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Secretariat of ISO/TC 176/SC 2

To the Members of ISO/TC 176/SC 2 - Quality Management and Quality Assurance/ Quality Systems

Ballot on the ISO 9001 Systematic Review recommendations

1. Introduction

The systematic review of ISO 9001:2015 closed on 2nd December 2020.

In accordance with the ISO/IEC Directives Part 1, clause 2.9.2, an ISO (sub)committee has six months in which to indicate the action it will take on a standard following a systematic review.

As the ISO 9001 User Survey did not close until the end of December, and allowing time for analysis of the results, ISO/TC 176/SC 2 has needed to use the time available, before making recommendations on the actions to be taken.

In addition to the survey, a number of other key inputs, e.g. the ISO/TC 176 work on "Future Concepts" and "Brand Integrity" were also delayed due to the COVID 19 pandemic.

2. ISO/TC 176/SC2/SPOTG examination of inputs

The ISO/TC 176/SC 2/ Strategic Planning and Operations Task Group (SPOTG) met on 26th March to examine the inputs into making the Systematic Review decision.

The SPOTG received and examined:

- The results of the systematic review (36 votes for "confirm"; 32 for "revise"; 2 abstentions)
- The results of the ISO 9001 User Survey (showing a similar majority to confirm ISO 9001)
- A report on the Future Concepts
- A report on Brand Integrity
- A report on the potential impacts of the revision of the Annex SL "High Level Structure" on ISO 9001
- A report on the WG24 Project Review Report
- Verbal reports from country and liaison members

The SPOTG agreed that there were insufficient factors given in the reports to overturn the majority voting responses given by the member bodies in the Systematic Review for "confirming" ISO 9001. However, the SPOTG also noted that this was a relatively small majority, and that many members wished to see the standard revised to a) improve clarity and b) to give greater value to users. This led to a discussion on the path forward.

Some members suggested that TC176/SC2 (and TC 176 itself) should first undertake a strategic review of the full portfolio of quality management standards, before deciding on a future direction for ISO 9001.

Others noted that if SC2 failed to plan for a revision, that it could be as far away as 2030 before a new edition of ISO 9001 would be published (following a further systematic review starting in 5 years, plus time for the review, and then allowing for 3 years of development time). Several members indicated that the business environment is currently changing so quickly (with many factors being accelerated by the COVID19 pandemic), that the standard needs to be revised much sooner, and not in 10 years' time.

The members of the SPOTG agreed that there is now a considerable amount of data available that needs to be further reviewed and analyzed, prior to a decision being taken on revising the standard, and prior to a Design Specification for a revision of the standard being developed.

The SPOTG then debated the merits of establishing a project for ISO 9001 at the "Preliminary stage", versus just undertaking the analysis of such data via a Task Group or other mechanism. It was explicitly noted that a project at the Preliminary stage does not automatically imply that a revision will be conducted. However, as the Preliminary stage is limited to 3 years duration, it does provide a time frame by when a proposal for a revision should be made.

The SPOTG is an advisory body and does not have the authority to makes decisions. Instead, and following its deliberations, the SPOTG now makes the recommendations given in section 3 of this report to ISO/TC 176/SC2. As indicated in section 4 of this report, these recommendations are now being circulated for a ballot by SC2's P-members (and for comment by its "O" and "L" members)

3. Recommendations on the systematic review of ISO 9001

- a) ISO 9001:2015 should be "confirmed" at this time.
- b) A project should be started at the Preliminary stage, to examine if a revision of ISO 9001 should be started earlier than would usually be determined through the systematic review process.
 - Noting that ISO/TC 176/SC2/TG 5 is already established with the purpose of "Preparing for a potential revision of ISO 9001", this project should be assigned to TG 5.
- c) A wider review of the SC2 portfolio of standards should be conducted by the SPOTG and should be coordinated with the work of the ISO/TC 176/Chair's Strategic Advisory Group (CSAG), as well as the Preliminary stage project on ISO 9001.

4. Ballot on the Systematic Review recommended decision

A ballot has been established on the ISO Committee Internal Ballot (CIB) portal to decide if ISO/TC 176/SC2 P-members will accept the recommendations: i) to "confirm" ISO 9001:2015 at this time, and ii) to establish a project at the Preliminary stage to examine if an early revision of ISO 9001 should be started.

(The SPOTG is already established to examine strategic matters, so no ballot is needed on recommendation c))

We would be pleased to receive comments from O-members and Liaison members on these recommendations.

Please submit your vote and comments by: 1st May 2021

Yours sincerely

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For the BSI Secretariat of ISO/TC 176/SC2