

The future ISO 9001 Sistemas de gestión de la calidad - Requisitos

Información sobre los primeros pasos del
proceso de revisión de la futura norma ISO
9001:20XX

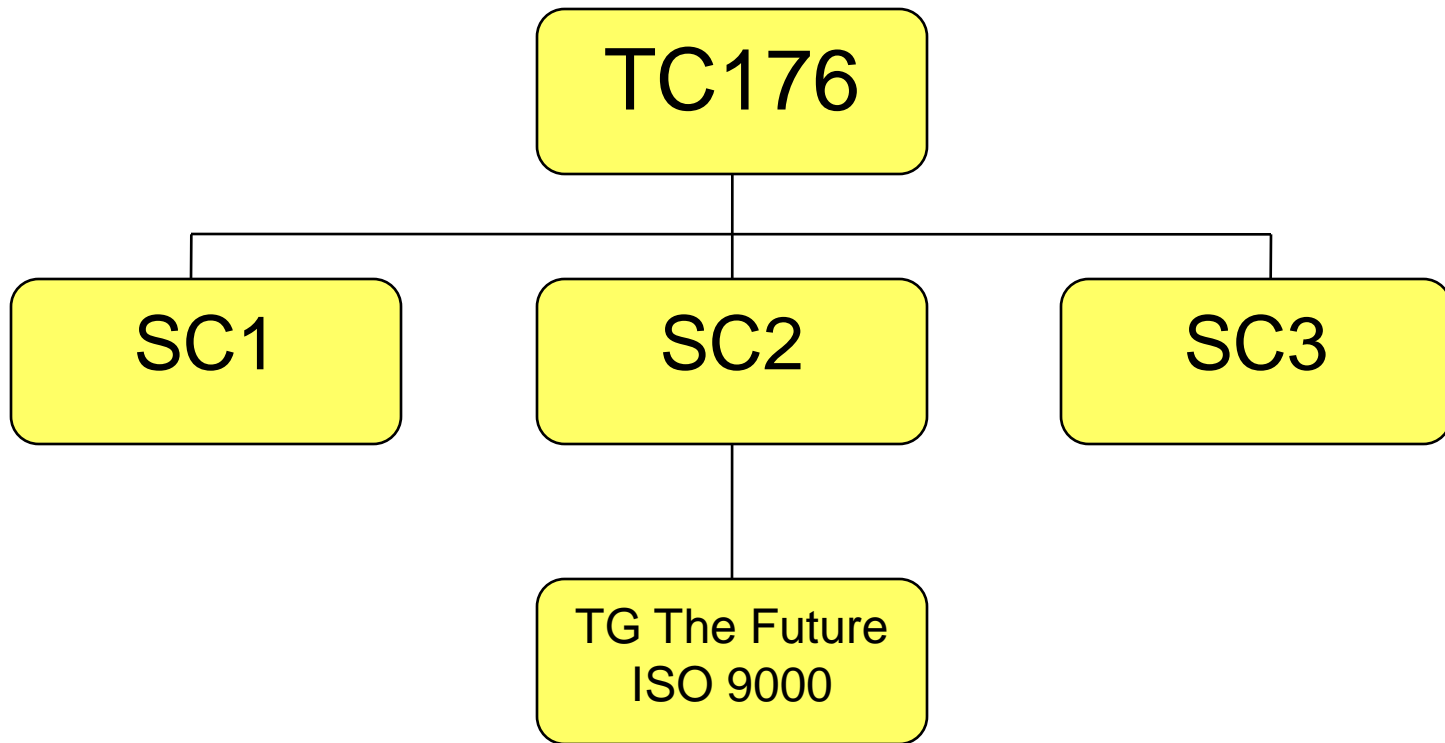
COHCIT
Tegucigalpa– Honduras
Agosto 2009

Responsable de la familia ISO 9000:

- ✓ desarrollo de normas genericas en los campos del aseguramiento de la calidad y la gestión de la calidad; y
- ✓ órgano de consulta para otras normas ISO

- 58 “P” miembros
- 20 “O” miembros
- 19 vínculos con otros comités técnicos
- 22 vínculos con organizaciones internacionales

TC176 - Estructura

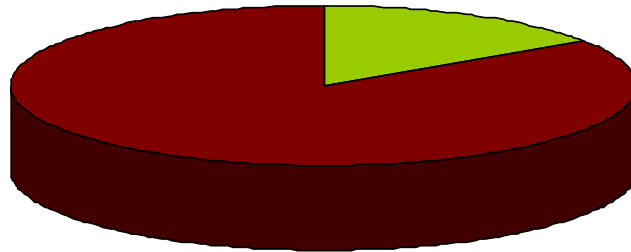


Participacion países habla hispana

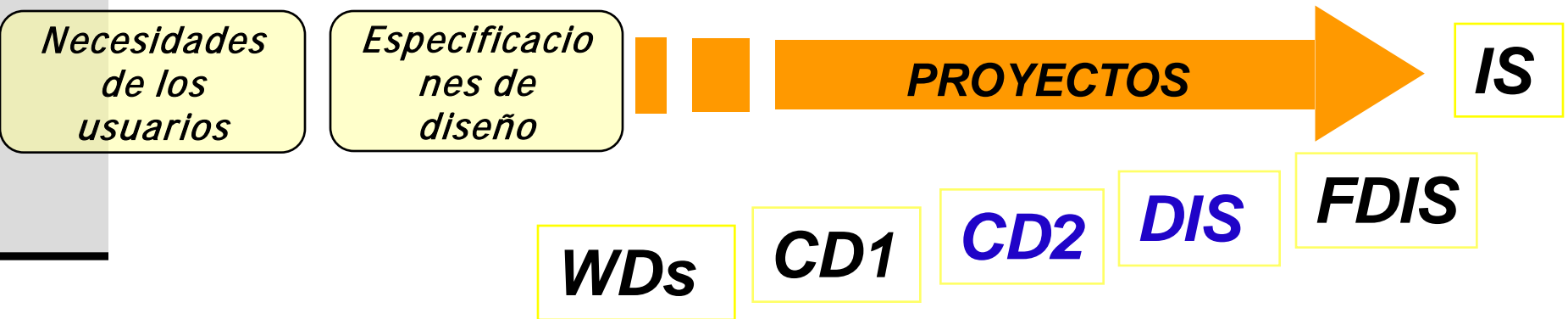
**Países hispano
parlantes**

16 %

**En
TC 176**



Proceso para el desarrollo de normas ISO





The Future ISO 9001



ISO 9001: 201X

Integration of risk management

Concept Number	Team 1-01
Concept Title	Integration of risk management
Description	<p>Whilst risk is addressed in many clauses of ISO 9001 it is not explicit. Some users do not recognise the elements of risk management that are already included. There is a need to address the topic of risk explicitly and decide whether this is in relation to risk with product, market, organization, quality management system, compliance, business continuity, supply chain management, resources and infrastructure.</p> <p>The concept for further development might include the following elements:</p> <ul style="list-style-type: none">• Applicability of risk management within the agreed scope and field of application of ISO 9001;• Flexibility and level of application depending on the needs of the organization;• The extent of control that is required for risk management activities.
Additional Notes	International standards for risk management already exist (, ISO 17766, ISO 14971, ISO/IEC Guide). 25999-1(Business Continuity) 2-01

Enhanced focus on product conformance

Concept Number	Team 1-02
Concept Title	Enhanced focus on product conformance
Description	<p>There is an ongoing concern that there are organizations that comply with ISO 9001 but are perceived as not producing a 'quality' product. There needs to be a greater emphasis on product conformance, reliability and the outputs of all processes including the design and development process. While these aspects are addressed there is little specificity, with considerable freedom for application by the organization.</p> <p>The concept for further development might include the following elements:</p> <ul style="list-style-type: none">• Balance between control of processes and outputs of processes;• How processes are validated;• How products are measured;• What measures are in place to establish success of the organization and the quality of products;• Need for product-specific requirements;• Linkage to requirements for process management;• The requirements within the standard and the practices of certification bodies;• Identify the needs and expectation of the customer.• Clarity of requirement definition from customer.• Balance of degree of prescription within the standard and flexibility of its application;• Application of design and development process to manufacturing processes as well as tangible products.
Additional Notes	N789-1 – Output matters document APG Paper – Output matters

Financial resource of the organization

Concept Number	Team 1-03
Concept Title	Financial resources of the organization
Description	<p>Finance resources and financial information are important requirements for an organization but the subject is not addressed in ISO 9001.</p> <p>The concept for further development might include the following elements:</p> <ul style="list-style-type: none">• Financial controls, management of financial resources within the Management System;• Interaction with the quality of output;• Reluctance in regulated industry to have financial systems assessed;• Links with strategic planning and top management responsibility;• Availability of financial data internally;• Need for appropriate confidentiality;• Need for financial data to be available for measurement and analysis of organizational performance.
Additional Notes	

Maintenance of infrastructure

Concept Number	Team 1-04
Concept Title	Maintenance of infrastructure
Description	<p>ISO 9001 refers to 'maintaining the infrastructure' (clause 6.3) and the word 'maintain' is used in different contexts within the standard (e.g. in terms of 'maintaining records'). The term 'maintenance' is not used but the concept of maintenance is important in relation to product quality.</p> <p>The concept for further development might include the following elements:</p> <ul style="list-style-type: none">• Aspects that might be subject to maintenance requirements<ul style="list-style-type: none">○ Physical processing equipment;○ Buildings;○ Utilities;○ IT equipment.• Flexibility of maintenance requirements for different industries based on the nature of their activities<ul style="list-style-type: none">○ Preventive maintenance○ Predictive maintenance○ Repairs• Definitions• Considerations of maintenance for other product types (e.g. service)
Additional Notes	<p>Link with specifically to cover this issue. They have the primary standard IEC 60300-1 Dependability management. See: http://tc56.iec.ch/index-tc56.html</p> <p>ISO TS 16949 ISO 27001 ISO 2000</p>

Alignment with business management practice

Concept Number	Team 1-05
Concept Title	Alignment with business management/practice
Description	<p>Business leaders do not understand the vocabulary and structure of ISO 9001. Examine the possibility of restructuring the standard to better reflect the way that businesses operate.</p> <p>The concept for further development might include the following elements:</p> <ul style="list-style-type: none">○ Redesign of the process model○ Linkage to MSS and overall structure○ Simplify the wording (business vocabulary)○ Business Management vs Quality Management○ Activities that are undertaken solely to comply with the standard○ Systemic approach (coherence principles)○ Business planning/reporting/reviewing approaches
Additional Notes	<p>Inter-related with concept of MSS-QMS and standard structure.</p> <p>Quality Management Principles.</p> <p>JTCG high level structure</p> <p>Guide 72</p> <p>See team 4</p>

Process management

Concept Number	Team 2-01
Concept Title	Process Management
Description	<p>ISO 9001:2008 claims to introduce requirements for a process based quality management system {see Fig.1}, however the concept of "Process Management" is not properly addressed yet.</p> <p>Therefore, the introduction of a sound concept of Process Management which includes the following is necessary:</p> <ul style="list-style-type: none"> • a generic operational process model, including, resources, infra, • concept of organization specific process framework including levels down to procedure level • concept of roles (Process ownership) & responsibilities of people involved, • concept of process supplier, • concept of process customer, • concept of process control <p>(includes control of KPIs, e.g. reliability) – carry over from 2-03 process improvement (includes ensuring reliability) – carry over from 2-03</p> <p>The introduction of this concept will increase the applicability of the standard for all kinds of organizations</p>
Additional Notes	<p>Note 1: Impact of IT supporting process management should be considered. (4-03)</p> <p>Note 2: Process effectiveness and efficiency are covered. However mandatory requirements are not predetermined.</p> <p>Note 3: The concept for Process Management could be included in ISO 9000.</p> <p>Note 4: This Top Concept obviously has a major impact on Top Concept "Structure of the Standard" (4-01)</p> <p>Note 5: ISO supporting document "Process approach"</p> <p>Note 6: Refer to document by AFNOR or other related documents</p>

Knowledge management

Concept Number	Team 2-02
Concept Title	Knowledge management
Description	Whilst the inclusion of Knowledge Management concept could have some overlap with the content of ISO 9004; additional research into the concept and the application within the context of ISO 9001 should be considered including definition of the concept. This work should be done in consultation with the development of the concept with ISO 9004
Additional Notes	Note 1: Refer to ISO 9004: 20XX, para 6.7, where this concept is described. Note 2: The concept of Knowledge Management can be useful for working on Top concept "Structure of standard" rather than to include in the standard.

Results/Improvement/Effectiveness

Concept Number	Team 2-03
Concept Title	Results/Improvement/Effectiveness
Description	This concept was considered to be a sub-element of the Process Management concept (2-01) and will not be investigated as a separate activity.
Additional Notes	Note 1: Refer to "Team 2-01 - Process Management" where all these issues are included Note 2: <u>Standardized KPIs</u> may be in contradiction to the intent of the standard, i.e. requirements WHAT the organization has to do, not HOW Note 3: Topic "Finance" is addressed by Concept 1-03

Life cycle management

Concept Number	Team 2-04
Concept Title	Life cycle management (LCM)
Description	<p>ISO 9001:2008 already addresses the issue of life cycle management such as “before service”, “after sales”, “disposal” etc. without explicitly using the term “LCM”. It could be considered to introduce the concept of LCM which would include:</p> <ol style="list-style-type: none"> 1. determination of the scope (e.g. product, process, equipment, technologies, IP, human resources and the organisation itself) 2. restructuring of the QMS standard.
Additional Notes	<p>Note: “Reliability” is covered as a topic within LCM</p> <p>Note:</p> <p>the 7 standards listed in the DIS 9004 bibliography:</p> <p>[15] ISO 14001:2004, Environmental management systems – Requirements with guidance for use</p> <p>[16] ISO 14040:2006, Environmental management – Life cycle assessment – Principles and framework</p> <p>[17] ISO 14044:2006, Environmental management – Life cycle assessment – Requirements and guidelines</p> <p>[18] ISO/TR 14047:2003, Environmental management – Life cycle impact assessment – Examples of application of ISO 140421)</p> <p>[19] ISO/TS 14048:2002, Environmental management – Life cycle assessment – Data documentation format</p> <p>[20] ISO/TR 14049:2000, Environmental management – Life cycle assessment – Examples of application of ISO 14041 to goal and scope definition and inventory analysis1)</p> <p>[21] ISO/TR 14062:2002, Environmental management – Integrating environmental aspects into product design and development</p> <p>Footnote:</p> <p>1) ISO 14041:2000 and ISO 14042:2000 have been superseded jointly by ISO 14040:2006 and ISO 14047:2006</p>

QM-Principles/Leadership

Concept Number	Team 2-05
Concept Title	QM – Principles (QMP) / Leadership
Description	<p>ISO 9001:2008 already makes reference in 0.1 last para that QMPs were taken into consideration (i.e. for the design of the standard).</p> <ul style="list-style-type: none">• Keep going to do so, no limitation• Refer to SC3• Consider link to TC 176 SC1 (ISO9000 revision)• Consider Work Item 10018 (preparatory report) from TC 176 SC3• Refer to result of Tokyo Workshop <p>As there is considerable work under way with SC1, the recommendation is not to move forward with this as a separate line of investigation as a concept by this TG. However, this TG will closely follow the activities to understand the development of the concepts.</p>
Additional Notes	<p>Note:</p> <ol style="list-style-type: none">1. QMPs are defined in ISO 9000, chapter 2 and comprehensively addressed in ISO 9004: 20xx2. Leadership is one of the QMPs and it is one of the top management characteristics3. Link to 4-01

Competence

Concept Number	Team 3 – 01
Concept Title	Competence
Description	<p>What are the implications of the concept of competence on our QMS standard and what are the impacts of future technologies, organizational structures, work environments, and business models? The concept for further development may include the following elements for investigation and understanding;</p> <ul style="list-style-type: none">•Effectiveness•Evaluation, measure, and monitoring•Competence vs. training vs. qualification•Balance of aspects of competence in evaluation•Individual or collective competence•Application (scope) of competence•Empowerment and motivation
Additional Notes	<ul style="list-style-type: none">- The current standard does address this topic to some level, this would be an expansion on current revision- ISO 9000:2005 Demonstrated ability to apply knowledge and skills <p>Current literature:</p> <ul style="list-style-type: none">- French standard- Swedish standard

Supply Chain Management/Outsourcing

Concept Number	Team 3-02
Concept Title	Supply Chain Management (and Outsourcing)
Description	<p>Evaluate the effect of Supply chain management (and Outsourcing) on the QMS and identify the limits of the responsibilities to manage efficiency and results.</p> <p>The concept for further development may include the following elements for investigation and understanding:</p> <ul style="list-style-type: none"> •Clarify differences/similarities between supply chain management and outsourcing •Identify qualification level of suppliers •Decide which process/-es are outsourced? •Determine why the organization chooses to outsource •Responsibilities (output/management and process/ops) •Determine boundaries of organization s QMS •Evaluation, measure, and monitoring (Supplier control) •Audit perspective (internal/external): Audit as tool to control supplier •Communication lines between “supplier & customer” •Clarify how Supply chain management can support the “process approach” perspective for the end users of ISO 9001. (Integrated or separate chapter).
Additional Notes	<p>Current literature & tools:</p> <ul style="list-style-type: none"> •Prince II – British tool of project management •CMM – I.T. model: Capability Maturity Model (chapter “Sub-contract management”) •CD/ISO 26000 – “Social Responsibility” chapter about Supply Chain and responsibility <p>Linkage to Process Management (Team 2-01)</p>

Quality tools

Concept Number	Team 3-03
Concept Title	Quality Tools
Description	<p>Evaluate which tools are relevant and suit the QMS and the effect they will have on the QMS, including planning, competence and responsibilities.</p> <p>The concept for further development may include the following elements for investigation and understanding:</p> <ul style="list-style-type: none"> • Identify which tools are complementary to ISO 9001 • Selection and use of relevant tools • Consider competence and management involvement • Identify suppliers/users of Quality Tools (and competence/qualification – e.g. formal levels/degrees of competence) • Audit perspective (are the tools being used, and if so, are they used correctly with efficiency and leading to results) • Consider relevant benchmarking and best practices and use relevant KPIs • Consider tools in other (management system) standards • Consider tools selection and use
Additional Notes	<p>Current literature & tools:</p> <ul style="list-style-type: none"> • Six Sigma (model?) • Lean (model?) • ISO 10014 – Guidelines for realizing financial and economic benefits • ISO/TC 176/SC2/N613R1 – Selection and Use Brochure (of selected standards in the ISO 10000-series). See figure in page 5. • Score Cards • SWOT management (analysis AND results perspective) <p>There is no current reference to Quality Tools in 9000:2005</p> <p>Reference linkage to Process Management (Team 2-01) and QMS Structure (Team 4-01) to Competence (Team 3-01)</p>

Communication

Concept Number	Team 3-04
Concept Title	Communication
Description	<p>Internal and external exchange of information with interested parties</p> <p>The concept for further development may include the following elements for investigation and understanding:</p> <ul style="list-style-type: none"> • Identify and follow up the objective of the communication, is it just information exchange or ...?) • Investigate the possibility to develop a criteria for a communication plan and procedures • Communication understandable (smart) for the recipient • Communication veracious and verifiable • Multidirectional (personnel vs. board (directive) and organization vs. interested parts, personnel vs personnel). • Presented of consistent and regular form (periodicity, the same format) expressed(emitted) • Across appropriate channels (bulletins, press, e-mails, etc. • To promote already existing channels for internal communication: planks, internal bulletins... • To include guidelines for extraordinary communications (disaster, emergency recovery...) • To take advantage of the possibilities that IT offers for the external communication • Consider the level of the urgency of the information. • Consider the confidentiality and accessibility of the information
Additional Notes	<p>Current literature & tools:</p> <ul style="list-style-type: none"> • ISO 14001 – Environmental Management - Requirement • ISO 14063 - Environmental Management - Environmental Communication Guidelines and examples. • ISO 22000 – Food Safety Management Systems • CD ISO 26000 – Guideline Social Responsibilities <p>Reference linkage to Technology topic (Team 4-03) and link to Process Management (Team 2-01) See ISO /DIS 9004:2009, p. 5.5:</p> <p>Truthful, sincere and ongoing communication of an organization's strategy, policies and plans to people in the organization and to all other interested parties is a necessary condition for sustained success. An effective communication process operates both vertically and horizontally and is tailored in both content and language to the differing needs of recipients, i.e., the same information is likely to be conveyed differently (and often using a different medium) to people within the organization than it would to customers or partners. Communication is of such importance to achieving and sustaining organization's success that the process should have a feedback mechanism, be subject to regular review and be capable of responding quickly to changed circumstances.</p>

Improvement & Innovation

Concept Number	Team 3-05
Concept Title	Improvement and innovation
Description	<p>Link between the existing in the standard improvement and innovation. The concept for further development may include the following elements for investigation and understanding:</p> <ul style="list-style-type: none"> •Define area and consider needs for improvement and innovation (not only technology) •Define the process to identify the most relevant innovation •Define criteria for innovation investment. •Define top management responsibilities. •Investigate what is the starting point for innovation (Organization, Market, Research or Technology?); identifying and managing customer requirements when there may not be a customer (externally) at the starting point •Identify the optimal working environment for innovation •Identify issues of innovation management
Additional Notes	<p>Current literature & tools:</p> <ul style="list-style-type: none"> •ISO/DIS 9004 Managing for the sustained success of an organization – A quality management approach •UNE 166001:2002 “Gestión de +D+I: Requisitos de un proyecto de I+D+I” (I+D+I Management: Requirements for a I+D+I project) •UNE 166002:2002 “Gestión de +D+I: Requisitos del Sistema de Gestión de +D+I” (I+D+I Management: Requirements for a I+D+I System Management) •CMM – I.T. model: Capability Maturity Model (chapter “Organizational Innovation and Deployment”) <p>See ISO 9004:2009, p. 9.1: Note "Improvement" relates to changes to existing factors (for example systems, organizational structures, processes, technologies, resources, competencies, and products), whereas "innovation" relates to new factors.</p> <p style="text-align: center;">An improvement activity where the current concept is still used after the improvement has been implemented can result in either a gradual change in the performance of a process, or a significant change (a significant change is often referred to as a "breakthrough" improvement).</p> <p style="text-align: center;">An innovation activity where the current concept is changed for a new one, would most often deliver a significant change in performance or functionality; however, in some cases, the change in performance could be limited in the initial stages of the innovation, with the expectation that there will be significant change in the later stages.</p>

Structure of QMS and Relations with MSS work

Concept Number	Team 4-01
Concept Title	Structure of QMS and Relationship with MSS Work
Description	<p>Review the considerations and implications to the structure of the QMS standard with regards to the following aspects;</p> <ul style="list-style-type: none">• The alignment or integration with other MSS• A model for multi-level structure that incorporates a demonstration of compliance at varying maturity levels of the QMS• The scope of the QMS standard depends on the concept and approach of Quality within the context of the organization (eg. conformity vs. implied needs, facets of quality, Quality Assurance, Quality Management, Organizational Quality)• The use of the standard in differing applications<ul style="list-style-type: none">○ Customer/supplier relationship○ Demonstration to society or external bodies○ For internal organizational use• Impacts of the outputs of the organizations processes on sustainability
Additional Notes	<ul style="list-style-type: none">• Refer to management system approaches from meeting in St. Gallen• Coordination with MSS• Relate to Template 5 from Team 1

Time Speed Agility and Related Aspects

Concept Number	Team 4-02
Concept Title	Time, Speed, Agility and Related Aspects
Description	<p>Review the implications of the concept of time, speed, and agility on our QMS standard and what are the impacts on organizational structures, work environments, and business models. This concept may include aspects related to;</p> <ul style="list-style-type: none">- The characteristics of the organization that allow it to be alert, flexible and adaptive to changes- The impact on effectiveness as well as efficiency- Time as an aspect of quality and a resource to be managed- The cycle time and synchronization of processes- Managed as an input to the Quality Planning process <p>There may be other aspects of quality that may be considered in this manner.</p>
Additional Notes	Output of the SC3/Ad Hoc group on Time, Speed and Agility

Impact of Technology and Changes in information management

Concept Number	Team 4-03
Concept Title	Impact of Technology and Changes in Information Management
Description	<p>Review the considerations of the changes in technology and information management on the drafting and application of the requirements of the QMS standard. The aspects for additional review include;</p> <ul style="list-style-type: none">- The application and demonstration of conformance to the requirements of the QMS standard (e.g. document and data control, communication, internal audit, management review, resource management, decision making, people competence, etc.)- Remote process controls and configuration management- Information security (confidentiality, integrity, disposal)- Outsourcing of information management or information technology- Interface with and between humans and the information systems and the related risks (eg. Interactive technologies and collaboration) <p>Note: Information management is not limited solely to computer based systems and should be managed as a resource.</p>
Additional Notes	Consider ISO/IEC 27001, ISO/IEC 20000, ISO 22301. Work of ISO/JTC1, including consultation and interaction with Information Technology Governance Models

Role of top management in the QMS


Concept Number	Team 4-04
Concept Title	Role of Top Management in the QMS
Description	<p>Review the considerations and implications on the current QMS standard to enhance the linkage and expectations of the relationship between the QMS, the role of top management, and the strategic planning process. The aspects include;</p> <ul style="list-style-type: none">- A definition of quality within the overall context of the organization- Design and relationship of the QMS within to context of the field of business, complexity of the organization, risks, opportunities, resources, competencies, etc.- Role of top management within in the QMS (with consideration of the size and complexity of the organization) driving the values to align the organization with respect to the QMS <p>This concept was considered by the full TG to have been fully covered within the context of the concept developed as, "Alignment with business management/practice" (Team 1-05). Therefore, this will not be considered by this TG as a separate concept for further development.</p>
Additional Notes	Consider merging with Team 1/05

Expanding the concept of customer

Concept Number	Team 4-05
Concept Title	Expanding the concept of Customer
Description	<p>Review the implications to the design and application of the QMS standards if the concept and use of the terms customer and supplier were expanded in scope related to internal and external. Determine how to apply the requirements of the QMS standard with an expanded definition. Consider the requirements for assessing conformity</p> <p>The aspects may include;</p> <ul style="list-style-type: none">- Internal customers as the “next step in the process”- Other entities or related companies within the same organization (eg. “brother or sister” sites, subsidiary, parent/child, division, etc.)- Consider also end users in the context of the QMS. <p>How are stakeholders of the organization determined and how do we determine their implied and changing needs?</p>
Additional Notes	<p>Consider related definitions in ISO 9000:2005</p> <p>Important to link this topic with Process Management topic (Team 2/01)</p>



Muchas Gracias



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