

ISO 9001:2015 Transition Presentation

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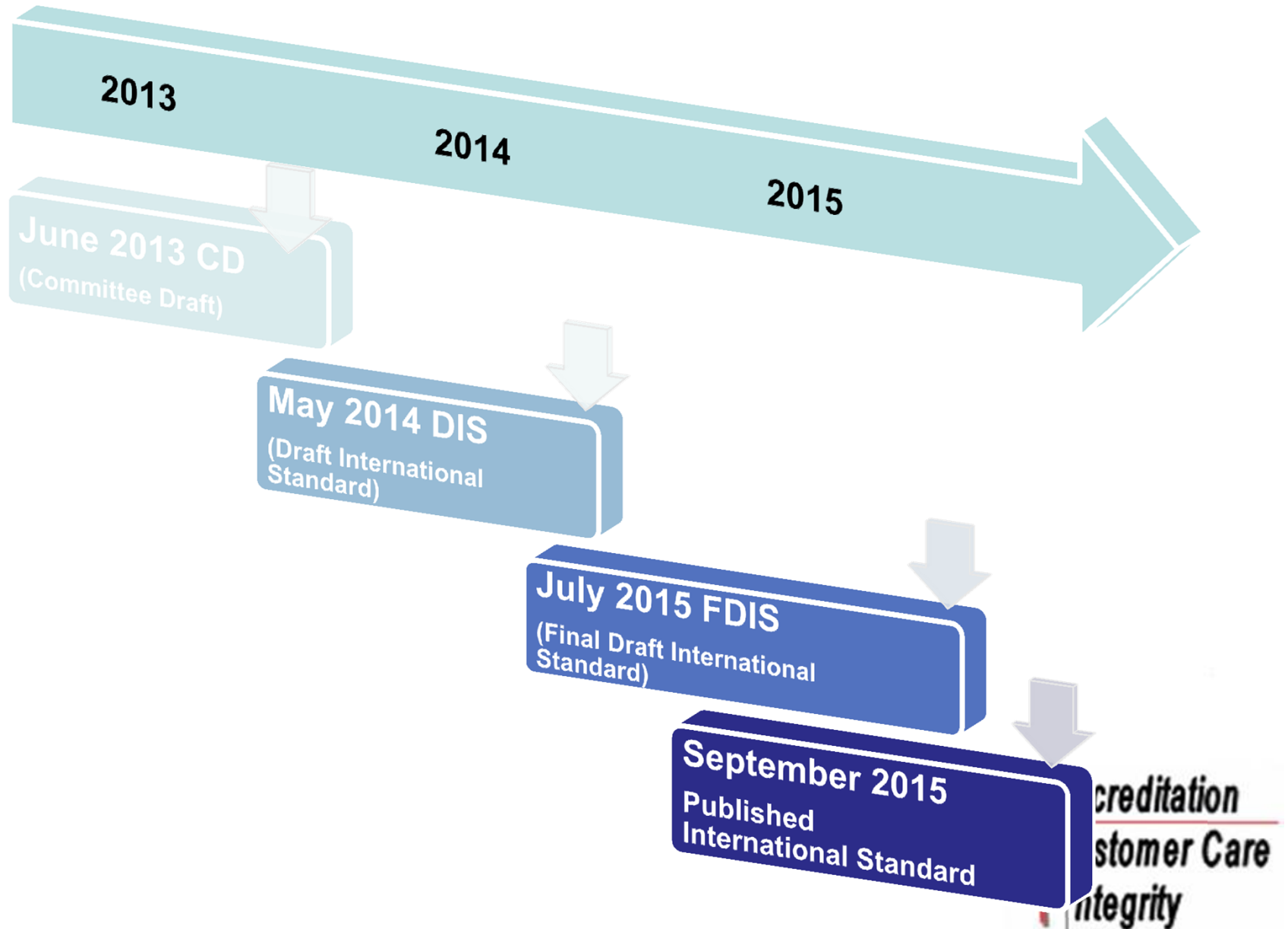
ISO Technical Committees TC 176



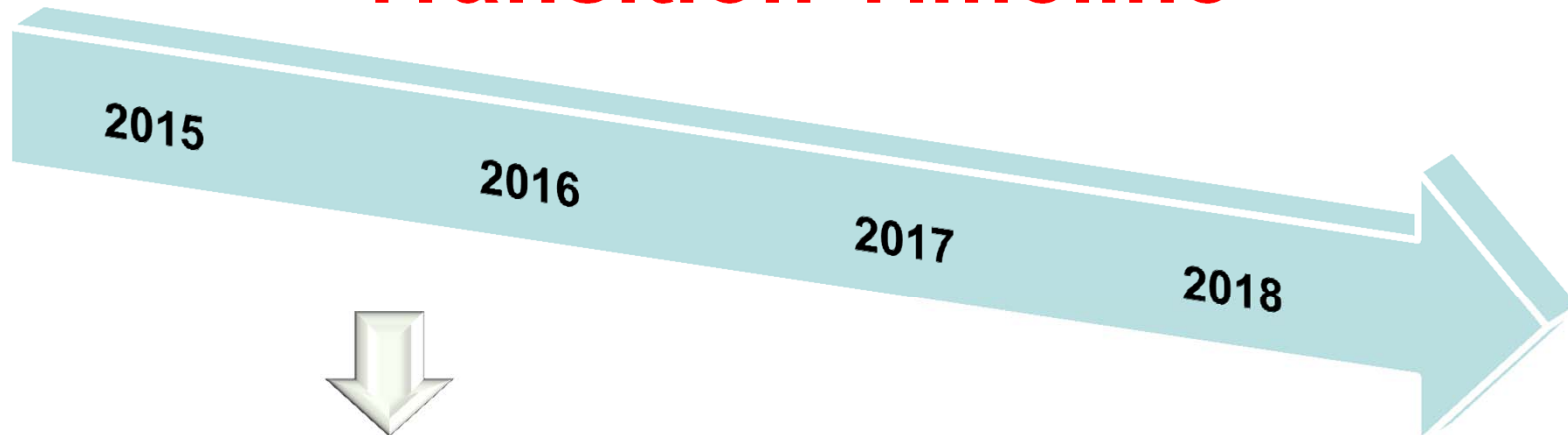
- “ISO” = International Organization for Standardization
- Standards development work is done by Technical Committees comprising experts nominated by their national standards body or liaison organization.
- “TC 176” = Technical Committee Number 176 for Quality Management and Quality Assurance
- “TC 176/SC 2” is the subcommittee responsible for ISO 9001



ISO 9001:2015 Timeline



ISO 9001:2015 Certification Transition Timeline



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

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Development of ISO9001

- 1987: Quality assurance
⇒ 20 elements
- 1994: Small revision
- 2000: Quality management
⇒ process approach ⇒
- 2008: Minor revision



Fig. 1 Quality Management Process Model

- 2015: Planned publication of the revised standard
⇒ New structure, including risk based thinking

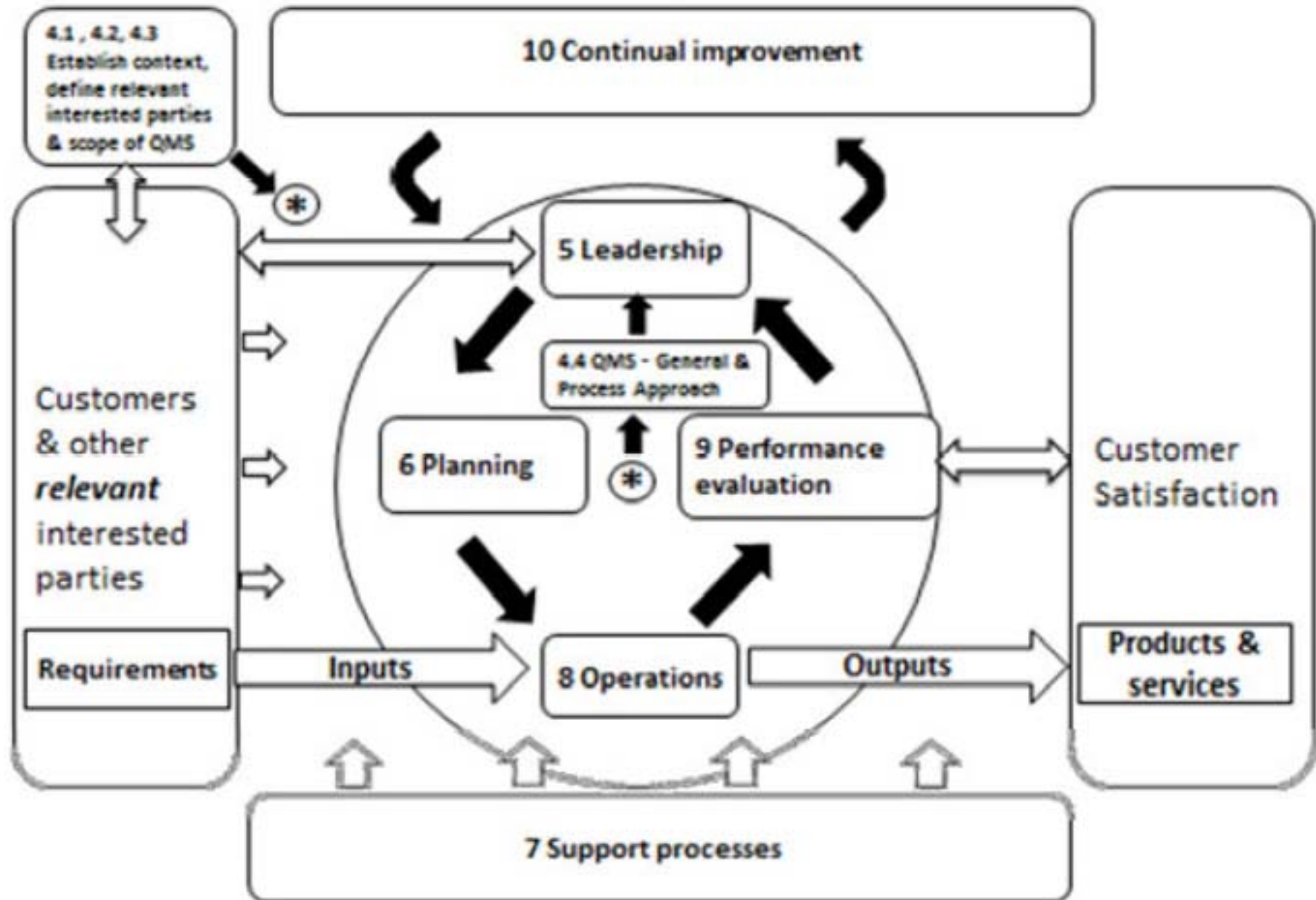
Core concepts of new standard

- Process approach
- Plan-Do-Check-Act cycle
- Risk-based thinking

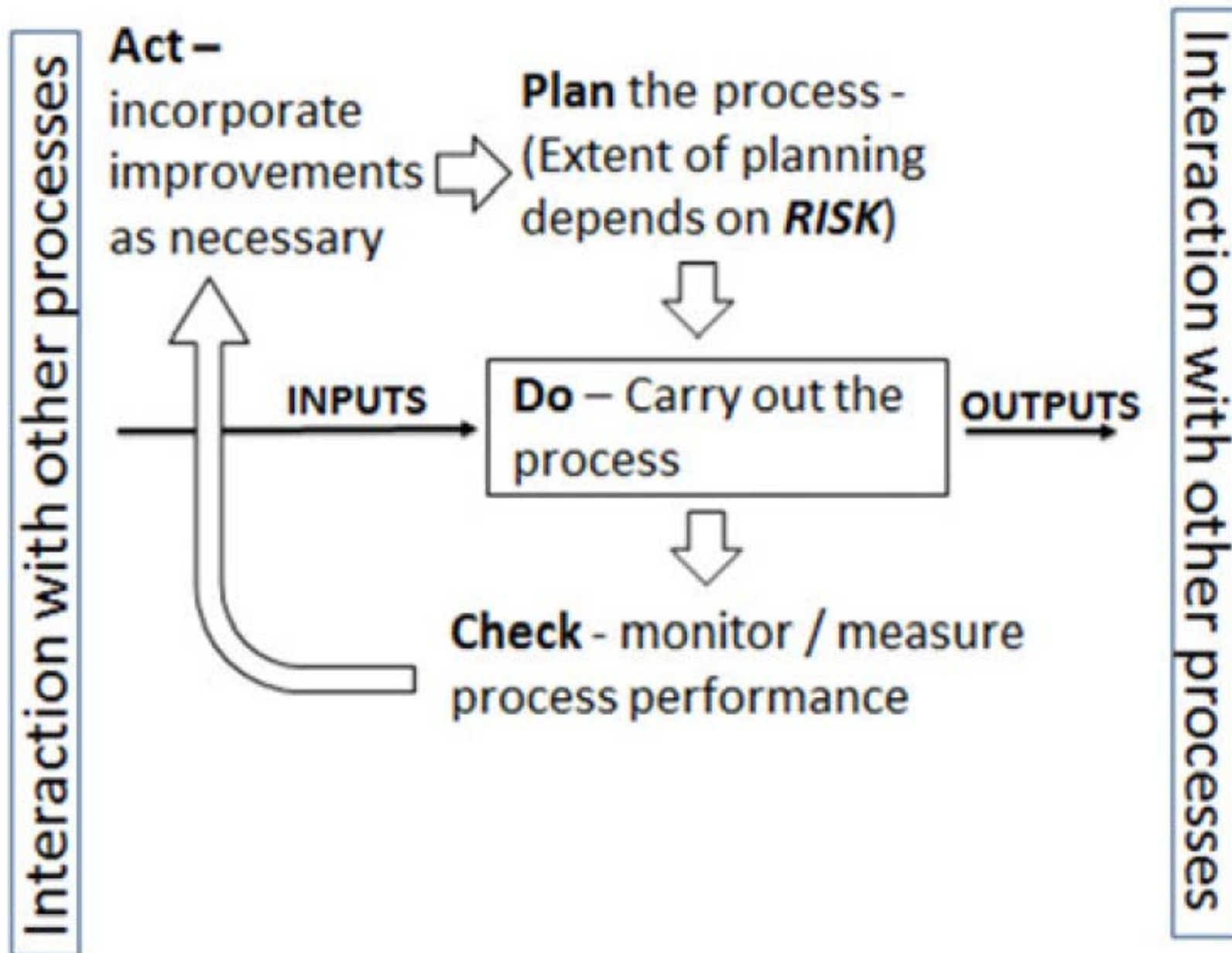


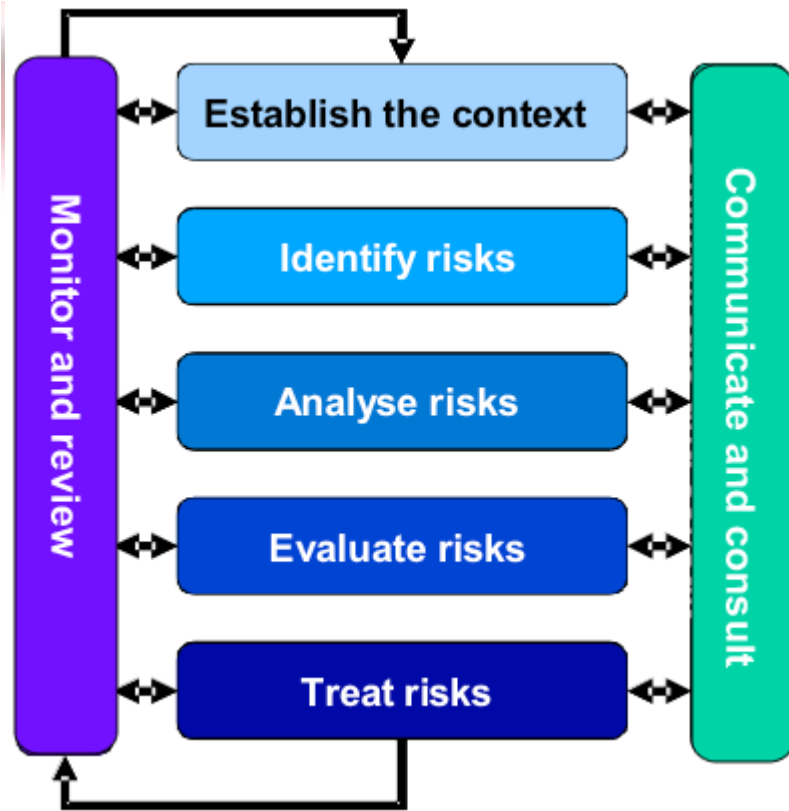
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Process approach



Plan-Do-Check-Act cycle





Risk-based thinking



What are the changes?

I DON'T CHANGE



I IMPROVE

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Basis for Quality Management

ISO9001:2015

- QMP 1: Customer focus
- QMP 2: Leadership
- QMP 3: Engagement of people
- QMP 4: Process approach

- QMP 5: Improvement
- QMP 6: Evidence-based decision making
- QMP 7: Relationship management

ISO9001:2008

- QMP 1: Customer focus
- QMP 2: Leadership
- QMP 3: Involvement of people
- QMP 4: Process approach
- QMP 5: System approach to management
- QMP 6: Continual improvement
- QMP 7: Factual approach to decision making
- QMP 8: Mutually beneficial supplier relationships



High level structure

ISO Directives Part 1:2012 “Annex SL”

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*

The high level structure and common text is public information and can be found in Annex SL of the www.iso.org/directives

ISO 9001:2008	ISO 9001:2015
0. Introduction	0. Introduction
1. Scope	1. Scope
2. Normative Reference	2. Normative Reference
3. Terms and Definitions	3. Terms and Definitions
4. Quality Management Systems	4. Context of the organisation
5. Management Responsibility	5. Leadership
6. Resource Management	6. Planning
7. Product Realisation	7. Support
8. Measurement, Analysis and Improvement	8. Operation
	9. Performance Evaluation
	10. Improvement

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Main changes



- i) An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach.
- ii) Fewer prescribed requirements.
- iii) Less emphasis on documents.

Quality manual? 6 mandatory procedures?

Main changes



- iv) Improved applicability for services.
- v) A requirement to define the boundaries of the QMS.
- vi) Increased emphasis on organizational context.
- vii) Increased leadership requirements.
- viii) Greater emphasis on achieving desired outcomes to improve customer satisfaction.

Structure of ISO 9001:2015

- 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 (Boundary)
 - 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 planning to achieve them
 - 6.3 Planning of changes
- 7 Support
 - 7.1 Resources (7.1.6 Organizational knowledge)
 - 7.2 Competence
 - 7.3 Awareness
 - 7.4 Communication
 - 7.5 Documented information

Structure of ISO 9001:2015

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

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

4. Context of the Organization

4.1 Understanding the organization and its context

The organization must determine external and internal issues relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its QMS



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4. Context of the Organization

4.1 Understanding the organization and its context

Example

Purpose: Steel Work Products Manufacturer

Intended outcome: Manufacture of steel work products including door, window and shutter

Internal issues

- Automation
- Workforce
- Design
- Capacity
- Company culture
- Innovation

External issues

- Customers
- Markets
- Competition
- Regulators
- Suppliers
- Utilities

4. Context of the Organization

4.2 Understanding the needs and expectations of interested parties

The organization must determine

- Interested parties relevant to the QMS, and
- The requirements of these interested parties

Interested parties may include:

- Direct customers
- End users
- Suppliers and partners
- Regulators
- Employees
- Owners/shareholders ²⁰



5.1 Leadership and commitment

Top management shall demonstrate leadership and commitment ...by:

Ensuring (i.e. **someone else can do it**)

- the quality policy and quality objectives are established for the QMS and are compatible with the strategic direction and the context of the organization;
- the quality policy is communicated, understood and applied within the organization;
- integration of the QMS requirements into the organization's business processes;
- the resources needed for the QMS are available;
- the QMS achieves its intended results

5.1 Leadership and commitment

Top management shall demonstrate leadership and commitment ...by:

Doing (i.e. *they must do it themselves*)

- taking accountability of the effectiveness of the QMS;
- promoting awareness of the process approach;
- communicating the importance of effective quality management and of conforming to the QMS requirements;
- engaging, directing and supporting persons to contribute to the effectiveness of the QMS;
- promoting continual improvement and innovation;
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility



6.1 Actions to address risks and opportunities

When planning the QMS, the organization shall consider the issues ... in 4.1 and the requirements ... in 4.2 and determine the risks and opportunities that need to be addressed to

- Assure the QMS can achieve its intended outcome(s)
- Prevent or reduce undesired effects
- Achieve improvement

The organization must plan:

- Actions to address these risks and opportunities, and how to
 - integrate and implement the actions into its QMS processes and
 - evaluate the effectiveness of these actions

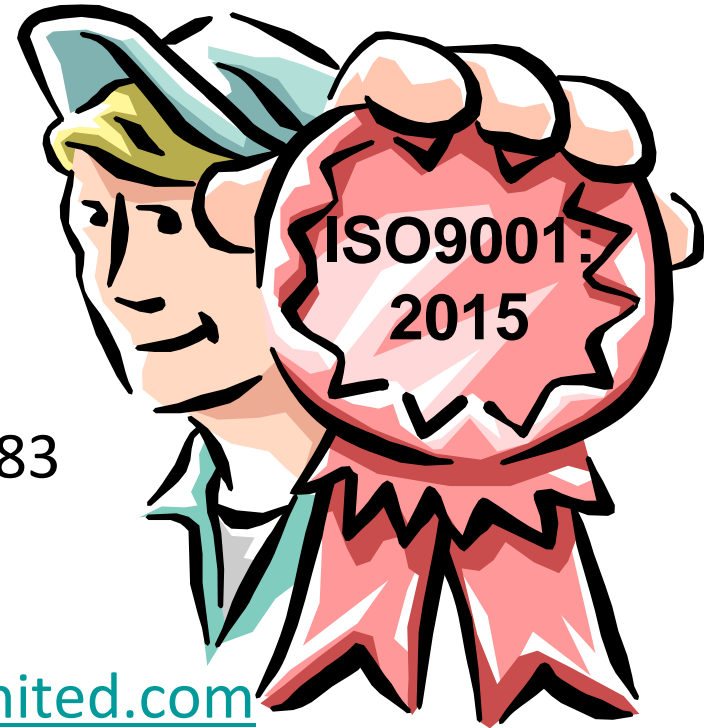
7.1.6 Organizational knowledge

- The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.
- This knowledge shall be maintained, and made available to the extent necessary.
- When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.



- ISO is aligning its portfolio of management system standards
- ISO 9001 is undergoing a “major revision”
- At DIS stage at the moment – scheduled publication in Sep 2015
- Significant changes in structure and clause sequence
- Process Approach + PDCA + Risk-based thinking
- Some new requirements
- Start preparing for the transition NOW!

*Any Questions?
Thank You!*



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