



ISQM 1

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"The FDA has issued a 483 for an MDR with a weak FMEA. When tracing the DHF, it seems the 510(k) did not reference the whole DMR. We have opened a CAPA to review all the NPD SOPs in our QMS to make sure this doesn't happen again."



How you know when you've been assimilated by the ISQM 1 Task Force.

Board Discussions To Date and Focus of March Discussion

September

- Overall scope of firms and services covered by ISQM 1
- Structure
- Approach to quality objectives, quality risks and responses
- The firm's risk assessment process.

December

- Scalability, tailoring, complexity, prescriptiveness and applicability to all firms
- Quality risk considerations
- Approach to quality objectives and responses
- Monitoring and remediation, including how to embed risk and inspection of engagements.
- Evaluation of the SOQM
- Networks



March

- Identifying and assess quality risks
- Monitoring and remediation – definition of findings, deficiencies and inspection of completed engagements
- Evaluation of the SOQM
- Approach to addressing service providers
- Communication with external stakeholders

Scalability, Prescriptiveness, Tailoring, Applicability to Firms: Feedback

- CAG
 - Acknowledged efforts to address scalability, latest draft is an improvement – still a need to consider if the standard is truly scalable
 - Importance of guidance to support SMPs
- SMPC
 - Recognized efforts to improve scalability, and support for what has been done in the firm's risk assessment process
 - Recognize challenges in dealing with competing views from other stakeholders
 - Encouragement to consider simplicity of certain language
 - Emphasized need for guidance materials, and for this to be a joint effort

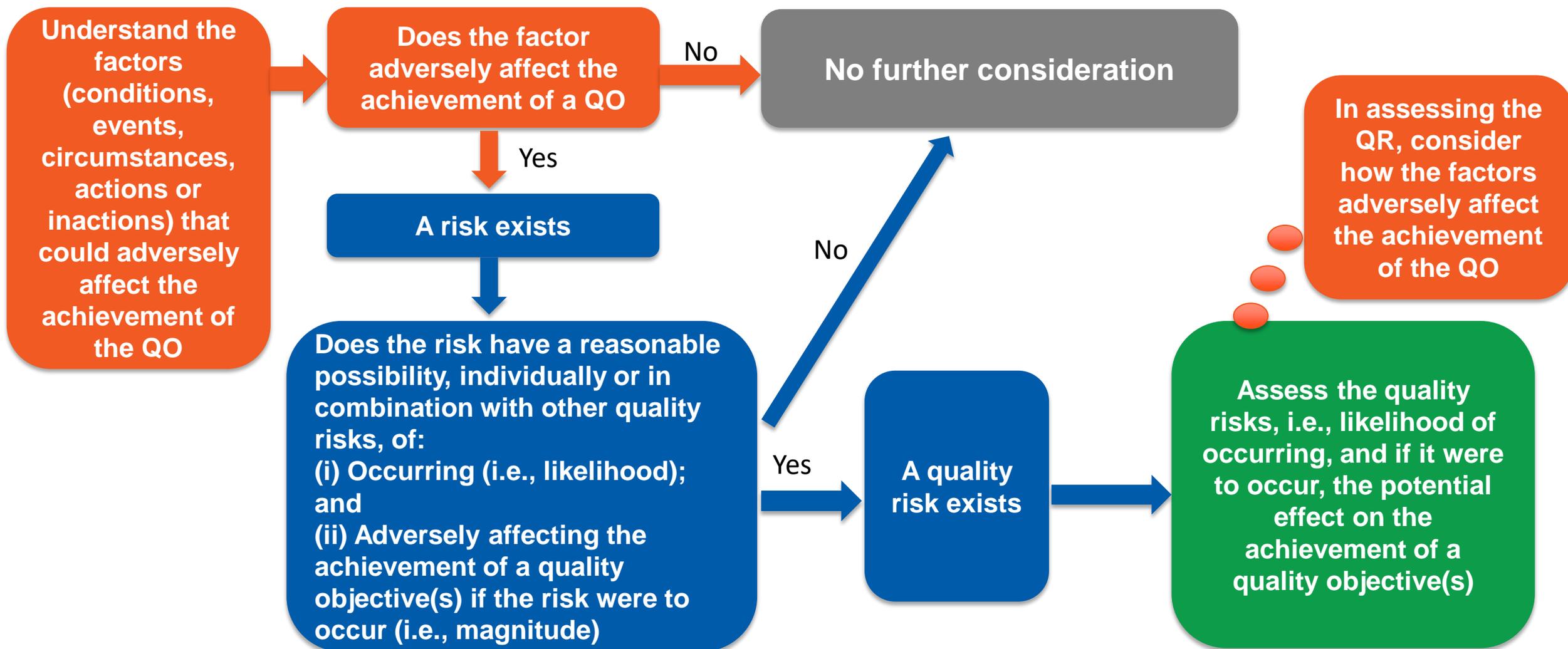
The Firm's Risk Assessment Process: CAG Feedback

- Support for risk factors, but need to demonstrate how they will operate for less complex firms and extent of documentation expectations
 - One representative supported term “quality risk considerations”
- Specific comments on the factors
 - Paragraph 22E(a)(i)(c) – characteristics and management style of leadership – appears subjective, needs to be more neutral
 - Include compensation, promotion and other incentives in the factors
- Various suggestions to enhance paragraph 22G and related application material

The Firm's Risk Assessment Process: Key Offline Comments

- Overall: Comments focused on requirements dealing with identification and assessment of quality risks, therefore appears to be overall support for most of the component
- Feedback on the definition of quality risks (“individually or in combination with”)
- A number of comments on applying paragraph 22E, including:
 - Differentiating between (i) conditions/events/circumstances, (ii) factors and (iii) quality risks
 - Complexity of the requirements, and integration with the definition of quality risks
- Paragraph 22G – focus on it being changes that affect the QO/QR/responses
- Feedback on granularity of quality objectives and responses in the components

The Firm's Risk Assessment Process: How it Works



The Firm's Risk Assessment Process: Additional Questions

Question A

Does the Board fundamentally agree with how the identification and assessment of quality risks in the firm's risk assessment process operates?

The Firm's Risk Assessment Process

Question 1:

Does the IAASB support the proposals addressing the identification and assessment of quality risks, in particular:

- a) Adjusting the quality risk considerations to “factors,” which are intended to be conditions, events, circumstances, actions or inactions?
- b) Revising the examples in paragraph A24N of Agenda Item 4-A to demonstrate how the nature and circumstances of the firm and the engagements it performs are related to conditions, events, circumstances, actions or inactions?
- c) The addition of the requirement in paragraph 22E(b)(i) of Agenda Item 4-A that addresses considering whether and how the factors could affect the achievement of the quality objectives?
- d) The revisions to the definition of quality risks in paragraph 19(q) of Agenda Item 4-A to directly include likelihood and magnitude?

Question 2:

Is the IAASB of the view that the changes to the firm's risk assessment process are responsive to the Board comments in December 2019?

Monitoring and Remediation Process: Feedback

- CAG
 - Supportive of direction
 - Definition of deficiencies - threshold for deficiencies needs to be clearer
 - Difference between findings and deficiencies not clear – suggest further guidance (e.g., flowchart)
 - Various suggestions on paragraphs 44 and 45 - more explicit reference to monitoring the monitoring activities, remove reference to ongoing and periodic monitoring activities, and reconsider relationship between paragraphs 44 and 45
 - Support for retaining reference to 3-year cycle for inspection of completed engagements
 - Individuals assigned operational responsibility for monitoring should be required to be objective
- IOSCO
 - Focused on root cause and ensuring that firms take into consideration information from a variety of sources, including IFIAR inspection results and information from other regulators
- SMPC
 - Monitoring and remediation – acknowledged that it is robust but questioned scalability for smaller firms
 - Guidance on what a root cause analysis is will be important

Monitoring and Remediation Process: Key Offline Comments

- Various comments on the definition of deficiencies and related application material
- Feedback on definition of findings – somewhat opposing so direction needed from IAASB
- Various comments on paragraph 44, in particular multiple comments regarding reference to “prevent or detect deficiencies”
- Feedback on paragraph 45 to clarify relationship between paragraph 44 and 45
- Multiple comments on paragraph A169A regarding last bullet, i.e., appropriateness of deferring the selection of the engagement partner for inspection of completed engagement
- Ad-hoc comments on paragraph 48 – perceived circularity of the requirement and clarifying purpose of evaluating severity/pervasiveness of deficiencies
- Ad-hoc comments on paragraphs 52-54 – a question about duplication with information and communication component and suggestion for further requirements for how leadership should use information communicated

Monitoring and Remediation Process

Question 3:

Does the IAASB support the proposed revisions to the definitions related to monitoring and remediation, in particular:

- a) The revised application material supporting the definition of deficiencies to clarify the meaning of “aspect” in the definition (paragraphs 19(a) and A9A–A10A of Agenda Item 4-A)?
- b) The revisions to the definition of findings (paragraph 19(gA) of Agenda Item 4-A)?

Question 4:

Does the IAASB support the approach to addressing the inspection of completed engagements (paragraphs 45 and A168–A170 of Agenda Item 4-A)?

Question 5:

Is the IAASB of the view that the remaining changes to monitoring and remediation are responsive to the Board comments in December 2019?

Evaluation of SOQM: Key Offline Comments

- CAG Feedback
 - Supportive of proposals
 - Suggestion to add explanation from issues paper (paragraph 27 of Agenda Item 4) in introduction of the standard to promote proactivity in identifying deficiencies
- Key offline comments – appears to be support overall
 - 65A and 65C – multiple comments about who is responsible
 - Large firms – those with ultimate responsibility will depend on others to do the evaluation
 - Is it the right person – e.g., in paragraph 65C they might no longer in in office if there is a negative conclusion
 - A210A - multiple comments - deficiencies remediated versus actively being remediated is confusing

Evaluation of SOQM

Question 6:

Does the IAASB support the proposals addressing the evaluation of the SOQM, in particular:

- a) The introduction of a two-part approach, i.e., leadership's evaluation of the SOQM and subsequent conclusion on the SOQM?
- b) The considerations supporting leadership's conclusion on the SOQM, including the concepts explaining severity and pervasiveness?

Question 7:

Does the IAASB support the remaining changes to the evaluation of the SOQM?

Introduction and Objective

- Key offline comments
 - Appears to be general support overall
 - Paragraph 7 and 8A – retain link to objective of the standard, but make paragraphs more concise

Question 8:

Does the IAASB support how proposed ISQM 1 addresses the firm's role in serving the public interest, including the enhancements to paragraph 7 of Agenda Item 4-A to bring greater prominence to it?

Question 9:

Does the IAASB agree with the view of the ISQM 1 TF that the objective of proposed ISQM 1 remains appropriate?

Question 10:

Does the IAASB support the remaining changes to the introduction of the standard?

Introduction – Public Interest: Suggested Change

7. The public interest is served by the consistent performance of quality engagements. The design, implementation and operation of the system of quality management supports the consistent performance of quality engagements by providing the firm with reasonable assurance that the objectives of the system of quality management, stated in paragraph 18(a) and (b), are achieved. Quality engagements are achieved through planning and performing engagements and reporting on them in accordance with professional standards and applicable legal and regulatory requirements. References in this ISQM to supporting the design, implementation and operation of the system of quality management include supporting the performance of engagements. ~~Achieving the objectives of those standards and complying with the requirements of applicable law or regulation involves exercising professional judgment and, when applicable to the type of engagement, exercising professional skepticism.~~ (Ref: Para. A2)
- ~~8A. The system of quality management supports the consistent performance of quality engagements by providing the firm with reasonable assurance that the objectives of the system of quality management, stated in paragraph 18(a) and (b), are achieved . Since the system of quality management supports the consistent performance of quality engagements, in this ISQM, references to the design, implementation and operation of the system of quality management include supporting the performance of engagements. (Ref: Para. A3)~~

System of Quality Management

- Key offline comments – general support, with ad-hoc comments related to
 - The knowledge, experience and time of the individual(s) assigned ultimate responsibility for the SOQM
 - The relationship between quality management and strategy, operations and business processes
 - Geography of requirements dealing with leadership roles and responsibilities

Question 11:

Does the IAASB agree that proposed ISQM 1 addresses the relationship between quality management and strategy, operations and business processes, and that further requirements addressing how the firm designs its operational processes may be too prescriptive, in particular given the efforts to reduce the prescriptiveness of the standard?

Question 12:

Does the IAASB support the proposed revisions addressing the knowledge, experience and time of the individual(s) assigned ultimate responsibility for the SOQM?

Governance and Leadership

- Key offline comments – general support with multiple comments on paragraph 23(a) – too aspirational and not measurable (also affects references to “commit to quality” throughout standard)

Question 13:

Is the IAASB of the view that the changes to governance and leadership are responsive to the Board comments in December 2019?

Relevant Ethical Requirements

- Key offline comments: Multiple comments on paragraph 32(a) regarding complexity and relevance of requirements to “others”

Question 14:

Does the IAASB agree that only explicit assignment of operational responsibility for compliance with independence requirements to a specified individual should be required?

Question 15:

Does the IAASB support the proposed changes to the relevant ethical requirements component, including the definition and related application material, in particular to clarify the scope of relevant ethical requirements for the firm’s SOQM?

Acceptance and Continuance

- Key offline comments: Appears to be general support with a specific comment regarding access to information

Question 16:

Does the IAASB support the proposed changes to the acceptance and continuance component?

Engagement Performance

- Key offline comments: Appears to be general support with a few specific comments regarding drafting (length of certain quality objectives)

Question 17:

Does the IAASB support the proposed changes to the engagement performance component?

Resources

- Key offline comments: Appears to be general support with comments focused on how service providers have been addressed

Question 18:

With respect to service providers:

- a) Does the IAASB support relocating the previous requirements for service providers to resources?
- b) Does the IAASB support how the scope of service providers has been addressed and clarified?
- c) Does the IAASB agree with the more risk-based approach for service providers (i.e., through the inclusion of a quality objective in the resources component)?

Question 19:

Does the IAASB support the proposals in paragraph A125 of **Agenda Item 4-A** to address the scoping of technological resources?

Question 20:

Does the IAASB support other proposed changes to the resources component?

Information and Communication: CAG Feedback

- Differing views overall
 - Supportive of the proposed approach
 - Varying practices globally and inconsistency in approaches – Europe further ahead than other jurisdictions
 - Not the role of the IAASB to address transparency reporting – could stifle further innovation
 - Not core to ISQM 1 – could inadvertently distract and derail the ISQM 1 project overall
 - More rigorous requirements needed
 - Important to investors
 - Holds auditors accountable – incentive for a more effective SOQM
 - Need for a framework or requirements that indicate the content of transparency reports
 - The form of communication not important; rather focus on what information should be communicated

Information and Communication

- Key offline comments
 - Mixed views on approach to transparency reporting
 - Otherwise, appears to be general support, with a few specific suggestions

Question 21:

Does the IAASB support the Task Force's views that the requirement addressing communication externally should be principles-based to encourage proactive and timely communication, and therefore the reference to transparency reports should be in application material?

Question 22:

Does the IAASB support the other proposed changes to the information and communication component?

Information and Communication: Suggested Revision to Quality Objective

- ~~40(c)(iv) Information is communicated by the firm to external parties when required by law, regulation or professional standards, or when the firm determines appropriate to support external parties' understanding of the system of quality management, including the quality of the engagements performed by the firm. (Ref: Para. A142–A153)~~
- 40(d) The firm is transparent and timely in communicating externally about how the firm manages quality to support external parties' understanding of the system of quality management.

Specified Responses

- Key offline comments: Concerns about location of requirements – disconnected from components / related quality objectives

Question 23:

Does the IAASB support the location of specified responses in a separate section, and how it has been linked to the firm's risk assessment process?

Networks: Feedback from Outreach with MG Members

- Feedback undertaken with IOSCO / Basel / IAIS
- Networks play important role – able to “objectively” look at the firm, create mechanism for sharing best practice and have ability to “command and control”
- Key concern is consistency across networks, and monitoring and external inspection of network requirements and network services
 - Encouraged IAASB to engage with IFIAR regarding external inspections – either collectively at network level or at firm level
 - Suggested that level of supplementation of the network requirements and network services by firms may indicate a need for a network to do more to drive consistency
- Supportive of changes made since ED (with reference to December 2019 draft of proposed ISQM 1)
 - Questioned consequences if the network requirements and network services is not monitored by the network

Networks: CAG Feedback

- If network firms adapting / supplementing network requirements or network services, may indicate a need for the network requirements or network services to be updated (similar comment as MG members)
- Varying comments on proposals to address network requirements and network services:
 - One member indicated not enough had been done on networks to address inconsistency of quality
 - Other member supportive of the progress and indicated approach will appropriately address issues – particularly support focus on firm and firm retaining responsibility for SOQM

Networks

- Key offline comments: Appears to be general support – very few comments overall

Question 24:

Is the IAASB of the view that the changes to network requirements and network services are responsive to the Board comments in December 2019?

Question 25:

Does the IAASB support the other proposed changes to networks?

Question 26:

During the plenary, the IAASB will be asked to share views on the feedback from the remaining outreach activities (feedback from the ISQM 1 TF Chair to be provided during the plenary session).

Documentation

- Key offline comments
 - Appears to be general support, with a few specific suggestions
 - Paragraph A214 – opposing views – Board direction needed

Question 27: Documentation

Does the IAASB support the proposed revisions to documentation?

Effective Date: CAG Feedback

- Concern about providing firms enough time for implementation
- Support for proposed description of effective date – further suggestion to more explicitly state that within one year from the effective date, the firm is required to evaluate the SOQM
- Questions about meaning of effective date – i.e., is firm expected to monitor and evaluate the SOQM by the effective date?
- Questions about practical implications of the effective date

Other Matters

Question 28: Meaning of Effective Date

Does the IAASB agree with the ISQM 1 TF's approach to the meaning of the effective date, including the proposed description of the effective date in paragraph 17 of **Agenda Item 4-A**?

Other Matters

Question 29: Title Change to “ISQM”

Does the IAASB agree with retaining the title change to the standard, i.e., the use of “ISQM”?



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