A Better Understanding

Whether they are new to quality management system (QMS) thinking or experts, many organizations and individuals think they have a sound understanding of the requirements of the AS9100 series of standards and ISO 9001. Many organizations, however, use books to understand implementation requirements and determine compliance written by authors whose backgrounds are inconsistent with the organization's process. Those authors also may have a biased view of the requirements.

Many organizations also use consultants, and while there are many good ones, there are just as many who aren’t active in standards development and put their own spin and interpretation on the requirements. Often, consultants are influenced by their past experiences and focused on selling methods and packages that are inconsistent with the actual intent of a QMS.

A little research usually can guide you to those with valuable experience. Many people claim to be on a standard writing team but are not. Look for warning signs, such as
when someone says, “I think they mean,” “What they really mean” or “In other words.”

Organizations often use certification body (CB) auditors to determine compliance. CB auditors must complete training and certification requirements successfully and be able to ensure consistency in how third-party audits are conducted. However, CB auditors often aren’t experts in the organization’s processes, products or services. To retain their independence, CB auditors are not allowed to consult, so they aren’t a viable or desirable option for determining compliance.

So how can you ensure a consistent understanding of and alignment with the standard writers and intent of the applicable QMS requirements? There are several resources available from authoritative sources to help maximize the effectiveness and success of your organization’s QMS.

**Written standards**

QMS standards must be written clearly to ensure understandability. This applies to AS9100 for aviation, space and defense, as well as ISO 9001. These QMS standards are
The QMS writing teams often are large—comprising more than 100 subject matter experts who have diverse backgrounds, including nationality, organization size and stakeholder segment representation. Due to the magnitude of the revision task, standards are evaluated for update every five years. This allows adequate time for standard stability, yet ensures the standard remains relevant.

These writing teams are criticized frequently for taking too long to write standards, but the teams must ensure the wording is clear, and that any improvements or changes to address a noted concern don’t create a larger concern. Improvements are introduced to ensure the standard stays relevant to the stakeholder group and that the benefits of a change outweigh the cost of implementation. Noted concerns can be identified through the feedback process, clarifications, interpretations and CB audit nonconformance analysis.

Ample resources written by the experts directly involved in standards development are available from standards committees to help organizations of all types and sizes implement and continually improve their QMS.

ISO 9001 communication and support information
ISO Technical Committee (TC) 176 Subcommittee (SC) 2 maintains a website with excellent information and resources regarding its standards. Based on a worldwide 2020 ISO user survey, 80% of respondents found this website to be beneficial (see Figure 1, p. 43).

- ISO 9001—Quality management systems—Requirements.
- ISO 10005—Quality management—Guidelines for quality plans.
- ISO 10007—Quality management—Guidelines for configuration management.

The SC 2 website includes valuable information, such as guidance on using ISO 9001, auditing to ISO 9001 and interpretations of ISO 9001. Guidance on using ISO 9001 includes several papers and presentations to emphasize the new revision (see Online Figure 2).

The auditing section refers to the use of ISO 19011 for guidelines for auditing management systems. ISO 19011 is an excellent guidance standard for benchmarking audit processes. The auditing section also points to the ISO 9001 Auditing Practices Group (APG)—a group of international QMS experts, auditors and practitioners who develop guidance papers. The APG has developed several guidance

AS9100 series communication and support information
The International Aerospace Quality Group (IAQG) maintains a public website to communicate information about IAQG, including membership, the organization, tools (including the Online Aerospace Supplier Information System database, Aerospace Improvement Maturity Model, Supply Chain Management Handbook and dictionary), standards, certification, events and news. The website also lists every IAQG standard and its supporting information including, at minimum, presentation materials on the standard and any clarifications. (See Online Figure 1, which can be found on this article's webpage at qualityprogress.com, for AS9100:2016 website information.) Organization users will find information to improve their understanding of the standard and are welcome to use the presentation materials and any other tools provided on the website.

IAQG has a clarification process during which the standard sector document representative (SDR) receives inquiries about IAQG standards. If the SDR believes the clarification is pertinent to a wider distribution, he or she can post clarifications on the standard’s website. These clarifications are evaluated for inclusion in the next revision of the standard, if appropriate. This listing is organized by standard clause and provides commentary so users can understand the standard’s intent. These clarifications reside on the IAQG website.
papers on general auditing and ISO 9001:2015 auditing topics. The APG papers are available on the TC 176 website (see Online Figure 3 for a list of topics). This content is primarily geared toward auditors, but it does provide significant value for practitioners.

ISO 9001 provides an interpretations process at the national standards body and international level. The U.S. Technical Advisory Group to TC 176 provides an interpretation for its members and standard users to resolve identified ambiguities in the standard. There have been 17 interpretations at the U.S. level for ISO 9001:2015. National standard bodies can elevate interpretation requests to the international level, where international experts develop consensus. That decision is balloted to member bodies. There have been five posted interpretations against ISO 9001:2015 that are included on the ISO 9001 SC 2 website.

ISO/TS 9002 provides user guidance on the intent of ISO 9001:2015 requirements. ISO/TS 9002 was written by several individuals who were instrumental to the development of ISO 9001, so users are assured of consistent understanding from the ISO 9001 standard writers. The ISO 9001 text is explained with examples of possible steps an organization can take to meet the requirements. For example, clause 4.2 for interested parties is about one-quarter of a page in ISO 9001, but it is expanded to about two pages in ISO/TS 9002 to explain the concept.

ISO/TS 9002 is a guidance document and does not add, subtract or change requirements. Based on the 2020 ISO user survey, 35% of users did not use ISO/TS 9002 to gain a better understanding of ISO 9001 (see Figure 2, p. 43), which is unfortunate.

ISO 9001:2015 for Small Enterprises is a handbook that guides smaller organizations on establishing and implementing ISO 9001:2015. Like ISO/TS 9002, it offers excellent guidance geared toward organizations that do not have complex QMS needs. It also does not add, subtract or modify any ISO 9001:2015 requirements.

ISO 9001 is intended for organizations of all types and sizes, no matter the products or services it provides. This handbook was developed for small organizations that face challenges due to a lack of resources and available expertise, but it is a good resource for organizations of any size. Due to the reduced number of internal interactions when compared to larger organizations, the handbook explains that many small and medium enterprises also can apply less complex QMSs that are fully compliant with ISO 9001. The handbook includes a QMS overview, practical advice, guidance to understand requirements, and annexes for implementation methods, certification/registration and QMS principles.

Ensuring a successful QMS
Ample resources written by the experts directly involved in standards development are available from standards committees to help organizations of all types and sizes implement and continually improve their QMS. An organization is responsible for ensuring its QMS is tailored to and appropriate for its business and processes. Successful implementation ensures effective use of resources, excellent results and continual improvement of the QMS.

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REFERENCES

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