

# Quality Management Systems

Advice from ISO/TC 176 for  
Sector-specific applications

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# Contents

- ❑ ISO/TC 176 Scope & QMS standards
- ❑ ISO Sector-Specific Policies & Directives
- ❑ ISO Guidance Documents for Sector-Specific QMS Documents
- ❑ Assessment of Sector-Specific Needs
- ❑ Technical Support from ISO/TC 176
- ❑ Conclusion



# 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



# Sector QMS Standards (1)

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)

# Sector QMS Standards (2)

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

# ISO/IEC Directives on Sector Policy <sup>(1)</sup>

- ❑ *“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”*



# ISO/IEC Directives on Sector Policy (2)

- *“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 <sup>(3)</sup>

- 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 <sup>(4)</sup>

- 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/TC176 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)

# Document Development

## 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/TC 176 N845 “Guidance & Criteria for the Development of Documents to meet the needs of Specific Product and Industry / Economic Sectors”
- ❑ 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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