## 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



- 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**

#### **Please note:**

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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
- boandaries 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 Flanning

actions to address risks and opportunities objectives and plans to achieve them planning of changes

# Structure

#### 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

# Structure

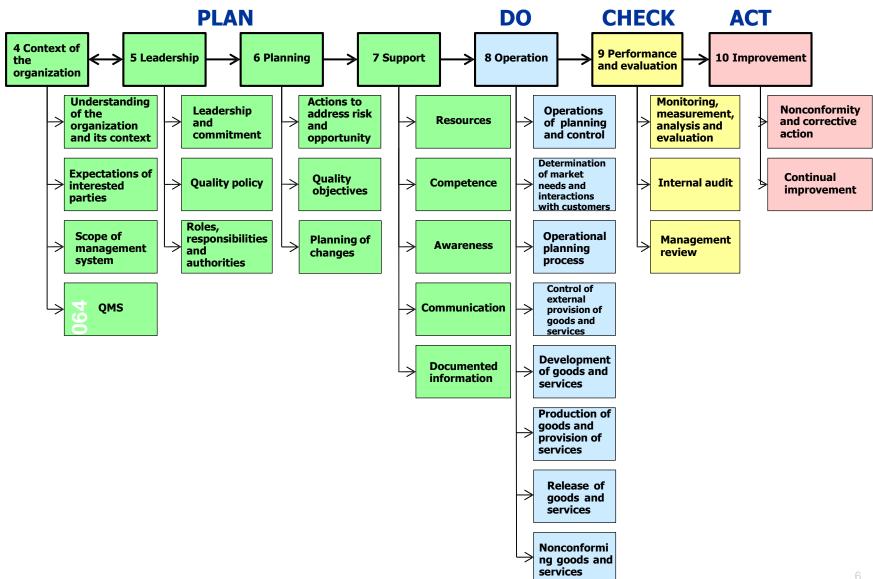
#### **9** Performance evaluation

monitoring, measurement, analysis and evaluation internal audit management review

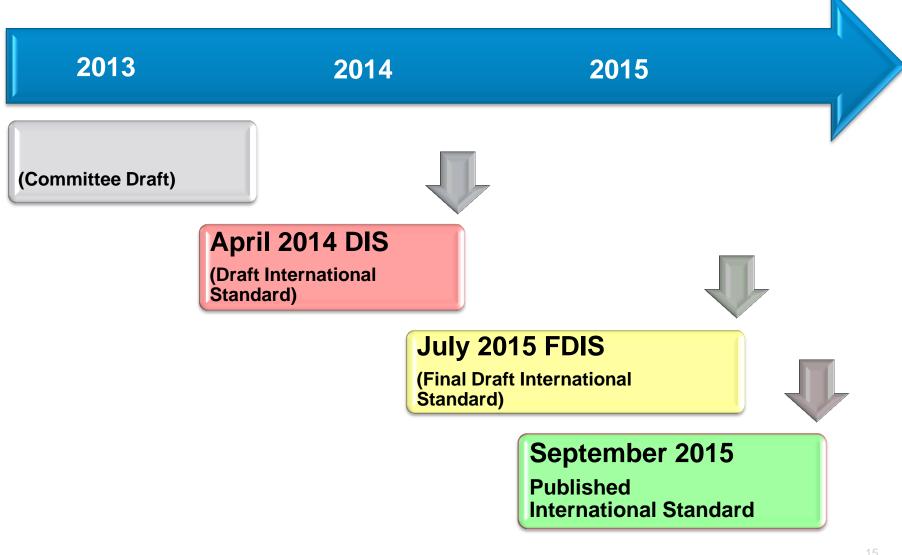
#### **10** Improvement

Non-conformity and corrective action improvement

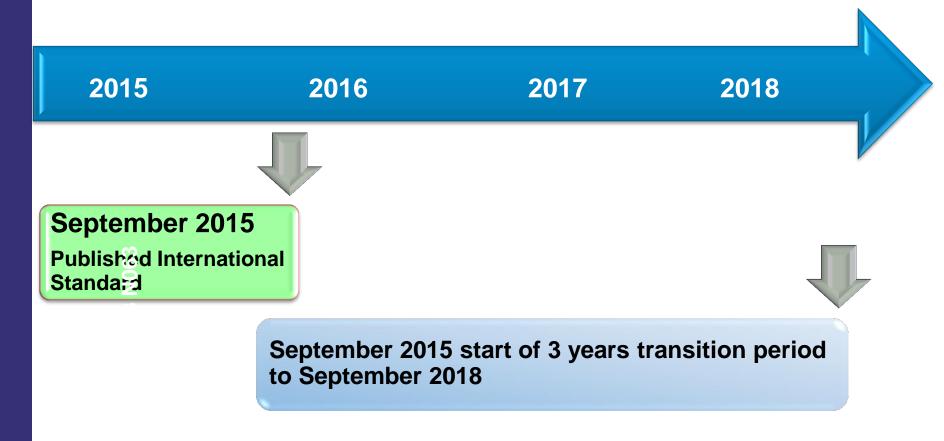
### **QMS Structure**



### **ISO 9001:2015 Timeline**



### ISO 9001:2015 Certification Transition Timeline



### **Supporting documents**

- certification transition plan and timeframe
- guidance documents on specific topics, e.g. the process approach
- comparison of ISO 9001:2008 and 9001:2015
- 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



# Updates will be made available as the revision proceeds