Hacking Risk Management

3 Ways to Easily Build Risk into Your Processes

Glen Fraser
Agenda

New focus on Risk
Why Risk can be a challenge
Ways to measure Risk
How to get started – 3 ways
New focus on Risk

Meeting the standards of compliance

ISO 31000

ISO 9001:2015
A good deal of risk management principles

ISO 14000
OHSAS 18000

ISO 13485/14969
ICH Q10/Q9

ISO 27000

ISO 22000
Increasing Rate of Change...
Increasing Complexity...

More complex organizations

More intense competition

Companies need to maintain compliance AND keep up!
Brings changes to the standards

Compliance keeps up with change

Compliance objectives are changing
Risk Management Process

- Risk Management is a broad standard (ISO 31000)

  - Risk Identification
  - Risk Evaluation
  - Development and evaluation of risk assessment methods
  - Risk management decisions
  - Implemented solution

Identify all relevant risks (e.g., hazard analysis)

Quantify the risk (e.g., probability and severity)

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
Why Risk can be a challenge

From “A Transformational Approach to Safety Risk Management” Bob Dodd, Aloft

Lack of common understanding / terms
Why Risk can be a challenge

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Lack of common understanding / terms

Too much focus on Process, when Content is Key
Why Risk can be a challenge

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Too much focus on Process, when Content is Key

Understand the Limitations of the Process

- People are not good at assessing risk
  - We don't expect the unexpected
  - We reconstruct instead of replay
  - We see patterns in random events
  - We confuse understanding with knowledge
  - We group think
- Prediction is hard (experts are no better)
- Dealing with very small sample sets (single occurrence)
Why Risk can be a challenge

From “A Transformational Approach to Safety Risk Management” Bob Dodd, Aloft

Lack of common understanding / terms
Too much focus on Process, when Content is Key
Understand the Limitations of the Process
Why Risk can be a challenge

- Thinking fast and Slow by Daniel Kahneman

- Future Babble: Why Expert Predictions Fail - and Why We Believe Them Anyway by Daniel Gardner

- Risk: The Science and Politics of Fear by Daniel Gardner
Ways to Measure Risk (only a sample)

Decision Tree
Risk Matrix
HACCP
Risk Survey
Failure Modes and Effects Analysis
Bowtie
Risk Register
Risk Assessment is the Core Methodology

- Repeatable and objective methods
- Easy to understand for the uninitiated
- Drives short term and long term change
- A way to evaluate risk in an operational context
- Beware a false sense of security
Decision Trees

Easy to integrate with everyday processes

- Did the employee experience an injury or illness? (Yes/No)
  - Yes: Is the injury or illness work-related? (Yes/No)
    - Yes: Is the injury or illness a new case? (Yes/No)
      - No: Updated the previously recorded injury or illness entry if necessary.
      - Yes: Does the injury or illness meet the general recording criteria or the application to specific cases? (Yes/No)
        - No: Do not record the injury or illness.
        - Yes: Record the injury or illness.
  - No: Do not record the injury or illness.
# Risk Matrix

Quick, easy, colorful

Quantifies the risk level using tested assumptions

## SEVERITY

<table>
<thead>
<tr>
<th></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><strong>Frequent (5)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Probable (4)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Occasional (3)</strong></td>
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<tr>
<td><strong>Remote (2)</strong></td>
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<td></td>
</tr>
<tr>
<td><strong>Improbable (1)</strong></td>
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</tr>
</tbody>
</table>
## Hazard Analysis (HACCP)

### Preventive approach to safety

<table>
<thead>
<tr>
<th>Step</th>
<th>Hazard</th>
<th>Preventive Measures</th>
<th>GMP/SSOP</th>
<th>Risk Assessment</th>
<th>CCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>B: Biological C: Chemical P: Pathogens</td>
<td>Steps taken to mitigate hazard</td>
<td>Standard Procedures related GMP</td>
<td>Q1</td>
<td>Yes</td>
</tr>
<tr>
<td>3.2</td>
<td>B: Biological C: Chemical P: Pathogens</td>
<td>Steps taken to mitigate hazard</td>
<td>Standard Procedures related GMP</td>
<td>Q2</td>
<td>Yes</td>
</tr>
<tr>
<td>3.3</td>
<td>B: Biological C: Chemical P: Pathogens</td>
<td>Steps taken to mitigate hazard</td>
<td>Standard Procedures related GMP</td>
<td>Q3</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Notes:**
- Q1, Q2, Q3, Q4: Indicate the level of risk assessment (e.g., Q1, Q2, Q3, Q4).
- CCP: Critical Control Point.
Risk Survey

Survey for ranking known, identifying new risks
## Failure Modes and Effect Analysis

For design of products and processes

### FMEA

**Revision 6.0 2/11/98**

<table>
<thead>
<tr>
<th>Item / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity Class</th>
<th>Potential Cause(s) / Mechanisms of Failure</th>
<th>Occurrence</th>
<th>Detection</th>
<th>P-D-A</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 freewall</td>
<td>Insufficient wax coverage over specified surface</td>
<td>Insufficient wax thickness specified</td>
<td>4</td>
<td>Supplier certification</td>
<td>1 16 None</td>
<td>N/A 2/11/98</td>
<td></td>
<td></td>
<td></td>
<td></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>0</td>
<td>Test spray pattern at startup and after idle periods, and ...</td>
<td>5 180 Add team evaluation using production spray equipment and specified wax</td>
<td>Engineering and Assembly Operations 2/18/08</td>
<td>Based on test results (Test #9600) spray head modified to ...</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spray heads clogged: Viscosity too high, Temperature too low, Pressure too low</td>
<td>4</td>
<td>Incomming audit per 200-16 certification, SPC Lot/Gr</td>
<td>2 48 Laboratary test using 'worst case' wax and application hole size</td>
<td>3 72 Add laboratory accelerated corrosion testing</td>
<td>Engineering Associates 2/18/98</td>
<td>Test results show ...</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>DOE shows 25% variation in specified thickness is acceptable</td>
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<tr>
<td>Feeder not properly or</td>
<td></td>
<td></td>
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</tbody>
</table>

**Part Name**

Filer

**Design Responsibility**

Brad Anderson

**Application/Model Year**

Sedan / 1996

**Prepared By**

Brad A. Anderson

**Date**

2/11/98
Bowtie Model

For low-occurrence events that are catastrophic

Threat
Preventive Controls

Threat
Preventive Controls

Threat
Preventive Controls

Undesired Event (Hazard)

Preventive Controls
Recovery Controls

Recovery Controls
Consequence

Recovery Controls
Consequence

Recovery Controls
Consequence

Frequency Likelihood Likelihood Severity

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Where to Assess (Operational) Risk

**Product and Process Design**
- Job Safety Analysis (EHS)
- Change Management
- Production Part Approval Process (PPAP)
- Failure Mode Effects Analysis (FMEA)
- Materials

**Manufacturing and Delivery**
- Incident and Accident Reporting (EHS)
- Nonconforming Reports and Planned Deviations

**Post-Production**
- Internal Audits
- Corrective /Preventive Actions (CAPA)
- Complaints Handling
- Supplier Performance Rating
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
Risk Register is the New Center
Ways to Measure Risk

Risk Technology is NOT automatic

– Tools support decision-making process, but people (experts) make the final decision
– Use a Risk Team to increase visibility and education
Getting started

Define standard meanings and terms

Use an appropriate assessment tool
–Vet your risk assessment methods using historical examples to ensure accurate results

Build your Risk Library (Register)
Thank You! Questions?

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