

# **ISO 9001:2015**

## **Revision overview**

### **- Quality experts**

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**January 2014**

**Developed from ISO/TC 176/SC 2/WG23 N063, N064 & N065**

# Purpose of presentation

## The intention of this presentation is to:

To provide an overview of changes and likely impacts of the 2015 revision of ISO 9001

# Disclaimers

- verbal statements made by the presenter may represent personal opinions and/or interpretations
- 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 may wish to consider the changes as these occur and plan accordingly**

# 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

# 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

# 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

# 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](http://www.iso.org/directives)



## 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

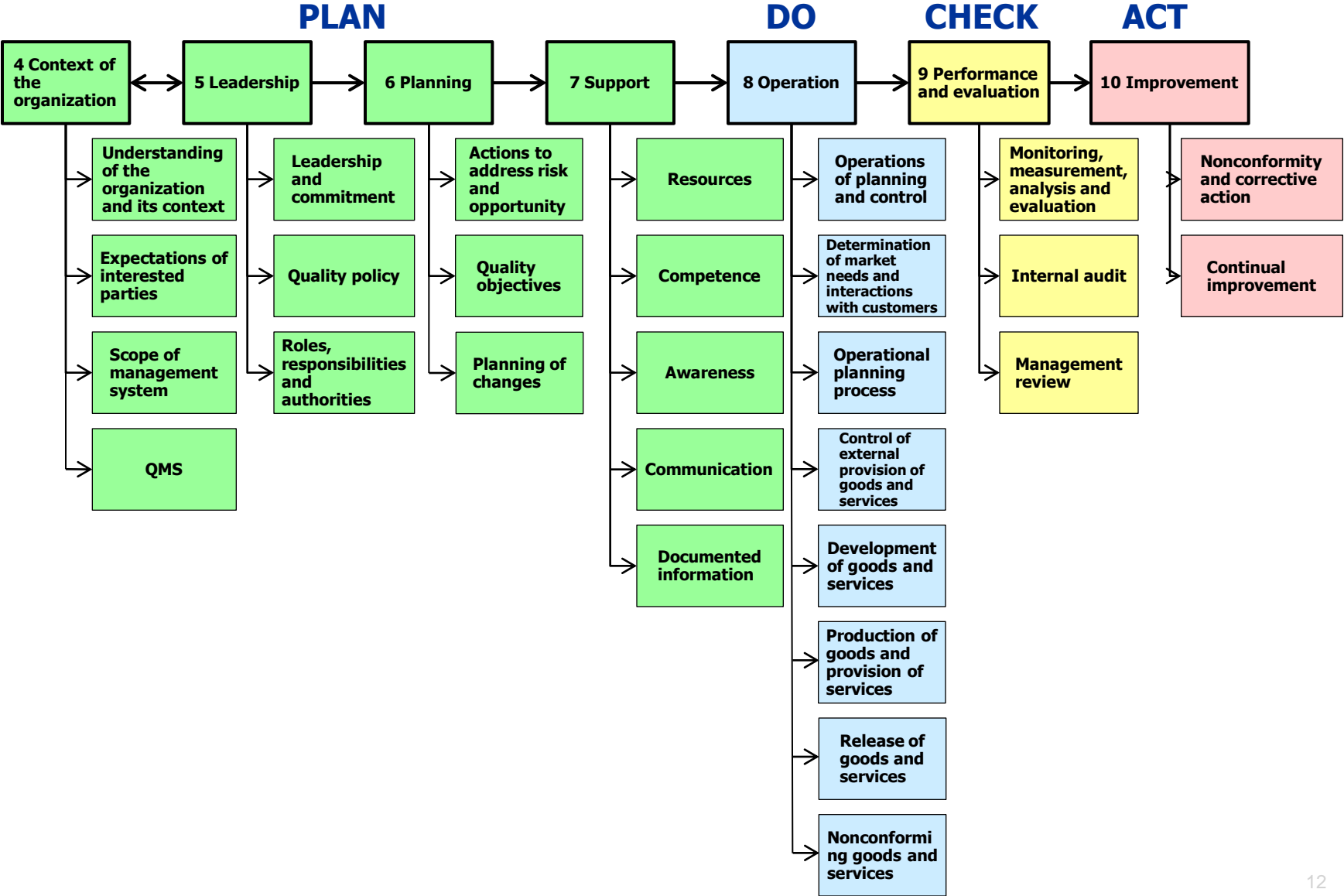
## 9 Performance evaluation

- monitoring, measurement, analysis and evaluation
- internal audit
- management review

## 10 Improvement

- Non-conformity and corrective action
- improvement

# QMS Structure



# 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

# “Risk Based Thinking”

**Most significant Change?**

# Purpose of presentation

Provide an overview of how the future ISO 9001:2015 standard addresses the topic of “risk”.



# What is “risk-based thinking”?

- risk-based thinking is something we all do automatically and often sub-consciously
- The concept of risk has always been implicit in ISO 9001 – this revision makes it more explicit and builds it into the whole management system
- risk-based thinking is already part of the process approach
- risk-based thinking makes preventive action part of the routine
- risk is often thought of only in the negative sense. Risk-based thinking can also help to identify opportunities. This can be considered to be the positive side of risk

**Where is risk addressed in  
the current draft of  
ISO 9001:2015?**

# The main objectives of ISO 9001

- to provide confidence in the organization's ability to consistently provide customers with conforming goods and services
- To enhance customer satisfaction

**The concept of “risk” in the context of ISO 9001 relates to the uncertainty in achieving these objectives**

# Risk in the clauses - Process Approach, Leadership, Planning

- in Clause 4 the organization is required to determine the risks which can affect its ability to meet these objectives
- in Clause 5 top management are required to commit to ensuring Clause 4 is followed
- in Clause 6 the organization is required to take action to address risks and opportunities

# Risk in Clauses – Operation, Evaluation, Improvement

- Clause 8 - the organization is required to have processes which identify and address risk in its operations
- Clause 9 the organization is required to monitor, measure, analyse and evaluate the risks and opportunities
- In Clause 10 the organization is required to improve by responding to changes in risk

# Why should I adopt “risk-based thinking”?

- to improve customer confidence and satisfaction
- to assure consistency of quality of goods and services
- to establish a proactive culture of prevention and improvement
- Successful companies intuitively take a risk-based approach



# What should I do?

## Use a risk-driven approach in your organizational processes

- **identify what the risks and opportunities are in your organization – it depends on context**
  - ISO 9001:2015 will not automatically require you to carry out a full, formal risk assessment, or to maintain a “risk register”
  - ISO 31000 (“Risk management — Principles and guidelines”) will be a useful reference (but not mandated)

# What should I do? (continued)

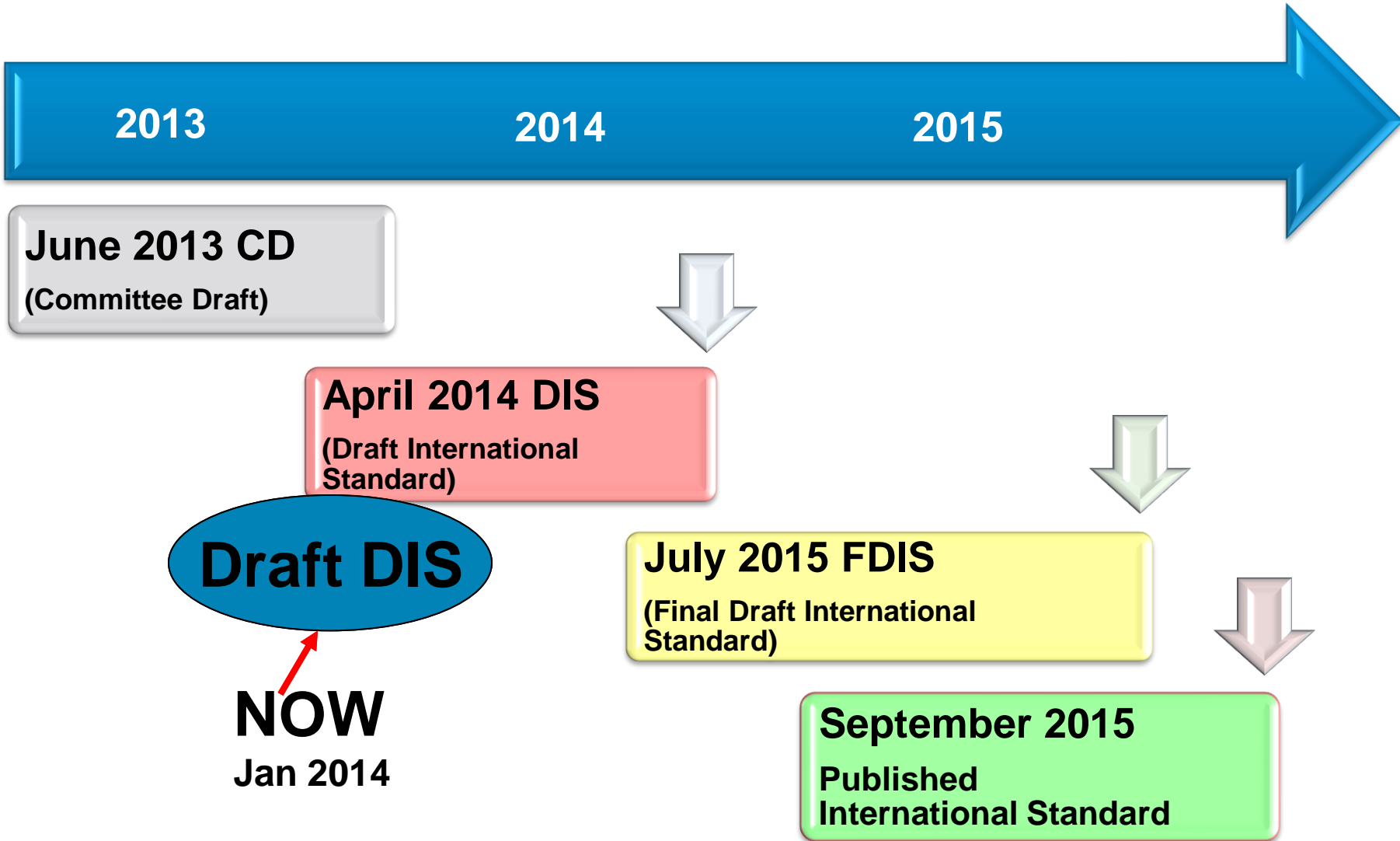
- **analyse and prioritize the risks and opportunities in your organization**
  - *what is acceptable?*
  - *what is unacceptable?*
- **plan actions to address the risks**
  - *how can I avoid or eliminate the risk?*
  - *how can I mitigate the risk?*
- **implement the plan – *take action***
- **check the effectiveness of the actions – *does it work?***
- **learn from experience – *continual improvement***



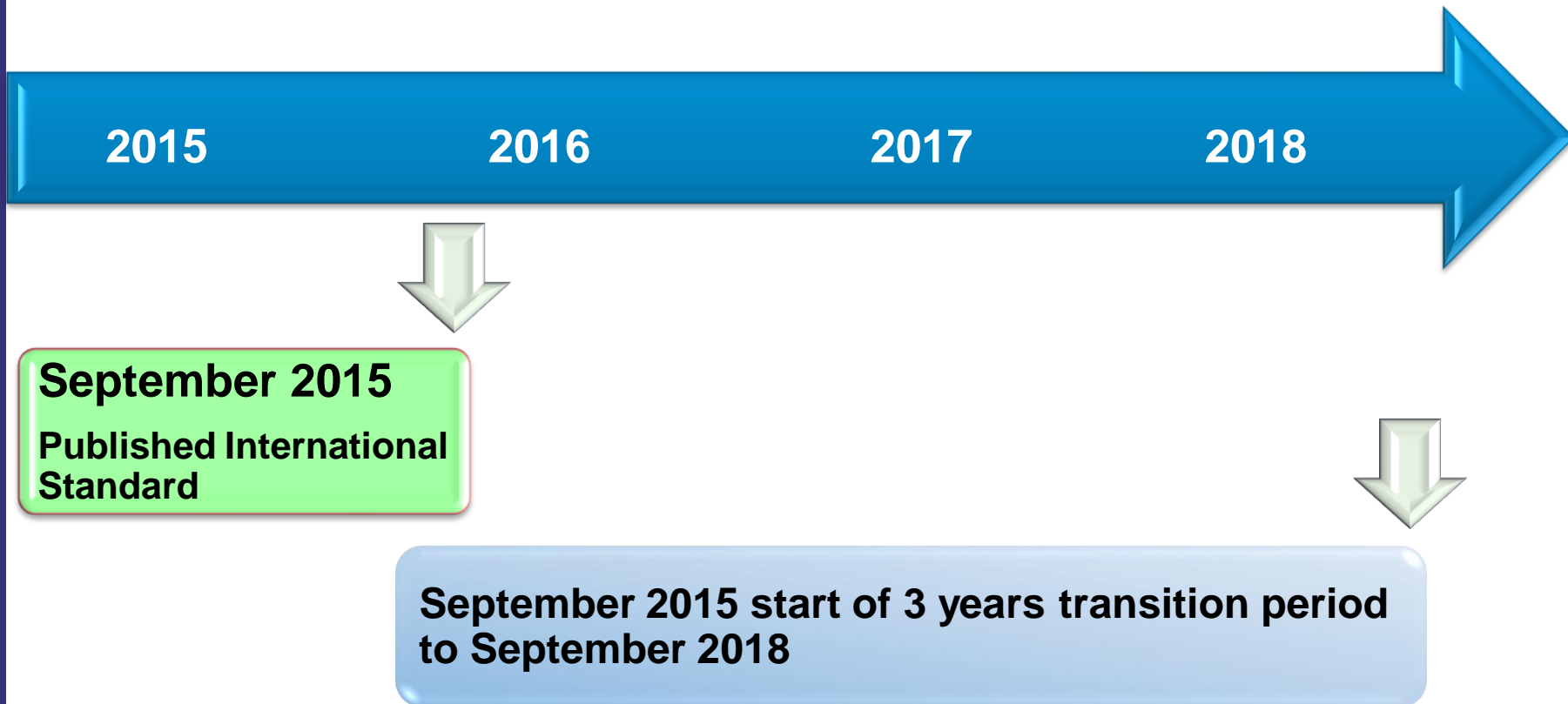
# What is next?

**Additional updates and information will be made available as the revision process proceeds**

# ISO 9001:2015 Timeline



# ISO 9001:2015 Certification Transition Timeline



# What's next?

**Updated information will be made available  
as the revision process proceeds**

**The End**

**Thanks for your attention**