FMEA, FEMA, & FAME

Would Mike Brown be famous today if FEMA had used FMEA?

ASQ North Jersey
Dinner Meeting
Wednesday, November 15, 2006

Presented by Ed May, ASQ CSSBB
Overview of Presentation

- Introduction
- **FEMA, Mike Brown, Hurricane Katrina**
- Failure Mode & Effects Analysis
- FMEA Examples
- FMEA Exercise
- Conclusions
- Q & A
FMEA

- Florida Music Educators Association
- Florida Municipal Electric Association
- Freshwater and Marine Ecosystems in Africa
- Federal Emergency Management Agency
Federal Emergency Management Agency

- FEMA
- 500 C Street SW, Washington, D.C. 20472
  Disaster Assistance: (800) 621-FEMA, TTY (800) 462-7585
- U.S. Department of Homeland Security
- www.fema.gov
FEMA Advice

Before a Hurricane take the following measures:

- Make plans to secure your property. Permanent storm shutters offer the best protection for windows. A second option is to board up windows with 5/8” marine plywood, cut to fit and ready to install. Tape does not prevent windows from breaking.
- Install straps or additional clips to securely fasten your roof to the frame structure. This will reduce roof damage.
- Be sure trees and shrubs around your home are trimmed.
- Clear loose and clogged rain gutters and downspouts.
- Determine how and where to secure your boat.
- Consider building a safe room.
Acronyms, Abbreviations & Terms

- The **FAAT List** is a handy reference for the myriad of acronyms and abbreviations used within the federal government, emergency management and the first response community.
- This year's new edition, which further reflects the establishment of the U.S. Department of Homeland Security, contains nearly 600 new entries and other add-ons bringing the total to over **4,200 acronyms** and abbreviations.
- Some organizations and terms listed are obsolete, but they are included because they may still appear in publications and correspondence.
Mike Brown
Expert in Failure Mode?
Hurricane Katrina

- **Katrina** was one of the most devastating hurricanes in United States history.
  - **Katrina** was the deadliest hurricane to strike the United States since 1928.
  - **Katrina** was the costliest hurricane ever recorded in North America.
  - **Katrina** produced damage estimated at $75,000,000,000 in the New Orleans area and along the Mississippi coast.
Katrina was devastating

- **Katrina** was responsible for approximately 1200 reported deaths, in Louisiana and Mississippi.
- **Katrina** caused catastrophic damage in southeastern Louisiana and southern Mississippi.
- Storm surge along the Mississippi coast caused total destruction of many structures, with the surge damage extending several miles inland.
- Similar damage occurred in portions of southeastern Louisiana southeast of New Orleans.
- The surge overtopped and breached levees in the New Orleans metropolitan area, resulting in the inundation of much of the city and its eastern suburbs.
Katrina was predicted

THE BIG ONE

By Mark Schleifstein & John McQuaid

A major hurricane could decimate New Orleans, but flooding from even a moderate storm could kill thousands.

It's just a matter of time.
Katrina was predicted

- KEEPING ITS HEAD ABOVE WATER
  New Orleans faces doomsday scenario
  By ERIC BERGER

- It's been 36 years since Hurricane Betsy buried New Orleans 8 feet deep.

- Since then a deteriorating ecosystem and increased development have left the city in an ever more precarious position.

- The problem went unaddressed for decades by a laissez-faire government, experts said.

- "To some extent, I think we've been lulled to sleep," said Marc Levitan, director of Louisiana State University's hurricane center.
History was bound to Repeat

- In September 1998 the debris along New Orleans' lakefront levees marked the wake of Hurricane Georges.
- It also measured the slender margin separating the city from mass destruction.
- The debris, showed that Georges, a Category 2 storm that only grazed New Orleans, had pushed waves to within a foot of the top of the levees.
- A stronger storm on a different course could have realized emergency officials' worst-case scenario.
  - Billions of gallons of lake water pouring over the levees into an area 5 feet below sea level with no natural means of drainage.
With computer modeling of hurricanes and storm surges, disaster experts had developed a detailed picture of how a storm could push Lake Pontchartrain over the levees and into New Orleans, the worst case being a hurricane moving in from due south.

That scenario would turn the city into a lake 30 feet deep, fouled with chemicals and waste from ruined septic systems, businesses and homes, trapping thousands of people in buildings and vehicles.
The scene has been played out for years in computer models and emergency-operations simulations. Officials at the local, state and national level are convinced the risk is genuine and are devising plans for alleviating the aftermath of a disaster that could leave the city uninhabitable for six months or more. The Army Corps of Engineers has begun a study to see whether the levees should be raised to counter the threat. But officials said that right now, nothing can stop "the big one."
Filling the Bowl

- New Orleans lies in a low, flat coastal area.
- New Orleans has hurricane levees that create a bowl with the bottom dipping lower than the bottom of Lake Pontchartrain.
- Though providing protection from weaker storms, the levees also trap any water that gets inside -- by breach, overtopping or torrential downpour -- in a catastrophic storm.
- "Filling the bowl" was the worst potential scenario for a natural disaster in the United States.
The hurricane approaches from the south.
People hope that hurricane-protection system “works”.
Water is pumped into Lake Pontchartrain.
The 20 foot deep lake becomes 30 feet deep.
Water flows through the gaps around the lake.
The eye of the hurricane continues to move north.
The winds over the lake start to come from the north.
The winds blow south at 100 mph.
The water moves south.
The winds generate 10 foot high waves.
The waves breaking and crash along the sea wall.
The waves start breaking over the levees.
The levee acts like a weir, as water pours over the top.
The water floods the lakefront, filling up low-lying areas.
Pumping systems are overwhelmed and submerged in a matter of hours.
Parts of the levee fail as erosion occurs.
Water flows through the city stopping only when it reaches the south levee.
The projected death and destruction eclipsed any natural disaster that emergency officials had dreamed up.
The risks were significant for New Orleans.
In a given year, the Army Corps of Engineers said that the risk of the lakefront levees being topped was less than 1 in 300.
But over 30 years, that risk approached 10 percent.
Federal Emergency Management Agency officials had begun working with state and local agencies to devise plans on what to do if a Category 5 hurricane struck.
The LSU Hurricane Center was appointed by the State of Louisiana to lead the state's forensic investigation of the Hurricane Katrina levee failures.

Dr. Ivor van Heerden leads a team of engineers and coastal scientists conducting analysis of the storm surge levels, levee construction, and levee failure mechanisms.

Known as Team Louisiana, this group consists of LSU engineers, scientists, and several well-known local geotechnical engineering experts.
I contacted the Hurricane Center

Hi

My name is Ed May. I am preparing a talk for my local chapter of the American Society for Quality about a technique called Failure Modes and Effects Analysis (FMEA). I thought it would be interesting to find out if FEMA (Federal Emergency Management Agency) used FMEA. Since FEMA was not much help I googled the internet and found your Hurricane Department at LSU. I would greatly appreciate finding out if FMEA has been applied to the failure mechanisms of the dikes around New Orleans before Hurricane Katrina. Or anything along those lines. Thanks.

Prof May, ASQ CSSBB
New Jersey Institute of Technology
The Hurricane Center Wrote Back

- Prof May

- I searched the entire 6,000 page IPET report so it is apparent that the Corps is not using FMEA.

- I recommend, however, that you look at Volume 9 that addresses the subject of risk and probabilistic failure modeling.

- Best, Paul

- G. Paul Kemp, Ph.D.
  - Associate Professor, Research
  - Director, Natural Systems Modeling Group
  - Louisiana State University
  - School of the Coast and Environment & LSU Hurricane Center
  - 1002Q Energy, Coast and Environment Bldg.
  - Baton Rouge, Louisiana 70803
So What is FMEA?

- Failure
- Mode &
- Effects
- Analysis
History of FMEA

- The FMEA process was originally developed by the US military in the late 1940’s to classify failures "according to their impact on mission success and personnel/equipment safety".
- FMEA was used by NASA on the 1960s Apollo space missions.
- FMEA was further developed by the aerospace industry.
- FMEA was adopted by the automotive industry.
- FMEA was used by Ford in the 1980’s to reduce risks after the Pinto suffered a fault in several vehicles causing the fuel tank to rupture and burst into flames after crashes.
- FMEA use in healthcare began in the early 1990s, around the time Six Sigma began to emerge as a viable process improvement methodology.
- Several industries maintain formal FMEA standards
FMEA around the World

- Analyse des Modes de Défaillances de leurs Effets
- Fehlermöglichkeiten - und Einflussanalyse
- Faal Toestand En Effect Analyse
- Effect verminderd wordt

Some FMEA Definitions

- Juran: “A preventative technique for the designer to use to study the causes and effects of failures before the design is finished”.

- Pyzdek: “An attempt to delineate all of the possible failure modes, their effect on the system, the likelihood of occurrence, and the probability that the failure will go undetected”.

- “All the ways that failure can occur are examined. Action taken to minimize the chances of failure and the effect of failure”.
FMEA is a step-by-step Approach

- ... for identifying all possible failures in a design, manufacturing / assembly process, or product / service.
- “Failure modes” means the ways, or modes, in which something might fail.
- Failures are any errors or defects, especially ones that affect the customer.
- Failures can be potential or actual.
- “Effects analysis” refers to studying the consequences of those failures.
- Failures are prioritized according to:
  - how serious their consequences are
  - how frequently they occur
  - how easily they can be detected.
FMEA is a step-by-step Approach

- The purpose of the FMEA is to take actions to eliminate or reduce failures
  - starting with the highest-priority ones.
- FMEA documents current knowledge and actions about the risks of failures
  - for use in continuous improvement.
- FMEA is used during design to prevent failures.
- Later it’s used for control, before and during ongoing operation of the process.
- FMEA begins during the earliest conceptual stages of design
- FMEA continues throughout the life of the product or service.
Types of FMEAs

- **FMECA (Failure Mode, Effects, Criticality Analysis):** Considers every possible failure mode and its effect on the product/service. Goes a step above FMEA and considers the criticality of the effect and actions, which must be taken to compensate for this effect. (critical = loss of life/product).

- **Design FMEA:** Used to analyze component designs. Focuses on potential failure modes associated with the functionality of a component caused by design. Failure modes may be derived from causes identified in the System FMEA.

- **Process FMEA:** Used to analyze transactional processes. Focus is on failure to produce intended requirement, a defect. Failure modes may stem from causes identified.

- **System FMEA:** A specific category of Design FMEA used to analyze systems and subsystems in the early concept and design stages. Focuses on potential failure modes associated with the functionality of a system caused by design.

- **Service FMEA:** focuses on service functions

- **Software FMEA:** focuses on software functions FMEA is most commonly applied but not limited to design (Design FMEA) and manufacturing processes (Process FMEA).
AIAG FMEAs

- **DFMEA = Design Failure Modes Effects Analysis** is a systemized group of activities intended to:
  - Identify potential failures of a design before they occur.
    - Establish the potential effects of the failures
      - their causes
      - how often they occur
      - when they might occur
      - their potential seriousness.

- **PFMEA = Process Failure Modes Effects Analysis** is a systemized group of activities intended to:
  - Recognize the potential failure of a process
  - Evaluate the potential failure
    - Predict its effect
      - Identify actions which could eliminate or reduce the occurrence
      - or improve detectability
      - Document the process
      - Track changes to process - incorporated to avoid potential failures.
As a tool embedded within Six Sigma methodology, FMEA can help identify and eliminate concerns early in the development of a process or new service delivery.

It is a systematic way to examine a process prospectively for possible ways in which failure can occur, and then to redesign the processes so that the new model eliminates the possibility of failure.

Properly executed, FMEA can assist in improving overall satisfaction and safety levels.
FMEA in DMAIC / DMADV Stages

- **Design**
  - determine high risk process activities
  - determine product features
- **Measure**
- **Analyze**
  - prioritize process activities prone to failure
  - prioritize product features prone to failure
- **Improve (Design)**
  - determine high risk process activities
  - determine high risk product features
- **Control (Verify)**

- **Hardware approach:**
  - DFSS projects on individual hardware items
- **Functional approach:**
  - DMAIC projects to improve processes and systems
  - DMADV projects to improve processes and systems
FMEA Requires Teamwork

- A cause creates a failure mode which creates an effect on the customer.
  - Each team member must understand the process, sub-processes and interrelations.
  - If people are confused in this phase, the process reflects confusion. FMEA requires teamwork: gathering information, making evaluations and implementing changes with accountability.
  - Combining Six Sigma, change management and FMEA you can achieve:
    - Better quality
    - Safer environment
    - Greater efficiency and reduced costs
    - Stronger leadership capabilities
    - Increased revenue and market share
    - Optimized technology and workflow
Benefits of FMEA

- FMEA is designed to help the team improve the quality and reliability of design.
  - Properly used the FMEA provides several benefits.
    - Improve product/process reliability and quality
    - Increase customer satisfaction
    - Early identification and elimination of potential product/process failure modes
    - Prioritize product/process deficiencies
    - Capture engineering/organization knowledge
    - Emphasizes problem prevention
    - Documents risk and actions taken to reduce risk
    - Provide focus for improved testing and development
    - Minimizes late changes and associated cost
    - Catalyst for teamwork and idea exchange between functions
Another Look at FMEA Benefits

- Captures the collective knowledge of a team
- Improves quality, reliability & safety of the process
- Logical, structured way to ID process concerns
- Reduces process development time and cost
- Documents and tracks risk reduction activities
- Helps to identify Critical-To-Quality characteristics
- Provides historical records; establishes baseline
- Helps increase customer satisfaction and safety
Applications of FMEA

- FMEA / FMECA is a tool that has been adapted in many different ways for many different purposes.
- It can contribute to improved designs for products and processes, resulting in higher reliability, better quality, increased safety, enhanced customer satisfaction and reduced costs.
- The tool can also be used to establish and optimize maintenance plans for repairable systems and/or contribute to control plans and other quality assurance procedures.
- It provides a knowledge base of failure mode and corrective action information that can be used as a resource in future troubleshooting efforts and as a training tool for new engineers.
- A FMEA or FMECA is often required to comply with safety and quality requirements, such as ISO 9001, QS 9000, ISO/TS 16949, Six Sigma, FDA Good Manufacturing Practices (GMPs), Process Safety Management Act (PSM), etc.
Using Technology Tools

- Pen and Paper
- White Board
- Flip Chart
- Microsoft Excel® spreadsheet
- MiniTab ®
- FMEA Software
Risk Management Basics

Before going into the specifics of using FMEA, a brief review of the risk analysis phase of risk management is in order.

In analyzing risk, the first step is to identify all hazards and harms associated with the device based on its characteristics and intended use. Why distinguish between hazard and harm? Because while a hazard is a potential source of harm, many hazards (such as electrical, mechanical, or thermal energy) result in multiple forms of harm. It is in fact the harm that we are addressing in the risk analysis process. Sometimes, of course, a given hazard may be linked with a single harm. In this case, the two terms can (and frequently are) used interchangeably.
Once all hazards and harms have been identified, the analysis process is completed by estimating the likelihood that the harm will occur and, in the event that it does, the severity of the resulting damage. Combining likelihood and severity (either graphically or mathematically) results in an expression of the risk associated with the hazard.

Following this analysis, the risk is evaluated. Is it necessary to reduce the risk? Or is it inherently acceptable? Where the risk is not considered acceptable, specific actions, or mitigations, are identified to reduce, or control, the risk.

After putting these controls in place, a new value for risk is established for the hazard or harm. The mitigation is then evaluated to determine whether any new hazards or harms have been created. Then the evaluation and, if necessary, control processes are repeated until the risk is found to be acceptable.
### FMEA FORM

<table>
<thead>
<tr>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Cause(s) of Failure</th>
<th>S</th>
<th>Potential Effects(s) of Failure</th>
<th>O</th>
<th>Current Process Controls</th>
<th>D</th>
<th>RPN</th>
<th>CRIT</th>
<th>Recommended Action(s)</th>
<th>Responsibility and Target Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispense amount of cash requested by customer</td>
<td>Does not dispense cash</td>
<td>Customer very dissatisfied</td>
<td>8</td>
<td>Out of cash</td>
<td>5</td>
<td>Internal low-cash alert</td>
<td>5</td>
<td>200</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incorrect entry to demand deposit system</td>
<td></td>
<td></td>
<td></td>
<td>Machine jams</td>
<td>3</td>
<td>240</td>
<td>24</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Power failure during transaction</td>
<td></td>
<td></td>
<td></td>
<td>Power failure during transaction</td>
<td>2</td>
<td>160</td>
<td>16</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dispense too much cash</td>
<td>Bank loses money</td>
<td>Bills stuck together</td>
<td>6</td>
<td>Denominations in wrong trays</td>
<td>2</td>
<td>Loading procedure (fill endpoint of stack)</td>
<td>7</td>
<td>84</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discrepancy in cash balancing</td>
<td></td>
<td></td>
<td></td>
<td>Two-person visual verification</td>
<td>3</td>
<td>72</td>
<td>18</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Takes too long to dispense cash</td>
<td>Customer somewhat annoyed</td>
<td>Heavy computer network traffic</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Power interruption during transaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Power interruption during transaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The basic process

- Describe the parts of a system
- List the consequences if each part fails
- Evaluate by three criteria and associated risk indices:
  - \( S \) = Severity
  - \( O \) or \( P \) = Probability of Occurrence
  - \( D \) = Inability of controls to detect it
- Each index ranges from
  - 1 (lowest risk) to
  - 10 (highest risk).
- The overall risk of each failure is
  - \( Risk Priority Number (RPN) \)
The basic process (continued)

- **RPN = S × O × D**
- For a failure with a:
  - severity of 6
  - detection of 3
  - occurrence of 6
- RPN will be 108 (6 × 6 × 3 = 108).
- The **RPN (ranging from 1 to 1000)** is used to prioritize all potential failures to decide upon actions leading to reduce the risk, usually by reducing likelihood of occurrence and improving controls for detecting the failure.
The basic process (continued)

- Since the purpose of an FMEA is to prevent failures, actions should be taken to prevent their occurrence.
- The recommended preventive actions are generally suggested by the FMEA team during a brainstorming session.
- The reasons for failures are multifaceted; every failure can have several causes, so recommended preventive actions are better generated by cross functional team.
Task owner and projected completion date

The task owner is the person or people who have been assigned the task of mending the aspects of the product, process or design that are subject to failure.

The projected completion date should also be determined to avoid procrastination and enforce accountability.

Once the recommended actions are taken calculate the new RPN

Here again, the Risk Priority Number will be the product of the Detection, the Occurrence and the Severity. After the improvements have been made, the RPN is expected to be significantly lower than it was before.
Caterpillar Tractor Example

- Component = spring
- Possible Failure = broken

- Cause 1– fatigue
  - Effect – lack of plate separation
  - Action 1– design for lower stress

- Cause 2– improper assembly
  - Effect – lack of plate separation
  - Action 2– provide assembly instruction
FMEA / FMECA Overview

- Failure Modes, Effects and Criticality Analysis (FMEA / FMECA) requires the identification of the following basic information:
  - Item(s)
  - Function(s)
  - Failure(s)
  - Effect(s) of Failure
  - Cause(s) of Failure
  - Current Control(s)
  - Recommended Action(s)
  - Plus other relevant details

- Most analyses of this type also include some method to assess the risk associated with the issues identified during the analysis and to prioritize corrective actions. Two common methods include:
  - Risk Priority Numbers (RPNs)
  - Criticality Analysis (FMEA with Criticality Analysis = FMECA)
Risk Priority Numbers

To use the Risk Priority Number (RPN) method to assess risk, the analysis team must:

- Rate the severity of each effect of failure.
- Rate the likelihood of occurrence for each cause of failure.
- Rate the likelihood of prior detection for each cause of failure (i.e. the likelihood of detecting the problem before it reaches the end user or customer).
- Calculate the RPN by obtaining the product of the three ratings:
  \[ \text{RPN} = \text{Severity} \times \text{Occurrence} \times \text{Detection} \]
- The RPN can then be used to compare issues within the analysis and to prioritize problems for corrective action.
Reducing S vs O vs D

- Reducing **Severity** Level requires a design change to the product or process – costly or impossible.
- Reducing **Occurrence** Level is often the best approach – reduction in process errors – reduces cost.
- Reducing **Detection** Level increases cost with no improvement to quality (inspection, etc.) – non value added – hidden factory - muda (waste) – costly short term solution.
### Severity Scale

#### SEVERITY TABLE

<table>
<thead>
<tr>
<th>LEVEL</th>
<th>Safety</th>
<th>Legal</th>
<th>Operations</th>
<th>Product / Service</th>
<th>Remedy</th>
<th>Customer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Life threatening</td>
<td>Violate law</td>
<td>Major disruption</td>
<td>100% loss</td>
<td>Significant</td>
<td>Loss of Goodwill</td>
</tr>
<tr>
<td>9</td>
<td>Severe injury</td>
<td>Potential violation</td>
<td>Significant disruption</td>
<td>Some loss</td>
<td>Moderate</td>
<td>Very dissatisfied</td>
</tr>
<tr>
<td>8</td>
<td>Severe injury</td>
<td>Potential violation</td>
<td>Moderate disruption</td>
<td>Some loss</td>
<td>Minor</td>
<td>Complaint</td>
</tr>
<tr>
<td>7</td>
<td>Severe injury</td>
<td>Potential violation</td>
<td>Minor disruption</td>
<td>Some loss</td>
<td>Slight</td>
<td>Dissatisfaction</td>
</tr>
<tr>
<td>6</td>
<td>Severe injury</td>
<td>Potential violation</td>
<td>Marginal Disruption</td>
<td>Some loss</td>
<td>None</td>
<td>Inconvenienced</td>
</tr>
<tr>
<td>5</td>
<td>Severe injury</td>
<td>Potential violation</td>
<td>Marginal Disruption</td>
<td>None</td>
<td>None</td>
<td>May notice</td>
</tr>
<tr>
<td>4</td>
<td>Severe injury</td>
<td>Potential violation</td>
<td>Slight disruption</td>
<td>None</td>
<td>None</td>
<td>No effect</td>
</tr>
<tr>
<td>3</td>
<td>Slight disruption</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>No effect</td>
</tr>
<tr>
<td>2</td>
<td>No effect</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>No effect</td>
</tr>
<tr>
<td>1</td>
<td>No effect</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>No effect</td>
</tr>
</tbody>
</table>
## Occurrence Scale

**Example**

<table>
<thead>
<tr>
<th>OCCURRENCE</th>
<th>Probable Failure</th>
<th>Failure Rate</th>
<th>Cpk Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>~Inevitable</td>
<td>&gt;1 in 2</td>
<td>&lt;.33</td>
</tr>
<tr>
<td>9</td>
<td>Very High</td>
<td>1 in 3</td>
<td>0.33</td>
</tr>
<tr>
<td>8</td>
<td>Fairly High</td>
<td>1 in 8</td>
<td>0.51</td>
</tr>
<tr>
<td>7</td>
<td>High</td>
<td>1 in 20</td>
<td>0.67</td>
</tr>
<tr>
<td>6</td>
<td>Moderate</td>
<td>1 in 80</td>
<td>0.83</td>
</tr>
<tr>
<td>5</td>
<td>Moderate</td>
<td>1 in 400</td>
<td>1.00</td>
</tr>
<tr>
<td>4</td>
<td>Moderate</td>
<td>1 in 2,000</td>
<td>1.17</td>
</tr>
<tr>
<td>3</td>
<td>Low</td>
<td>1 in 15,000</td>
<td>1.33</td>
</tr>
<tr>
<td>2</td>
<td>Very Low</td>
<td>1 in 150,000</td>
<td>1.50</td>
</tr>
<tr>
<td>1</td>
<td>Remote</td>
<td>&lt; 1 in 150,000</td>
<td>&gt;1.67</td>
</tr>
</tbody>
</table>
## Detection Scale

<table>
<thead>
<tr>
<th>LEVEL</th>
<th>Description</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Nearly certain that failure won't be detected</td>
<td>~100 %</td>
</tr>
<tr>
<td>9</td>
<td>Extremely poor chance of detection</td>
<td>95 to 99 %</td>
</tr>
<tr>
<td>8</td>
<td>Poor chance of detection</td>
<td>90 to 95 %</td>
</tr>
<tr>
<td>7</td>
<td>Highly unlikely to be detected before customer</td>
<td>70 to 90 %</td>
</tr>
<tr>
<td>6</td>
<td>Unlikely to be detected before customer</td>
<td>50 to 70 %</td>
</tr>
<tr>
<td>5</td>
<td>Might be detected before customer</td>
<td>20 to 50 %</td>
</tr>
<tr>
<td>4</td>
<td>Likely to be detected before customer</td>
<td>5 to 20 %</td>
</tr>
<tr>
<td>3</td>
<td>Very low probability of reaching customer</td>
<td>1 to 5 %</td>
</tr>
<tr>
<td>2</td>
<td>Extremely low probability of reaching customer</td>
<td>0 to 1 %</td>
</tr>
<tr>
<td>1</td>
<td>Nearly certain to detect before customer</td>
<td>~ 0 %</td>
</tr>
<tr>
<td>Columns</td>
<td>Function = Tank overflow valve</td>
<td></td>
</tr>
<tr>
<td>-------------------------</td>
<td>------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Potential Failure Mode = Valve stem sticks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Potential Failure Effect = Tank overflows</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Potential Causes = Packing ID undersize</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Current Prevention Controls = Tolerance on packing ID Severity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Current Detection Methods = Test valve after assembly</td>
<td></td>
</tr>
<tr>
<td>Before Severity</td>
<td>9; Before Occurrence 6; Before Detection 5</td>
<td></td>
</tr>
<tr>
<td>RPN</td>
<td>270</td>
<td></td>
</tr>
<tr>
<td>Recommended Action</td>
<td>Alignment Guides</td>
<td></td>
</tr>
<tr>
<td>Responsibility</td>
<td>Jones</td>
<td></td>
</tr>
<tr>
<td>Due Date</td>
<td>4/8/3</td>
<td></td>
</tr>
<tr>
<td>Actions taken</td>
<td>Guides added</td>
<td></td>
</tr>
<tr>
<td>After Severity</td>
<td>9; After Occurrence 1; After Detection 5</td>
<td></td>
</tr>
<tr>
<td>After RPN</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>Part Number</td>
<td>Identify</td>
<td>Potential Failure Modes</td>
</tr>
<tr>
<td>-------------</td>
<td>----------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Tank</td>
<td>Tank</td>
<td>Valve</td>
</tr>
<tr>
<td>Overflow</td>
<td>Stem</td>
<td>Overflows</td>
</tr>
<tr>
<td>Valve</td>
<td>Sticks</td>
<td>Undersize</td>
</tr>
<tr>
<td>Make</td>
<td>Who</td>
<td>Action</td>
</tr>
<tr>
<td>--------</td>
<td>-------</td>
<td>--------</td>
</tr>
<tr>
<td>Install</td>
<td>Ima</td>
<td>Plan</td>
</tr>
<tr>
<td>Align</td>
<td>Plumber</td>
<td>October</td>
</tr>
<tr>
<td>Guides</td>
<td></td>
<td>13th</td>
</tr>
</tbody>
</table>
FMEA Steps

- Brainstorm all the potential failures modes
- List them
- Identify potential causes
- Develop a rating scale
- Rate factors re S O D
- \( S \times O \times D = RPN \)
- Rank by descending RPN
- How to reduce RPNs
- Actions
- New RPN
A problem with RPN?

- The Six Sigma Practitioner’s Guide to Data Analysis by Donald Wheeler
- Versus RPN’s ! ~ Only 120 RPN values
- Not uniformly spread out between 1 and 1000
- 1000 different situations mapped onto 120 values in a nonlinear manner
- Equivalent RPN’s not really equal ~ Not correct to rank by RPN !?
- SOD = ordinal scale data
- Adding and subtracting require interval scale data (degrees F or C)
- Multiplying and dividing require ratio scale data (Absolute or Kelvin scales)
- In the Design Phase there is a rationale for doing FMEA
- Three scales and ranking are OK but not RPN
- Solution:
  - Systematic overall ranking
    - use 0 to 9 plus a 3 digit code for each failure mode SOD code
    - 1000 values for 1000 situations
    - S then O then D
Other Scales & Guidelines

- Other Scales:
  - 1 to 3
  - 1 to 5
  - 0 to 9

- Other Guidelines:
  - RPN > 100, Severity first (AIAG)
  - RPN > 120 (Boeing)
Criticality Analysis
The MIL-STD-1629A document describes two types of criticality analysis:

To use the **Quantitative Criticality Analysis Method**, the analysis team must:
- Define the reliability/unreliability for each item, at a given operating time.
- Identify the portion of the item’s unreliability attributed to each potential failure mode.
- Rate the probability of loss (or severity) that will result from each failure mode.
- Calculate the criticality for each potential failure mode by obtaining the product of the three factors:
  - \( \text{Mode Criticality} = \text{Item Unreliability} \times \text{Mode Ratio of Unreliability} \times \text{Probability of Loss} \)
- Calculate the criticality for each item by obtaining the sum of the criticalities for each failure mode that has been identified for the item.
  - \( \text{Item Criticality} = \text{SUM of Mode Criticalities} \)

To use the **Qualitative Criticality Analysis Method**, the analysis team must:
- Rate the severity of the potential effects of failure.
- Rate the likelihood of occurrence for each potential failure mode.
- Compare failure modes via a Criticality Matrix:
  - identifying severity on the horizontal axis
  - identifying occurrence on the vertical axis.
Basic Analysis Procedure for FMEA or FMECA

- Assemble the team
- Establish the ground rules
- Gather and review relevant information
- Identify the item(s) or process(es) to be analyzed
- Identify the function(s), failure(s), effect(s), cause(s) and control(s) for each item or process
- Evaluate risk associated with the issues identified
- Prioritize and assign corrective actions
- Perform corrective actions and re-evaluate risk
- Distribute, review, update the analysis
There are a number of published guidelines and standards for the requirements and recommended reporting format of FMEA:

- SAE J1739
- AIAG FMEA-3
- MIL-STD-1629A (criticality analysis)
- MIL-STD-882D (4 levels of severity, 22 tasks to eliminate)
- 21 CFR §820 (FDA GMP)
- JCAHO Standard Req. L.D. 5.2

In addition, a FMEA (or FMECA) is often required to comply with safety and quality requirements, such as:

- ISO 14971 medical devices
- EN 1441
- IEC 60601-1
- IEC 60812 system reliability
- QS 9000 American Automotive
- ISO/TS 16949 Global Automotive
- Process Safety Management Act (PSM)
Related Tools

- **AFD Anticipatory Failure Determination** - an application of I-TRIZ specifically designed for Failure Analysis and Failure Prediction.

- **FTA Fault Tree Analysis** – another method for studying potential failures – applied only to failures considered serious enough to warrant detailed analysis - top down approach that starts with supposing that an accident takes place – then looks for origins of causes – then ways to avoid origins and causes. *Reverse of FMECA* which starts with origins and causes and looks for resulting bad effects.

- **HTA Hazard Tree Analysis**

- **HAZOP Hazard and Operability Analysis**
Printed Resources for FMEA and FMECA

- Society of Automotive Engineers (SAE), Aerospace Recommended Practice ARP5580: Recommended Failure Modes and Effects Analysis (FMEA) Practices for Non-Automobile Applications, June 2000.
- Society of Automotive Engineers (SAE), Surface Vehicle Recommended Practice J1739: (R) Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA), and Potential Failure Mode and Effects Analysis for Machinery (Machinery FMEA), June 2000.
Other FMEA References

- Total Quality Control, 3e by Feigenbaum
- Quality Control Handbook 3e by Juran
- Juran’s Quality Planning & Analysis for Enterprise Quality 5e by Gryna, Chua, DeFeo
- The Six Sigma Handbook 2e by Pyzdek
- The Certified Six Sigma Black Belt Handbook by Benbow and Kubiak
- Six Sigma DeMystified by Keller
- The Six Sigma Way Team Fieldbook by Pande, Neuman, Cavanagh
- Rath & Strong’s Six Sigma Pocket Guide Revised Edition
- Six Sigma for the Millennium - A CSSBB handbook by Kim Pries
- The Six Sigma Practitioner’s Guide to Data Analysis by Donald Wheeler
- Quality Progress articles by Dan Reid
INFO ON WEB

References:

- www.fmeainfocentre.com
- www.isixsigma.com

- SAE International: The Society for Automotive Engineers provides the ability to purchase the J1739 and ARP5580 standards, as well as the AIR4845 document.
- AIAG: The Automotive Industry Action Group provides the ability to purchase the AIAG FMEA Third Edition (FMEA-3) guidelines.
- IEC: The International Electrotechnical Commission provides the ability to purchase the IEC 60812 standard.
- Reliability-Related Military Handbooks and Standards on weibull.com: This site provides access to U.S. Department of Defense standards and handbooks in PDF format, including the MIL-STD-1629A standard for Failure Modes, Effects and Criticality Analysis (FMECA) analysis.
- FMEA Info Center: This site provides information on books, publications, standards, software, consultants and other resources related to Failure Mode and Effects Analysis (FMEA). It also provides an on-line discussion list.
- NASA STI Special Bibliography for FMEA: NASA's Scientific and Technical Information (STI) program provides a "sampler bibliography" that contains abstracts for documents related to Failure Mode and Effects Analysis (FMEA) and Failure Modes, Effects and Criticality Analysis (FMECA) in the NASA STI Database.
Conclusions

- FMEA is a useful tool
- Mike Brown had his 15 minutes of FAME
- FEMA should have used FMEA
- Questions ?
Ed May - Short Bio

- Ed May is an American Society for Quality ‘Certified Six Sigma Black Belt’
- who specializes in ISO 9000, Six Sigma Quality, and Lean Thinking.
- Ed has degrees in engineering and business.
- He held positions in management, engineering, manufacturing, and quality in several manufacturing companies before he became a quality consultant, adjunct instructor, and on-site trainer.
- Ed is the founder of MAYplewood Consulting,
  an Adjunct Instructor for both New Jersey Institute of Technology and Union County College, and a quality trainer at many local companies.
- Ed also teaches Saturday Six Sigma Classes for North Jersey ASQ.
- Ed has been the guest speaker at many technical society meetings and conferences including ASQ.
For More Info

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FMEA, FEMA, & FAME

Would Mike Brown be famous today if FEMA had used FMEA?

ASQ North Jersey
Dinner Meeting
Wednesday, November 15, 2006

Presented by Ed May, ASQ CSSBB