The next version of ISO 9001 – What to expect

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Seminar Outline

- Background
- Future strategic direction of the ISO 9000 standards
- Inputs into the next revision of ISO 9001
- The new “ISO Directives Annex SL” - the common structure and format for all future ISO management system standards
- Timeline for the revision process
ISO Mission

- ISO develops high quality voluntary International Standards which facilitate international exchange of goods and services, support sustainable and equitable economic growth, promote innovation and protect health, safety and the environment.
ISO Technical Committee TC 176

- “ISO” = International Organization for Standardization
  - Confederation of National Standards Bodies
  - Based in Geneva
- Standards development work is done by Technical Committees comprising experts nominated by their national standards body or liaison organization.
- “TC1” was the first Technical Committee (1948!!) for standardization of screw threads
- “TC 176” = Technical Committee Number 176 for Quality Management and Quality Assurance
  - “TC 176/SC 2” is the subcommittee responsible for ISO 9001 and ISO 9004 standards, among others
Overall Scenario of ISO/TC176

- Development of generic quality management system standards that have broad application:
  - all market sectors
  - both private and public organizations
- Over 1,000,000 worldwide certifications to ISO 9001

**BUT**

- It’s about more than just “certification”
  - “Certification to ISO 9001” should be a result of a well-implemented quality management system!
  - Other ISO/TC 176 products are aimed to assist organizations in improving their quality management system.
Quality Systems (ISO 9001, ISO 9004 & others)

Fundamentals & Vocabulary (ISO 9000)

Supporting technologies (ISO 100xx)

SC 1

SC 2

SC 3

ISO/TC 176

CALG

CSAG

Automotive TG

Spanish Trans TG

Arabic Trans TG

ISO

Sept 2012

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TC176/SC2 Mission

- To *develop, maintain and support a portfolio of products that enable organizations to improve their performance* and to benefit from the implementation of a robust quality management system.

- To *establish generic quality management system requirements* that provide the foundations to build confidence in goods and services delivered throughout the supply chain to organizations and people worldwide.

- To *provide guidance and support*, where needed, to ensure the continued credibility of our products.
TC176/SC2 Vision

“SC2’s products are recognized and respected worldwide, and used by organizations as an integral component of sustainable development”
What is a “management system”?

- Formal definition........
  “set of *interrelated or interacting elements* of an organization *to establish policies and objectives*, and *processes to achieve those objectives*”

- In other words:
  System should be **results focused**
  A “*documented system*” – **NOT a “system of documents”**
3 core concepts...........

- Identify the processes needed for the system
- Manage the processes and the system using “Plan-Do-Check-Act”
- Continually monitor the risks (“Cause and effect”)
Generic Process

How to carry out Process” – documented or not

INPUTS

“Set of interrelated activities”

• Effect on Product conformance
• Environmental Aspects / Impacts
• Health and Safety Risks
• Social implications
• Etc etc

MONITOR/MEASURE

P

DESIRED OUTPUTS

“PRODUCT”

CUSTOMER

(Internal or external)

UNDESIRED OUTPUTS

(“WASTE”)
The Global Challenges for Quality Management Systems

- Increased customer expectations for confidence in products and services
- Increasing use of QMS standards for global trade.
- Increasing use of ISO 9001 by various industry sectors
- Credibility of 3rd party certification.
- Drive for greater efficiency (lean initiatives)
- Increased sophistication of quality management tools.
- Increasing regulatory emphasis on public health and safety (e.g., food; medical devices);
- Multiple management systems standards, programs and schemes;
The future of ISO 9001...........

- Long-term strategic planning has been underway for 2 years within TC176/SC2
  - Recognition of the need for a major overhaul of ISO 9001
  - Needs to take us well into the “2020’s”!!
- ISO “Systematic review” (March 2012) has given approval to begin a major new revision to ISO 9001
- WG 24 established and began preliminary work on draft design specification (June 2012)
- Ballot on design specification closes Oct 1st 2012
- Work on drafting expected to begin Nov 2012
Positioning of ISO 9001 and ISO 9004

- **ISO 9001**
  - Focus on providing confidence in the organization’s PRODUCTS (Organizational improvement is a secondary objective)
  - Most probable “entry point” for many organizations
    - Needs to stimulate interest to “look BEYOND certification”

- **ISO 9004**
  - Focus on providing confidence in the ORGANIZATION
  - Should provide links to other management systems and methodologies

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Key objectives for “ISO 9001:2015”

- Draft design specification includes recommendations to:
  - Provide a stable core set of requirements for the next 10 years or more
  - *Maintain the current focus on effective process management to produce desired outcomes*
  - Take account of changes in quality management systems practices and technology since the last major revision in 2000
  - *Apply Annex SL of the ISO Directives to enhance compatibility and alignment with other ISO management system standards*
  - Facilitate effective organizational implementation and effective conformity assessment by first, second and third parties
  - *Use simplified language and writing styles to aid understanding and consistent interpretations of its requirements.*

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Key inputs into “ISO 9001:2015”

- TC176/SC2 Strategic Plan
  - Greater emphasis on organization’s ability to provide conforming products – “Output Matters!”
  - Greater clarity and simplicity of language for better implementation
- 12,000+ responses to online user survey
- Revision of the 8 Quality Management Principles
- Output from the “Future Concepts” Task Group
  - Includes suggestions that could not be incorporated in the 2008 revision
- Output from the ISO Joint Technical Coordination Group (now published in the ISO Directives)
Review of Quality Management Principles

- Joint SC1/SC2 Task Group
  - Led by Prof. Y. Iizuka (Japan – Deming prizewinner!)
  - High level “strategic thinkers”

- Aim is to review existing 8 QMP’s
  - Are they still relevant?
  - Any modifications needed?
  - Any new principles to be added?
    - Ethics?
    - Organizational agility?
    - Others?

- Draft recommendations currently circulating in SC1 & SC2 for comment
  - Only minor amendments being proposed
Some of the topics addressed by the “Future Concepts” Task Group*

- Integration of “risk based thinking”
- More emphasis on the Quality Management Principles
- Better alignment with business management processes
- “Output matters” (Product conformity and process effectiveness)
- Knowledge management
- Life cycle management (LCM)
- Improvement and innovation
- “Time/Speed/Agility”
- Technology and Changes in IT
- Incorporation of “Quality Tools” like 6σ, QFD, benchmarking etc

* NOTE: Not all of these concepts will necessarily be incorporated into ISO 9001:2015
Alignment of management system standards ("MSS")

- ISO 22000 (FSMS)
- ISO 9001 (QMS)
- ISO 14001 (EMS)
- ISO 50001 (Energy Management)
- ISO 13485 (Medical devices)
- ISO 27001 (ISMS)
- OHSAS 18001 (Health & Safety)
- ISO 20121 (Sustainable event management)
- ISO 30301 (Records management)
- ISO 39001 (Road safety management)
- ISO 22301 (Societal security)
- ISO 20121 (Sustainable event management)
- etc
- etc
Alignment of management system standards

- ISO’s Joint Technical Coordination Group:
  - Joint vision for management system standards
  - High level structure for all ISO management systems standards
  - Identical sub-clause titles under the high level structure
  - Generic core vocabulary for management system standards
Incorporates the recommendations of the JTCG work
Defines the common structure and format for all new ISO management system standards and revisions to existing standards
Common text (approx 30% of each standard will be identical text)
Will have a profound impact on future ISO 9001
MSS - Management System Standard (ISO Definition)

Standard that provides requirements or guidelines for organizations to develop and systematically manage their policies, processes and procedures in order to achieve specific objectives.

- NOTE 1 An effective management system is usually based on managing the organization’s processes using a “Plan-Do-Check-Act” approach in order to achieve the intended outcomes
- NOTE 2 Such documents typically address following components:
  - policy;
  - planning;
  - implementation and operation;
  - performance assessment;
  - improvement;
  - management review.
“High level structure”……

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement
Some examples…..
4.1 “Understanding the organization and its context”

“The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its “XXX” management system.”

NOTE: “XXX” = “quality”, “environmental”, “information security” etc
4.4 XXX management system

The organization shall establish, implement, maintain and continually improve an XXX management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

(This is key to maintaining the “process approach”, which will now be embedded in ALL ISO management system standards)

(Current clause 4.1 of ISO 9001:2008 likely to be incorporated into this clause)
6.1 Actions to address risks and opportunities

“When planning for the XXX management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to

- assure the XXX management system can achieve its intended outcome(s)
- prevent, or reduce, undesired effects
- achieve continual improvement.

The organization shall plan:

a) **actions to address these risks and opportunities**, and
b) how to

- integrate and implement the actions into its XXX management system processes
- evaluate the effectiveness of these actions.”
6.2 XXX objectives and planning to achieve them

“The organization shall establish XXX objectives at relevant functions and levels.

The XXX objectives shall

- be consistent with the XXX policy
- be measurable (if practicable)
- take into account applicable requirements
- be monitored
- be communicated, and
- be updated as appropriate.

The organization shall retain documented information on the XXX objectives.”
6.2 XXX objectives and planning to achieve them (contd…)

“When planning how to achieve its XXX objectives, the organization shall determine

- what will be done
- what resources will be required
- who will be responsible
- when it will be completed
- how the results will be evaluated.”
7.4 Communication

“The organization shall determine the need for internal and external communications relevant to the XXX management system including

- **on what** it will communicate
- **when** to communicate
- **with whom** to communicate”
10 Improvement

10.1 Nonconformity and corrective action

“When a nonconformity occurs, the organization shall:

a) react to the nonconformity, and as applicable
   - take action to **control and correct it**, and
   - **deal with the consequences**;

b) evaluate the need for action to eliminate the causes of the nonconformity, **in order that it does not recur or occur elsewhere**, by
   - reviewing the nonconformity
   - **determining the causes** of the nonconformity, and
   - determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken; and

e) make changes to the XXX management system, if necessary.”
Probable High-Level Timing for ISO 9001:2015

- SC2 Strategic Plan
- Review of QMP’s
- User Survey
- TG Future Concept Papers
- ISO Directives Annex SL

**June 2012**
- Draft Design Spec & “WD0”

**Nov 2012**
- Approved Design Spec & WD1

**Mar 2013**
- CD for comment & ballot

**Jan 2014**
- DIS for ballot

**Sept 2014**
- Draft FDIS

**Jan 2015**
- FDIS for ballot

**Sept 2015**
- Publication

Verification and validation activities

Interactions with SC1 (ISO 9000) on terminology issues

Liaison with IAF & ISO/CASCO regarding transition
Conclusions

- New revision process for ISO 9001 already underway
- Major changes likely
  - Update ISO 9001 to reflect modern business practices, changing business environment etc, since last major revision
  - Provide more emphasis on achieving product conformity
  - Simplification of language
  - Improve compatibility with other management system standards
- Validation projects will be undertaken with users
- Scheduled publication date is September 2015
- We will be working closely with IAF to define transition policy at the appropriate time
THANK YOU! – ANY QUESTIONS?

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