ISO/DIS 9001: 2015 – A Preview of Things to Come

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This presentation

- provides an overview of the revision of ISO 9001 to be published in 2015

- is being developed by the ISO sub-committee for communication

Agenda

- Overview of ISO/DIS 9001:2015 revision
- Video Presentation of Key Changes in the revision
- Slides reviewing some key provisions (e.g., Risk-Based-Thinking Concept)
- Q & A

Disclaimer

- The viewpoints in this presentation are the presenter's and do not represent the views of the International Organization of Standardization (ISO) or the American Society for Quality (ASQ).

- Information in this presentation related to the revisions made as of May, 2015.

- Further changes may occur.

- FDIS on track for July, 2015

International Organization for Standardization (ISO)

- all ISO standards are based on consensus
- ISO work involves experts from business, government, academia, etc.
- representation from over 160 countries

Figure 1: Even the Baltimore County Public Schools' QMS is Certified to ISO 9001: 2008
Source: https://www.bcps.org/offices/accountability_research_testing/quality_management_system.html

Reasons for revisions

The world changes:

- increased prominence of services

- globalization

- more complex supply chain

- increased interested parties' expectations

- information availability

Key perspectives

ISO 9001 needs to change, to:

- adapt to a changing world

- enhance an organization's ability to satisfy its customers

- provide a consistent foundation for the future

- reflect the increasingly complex environments in which organizations operate

- ensure the new standard reflects the needs of all interested parties

- integrate with other management systems

Main changes

emphasis on:

- greater focus on the customer

- risk-based thinking (where risk is any disruption that prevents organizations from achieving its objectives)

- aligning QMS policy and objectives with the organization's business strategy

- greater flexibility with documentation

High Level Structure (HLS)

A new common format has been developed for use in all management system standards:

- *standardized core text and structure for multiple ISO management systems for integration*

- *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

Structure of ISO 9001:2015

1/3

1 Scope

2 Normative references

3 Terms and definitions

4 Context of the organization
  4.1 Understanding the organization and its context
  4.2 Understanding the needs and expectations of interested parties
  4.3 Determining the scope of QMS
  4.4 Quality management system and its processes

5 Leadership
  5.1 Leadership and commitment
  5.2 Quality policy
  5.3 Organizational roles, responsibilities and authorities

6 Planning for the QMS
  6.1 Actions to address risks and opportunities
  6.2 Quality objectives and plans to achieve them
  6.3 Planning of changes

Structure of ISO 9001:2015

2/3

7 Support

    7.1 Resources

    7.2 Competence

    7.3 Awareness

    7.4 Communication

    7.5 Documented information

8 Operation

    8.1 Operational planning and control

    8.2 Determination of requirements for products and services

    8.3 Design and development of products and services

    8.4 Control of externally provided products and services

    8.5 Production and service provision

    8.6 Release of products and services

    8.7 Control of non conforming process outputs, products and services

Structure of ISO 9001:2015

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal audit

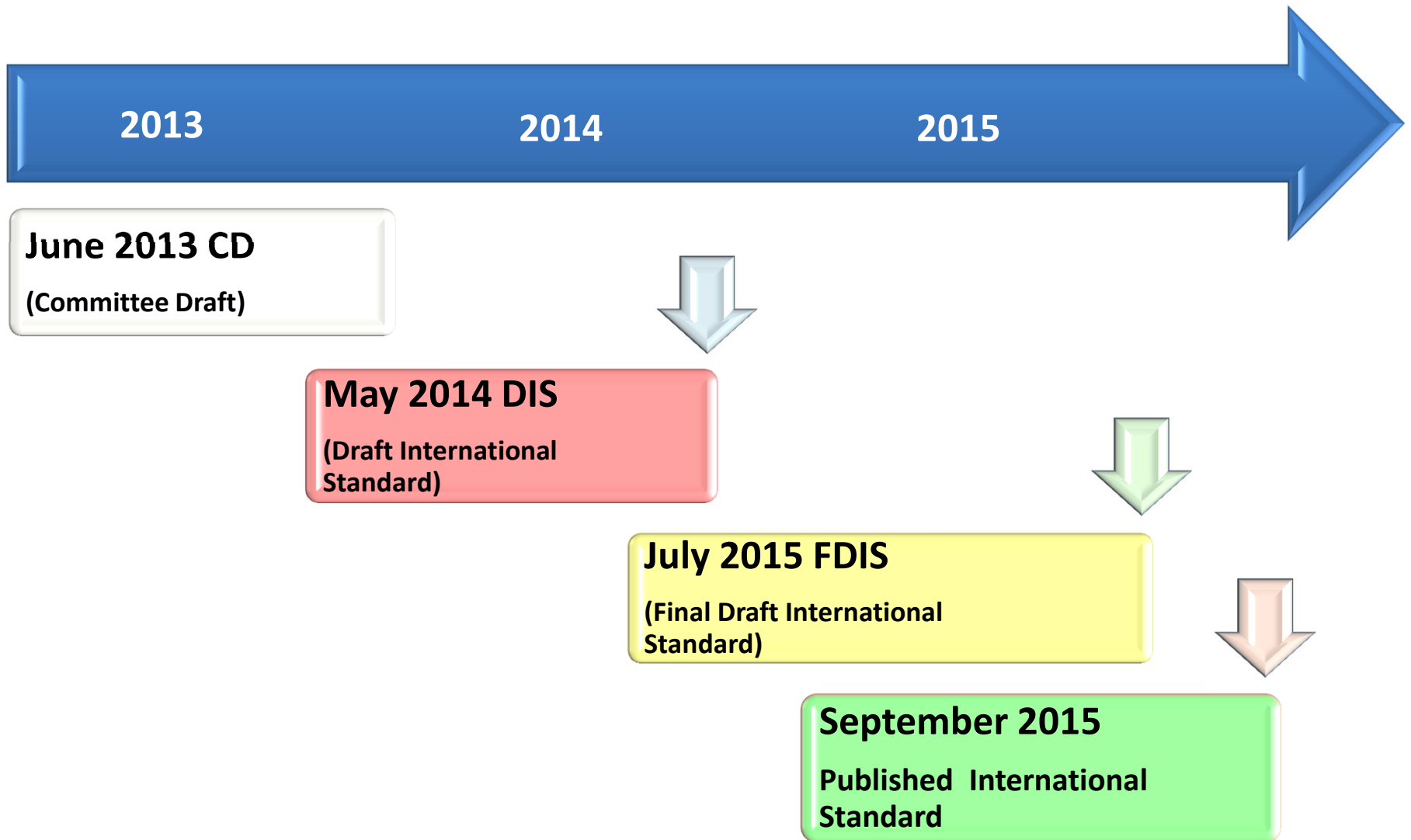9.3 Management review

10 Improvement

10.1 General

10.2 Non-conformity and corrective action
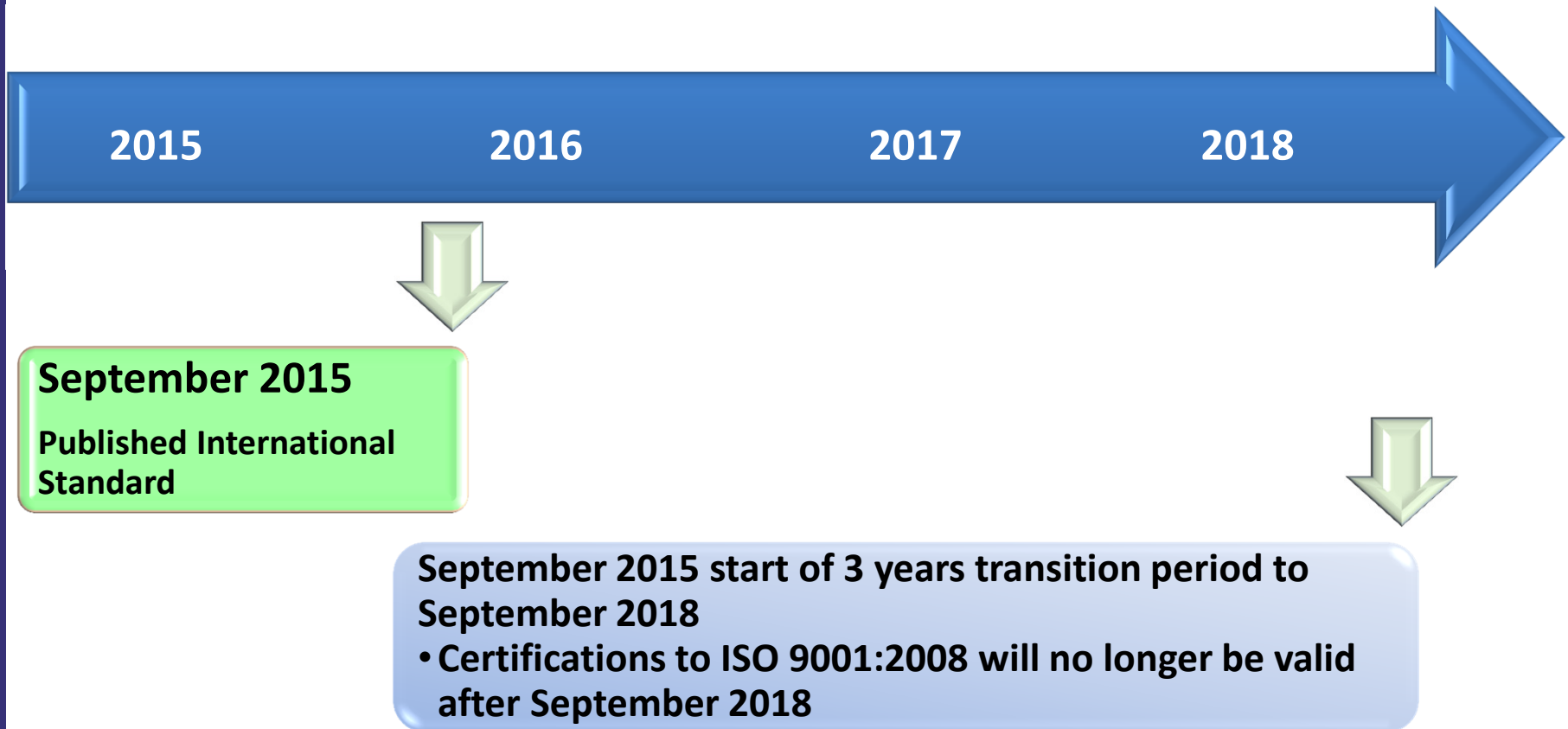
10.3 Continual improvement

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

ISO 9001:2015 Timeline

2013 **2014** **2015**

June 2013 CD

(Committee Draft)

May 2014 DIS

(Draft International Standard)

July 2015 FDIS

(Final Draft International Standard)

September 2015

Published International Standard

ISO 9001:2015 Certification Transition Timeline

| 2015 | 2016 | 2017 | 2018 |

September 2015

Published International Standard

September 2015 start of 3 years transition period to September 2018
- **Certifications to ISO 9001:2008 will no longer be valid after September 2018**

Other important Information

The revision of ISO 9001 will impact on other related standards and documents.

Expect changes to:

- industry-specific standards

- supporting documents

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

ISO/DIS 9001 to ISO 9001:2008 Correlation Matrix

Source: ISO/TC 176/SC 2 Document N**1224**, July 2014

http://isotc.iso.org/livelink/livelink/fetch/2000/2122/-8835176/-8835848/8835872/8835883/ISO%209001Correlation_Matrices.doc

ISO/DIS 9001		ISO 9001:2008	
4	Context of the organization	1.0	Scope
4.1	Understanding the organization and its context	1.1	General
4.2	Understanding the needs and expectations of interested parties	1.1	General
4.3	Determining the scope of the quality management system	1.2 4.2.2	Application Quality manual
4.4	Quality management system and its processes	4 4.1	Quality management system General requirements
5	Leadership	5	Management responsibility
5.1	Leadership and commitment	5.1	Management commitment
5.1.1	Leadership and commitment for the quality management system	5.1	Management commitment
5.1.2	Customer focus	5.2	Customer focus
5.2	Quality policy	5.3	Quality policy

ISO/DIS 9001 to ISO 9001:2008 Correlation Matrix

ISO/DIS 9001	ISO 9001:2008
5.3 Organizational roles, responsibilities and authorities	5.5.1 Responsibility and authority 5.5.2 Management representative
6 Planning for the quality management system	5.4.2 Quality management system planning
6.1 Actions to address risks and opportunities	5.4.2 Quality management system planning 8.5.3 Preventive action
6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives
6.3 Planning of changes	5.4.2 Quality management system planning
7 Support	6 Resource management
7.1 Resources	6 Resource management
7.1.1 General	6.1 Provision of resources
7.1.2 People	6.1 Provision of resources
7.1.3 Infrastructure	6.3 Infrastructure
7.1.4 Environment for the operation of processes	6.4 Work environment
7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment
7.1.6 Organizational knowledge	New
7.2 Competence	6.2.1 General 6.2.2 Competence, training and awareness

ISO/DIS 9001 to ISO 9001:2008 Correlation Matrix

ISO/DIS 9001	ISO 9001:2008
7.3 Awareness	6.2.2 Competence, training and awareness
7.4 Communication	5.5.3 Internal communication
7.5 Documented information	4.2 Documentation requirements
7.5.1 General	4.2.1 General
7.5.2 Creating and updating	4.2.3 Control of documents 4.2.4 Control of records
7.5.3 Control of documented Information	4.2.3 Control of documents 4.2.4 Control of records
8 Operation	7 Product realization
8.1 Operational planning and control	7.1 Planning of product realization
8.2 Determination of requirements for products and services	7.2 Customer-related processes
8.2.1 Customer communication	7.2.3 Customer communication
8.2.2 Determination of requirements related to products and services	7.2.1 Determination of requirements related to the product
8.2.3 Review of requirements related to the products and services	7.2.2 Review of requirements related to the product
8.3 Design and development of products and services	7.3 Design and development
8.3.1 General	New

ISO/DIS 9001 to ISO 9001:2008 Correlation Matrix

ISO/DIS 9001	ISO 9001:2008
8.3.2 Design and development planning	7.3.1 Design and development planning
8.3.3 Design and development Inputs	7.3.2 Design and development inputs
8.3.4 Design and development controls	7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation
8.3.5 Design and development outputs	7.3.3 Design and development outputs
8.3.6 Design and development changes	7.3.7 Control of design and development changes
8.4 Control of externally provided products and services	7.4.1 Purchasing process
8.4.1 General	7.4.1 Purchasing process
8.4.2 Type and extent of control of external provision	7.4.1 Purchasing process 7.4.3 Verification of purchased product
8.4.3 Information for external providers	7.4.2 Purchasing information
8.5 Production and service provision	7.5 Production and service provision
8.5.1 Control of production and service provision	7.5.1 Control of production and service provision
8.5.2 Identification and traceability	7.5.3 Identification and traceability
8.5.3 Property belonging to customers or external providers	7.5.4 Customer property
8.5.4 Preservation	7.5.5 Preservation of product

ISO/DIS 9001 to ISO 9001:2008 Correlation Matrix

ISO/DIS 9001	ISO 9001:2008
8.5.5 Post-delivery activities	7.5.1 Control of production and service provision
8.5.6 Control of changes	7.3.7 Control of design and development changes
8.6 Release of products and services	8.2.4 Monitoring and measurement of processes 7.4.3 Verification of purchased product
8.7 Control of nonconforming process outputs, products and services	8.3 Control of nonconforming product
9 Performance evaluation	New
9.1 Monitoring, measurement, analysis and evaluation	8 Measurement, analysis and improvement
9.1.1 General	8.1 General
9.1.2 Customer satisfaction	8.2.1 Customer satisfaction
9.1.3 Analysis and evaluation	8.4 Analysis of data
9.2 Internal audit	8.2.2 Internal audit
9.3 Management review	5.6 Management review
10 Improvement	8.5 Improvement
10.1 General	8.5.1 Continual improvement
10.2 Nonconformity and corrective action	8.3 Control of nonconforming product 8.5.2 Corrective action
10.3 Continual Improvement	8.5.1 Continual improvement

What is Risk?

The definition according to the DIS is the following:

Risk: effect of uncertainty on an unexpected result

Source: Shawn Rogers, "Auditing to ISO 9001:2015," *The Audit Report*, ASQ Audit Division, March, 2015, pp 3-4.

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?

Risk in the clauses - Process Approach, Leadership, Planning

- Introduction explains the concept of risk-based thinking (RBT)

- Clause 4 requires the organization to determine the risks which can affect its ability to meet the quality and business objectives

- Clause 5 requires top management to commit to ensuring Clause 4 is followed

- Clause 6 requires the organization to take action in identifying risks and opportunities

Risk in Clauses – Operation, Evaluation, Improvement

- Clause 8 requires the organization to implement processes that addresses risk

- Clause 9 requires the organization to monitor, measure, analyze, and evaluate risks and opportunities

- Clause 10 requires the organization 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 <u>your</u> 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

What should I do? (continued)

- ISO Guide 73, 2009 ("Risk management — Vocabulary") provided the definitions of terms related to risk management

- ISO 31000, 2009 ("Risk management — Principles and guidelines") may be a useful reference for organizations which want a more formal risk process, but is not obligatory

- ISO 31010, 2009 ("Risk Assessment Techniques") catelogued general techniques used to assess and analyze risk

What should I do? (continued)

- analyze 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 realize opportunities?*

What should I do? (continued)

- implement the plan – *take action*
- check the effectiveness of the actions – *does it work?*
- learn from experience – *continual improvement*

Identify what YOUR risks and opportunities are – it depends on context

Example

- *If I cross a busy road with many fast-moving vehicles, the risks may not be the same as if the road is small with very few moving vehicles.*

- *It is also necessary to consider such things as weather, visibility, personal mobility, and specific personal objectives.*

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Analyze and prioritize your risks and opportunities

Example Objective: I need to safely cross a road to reach a meeting at a given time.

- *It is UNACCEPTABLE to be injured or late.*

- *The OPPORTUNITY to quickly reach the other side is balanced against the likelihood of injury. It is more important that I make my meeting uninjured than to reach my meeting on time.*

- *I may find it ACCEPTABLE to delay arriving at the other side of the road by using a footbridge (skywalk) if the likelihood of injury by crossing the road directly is high.*

Figure 1: http://techybit.com/index.php/misc-skywalk/baltimore-skywalks2/

Figure 2: Baltimore VA Medical Center Skywalk

Analyze and prioritize your risks and opportunities (continued)

Example Objective: I need to safely cross a road to reach a meeting at a given time.

- *After analyzing the situation, the footbridge (or skywalk) may add time to my journey. With good weather and visibility, I can see that the road has few vehicles at this time.*

- *So I decide that walking directly across the road carries an acceptably low level of risk of injury (no visible vehicles from a distance) with an opportunity to reach my meeting on time.*

How can I avoid or eliminate the risk? How can I mitigate risks?

- *Example: I could eliminate risk of injury by using the footbridge (or skywalk) but I have already decided that the risk of crossing the road was acceptable.*

- *Next, I plan how to reduce the likelihood of injury and/or the effect of injury. I don't expect to control the effect of being hit by a motor vehicle hitting me. I can reduce the probability of being hit by a vehicle.*

- *I plan to cross at a time when there are no moving vehicles near me and so reduce the likelihood of an accident.*

- *I also choose to cross the road at a place where I have good visibility and can safely stop in the middle to re-assess the number of moving vehicles, further reducing the probability of an accident.*

Implement the plan – *take action*

Example

- *I move to the side of the road, check to see that there are no barriers to crossing and that there is a safe place to stand in the center of the moving traffic.*

- *I check that there are no vehicles coming.*

- *I cross half of the road and stop in the central safe place (traffic island or median). I assess the situation again and then cross the second part of the road.*

Learn from experience – *continual improvement*

Example

- *I repeat the plan over several days, at different times and in different weather conditions.*

- *This gives me data to understand that changing context (time, weather, quantity of vehicles) directly affects the effectiveness of the plan and increases the probability that I will not achieve my objectives (being on time and avoiding injury).*

- *Experience teaches me that crossing the road at certain times of day is very difficult because there are too many vehicles.*

Check the effectiveness of the actions – *does it work?*

Example

- *I arrive at the other side of the road unharmed and on time: this plan worked and undesired outcomes were avoided.*

In Summary
The main objectives of ISO 9001

- Gives confidence in the organization's ability to consistently provide customers with conforming goods and services

- Enhances 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

I need to ensure my organization . . .

- knows and understands the key changes and concepts

- plans to implement the new requirements

- stays informed as the revision proceeds

- takes full advantage of the revised ISO 9001

What is next?

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

www.iso.org/tc176/sc02/public

Where to get more information

http://asq.org/standards-iso-9001-2015.html

http://asq.org/knowledge-center/member-meeting-kit-iso-9001-2015.html

Members Viewing ASQ's Standards Channel can earn Recertification Units
http://videos.asq.org/asq-standards-channel

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Questions?

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