Risk-based Thinking in IATF 16949:2016

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ISO 9001/IATF 16949 QMS Expert

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MMOG/LE Expert
Do you ever apply Risk-based Thinking in your life?
Risk-based Thinking is. . .

- **Risk**: effect of uncertainty
- **Context + Risk** = Basis for QMS planning
- Preventive actions are one result of risk-based thinking
- Formal vs. informal approaches
Risk-based Thinking = Better Decision-making
Did You Know. . .

IATF 16949

36 specific Requirements referencing RISK

Plus several mentions in MMOG/LE!
Risk-based Thinking

A Common Theme

ISO 9001:2015
International Quality

IATF 16949:2016
Automotive Quality

MMOG/LE v4
Supply Chain

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What we will cover in this session...

- Why Risk-based Thinking supports effective Quality and Supply Chain Management
- Which IATF 16949 and MMOG/LE requirements refer to Risk-based Thinking
- How Risk-based Thinking is applied in IATF 16949 and MMOG/LE
- How to recognize Risk-based Thinking in your organization
Intersection of Risk-based Thinking Requirements

- Internal & External Issues
- Interested Parties & their Requirements
- Risks & Opportunities (Identify & Evaluate)
- ISO 9001:2015 requirements
- Actions to address Risks & Opportunities
- Preventive Action
- Emergency Action Plans
- Contingency Plans
- Business Continuity Plan

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Risk-based Thinking can be applied to all levels of the business.
<table>
<thead>
<tr>
<th>IATF 16949</th>
<th>Description</th>
<th>Requirement</th>
<th>Business Ladder Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1.2.1</td>
<td>Risk Analysis</td>
<td>Minimum inputs</td>
<td>All</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>6.1.2.2</td>
<td>Preventive Action</td>
<td>Process to lessen impact of negative effects of risk</td>
<td>All</td>
</tr>
</tbody>
</table>
## Key Elements of Preventive Action

<table>
<thead>
<tr>
<th>Description of Risk and Results of Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determination of Risk Trigger/Cause</td>
</tr>
<tr>
<td>Identification and Evaluation of Risk Elimination Actions</td>
</tr>
<tr>
<td>Implementation Plan of Risk Elimination Actions</td>
</tr>
<tr>
<td>Evidence of Risk Elimination Effectiveness</td>
</tr>
<tr>
<td>IATF 16949</td>
</tr>
<tr>
<td>------------</td>
</tr>
<tr>
<td>6.1.2.3 a), b)</td>
</tr>
</tbody>
</table>
Contingency Plan:  plan devised for an outcome other than usual/expected plan

- What could happen?
- How will we respond?
- How can we prepare in advance?
Need for Improved Contingency Plans

- Risk-based thinking focus in ISO 9001/IATF 16949 quality management systems standards & MMOG/LE
- Complexity and diversity of automotive supply chain
- Critical supply-chain disruptions
- Lack of organization-wide contingency planning at suppliers
- Top IATF 16949 transition audit nonconformity
In Reality, Plants are Assessing…
Lack of Poor Risk Planning Results in . . .

- $600K
- $2M
- $500K
A Tale of Three Companies: 2011 Tsunami

Case Study: Renesas

- Result: $615.3 Million Cost
  - Repairs
  - Inventory
  - Fixed assets
  - Inability to operate
  - Cancelled contracts

Source: Renesas Annual Report 2011
Case Study:

- Result: Supply Chain Preparedness
  - 6 weeks after 2011 tsunami GM was still locating suppliers
  - Subsequently, GM implemented an event watch system
  - 6 hours after the earthquake in Japan in 2016 GM understood the supplier impacts
Case Study:

• Xirallic
  – Pigment used in paint
  – Many OEMs rely on Xirallic
  – Produced by a single source from a single factory in Japan

• Result: 4 month recovery advantage
  – Already seeking alternatives
  – Cut-over to new supplier in **5 weeks**
  – Other OEMs didn’t resume production for **5 months**
### 4. Logistics

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
<th>POC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply</td>
<td>Maintain 1 month of stock at NC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ensure suppliers maintain 1 month stock</td>
<td></td>
</tr>
<tr>
<td>Transportation</td>
<td>Call alternate transportation providers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Utilize ASC trucks</td>
<td></td>
</tr>
<tr>
<td>Hazardous Material Spill</td>
<td>Medical emergency support</td>
<td>Chem-Tron (440) 937-6348</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chemtech (419) 886-4375</td>
</tr>
<tr>
<td></td>
<td>Call D+M Contracting Co.</td>
<td>(800) 334-0003</td>
</tr>
</tbody>
</table>
Contingency Planning Requirements
(in IATF 16949 & MMOG/LE)
IATF 16949:2016 6.1.2.3

Contingency Plans

- Requirement significantly enhanced from ISO/TS 16949:2009
- More than just a documented plan
- Contingency planning as a process!
What is MMOG/LE?

- Materials
- Management
- Operations
- Guideline
- Logistics
- Evaluation
What is MMOG/LE?

- Developed by AIAG/Odette with OEMs, Suppliers and QAD
- Assessment tool to evaluate/select suppliers
  - Completed at the site level
  - Compare logistics capabilities against best practice
  - Used for production and after sales
- Determines level of plant performance (e.g. A, B, C)
- Some OEMs require MMOG/LE in IATF customer-specifics

**MMOG/LE = Delivery**
**ISO 9001/ IATF 16949 = Quality**
### Minimum Risks to Consider

*Per IATF 16949:2016 & SI #3 and MMOG/LE*

<table>
<thead>
<tr>
<th>Internal Risks</th>
<th>External Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Equipment Failures</td>
<td>Interruption from Externally Provided Products, Processes &amp; Service</td>
</tr>
<tr>
<td>Fire</td>
<td>Recurring Natural Disasters</td>
</tr>
<tr>
<td>Utility Interruptions</td>
<td>Labor Shortages</td>
</tr>
<tr>
<td>Infrastructure disruptions (e.g. EDI)</td>
<td>Cyber-attacks on Information Technology Systems</td>
</tr>
<tr>
<td>Packaging</td>
<td>Transportation</td>
</tr>
</tbody>
</table>

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## Additional Risks to Consider

<table>
<thead>
<tr>
<th>Internal Risks</th>
<th>External Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Security</td>
<td>Regulatory issues</td>
</tr>
<tr>
<td>Chemical spills</td>
<td>Recalls</td>
</tr>
<tr>
<td>Financial</td>
<td>Customer disruption</td>
</tr>
<tr>
<td>Capacity interruptions</td>
<td>Natural resource availability</td>
</tr>
<tr>
<td>Unexpected loss of organizational knowledge</td>
<td>Political uncertainty</td>
</tr>
<tr>
<td>Project-specific</td>
<td>Technology shifts</td>
</tr>
</tbody>
</table>

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MMOG/LE Requirements

- Document risk management process
  - Including prioritization
  - Proactively manage/reduce risk
- Create action plans
  - Review, train, test, and validate
  - Lessons Learned
- Manage sub supplier risk
  - Customer-owned processes
  - Require risk assessment and action plans
Contingency Planning Roadmap

1. Identify & Evaluate Risks
   - Key issues & events
   - Interested Parties requirements
   - Evaluation criteria

2. Develop Plans
   - Contingency Action process
   - Contingency Plan content

3. Communicate & Implement
   - Availability of Contingency Plans
   - Communication Plan
   - Awareness & Training

4. Review & Test
   - Periodic evaluation
   - Structured assessment

5. Update
   - Lessons learned
   - New/evolving risks

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Additional IATF 16949:2016 Risk-based Thinking Requirements and Methods
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>7.1.3.1</td>
<td>Plant, facility &amp; equipment planning</td>
<td>Risk identification &amp; risk mitigation methods</td>
<td>Plan, Process</td>
</tr>
<tr>
<td>7.1.5.1.1 (Note)</td>
<td>Measurement systems analysis</td>
<td>Prioritization of MSA studies</td>
<td>Process, Product</td>
</tr>
<tr>
<td>7.1.5.2.1 c)</td>
<td>Calibration/verification records</td>
<td>Assessment of risk for out-of-specification conditions</td>
<td>Process, Product</td>
</tr>
</tbody>
</table>
7.1.3.1 Plant, Facility & Equipment Planning

➢ Optimize material flow, (synchronous material flow)
➢ Value-added use of floor space
➢ Manufacturing feasibility assessments, (8.2.3.1.3) – input to management review
➢ Capacity planning – input to management review
➢ Re-evaluation relative to risk
<table>
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<tbody>
<tr>
<td>7.3.1</td>
<td>Awareness – supplemental</td>
<td>Risks involved for customer with nonconforming product</td>
<td>Product, Customer</td>
</tr>
<tr>
<td>8.2.3.1.3</td>
<td>Organization manufacturing feasibility</td>
<td>Feasibility analysis for new or changed products &amp; processes</td>
<td>Plan, Process</td>
</tr>
<tr>
<td>8.3.2.1</td>
<td>Design &amp; Development planning</td>
<td>Product design and manufacturing process risk analysis</td>
<td>Plan, Process, Product</td>
</tr>
<tr>
<td>IATF 16949</td>
<td>Description</td>
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</tr>
<tr>
<td>8.3.2.3</td>
<td>Development of products with embedded software</td>
<td>Prioritization based on risk and potential impact to customer</td>
<td>Plan, Product</td>
</tr>
<tr>
<td>8.3.3.1</td>
<td>Product design input</td>
<td>Assessment of risks with input requirements</td>
<td>Plan, Product</td>
</tr>
<tr>
<td>8.3.3.1 &amp; 8.3.3.2</td>
<td>Product &amp; manufacturing process design inputs</td>
<td>Design alternatives</td>
<td>Plan, Process, Product</td>
</tr>
<tr>
<td>IATF 16949</td>
<td>Description</td>
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</tr>
<tr>
<td>8.3.3.2</td>
<td>Manufacturing process design input</td>
<td>Error-proofing methods commensurate with risks encountered</td>
<td>Plan, Process</td>
</tr>
<tr>
<td>8.3.3.3</td>
<td>Special characteristics</td>
<td>Based on risk analysis, (FMEAs)</td>
<td>Plan, Process, Product</td>
</tr>
<tr>
<td>8.3.4.1 (Note)</td>
<td>Monitoring</td>
<td>Measurements include quality risks</td>
<td>Plan</td>
</tr>
</tbody>
</table>

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8.3 Product & Manufacturing Process Design

- DFMEA & PFMEA
- Trade-off analysis
- DFMA, (design for manufacturing and assembly)
- DFSS, (design for Six Sigma)
- Fault tree analysis
- Special characteristics
### IATF 16949 Risk-based Thinking Requirements

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<tr>
<td>8.3.5.1 &amp; 8.3.5.2</td>
<td>Design &amp; Development and Manufacturing Process design outputs</td>
<td>Design risk analysis (FMEA), capacity analysis, manufacturing process FMEA</td>
<td>Plan, Process</td>
</tr>
<tr>
<td>8.4.1.2</td>
<td>Supplier selection process</td>
<td>Assessment of selected supplier’s risk to product conformity, uninterrupted supply</td>
<td>Plan</td>
</tr>
<tr>
<td>IATF 16949</td>
<td>Description</td>
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<td>-----------------------------------------------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>8.4.2.1</td>
<td>Type &amp; extent of control –</td>
<td>Adjust type and extent of control based on supplier performance and</td>
<td>Plan</td>
</tr>
<tr>
<td></td>
<td>supplemental</td>
<td>assessment of product, material or service risks</td>
<td></td>
</tr>
<tr>
<td>8.4.2.3 + SI #8</td>
<td>Supplier QMS development</td>
<td>Using risk-based model, define minimum acceptable and target QMS development level</td>
<td>Plan</td>
</tr>
</tbody>
</table>
8.4.2.3 Supplier QMS Development

Ultimate objective become certified to this Automotive QMS standard

- IATF 16949 3rd party certification
- IATF 16949 2nd party conformity
- ISO 9001 registration + customer-defined QMS
- ISO 9001 3rd party registration

Supplier’s QMS

Only with customer approval:

- ISO 9001 2nd party conformity

Initial minimum acceptable level of QMS development

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<tbody>
<tr>
<td>8.4.2.3.1</td>
<td>Automotive product-related software or products with embedded software</td>
<td>Prioritization based on risk and potential impact to customer, require supplier software development capability self-assessment</td>
<td>Plan</td>
</tr>
<tr>
<td>8.4.2.4.1</td>
<td>Second-party audits</td>
<td>Supplier risk assessment; based on risk analysis, criteria for determining need, type, frequency, scope of 2nd party audits</td>
<td>Plan</td>
</tr>
</tbody>
</table>
Types of 2\textsuperscript{nd} party Audits

- Initial supplier selection
- Management Systems review
- Quality Planning
- Project Kick-off
- Launch Readiness
- Verification/Validation
- Product Realization Release
- Ongoing Performance, (containment, change)
## IATF 16949 Risk-based Thinking Requirements

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</thead>
<tbody>
<tr>
<td>8.4.2.5</td>
<td>Supplier development</td>
<td>Determination for supplier development actions including risk analysis</td>
<td>Plan</td>
</tr>
<tr>
<td>8.5.1.1</td>
<td>Control Plan</td>
<td>Linkage and information from design risk analysis, manufacturing process risk analysis outputs; review and <strong>update control plans at a set frequency based on a risk analysis</strong></td>
<td>Plan, Process, Product</td>
</tr>
<tr>
<td>IATF 16949</td>
<td>Description</td>
<td>Requirement</td>
<td>Business Ladder Level</td>
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</tr>
<tr>
<td>8.5.2.1</td>
<td>Identification &amp; traceability – supplemental</td>
<td>Develop traceability plans based on levels of risk or failure severity</td>
<td>Plan, Process, Product</td>
</tr>
<tr>
<td>8.5.6.1</td>
<td>Control of changes – supplemental</td>
<td>Evidence of related risk analysis</td>
<td>Plan, Process</td>
</tr>
<tr>
<td>8.5.6.1.1</td>
<td>Temporary changes of process controls</td>
<td>Based on risk analysis, (e.g. FMEA), internal approvals prior to implementation</td>
<td>Process, Product</td>
</tr>
</tbody>
</table>
Product Traceability Plan

- Product markings
- Lot/batch
- Test results
- Outsourced process
- Manufacturing data
- Material certification

- Finished product
  - Sub-assembly
    - Component
  - Interim process
    - Component
  - Raw material
<table>
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<th>Business Ladder Level</th>
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<tbody>
<tr>
<td>8.7.1.4</td>
<td>Control of reworked product</td>
<td>Utilize risk analysis to assess risks in rework process</td>
<td>Process, Product</td>
</tr>
<tr>
<td>8.7.1.5</td>
<td>Control of repaired product</td>
<td>Utilize risk analysis to assess risks in repair process</td>
<td>Process, Product</td>
</tr>
<tr>
<td>9.1.1.2</td>
<td>Identification of statistical tools</td>
<td>Include in design risk analysis, (DFMEA), process risk analysis, (PFMEA)</td>
<td>Plan, Process</td>
</tr>
<tr>
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</tr>
<tr>
<td>9.2.2.1</td>
<td>Internal audit program</td>
<td>Audit program prioritized based on risk, etc.</td>
<td>System</td>
</tr>
<tr>
<td>9.2.2.3</td>
<td>Manufacturing process audit</td>
<td>Audit effective implementation of process risks analysis, (PFMEA)</td>
<td>Process</td>
</tr>
<tr>
<td>9.3.1.1</td>
<td>Management review – supplemental</td>
<td>Frequency of management review increased based on risk</td>
<td>System</td>
</tr>
<tr>
<td>9.3.2.1 j)</td>
<td>Management review inputs - supplemental</td>
<td>Potential field failures identified thru risk analysis</td>
<td>System, Customer</td>
</tr>
</tbody>
</table>
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</thead>
<tbody>
<tr>
<td>10.2.3 d)</td>
<td>Problem solving</td>
<td>Consideration of impact on similar processes and products</td>
<td>Process, Product</td>
</tr>
<tr>
<td>10.2.4</td>
<td>Error-proofing</td>
<td>Methods used documented in process risk analysis</td>
<td>Process, Product</td>
</tr>
<tr>
<td>10.3.1</td>
<td>Continual improvement – supplemental</td>
<td>Include risk analysis (e.g. FMEA)</td>
<td>All</td>
</tr>
</tbody>
</table>

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Other Risk-based Thinking Resources

- AIAG M-12 – Business Continuity Planning for the Automotive Supply Chain
- AIAG/VDA FMEA manual – in draft

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Future Perfect

What the future holds:

- Better transparency
- Increased Market opportunity
- Reduced costs
- More efficient supply chains
- Increased skills
- Less companies going bankrupt or becoming extinct

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Implementing Risk-based Thinking

- Identify how your organization is applying Risk-based thinking to key business processes
- Investigate Risk-based Thinking methods appropriate for your organization
- Develop and implement processes to support Risk-based Thinking in your business
Final Thought. . .

How is your organization applying Risk-based Thinking to ensure transition of your QMS to ISO 9001:2015/IATF 16949:2016 by the September 14, 2018 deadline?
Thank you for joining us for today’s session

Cathy Fisher  
President, Quistem, LLC  
ISO 9001/IATF 16949 QMS Expert

Terry Onica  
Director, Automotive, QAD  
MMOG/LE Expert

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