
Tim Lozier, EtQ, Inc.
Gain Visibility and Control over Compliance.

- Configurable workflow-based business process automation tool
- Web-based workflow ensures consistent processes
- Enterprise Reporting and Analytics
- Quantitative Operational Risk Management methodology and tools

Learn more at:
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Agenda

• Understanding Operational Risk Management
• How Risk Management processes drive new ways of looking at compliance in operations
• ISO 9000:2015 and Risk Management
• Common tools for leveraging risk in compliance
Increasing Rate of Change
There is an Increasing Rate of Change

• We are more complex
  • Global Scale of Production, Design, Sourcing
  • More Mergers, Acquisitions
  • Growing Supply-Chain

• There is more competition
  • Competition leads to shorter product lifecycles
  • Increases in product complexity
  • More variety of goods in more areas

• Companies need to maintain compliance AND keep up with the pace of business!
Time to shift our mindset?

- How compliance keeps up with change
  - Automation of compliance processes
  - Integration with business systems
  - Harmonization of compliance processes

- Cost of compliance is skyrocketing
  - Cost of systems, people and time
  - Cost of holding back operations
  - Cost of holding back inventory

- Quality and Compliance need to expand!
  - We must think beyond Quality silo
  - From audit results to risk assessments
  - Risk is a more efficient measure of compliance
Risk Management Primer: Hazard vs Risk

• The terms "hazard" and "risk" are often used interchangeably. However, in terms of risk assessment, these are two very distinct terms.
Risk Management Primer: Hazard

• **1. Insurance:** Condition or situation that creates or increases chance of loss in an insured risk, separated into two kinds (1) **Physical hazard:** physical environment which could increase or decrease the probability or severity of a loss. It can be managed through risk-improvement, insurance policy terms, and premium rates. (2) **Moral hazard:** attitude and ethical conduct of the insured. It cannot be managed but can be avoided by declining to insure the risk.

• **2. Workplace safety:** Dangerous event or situation that may lead to an emergency or disaster. It could also be a biological, chemical, or physical agent in (or a property of) an environment that may have an adverse health effect, or may cause injury or loss. As such, a hazard is a potential and not an actual possibility.

Read more:
http://www.businessdictionary.com/definition/hazard.html#ixzz3miUj2jq1
Risk Management Primer: Risk

- Risk is defined as the probability that exposure to a hazard will lead to a negative consequence, or more simply:

\[ \text{Risk} = \text{Hazard} \times \text{Exposure} \]

- Thus, a hazard poses no risk if there is no exposure to that hazard.
Risk Management Primer: Hazard vs Risk

Consider the following example from David Okrent's 1980 article, "Comment on Societal Risk":

3 in a boat
Three people crossing the Atlantic in a rowboat face a hazard of drowning...

300 in a ship
Three hundred people crossing the Atlantic in an ocean liner face the same hazard of drowning...
Risk Management Primer: Hazard vs Risk

Consider the following example from David Okrent's 1980 article, "Comment on Societal Risk":

The risk to each individual per crossing is given by the probability of the occurrence of an accident in which he or she drowns.

\[
RISK = \text{probability of accident occurring} \times \text{hazard}
\]

High Probability = equipment, # of people, environment

Low Probability = equipment, # of people, environment
Risk Management Primer: Hazard vs Risk

Consider the following example from David Okrent's 1980 article, "Comment on Societal Risk":

The hazard [drowning] is the same for each individual, but the risk [probability of drowning] is greater for the individuals in the rowboat than in the ocean liner.

Hazard = Hazard
Probability > Probability

MORE RISK

LESS RISK
Risk Management Primer – the Process

- Risk Management is a broad standard (ISO 31000)

  - **Risk Identification**
    - Identify all relevant risks (e.g., hazard analysis)
  
  - **Risk Evaluation**
    - Quantify the risk (e.g., probability and severity)
  
  - Development and evaluation of risk assessment methods
  
  - Risk management decisions
  
  - Implemented solution
    - Implement a process
    - Use objective and proven tools
    - Accept (worth it), reduce (mitigate), compensate (insure), transfer (partner), avoid (stop)
    - Change management to introduce or improve controls
Risk Management Primer: Areas of Coverage

Enterprise Risk Management

- Quality
- Regulatory
- Environmental
- Safety
- Financial
- Commercial
Risk Management Primer: Rationale for Risk

Risk Management is the Core Methodology

- Easy to understand for the uninitiated
- Repeatable and objective methods
- Drives short term and long term change
- A way to evaluate risk in an operational context
- Beware a false sense of security
ISO 9000:2015….it’s not just requirements, It’s a company mindshare of Quality.

There should be a company-wide commitment/leadership around Quality.
ISO 9000:2015 view on risk

Section 5: Leadership
Provide leadership by encouraging a focus on quality
Promote the use of risk-based thinking.

Section 6: Planning
Consider risks and opportunities when you plan your QMS
Plan how you’re going to manage risks and opportunities

DISCLAIMER: The ISO view on risk is SIMPLY STATED. “Use Risk-based thinking” to manage and plan…. But what does that really mean? Broad, and simple – lots of interpretation!
Planning your QMS with risk in mind

- Identify risks and opportunities to influence QMS performance
- Determine how you’re going to measure those risks
- Build risk treatment options
- Define actions to address these risks
Planning your QMS with risk mind

- How to start Identifying risks?
  - Survey your operations
  - Audit, Survey, collect, analyze

Diagram showing the process of planning with risk mind, including Identify Risks, Evaluate Risks, Treatment of Risks, and Take Action.
Planning your QMS with risk in mind

- Evaluate How to handle the risk
- Risk Assessment
  - Should be repeatable, objective
  - Should be backed by REAL-WORLD DATA
- Quantitative means to build a risk assessment
Planning your QMS with risk in mind

- We know the risk....how do we handle it?

  - Acceptance: “Worth it”
  - Reduction: “Mitigation”
  - Compensation: “Insurance”
  - Transference: “Move it”
  - Avoidance: “Stop it”
Planning your QMS with risk in mind

- Identify Risks
- Evaluate Risks
- Treatment of Risks
- Take Action

• Take Action: Create Visibility and Control the Risk

- Corrective/Preventive Action
- Controls/Action Plans
- Reporting/Trending
Planning your QMS with risk in mind

Document the process in order to have traceability.

Identify Risks → Evaluate Risks → Treatment of Risks → Take Action

DOCUMENT YOUR ACTIVITIES

How? Audit Findings
Survey Results
Report on Findings

Document your Evaluation: Control your methods, tools, processes

Document the treatment, the overall decision factors

Link Assessments to Actions taken, improvements made
Planning your QMS with risk in mind

Identify Risks → Evaluate Risks → Treatment of Risks → Take Action

Potential but not realized Hazards: Survey improvement areas

How can we determine the impact of potential events?

Where can we measure impact and determine improvement?

Change Management, Process Improvements, Etc.

It’s not all for just the Risks! Identify Opportunities too!
Common Tools for Risk Management Treatment (a sample)

- Decision Tree
- Risk Matrix
- Failure Modes and Effects Analysis (FMEA)
- Bowtie
- Risk Register
Decision Tree Analysis

Easy to integrate with everyday processes

1. Did the employee experience an injury or illness?
   - Yes
   - No
     - Is the injury or illness work-related?
       - Yes
       - No
         - Updated the previously recorded injury or illness entry if necessary.
       - No
         - Is the injury or illness a new case?
           - Yes
           - No
             - Does the injury or illness meet the general recording criteria or the application to specific cases?
               - Yes
               - No
                 - Do not record the injury or illness
               - Record the injury or illness
Decision Tree Example

• When to report to the FDA
  • Medical device manufacturer
  • Reporting decision embedded in complaint handling process
  • Filled out by analysts for every potential adverse event
  • Drives decision to report (Yes/No) and acceptable delay (when?)

• Prioritize internal notification
  • Global Utilities company
  • Automated determination of who needs to be notified of incidents based on risk level
  • Immediate initial risk assessment determines risk level
  • Risk level determines email distribution list, including SMS (text) alerts for highest level
  • Follow up risk assessment performed after investigation is completed (for long term trend analysis)
  • Take immediate action on critical issues, and implement long term improvements on unacceptable trends
## Risk Matrix

### Quick, easy, colorful

Quantifies the risk level using tested assumptions

<table>
<thead>
<tr>
<th>PROBABILITY</th>
<th>Minor (1)</th>
<th>Negligible (2)</th>
<th>Marginal (3)</th>
<th>Critical (4)</th>
<th>Catastrophic (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent (5)</td>
<td></td>
<td></td>
<td>Red</td>
<td>Red</td>
<td>Red</td>
</tr>
<tr>
<td>Probable (4)</td>
<td></td>
<td></td>
<td>Yellow</td>
<td>Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Occasional (3)</td>
<td></td>
<td></td>
<td>Yellow</td>
<td>Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Remote (2)</td>
<td></td>
<td></td>
<td>Yellow</td>
<td>Green</td>
<td>Green</td>
</tr>
<tr>
<td>Improbable (1)</td>
<td></td>
<td></td>
<td>Green</td>
<td>Green</td>
<td>Green</td>
</tr>
</tbody>
</table>
Risk Matrix Example

Identify potential adverse events
- Medical device manufacturer (a different one)
- Customer complaints routed for investigation
- Subject matter experts perform risk assessment (meeting)
- Risk levels drive decisions for recalls, notifications, CAPA

Survey of known and unknown threats
- Services organization
- Periodic survey to all business functions
- Managers re-calculate risk levels for known threats and suggest new threats
- Prioritization of compiled risk levels drives strategic risk mitigation initiatives (managed through CAPA process)
# Failure Modes and Effect Analysis

For design of products and processes

<table>
<thead>
<tr>
<th>Item / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Source</th>
<th>Potential Cause(s) / Mechanisms of Failure</th>
<th>Occur</th>
<th>Design Controls</th>
<th>Defect</th>
<th>R. P. N.</th>
<th>Recommended Action(s)</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter for assembly with B44 to firewall</td>
<td>Insufficient wax coverage over specified surface</td>
<td>Deteriorated life of door leading to: Unsatisfactory appearance due to rust through paint over time, Impaired function of interior door hardware</td>
<td>4</td>
<td>Insufficient wax thickness specified</td>
<td>4</td>
<td>Supplier certification</td>
<td>1</td>
<td>16</td>
<td>None</td>
<td>N/A</td>
<td>2/11/98</td>
</tr>
<tr>
<td>Corroded interior lower door panels</td>
<td>Improper oxide coating</td>
<td>Entrapped air prevents wax from entering corner/edge access</td>
<td>6</td>
<td>Inappropriate wax specified</td>
<td>5</td>
<td>Set up</td>
<td>4</td>
<td>80</td>
<td>None</td>
<td>N/A</td>
<td>2/11/98</td>
</tr>
<tr>
<td></td>
<td>Spray heads clogged: Viscosity too high, Temperature too low, Pressure too low</td>
<td>Laboratory test using &quot;worst case&quot; wax and application hole size</td>
<td>4</td>
<td>Incoming audit per 200-16 certification, SPC Lat/Or</td>
<td>2</td>
<td>48</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Feeder not properly or | | | 3 | | | | | | | | |

| Org. Date | 2/11/98 | Page | 1 of 2 | Dwg. Rev. | Key Date | 2/11/98 | FMEA No. | DPMEA-001 | | |

Part Name: Filter
Design Responsibility: Brad Anderson
Prepared By: Brad A. Anderson
Date: 2/11/98

Subsystem: Chrysler Motors Corporation
Supplier: Any Company, Inc.
Code: ACI-001
Supplier Part No.: A-9514
Dwg. Rev.: B

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FMEA Process

Planning Stage
- Develop and Execute FMEA Strategic Plan
- Develop and Execute FMEA Resource Plan

Analysis Stage
- Develop Program Specific FMEAs
- Test and Field Failures

Review Stage
- Management Review
- FMEA Quality Audit

Implementation Stage
- Execute Actions to Reduce or Eliminate Risk
- Linkage to Other Processes
<table>
<thead>
<tr>
<th>Item / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity</th>
<th>Potential Cause(s) / Mechanisms of Failure</th>
<th>Occurrence</th>
<th>Current Design Controls</th>
<th>Detection</th>
<th>RPN</th>
<th>Recommended Action(s)</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Action Results</th>
</tr>
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<td>Filter for assembly with B44 to firewall</td>
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<td>4</td>
<td>Insufficient wax thickness specified Inappropriate wax specified</td>
<td>4</td>
<td>Supplier certification</td>
<td>1</td>
<td>18</td>
<td>None</td>
<td>N/A</td>
<td>2/11/98</td>
</tr>
<tr>
<td>Corroded interior lower door panels</td>
<td>Improper oxide coating</td>
<td>Entrapped air prevents wax from entering corner/edge access</td>
<td>8</td>
<td></td>
<td>6</td>
<td>Test spray pattern at startup and after idle periods, and ...</td>
<td>5</td>
<td>180</td>
<td>Add team evaluation using production spray equipment and specified wax</td>
<td>Engineering and Assembly Operations 2/18/98</td>
<td>Based on test results (Test #9089) spray head modified to ...</td>
</tr>
<tr>
<td></td>
<td>Spray heads clogged: Viscosity too high. Temperature too low, Pressure too low</td>
<td></td>
<td>4</td>
<td>Incoming audit per 200-16 certification, SPC Lot/Qtr</td>
<td>2</td>
<td>Add laboratory accelerated corrosion testing</td>
<td>3</td>
<td>72</td>
<td>Add laboratory accelerated corrosion testing</td>
<td>ABC Labs 2/27/98</td>
<td>Test results show specified ...</td>
</tr>
<tr>
<td>Feeder not properly or</td>
<td></td>
<td></td>
<td>3</td>
<td>Laboratory test using “worst case” wax and application hole size</td>
<td></td>
<td>Conduct DOE on wax thickness</td>
<td></td>
<td></td>
<td>Engineering Associates 2/18/98</td>
<td>DOE shows 25% variation in specified thickness is acceptable</td>
<td></td>
</tr>
</tbody>
</table>
FMEA Example

• Demonstrate acceptable quality to customer
  • Global engineering company
  • Uses PPAP to coordinate design changes with parts suppliers
  • FMEA submitted by supplier and evaluated by engineers
  • Risk Priority Number (RPN) drives remedial actions and general acceptability
Bowtie Model

For low-occurrence events that are catastrophic

- Threat
  - Preventive Controls
- Threat
  - Preventive Controls
- Threat
  - Preventive Controls

Undesired Event

- Recovery Controls
- Recovery Controls
- Consequence

Frequency → Likelihood → Likelihood → Severity
Bowtie Example

For low-occurrence events that are catastrophic

- Bad Weather
- Tired Driver
- Poor Visibility

- Windshield Wipers
- Coffee
- Headlights

- Seatbelts
- Airbags
- Crash Barrels
  Guard Rails

- Vehicle Damage
- Driver Injury
- Driver Death
Risk Register

• Monitors risk levels over time
  • Library of hazards (typically known for each industry)
  • Collects risk assessment data from many processes
  • Provides visibility into critical events and data for trend reporting
Summary

• Complexity and scale breeds the need for change
• Risk is a universal compliance constant
• ISO 9000:2015 is about enrolling everyone in Quality
• Risk in ISO 9000:2015 is simply stated, but maps well to the risk methodology
• Figure out your path to risk, and leverage tools to expand to a risk-based QMS
• There are tools to help ease this transition!
Thank you! Questions?

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Dir. Product Strategy

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