Quality Management Systems

Advice from ISO/TC 176 for Sector-specific applications
ISO Technical Committee 176

- ISO/TC 176 Scope:
  - Standardization in the field of quality management, including generic quality management systems (QMS)
  - Supporting technologies, and related standardization in specific sectors if requested by the ISO Technical Management Board.
  - An advisory function with all ISO and IEC technical committees to ensure effective implementation of the ISO/IEC sector policy
ISO/TC 176’s Scope & QMS Standards

- ISO/TC 176 produces a number of QMS standards that are well recognized around the globe.
- These include:
  - ISO 9000:2005
  - ISO 9001:2000
  - ISO 9004:2000
ISO/TC 176 Mission

- Identify and understand the needs of society and of standards users in the field of quality management,
- Develop, support and improve **generic QMS standards** that respond to identified needs,
- Safeguard the integrity of its standards in their use including conformity assessment activities,
- **Minimize proliferation of quality management system (QMS) standards** and
- Contribute to the compatibility of management system standards (MSS).
ISO/TC 176 Vision

ISO/TC 176

- Be recognized for providing valuable contributions on issues related to management systems including:
  - standards,
  - conformity assessment,
  - the developing concept of quality,
  - the impact of technology, and
  - business excellence models,
ISO/TC 176 Vision
(continued)

- Continue to offer QMS standards suitable for improving the performance of an organization and enhancing satisfaction of interested parties,

- Be the recognized advisory body when a sector-specific application of generic QMS standards is considered.
Why might Sector-Specific Standards be needed?

- Some reasons
  - Sector-specific terminology
  - More prescriptive requirements and controls
  - Explanation/expansion of generic requirements
  - Sector-specific regulatory requirements, and/or codes of good practice
To get started a sector should carry out an assessment of its NEEDS:

- Regulatory requirements for management? (e.g. safety)
- Sector-specific terminology?
- Need for more prescriptive requirements?
- Sector best management practice? (e.g. a published Code of Practice)
Consider also possible consequences:

- Effect on suppliers and partners, new/different QMS requirements?
- Sector-specific certification and accreditation?
- Specific personnel training and qualification? (e.g. auditors)
- Need for Relations with ISO/CASCO and IAF (International Accreditation Forum)
Only begin development of a sector-specific QMS standard if it’s absolutely necessary
Key Objectives of the ISO/IEC Sector Policy

- Maximize the use of Generic QMS International Standards
- Support international trade & remove trade barriers
- Support developing countries
“In case a sector-specific development of ISO 9001/9004 is necessary, the rules of the ISO/IEC Directives Part 2, paragraph 6.8.2 “Sector Policy” must be applied.”

“All questions concerning the sector policy or interpretations of ISO 9000/9001/9004 standards should be addressed to the ISO/TC 176”
The instructions and criteria, as laid down in ISO/TC 176 N845 “Quality management systems - Guidance and criteria for the development of documents to meet needs of specific product and industry/economic sectors”, issued by ISO/TC 176, should be taken into account for determination of necessity for any sector-specific document as well as the development of such documents
ISO/IEC Directives on Sector Policy (3)

- Rules to be respected for the development of sector-specific documents:
  - Terms and definitions specified in ISO 9000:2005 must be referred to in a normative manner
  - Normative reference must be made to ISO 9001:2000 in its entirety or, subject to the ‘applicability’ provisions detailed in the scope of ISO 9001:2000, to its clauses or sub-clauses
ISO/IEC Directives on Sector Policy (4)

- Rules to be respected for the development of sector-specific documents:
  - If text from ISO 9001:2000 is reproduced it must be clearly distinguishable from the sector-specific wording
  - Text from ISO 9001:2000 must be reproduced verbatim (any add-on, amendment, deletion or interpretation of the requirements laid down in ISO 9001 is not permitted)
  - Sector-specific requirements may be added.
ISO/IEC Sector Policy - ISO/TC 176 Guidance and Criteria

- Applicable to ISO/IEC committees and outside organisations
- Establish the need (for sector document)
- Develop the document
- Liaise with ISO/TC 176
- Comply with ISO Guide 72

Ref: ISO/TC 176 N845
ISO Guide 72
Management System Standards (MSS)

- Applicable to all types of MSS, Including Sector applications of generic MSS
- New ISO work requires justification – criteria similar to ISO/TC 176 guidance
- Independent justification study required
- Development process and document structure model
- Establish liaison arrangements with stakeholders
ISO/TC 176 Support to Sectors

- ISO/TC 176 offers direct assistance to organisations thinking about preparing sector-specific documents to:
  - examine applicability of ISO 9001 to sector needs *(Consider establishing Liaison status)*
  - examine justification for sector-specific document *(Formal Liaison application recommended)*
  - participate in the development of justified sector-specific standards *(Formal Liaison status required)*
Technical Support from ISO/TC 176

- Process to provide technical support to sectors for document development.
  - Support / guidance to establish the need for sector-specific QMS document
  - Support in the development of sector-specific QMS document
  - Support to review sector-specific QMS document for compliance with ISO protocol
  - Production of sector-specific QMS document by ISO TC 176 when requested by ISO/TMB
Technical Support from ISO/TC 176

- Upon request, ISO/TC 176 will nominate a contact and expert personnel to work with the sector organization to
  
  ✓ Assess sector needs
  ✓ Advise on the direction on the scope of the project and support to be provided by ISO/TC 176
Document Development and Liaisons

- Justify need for new work – see also ISO Guide 72 (ISO/IEC committees)
- Ensure adequate representation of main stakeholders
- Consider Ownership of “intellectual property” (ISO / non ISO sector organisations)
Cautionary Note:
A sector document which detracts from or dilutes the generic standards shall state that the user of the document must not claim conformity with ISO 9001
ISO and ISO/TC 176
Reference QMS Documents

- ISO/IEC Sector Policy
- ISO Guide 72
- ISO family of QMS Standards (9000, 9001, 9004,...)
Conclusions (1)

- Use ISO/TC 176 generic QMS standards to the maximum extent possible
- ISO/TC176 aims to reduce proliferation of sector-specific QMS standards
- ISO/TC 176 will work with sectors to harmonise sector-specific applications of ISO 9001:2000

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Conclusions (2)

- Sector-specific documents should be prepared only when justified.

- ISO/IEC Sector Policy and ISO Guide 72 is applied.

- ISO/TC 176 provides guidance (ref. N845) and assistance with sector-specific standards.
For Further Information ...

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