ISO 9001:2015
Change is Upon Us

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Agenda

• Timeline of ISO 9001:2015
• Structural Changes to ISO 9001- Annex SL
• New Requirements
  • Vocabulary/Terms
  • Significant Changes
    • What do they mean?
    • What tools are available
    • How to bridge the gap
  • Small Changes
Timeline

Release
- Released September 23, 2015

Completion
- Due September 2018
  - Aim for May 2018

Transition
- Registrar will release their plans
- New registrations to 2008 versions – March 2017
- Any new/recerts to 2008 version will have expiry date of Sept 2018.
IAF Guidance

• “..., additional time is likely to be required to ensure that all activities are covered for the existing and new standards.”
  • Talk to your registrar- avoid surprises!

• If you miss the transition dates, the organization will lose its certificate. In order to get certified again it will have to go through Stage I and Stage II audit.

• Timing your audit to your regular surveillance/recertification audit is ideal but not mandatory.

• The expiry date of new certifications under ISO 9001:2008 after publication of ISO 9001:2015 shall be the same as the transition completion date.
New Look & Feel

• Clause structure and some terminology have changed to improve alignment with other management system standards

• The consequent changes in the structure and terminology do not need to be reflected in the documentation of an organization QMS.

• The structure of clauses is intended to provide a coherent presentation of requirements rather than a model for documenting an organization’s policies, objectives and processes. There is no requirement for the structure of an organization’s QMS documentation to mirror the standard.
Annex SL

- A framework for all ISO management system standards (i.e. 9001, 14001, 45001) providing:
  - high level structure (HLS)
  - identical subclause titles
  - identical text
  - common terms and core definitions

10 Section Blueprint to be used for ISO standards
## Annex SL

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>4. Context of the Organization</td>
<td>4.0 Quality Management System</td>
</tr>
<tr>
<td>5. Leadership</td>
<td>5.0 Management Responsibility</td>
</tr>
<tr>
<td>6. Planning for the Quality Management System</td>
<td>5.0 Management Responsibility (QMS Planning)</td>
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<td>7. Support</td>
<td>6.0 Resource Management</td>
</tr>
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<td>8. Operation</td>
<td>7.0 Product Realization</td>
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<td>10. Improvement</td>
<td>8.0 Measurement, Analysis and Improvement</td>
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## Terminology Changes

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Products</td>
<td>Products and services</td>
</tr>
<tr>
<td>Exclusions</td>
<td>Not used- (Applicability)</td>
</tr>
<tr>
<td>Management Representative</td>
<td>Not Used</td>
</tr>
<tr>
<td>Documentation, Quality Manual, Documented Procedures, Records</td>
<td>Documented Information</td>
</tr>
<tr>
<td>Work environment</td>
<td>Environment for the operation of processes</td>
</tr>
<tr>
<td>Monitoring &amp; Measurement Equipment</td>
<td>Monitoring &amp; Measurement Resources</td>
</tr>
<tr>
<td>Purchased product</td>
<td>Externally provided products and services</td>
</tr>
<tr>
<td>Supplier</td>
<td>External provider</td>
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</table>
Main Changes

- The adoption of the High Level Structure as set out in Annex SL
- An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach
- Fewer prescribed requirements
- Less emphasis on documents
- Improved applicability for services
- Requirements to define the boundaries of the QMS
- Increased emphasis on organizational context
- Increased leadership requirement
- Greater emphasis on achieving desired outcomes to improve customer satisfaction.
ISO Change Impact

Assumption: Mature and robust QMS
PDCA in the context of ISO

Context of the Organization

Leadership

Planning

Support

Operation

Performing Evaluation

Improvement

Understanding the Organization and its Context

Leadership & Commitment

Actions to address risks & opportunities

Resources

Operational planning & Control

Monitoring, measurement, analysis & evaluation

General

Understanding the needs and expectations of interested parties

Policy

Quality Objectives & planning to achieve them

Competence

Requirements for Products & Services

Internal Audit

Nonconformity & Corrective Action

Determine the Scope of the QMS

Organizational roles, responsibilities & authorities

Planning of Changes

Awareness

Design & Development of Products & Services

Management Review

Continual Improvement

QMS & its processes

Planning of Changes

Comunication

Control of externally provided processes, products & services

Control of nonconfor-ming outputs

Review

General

Nonconformity & Corrective Action

Continual Improvement
4.0 Context of the Organization

• Overall intend of the section is to help frame the QMS.
  • 4.1 Understanding the organization and its context
  • 4.2 Understanding the needs and expectations of interested parties
  • 4.3 Determining the Scope of the QMS
  • 4.4 QMS and its processes
6.1 Actions to address Risk and Opportunities

- When planning the QMS the organization shall consider the Context of the Organization and then determine the risks and opportunities that need to be addressed to:
  - Give assurance the QMS can achieve its intended result(s)
  - Enhanced desirable effects
  - Prevent, or reduce, undesired effects
  - Achieve improvement

- The organization must plan:
  - Actions to address these risks and opportunities
  - How to:
    - Integrate and implement the actions into the QMS processes
    - Evaluate the effectiveness of these actions.
  - Actions taken must be proportionate to the potential impact on the conformity of products and services.
Readily available Tools

**SWOT Analysis**

**Severity vs. Likelihood**

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**Risk Severity Matrix**

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost Certain</td>
<td>Insignificant</td>
<td>Minor</td>
<td>Moderate</td>
<td>Major</td>
<td>Critical</td>
</tr>
<tr>
<td>Likely</td>
<td>Moderate</td>
<td>High</td>
<td>Extreme</td>
<td>Extreme</td>
<td>Extreme</td>
</tr>
<tr>
<td>Possible</td>
<td>Low</td>
<td>Moderate</td>
<td>Moderate</td>
<td>High</td>
<td>Extreme</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Low</td>
<td>Low</td>
<td>Moderate</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Rare</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Moderate</td>
<td>Moderate</td>
</tr>
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</table>
Readily available Tools

FMEA

- Financial analysis
- KPIs or metrics
- Hoshin Planning
- Self developed tools
- Financial/Performance Suppliers
- Ease of Implementation of Changes

Others
Knowledge Management

• Knowledge- what, how, when and often why- required to generate consistent and conforming products/services.
• The right people need access to this knowledge to create desired outcome.
• Management of this knowledge will be unique from organization to organization.
  • Careful analysis and planning
  • Leverage use of technology
• Transfer of knowledge over time- “Tribal Knowledge”
7.1.6 Organizational Knowledge

- The organization must determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.
- Knowledge must be maintained and be 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 any necessary additional knowledge and required updates.
Where to find information

- IT – help to determine access to electronic data
- QMS software - access levels and restrictions
- HR - Job Descriptions
- Current QMS documentation
Control of Changes

• It aims to ensure that changes to the QMS are indeed plan
• Wider scope potential
• Also includes changes to products and processes
• Risk based thinking is also considered
Sections that include Change

• 6.3 Planning of Change
  • When the organization determines the need for changes to the QMS, the changes must be carried out in a planned manner
  • The organization must consider:
    • Purpose of the change and the potential consequences
    • The integrity of the QMS
    • The availability of resources
    • The allocation or reallocation of responsibilities and authorities

• 8.1 Operational Planning and control
  • The organization must control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

• 8.5.6 Control of Changes
  • The organization must review and control changes for production and service provision, as necessary to ensure continuing conformity with requirements
  • The organization must retain documented information describing the results of the review of the changes, personnel authorizing the change and any actions from the review.
Where to find information

• Determine what has been your definition of change and does it line up with the standard
• Engineering Change Notices
• Process Change Notices
• If you have outsourced processes have you defined if changes need to be communicated
  • Supplier Agreements
  • PO Terms and Conditions
  • Quality Buy Clauses
Minor changes

Additional requirements have been introduced in the standard but they related to ensure that your QMS is indeed addressing requirements taking into account its context and that risk-based thinking is being applied. Example:

- 5.1 Leadership and commitment
  - 5.1.1 General
    - Top management must ensure that the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the organization
    - Top management must promote the use of process approach and risk-based thinking.
Minor changes

• 7.1 Resources
  • 7.1.4 Environment for the operation of processes
    • The organization shall determine, provide and maintain the
      environment necessary for the operation of its processes and to
      achieve conformity of products and services.
    • NOTE: A suitable environment can be a combination of human and
      physical factors, such as:
      • A) Social
      • B) Psychological
      • C) Physical
Minor changes

• 7.3 Awareness
  • The organization must ensure that persons doing work under the organization’s control are aware of:
    • C) their contribution to the effectiveness of the QMS, including the benefits of improved performance
    • D) the implications of not conforming with QMS requirements.

• 8.2.1 Customer communication
  • E) communication must include establishing specific requirements for contingency actions, when relevant.

• 8.2.2 Determining the requirements related to products and services
  • The organization must ensure that it can meet the claims for the products and services it offers.
Minor changes

- 8.5 Control of production and Service Provision
  - Customer Property now it includes Supplier items: 8.5.3 Property belonging to customers or external providers

- 9.3.2 Management Review Inputs
  - Added the following items:
    - Performance by suppliers
    - Effectiveness of actions taken to address risks and opportunities.
What can you do?

- Learn more about the requirements
- Look at your system and identify gaps- gap tools
- Develop plans to bridge the gap(s)
- Engage your registrar and request their transition plans
- Budget time and money
- Finalize your plans and execute.
- Pay attention the next few months as interpretations to the new requirements will start becoming available