ISO 9001:2015 Management Overview of Changes

PRESENTED BY PQA INTERNATIONAL

ON 6/14/16 AND 6/15/16

Who is PQA?

- Certifying body for ISO 9001, ISO 13485, ISO 14001, and OSHAS 18001
- In business since 1984, accredited to ISO 17021 since 1990
- Serve clients of 2-200 employees in the USA, Canada, Mexico and the UK
- Training, assessment and certification for over 30 years
- Here to serve you!

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Overview Outline

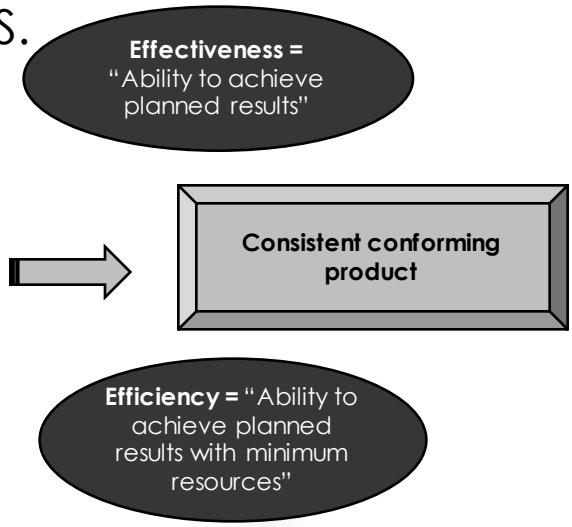
- Background to the revision
- New structure
- New requirements / clarifications
- Transition planning
- A brief overview, for top management, not full text of the standard or all requirements.
- Not sufficient for internal auditor transition training!
- We'll send you a copy of the slides

Background to ISO 9001

- 9001 is designed to be a generic quality management system standard
  - Can be used in any company (Private and public)
  - Over 1.1 million certifications worldwide in 186 countries. (@33,000 in the US, 40,000 in the UK, 342,000 in China)
  - Not limited to manufacturing. Growing use in service and knowledge industries
- Certification is intended to be the result of a well-implemented QMS

Background to ISO 9001

- CAUSE & EFFECT in a QMS.
  - Committed top management
  - Competent people
  - Management review & strategy
  - Internal audits
  - Calibrated equipment
  - Monitoring & measurement
  - Work instructions etc
  - Documented information
  - Etc, etc, etc,



Background to ISO 9001

- 3 core concepts
  - Identify the **processes** needed to achieve planned results
  - Continually monitor the **risks** (Risk based thinking, cause & effect)
  - Manage the processes using **PDCA** (Plan-Do-Check-Adjust)
    - Plan: What to do? (objectives address risks) & How to do it? (procedure)
    - Do: Follow the plan (work instructions, retained info/records of what happened)
    - Check: Monitor & measure results (did things happen according to plan?)
    - Adjust: How do we improve next time? (review objectives, plans, risks, & results)

What To Look For in the 2015 Revision

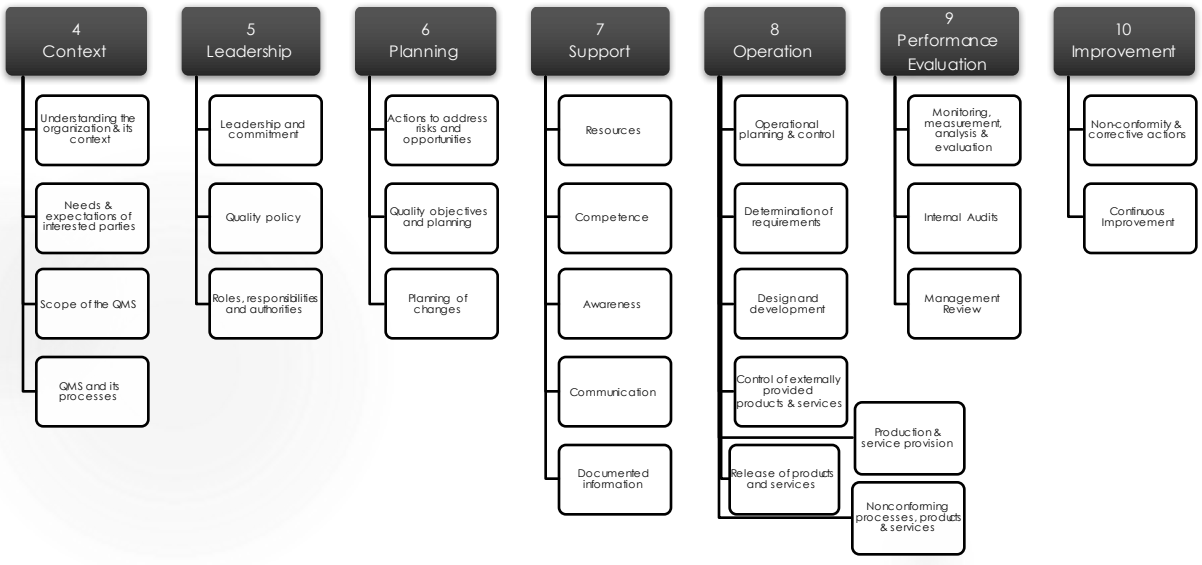
- New Structure
- New Requirements / Clarifications
- Unchanged Requirements
- Deleted Requirements
- Transition deadline: September 2018

New Structure

9001:2008 vs. 9001:2015

9001:2008	9001:2015
0 Introduction	0 Introduction
1 Scope	1 Scope
2 Normative references	2 Normative references
3 Terms & definitions	3 Terms and definitions
4 Quality Management System	**4 Context of the Organization**
5 Management Responsibility	**5 Leadership**
6 Resource Management	**6 Planning**
7 Product Realization	**7 Support**
8 Measurement Analysis & Improvement	**8 Operation**
	9 Performance Evaluation
	10 Improvement

New Structure

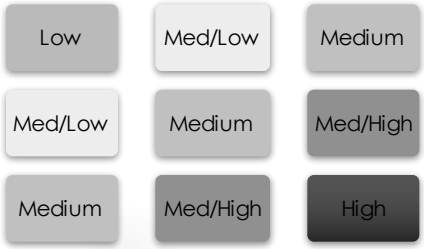


Why the New Requirements / Clarifications

- More flexibility in documentation
- Increased emphasis on achieving desired process results, for the company and customers
- Explicit requirement for risk-based thinking to support and improve process approach
- Clarified requirements for leadership engagement
- Increased emphasis on planning
- Emphasis on supply chain management

New Requirements/Clarifications

- 0.3.3 Plan and implement actions to address risks & opportunities
- **RISK BASED THINKING** integrates strategy & systems. Applying risk-based decision making at every level and in every process allows resources to be better allocated.
- Risk = "The effect of uncertainty on an expected result"
- Risk isn't always negative – opportunities are a positive risk (new customers/products/markets, less waste, improved productivity)
- **Risk Evaluation** needs a structure of qualifications for each level, and criteria for defining when action is needed. Grading can be Quantitative (where Likelihood x Severity = Risk level) or Qualitative (high, medium, low)



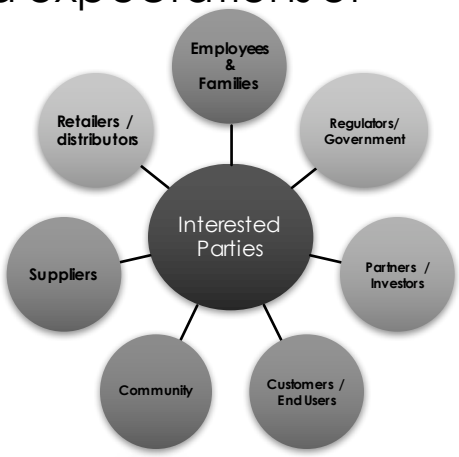
New Requirements / Clarifications

- 4.1 Understanding the organization & its context:
- Define business environment: Intended results of the QMS, plus relevant internal and external issues that affect your ability to achieve those results: Basic strategic planning.

External Issues	• Market (local, national, international) • Competitors, Cultural, Legal, Social, Technology, Economic, Workforce
Internal Issues	• Culture, Values • Knowledge, Performance
Intended results of QMS	•Company strategic objectives •KPIs and metrics used to evaluate performance

New Requirements / Clarifications

- 4.2: Understanding the needs and expectations of <u>relevant</u> interested parties
  - The intent: anticipate current and future needs/expectations; could lead to **identifying opportunities for improvement or innovation**
  - "Relevant" includes customers and all others affected by the company and its products/services.
  - The organization is required to <u>monitor</u> and <u>review</u> this information about interested parties and their requirements



Revised Requirements

- 4.3 Scope of the QMS
  - Must consider the **internal and external issues** (4.1)
  - Must consider **requirements of interested parties** (4.2)
  - Scope must be available as documented information
  - Must state the types of products and services covered
  - Must provide justification for any requirements that are **Not Applicable** (only if the N/A does not affect ability or responsibility to ensure product conformity or enhancement of customer satisfaction)

New Requirements/Clarifications

- 4.4 Quality Management Systems and its Processes
  - A-D - Are the same requirements as in 2008
  - E – Assign responsibilities & authorities for those processes (likely not all 1 person)
  - F – Must address **Risks and Opportunities**, (see 6.1 & 10.2)
  - G – Evaluate processes & implement changes needed to ensure they achieve their intended results
  - H – Improve the processes and the QMS

New Terms

- 4.4.2 "**Documented Information**" instead of Manual/Procedures/Work Instructions
- 4.4.2 "**Retained Information**" instead of Records
  - Reflects a growing trend for electronic information
  - The company decides the necessity and type of documented information. Existing documentation may be retained if useful, or may be converted to something more useful to the company.
  - NOTE: there are now many more instances where the **organization must "determine**" – and in order to be audited, this information must be retained somewhere.

Changed Responsibilities

- 5.1 Leadership & commitment
  - "Management representative" role deleted, encouraging a more proactive participatory role from all managers,
  - Top management responsible for (10 bullets altogether)
    - Effectiveness of QMS
    - Ensuring integration of QMS into the organization's business processes
    - Ensuring that the QMS achieves its intended results
    - Promoting improvement
    - Ensuring that the quality policy and quality objectives are established, and are compatible with the company's context and strategic direction

Revised Requirements

- 5.1.2 Customer Focus
  - **New**: "applicable statutory and regulatory requirements"
  - **Clarification**: Risks and opportunities determined and addressed
  - "Enhancing customer satisfaction" still the aim.

New Requirements

- 6.1 Actions to address RISKS and OPPORTUNTIES
  - "Identify risks" in 4.1, 4.2, 4.4
  - Here you "plan actions" to address those risks.
  - The NOTE clarifies options to address Risks & Opportunities
  - Addressing Risk replaces Preventive Actions, by using risk-based thinking to integrate actions into the QMS, and monitor their effectiveness.
    - What is the risk/opportunity? How do we control it? Is the process adequately defined?
    - More guidance at **www.iso.org/tc176/sc2/public**

Revised Requirements

- 6.2 'Quality objectives' now includes planning to achieve them.
  - Objectives must be measurable, monitored, and updated as needed
  - Planning how to achieve them includes determining:
    - What will be done,
    - Required resources
    - Who will be responsible,
    - When it will be completed, and
    - How results will be evaluated.

New Requirements

- 6.3 Planning of Changes
  - "undertake changes in a planned and systematic manner" by considering:
    - Potential consequences of change
    - Integrity of the QMS
    - Availability of resources
    - Allocation or reallocation of responsibilities and authorities

Revised Requirements: Support

- 7.1.4 Environment necessary for the operation of process and to achieve conformity product and services
- Can be a combination of human and physical factors
  - Social (non-discriminatory, calm, non-confrontational)
  - Psychological (stress-reducing, burnout prevention)
  - Physical (temperature, heat, humidity, light, airflow, noise, hygiene)
  - Factors vary depending on the products and services provided.

New Requirements

- Resource management now includes 7.1.6, **Organizational Knowledge**
  - Maintained and available as necessary
  - Determine how to acquire or access any needed additional knowledge and required updates.
  - Generally, knowledge specific to an organization (or industry)
  - Internal sources – e.g. intellectual property, experience, lessons learned from failures & successes, results of improvements
  - External sources – e.g. standards, academia, conferences, customers, external providers

Revised Requirements

- 7.4 Communication is more specific
- "The organization shall determine the internal and external communications relevant to the QMS," including:
  - On What it will communicate
  - When to communicate
  - With Whom to communicate
  - How to communicate
  - Who will communicate

Revised Requirements

- 8.4 Control of Externally Provided processes, products and services - revision of Purchasing.
  - Externally provided processes remain within the control of the QMS whether
    - incorporated into product,
    - provided directly to customer, or
    - provided to the company.
  - Information to providers shall include requirements (see Standard for list)

Revised Requirements

- 8.5.1 Production control
  - Definition of controlled conditions includes:
    - Documented information (characteristics, activities, and results)
    - Monitoring & measuring equipment and activities
    - Competence of staff
    - Process validation and monitoring
    - Implementations to prevent human error (New)
    - Release, delivery, and post-delivery activities
- 8.5.6 Control of changes (within Production)
  - Retain documented information of review, authorization, and actions taken as a result of the review.

Revised Requirements

- 8.5.3 Property belonging to customers or external providers
  - Same requirements for protection of customer property, now extended to that provided by external providers
  - Can include materials, components, tools & equipment, premises, intellectual property & personal data
- 8.5.4 Preservation
  - Now includes contamination control

Revised Requirements

- 8.6 Release of products and services
  - Verify that requirements have been met, at appropriate stages
  - No release until completed, unless approved by relevant authority or customer.
  - Retained documented information shall include:
    - Evidence of conformity with acceptance criteria
    - Traceability to the persons authorizing release (New).

Revised Requirements

- 8.7 Control of nonconforming outputs
- Retain documented information that:
  - Describes the NC
  - Describes the actions taken
  - Describes any concessions obtained
  - Identifies the authority deciding the action to be taken

Revised Requirements

- 9.1 Performance monitoring, measurement, analysis and evaluation of performance & QMS effectiveness
  - Determine:
    - What needs to be monitored & measured (KPIs)
    - Methods needed to ensure valid results
    - When the monitoring & measuring shall be performed
    - When results shall be analyzed and evaluated
  - Retain documented info as evidence of results

Revised Requirements

- 9.1.3 Analysis and evaluation, using data from monitoring & measurement, to determine:
  - Conformity of products & services
  - Degree of customer satisfaction
  - If planning was implemented effectively
  - Performance of external suppliers
  - QMS performance & effectiveness
  - Need for improvements to the QMS
  - Effectiveness of actions to address risks/opportunities

New Requirements

- 10.1 Improvement
- "Determine and select opportunities for improvement including implementing any necessary actions to meet customer requirements and enhance customer satisfaction." Shall include:
  - Improving products and services to meet requirements, future needs and expectations.
  - Correcting, preventing, reducing undesired effects
  - Improving the performance of the QMS
    - E.g. correction, corrective action, continual improvement, breakthrough change, innovation and re-organization

Revised Requirements

- 10.2 Nonconformity and corrective action
  - React - control, correction, & dealing with consequences of NC
  - Evaluate the need for action so that it doesn't recur or occur elsewhere
  - Implement needed action (CAs appropriate to effects of the NCs)
  - Review effectiveness of any corrective actions taken
  - Update Risks & Opportunities identified during planning
  - Revise the QMS, if necessary
  - Retain documented information as evidence of
    - Nature of NC's & subsequent actions
    - Results of any corrective actions

Transition Planning: Deadline Sept 2018

- Become familiar with 9000 and 9001 standards
- Identify organizational gaps to address
- Develop implementation plan, assign responsibilities, create timeline
- Provide needed training (PQA can help)
- Update your QMS as needed
- Full cycle of internal audits to new requirements
- Consider adding a gap audit
- Transition to 2015 as soon as you're ready – we are!
- Last PQA audits to the 2008 revision = June 2017

Questions?

- Any questions during presentation --
- Remember, you can call 303-800-5345
- or email us with your questions/concerns:
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  - Markm@pqacertification.com