Applying Risk-based Thinking to Operations

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Agenda

• Understanding Operational Risk Management
• How Risk Management processes drive new ways of looking at compliance in operations
• ISO 9001:2015 and Risk Management
• Common tools for leveraging risk in compliance
Risk Management: 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: 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: Hazard vs 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: Hazard vs 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 = probability of accident occurring x hazard

High Probability = equipment, # of people, environment

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

- Risk Management is a broad standard (ISO 31000)

1. **Risk Identification**
   - Identify all relevant risks (e.g., hazard analysis)

2. **Risk Evaluation**
   - Quantify the risk (e.g., probability and severity)

3. Development and evaluation of risk assessment methods
   - Implement a process
   - Use objective and proven tools

4. **Risk management decisions**
   - Accept (worth it), reduce (mitigate), compensate (insure), transfer (partner), avoid (stop)

5. **Implemented solution**
   - Change management to introduce or improve controls
Risk Management: Areas of Coverage

Enterprise Risk Management

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

Risk Management is the Core Methodology

- Repeatable and objective methods
- Easy to understand for the uninitiated
- A way to evaluate risk in an operational context
- Drives short term and long term change
- 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 9001:2015 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

![Risk Management Diagram]

- Identify Risks
- Evaluate Risks
- Treatment of Risks
- 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

- Take Action: Create Visibility and Control the Risk

  - Corrective/Preventive Action
  - Controls/Action Plans
  - Reporting/Trending

Identify Risks ➔ Evaluate Risks ➔ Treatment of Risks ➔ Take Action
Planning your QMS with risk in mind

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

• Document the process in order to have traceability.
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

- Decision Tree
- Risk Matrix
- FMEA
- Bowtie
- Risk Register
Decision Tree Analysis

Easy to integrate with everyday processes

1. Did the employee experience an injury or illness?
   - No
   - Yes

2. Is the injury or illness work-related?
   - No
   - Yes

3. Is the injury or illness a new case?
   - No
   - Yes

4. Does the injury or illness meet the general recording criteria or the application to specific cases?
   - No
   - Yes

5. Do not record the injury or illness
6. Record the injury or illness

Updated the previously recorded injury or illness entry if necessary.
Risk Matrix

Quick, easy, colorful

Quantifies the risk level using tested assumptions

<table>
<thead>
<tr>
<th><strong>PROBABILITY</strong></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></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probable (4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occasional (3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remote (2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improbable (1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SEVERITY**
## Failure Modes and Effect Analysis

For design of products and processes

<table>
<thead>
<tr>
<th>Element/Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Class</th>
<th>Potential Cause(s)</th>
<th>Mechanisms or Failure</th>
<th>Description</th>
<th>Design Counter</th>
<th>DUE Code</th>
<th>RPN</th>
<th>Recommended Action(s)</th>
<th>Date Prepared</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter for assembly with BH vs. in-travel</td>
<td>Insufficient wax coverage on specified surface</td>
<td>Deteriorated fit of door panels due to unsatisfactory appearance due to wax through paint over time. Impaired function of interior door hardware.</td>
<td>4</td>
<td>Insufficient wax thickness specified</td>
<td>4 Supplier certification</td>
<td>1 16 None</td>
<td>N/A</td>
<td>2/1/98</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Core团队</td>
<td>Core team</td>
<td>Inadequate wax coverage on specified surface</td>
<td>5</td>
<td>Inadequate wax specification</td>
<td>4</td>
<td>69</td>
<td>None</td>
<td>N/A</td>
<td>2/1/98</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrosion internal lower door panels</td>
<td>Improper adhesion</td>
<td>Exposed internal panel due to improper adhesion</td>
<td>5</td>
<td>Inappropriate adhesive specification</td>
<td>4</td>
<td>69</td>
<td>None</td>
<td>N/A</td>
<td>2/1/98</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improper adhesion</td>
<td>6</td>
<td>Test spray pattern at start and after 5 cycles</td>
<td>5</td>
<td>180</td>
<td>Add team evaluation spray equipment and specified wax</td>
<td>Engineering and Assembly Operations 2/1/98</td>
<td>Based on test results (Test 400880) spray head modified to ...</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spray head</td>
<td>4</td>
<td>Improving paint adhesion</td>
<td>4 2</td>
<td>48</td>
<td>None</td>
<td>N/A</td>
<td>2/1/98</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Laboratory test using worst case wax and adhesion hole site</td>
<td>3</td>
<td>Conduct DOE on wax thickness</td>
<td>3</td>
<td>64</td>
<td>Add laboratory accelerated corrosion testing</td>
<td>Engineering Associates 2/1/98</td>
<td>Test results show specified wax thickness is acceptable</td>
<td>6 2 2 24</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feeders not properly used</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
- Supplier FMEAs

Implementation Stage
- Execute Actions to Reduce or Eliminate Risk
- Linkage to Other Processes
# Sample FMEA Form

## Design FMEA

<table>
<thead>
<tr>
<th>Item / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect of Failure</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Risk Priority Number</th>
<th>Recommended Action(s)</th>
<th>Responsible Actions</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter for assembly with 644 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>4</td>
<td>10</td>
<td>60</td>
<td>Supplier certification</td>
<td>N/A</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>6</td>
<td>100</td>
<td>Add team evaluation using production spray equipment and specified wax</td>
<td>Engineering and Assembly Operations</td>
<td>Based on test results (Test #6686) spray head modified to...</td>
</tr>
<tr>
<td>Spray heads plugged</td>
<td>Vicinity too high, Temperature too low, Pressure too low</td>
<td>Incomplete audit per 20D.16 certification, SPF Lot/Gr</td>
<td>4</td>
<td>2</td>
<td>48</td>
<td>Add laboratory accelerated corrosion testing</td>
<td>ABC Labs</td>
<td>Test results show specified...</td>
</tr>
<tr>
<td>Feeder not properly or</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Conduct DOE on wax thickness</td>
<td>Engineering Associates</td>
<td>DOE shows 25% variation in specified thickness is acceptable</td>
</tr>
</tbody>
</table>
Bowtie Model

For low-occurrence events that are catastrophic

- Threat
  - Preventive Controls
  - Preventive Controls
  - Preventive Controls

- Undesired Event (Hazard)
  - Recovery Controls
  - Recovery Controls
  - Recovery Controls

- Consequence
- Consequence
- Consequence

- Frequency
- Likelihood

- Likelihood
- Severity
Bowtie Example

For low-occurrence events that are catastrophic

- Bad Weather
  - Windshield
  - Wipers
- Tired Driver
  - Coffee
- Poor Visibility
  - Headlights
- Car Accident
- 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

PDCA Cycle
Summary

• Risk is a universal compliance constant
• ISO 9001:2015 is about enrolling everyone in Quality
• Risk in ISO 9001:2015 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!