ISO 9001:2015
Revision overview

December 2013

ISO/TC 176/SC 2/WG23 N063
Purpose of presentation

To provide an overview of the revision of ISO 9001 which will be published in 2015
Background to this presentation

- developed by the ISO sub-committee responsible for communicating key information about the current revisions to ISO 9001
- this information will be updated as the revision progresses
Disclaimers

- the presentation includes information related to the revision process up to and including December 2013
- further changes are likely to occur as the revision process progresses
- you will want to consider the changes as these occur and plan accordingly
Copyright for Draft Standards

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ISO facts

- ISO is the International Organization for Standardization

  *ISO is based in Switzerland, over 160 nations participate with approximately 20,000 standards*

  *all ISO standards are based on consensus*

- ISO standards are usually developed by Technical Committees (TCs) or their sub-committees, or by Project Committees

- ISO work involves experts nominated by their national standards bodies
ISO 9001:2015 development process

- an international ballot agreed the need for revision
- there are several distinct stages when developing an ISO standard; the key ones being:
  1. Working Drafts (WDs)
  2. Committee Draft (CD)
  3. Draft International Standard (DIS)
  4. Final Draft International Standard (FDIS)
  5. International Standard (IS)

The standard is published after approval of the FDIS by participating national standards bodies and is reviewed at regular intervals after then.
Revision intent

ISO 9001 needs to:

- maintain relevance
- integrate with other management systems
- provide an integrated approach to organizational management
- provide a consistent foundation for the next 10 years
- reflect the increasingly complex environments in which organizations operate
- ensure the new standard reflects the needs of all potential user groups
- enhance an organization's ability to satisfy its customers
What was considered?

- the results of an extensive web-based user survey
- the increasing diversity of ISO 9001 users
- developments in knowledge and technologies
- broader user interests
- changes in industry
High level structure

- A new common format has been developed for use in all management system standards

  standardized core text and structure
  standardized core definitions

Organizations implementing multiple management systems (e.g. quality, environmental, information security) can achieve better integration and easier implementation.

The high level structure and common text is public information and can be found in Annex SL of the www.iso.org/directives
Main changes

- an emphasis on risk-based thinking
- increased emphasis on achieving value for the organization and its customers
- increase flexibility on the use of documentation
- more readily applicable by “service” type organizations

customers remain the primary focus
Main changes

- use of the High Level Structure (HLS)
- improved applicability for services
- fewer prescribed requirements
- increased emphasis on organizational context
- boundaries of the QMS must now be defined
- consideration of exclusions
Main changes

- risk-based thinking throughout the standard supersedes a single clause on preventive action
- the term ‘documented information’ replaces ‘documents and records’
- the term ‘outsourcing’ is replaced by ‘external provision’
- increased leadership requirements
- no requirement for a management representative
Changes to requirements

- objectives must include reference to who, what, when
- planning of changes
- explicit reference to knowledge management
- no need for a Quality Manual
- operational planning includes addressing risks
- greater emphasis on processes achieving requirements for goods or services and customer satisfaction
Changes to requirements

- control of changes
- monitoring and measurement
- internal audits now require the consideration of related risks
- management review to take into consideration strategic direction of the organization
Structure

1 Scope
2 Normative references
3 Terms and definitions
4 Context of the organization
   context
   interested parties
   scope of QMS
   quality management system
5 Leadership
   general
   management commitment
   policy
   roles, responsibility and authority
6 Planning
   actions to address risks and opportunities
   objectives and plans to achieve them
   planning of changes
7 Support
   resources
   competence
   awareness
   communication
   documented information

8 Operation
   operational planning and control
   determination of market needs and interaction with customers
   operational planning process
   control of external provisions of goods and services
   development of goods and services
   production of goods and provision of services
   release of goods and services
   non conforming goods and services
9 Performance evaluation
  monitoring, measurement, analysis and evaluation
  internal audit
  management review

10 Improvement
  Non-conformity and corrective action
  improvement
QMS Structure

**PLAN**
- 4 Context of the organization
  - Understanding of the organization and its context
  - Expectations of interested parties
  - Scope of management system
  - QMS
- 5 Leadership
  - Leadership and commitment
  - Quality policy
  - Roles, responsibilities and authorities
- 6 Planning
  - Actions to address risk and opportunity
  - Quality objectives
  - Planning of changes
- 7 Support
  - Resources
  - Competence
  - Awareness
  - Communication
  - Documented information

**DO**
- 8 Operation
  - Operations of planning and control
  - Determination of market needs and interactions with customers
  - Operational planning process
  - Control of external provision of goods and services
  - Development of goods and services
  - Production of goods and provision of services
  - Release of goods and services
  - Nonconforming goods and services

**CHECK**
- 9 Performance and evaluation
  - Monitoring, measurement, analysis and evaluation
  - Internal audit
  - Management review

**ACT**
- 10 Improvement
  - Nonconformity and corrective action
  - Continual improvement
ISO 9001:2015 Timeline

2013
(Committee Draft)

2014
April 2014 DIS
(Draft International Standard)

2015
July 2015 FDIS
(Final Draft International Standard)

September 2015
Published International Standard
ISO 9001:2015 Certification Transition Timeline

September 2015
Published International Standard

September 2015 start of 3 years transition period to September 2018
Supporting documents

- certification transition plan and timeframe
- guidance documents on specific topics, e.g. the process approach
- frequently asked questions
- ISO website updates
Other important Information

The revision of ISO 9001 will impact on other related standards and documents.

Expect changes to:

- industry-specific standards
- supporting documents
Ensure your organization

- knows about the key changes
- understands the key concepts
- plans to implement the new requirements
- stays informed as the revision proceeds
- takes full advantage of the revision of ISO 9001
What is next?

Updates will be made available as the revision proceeds