Transitions Completed!!!

Where do we go from Here?

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Standards Transition & Supply Chain Evolution

• Message
  • The ASD Supply Chain Made it through the AS9100 Transition
  • 99.9% of ASD Supply Chain Transitioned to New Standard

• But…….
  • Are we There Yet??
  • Is there Still More to do??

• Goal
  • Educate Auditor Community on Transition Outcomes
  • Share Experiences on Past Standards Transitions
  • Connect Transition Outcomes to Potential areas of Industry focus for Evolving Supply Chain Performance
2018 Goals For IAQG - Transition, Transition, Transition

- How did we Do?
  - Is the Industry & Auditors Evolving
- What Have Evolutions have We Seen in Previous Major Transitions?
  - Takes Time To Understand
  - More Time to Optimize

- What is still Left to do??
  - Certified ASD Organizations
  - Certification Bodies
  - ASD Auditors
Standards/Supply Chain Evolution

• Past Transitions
  • AS9100:2008 (Operational Risk, Critical Items, etc.)
  • ISO 9001: 2000 (Process Model)

• What Were The Industry Experiences
  • Initial Learning (Supply Chain & CB)
  • Transition Compliance (Clearing the Bar)
  • Additional Learning & Evolution
  • Focus on Supply Chain Evolution
    » Supplier, Auditors (Supply Chain & CB)

• Where are we at Now??
Standards/Supply Chain Evolution

- Where are we at Now??

- What does the Model tell us?
  - Industry AS9100 Transition Completed
  - Supply Chain Should now be maturing in the Optimization Phase
  - Auditors Should Be Maturing Also!

- What does the Data tell us?
What Do We Focus On?

• What Does the Data Tell us
  • What do we Notice about NC data
    – Low NC numbers in the newer and more complex areas of Standard
      » More Complex areas of Standard require linking shall statements in threads to achieve effective implementation
    – CB Nonconformance outcomes not Aligning with Supplier Performance
    – NCs seem to focus on Compliance parts of Standard (Less on Effectiveness/Outcomes)
  • Compliance & Effectiveness
    – Compliance – Focus on Meeting the requirements of the ‘Shall’ Statements
    – Effectiveness/Outcomes - Focus on effectiveness. Specifically using downstream data and customer feedback, returns, NCs, scorecards, etc.

• What does our Senses tell us?

• What should our collective Goal be?
  • Work with Certified Organizations to Focus on Accelerating the Supply Chain through the Optimization Phase
  • Educate Global Partners on Transition Outcomes
  • Share Experiences on Past Standards Transitions
  • Connect Transition Outcomes to Potential areas of Industry Auditor focus for Evolving Certified Organization Performance
Evolving The ASD Supply Chain

• Do All Levels Understand the New Requirements and the New Requirement Threads and how they affect Outcomes??

• The Standard and the Supply Chain
  • Certain Parts of the Standard have More Relevancy at different levels of the Supply Chain
    • Upper Tiers have both Internal and Supply Chain areas of Focus
    • Lower Tiers are more Focused on Customer Flow-Downs and internal Evolution
  • Certain Levels of the Supply Chain are Experiencing different Challenges
  • Certain Requirements Transcend the Organization Structure & SC Tiers
    • Design Output (CI/KC) > Purchasing > Raw Material Testing
    • No CI designation at Customer Creates Risk of No Testing by Supplier

• Supply Chain most likely doesn’t fully understand the use of the connective threads of the Standards that can be used to manage risks in addressing NC Product escape prevention and meeting all customer and regulatory requirements
Where Do We Stand

- **QMS Risk Focus by CB Auditors**
  - Higher Level QMS Compliance Seems to be Main Focus
  - Lesser Focus on Nuances Associated with Process & Product Risk

- **Outcome Focus**
  - Better Utilized at Higher QMS Levels, but much room for improvement
  - Need for More Focus in Tying Process/Product Outcomes to Upstream Risk Based Decisions

- **Broader Risk Focus Across both Compliance and Outcome Aspects Improve at Higher Levels of SC.**

<table>
<thead>
<tr>
<th>Risk Focus</th>
<th>QMS Compliance Focus</th>
<th>Outcome Focus</th>
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</thead>
<tbody>
<tr>
<td>General QMS</td>
<td>G</td>
<td>Y</td>
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<tr>
<td>Process</td>
<td>Y/G</td>
<td>Y</td>
</tr>
<tr>
<td>Product</td>
<td>Y/G</td>
<td>Y</td>
</tr>
</tbody>
</table>
• Understand the 3 Important aspects of the Standards
  • The requirements are not stand alone.
    – They are connective and interactive
  • **Outcomes Matter**
    • Risk Based Thinking needs to be applied at all decision levels of a process
• What are the Organizational Goals of Certified Organizations
  • 100% OTD, 100% Compliant, Paperwork Perfect, Complaint with Laws
• What are the Gaps
  • Contractual Requirements – Many Times Missing the Mark
  • Impacts to Parts Qualification – Myriad of Product and Process Change Requirements
  • Notifications and Communications – Not Occurring in a way that would allow Suppliers to manage impacts
  • Escapes Occur – Product & Documentation Issues
  • Etc.
• Let’s discuss methods and approaches
Audit Strategy and Planning
- Ask Yourselves -

- Does Your Audit approach uncover the causal areas of weaknesses in the Organization performance specific to their customer?
- Does your Audit Approach get an adjustment in focus based on the organizations performance outcomes?
- Does your Audit strategy focus on the Risk based thinking approach used by Certified Organizations to address risks?
QMS Technical Focus Audit Approach

- What is a Thread
  - Linkage of various individual requirements in Standard that address more complex processes
  - Risk is focused on preventing occurrence of hypothetical issues that could happen
- Examples
  - CPP In House - Engineering Design > Eng. or Purch. Part Selection > Obsolescence > Lifecycle Parts Management
  - Design Output (CI/KC) > Purchasing > Supplier Testing

- What is an Outcome
  - Results of enacted processes that produce a product or service to downstream processes or Customers
  - Risk is focused on preventing recurrence of issues that did happen
- Examples
  - NC Escapes to Customer
    - Product or Contractually Required Items
  - OTD – Late Delivery
  - Customer Experience or Satisfaction
  - Internal Phase Escapes from one Process to Another

- Where Can We Evolve in Auditing the ASD Supply Chain
  - Process Focus - Tie Requirement Threads to Risk Based Thinking
  - Product Focus - Tie Outcomes to Risk Based Thinking
  - Understand that there is an interrelation between Product and Process that tie the Threads and Outcomes together
• Key Components of Risk Based Audit Strategy
  • Context of Organization & Interested Party Impacts
  • How Risk Can Impact Compliance and Effectiveness
  • **Occurrence** – v – **Recurrence** Focus in Risk Auditing
• Understanding Requirements Threads
  • Individual Requirements Weave Together to Form Cross Cutting Larger Requirements
• Understand Best Strategy for Auditing Risk For Various Scenarios
  • What Audit Paths to Focus on
  • How to Combine Techniques and Paths for Maximum Effectiveness
  • **Where to Start!!**
• Which Are the Best Methods, Approaches and Techniques to Use For Various Risk Auditing Situations??
• Connecting Strategy to Execution
  – How we Do it
    • Do you know the Organizations issues prior to the audit activity
    • Do your audits of your organization include reviewing the organizations performance data prior to conducting the audit
  – Key Techniques and Methods for addressing Process Risks
    – Occurrence Prevention – Down Stream
    – Recurrence Prevention – Upstream
Risk and Down Stream Audit Approach

• Down Stream Auditing
  • Start at the Beginning of a Process and Follow Trails to End of Process(s)
  • Good for Following Planning to Outcome Trail (PDCA)

• How To Use For Auditing ‘Risk Based Thinking’
  • Look at Leading Indicators for Potential of Risk Impacts to Process
  • Look for Risk ID, Communication & Understanding for Prevention of Occurrence

• Up-stream Auditing
  • Start at the End of a Process and Follow Trails to Earlier Stage of Process(s)
  • Good for Following Trails on Adverse Process Outcomes (CAPD)

• How To Use For Auditing ‘Risk Based Thinking’
  • Start with a ‘Known’ Negative Issue or Lagging Indicators Showing ‘Unintended Outcomes’
  • Follow Trail Back to Planning and Decisions
    • How Where Potential Risk were ID, Communication & Understood
    • Were Appropriate Risk Decisions Applied Based On Understanding of Risk
    • Look for How Risk ID, Communication & Understanding will be used for Prevention of Recurrence
• Audit Paths
  – Path 1 Audit Plan – Functional Audits
  – Path 2 Audit Plan – Cross Cutting Process Audits
    ▪ Downstream – Prevention of Occurrence
    ▪ Upstream – Prevention of Recurrence

• Which Methods Do Auditors Typically Use??
Audit Strategy & Planning
- New Requirements -

• Audit Paths for New Requirements
• Which Path Works best for New Requirements??
  – Downstream – View Organization’s Risk ID and Control Methods
  – Upstream – View Organization’s Review of Outcomes/Data and Control Methods
• Both have Benefits
  – Key is Pre-Audit Understanding of Organization’s Context & Risks
  – Then Utilize in Constructing Appropriate Audit Plan

Path 1

Downstream

Upstream

Path 2a

Path 2b

Engineering

Purchasing

Manufacture

Inspection

Escape

Prevention

Parts

Prevention

Management

Change

Notification

Sub tier

Supplier

Management

Cert Verif

Report Valid

Raw Material
Scenarios and Application Discussions

• What Have We Covered?
  – Industry Transition Outcomes
  – Importance of the Accelerated Evolution of the ASD Certified Companies
  – Concepts on Needs To Evolve the Audit Approach
  – Concepts for Evolving Audit Strategies, Methods and Techniques Associated with Risk Based Thinking

• Case Study Examples
You are auditing an organization that manufactures and assembles valves and pressure-related piping components for the AS&D industry. In the pre-audit planning call, you find that the leadership team remains the same except for a new manager of Purchasing & Supplier Control. The Quality Manager indicates that internal audits and all CA response were completed.

In auditing a contract for a Defense Aviation customer, you find that valves are being used in the hydraulic systems for flight control and are Flight Safety Items. The organization buys various internal parts from a customer-directed supplier.

- What groups/processes should the audit plan address??
- What trails should be followed??
- What are the risk-based decisions you might look at?

**CASE STUDY Part 1**

**Inputs**
- Customer schedule (8.2.1)
- Raw materials (8.4.1)

**Process**
- Manufacturing Process (8.5)
- Supply Chain (8.4)

**Outputs**
- Conforming product delivered to customer schedule (8.6)

**Audit Trail**

**With What?**
- Customer schedule (8.2.1)
- Raw materials (8.4.1)

**With Who**
- Supplier Performance (9.1.3)
- Audit records (9.2)

**What Results?**
- Analysis of data (9.1.3)
- Customer satisfaction (9.1.2)
- Supplier Performance (9.1.3)
- Audit records (9.2)
**CASE STUDY Part 2**

- In review of customer return metrics in Management Review you find that the customer rejected a lot of 50 valves due to lack of material certifications that were required due to the Customer’s contract. In addition your review found a few rejections due to parts traceability issues.
- In your audit of the Purchasing Department organization you found that they were not aware that they needed to specifically request material certifications from the supplier.
- In review of the Supplier Performance Metrics you notice that there was a spike in Supplier NCs.
- In further review, you found that the engineering group dispositioned the supplier NCs to allow for the change in the part number as it was the same part from a different supplier.

- What Groups/Processes Should the Internal Audit plan address??
- What Trails should be followed??
- What are some risk based decisions you might look at?
- What Issues or NCs are emerging

**Outputs**
- Conforming product delivered to customer schedule (8.6)

**Process**
- Manufacturing Process (8.5)
- Supply Chain (8.4)

**Inputs**
- Customer schedule (8.2.1)
- Raw materials (8.4.1)

**With Who**
- 6.1

**With What?**
- 6.1

**How?**
- 6.1

**Audit Trail**
- 6.1

**What Results?**
- Analysis of data (9.1.3)
- Customer satisfaction (9.1.2)
- Supplier Performance (9.1.3)
- Audit records (9.2)
CASE STUDY Part 3

- In auditing the organization's internal audit process, you noticed it was completed a month ago.
- The audit results had various NCs all from the manufacturing floor, mostly associated with FOD control, shelf life issues, and job traveler signoff issues.
- No NCs were identified in other areas.
- In looking at the audit plan, you noticed that it was mostly Department Based (Contract Review, Engineering, Purchasing, manufacturing, assembly, and inspection). It also had time allocated to auditing the general QMS and infrastructure activities.

- What Line of Questioning would you pursue??
- What Type of Issues or NCs might you identify??

**Inputs**
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**With What?**
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**What Results?**
- Analysis of data (9.1.3)
- Customer satisfaction (9.1.2)
- Supplier Performance (9.1.3)
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In Closing

Improving Ourselves To Improve ASD Suppliers

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<tr>
<th>Customer Evolution</th>
<th>Aspiration</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td></td>
<td>100% Certificate Transition</td>
<td>• Done</td>
</tr>
<tr>
<td></td>
<td>Understanding Requirement Threads</td>
<td>• Good at Upper Tiers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lower Tiers Need Improvement</td>
</tr>
<tr>
<td></td>
<td>Risk Based Thinking at Product, Process, People, QMS &amp; Business Levels</td>
<td>• Conceptual At Upper Tiers</td>
</tr>
<tr>
<td></td>
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<td>• Weak Understanding at Lower Tiers</td>
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- **Auditor Support in Accelerating Supplier Performance**
  - Connecting Industry Outcomes to Audit Planning
  - Choice of Audit Methods/Techniques To ASD Supplier Risks
  - Focus on Connective & Crosscutting Requirement Threads
  - Focus on Risk Based Thinking at Product, Process & QMS Level
Thanks for Participating

Questions