Failure Mode and Effects Analysis (FMEA)

UNDERSTANDING THE FUNDAMENTAL DEFINITIONS AND CONCEPTS OF FMEAS

Material for this presentation is based on the book Effective FMEAs, by Carl S. Carlson, published by John Wiley & Sons, © 2012
Definition of FMEA

Failure Mode and Effects Analysis (FMEA) is a method designed to:

- Identify and fully understand potential failure modes and their causes, and the effects of failure on the system or end users, for a given product or process.
- Assess the risk associated with the identified failure modes, effects and causes, and prioritize issues for corrective action.
- Identify and carry out corrective actions to address the most serious concerns.
An FMEA is an engineering analysis
- done by a cross-functional team of subject matter experts
- that thoroughly analyzes product designs or manufacturing processes
- early in the product development process.
- Finds and corrects weaknesses before the product gets into the hands of the customer.
What is FMEA?

An FMEA should be the guide to the development of a complete set of actions that will reduce risk associated with the system, subsystem, and component or manufacturing/assembly process to an acceptable level.
What is FMEA?

- Performing an FMEA just to fill a checkbox in the Product Development Process and then filing it away, never to be seen again, is a waste of time and adds no value.
- If not for use as guidance through the development process, why waste the time and resources to do it in the first place?
- If effectively used throughout the product life cycle, it will result in significant improvements to reliability, safety, quality, delivery, and cost.
The primary objective of an FMEA is to improve the design.

- For System FMEAs, the objective is to improve the design of the system.
- For Design FMEAs, the objective is to improve the design of the subsystem or component.
- For Process FMEAs, the objective is to improve the design of the manufacturing process.
Primary Objective of FMEA

There are many other objectives for doing FMEAs, such as:

- identify and prevent safety hazards
- minimize loss of product performance or performance degradation
- improve test and verification plans (in the case of System or Design FMEAs)
- improve Process Control Plans (in the case of Process FMEAs)
- consider changes to the product design or manufacturing process
- identify significant product or process characteristics
- develop Preventive Maintenance plans for in-service machinery and equipment
- develop online diagnostic techniques
The three most common types of FMEAs are:

- System FMEA
- Design FMEA
- Process FMEA
System FMEA

Analysis is at highest-level analysis of an entire system, made up of various subsystems. The **focus** is on system-related deficiencies, including:

- system safety and system integration
- interfaces between subsystems or with other systems
- interactions between subsystems or with the surrounding environment
- single-point failures (where a single component failure can result in complete failure of the entire system)
The **focus** (continued)

- functions and relationships that are *unique* to the system as a whole (i.e., do not exist at lower levels) and could cause the overall system not to work as intended
- human interactions
- service

*Some practitioners separate out human interaction and service into their own respective FMEAs.*
Analysis is at the subsystem level (made up of various components) or component level. The **Focus** is on product design-related deficiencies, with emphasis on

- improving the design
- ensuring product operation is safe and reliable during the useful life of the equipment.
- interfaces between adjacent components.

*Design FMEA usually assumes the product will be manufactured according to specifications.*
Process FMEA

Analysis is at the manufacturing/assembly process level.

The **Focus** is on manufacturing related deficiencies, with emphasis on

- Improving the manufacturing process
- ensuring the product is built to design requirements in a safe manner, with minimal downtime, scrap and rework.
- manufacturing and assembly operations, shipping, incoming parts, transporting of materials, storage, conveyors, tool maintenance, and labeling.

*Process FMEAs most often assume the design is sound*
FMEA Definitions and Examples
<table>
<thead>
<tr>
<th>Item</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity</th>
<th>Potential Cause(s) of Failure</th>
<th>Occurrence</th>
<th>Current Design Controls (Prevention)</th>
<th>Current Design Controls (Detection)</th>
<th>Detection</th>
<th>RPN</th>
<th>Recommended Action(s)</th>
<th>Responsible Person</th>
<th>Actions Taken</th>
<th>Revised Rankings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
An “item” is the focus of the FMEA project.

- For a System FMEA this is the system itself.
- For a Design FMEA, this is the subsystem or component under analysis.
- For a Process FMEA, this is usually one of the specific steps of the manufacturing or assembly process under analysis, as represented by an operation description.

*Example: Bicycle hand brake subsystem*
All-Terrain System Hierarchy
(with components for Hand Brake Subsystem)

1.0 All-Terrain Bicycle System
   1.1 Frame Subsystem
   1.2 Front Wheel Subsystem
   1.3 Rear Wheel Subsystem
   1.4 Sprocket-Pedal Subsystem
   1.5 Chain-Derailleur Subsystem
   1.6 Seat Subsystem
   1.7 Handle Bar Subsystem
   1.8 Hand Brake Subsystem
      1.8.1 Brake Lever
      1.8.2 Brake Cable
      1.8.3 Brake Pads
      1.8.4 Brake Calliper
   1.9 Suspension Subsystem

Item identification for All-Terrain System FMEA
Item identification for All-Terrain Hand Brake Design FMEA
Item identification for All-Terrain Cable Design FMEA

This illustration is from the book *Effective FMEAs*, by Carl S. Carlson, published by John Wiley & Sons, © 2012
A “function” is what the item or process is intended to do, usually to a given standard of performance or requirement.

- For Design FMEAs, this is the primary purpose or design intent of the item.
- For Process FMEAs, this is the primary purpose of the manufacturing or assembly operation.
- Functions are typically described in a verb-noun format.
- There can be many functions for each item or operation.

Example: *Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.*
<table>
<thead>
<tr>
<th>Item/Function</th>
<th>Potential Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand Brake S/S: Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.</td>
<td>Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.</td>
</tr>
</tbody>
</table>
The term “failure mode” combines two words that both have unique meanings.

- The Concise Oxford English Dictionary defines the word “failure” as *the act of ceasing to function or the state of not functioning*.
- “Mode” is defined as *a way in which something occurs*.
A “failure mode” is the manner in which the item or operation potentially fails to meet or deliver the intended function and associated requirements.

- may include failure to perform a function within defined limits
- inadequate or poor performance of the function
- intermittent performance of a function
- and/or performing an unintended or undesired function

Example: Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.
<table>
<thead>
<tr>
<th>Item/Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand Brake S/S: Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.</td>
<td>Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.</td>
<td>Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.</td>
</tr>
</tbody>
</table>
An “effect” is the consequence of the failure on the system or end user.

- This can be a single description of the effect on the top-level system and/or end user, or three levels of effects (local, next-higher level, and end effect).
- For Process FMEAs, consider the effect at the manuf. or assembly level, as well as at the system or end user.
- There can be more than one effect for each failure mode. However, typically the FMEA team will use the most serious of the end effects for the analysis.

*Example: Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.*
<table>
<thead>
<tr>
<th>Item/Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>S E V</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hand Brake S/S:</strong></td>
<td>Insufficient friction delivered by hand brake subsystem between brake pads and wheels</td>
<td>Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in</td>
<td>10</td>
</tr>
<tr>
<td>Provides the correct level</td>
<td>during heavy rain conditions.</td>
<td>accident.</td>
<td></td>
</tr>
<tr>
<td>of friction between brake</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pad assembly and wheel rim</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>to safely stop bicycle in the</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>required distance, under all</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>operating conditions.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This illustration is from the book *Effective FMEAs*, by Carl S. Carlson, published by John Wiley & Sons, © 2012.
“Severity” is a ranking number associated with the most serious effect for a given failure mode

- based on the criteria from a severity scale.
- a relative ranking within the scope of the specific FMEA
- determined without regard to the likelihood of occurrence or detection.

*Example: 10*
<table>
<thead>
<tr>
<th>Effect</th>
<th>Criteria: Severity of Effect on Product (Customer Effect)</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to Meet Safety and/or Regulatory Requirements</td>
<td>Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.</td>
<td>10</td>
</tr>
<tr>
<td>Loss or Degradation of Primary Function</td>
<td>Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Degradation of primary function (vehicle operable, but at reduced level of performance).</td>
<td>7</td>
</tr>
<tr>
<td>Loss or Degradation of Secondary Function</td>
<td>Loss of secondary function (vehicle operable, but comfort / convenience functions inoperable).</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Degradation of secondary function (vehicle operable, but comfort / convenience functions at reduced level of performance).</td>
<td>5</td>
</tr>
<tr>
<td>Annoyance</td>
<td>Appearance or Audible Noise, vehicle operable, item does not conform. Defect noticed by most customers (&gt; 75%).</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Appearance or Audible Noise, vehicle operable, item does not conform. Defect noticed by many customers (50%).</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Appearance or Audible Noise, vehicle operable, item does not conform. Defect noticed by discriminating customers (&lt; 25%).</td>
<td>2</td>
</tr>
<tr>
<td>No Effect</td>
<td>No discernible effect.</td>
<td>1</td>
</tr>
</tbody>
</table>
A “cause” is the specific reason for the failure, preferably found by asking “why” until the root cause is determined.

- For Design FMEAs, the cause is the *design deficiency* that results in the failure mode.
- For Process FMEAs, the cause is the *manufacturing or assembly deficiency* that results in the failure mode.
- At the component level, cause should be taken to the level of failure mechanism.
- If a cause occurs, the corresponding failure mode occurs.
- There can be many causes for each failure mode.

*Example: Cable breaks*
<table>
<thead>
<tr>
<th>Item/Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>SEV</th>
<th>Potential Cause(s) of Failure</th>
<th>OCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand Brake S/S: Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.</td>
<td>Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.</td>
<td>Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.</td>
<td>10</td>
<td><strong>Cable Binds due to inadequate lubrication or poor routing</strong></td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>External foreign material reduces friction</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Cable breaks</strong></td>
<td>6</td>
</tr>
</tbody>
</table>
“Occurrence” is a ranking number associated with the likelihood that the failure mode and its associated cause will be present in the item being analyzed.

- For System and Design FMEAs, consider the likelihood of occurrence during the design life of the product.
- For Process FMEAs consider the likelihood of occurrence during production.
- based on the criteria from the corresponding occurrence scale.
- has a relative meaning rather than absolute value, determined without regard to the severity or likelihood of detection.

Example: 6
### Suggested DFMEA Occurrence Evaluation Criteria

<table>
<thead>
<tr>
<th>Likelihood of Failure</th>
<th>Criteria: Occurrence of Cause (Design Life/Reliability of Item/Vehicle)</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Very High</strong></td>
<td>New technology/new design with no history.</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Failure is inevitable with new design, new application, or change in duty cycle/operating conditions.</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Failure is likely with new design, new application, or change in duty cycle/operating conditions.</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Failure is uncertain with new design, new application, or change in duty cycle/operating conditions.</td>
<td>7</td>
</tr>
<tr>
<td><strong>High</strong></td>
<td>Frequent failures associated with similar designs or in design simulation and testing.</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Occasional failures associated with similar designs or in design simulation and testing.</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Isolated failures associated with similar design or in design simulation and testing.</td>
<td>4</td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>Only isolated failures associated with almost identical design or in design simulation and testing.</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>No observed failures associated with almost identical design or in design simulation and testing.</td>
<td>2</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>Failure is eliminated through preventative control.</td>
<td>1</td>
</tr>
<tr>
<td><strong>Very Low</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.**
- **Brake system misadjusted by bicycle user.**

This illustration is from the book *Effective FMEAs*, by Carl S. Carlson, published by John Wiley & Sons, © 2012.
“Controls” are the methods or actions currently planned, or are already in place, to reduce or eliminate the risk associated with each potential cause.

- Controls can be the methods to prevent or detect the cause during product development, or actions to detect a problem during service before it becomes catastrophic.

- There can be many controls for each cause.
Prevention-type Controls

- For System or Design FMEAs, prevention-type design controls describe how a cause, failure mode, or effect in the product design is *prevented* based on current or planned actions.
- They are intended to reduce the likelihood that the problem will occur, and are used as input to the occurrence ranking.

*Example: Cable material selection based on ANSI #ABC.*
Detection-type Controls

- For System or Design FMEAs, detection-type designs controls describe how a failure mode or cause in the product design is detected, based on current or planned actions before the product design is released to production, and are used as input to the detection ranking.
- They are intended to increase the likelihood that the problem will be detected before it reaches the end user.

Example: Bicycle system durability test # 789
<table>
<thead>
<tr>
<th>Item/Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>S E V</th>
<th>Potential Cause(s) of Failure</th>
<th>OCC</th>
<th>Current Design Controls (Prevention)</th>
<th>Current Design Controls (Detection)</th>
<th>DET</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand Brake S/S:</td>
<td>Provides the correct level of friction between brake pad assembly and wheel rim to</td>
<td>Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.</td>
<td></td>
<td>Bicycles wheel does not slow down when the brake lever is pulled potentially resulting in accident.</td>
<td>10</td>
<td>Hand Brake Design Guide #123</td>
<td>Bicycle system durability test # 789</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>safely stop bicycle in the required distance, under all operating conditions.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cable Binds due to inadequate lubrication or poor routing</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>External foreign material reduces friction</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cable breaks</td>
<td>6</td>
<td>Cable material selection based on ANSI #ABC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Bicycle system durability test # 789</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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“Detection” is a ranking number associated with the best control from the list of detection-type controls, based on the criteria from the detection scale.

- considers the likelihood of detection of the failure mode/cause, according to defined criteria.
- a relative ranking within the scope of the specific FMEA
- determined without regard to the severity or likelihood of occurrence.

Example: 4
### Suggested DFMEA Detection Evaluation Criteria

<table>
<thead>
<tr>
<th>Opportunity for Detection</th>
<th>Criteria: Likelihood of Detection by Design Control</th>
<th>Rank</th>
<th>Likelihood of Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>No detection opportunity</td>
<td>No current design control; Cannot detect or is not analyzed.</td>
<td>10</td>
<td>Absolute Uncertainty</td>
</tr>
<tr>
<td>Not likely to detect at any stage</td>
<td>Design analysis/detection controls have a weak detection capability; Virtual Analysis (e.g. CAE, FEA, etc.) is not correlated to expected actual operating conditions.</td>
<td>9</td>
<td>Very Remote</td>
</tr>
<tr>
<td>Post Design Freeze and prior to launch</td>
<td>Product verification/validation after design freeze and prior to launch with <strong>pass/fail</strong> testing (Sub-system or system testing with acceptance criteria e.g. ride &amp; handling, shipping evaluation, etc.)</td>
<td>8</td>
<td>Remote</td>
</tr>
<tr>
<td></td>
<td>Product verification/validation after design freeze and prior to launch with <strong>test to failure</strong> testing (Sub-system or system testing until failure occurs, testing of system interactions, etc.)</td>
<td>7</td>
<td>Very Low</td>
</tr>
<tr>
<td></td>
<td>Product verification/validation after design freeze and prior to launch with <strong>degradation</strong> testing (Sub-system or system testing after durability test e.g. function check).</td>
<td>6</td>
<td>Low</td>
</tr>
<tr>
<td>Prior to Design Freeze</td>
<td>Product validation (reliability testing, development or validation tests) prior to design freeze using <strong>pass/fail</strong> testing (e.g. acceptance criteria for performance, function checks, etc.)</td>
<td>5</td>
<td>Moderately</td>
</tr>
<tr>
<td></td>
<td>Product validation (reliability testing, development or validation tests) prior to design freeze using <strong>test to failure</strong> (e.g. until leaks, yields, cracks, etc.).</td>
<td>4</td>
<td>Moderately High</td>
</tr>
<tr>
<td></td>
<td>Product validation (reliability testing, development or validation tests) prior to design freeze using <strong>degradation</strong> testing (e.g. data trends, before/after values, etc.)</td>
<td>3</td>
<td>High</td>
</tr>
</tbody>
</table>

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“RPN” is a numerical ranking of the risk of each potential failure mode/cause, made up of the arithmetic product of the three elements:

- severity of the effect
- likelihood of occurrence of the cause
- likelihood of detection of the cause.

Example: 240 (10 x 6 x 4)
Limitations of RPN

RPN is not a perfect representation of the risk associated with a failure mode and associated cause.

- subjective
- not continuous

_High severity must be considered regardless of RPN value_
“Recommended actions” are the tasks recommended by the FMEA team to reduce or eliminate the risk associated with potential causes of failure. They should consider

- existing controls
- relative importance (prioritization) of the issue
- cost and effectiveness of the corrective action.
- there can be many recommended actions for each cause.

**Example:** Require cable DFMEA/PFMEA from cable supplier approved by All-Terrain FMEA team.
<table>
<thead>
<tr>
<th>Item/Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Potential Cause(s) of Failure</th>
<th>O C C</th>
<th>Current Design Controls (Prevention)</th>
<th>Current Design Controls (Detection)</th>
<th>DET</th>
<th>RPN</th>
<th>Recommended Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand Brake S/S</td>
<td>Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.</td>
<td>Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.</td>
<td>10</td>
<td>Cable Binds due to inadequate lubrication or poor routing</td>
<td>4 Hand Brake Design Guide #123</td>
<td>Bicycle system durability test #789</td>
<td>2</td>
<td>80</td>
<td>Redesign hand brake cable routing to reduce friction and make system insensitive to lubrication degradation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Modify bicycle durability testing to include periodic brake cable checks for binding</td>
</tr>
<tr>
<td>External foreign material reduces friction</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>60</td>
<td>Require cable DFMEA/PFMEA from cable supplier approved by All-Terrain FMEA team.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Based on results of Cable DFMEA, develop cable strength test and modify cable design to improve strength</td>
</tr>
<tr>
<td>Cable breaks</td>
<td>6 Cable material selection based on ANSI #ABC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td>240</td>
<td></td>
</tr>
<tr>
<td>Brake Lever breaks</td>
<td>1 Hand Brake Design Guide #123</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Selected brake pad material does not apply required friction to wheel</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>40</td>
<td></td>
</tr>
</tbody>
</table>
“Action Taken” is the specific action that is implemented to reduce risk to an acceptable level.

- it should correlate to the specific recommended action
- and is assessed as to effectiveness by a revised severity, occurrence, detection ranking, and corresponding revised RPN.

Example: Cable supplier completed DFMEA/PFMEA and approved by All-Terrain team
The Logical Relationship Between FMEA Elements
(illustration numbers correlate to chapter 6 procedure numbers)

1. System Hierarchy Items
   - Items
   - Functions

2. Functions
   - Functions
   - Failure Modes

3. Failure Modes
   - Failure Modes

4. Effects
   - Most Serious Effect

5. Severity

6. Classification (optional)
   - Prevention Controls
   - Detection Controls

7. Causes
   - Causes

8. Occurrence

9. Controls
   - Recommended Actions

10. Detection

11. RPN = Severity \times Occurrence \times Detection

The Goal
Risk reduced to acceptable level

* Recommended Action procedure covered in chapter 7

This illustration is from the book "Effective FMEAs" by Carl S. Carlson, published by John Wiley & Sons, © 2012
Is that all there is to FMEA?

- If FMEA were only an exercise in “filling out a form” then the definitions would be all you need to know.
- There is much more to learn about FMEAs!
What else is needed?

- FMEA has the *potential* to anticipate and prevent problems, reduce costs, shorten product development times, and achieve safe and highly reliable products and processes.
- To obtain the best possible results from FMEA, companies need to focus on key success factors.
FMEA Success Factors

- understanding the fundamentals and procedure of FMEAs, including the concepts and definitions
- preparation steps for each FMEA project
- applying lessons learned and quality objectives
- providing excellent facilitation
- and implementing an effective company-wide FMEA process.

Implementing FMEA success factors will uniformly ensure FMEAs achieve safe, reliable and economical products and processes.
Preparation Steps for Each FMEA Project

- Determine the scope of the FMEA project
- Make the scope visible and get consensus on boundaries
- Assemble the right FMEA team (not done by one or two people)
- Establish ground rules and assumptions
- Gather information
- Prepare for the FMEA meetings
Much is learned by observing the mistakes companies have made in doing FMEAs. Based on the experience of over two thousand FMEAs and working with hundreds of companies in a wide variety of applications, certain common mistakes show up repeatedly.

- What are the primary ways that FMEAs can be done wrongly (mistakes made)?
- What are the leading factors that make for effective FMEAs (quality objectives)?
Providing excellent facilitation

- FMEA facilitation is a different subject than FMEA methodology.
- To be successful, FMEA leaders need to develop expert facilitation skills
  - Brainstorming
  - Encouraging Participation
  - Active Listening
  - Controlling Discussion
  - Making Decisions
  - Conflict Management
  - Managing Level of Detail
  - Managing Time
  - Unleashing Team Creativity
Implementing an effective FMEA process

A company-wide FMEA process is the entire set of systems and tasks essential to support development of high-reliability products and processes through timely accomplishment of well-done FMEAs.

- Management support for strategy and resources
- Roles and responsibilities
- Management review of high risk issues
- FMEA quality audits
- Execution of FMEA recommended actions
- Feedback loop to incorporate lessons learned
In Summary . . .

- Everyone wants to support the accomplishment of safe and trouble-free products and processes while generating happy and loyal customers.
- When done correctly, FMEA can anticipate and prevent problems, reduce costs, shorten product development times, and achieve safe and highly reliable products and processes.
FMEA PROBLEMS

AND SOLUTIONS
Problem 1

Which of the following are true statements about FMEA? (Select all that apply)

1. An FMEA is an engineering analysis done by the most knowledgeable person on the engineering team.
2. Part of the FMEA is to identify and carry out corrective actions to address the most serious concerns.
3. The primary objective of an FMEA is to understand the design.
4. Risk assessment is not part of the FMEA procedure.
Solution 1

Which of the following are true statements about FMEA? (Select all that apply.)

1. An FMEA is an engineering analysis done by the most knowledgeable person on the engineering team. (False. An FMEA is an engineering analysis done by a cross-functional team of subject-matter experts.)

2. Part of the FMEA is to identify and carry out corrective actions to address the most serious concerns. (True)

3. The primary objective of an FMEA is to understand the design. (False. The primary objective of an FMEA is to improve the design.)

4. Risk assessment is not part of the FMEA procedure. (False. Risk assessment is an integral part of the FMEA procedure.)
Problem 2

Indicate whether each statement about the application of FMEA is true or false.

1. One of the uses of FMEA is to improve the reliability of the product.
2. One of the uses of FMEA is to improve the safety of the product.
3. FMEAs can be used to improve the quality of the manufacturing process.
4. One of the primary applications of FMEA is to fix field problems.
Solution 2

Indicate whether each statement about the application of FMEA is true or false.

1. One of the uses of FMEA is to improve the reliability of the product. (True)
2. One of the uses of FMEA is to improve the safety of the product. (True)
3. FMEAs can be used to improve the quality of the manufacturing process. (True)
4. One of the primary applications of FMEA is to fix field problems. (False)
Problem 3

In an FMEA, which of the following is true about a “function”? (Select all that apply)

1. A “function” is what the item is intended to do, without respect to any standard of performance.
2. A “function” is what the item is intended to do, usually to a given standard of performance.
3. There is one function for each item in an FMEA.
4. The function description in an FMEA must include the consequence or impact on the end user.
Solution 3

In an FMEA, which of the following is true about a “function”? (Select all that apply)

1. A “function” is what the item is intended to do, without respect to any standard of performance. (False. A function description needs to include the standard of performance.)
2. A “function” is what the item is intended to do, usually to a given standard of performance. (True)
3. There is one function for each item in an FMEA. (False. There can be many functions for an item.)
4. The function description in an FMEA must include the consequence or impact on the end user. (False. An effect must include the consequence or impact on the end user, not a function.)
Problem 4

In an FMEA, which of the following is true about a “failure mode”? (Select all that apply)

1. A “failure mode” is the specific reason for the failure.
2. A “failure mode” is the manner in which the item or assembly could fail to meet the intended function and its requirements
3. In an FMEA, there is one failure mode for each function.
4. The failure mode description in an FMEA must include the consequence or impact on the end user.
Solution 4

In an FMEA, which of the following is true about a “failure mode”? (Select all that apply)

1. A “failure mode” is the specific reason for the failure. (False. A “failure mode” is the manner in which the item or assembly could fail to meet the intended function and its requirements.)
2. A “failure mode” is the manner in which the item or assembly could fail to meet the intended function and its requirements. (True)
3. In an FMEA, there is one failure mode for each function. (False. There can be many failure modes for each function.)
4. The failure mode description in an FMEA must include the consequence or impact on the end user. (False. An effect must include the consequence or impact on the end user, not a failure mode.)
Problem 5

In an FMEA, which of the following is true about a “control”? (Select all that apply)

1. A “control” is the specific recommendation by the FMEA team to control the risk associated with the cause of failure.
2. A “control” needs to be taken to the level of root cause of the failure.
3. There are often two types of controls identified in an FMEA: prevention-type controls and detection-type controls.
4. “Controls” are the methods or actions that are not currently planned, but need to be done to reduce or eliminate the design-related risk associated with the cause of failure.
5. “Controls” are the methods or actions that are planned or currently in place to reduce or eliminate the design-related risk associated with the cause of failure.
Solution 5

In an FMEA, which of the following is true about a “control”? (Select all that apply)

1. A “control” is the specific recommendation by the FMEA team to control the risk associated with the cause of failure. (False. Controls are the methods or actions that are planned or currently in place to reduce or eliminate the design-related risk associated with the cause of failure. Recommendations need to be in the Recommended Actions column of the FMEA.)

2. A “control” needs to be taken to the level of root cause of the failure. (False. Causes in the FMEA need to be taken to the level of root cause, not controls.)

3. There are often two types of controls identified in an FMEA: prevention-type controls and detection-type controls. (True)

4. “Controls” are the methods or actions that are not currently planned, but need to be done to reduce or eliminate the design-related risk associated with the cause of failure. (False. Controls are methods or actions that are planned or currently in place.)

5. “Controls” are the methods or actions that are planned or currently in place to reduce or eliminate the design-related risk associated with the cause of failure. (True)
FMEA Resources

• This presentation is based on the book *Effective FMEAs*, by Carl S. Carlson, published by John Wiley & Sons, © 2012
• Information about the book and links to useful FMEA articles and aids can be found on www.effectivefmeas.com.
• If you have questions or comments about this presentation, the subject of FMEAs, or the book *Effective FMEAs*, please send an email to the author at Carl.Carlson@EffectiveFMEAs.com.
Biography

Carl S. Carlson is a consultant and instructor in the areas of FMEA, reliability program planning and other reliability engineering disciplines, currently supporting clients of ReliaSoft Corporation.

He has 30 years experience in reliability testing, engineering, and management positions, including manager of product reliability at General Motors.

He co-chaired the cross-industry team that developed the commercial FMEA standard (SAE J1739, 2002 version) and was a past member of the Reliability and Maintainability Symposium (RAMS) Advisory Board.

He holds a B.S. in Mechanical Engineering from the University of Michigan, is a senior member of ASQ and a Certified Reliability Engineer.