ISO 9001:2015
Risk-based thinking
Purpose of this presentation

To explain the concept of risk-based thinking in ISO 9001:2015
This presentation

- Developed by the ISO subcommittee responsible for ISO 9001
- Available for unrestricted public use
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 edition makes it more explicit and builds it into the whole management system.

- Risk-based thinking ensures risk is considered from the beginning and throughout.

- Risk-based thinking makes preventive action part of strategic and operational planning.
Where is risk addressed in ISO 9001:2015?
Risk-based thinking is in:

- Introduction - the concept of risk-based thinking is explained
- Clause 4 - organization is required to determine its QMS processes and address its risks and opportunities
- Clause 5 – top management is required to
  - Promote awareness of risk-based thinking
  - Determine and address risks and opportunities that can affect product /service conformity
- Clause 6 - organization is required to identify risks and opportunities related to QMS performance and take appropriate actions to address them
Risk-based thinking is in:

- Clause 7 – organization is required to determine and provide necessary resources
- Clause 8 - organization is required to manage its operational processes
- Clause 9 - organization is required to monitor, measure, analyse and evaluate the effectiveness of actions taken to address risks and opportunities
- Clause 10 - organization is required to correct, prevent or reduce undesired effects and improve the QMS and update risks and opportunities
- Note, risk is implicit whenever suitable or appropriate is mentioned (clause 7 and 8)
Why use risk-based thinking?

Successful organizations intuitively apply risk-based thinking because it brings benefits that:

- improve governance
- establish a proactive culture of improvement
- assist with compliance
- assure consistency of quality of products and services
- improve customer confidence and satisfaction
How do I do it?

- Identify what your risks are – it depends on context
- Use risk-based thinking to prioritize the way you manage your processes
- ISO 9001:2015 does not require formal risk management
- ISO 31000 *Risk management — Principles and guidelines* may be a useful reference for organizations that want or need a more formal approach to risk (but its use is not obligatory)
How do I do it?

- Balance risks and opportunities
- Analyse and prioritize your risks
  what is acceptable?
  what is unacceptable?
- Plan actions to address the risks
  how can I avoid, eliminate or mitigate risks?
- Implement the plan; take action
- Check the effectiveness of the action; does it work?
- Learn from experience; improve
Conclusions

Risk-based thinking:
- is not new
- is something you probably do already
- is ongoing
- ensures greater knowledge of risks and improves preparedness
- increases the probability of reaching objectives
- reduces the probability of negative results
- makes prevention a habit