ISO 9001:2015
“Risk Based Thinking”

July 2014

ISO/TC 176/SC 2/ N1221
Provide an overview of how the future ISO 9001:2015 standard addresses the topic of “risk”.

Purpose of presentation
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