

ISO 9001:2015

PHILOSOPHY AND INTRODUCTION



- * Maintain relevance in the marketplace
- * Integration of management system standards (common structure, text, terminology) –Annex SL
- * Increase variety of business users (Service industries, office environments)
- * Address increased complexity of business environment
- * Less emphasis on documents and instead alignment with ERP systems
- * Greater emphasis on results to improve customer satisfaction; add value; less prescriptive = performance based

* Revision objectives

- * Designed for fully integrated management systems – based on Annex SL – utilize a single management system (Appendix 3 of ISO/IEC Directives, Part 1 Annex SL)
- * Risk-based thinking throughout all processes
- * PDCA/Process-based implementation maintained and enhanced

* **Philosophy**

- Change in numbering structure of the standard
- Define the Context of the organization
- Plan the QMS (including Risk), related to the business
- Leadership emphasis / Leveraging management review process
- Change Management
- Knowledge Management
- “Documented information” and “Retained information”
- No quality manual or Management Representative required
- Improved PDCA philosophy
- Preventive Action removed and implied with Risk-based thinking methodology through-out all processes

*** In a nut shell – new twists**

- * Customer-related process
- * Purchasing process
- * Design and Development process
- * Resources
- * Production and Servicing process
- * Calibration
- * Corrective action process
- * Internal Audit Process
- * Nonconforming product process
- * Customer Satisfaction
- * Analysis and evaluation
- * Improvement

* **Minor Changes (look for risk references)**

- * Product is now **Products and Services**
- * Purchased product is now **Externally provided product and services**
- * Supplier is now **External provider**
- * Outsourcing is now **External Provision**
- * Document Control and Record Control is now **Documented information and Retained information**

* Terminology

- * ISO 9000 – Fundamentals and Vocabulary
- * ISO 9004 – Managing for sustained success of an organization - Guidance document
- * ISO 31000 – Risk Management Principles and Guidelines

* Referenced Documents

* Annex A (ISO 9001) – Clarification of new structure, terminology and concepts

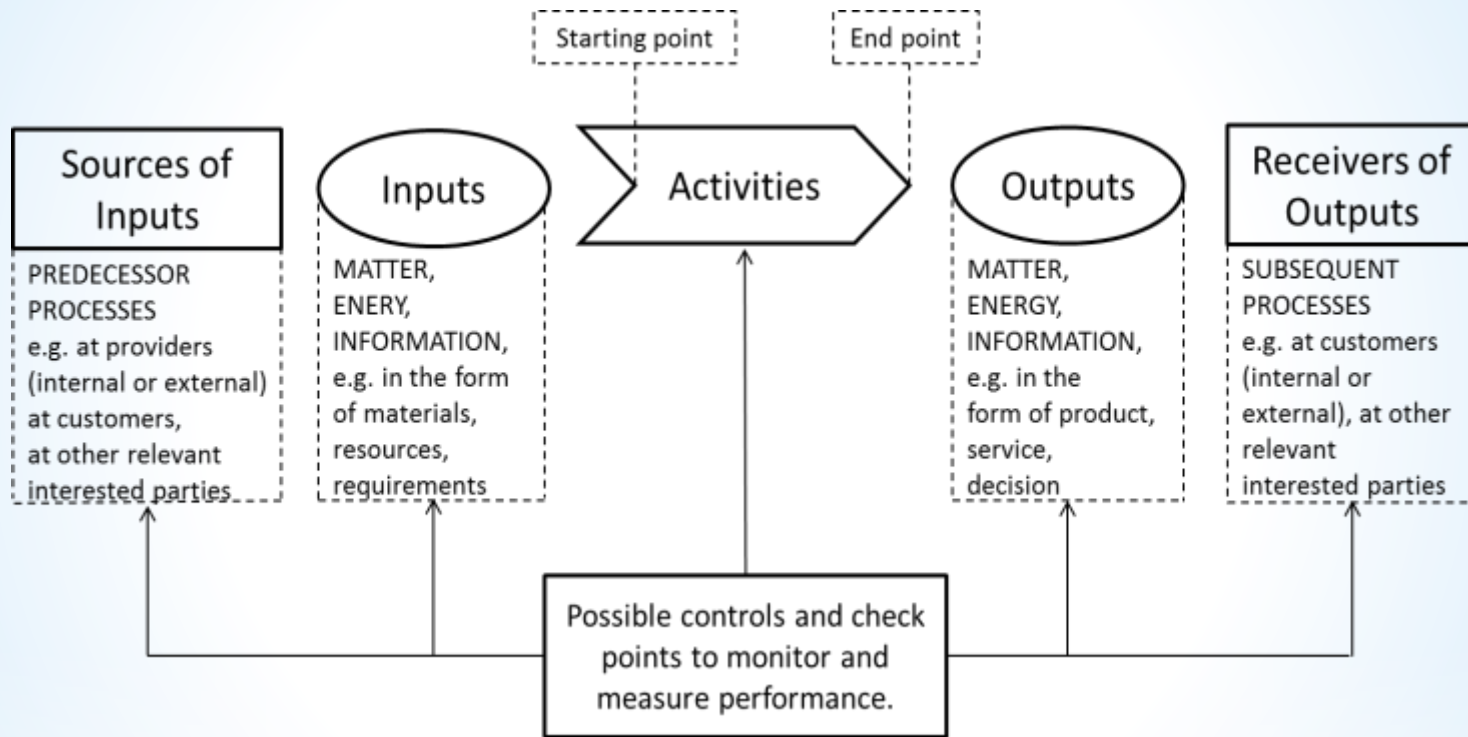
- Structure and Terminology
- Products and Services
- Understanding the needs and expectations of interested parties
- Risk-based thinking
- Applicability
- Documented information
- Organizational knowledge

* Annex B (ISO 9001) – Other International Standards on QMS

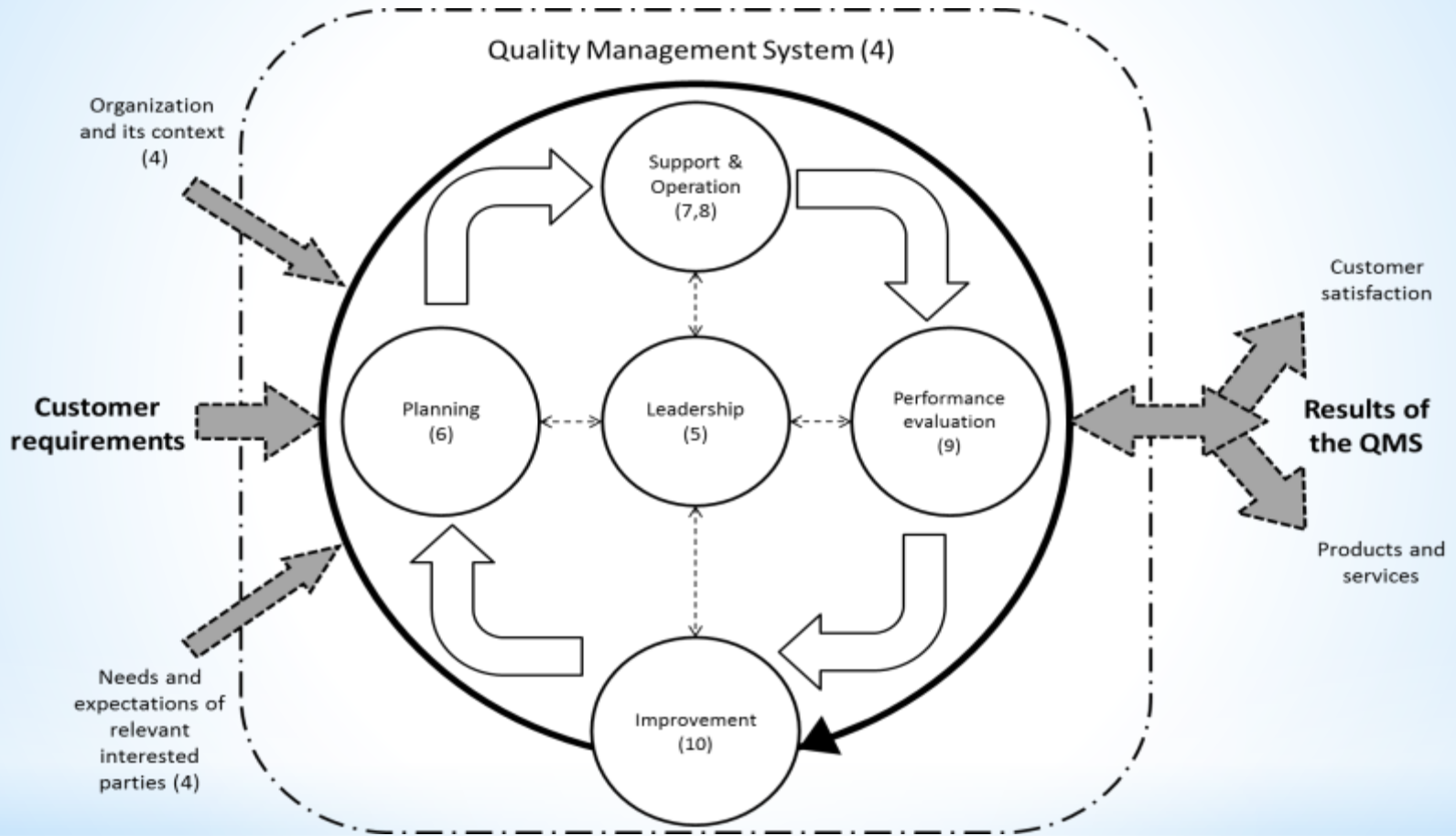
* Annexs

- * New Plan-Do-Check-Act
- * Risk-based thinking defined
- * Intent is harmonization with other ISO management systems.
- * Appendix 3 of ISO/IEC Directives, Part 1 **Annex SL**

*** Read the Introduction**



* Introduction: Process Model



*** Introduction: PDCA – applied to all processes**

- * Clause 4 – Context of the organization
- * Clause 5 – Leadership
- * Clause 6 – Planning for the quality management system
- * Clause 7 – Support
- * Clause 8 – Operation
- * Clause 9 – Performance Evaluation
- * Clause 10 – Improvement
- * See handout Correlation of Clauses previous/new standard.
- * www.iso.org/iso/176/sc02/public

 **New Structure**