RISK BASED THINKING FLOWS THROUGH ISO 9001:2015 DRIVING A FASTER, BETTER ORGANIZATION.
STRUCTURAL CHANGES

- High Level Structure (All ISO Mgt Systems)
  - QMS, EMS, IT security etc.
  - standard core text and structure

- Inclusion of services

- Organizational context

- Fewer prescribed requirements

- No Automatic Exclusions

- Management Review moved to ‘Monitoring’
CONTENT CHANGES

- Risk-based thinking
  - replaces preventive action
- ‘Documented information’
  - replaces ‘documents and records’
- ‘External provision’
  - Replaces ‘Purchasing and Outsourcing’
- Increased ‘Leadership’ requirements
- Management representative
  - Title removed
ISO 9001:2008 FLOW

5. Management Responsibility
- 5.1 Management Commitment
- 5.2 Customer Focus
- 5.3 Quality Policy
- 5.4 Planning
- 5.5 Responsibility, Authority and Communication
- 5.6 Management Review

6. Resources Management
- 6.1 Provision of Resources
- 6.2 Human Resources
- 6.3 Infrastructure
- 6.4 Work Environment

7. Service Realization
- 7.1 Planning of service Realization
- 7.2 Customer Related Processes
- 7.3 Design and Development
- 7.4 Purchasing
- 7.5 Service Operations
- 7.6 Control of Monitoring and Measuring Devices

8. Measurement, Analysis and Improvement
- 8.1 General (Planning)
- 8.2 Monitoring and Measurement
- 8.3 Control of Non Conforming service
- 8.4 Analysis of Data
- 8.5 Improvement
ISO 9001:2015 STRUCTURE

4 Context of the Organization

Plan

5 Mgt Responsibility

5 Leadership
5.1 Leadership commitment
5.2 Quality policy
5.3 Roles, responsibilities

6 Planning
6.1 Risks and opportunities
6.2 Planning to achieve objectives
6.3 Planning of changes

Act

8 Meas’m’t Analysis Imp’t

9 Performance Evaluation
9.1 Meas’m’t analysis evaluation
9.2 Internal audit
9.3 Management review

10 Improvement
10.1 General
10.2 Nonconformity + C/A
10.3 Continual improvement

Do

7 Product Realization

8 Operations
8.1 Planning and control
8.2 Product and service reqts
8.3 Design and development
8.4 External provision
8.5 Production/service provision
8.6 Release of product/service
8.7 Control Nonconforming Output

Check

6 Resources Mgt

7 Support
7.1 Resources
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented information
A System is ‘A Set of inter-related and interacting elements
A Management System is a Network of People, Process and Technology
4 CONTEXT OF THE ORGANIZATION

- 4.1 The organization and its context
  - Strategic issues

- 4.2 Needs/Expectations interested parties
  - Not just customers

- 4.3 Scope of the QMS
  - Define Boundaries - Exclusions

- 4.4 QMS and its processes
  - As 9001:2008 §4.1
## 4.1 CONTEXT ISSUES FOR EXTERNAL RISK

<table>
<thead>
<tr>
<th>Context Issues (Examples)</th>
<th>Impact (1-5)</th>
<th>Probability (1-5)</th>
<th>Detectability (1-5)</th>
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PROCESS MAP FOR INTERNAL RISK POINTS
SOME CAUSES OF INTERNAL RISK

- Low Competency
- Frequent Change of Persons
- Task Performed Infrequently
- Complex Process
- Old Equipment (i.e. Failure) or
- Unclear Customer Requirements?
5 LEADERSHIP

- 5.1 Leadership and commitment
  - Accountability, awareness, engagement

- 5.2 Quality policy
  - similar to 9001:2008. + ‘applied’

- 5.3 Roles, responsibilities and authorities
  - QMS Reporting (Mgt Rep title removed)
6.1 Address risks and opportunities
   - QMS ability to achieve intent, mitigate risk.

6.2 Objectives + planning to achieve them
   - Measurable, link to policy, updated
   - Resources to meet objectives, evaluate results

6.3 Planning of changes
   - Purpose of change
   - Resource and responsibility
6.1 CONTROLLING AREAS OF RISK

ISO 9001:2015 requires *processes are controlled* (See 8.5.1)
6.2 CASCADE OF OBJECTIVES

- Policy 5.2
- Planning 6.2
- Awareness 7.3
PLANNING TO ACHIEVE OBJECTIVES (6.2.2)

<table>
<thead>
<tr>
<th>Objective</th>
<th>What is to be done</th>
<th>Resources needed</th>
<th>Who is responsible</th>
<th>When it will be done</th>
<th>How results will be evaluated</th>
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7 SUPPORT

- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documents
7 SUPPORT; 7.1 RESOURCES

7.1.1 General
  • Resource constraints, external resources

7.1.2 People
  • Provide necessary persons

7.1.3 Infrastructure
  • Information and communication technology

7.1.4 Environment for operating processes
  • As 9001:2008 §6.4

7.1.5 Monitoring and measuring resources
  • Calibration.

7.1.6 Organizational knowledge
  • Knowledge acquisition and management
7.1.6 ORGANIZATIONAL KNOWLEDGE

- determine knowledge for process operation
- maintain knowledge, make it available.
- address changing needs and trends,
- how to acquire additional knowledge.

consider;

- internal sources
  - learning from failure and success,
  - experts within the organization
- external sources
  - standards, academia, conferences,
  - customers or providers
7.2 COMPETENCE

- Competence;
- The ability to apply knowledge to achieve intended results

- determine the necessary competence of person(s)
- take actions to acquire competence,
- evaluate the effectiveness of actions taken:
- actions can include,
  - training, mentoring, hiring competent persons.
- retain documented evidence of competence.
7.5 DOCUMENTS

7.5.1 General

The extent of documents for a QMS can differ due to:
- organization size, process complexity, competence.

7.5.2 Creating and updating

Ensure identification, review and approval.

7.5.3 Control of documents

- ensure availability, confidentiality
- address distribution, access, storage and preservation,
- legibility; control of changes and disposition.

Documents of external origin shall be controlled.
NEW WORDING – FOCUS ON INFORMATION

Document → Maintain Documented Information

Record → Retain Documented Information
DOCUMENTATION REQUIREMENTS

ISO 9001:2015 requires

‘documented information’ to be maintained;
  • Defining boundaries and applicability of QMS (see 4.3)
  • Defining the scope of the QMS (see 4.3)
  • Justifying any requirement not applicable (see 4.3)

Organization decides

which supporting information to document;
  • Supporting the operation of the organizations processes (See 4.4.2).
  • Necessary for the effectiveness of the QMS. (see 7.5.1)
  • Describing the interaction between the processes (See 4.4.1)

demonstrate that processes are controlled (See 8.5.1).
8 OPERATION CLAUSES (ISO9001:2008 §7)

- 8.1 Operational planning and control
- 8.2 Requirements for products + services
- 8.3 Design and development
- 8.4 Externally provided products and services
- 8.5 Production and service provision
- 8.6 Release of products and services
- 8.7 Control of nonconformity
9 PERFORMANCE EVALUATION
CLAUSES

- 9.1 Monitoring, measurement, analysis, evaluation
  - 9.1.1 General
  - 9.1.2 Customer satisfaction
  - 9.1.3 Analysis and evaluation

- 9.2 Internal audit

- 9.3 Management review
FEED RESULTS TO MANAGEMENT REVIEW

Exec Summary

Follow-up Internal Audit Monitors C/A

Management Review

Problems or Projects for Action with Resources Agreed

Utilize Resources
10 IMPROVEMENT

10.1 General
• Similar to 9001:2008 §8.5.1

10.2 Nonconformity and corrective action
• Similar to 9001:2008 §8.5.2
• Addition of complaints

10.3 Continual improvement
• Link to analysis, evaluation, management review
• Address underperformance
THE IMPROVEMENT CYCLE

- Internal audit (9.2)
- Process and Service Monitoring (9.1)
- Customer Feedback (9.1.2)
- Improvement (10.1)
- Executive Summary (5.3)
- Management Review (9.3) (Allocate Resources) 7.1)
ISO 9001:2015 CERTIFICATION TRANSITION TIMELINE

September 2015 start of 3 years transition period to September 2018

September 2015
Published International Standard
## ISO 9001:2015 Implementation Timetable

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<td>Strategic Plan</td>
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<td>Refine Procedures</td>
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<td>System Adjustment</td>
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<tr>
<td>Main Audit</td>
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THANK YOU

Questions?

Presented by
Peter Merrill
www.questmgt.com