



CQI Standards Coordination Committee member survey on the case for revising ISO 9001 before the next strategic review



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Executive summary

The Chartered Quality Institute (CQI) presents this executive summary to highlight the need for a revision of ISO 9001:2015 Quality management systems – Requirements. The CQI has conducted extensive consultations with its members to gather their perspectives on the current state of ISO 9001 and the potential areas for improvement.

The CQI conducted a survey in 2023 to examine the fitness for purpose of ISO 9001:2015, as well as the priority areas for inclusion in any future revision, as identified by both the CQI Standards Coordination Committee (SCC) and ISO/TC 176/SC 2/TG5, and thus the urgency for revision activity to commence. It involved 820 responses from CQI and International Register of Certificated Auditors (IRCA) members, representing a wide range of expertise in quality management and management systems audit.

While 50% of respondents expressed agreement that the standard is fit for purpose, the other 50% called for change or remained uncertain. However, several key themes emerged from the survey responses, indicating the need for revision. These themes include the importance of continual improvement, the demand for clarity in certain clauses, the necessity to address emerging digital technologies, changing work practices, and the need to reinforce leadership commitment.

When comparing the priority areas identified by the CQI SCC and the topics proposed by ISO/TC 176/SC 2/TG5 with the content of ISO 9001:2015, it became evident that the current standard falls short in adequately addressing these areas. The CQI SCC concluded that of the nine priority areas identified by the CQI SCC and the 15 proposed by TG5, a total of 13 are insufficiently addressed, or not addressed at all, in ISO 9001:2015. The remaining 11 are only “somewhat” addressed.

Based on the survey results and analysis, the CQI strongly recommends a revision of ISO 9001 to ensure its continued relevance, applicability, and value. The risks associated with not progressing a review at this time may result in the standard becoming less relevant to business and society. By revising ISO 9001, organisations of all types and sizes can thrive by providing exceptional value to customers, stakeholders, and society at large, embracing the necessary changes to meet the evolving needs of quality management.

Introduction

The Chartered Quality Institute (CQI) is the professional body for experts in improving product, project, and service quality. For more than 100 years, it has been championing organisational excellence by setting professional standards for quality management in the UK and globally.

With 18,000 members in 100 countries, the CQI is the partner of choice for quality management practitioners and, through its International Register of Certificated Auditors (IRCA) certification, for management systems audit professionals. Its mission is to champion quality management for the benefit of society, and its vision is to bring about a world in which organisations of all types and sizes thrive by providing outstanding value for customers, stakeholders, and society.

One of the means to support these ambitions has been a long association with the UK's National Standards Body, the British Standards Institute (BSI), and on a global basis, with the International Organization for Standardization (ISO). As a fully committed and widely respected contributor to standards development over the course of many years, the CQI has been granted category A liaison status to a diverse range of BS and ISO technical committees and their associated working groups.

This report has been produced in response to the work of one such group, TC 176/SC 2/TG5 which, in March 2021, was tasked with producing a design specification for the next edition of ISO 9001. The report describes the process through which the CQI has consulted its members on the both the need for change, and those topics and themes which require consideration in any future revision of ISO 9001 and presents its conclusions on the need to revise ISO 9001:2015.

“With 18,000 members in 100 countries, the CQI is the partner of choice for quality management practitioners”

Background

In March 2021, a task group, ISO/TC 176/SC 2/TG5, was given the mandate to collect data and perform preliminary analysis to indicate whether there was any evidence that ISO 9001 should be revised earlier than the next scheduled systematic review, due in 2026.

Thirteen (13) sources of evidence were examined, and 496 individual items were provided for evaluation. These items were analysed using an Impact-Benefit matrix. Whilst no single item, or source of evidence, was found to be strong enough on its own for TG 5 to recommend a revision of ISO 9001:2015, 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) were considered sufficient to justify creating a design specification for the next edition. By producing this document in advance, when a decision to proceed is made, the development team will have an existing blueprint to work with and will not have to invest time its creation. This will shorten the overall development process by several months. The CQI was represented on ISO/TC 176/SC 2/TG 5 and contributed to the production of this specification.

The CQI Standards Coordination Committee (SCC), which is responsible for coordinating and direct CQI standards activity, has undertaken a similar exercise identifying priorities for any future revision of ISO 9001, and presents the following content for consideration by TG5, based on the CQI's desire for the world's most prolific quality management system standard to remain relevant, applicable, and of value.

This work was undertaken with reference to the CQI's globally recognised research on Quality 4.0, its Competency Framework and Professional Map, and to the views of its members and corporate partners.

Purpose of this report



The purpose of this report is to communicate the views of CQI stakeholders in respect of:

- The extent to which ISO 9001:2015 it fit for purpose and does not need revising before the next strategic review.
- The extent to which members support the inclusion of potential content identified by the CQI SCC.
- The extent to which members support the inclusion of potential content identified by TC176/SC2/ TG5 in their design specification document.

Survey of CQI and IRCA members

To inform the answers to these questions, the CQI SCC undertook a survey of all CQI and IRCA members. The survey was comprised of three parts:

Part A asked to what extent respondents agreed with the statement “ISO 9001:2015 is fit for purpose ‘as is’ and does not require revision before its next review in 2026.”

Part B listed nine priority areas for inclusion and/or addition to any future revision of ISO 9001, which had been identified, reviewed, and verified by the CQI SCC. Respondents were asked whether they ‘Strongly agreed’, ‘Agreed’, ‘Neither agreed nor disagreed’, ‘Disagreed’ or ‘Strongly disagreed’ with their inclusion.

Part C listed potential topics for potential inclusion in the next edition of ISO 9001, as identified by members of ISO TC176/SC2/TG5 and embedded within their draft design specification. The topics were identified followed extensive discussion by international subject matter experts, representatives from the CQI SCC.

Respondents were asked whether they ‘Strongly agreed’, ‘Agreed’, ‘Neither agreed nor disagreed’, ‘Disagreed’ or ‘Strongly disagreed’ with their inclusion.

The survey was published on 20 February 2023 and closed on 13 March 2023.

The survey received 820 responses. Based on this, we can be 95% confident that the results achieved are representative of the membership as a whole, with a margin of error of just over 3%.

Survey results

Responses by grade

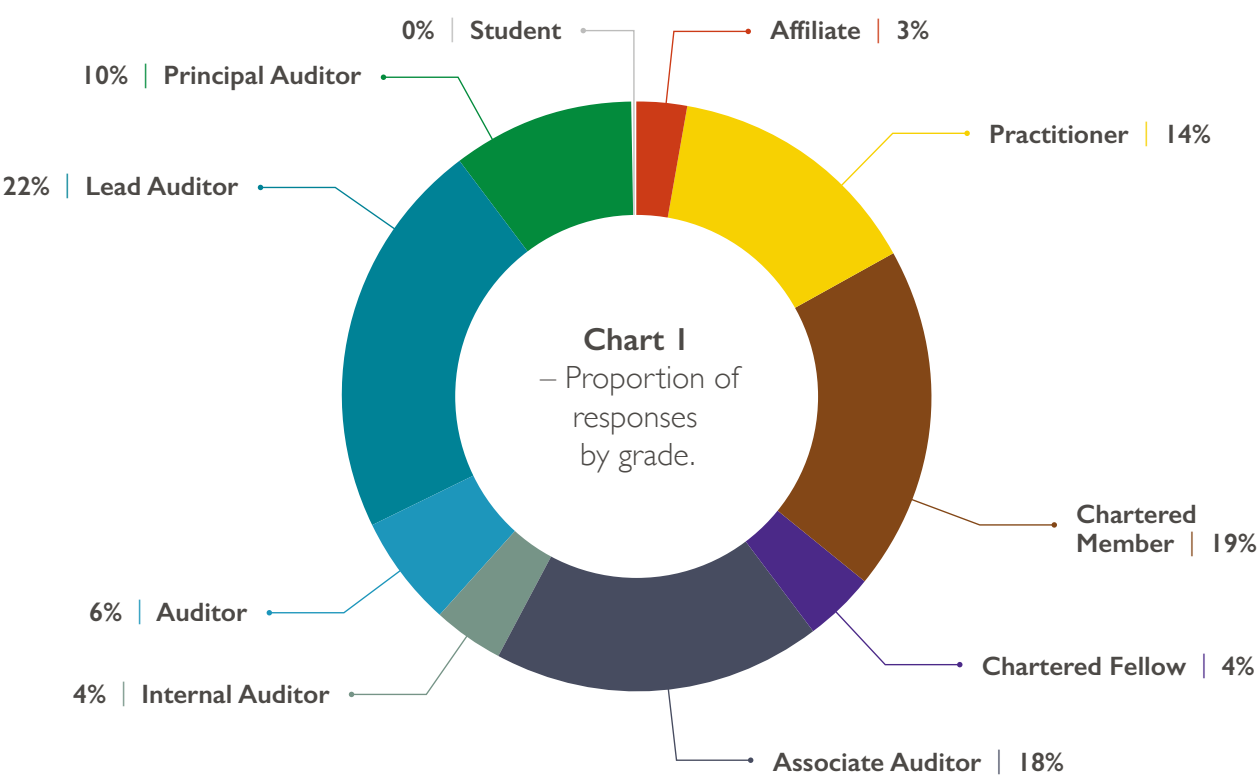


Table 1 compares the grade profile of respondents to the profile of CQI and IRCA membership by grade.

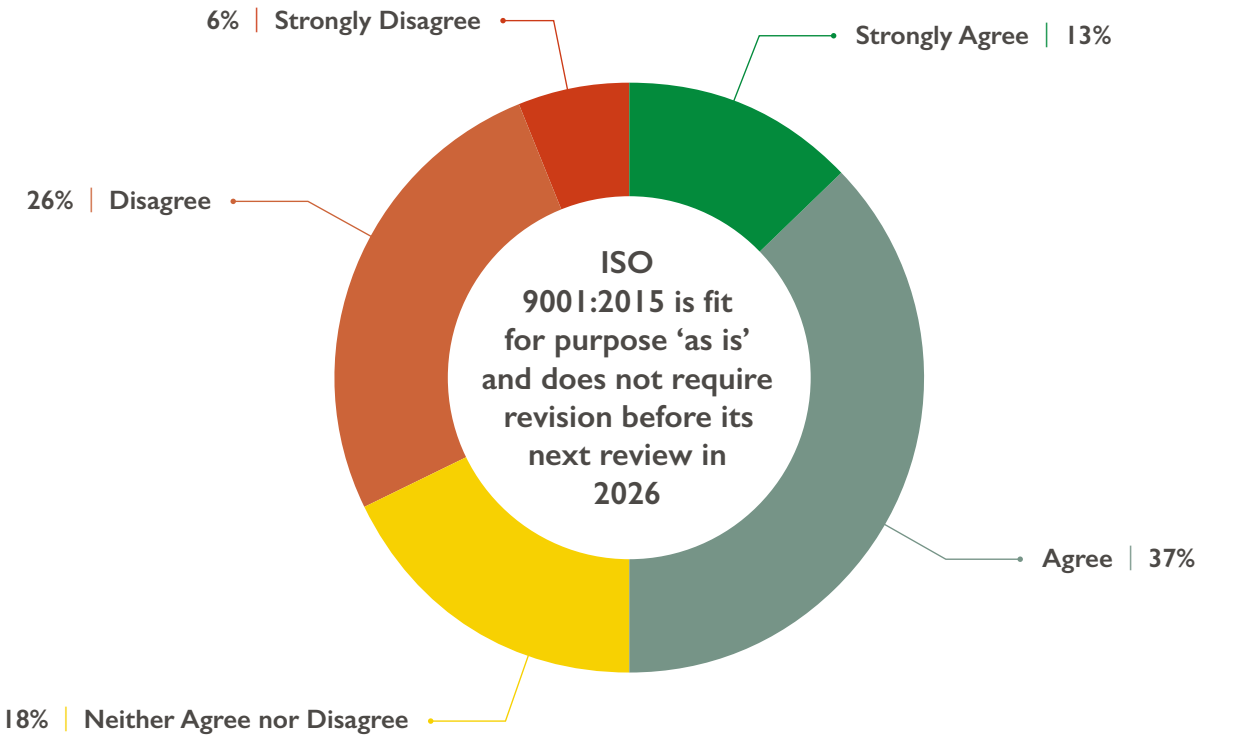
Response by Grade	% share of membership at this grade	% share of survey responses by grade
Fellow CQI	2%	4%
Chartered Member	18%	19%
Practitioner	18%	14%
Affiliate	6%	3%
Student	1%	0%
Principal auditor	5%	10%
Lead auditor	18%	22%
Auditor	5%	6%
Internal auditor	2%	4%
Associate auditor	25%	18%
	100%	100%

The profile of responses broadly corresponds to the profile of membership, indicating that input was received from the full spectrum of grades across the CQI and IRCA. In general, response rates were higher from more qualified members of the CQI and IRCA (chartered quality professionals, lead auditors, and principal auditors), those who may typically be expected to lead the implementation, management, and audit of quality management systems based on ISO 9001:2015.

Part A – Is ISO 9001:2015 fit for purpose?

Valid responses: 'Strongly agree', 'Agree', 'Neither agree nor disagree', 'Disagree' or 'Strongly disagree'.
Respondents were asked to add a comment explaining the rationale behind the answer provided.

Chart 2 - Summary of results, Part A



The results show no clear majority view, with 50% of those responding stating they strongly agreed or agreed the 2015 is fit for purpose 'as is', and 50% actively called for change or uncertain. While this gives no clear mandate for change, neither does it demonstrate great confidence in the currency of ISO 9001:2015.

Summary of qualitative responses

Respondents were invited to provide additional comments to support their responses. From these, several key themes emerged both in support and in opposition of revising ISO 9001:2015. These included:

In support of revision

- Respondents citing the continual improvement of ISO 9001 as being good practice.
- There is demand for clarification over clauses which are considered difficult to understand, apply, or audit.
- Key topics and themes which are of increasing importance to organisations in general and the management of quality in particular (eg risk) are considered to be insufficiently covered.
- That leadership and top management commitment is lacking and requirements around this need to be reinforced.
- The standard which ISO 9001:2015 sets is insufficient for a quality management system which is truly effective and adds value.
- Since 2015, much has changed. Technology and ways of working in particular have transformed business and society, and ISO 9001:2015 does not reflect the world today.

In opposition to revision

- Sector-specific variants plug the gaps in ISO 9001:2015.
- The need for change is not urgent.
- Users need more help implementing the requirements.
- Some respondents considered “new” requirements (eg climate change, digital transformation) to already be accommodated in ISO 9001:2015.
- Revising ISO 9001:2015 will have “knock-on” effect on related standards.
- Some responders cited needing more time to understand and adopt the standard.

Chart 3 – Agreement with CQI SCC priority areas for inclusion in ISO 9001 (Part B)

To what extent do you agree that any future revision to ISO 9001 shall...

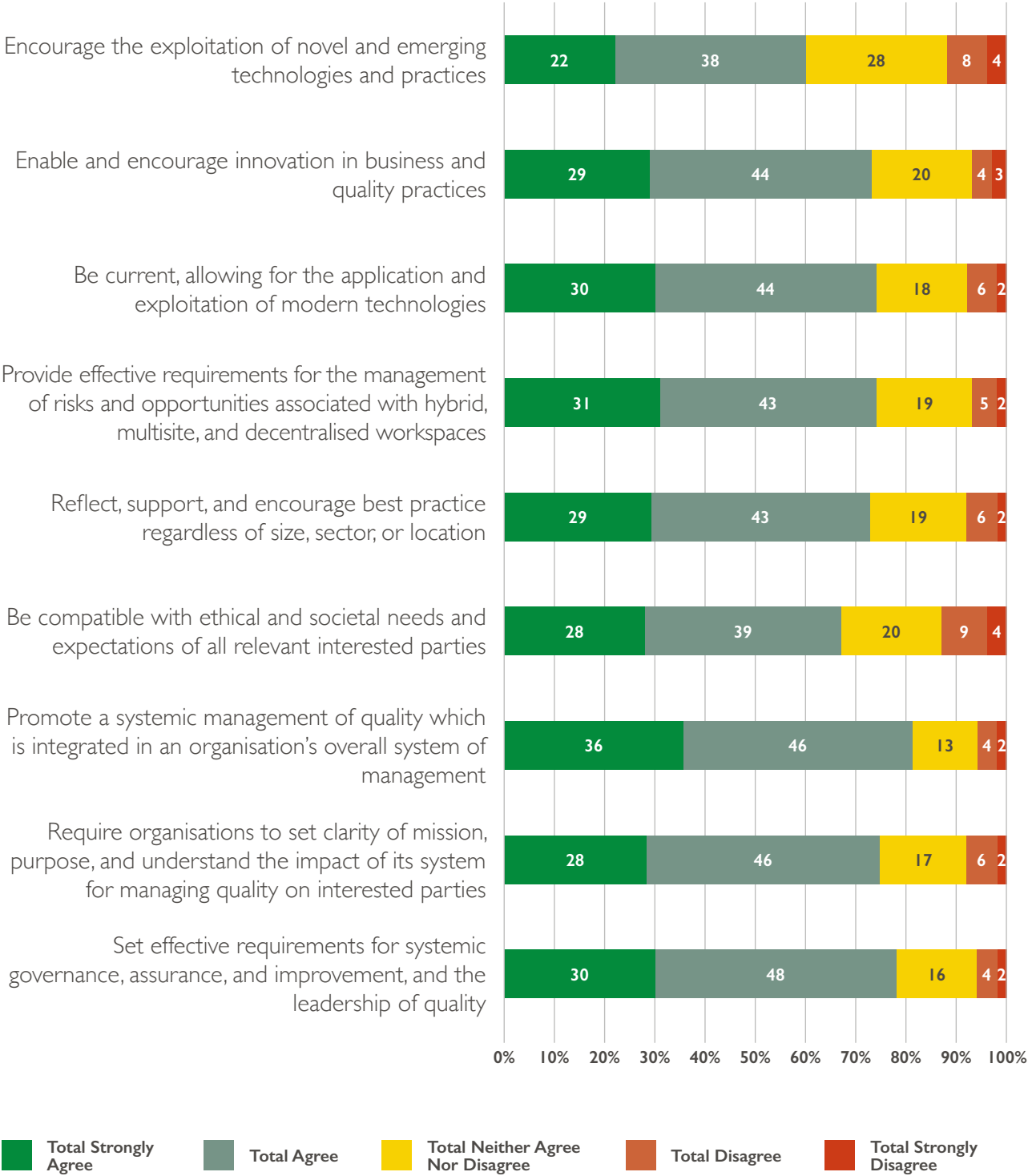
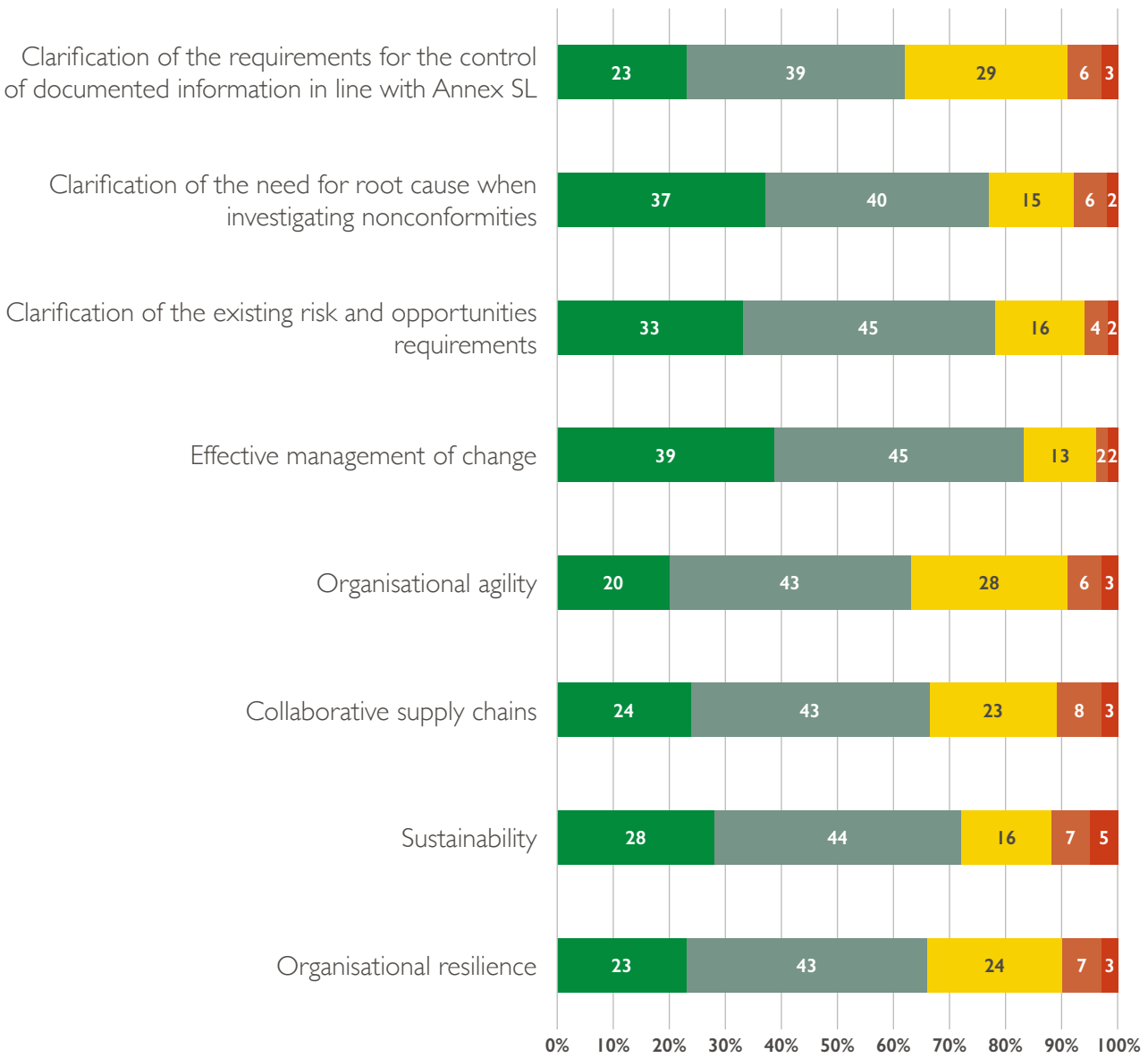
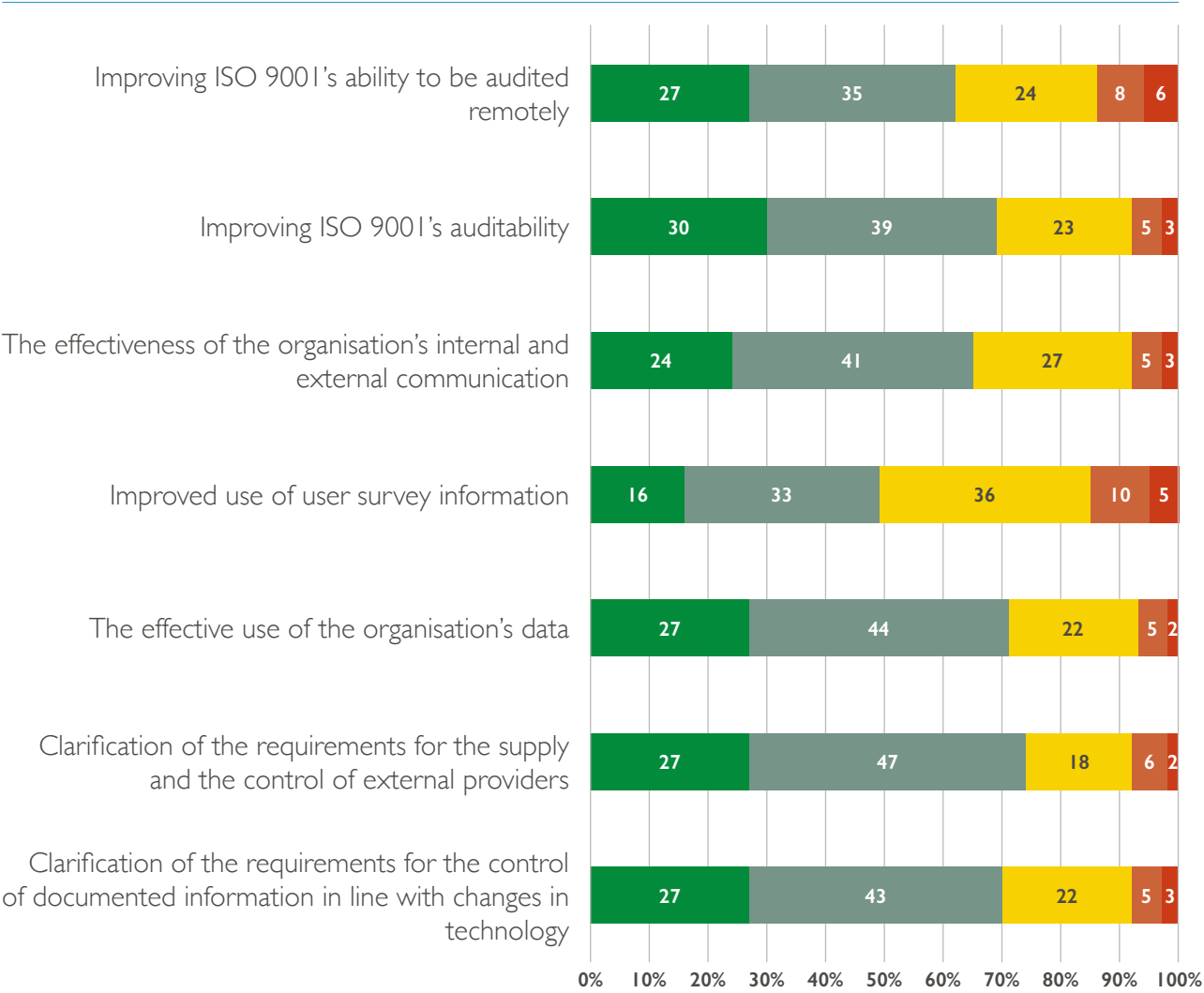


Chart 4 - Agreement with TC 176/SC 2/TG 5 topics to feature in ISO 9001 (Part C)



Total Strongly Agree
Total Agree
Total Neither Agree Nor Disagree
Total Disagree
Total Strongly Disagree

Comparing results with the content of ISO 9001:2015

Having established that a significant majority of respondents agree or strongly agree that all the priority areas for inclusion as identified by the CQI SCC and the topics set out in the TG5 should be included in ISO 9001, the CQI SCC determined the extent to which the standard in its current form addresses each priority area and topic. It also described:

- The basis on which this conclusion had been drawn.
- How each topic could be addressed by TC 176/SC2 in any future revision to ISO 9001.
- The relevant clauses which could be revised to address each of these topics.

The detailed analysis for each topic is contained in the supplementary report, “Analysis of CQI SCC ISO 9001 member survey against ISO 9001:2015”.

On this basis, the CQI SCC concluded that, of the nine topics it identified:

- three were somewhat addressed in ISO 9001:2015
- six were addressed insufficiently.

Table 2. Extent to which priority areas for inclusion and/or addition to any future revision of ISO 9001, as identified by the CQI SCC, are addressed in ISO 9001:2015

Topics for inclusion and/or addition to any future revision of ISO 9001, as identified by the CQI SCC	Addressed in ISO 9001:2015
Set effective requirements for systemic governance, assurance, and improvement, and the leadership of quality	Somewhat
Require organisations to set clarity of mission, purpose, and understand the impact of its system for managing quality on interested parties	Insufficiently
Promote a systemic management of quality which is integrated in an organisation's overall system of management	Insufficiently
Be compatible with ethical and societal needs and expectations of all relevant interested parties	Insufficiently
Reflect, support, and encourage best practice regardless of size, sector, or location	Somewhat
Provide effective requirements for the management of risks and opportunities associated with hybrid, multisite, and decentralised workspaces	Insufficiently
Be current, allowing for the application and exploitation of modern technologies	Somewhat
Enable and encourage innovation in business and quality practices	Insufficiently
Encourage the exploitation of novel and emerging technologies and practices	Insufficiently

Of the 15 topics contained with the TC 176/SC2/TG5 design specification for ISO 9001, the CQI SCC determined that:

- Five are somewhat addressed in ISO 9001:2015
- Seven are insufficiently addressed in ISO 9001:2015
- Three are not addressed at all.

Table 3. Extent to which topics for inclusion and/or addition to any future revision of ISO 9001 contained in the TC 176/SC2/TG5 design are addressed in ISO 9001:2015

Topics for inclusion and/or addition to any future revision of ISO 9001, as identified by the CQI SCC	Addressed in ISO 9001:2015
Organisational resilience	Not at all
Sustainability	Insufficiently
Collaborative supply chains	Not at all
Organisational agility	Not at all
Effective management of change	Somewhat
Clarification of existing risk and opportunity requirements	Insufficiently
Clarification of the need for root cause analysis when investigating nonconformity	Insufficiently
Clarification of the requirements for the control of documented information in line with Annex SL	Insufficiently
Clarification of the requirements for the control of documented information in line with changes in technology	Insufficiently
Clarification of the requirements for the supply and the control of external providers	Somewhat
The effective use of the organisation's data	Insufficiently
Improved use of user survey information	Somewhat
The effectiveness of the organisations internal and external communication	Insufficiently
Improving ISO 9001's auditability	Somewhat
Improving ISO 9001's ability to be audited remotely	Somewhat

Conclusion

The findings presented in the report indicate a pressing need to revise ISO 9001. While there is a divided opinion among CQI and IRCA members regarding the overall need for revision, the survey results and subsequent analysis clearly identify that ISO 9001:2015 does not adequately reflect the current world, which has witnessed transformative changes in technology, ways of working, and advances in the management of quality and organisations. This implies that ISO 9001 must adapt to remain relevant and effective.

The CQI SCC, along with the TC176/SC2/TG5, has recognised the importance of addressing digital technologies in any future revision of ISO 9001. The identified topics within the design specification, such as the control of documented information in line with technological changes, the effective use of organisational data, and the ability to be audited remotely, all underscore the need for ISO 9001 to incorporate provisions that align with emerging digital trends.

Furthermore, respondents to the survey have clearly expressed their support for the inclusion of potential content related to digital technologies in ISO 9001. This indicates a recognition within the quality management community that ISO 9001 must evolve to embrace and enable the effective use and exploitation of novel and emerging technologies.

Considering the weight of agreement on the need to address those areas and topics described in this report, it is imperative for the CQI, ISO, and other relevant stakeholders to collaboratively work towards revising the standard. By incorporating provisions that encompass the effective use of digital technologies, ISO 9001 can provide organisations with the necessary framework to navigate the challenges and harness the opportunities presented by the digital era.

In conclusion, the revision of ISO 9001 is crucial for ensuring the continued relevance and applicability of the standard in a rapidly changing landscape. By embracing these advancements, ISO 9001 can equip organisations with the necessary tools and guidelines to thrive in an increasingly digital-driven world.

