Preparing for ISO 9001:2015
An Auditor’s Perspective
OUR ANNUAL ISO 9000 AUDIT IS NEXT WEEK.

WE CAN PASS THE AUDIT IF WE PUT ALL OF OUR NON-CONFORMING DOCUMENTS IN THE TRUNKS OF OUR CARS.

DOESN'T THAT DEFEAT THE PURPOSE OF A VOLUNTARY AUDIT? AND THEN TORCH THE CARS.
Presented by:
Randall D’Amico
Management System Auditor
TÜV SÜD America
LinkedIn: http://ca.linkedin.com/in/peteralouche

Presented by:
Peter-Elias Alouche, P. Eng., CSPO
Market Strategy Quality Practice Manager
Intelex
LinkedIn: http://ca.linkedin.com/in/peteralouche
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2 years in a row
Agenda

1. What to Confirm with Your Registrar
2. Auditor Expectations
3. Key Changes to Address
4. Transition Problems & Traps
6. Questions
What to Confirm with Your Registrar
## What to Confirm with Your Registrar Today

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<tr>
<th>What to Confirm</th>
<th>Impact</th>
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<tr>
<td>ISO 9001:2008 Certificate Expiry?</td>
<td>How much time do I have?</td>
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<tr>
<td>When will Registrar Stop Issuing ISO 9001:2008 Certificates?</td>
<td>You might have to comply to ISO 9001:2015 sooner than you think.</td>
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<td>Any training available on the new standard</td>
<td>What can I learn from my registrar that will help me become certified to ISO 9001:2015</td>
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<td>Time Required to Audit &amp; Audit Scope</td>
<td>Major certification audit vs. our surveillance audit</td>
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Auditor Expectations: How to Prepare
1. Perform a gap analysis
2. Stress test your system
3. Develop an implementation plan and timetable

- We’ll expect you to have had a management review and a full round of audits to the new standard
- A formal implementation plan and schedule will help your organization address the required changes within the anticipated three year transition period
- Don’t wait until 2 days before the audit to audit the system, you won’t have time to correct anything your auditors uncover
4. Provide appropriate training for all parties

- Ongoing education and training for all relevant personnel is critical to achieving the goals of your transition plan.
- Verify the effectiveness of your training and address any gaps that are discovered through corrective action.

5. Update existing quality management system documentation

- Clear and thorough documentation is essential to demonstrate compliance with the requirements of the revised standard and to help reduce the risk of nonconformities.
- No formal documentation required however documented information is still necessary (i.e., Records, Procedures).
Expectations from the Auditor

6. Maintain Documented Information versus Retain Documented Information

- Maintain is essentially a procedure
- Retain is a quality record

Greater emphasis on retaining documented information instead of prescribed quality records
Key Changes to Address
Key Changes to Address

- **Major Changes**

  - Eight elements to ten
  - Relaxed requirements for documentation
  - Changed methodology to define scope of QMS – Removed emphasis on formal documentation of exclusions in Quality Manual
  - No requirement for a designated management representation
  - Shift from management responsibility to leadership
  - Focus on stakeholder relationship management
  - Must understand context of the organization
  - Risk-based thinking approach
  - Improves alignment with other standards
Key Changes to Address

- Removed requirement for a designated management representative
- Top management now responsible for all the activities formerly assigned to management rep
  - Taking accountability of effectiveness of QMS
  - Promoting awareness of process approach
  - Retain ultimate responsibility for implementation consistent with the requirements of the standard
- Added requirement for “engaging”
Key Changes to Address

- Two clauses relating to the context of the organization

4.1 Understanding the organization and its context

- Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments
- Internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization

4.2 Understanding the needs and expectations of interested parties

- The organization shall determine a) the interested parties that are relevant to the QMS and b) the requirements of these interested parties that are relevant to the QMS
Key Changes to Address

Does not…

- Require the application of a standardized risk management approach (i.e. FMEA, PFMEA)
- Contain requirement for Preventive Action (replaced by Risk Based Thinking)

“Actions taken to address risk and opportunity shall be proportionate to the potential impact of the conformity of products and services”
Key Changes to Address

- Risk Analysis: Consider the risk / opportunity before deciding how to proceed.
- No formal requirement for approach: Manage risk like any other decision.
- Suitable for the organization: The bigger the risk, the more formal process should be.
Key Changes to Address

Strengthens the importance of applying a process approach in developing, implementing and improving the effectiveness of an organization’s quality management system.

Required to define inputs and expected outputs of each process, and to identify key performance indicators.

Each process map should consider:

• What will be done?
• What resources will be required?
• Who will be responsible?
• When will it be completed?
• How results will be evaluated?
Key Changes to Address

- Revised documentation requirements are likely to introduce a different kind of recordkeeping burden

- Greater flexibility in the types of documentation that are permitted

- Need to provide evidence of a robust recordkeeping system that provides a thorough history of all quality management activities

- Understanding external and internal issues that are relevant to its purpose and strategic direction
  - External can include legal, technological, competitive, economic or other issues, being foreign or domestic
  - Internal can include values or culture that affect ability to achieve intended results and an organization’s unique capabilities

- Can include positive and negative factors
Be wary of excluding things you need or do

Justification must be provided, explaining why it doesn’t have any effect on your quality system

Not a free for all where you can stop doing things you don’t like
Conclusion

- **Gap analysis**
  - Perform a self-evaluation to find your weaknesses

- **Implementation Schedule**
  - A slow, deliberate process better than fire drill

- **Training**
  - Send one or more people to a training session so they can champion the conversion

- **Update documentation**
  - While no formal documented procedures are required, documentation requirements exist, so not a bad idea to keep what you’ve got and revise to include 2015 requirements
Conclusion

- Complete revision
  - Pulls in elements of other standards

- No need to change numbering of your documents
  - Could create a cross reference table

- Must incorporate risk analysis for decisions
  - Determine program
  - Be consistent with application
  - Document decisions
Conclusion

- Better control of externally provided products, processes and services
- Reduced documentation requirements
- Increased focus on leadership
- Greater emphasis on retaining documented information instead of prescribed quality records
Transition Problems & Traps
Problem #1: “If it ain’t broke, don’t fix it”

- Don’t make changes for the sake of change
- Don’t overcomplicate things…simplify
- Identify the opportunities to improve
Problem #2: Resistance to Change

- Engage your employees throughout the program
- Make it fun & interactive
- Focus on Face-to-Face vs. digital communication with internal staff
Problem #3: 
Training

- Ensure that your Quality and Management teams have been trained
- Leverage 3rd party courses on-site or online
Problem #4: Poor Infrastructure

• Assess your current tools used to manage your QMS

• Consider support from management consultants

• Work with IT to assess better tools on the market
Tips to Get Ready for ISO 9001:2015

1. Clearly define your objectives and goals for ISO 9001:2015 certification for your company

2. Purchase ISO 9001:2015 if you haven’t already

3. Understand what you need to get certified

4. Always evaluate your options

5. Remain committed and persistent
Tips to Get Ready for ISO 9001:2015
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Randall D’Amico
Peter-Elias Alouche