



Analysis of CQI SCC ISO 9001 Member Survey against ISO 9001:2015



The following supplementary support sets out the CQI Standards Coordination Committee's (SCC) analysis of the extent to which the priority areas for inclusion in any future revision of ISO 9001, and the topics set out in the TG5 design specification are addressed in ISO 9001:2015.

It 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, and the relevant clauses which could be revised to address each of these topics.

The tables are ordered in terms of the level of support for each topic, with the topics gaining most support at the start of this section and those securing the least support appearing at the end of the section. 'Most support' was determined by adding the percentage of those who 'strongly agreed' to the percentage of those who 'agreed' with the inclusion of each area or topic.

Additionally, the most popular response from the five possible responses is coloured dark green, the next most popular light green, then yellow, orange and finally red for the response receiving the least support.

Area for inclusion and/or addition	SA	A	NAD	D	SD	TOT	RANK
Promote a systemic management of quality which is integrated in an organisation's overall system of management	266	342	98	31	12	749	I (82%) (6%)
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	Annex L provides a framework which may enable the integration of management systems based on Annex L-based standards. However, ISO 9001 falls short of providing explicit requirements for organisations to embed the management of quality within the overall systems of managing organisations.						
How could this be addressed in the next edition of ISO 9001?	<p>“Include specific requirements for organisations to integrate common elements of managements systems (e.g., OHSAS based on ISO 45001, RMS based on ISO 31000, etc.)</p> <p>Include specific requirements for organisations to integrate their system for managing quality into appropriate systems for managing the business.”</p>						
Potentially relevant clauses	4.4 5 8 10						
Notes	Digital technologies facilitate greater integration of data from a many different sources. This is likely to accelerate the drive to a more “integrated management systems” approach. This is not a request for the development of an integrated management system standard, however. Rather it is an extension of the need for a holistic approach when more than one management system is present in an organisation. At present this is discussed in 0.4 ‘Relationship with other management system standards’ however given that this forms part of the Introduction there is no requirement for this approach to be adopted. At present different management systems can be as distinct and separate as the organisation determines.						

Area for inclusion and/or addition	SA	A	NAD	D	SD	TOT	RANK																		
Set effective requirements for systemic governance, assurance, and improvement, and the leadership of quality	222	360	117	33	17	749	2 (78%) (6%)																		
<table><caption>Bar Chart Data</caption><thead><tr><th>Category</th><th>Count</th><th>Percentage</th></tr></thead><tbody><tr><td>SA</td><td>222</td><td>30%</td></tr><tr><td>A</td><td>360</td><td>48%</td></tr><tr><td>NAD</td><td>117</td><td>16%</td></tr><tr><td>D</td><td>33</td><td>4%</td></tr><tr><td>SD</td><td>17</td><td>2%</td></tr></tbody></table>								Category	Count	Percentage	SA	222	30%	A	360	48%	NAD	117	16%	D	33	4%	SD	17	2%
Category	Count	Percentage																							
SA	222	30%																							
A	360	48%																							
NAD	117	16%																							
D	33	4%																							
SD	17	2%																							

Extent to which this is already addressed in ISO 9001:2015

Somewhat

Basis for the response above

The adoption of a process approach involves the systematic definition and management of processes and their interactions so as to achieve intended results. In this respect, conformity with the requirements set out in the current edition provides a high degree of ASSURANCE that the customer will receive conforming products and services. Similarly, the existing edition requires organisations to determine and select opportunities for IMPROVING products and services, addressing any undesired effects and for improving the QMS overall. LEADERSHIP is addressed with respect to the quality management system (QMS) and 5.1.1 b requires the quality objectives to be 'compatible' with the context and strategic direction of the organisation, whilst 5.1.1 c requires the integration of QMS requirements into the organisation's business processes. Similarly, the current edition requires leadership to address governance of the QMS by means of setting policy, controls and making decisions. The issue here is not an absence of requirements in these areas, but the lack of emphasis that this is a top management function which should not be delegated down the managerial hierarchy.

Area for inclusion and/or addition	SA	A	NAD	D	SD	TOT	RANK
How could this be addressed in the next edition of ISO 9001?	<p>Alignment and integration with and ability to drive/ deliver organisations strategy and operations. Where the organisation as defined by the scope of certification is the same as the organisation defined as a business unit, governance, assurance, improvement, and leadership arrangements will be common. Where the organisation as defined by the scope of certification is different to the organisation as defined by the business, this is not necessarily the case. Whilst ISO 9001 identifies the need to link the QMS to the business, there is also a need to link the business to the QMS. In this respect ISO 9001 needs to do more to ensure that the governance, assurance, improvement, and leadership requirements it sets out are understood not only by leaders at the QMS level, but by leaders at the business level too. They need to recognise that the 'corporate' controls, strategies, and decisions they put in place must support the QMS, not detract or encumber it.</p>						
Potentially relevant clauses	<p>4 9.2 9.3</p>						
Notes	<p>Many organisations fail to understand who top management are in respect to the operation of the QMS. They view top management as the most senior managers in the business, not those who control and direct the operations covered by the scope of the certificate. In these cases, there is a need for the governance demonstrated by the QMS top management to align with the governance of the organisation as a whole, and vice versa. Evidence from audit suggests the QMS is often viewed by leaders managing group structures as a matter for the certificated business unit themselves. This has the potential to cause issues where the aims and requirements of corporate policies, strategies and objectives are set without reference to the requirements for such arising from need to demonstrate 9001 compliance.</p>						

Area for inclusion and/or addition	SA	A	NAD	D	SD	TOT	RANK
Require organisations to set clarity of mission, purpose, and understand the impact of its system for managing quality on interested parties.	206	348	131	48	16	749	3 (74%) (8%)
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	At present the requirements of ISO 9001 are overwhelmingly focussed on the ‘here and now’ but if an organisation is to be successful in the medium to long term it has to establish and communicate its mission, vision and values (MVV) to its stakeholders and it must also create a culture of quality capable of supporting its MVV. Part of establishing this culture of quality is the production of strategies and policies to support the attainment of MVV. The current edition of ISO 9001 makes reference to the need to align the Quality Policy and Quality Objectives with ‘the strategic direction of the business’ but fails to fully define the ‘golden thread’ which links high level mission to the performance of operational tasks.						
How could this be addressed in the next edition of ISO 9001?	There is well established guidance in ISO 9004 relating to importance of establishing MVV, the linking of these to strategy and policy and the creation of a quality culture. Much of this guidance could be readily translated into requirements and inserted in the same position within the next edition of ISO 9001, namely within clauses 4 Context of the Organisation and 5, Leadership and commitment.						
Potentially relevant clauses	4 5						
Notes	An organisation cannot serve the interests of its customers if it ceases to trade. ISO 9004 is an excellent standard and arguably of greater benefit to an organisation than 9001. The fact it cannot be certificated against should not prevent us taking and adapting key concepts from it to use in other standards, including 9001. 9004 addresses mission, vision, values, and culture well and these are all critical success factors in ensuring an effective QMS.						

Area for inclusion and/or addition	SA	A	NAD	D	SD	TOT	RANK
Provide effective requirements for the management of risks and opportunities associated with hybrid, multisite, and decentralised workspaces.	229	321	142	41	16	749	4= (74%) (7%)
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	ISO 9001:2015 requires that organisations determine, provide, and maintain the infrastructure necessary for the operation of its processes, including its locations, buildings, etc. It is increasingly the case that these locations may include those outside the direct control of the organisations, e.g., home-based, shared, and/or public workspaces.						
How could this be addressed in the next edition of ISO 9001?	ISO 9001 must reflect these significant changes in workforce, workflow, and workplace to reflect current practice and accommodate future trends in ways of working. Additional guidance could be provided within Annex A to remind organisations what they need to consider when addressing the requirements of clauses 7.1.3 Infrastructure and 7.1.4 environment for the operation of processes.						
Potentially relevant clauses	7.1.3 7.1.4						
Notes	<p>Changes in workflow, workforce, and workplace practices, which have been in some circumstances been exacerbated by actions taken in response to the Covid-19 pandemic, have led to significant changes in where and how work can take place.</p> <p>TC283 have already identified this as an area for possible additional requirement inclusion in the next edition of ISO 45001.</p> <p>Organisations must also be encouraged to recognise the risks associated with a failure to manage their ethical, societal and governance responsibilities appropriately, as well as the potential rewards arising from managing these aspects well.</p>						

Area for inclusion and/or addition	SA	A	NAD	D	SD	TOT	RANK
Be current, allowing for the application and exploitation of modern technologies	225	326	137	43	17	748	4= (74%) (8%)
	30%	44%	18%	6%	2%		
Extent to which this is already addressed in ISO 9001:2015	Somewhat						
Basis for the response above	There is limited reference to 'hardware and software' in clause 7.1.3 – Infrastructure, however the focus of this cause is on 'providing and maintaining' rather than the exploitation of new technologies.						
How could this be addressed in the next edition of ISO 9001?	The focus of 7.1.3 could be extended to include not only how the organisation must ensure its current infrastructure can support the achievement of conforming products and services but how changes to the infrastructure could be made to improve effectiveness of product and service delivery further.						
Potentially relevant clauses	7.1.3 10						
Notes	<p>When previous editions of ISO 9001 were being considered, proposals were made for the inclusion of an innovation clause, however these were not progressed. Improvement on its own is not sufficient, that focuses on making existing things better. Innovation is aimed at new ideas, concepts and practices and therefore should be considered in association with Improvement.</p> <p>Additionally, where organisations are exploiting new or disruptive technologies in novel ways, it will be necessary to provide assurance of those technologies. This is especially the case with regards autonomous or semi-autonomous systems, the assurance of Artificial Intelligence, etc.</p>						

Area for inclusion and/or addition	SA	A	NAD	D	SD	TOT	RANK
Enable and encourage innovation in business and quality practices	215	333	149	33	19	749	6 (73%) (8%)
	29%	44%	20%	4%	3%		
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	ISO 9001:2015 requires organisations to seek opportunities for improvement but falls short of requiring organisations to actively seek out opportunities to innovate, e.g., introducing new or significantly improved products, services, and/or processes which meet the needs and expectations of interested parties.						
How could this be addressed in the next edition of ISO 9001?	Include requirements for organisations to identify specific needs for innovation, establish processes necessary for effective innovation, and provide the resources required.						
Potentially relevant clauses	10						
Notes	When previous editions of ISO 9001 were being considered, proposals were made for the inclusion of an innovation clause, however these were not progressed. Improvement on its own is not sufficient, that focuses on making existing things better. Innovation is aimed at new ideas, concepts and practices and therefore should be considered in association with Improvement.						

Area for inclusion and/or addition	SA	A	NAD	D	SD	TOT	RANK
Reflect, support, and encourage best practice regardless of size, sector, or location.	219	325	144	48	13	749	7 (72%) (8%)
	29%	43%	19%	6%	2%		
Extent to which this is already addressed in ISO 9001:2015	Somewhat						
Basis for the response above	ISO 9001 sets out minimum requirements for an organisation wishing to supply conforming products and services to its customers. It does not set out to establish best practice, nor do those who implement the standard necessarily wish to aspire to best practice.						
How could this be addressed in the next edition of ISO 9001?	Whilst the standard contains requirements for improvement in products and services and the QMS overall, it does not link such improvement to the sustained success of the organisation. This is an important causal relationship which should be made more explicit. There needs to be a greater 'aspirational' focus to the standard, just doing sufficient to satisfy the requirements will not elevate quality to the next level. The introduction could be amended to state conformance with the requirements is the starting point, not the end point and that an understanding of best practice within the sector should be an input into the determination of the Context of the Organisation.						
Potentially relevant clauses	Introduction 4						
Notes	The requirements of ISO 9001 must be universally applicable to organisations, regardless of size, sector, or location. Organisations must demonstrate how these factors have been considered in determining the scope and context of their systems for managing quality.						

Area for inclusion and/or addition	SA	A	NAD	D	SD	TOT	RANK
Be compatible with ethical and societal needs and expectations of all relevant interested parties	210	295	151	66	27	749	8 (67%) (13%)
	28%	39%	20%	9%	4%		
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	ISO 9001 does not set out any requirements in respect of ethical behaviour; provided the desired results are achieved the role of top management has been fulfilled. Societal needs should be considered as part for the understanding of the needs and expectations of interested parties but often organisations fail to include society when determining their stakeholders.						
How could this be addressed in the next edition of ISO 9001?	Include specific requirements for organisations to demonstrate they have considered the ethical and societal needs and expectations of all interested parties in defining the scope and context of their system for managing quality, including in post-delivery activities. Also include specific requirements regarding externally provided processes, products and services conforming with ethical and societal requirements of the organisation.						
Potentially relevant clauses	4 8.4.1						
Notes	<p>Whilst this was not seen by the CQI membership as an area for particular focus, it is clear from developments in the wider world that ethical and societal needs and expectations are playing an ever-increasing role in the shaping of organisational behaviour.</p> <p>Driven on the one hand by legislation, and on the other by social conscience, organisations are increasingly aware of their political, environmental, social, technological, legal, and economic imprint on those who are directly and indirectly impacted by their operations. A failure to act responsibly now brings with it significant risk as a result of social and other media's immediacy of communication.</p> <p>It is time for ISO 9001 to recognise the need for organisation's to not just act effectively, but also to act appropriately.</p>						

Area for inclusion and/or addition	SA	A	NAD	D	SD	TOT	RANK
Encourage the exploitation of novel and emerging technologies and practices	165	286	209	61	28	749	9 (60%) (12%)
	22%	38%	28%	8%	4%		
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	Digital transformations have the potential to significantly affect the practice of quality management. While not all organisations may wish to digitally transform, there should be a requirement to consider whether by doing so the outcomes for interested parties can be improved.						
How could this be addressed in the next edition of ISO 9001?	Include requirements for organisations to identify opportunities to adopt novel and emerging technologies, to constructively transform processes, especially with regards to performance evaluation, management review, leadership.						
Potentially relevant clauses	10						
Notes	When previous editions of ISO 9001 were being considered, proposals were made for the inclusion of an innovation clause, however these were not progressed. Improvement on its own is not sufficient, that focuses on making existing things better. Innovation is aimed at new ideas, concepts and practices and therefore should be considered in association with Improvement.						






Section C – Potential areas for inclusion in the next edition ISO 9001 as identified in the TC 176/SC2/TG5 design specification.

The following topics for potential inclusion in the next edition of ISO 9001 were identified by members of ISO TC176/SC2/TG5 and embedded within their draft design specification, due to be presented to SPOTG on 17 May 2023.

The topics were identified followed extensive discussion by international subject matter experts, including a representative from the CQI, which is a Category A liaison to this ISO technical group.

During Part C of the survey, Members of the CQI were invited to comment on the fifteen topics contained within the draft design specification. The results appear in the tables which follow.

Members were asked to categorise their response as follows:

-  **SA** = strongly agree with the topic's inclusion.
-  **A** = agree with the topic's inclusion.
-  **NAD** = neither agree nor disagree with the topic's inclusion.
-  **D** = disagree with the topic's inclusion.
-  **SD** = strongly disagree with the topic's inclusion.

The tables are ordered in terms of the level of support for each topic, with the topics gaining most support at the start of this section and those securing the least support appearing at the end of the section. 'Most support' was determined by adding the percentage of those who 'strongly agreed' to the percentage of those who 'agreed' with the topic's inclusion.

Additionally, the most popular response from the five possible responses is coloured dark green, the next most popular light green, then yellow, orange and finally red for the response receiving the least support.

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
Effective management of change	277	322	93	11	13	716	1 (84%) (4%)
	39%	45%	13%	2%	2%		
Extent to which this is already addressed in ISO 9001:2015	Somewhat						
Basis for the response above	The 2015 edition of ISO 9001 does include provision for the review and control of changes for production or service provision to the extent necessary to ensure continuing conformity with requirements and for related documentation to be retained.						
How could this be addressed in the next edition of ISO 9001?	6.3 addresses planning of changes to the QMS itself. This subclause should be revisited to determine whether there is a need for additional wording or the clarification of existing wording.						
Potentially relevant clauses	8.5.6 6.3						
Notes	Of the suggested topics contained within the draft design specification for the next edition of ISO 9001, it was the effective management of change which received the most support from CQI members. The current content of 6.3 focusses on planning rather than management of change and does not require lessons learned to be learned.						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
Clarification of existing risk and opportunity requirements	238	322	111	30	15	716	2 (78%) (6%)
	33%	45%	16%	4%	2%		
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	There is still considerable confusion as to what constitutes a risk or an opportunity, and which risks and opportunities need to be considered by a 9001 certificated organisation. Some organisations appear to list every risk imaginable whilst others only list one or two. Many do not plan actions to address opportunities. Clarification is needed within 9001 itself in respect of the above. Understanding of risk and opportunity requirements, and risk-based thinking were frequently cited in the CQI survey results as an “issue” with ISO 9001:2015.						
How could this be addressed in the next edition of ISO 9001?	Update A.4 risk-based thinking, possibly with a diagram, to illustrate which risk and opportunities are ‘in scope’ and how clauses 4, 6 and 8 link together from a risk perspective.						
Potentially relevant clauses	6.1 Annex A						
Notes	Business leaders are likely to challenge their functional leads to “join the dots” of risk and assurance across all areas of quality, environmental, safety, finance, supply chain, etc. The driver of this will be overall business risk, collated at enterprise level and driven by a top-down approach that balances risk appetite, costs of assurance and potential business impact. This will significantly affect the design of the organisation’s assurance framework. ISO 9001 needs to support this approach.						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
Clarification of the need for root cause analysis when investigating nonconformity	264 37%	285 40%	108 15%	45 6%	13 2%	715	3 (77%) (8%)
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	The 2015 edition of the standard calls for organisations to determine the 'cause' of the nonconformity and to determine the need to eliminate the 'cause'.						
How could this be addressed in the next edition of ISO 9001?	This wording should be amended to 'root cause'.						
Potentially relevant clauses	10.2						
Notes	<p>Root cause analysis is essential in order to determine the true cause of a nonconformity from a potential cause. If root cause is not determined, then there is a risk that the corrective action taken will be ineffective and that the problem will manifest itself again at a future date.</p> <p>There are many quality tools and techniques focused on identifying root cause. The existence of these needs to be highlighted, perhaps in Annex A.4</p>						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
Clarification of the requirements for the supply and the control of external providers	195	336	128	42	14	715	4 (74%) (8%)
	27%	47%	18%	6%	2%		
Extent to which this is already addressed in ISO 9001:2015	Somewhat						
Basis for the response above	Clause 8.4 of ISO 9001:2015 sets out requirements relating to the control of externally provided processes, products, and services.						
How could this be addressed in the next edition of ISO 9001?	Revisit and update the existing guidance provided in Annex A. Provide more detail in respect of the expectations around monitoring and assessing of external providers. Also update clause 8.4.1 if the revised guidance suggests additional requirements / revised requirements are necessary.						
Potentially relevant clauses	Annex A.8						
Notes	<p>Confusion still exists as to how to monitor and evaluate external providers. Some organisations still believe this should be a one-off exercise. Others are unclear 'external providers can include parts of the same business who are not covered by the scope of the certificate. Clarification is needed on these points.</p> <p>Digital transformations will create opportunities for more complex networks This will extend the scope of external providers. The interrelationships will also have a digital and possibility prescriptive (e.g., automated) element. ISO 9001 must be able to address this.</p>						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
Sustainability	203	313	117	50	34	717	5 (72%) (12%)
	28%	44%	16%	7%	5%		
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	ISO 9001 lacks any significant sustainability content which is illogical for a document with such potential to mandate sustainability improvements.						
How could this be addressed in the next edition of ISO 9001?	By adding in additional requirements in respect of the design and development of products and services and Production and Service Provision. Consider also bringing in as requirements content from ISO 9004 clause 4.2 - Managing for the sustained success of the organisation.						
Potentially relevant clauses	8.3 8.5 4						
Notes	<p>The United Nations Sustainable Development goals developed in 2015 are viewed as central to ensuring the peace and prosperity of our planet.</p> <p>Corporate social responsibility, ethical operation and sound governance are all essential ingredients for ensuring the sustained success of an organisation. When considering sustainability, these key contributors must also be explicitly considered.</p>						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
The effective use of the organisation's data	190	314	157	39	15	715	6 (71%) (7%)
Extent to which this is already addressed in ISO 9001:2015							
Basis for the response above	<p>This suggested area for development is wider in scope than the one which follows (user survey data) and attracted more support from the CQI membership. Making effective use of data facilitates better decision making and hence improved QMS outcomes. There is nothing in the standard which emphasises this relationship. This should be addressed, perhaps by means of a new clause in Annex A.</p>						
How could this be addressed in the next edition of ISO 9001?	<p>There are existing requirements in the standard relating to the analysis and evaluation of customer satisfaction and other data. With the proliferation, immediacy, and complexity of data from both within and without an organisation's business model, there may be increasing need to use and control data of strategic value, of diverse origin. Additional requirements could usefully be added at this time to ensure the results of data evaluation are acted upon.</p>						
Potentially relevant clauses	<p>9.1.3 Annex A</p>						
Notes	<p>Digital is transforming quality and ISO 9001 needs to be able cope with this and be applicable to all organisations even those at the cutting edge of digitally enabled quality.</p> <p>Businesses will benefit from the use of “extragenic” data (outside of the organisation) in achieving assurance.</p> <p>ISO/IEC 27001 provides requirements relating to the protection and preservation of the confidentiality, integrity, and accessibility of an organisation's information, with ISO/IEC 27002 setting out associated controls. ISO/IEC 27000 provides a useful information security management system overview.</p>						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
Clarification of the requirements for the control of documented information in line with changes in technology	196	308	156	35	20	715	7 (70%) (8%)
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	CQI members supported TG5's suggestion that additional consideration is given as to whether clause 7.5.3 needs to be amended to reflect the increased use of technology in evidencing the conformity of an organisation's QMS. Whilst the existing high-level requirements do address the availability and protection of documented information additional guidance around achieving this could be added into Annex A.						
How could this be addressed in the next edition of ISO 9001?	Changes to Annex SL Appendix 2 need to be echoed to ISO 9001 including those relating to documented information being 'available'. For digital documented information, technical controls will need to be employed in order to meet the requirements of 7.5.3. The existing requirements should be reviewed to establish their sufficiency.						
Potentially relevant clauses	7.5.3						
Notes	ISO/IEC 27001 - information security management systems could be used to inform the development of new ISO 9001 requirements relating to protecting and preserving the confidentiality, integrity, and availability of documented information.						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
Improving ISO 9001's auditability	215	277	162	38	22	714	8 (69%) (8%)
	30%	39%	23%	5%	3%		
Extent to which this is already addressed in ISO 9001:2015	Somewhat						
Basis for the response above	Whilst a general competence requirement for persons doing work that affects the performance and effectiveness of the QMS is contained in ISO 9001, it is ISO 19011 and IOS 17021-3 that provides the detail behind this. 19011 however is only guidance and audit experience indicate not all internal auditors are aware of its contents.						
How could this be addressed in the next edition of ISO 9001?	Improving ISO 9001's auditability will require any requirements which are not well understood to be identified and clarified. Internal auditors need to be competent to undertake their duties.						
Potentially relevant clauses	7.2 Annex A						
Notes	<p>This was not seen as a priority area for addressing amongst CQI members. The requirements set out in ISO 9001:2015 are generally well defined, it is their interpretation that leads to the majority of issues.</p> <p>For this reason, it is the guidance contained within ISO 9001 and its' partner standards that need to be focussed on as opposed to the core requirements themselves.</p>						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK																		
Collaborative supply chains	170	308	163	54	22	717	9 (67%) (11%)																		
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Extent to which this is already addressed in ISO 9001:2015	Not at all																								
Basis for the response above	This topic is not included in ISO 9001:2015																								
How could this be addressed in the next edition of ISO 9001?	Inclusion of additional quality and control requirements in clause 8.4 - Control of externally provided processes, products and services relating to supply chains, not just the immediate (once removed) external provider.																								
Potentially relevant clauses	8.4																								
Notes	<p>At present most organisations limit the scope of their interaction with external providers to the company that they buy their raw materials, products, or services from. There is little consideration of the wider supply chain. By encouraging organisations to manage supply chains as opposed to simply direct suppliers, there is the potential to drive quality improvement more widely.</p> <p>If an organisation fails to take reasonable action to make sure that its supply of labour is legitimate it can lead to significant legal, financial, and reputational damage.</p> <p>The Supply Chain Due Diligence Act which came into effect in Germany on Jan 1st this year for larger organisations will require those businesses to adapt and update their compliance, purchasing and contract drafting processes. In the UK, the Modern Slavery Act 2015 (the 'MSA') contains provisions relating to transparency in supply chains. Requirements relating to collaborative supply chains should be extended to also recognise the growing acceptance of the need for due diligence within supply chains.</p>																								

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
Organisational resilience	167	309	170	47	24	717	10 (66%) (10%)
	23%	43%	24%	7%	3%		
Extent to which this is already addressed in ISO 9001:2015	Not at all						
Basis for the response above	This topic is not included in ISO 9001:2015						
How could this be addressed in the next edition of ISO 9001?	Through the inclusion of additional requirements necessitating the introduction of arrangements to protect infrastructure and the environment for operation of processes						
Potentially relevant clauses	7.1.3 7.1.4						
Notes	It would be straightforward to add high level requirements requiring organisations to put in place contingency arrangements designed to ensure the QMS can continue to function to the best extent possible in a crisis situation. The extent of the arrangements should be determined via risk analysis and consideration of the impact of a crisis on the organisation's ability to deliver the intended outcomes of its QMS.						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
The effectiveness of the organisations internal and external communication	169	295	191	39	20	714	11 (65%) (8%)
	24%	41%	27%	5%	3%		
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	There remains confusion as to what is actually required by clause 7.4. Some organisations have produced extensive matrices setting out who they will communicate with, how often, about what etc. Some have based this on their determination of interested parties. Others claim to have made the determination however the absence of the need for retained documented information makes this difficult to verify.						
How could this be addressed in the next edition of ISO 9001?	Consider adding additional guidance to bolster the content of clause 7.4						
Potentially relevant clauses	Annex A						
Notes	The wording in the current edition has led to some organisations producing very detailed matrices covering every communication type and method both within and external to their business. Furthermore, the only requirement at present is for organisations 'to determine' such information. Once this determination is completed there is no explicit requirement to use the results of the determination or to monitor the effectiveness of the communication process.						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK																		
Organisational agility	144	308	198	42	23	715	12 (63%) (9%)																		
<table><thead><tr><th>Category</th><th>Count</th><th>Percentage</th></tr></thead><tbody><tr><td>SA</td><td>144</td><td>20%</td></tr><tr><td>A</td><td>308</td><td>43%</td></tr><tr><td>NAD</td><td>198</td><td>28%</td></tr><tr><td>D</td><td>42</td><td>6%</td></tr><tr><td>SD</td><td>23</td><td>3%</td></tr></tbody></table>								Category	Count	Percentage	SA	144	20%	A	308	43%	NAD	198	28%	D	42	6%	SD	23	3%
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D	42	6%																							
SD	23	3%																							
Extent to which this is already addressed in ISO 9001:2015	Not at all																								
Basis for the response above	This topic is not included in ISO 9001:2015																								
How could this be addressed in the next edition of ISO 9001?	Inclusion of additional requirements requiring organisations to consider how best to structure themselves in order to be able to react swiftly to changes in context. Increased emphasis on revisiting context regularly.																								
Potentially relevant clauses	4																								
Notes	The need for organisational agility is linked to both sustainability and the management of change. Organisations need to be able to react quickly to changes in their context whilst ensuring that during this time of evolution normal service continues to be provided.																								

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
Clarification of the requirements for the control of documented information in line with Annex SL	166	282	205	43	18	714	13 (62%) (9%)
	23%	39%	29%	6%	3%		
Extent to which this is already addressed in ISO 9001:2015	Insufficiently						
Basis for the response above	CQI members acknowledge that the next edition of ISO 9001 will need to incorporate the changes made to the HLS during the 2021 revision of annex SL.						
How could this be addressed in the next edition of ISO 9001?	Changes to Annex SL Appendix 2 need to be echoed to ISO 9001 including those relating to documented information being 'available'.						
Potentially relevant clauses	7.5.3						
Notes	Whilst this topic failed to ignite the enthusiasm of CQI members, there is nevertheless an ISO imperative to incorporate amendment made to annex SL appendix 2 in all future editions of type A management system standards. Accordingly, the development team for the next edition of ISO 9001 will need to ensure that the latest version of the ISO/IEC Directives (and Consolidated ISO Supplement) forms an input into their revision work.						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
Improving ISO 9001's ability to be audited remotely	196 27%	250 35%	173 24%	56 8%	40 6%	715	13 (62%) (14%)
Extent to which this is already addressed in ISO 9001:2015	Somewhat						
Basis for the response above	Specific guidance on auditing virtually is provided in ISO 19011 A.16 and the solution here may be to ensure that this is explicitly referenced in ISO 9001.						
How could this be addressed in the next edition of ISO 9001?	Simply amending the requirements of ISO 9001 is unlikely to materially improve its remote auditability. As for the above suggested revision above, the greatest gains are likely to arise from improving the auditor's ability to remote audit which is a matter for ISO 19011 and ISO 17021-3.						
Potentially relevant clauses	7.2 Annex A						
Notes	<p>There is no reason ISO 9001 cannot be audited effectively remotely as it currently stands. Covid-19 forced both certification bodies and organisations themselves to carry out conformity assessments in this manner and many have continued to perform a proportion of their audits remotely despite an improving Covid situation. The ability to carry out audits effectively has always and will always be predominantly dependent on the auditors' skill set, and organisations such as the CQI need to ensure that their training partners are suitably equipping auditors to operate in remote environments.</p> <p>Whilst there was some support for this topics' potential inclusion in the next edition this was not seen as a priority.</p> <p>A greater concern and priority should be to establish how ISO 9001 may be audited automatically or semi-automatically, as organisations increasingly exploit digital technologies to provide assurance in real-time.</p>						

Topic for potential inclusion	SA	A	NAD	D	SD	TOT	RANK
Improved use of user survey information	113	237	260	70	35	715	15 (49%) (15%)
	16%	33%	36%	10%	5%		
Extent to which this is already addressed in ISO 9001:2015	Somewhat						
Basis for the response above	There are existing requirements in the standard relating to the analysis and evaluation of customer satisfaction and other data.						
How could this be addressed in the next edition of ISO 9001?	It is unclear as to what additional requirements could usefully be added at this time. The scope of user surveys could be expanded upon using surveys to solicit a wider range of views on a wider range of topics and then utilising the results as an input into Context of the Organisation.						
Potentially relevant clauses	4 9.1.3						
Notes	Whilst this was suggested by TG5 members for inclusion in the draft design specification, this was not seen as a priority area for future consideration by CQI members.						

