



ISO/TC 176/SC 2/TG 5 "Preparing for a potential revision of ISO 9001"

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TG 05 Report to SPOTG (2022-03) Rev 0

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TG 05 Report to SPOTG, 2022-03 - Executive Summary

Task Group 5 (TG 5) to ISO/TC 176/SC 2 was given the mandate by the SPOTG (i.e., ISO/TC 176/SC 2/AHG 01) in March 2021 to collect data and perform preliminary analysis to indicate whether there is any evidence that ISO 9001 should be revised earlier than the next scheduled Systematic Review (due in 2026, as the last Systematic Review closed in December 2020).

While this project was within the scope of TG 5, i.e., *Preparing for a potential revision of ISO 9001*, it was a change of focus as TG 5 had previously managed the ISO 9001 User Survey 2020.

Thirteen (13) sources of evidence were examined, and provided four hundred and ninety-six (496) individual items for evaluation. These items were analyzed using an Impact-Benefit matrix. The majority of items which should be included in the next revision for ISO 9001 came from the recent revision of Annex SL (i.e., the Harmonized Approach which includes the Harmonized Structure).

No single item, or source of evidence, on its own was found to be strong enough for TG 5 to recommend a revision of ISO 9001. It is recommended that the SPOTG **consider** the collective impact of a number of factors (including responses to the Covid-19 pandemic, changes to Annex SL, new and emerging technologies, remote working, and global systems) which may support *starting* a revision of ISO 9001 before the next scheduled Systematic Review in 2026.

The Annex contains the methodology for analysis including the Impact-Benefit matrix. The disposition of the four hundred and ninety-six (496) individual items evaluated are provided as a separate document (N-192, TG05 Preliminary Stage responses Master 2022.01.31 with further analysis).

Outline of Sections

Executive Summary

1. Background
 2. [Sources of evidence reviewed & methodology](#)
 3. [Results of analysis](#)
 4. [Comments & Observations](#)
 5. [Conclusion & Recommendation](#)
- [Annex A](#)
-

1. Background

During its plenary meeting in Bridgetown, Barbados in November 2019, ISO/TC 176/SC 2 identified the need to prepare for a potential revision of ISO 9001. A team was established (ISO/TC 176/SC 2/TG 5) which:

- From November 2019 to March 2021 conducted, analysed and reported on a world-wide user survey which yielded responses from 8397 respondents across 149 countries. The results of the user survey were presented together with the results of the Systematic Review (which closed in December 2020) at the SPOTG meeting in March 2021. As a result of the SPOTG meeting a decision was made to recommend confirming the ISO 9001:2015 standard, and to have TG 5 continue its work,
- From March 2021 to February 2022 started a project 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 (due in 2026). The results of this project are presented in this report.

At the time of this report, TG 5 comprises over eighty (80) members representing over thirty-five (35) National Standards Bodies and Liaison Organizations.

2. Sources of evidence reviewed & methodology

Data from thirteen (13) categories and sources of evidence was collected and reviewed, as shown in the following table. The number of inputs assessed for each source is also provided:

| <u>Source</u> | <u>Number of Inputs</u> |
|---|-------------------------|
| 1) HS = ISO Harmonized Structure | 68 |
| 2) TC 67 = Oil & Gas group responsible for ISO 29001 | 12 |
| 3) SR = Systemic Review ISO/TC 176/SC 2/N 1550 | 51 |
| 4) 10007 = ISO 10007; Configuration Management Standard | 1 |
| 5) INT = Interpretations from ISO/TC 176/SC 2/TG 4 | 1 |
| 6) APG = Auditing Practices Group | 13 |
| 7) Canada = Canada Input | 1 |
| 8) PLN = ISO 10005 Quality Planning | 1 |
| 9) US = ISO 9001 User Survey 2020 | 14 |
| 10) IR = ISO 20000-1 | 7 |
| 11) WG24 = Actionable items from ISO 9001:2015 | 2 |
| 12) DIS = Comments from WG24 which were previously out of scope or not accepted | 313 |
| 13) TG4 = Emerging Trends | 11 |
| Total | 496 |

Table 1

A notable absence was input from the Brand Integrity group (ISO/TC 176/TG 02/AHG 03) about revisions to ISO 9001, as their work was not available at the time of this report.

The methodology used is described in [Annex A](#).

3. Results of analysis

Analysis of the 496 comments from the wide range of sources included a review of the number of suggestions that were assigned each of the possible designated options of:

- ‘Accept’,
- ‘Modify’
- ‘Future consideration’ and
- ‘Not accepted’.

These selections were further analysed to determine how they related to clauses and requirements of the standard, followed by a review of the evaluation scorings that had been assigned to indicate the possible user benefits against user impacts. The final layer of analysis was to establish whether any items of significance had been identified to support a decision for revision. It was noted as part of the review that any revision would require the adoption of updates relevant to the harmonized structure (Annex SL) and these represented 61 of the 126 accepted suggestions.

The table below indicates the number of references to each clause or for changes that have a broader impact on the standard. These have been split to demonstrate the impact of changes that will be required under the harmonised structure approach.

| Clause ref. | Number of accepted comments including Harmonised Structure | Number of accepted comments <i>excluding</i> Harmonised Structure |
|------------------|--|---|
| Clauses 0 - 3 | 0 | 0 |
| Clause 4 | 7 | 4 |
| Clause 5 | 0 | 0 |
| Clause 6 | 4 | 1 |
| Clause 7 | 17 | 3 |
| Clause 8 | 27 | 3 |
| Clause 9 | 22 | 10 |
| Clause 10 | 10 | 6 |
| General | 32 | 31 |
| Multiples | 7 | 7 |
| Sub-total | 126 | 65 |
| Add HS comments | (N/A) | 61 |
| Totals | 126 | 126 |

Table 2

As this table shows, the most significant proportion of accepted suggestions for change relate to general updates or multiple clauses which, when considered collectively, may justify a revision of ISO 9001.

A further 61 suggestions for change were given a ‘modify’ rating which indicated that the comment was not accepted although the principles were noted.

87 suggestions were rated as for ‘future consideration’ which demonstrated that the comment was not accepted for the next revision but was considered useful to retain for future revisions of ISO 9001. With the fast pace of changes, the team felt that there may be value in considering these items as suitable for inclusion under the next review.

221 suggestions were not accepted which may offer confidence that the comments were reviewed without bias.

The table below shows the breakdown of assigned responses against clauses

| Clause ref. | Number of comments accepted | Number of comments accepted as 'modify' | Number of comments for future consideration | Number of comments not accepted |
|---------------|-----------------------------|---|---|---------------------------------|
| Clauses 0 - 3 | 0 | 0 | 7 | 1 |
| Clause 4 | 7 | 0 | 10 | 39 |
| Clause 5 | 0 | 0 | 4 | 21 |
| Clause 6 | 4 | 7 | 0 | 9 |
| Clause 7 | 17 | 9 | 2 | 54 |
| Clause 8 | 27 | 1 | 58 | 37 |
| Clause 9 | 22 | 19 | 1 | 33 |
| Clause 10 | 10 | 1 | 2 | 14 |
| General | 32 | 17 | 1 | 10 |
| Multiples | 7 | 3 | 0 | 0 |
| New | 0 | 4 | 2 | 3 |
| Totals | 126 | 61 | 87 | 221 |

Table 3

Of those items that have been ‘Accepted’ or identified as ‘Modify’ or for ‘Future consideration’ the evaluation scores were analysed to support understanding of the balance of potential user benefits against potential user impact.

The summary of these scores against these disposition responses is shown below.

| Evaluation score | Accept | Modify | Future consideration |
|------------------------------|--------|--------|----------------------|
| 1 | 60 | 0 | 0 |
| 2 | 25 | 4 | 2 |
| 3 | 8 | 10 | 2 |
| 4 | 20 | 15 | 10 |
| 6 | 1 | 11 | 30 |
| 9 | 12 | 21 | 43 |
| Average of evaluation scores | 2.53 | 5.77 | 7.09 |

Table 4

This analysis supports the conclusion that the accepted items are those that are most likely to achieve user benefit without significant impact (see [Annex A](#) for a description of the categories of benefit and impact).

This is further supported when evaluation scores for accepted comments are analysed against the clauses.

| Clause ref. | 1 | 2 | 3 | 4 | 6 | 9 | Average |
|---------------|----|----|---|----|---|----|---------|
| Clauses 0 - 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Clause 4 | 4 | 2 | 1 | 0 | 0 | 0 | 1.57 |
| Clause 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Clause 6 | 3 | 1 | 0 | 0 | 0 | 0 | 1.25 |
| Clause 7 | 13 | 3 | 1 | 0 | 0 | 0 | 1.29 |
| Clause 8 | 23 | 3 | 1 | 0 | 0 | 0 | 1.19 |
| Clause 9 | 12 | 1 | 1 | 0 | 0 | 8 | 4.05 |
| Clause 10 | 3 | 0 | 2 | 1 | 1 | 3 | 4.6 |
| General | 1 | 11 | 2 | 17 | 0 | 1 | 3.31 |
| Multiples | 1 | 4 | 0 | 2 | 0 | 0 | 2.43 |
| New | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Totals | 60 | 25 | 8 | 20 | 1 | 12 | 126 |

Table 5

This could address concerns that revision of the standard would result in the need for significant system updates which was raised as one of the reasons a revision was not desired at this time.

It should be noted that the analysis of the data **did not** consider the potential impact of other MSS committees updating their standards (e.g., ISO 14001, 27001, 28001, 45001 and 55001) and ISO 9001 not being revised. This could lead to a lack of integration rather than increase it.

Of further note when considering the analysis of this data is that other potential drivers for change such as demand for sustainability, carbon emissions, requirements for business continuity and increased remote working were not always considered as part of the development of source information, some of which pre-date the global pandemic.

The review of these sources of information did not identify any single suggestions for change that represented a significantly urgent or important need for revision of the standard.

4. Comments & Observations

Comments from various sources are consolidated below:

- i. The input suggestions reflect the desire for relatively minor, incremental updates that will modernize the standard to support current and future organizational needs such as those associated with increased use of technologies; remote working; global systems.
- ii. Globally relevant business and societal changes also point to the need to include considerations for resilience; sustainability; collaborative supply chains; and effective management of changes.
- iii. Changing environments and introduction of business continuity given our worldwide pandemic underscore the need to promote business sustainability.
- iv. These suggested changes subtly affect most clauses and will need to be well-coordinated.
- v. The suggestions do not represent any significant changes to requirements and therefore should not be too onerous to apply which would address concerns raised by some members when ISO 9001 was confirmed.

The several changes made to Annex SL related to documented information will improve ISO 9001 including eliminating the need for “maintain” and “retain” wording. This wording was a translation issue for many countries during the last revision and could be clarified for non-English speaking users.

The additional inputs reviewed and dispositioned by TG5 included proposed revisions in the following areas with source of input in parenthesis:

- a) 4.3 - Scope concerns (APG)
- b) 6.1 – Clarifying risk especially with operational risk (SR)
- c) 6.1/8.2 - Improved focus on identification and management of risks, contingency actions, and organizational resilience (business continuity) (APG/SR)
- d) 7.2 - Clarity on requirements for competence records (APG)
- e) 7.4 - Effectiveness of internal and external communication (SR)
- f) 7.5 - Updates to text regarding documented information (DIS, TC67, HS)
- g) 9.1.3 – Guidance to support effective use of data – records, analysis, and improvement (DIS/US)
- h) 9.2 - Internal audit remote auditing controls and effectiveness/efficiency focus (APG – ISO 19011)
- i) 10.2 – Development of text regarding analysis of root cause when investigating nonconformities (SR)
- j) All – Inclusion of elements to support organizational agility and change management (SR)
- k) All - Importance of Supply Chain management should be reflected within the standard
- l) All - Incorporating Emerging Trends (TG4/SR)
- m) All – User Survey improvements (US)
- n) All - Incorporating Harmonized Structure text (SR/HS)

5. Conclusion & Recommendation

The 13 sources of input (and associated 496-line items that were examined) do not individually provide sufficient evidence to justify an early revision of ISO 9001.

However, collectively the inputs warrant consideration by SPOTG of an early revision of ISO 9001.

Annex A - Methodology

TG 05 (and other SC 2) members did an initial review of the 496 line-items, followed by a second review & disposition by a (mostly) different group of members.

The column headings in the Excel format used for evaluation were:

1. Team Source of Evidence (e.g., Emerging Trends, APG, Interpretations):
2. Team Contact Name:
3. Clause Reference (e.g., 8.4.2 or Type "New" if not a current requirement):
4. Suggested ISO 9001 Change:
5. Justification for Change:
6. Impact (1 - Low, 2 - Medium, 3 - High):
7. Benefit (1 - High, 2 - Medium, 3 - Low):
8. Decision Matrix Value (Results = 1-9):
9. TG05 Disposition (Accept/Modify/Not Accepted and Rationale):

The following decision-matrix was used for assessing the impact and potential benefits of the proposed changes to ISO 9001, and provided data for the final two columns in the Excel format. It is consistent with the decision matrix used for the design specification for an amendment to ISO 9001:2000, ISO/TC 176/SC 2/N 730.

| | | Benefits | | | |
|--------|---|----------|--------|-----|---|
| | | 1 | 2 | 3 | |
| Impact | | High | Medium | Low | |
| | 1 | Low | 1 | 2 | 3 |
| | 2 | Medium | 2 | 4 | 6 |
| | 3 | High | * 3 | 6 | 9 |

| | |
|-----|--|
| 1-2 | Incorporate the change. |
| 3-4 | Additional analysis should be conducted prior to making the decision. <i>Note: ‘*3 - high impact x high benefits’ is treated as an exception, since no changes which are high impact are expected to be accepted at this time. In this instance the drafters should ensure that a record is retained of the proposed change, and their analysis of this change, to provide input into future revisions.</i> |
| 6-9 | Do not incorporate the change. |

Categories of Impact

For each change recommendation, select the appropriate level for each proposed change. When completed, take the highest number from the applicable categories, and apply it to the decision matrix.

a) Changes or creation of ISO 9001:2015 user documented information

1. Low – No change to documented information
2. Medium – Requires minimum changes to documented information
3. High – Requires extensive changes or creation to documented information

b) Changes to existing processes of the organization

1. Low – No change to processes
2. Medium – Requires minimum change to processes
3. High – Requires extensive change to processes

c) Need for additional training for users of ISO 9001

1. Low – No additional training required
2. Medium – Minimal training required (e.g. ½ day awareness training)
3. High – Extensive 1 – 5 days of training required

d) Effect on certification

1. Low – No effect on current certification
2. Medium – Recertification within the certified organizations certification cycle
3. High – Recertification required within a defined transition period

Categories of Benefits

For each change recommendation, select the appropriate level for each proposed change. When completed, take the lowest number from the applicable categories, and apply it to the decision matrix.

a) Provides clarity

1. High – Removes ambiguity in the requirements
2. Medium – Provides better clarity than before
3. Low – Does not improve the clarity

b) Increases compatibility with other standards

1. High – Considerably increases compatibility with other standards
2. Medium – Improves the compatibility with other standards
3. Low – Has no impact on the compatibility with other standards

c) Maintains consistency with ISO 9000 family of standards

1. High – Significant improvement in consistency with the ISO 9000 family of standards
2. Medium – Some improvement in consistency with the ISO 9000 family of standards
3. Low – No impact on consistency with the ISO 9000 family of standards

d) Improves translatability

1. High – Significant improvement on translatability
2. Medium – Slight improvement on translatability
3. Low – No improvement on translatability