BUSINESS ASSURANCE

Overview

A Survey of Proposed Changes to ISO 9001:2008

Burt Holm
Northern District Sales Manager
Who is DNV GL?

Is now
- DNV founded in Norway 140 years ago
- Merged with GL in 2013
- Certified Body/Registrar since 1990 (US)
  - System Certification audits
  - Training
  - Sustainability Services
- Accredited through ANAB, RvA & UKAS
- Multiple North American locations
  - Multiple Global locations
Change is on the way
Agenda

- ISO Survey
- What is ISO
- Why ISO 9001 is being revised
- The ISO Framework
- What is changing
- The timeline for transition
- What to do now
- References and Resources
ISO 9001 Certifications in the US

Source: ISO Survey 2012
ISO 9001 Certifications Globally

Source: ISO Survey 2011
Types of Businesses Earning Certification

3.3 - What is your Generic Product Category?
(Based on 5,754 responses)

- Software: 7%
- Hardware: 31%
- Services: 43%
- Processed materials: 19%
Factors which Influenced Organization to Become Certified

- Customer satisfaction: 4,222
- Market need: 3,689
- Mandated customer requirement: 3,290
- Self declared conformance: 2,272
- Other: 560

Document: ISO/TC 176/SC 2/N 1017
What is ISO?

- ISO is the International Organization for Standardization, headquartered in Geneva, Switzerland
  - [www.iso.org](http://www.iso.org)

- ISO is a worldwide federation of the national standards organizations of 157 countries
  - ANSI is the US member body

- More than 19,000 International Standards and growing
ISO/TC 176

ISO/TC 176
Quality management and quality assurance

SC 1 Fundamentals & Vocabulary (ISO 9000)

SC 2 Quality Systems (ISO 9001, ISO 9004)

SC 3 Supporting Technologies (E.g.: ISO 10011)

WG 22 Interpretations

WG 23 Communications & Product Support

WG 24 Revision of ISO 9001

Source: ISO 9001:2015 – From CD to DIS, Dr. Nigel H Croft 2013
The ISO 9000 Document Group

- ISO 9000:2005 Fundamentals and Vocabulary
- ISO 9004:2009 Managing for the Sustained Success of an Organization

The Certified Body or Registrar

- ISO 17021
- IRCA and RAB QSA
- IAF and Mandatory Documents
Why ISO 9001 is Being Revised

- Maintain Relevance
- Integration among all standards
- Consistent foundation for the long-term (next 10-25 years)
- Increase adoption of the standard
- Address increased variety of business users
  - Service industries
  - Office environments
- Address increasing complexity of business environment
  - Non-office/virtual office
Caution and Disclaimer

- ISO 9001:2015 as a Draft International Standard is not available publicly.
- No portion of the Draft International Standard may be
  - Reproduced
  - Transmitted
  - Stored
  - Copied, recorded, etc.
- Available information is from TC176 member organizations
  - Public webinars
  - Commentaries
  - Limited information releases
ISO and Management System Standards

- 2012: all Management Systems standards will have common Framework
  - High level structure
  - Common text and terminology
  - New standards and revisions to existing standards

  - Annex SL is the generally used shorthand
The Common Framework

- Standardize and effectively develop standards
- Enhance alignment and compatibility of standards
  - Useful for organizations which pursue multiple standards
- Some standards already under Common Framework
  - ISO 22000
  - ISO 20001
  - ISO 50001
- Under revision to the Common Framework
  - ISO 14001
  - ISO 27001
  - ISO 9001
# What is Changing?

## ISO 9001:2008

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## ISO 9001:2015

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Key Changes

- Emphasis on Risk-based management
  - Preventive action
- Increase emphasis on achieving value for organization and its customers
- Documented Information
  - Decreased emphasis on documentation
  - Expands concept of documentation
  - Replaces Documents and Records
- Organizational Context
  - Responsiveness to business environment
- Outsourcing is now External Provision
- Enhanced leadership requirements
- No requirement for Management Representative
- No requirement for Quality Manual
# High Level Structure

## New Clause Numbers

1. Scope
2. Normative References
3. Terms and Definitions
4. Context of the Organization
   1. Understanding the Organization and its context
   2. Needs and expectations
   3. Scope
   4. Management system
5. Leadership
   1. Management commitment
   2. Policy
   3. Roles, Responsibility and Authority
6. Planning
   1. Actions to address risks and opportunities
   2. Objectives and plans to achieve them
7. Support
   1. Resources
   2. Competence
   3. Awareness
   4. Communications
   5. Documented Information
8. Operations
   1. Operational planning and control
9. Performance evaluation
   1. Monitoring, measurement, analysis and evaluation
   2. Internal audit
   3. Management review
10. Improvement
    1. Nonconformity and corrective action
    2. Continual improvement
4. Context of the Organization

4.1 Understanding the organization and its context

The organization must determine external and internal issues relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its QMS.
4. Context of the Organization

4.2 Understanding the needs and expectations of interested parties

The organization must determine
• interested parties relevant to the QMS, and
• the requirements of these interested parties

List of interested parties the organization must consider:
• Direct customers
• End users
• Suppliers, distributors, retailers or others involved in the supply chain
• Regulators, and
• Any other relevant interested parties
4. Context of the Organization

4.4 Quality management system

The organization must establish, implement, maintain and improve a QMS, including the processes needed and their interactions, in accordance with the requirements of this standard.

“Process approach” is maintained, and it will be embedded in all ISO management system standards.
5.1 Leadership

Top management must demonstrate leadership and commitment with respect to the quality management system, by …

- Ensuring the integration of the QMS requirements into the organization’s business processes
- Promoting awareness of the process approach
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility

Top management must demonstrate leadership and commitment with respect to customer focus
6.1 Actions to address risks and opportunities

When planning for the QMS, the organization must consider the issues … in 4.1 and the requirements … in 4.2 and determine the risks and opportunities that need to be addressed to

- Assure the QMS can achieve its intended outcome(s)
- Prevent or reduce undesired effects
- Achieve improvement

The organization must plan:

- Actions to address these risks and opportunities, and
- how to
  - Integrate and implement the actions into its QMS processes and
  - Evaluate the effectiveness of these actions
7.1 Resources

The organization must determine and provide the resources needed for the QMS (establishment, implementation, maintenance and improvement of the QMS).

Resources may include:

- Infrastructure (7.1.2)
- Process environment (7.1.3)
- Monitoring (7.1.4)
- Knowledge (7.1.5)
8.1 Operational Planning and Control

The organization must plan, implement and control the processes needed to meet requirements and to implement the actions determined in 6.1, by:

- Establishing criteria for those processes
- Implementing the control of the processes in accordance with the criteria
- Keeping sufficient documented information to demonstrate the processes have been carried out as planned

The organization must control planned and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization must ensure the operation of a function or process of the organization by an external provider is controlled (outsourcing).
8.4 Control of external provision of goods and services

The organization must ensure that externally provided goods and services satisfy the specified requirements.

Note: These include outsourcing.
9. Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation
9.2 Internal audit
9.3 Management review
10. Improvement

10. Improvement

10.1 Nonconformity and corrective action
10.2 Continual improvement

Comment

- Note that “Preventive action” is not included as separate clause. However, this may be considered as part of 6.1 (although not too explicitly stated)
Terminology: Changes and Concepts

1. Product is now Goods and Services
2. Process Approach is now stated requirement (Clause 4.4.2)
3. “Risk” is defined as effect of uncertainty
   1. ISO 31000
4. Design and Development is now Development
5. Monitoring and Measurement are now separate
   1. Monitoring: status of a system, a process or an activity
   2. Measurement: a process to determine a value
6. Context of Organization
   1. From stakeholders, industry groups, trading partners, others
   2. Laws, regulations, standards, codes of practice, Industry regulation, corporate governance, others
   3. Economic, financial, environmental, social
   4. Industry or government analysis
7. Media information
Other Considerations

- Change to the standard brings challenges
  - To the user community
  - To Certified Bodies/Registrars
- ISO 9001:2008 is central to other standards
  - AS9100 Aerospace
  - TS16949 Automotive
  - FSSC22001 Food Safety
- Comments and Feedback can still be provided to TC176
Tentative Transition Timeline

- February 2014 Draft International Standard
- July 2015 Final Draft International Standard
- September 2015 Publish International Standard
Tentative Implementation Timeline

- **December 2015**: Publish International Standard
- **January 2016**: Begin Implementation
- **2019**: Complete 3-year Implementation Period
What should we be doing?

- Learn about the key changes
- Evaluate the impact on your organization
- Begin planning to revise your management system
- Keep informed of the Draft International Standard
- Begin a dialogue with your Registrar
References and Resources

- Webinars
  - Brand X
    - Google will net many similar reviews
    - Detailed review including supporting standards
  - [www.iso.org](http://www.iso.org)
    - General information only
  - IAF
  - IRCA
Questions
Thank you