

# ISO 9001:2015

## “Risk Based Thinking”

**July 2014**

**ISO/TC 176/SC 2/ N1221**

# Purpose of presentation

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

# Revision presentation

- developed by the ISO subcommittee responsible for communication about the upcoming revisions to ISO 9001
- will be updated periodically as the revision progresses
- is available to anyone

# What is “risk-based thinking”?

- risk-based thinking is something we all do automatically and often sub-consciously to get the best result
- 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 ensures risk is considered from the beginning and throughout the process approach
- risk-based thinking makes preventive action part of strategic planning
- 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 ISO DIS 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 of achieving such objectives**

**The concept of “opportunity” in the context of ISO 9001 relates to exceeding expectations and going beyond stated objectives**

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

- in the Introduction the concept of risk-based thinking is explained
- 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 identify risks and opportunities

# Risk in Clauses – Operation, Evaluation, Improvement

- Clause 8 - the organization is required to implement processes to address risk
- 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”?

- successful companies intuitively take a risk-based approach because it brings benefits
- to **improve** customer confidence and satisfaction
- to **assure** consistency of quality of goods and services
- to establish a **proactive** culture of prevention and improvement

# 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 does not require a formal risk assessment or specific single document
  - the information must be kept and available and could be electronic, audio, video, written or any other type of media
  - ISO 31000 (“Risk management — Principles and guidelines”) may be a useful reference for organizations which want a more formal risk process, but is not obligatory

## What should I do? (continued)

- **analyse and prioritize the risks and opportunities in your organization**
  - *what is acceptable?*
  - *what is unacceptable?*
  - *which opportunities should be acted on?*
- **plan actions to address the risks and opportunities**
  - *how can I avoid, eliminate or mitigate the risk?*
  - *how can I realise opportunities?*
- **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**

**[www.iso.org/tc176/sc02/public](http://www.iso.org/tc176/sc02/public)**