# Standard Issues

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ISO 9001

# Let the Preparation



What goes into revising one of the most popular ISO standards? by L.L. "Buddy" Cressionnie

ISO 9001—Quality management systems—Requirements, developed by International Organization for Standardization (ISO) technical committee (TC) 176 for quality management and quality assurance, is one of the most recognized standards in the world.

According to a 2018 survey,<sup>1</sup> there are 878,664 valid ISO 9001 certificates related to 1.2 million sites around the world. ISO 9001 also is the basis for several industry-specific standards, including automotive, aerospace, medical device and telecommunications. It can be said with confidence that tens of millions of people around the world are engaged with quality management systems (QMS) based on the ISO 9001 standard.

QMSs are an important part of ensuring the reliability of regional and global supply chains of various types. They play an equally important role in ensuring the quality of a wide variety of services around the world to demonstrate an organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

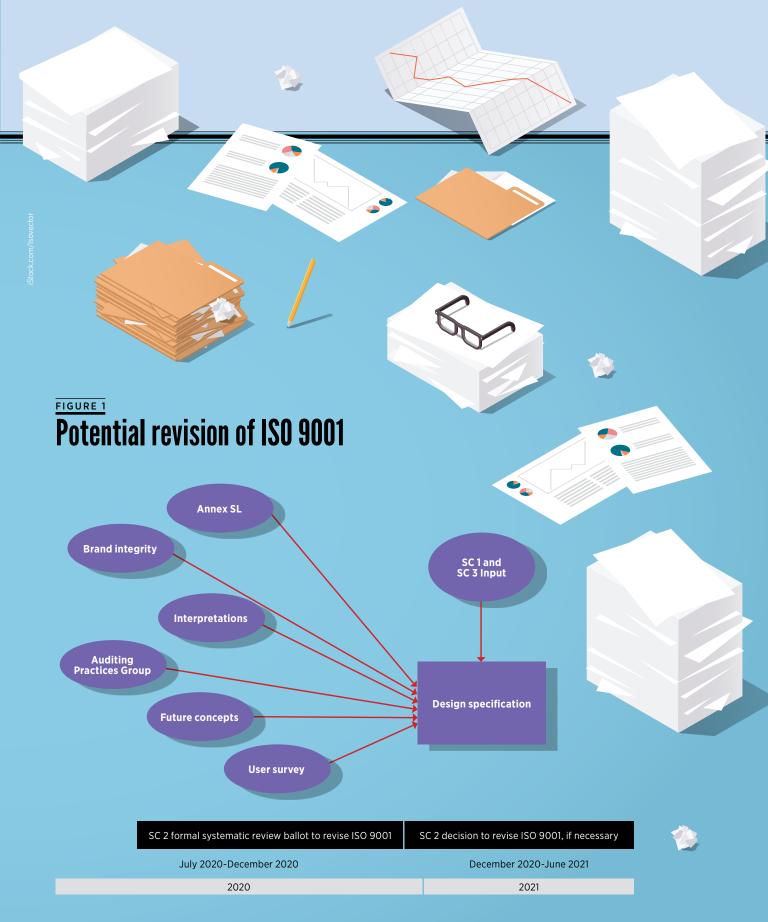
### ISO 9001 potential revision planning

ISO 9001 was first published in 1987 and is reviewed five years after the publication of a new edition—or since its last review if it was left unchanged—to determine the need for a revision. The ISO 9001 standard has been revised four times to address stakeholder needs, including challenges of changing economies, advances in technology and trends in society. The current version of ISO 9001 was released in 2015, so it is nearing its five-year limit, and a decision will be made soon on whether a revision is necessary.

In November 2019, TC 176/subcommittee (SC) 2 decided to establish task group (TG) 5 to prepare for the potential revision of ISO 9001. The preparation process includes numerous activities as inputs to the design specification (see Figure 1 for activities and a brief timetable):

 Annex SL: The ISO Technical Management Board established a common structure and vocabulary for management system standards. Annex SL resulted in the current ISO 9001 10-clause structure. Annex SL recently has been through its own process of review and is nearing the end of being revised. While only minimal changes are expected to Annex SL, any change must be incorporated into the next revision of ISO 9001.

- + Brand integrity: The goal of TC 176/ TG 2, the brand integrity TG, is to preserve the ongoing credibility of ISO 9001 and other TC 176 standards when used as a basis for conformity assessment or certification. This TG may have inputs into the ISO 9001 revision activity to maintain the ISO 9001 brand.
- Interpretations: Interpretations by TC 176 and country national standards bodies will be examined to determine whether additional clarity is required for ISO 9001 requirements to improve understanding and implementation.
- + Auditing practices group (APG): The APG develops papers and presentations on auditing QMSs.<sup>2</sup> TG 5 will review what papers and presentations are being downloaded



**SC =** subcommittee







## The preparation process includes numerous activities as inputs to the design specification.

most frequently and the number of requests for new content as inputs into the ISO 9001 revision.

- + Future concepts: TC 176 established task force (TF) 4 in September 2017 to develop future concepts for consideration in all works of ISO/TC 176. TF 4 is creating a formal document on future concepts, covering descriptions of the concepts, current literature and applications of the concepts from a multi-industry or sector view, and potential effects on ISO/TC 176 standards and documents with recommendations. These future concepts are included in the user survey to get stakeholder feedback for consideration to be included in a revised ISO 9001.
- User survey: It was decided that a global survey on the future of ISO 9001 would be conducted. The objectives of the survey are to:
  - Provide data on the value to organizations of implementing a QMS based on the current ISO 9001 standard.
  - Provide data on the advantages and disadvantages of the current ISO 9001 standard.
  - Capture user opinions on how to ensure this standard remains relevant in the future, including receiving input on future concepts.
  - 4. Receive user input on the future of ISO 9001. Should it be left as is for the next five years, revised or supplemented by standards with an enhanced or reduced set of requirements?

It was decided that the user survey will not include questions about certification, Annex SL or other standards (such as ISO 9004). This was done to focus user feedback on ISO 9001.

TC 176 TG 5 invites all ISO 9001 users to participate in a global survey about the future of ISO 9001.<sup>3</sup> For convenience, the survey was developed in 13 languages, so at the beginning of the survey, the user can choose the most convenient language and even toggle between languages. The survey will be available until the end of 2020. User input is important to ensure continued relevance, usefulness and recognition of ISO 9001.

After ISO/TC 176 members vote whether to revise ISO 9001, these inputs will culminate in the development of a design specification that will be developed by midyear 2021. The design specification provides the purpose and direction regarding the strategic intent of the ISO 9001 revision, and clear boundaries for the revised standard and scope of the revision. The design specification will be balloted to national standards bodies for approval.

#### How to engage with ISO 9001

If standard writing sounds interesting, experts often are brought into writing committees for additional technical guidance. TC 176 is always looking for experts

to work on these standards. You must be nominated by your national standards body, or an ISO-recognized liaison organization, to participate internationally.

 National standards bodies: ISO membership includes national standards bodies that represent ISO in their countries. In the United States, ASQ is the administrator for the American National Standards Institute and has established the U.S. technical advisory group to TC 176.4

 Liaisons: TC 176 has numerous liaisons with international organizations that are stakeholders to TC 176 work products.

Numerous activities occur prior to revising a standard to get stakeholder input. During the last revision to ISO 9001, more than 12,000 responses were received to the user survey. It is an important tool to ensure ISO 9001 remains relevant in the future. QP

#### **EDITOR'S NOTE**

This article was written by the deputy convenor of the ISO/TC 176/SC 2/TG 5 team, and article content includes collaboration materials from the team.

#### REFERENCES AND NOTES

- "ISO Survey 2018," International Organization for Standardization (ISO), www.iso.org/the-iso-survey.html.
- "ISO 9001 Auditing Practices Group," ISO, https://committee.iso.org/home/tc176/ iso-9001-auditing-practices-group.html.
- The survey is available at https://tinyurl. com/2020-iso-survey, and also on the ISO/ TC 176/SC 2 website at https://committee. iso.org/home/tc176sc2.
- For more information about the U.S. technical advisory group to technical committee 176, contact standards@asq.org.

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Expertise LLC, with industry leadership positions of Americas Aerospace Quality System Committee (AAQSC) chair and AAQSC leader of requirements, projects and

AS9100. He is active in standards development as a liaison member to the International Organization for Standardization (ISO) Technical Committee (TC) 176, including developing future concepts, planning the next ISO 9001 revision, writing ISO 9001:2015 and ISO 9004:2018, and participating in the ISO 9001 Interpretations Committee.