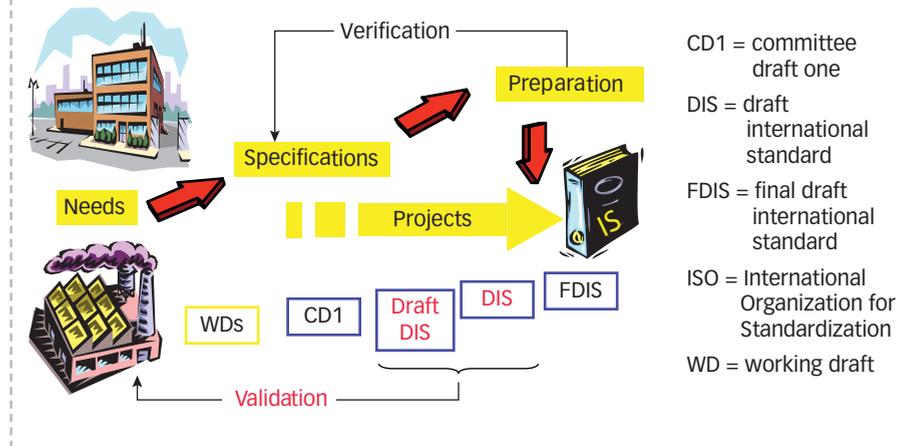
The common structure is different from the structure of ISO 9001:2008, which may offer some challenges to current users of ISO 9001:2008 or the sector standards based on it.

On the other hand, those with management systems implemented—or planned—to meet two or more of the other ISO MSSs (for example, ISO 14001) may find the aligned MSS structure and text of the Annex SL beneficial.

It is highly likely there will be changes to the specific requirements in the ISO 9001 DIS. However, it can be anticipated that some of the general themes for the revision will carry through until publication. Some of these themes include the following:

More generic. User feedback indicates the current standard is difficult to apply in all types of industries, especially the service industry. For that reason, the language in the revised standard is proposed to make ISO 9001 easier to use for

ISO standards development process / FIGURE 1



these types of organizations.

The DIS of ISO 9001, for example, uses the phrase “goods and services” instead of “product” throughout the DIS when referring to the deliverables to the customer.

Another proposed change to make the standard more generic revolves around some of the requirements that were focused on manufacturing industries—specifically, *Clause 7.1.5—Monitoring and measuring devices* (previously clause 7.6) and *Clause 8.5—Development of goods and services* (previously clause 7.3).

Both of these clauses currently list specific requirements for demonstrating compliance. The specific requirements have been removed and made more general to make the clauses easier to implement for all industries.

Context of the organization. The required high-level structure and identical text necessitates the MSS to have clauses related to understanding the organization and its context (clause 4.1) and understanding the needs and expectations of interested parties (clause 4.2).

These requirements, while new in the text of the DIS, were included in *Sub-clause 0.1—General* in ISO 9001:2008, which indicated the quality management

system (QMS) is influenced by the environment the organization is in, including changes and risks.

The new language may cause confusion to users, but the intent should be the same.

Interested parties. One of the concerns with the new core text relates to the term “interested parties.” The interpretation for this phrase is that there is no new requirement to ensure goods and services meet the requirements of interested parties because this would go beyond the scope of the QMS. It can be anticipated that steps will be taken in future drafts to make this distinction more clear.

Process approach. Both the 2000 and 2008 versions of ISO 9001 promoted the process approach in the QMS. The requirements in DIS *Clause 4.4.2—Process approach* (previously clause 4.1) include specific requirements for adopting the process approach.

Some might argue, however, that these specific requirements go outside the boundaries of making the standard more generic. The balance between improving the requirements for embracing the process approach while maintaining generic requirements is vital to be

maintained as the standard advances.

In addition, there will be a need to integrate the thinking related to the system approach to management (QMS principle No. 5) with the process approach to address how consistent and predictable results will be achieved when activities are understood and managed as interrelated processes that function as a coherent system.

Risk and preventive action. The CD for ISO 9001 does not use the term preventive action. This is consistent with the core text from Annex SL. The language now in the DIS looks at how an organization determines the risks and opportunities that need to be addressed for an effective QMS. Clause 6.1 in the CD addresses actions to address risks and opportunities, and it includes requirements to ensure the QMS can achieve its intended outputs.

The clause also addresses taking action appropriate to the potential effect of conformity to goods and services. This requirement is consistent with requirements of preventive action.

It is expected that even those organizations that struggled with preventive action will find the concept of incorporating preventive action to be a significant change. This change, however, can be leveraged with leadership because managing risks is typically the language leadership uses when making organizational decisions.

There may also be a need to think through the requirements for corrective action and how it is deployed because currently many organizations closely link preventive and corrective action, which are quite different activities.

Documented information. The technology used to run the business world has changed significantly, and it is important for the standard to move forward and be consistent with these changes.

Since the very first version of ISO 9001 was adopted, the terms “documents” and “records” have been used. The core text

required by Annex SL has now adopted the term “documented information.”

The manner in which we now control information is typically electronic and the difference between documents and records is seamless. There will be challenges for organizations because the standard no longer differentiates between document and record. Instead, it uses “documented information” in both instances.

Bigger picture

The upcoming update to ISO 9001 can be viewed as a challenge and an opportunity. Users should pay attention to the additions, deletions and modifications that are being considered in terms of the impact on their organizations and the opportunities that exist for improving the QMSs of their organizations. This will be true even when an organization should be going beyond current and anticipated requirements.

Users also should consider the impact of an updated ISO 9001 on their suppliers to assess any potential impact on the confidence organizations would have in a supplier’s ability to deliver conforming products and services. In other words, ask: Will the QMS requirements for an organization be strengthened, weakened or remain about the same?

Beyond these general themes, the DIS contains many more specific additions, deletions and modifications to the currently existing ISO 9001:2008 requirements. It is much too early in the process to discuss any specifics because the work is still immature. As work progresses, we will provide you with details as they become available and credible.

The current schedule indicates the revision will be issued in 2015. This may happen, but there is certainly a long way to go and a lot of hard work required to get there.

If you live in the United States, you still have time to participate in this work by applying to become a participating

member of the U.S. Technical Advisory Group (TAG) to ISO/TC 176, the group that develops and provides the U.S. position on all work related to ISO 9001.

You can start the application process by calling ASQ headquarters (1-800-248-1946) and asking to speak with a member of the standards staff, or email standards@asq.org.

As a final thought, we encourage all users and potential users of ISO 9001 to consider the standard as a model organizations can use to deploy and continually improve their QMSs.

No matter what form or content results from the revision process for ISO 9001, your challenge and opportunity is to use the model to migrate your organization to world-class levels of performance. **QP**

REFERENCE

1. International Organization for Standardization, *ISO/IEC Directives, Part 1, Consolidated ISO Supplement—Procedures Specific to ISO*, fourth edition, 2013, <http://bit.ly/ISODirectives> (case sensitive).



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