Fitting ISO 9001:2000 into a 20 Element Quality System

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Presented by
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Agenda

- Brief summary of new standard
- How to find the Deltas
- Mapping requirements & Strategies
- Revised Table of Contents
1994 versus 2000

1. Management responsibility
2. Quality system
3. Contract review
4. Design control
5. Purchasing
6. Statistical techniques

4. QMS requirements
5. Management responsibility
6. Resource management
7. Product and/or service realization
8. Measurement, analysis and improvement
The 1994 ISO Model

Typical life-cycle phases of a product (Source ISO 9001-1994)

- Purchasing
- Product design & development
- Production
- Verification
- Packaging & storage
- Sales & distribution
- Installation & operation
- Servicing
- Disposal
- Marketing & market research
ISO/CD 9001:2000 Process Model

Fig. 1 Quality Management Process Model
How to find the Deltas

- Copy of ISO/CD2
- Develop Side-by-Side table
- Forward engineer
- Reverse engineer
- Summarize results
- Fit into 20 element QS
<table>
<thead>
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<tbody>
<tr>
<td>5</td>
<td>Management responsibility</td>
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<tr>
<td>5.6.2</td>
<td>Responsibility and authority</td>
<td>Roles and their interrelations, responsibilities and authorities shall be defined in order to facilitate effective quality management and shall be communicated to relevant levels of the organization.</td>
<td>4.1.2.1</td>
<td>Added “communicated”</td>
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<tr>
<td></td>
<td>Organizational freedom necessary to perform tasks that affect quality shall be defined.</td>
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<td>Sentence a) to e) summarized as “tasks.” Words in 9004</td>
<td>R</td>
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</table>
5 Management Responsibility

- Customer requirements [New]
- Legal requirements [New]
- Policy [Expanded]
- Planning [Reduced]
- QMS [Expanded]
- Management Review [Expanded]
5.7 Management review [Expanded]

- Requires a procedure
- Added review for adequacy
- Review focus on QMS not standard and need for changes to QMS
- List a) to f) - more prescriptive of what to review (input)
- List g) to i) - list of required review outputs
- Results of reviews recorded vs. records of reviews maintained
6 Resource Management

- Human Resources [Expanded]
- Information [New]
- Infrastructure [New]
- Work environment [New]
7 Product and/or Service Realization

- Customer-related processes [Expanded]
- Design and development [Minor]
- Purchasing [Reduced]
- Production and services operations [Reduced]
8 Measurement, Analysis and Improvement

- Measuring and monitoring [New & expanded]
  - System, customer, processes, products & services
- Control of nonconformity [Revised]
- Analysis of data for improvement [Revised]
4.1 Management responsibility

- **Add:**
  - 5.2 Customer requirements
  - 5.3 Legal requirements
  - 5.6.4 Internal communication (add to quality policy)

- **Expand:**
  - 5.4 Quality policy
  - 5.5.1 Objectives
  - 5.6.3 Management representative
  - 5.7 Management review (requires a procedure, add adequacy, list of review items, actions from review, audits, resource needs, and records)
4.1 Management responsibility

- Reduce:
  - 5.6.2 Responsibility and authority
  - 6.2.2 Move 4.1.2.2 Resources to new 4.18 Resources (Training)
4.2 Quality (Management) System

- **Expand:**
  - 4 QMS requirements (place to shift to QMS and incorporate process management model)
  - 5.5.2 Quality planning (organizational change)

- **Reduce:**
  - 5.5.2 Quality planning (list)
  - 5.6.5 Quality manual (exception reduction in scope)

- **Add:**
  - 7.1 which is the framework for process management (might also fit in 4.9 Process control)
4.3 Contract review (Customer-related processes)

- Add 7.2.1 Customer requirements, e.g.,
  - Completeness
  - Implied requirements
  - Regulatory & legal
  - Availability, delivery & support
- Change Contract review to 7.2.2 Review of customer requirements
  - Add step for follow-up actions
- Expanded Note 9 & now required under 7.2.3 Customer communication
  - Inquiry and order handling
  - Customer complaints
  - Response to performance
4.4 Design control (Design and development)

- In general, structure is the same!
- Some rewording:
  - Managed vs. defined
  - Legal vs. statutory
  - Customer vs. user
- Some additions:
  - Environmental
  - Follow-up
- Some changes
  - Design approved vs. reviewed
  - V&V NOTES dropped

- Expanded control of changes:
  - Interactions between
    - Elements of design
    - Component parts
    - Existing products and/or services
4.5 Document control (Control of documents)

- Add:
  - Shift from relate to standard to required for operation of QMS
  - Legible, readily identifiable and retrievable

- Reduced:
  - Review and authorized personnel

- Eliminated:
  - Term Data
  - For changes, same function/organization
4.6 Purchasing

- **Wording changes:**
  - Organization vs. supplier
  - Subcontractor vs. Supplier
  - Dropped Data
  - Management system vs. quality system

- **Expanded:**
  - Add follow-up to evaluation of supplier

- **Reduced:**
  - Explanatory wording for control of subcontractor
  - Dropped data list
  - Dropped review & approval
4.7 Control of customer-supplied product (Customer property)

- 7.5.3 More general statement of requirements
- Added identification of property
4.8 Product identification & traceability (Identification & traceability)

- 7.5.2 combines 4.8 and 4.12 (Inspection and test status)
- Changed list to simply process
- Added component parts
4.9 Process control (Process management or Production & service operations)

- Expanded:
  - 7.1 General requirements (framework for process management, could go in QMS)
  - 7.5.1 Shifts Process control to Production & service operations
  - 7.5.1 Links to measuring & monitoring equipment and monitoring & verification activities
  - 7.5.1 Added method for release
  - 7.5.5 Validation of processes (special processes)
4.9 Process control (Process management or Production & service operations)

- Word changes:
  - Characteristics vs. process parameters and workmanship
  - Conformity of product and/or services vs. directly (and adversely) affect quality
  - Validated vs. qualification
  - Dropped process capability
4.10 Inspection and testing (Measuring and monitoring of product and/or services)

- 7.4.3 Verification of purchased products and/or services replaces 4.10.2 Receiving inspection and testing

- 8.2.3 Measuring and monitoring of product and/or services replaces nearly all of this 4.10
4.10 Inspection and testing (Measuring and monitoring of product and/or services)

- Change 4.10 to “Measuring, monitoring and analysis” and expand to include:
  - 8.2.1 System performance
    - 8.2.1.1 Customer satisfaction
  - 8.2.2 Maintain and improve processes
  - 8.2.3 Characteristics of products and/or services
  - 8.4 Analysis of data for improvement (could be 4.20)
4.11 Control of inspection, measuring & test equipment

- 7.6 structure basically the same
- Wording changes:
  - Monitoring and measuring vs. inspection, measuring and test equipment
- Details and lists eliminated
- Test software or comparative references changed and points to design/development clause
4.13 Control of nonconforming product (Control of nonconformity)

- **8.3.2 Changed to accommodate services**
  - Dropped segregation
  - Customer representative

- **Wording changes, e.g.,**
  - Corrected or adjusted vs. rework
  - Accepted under concession vs. repair or UAI
  - Verification vs. reinspect
  - Resolving vs. dispositioning
4.14 Corrective & preventive action (Improvement)

- Add procedure on how continual improvement will be facilitated

8.5.2 CA:

- Wording changes:
  - Identification vs. handling and reporting
  - Determination vs. investigation
  - Evaluation vs. determination
  - Implementation vs. CA taken
  - Record action taken vs. results of investigation
4.14 Corrective & preventive action (Improvement)

8.5.3 PA:
- Added
  - Prevent occurrence
  - Record results
- Dropped sources of information list
- Wording changes:
  - Identify vs. detect
  - Determination vs. analyze
  - Implementation vs. initiative
  - Review vs. application of control
4.15 Handling, storage, packaging, preservation, and delivery

- 7.5.4 Handling, packaging, storage, preservation and delivery
  - Summarized into “do not affect conformity with product and/or services requirements”
  - Product release and/or service delivery moved from 4.10.4 Final inspection and testing
- Could UAI or move to 4.9
4.16 Quality records (Control of records)

- Reduced:
  - Eliminated process and prescriptive requirements, e.g.,
    - Identification, collection, indexing, access,…
    - … retained in such a way that they are readily retrievable…
4.17 Internal Quality Audits (Internal audits)

- Shift to QMS & ISO vs. “planning arrangements”
- May audit for improvement
- Added previous audits
- Procedure to cover scope, frequency, etc.
- Shift independence to “performed the work”
4.18 Training (Resource management)

- **Human Resources**
  - Shift assignment from “trained” to “competent”
  - Replaced list with “responsibilities defined in QMS”
  - Expands on “policy is understood”
  - Evaluate training
  - Records of education, training, skills, and experience

- **Information**
  - Develop procedure for managing information

- **Infrastructure**
  - Put infrastructure under QMS

- **Work environment**
  - May fit here or in 4.9 Process control
4.19 Servicing & 4.20 Statistical Techniques

- 7 Product and/or service realization
  - If used, integrate element 7

- 8 Measurement, analysis and improvement
  - 4.20 Greatly reduced
  - Dropped process capability
  - Use as base for
    - 8.1 general requirements for measure & analysis
    - 8.2.2 M&M of processes
  - If not used today, roll into 4.10
Quality Manual TOC

4.1 Management Responsibility
4.2 Quality Management System
4.3 Customer-Related Processes
4.4 Design and Development
4.5 Control of Documents
4.6 Purchasing
4.7 Customer Property
4.8 Identification & Traceability
4.9 Production & Service Operations
4.10 Measuring, Monitoring & Analysis
Quality Manual TOC

4.11 Control of Measuring & Monitoring Devices
4.12 Control of Nonconformity
4.13 Improvement (CI, CA & PA)
4.14 Control of Records
4.15 Internal Audits
4.16 Resource Management

Note - Originals Deleted:
4.10 Inspection and testing (significantly modified)
4.12 Inspection and test status
4.15 Handling, storage, etc.
4.19 Servicing
4.20 Statistical techniques