Developing a FMEA …

- Get the Boundary Diagram – this helps define the scope of the FMEA
- Get the Interface Matrix, P-Diagram, Process Flow Chart (identify the sources of variation)
- Include a reference to rating tables

**General (header)**
- List all assumptions in detail in the first couple of lines of the FMEA
- Note the part name & number in the header
- List all team members in the header
  (involve the cross-functional team early and as warranted – don't develop a FMEA in a vacuum).
- Revision date, as appropriate, must be documented

**Function**
- Write the function in physical, technical and measurable (verb-noun) terms
  
  example:
  
  during operation, the door must not fragment.

  Or - as specified in functional spec #________; rev. date________

**Failure Mode**
- Identify all 5-types of failure modes:
  total failure, partial failure, intermittent failure, over-function & unintended function
- Write the failure modes as “anti-functions” using verb-noun format
  
  example:
  
  door fragmentation results in pieces thrown at the occupant.

**Effect(s) of Failure**
- List effects in a manner that the customer would describe them
- Include the next higher assembly, system, vehicle, machine/equipment, safety, next operation(s), customer & regulatory requirements, manufacturing, assembly, service (as appropriate)
  
  example:
  
  occupant injury caused by door fragments

**Severity (Rating)**
- Severity values should correspond with standard guidelines
- Make sure that there is one severity rating for each failure mode by taking the most serious case for the failure mode and using the rating table
  
  example:
  
  occupant injury caused by door fragments – severity 9
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Classification

- Classification should be used to define potential critical and significant characteristics
- Critical characteristics (9 or 10 in severity) must have associated recommended actions
- Significant characteristics (5 thru 8 in severity with 4 thru 10 in occurrence) should have associated recommended actions (example - see the formula used in Excel – to determine YC & YS)

<table>
<thead>
<tr>
<th>REF #</th>
<th>Item/Function Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity</th>
<th>Class</th>
<th>Potential Failure(s) of Failure</th>
<th>Occurrence</th>
<th>Current Design Controls / Verification Methods</th>
<th>Detection</th>
<th>RPN</th>
<th>Recommended Action(s)</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9</td>
<td></td>
<td></td>
<td>1</td>
<td>45</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

example:
cover not stiff enough – causing injury

Cause(s) of Failure

- Limit the causes to design concerns - use the P-Diagram & Interface Matrix to determine causes
- Analysis must stay within the defined scope – per the Boundary Diagram
- Causes at component level analysis should be identified as part or system characteristic (a feature that can be controlled or fixed at process)
- Try to identify all causes for each failure mode, circle back as needed – (there is usually more than one cause of failure for each failure mode)
- Exclude manufacturing/assembly causes in the DFMEA but include them in the PFMEA
- Identify the causes for a failure mode, not an individual effect

example:
incorrect door material specified
inadequate design validation testing at different temperatures

Occurrence (Rating)

- Occurrence values should correspond with standard guidelines
- Occurrence ratings for design FMEA are based upon the likelihood that a cause may occur, past failures, performance of similar systems in similar applications, or percent new content. Rating should be based on the likelihood of detecting the first level causes (element failure modes) or the failure mode prior to engineering, manufacturing or assembly release
- Occurrence values of 1 must have objective data to provide justification, data or source of data must be identified in ‘Recommended Actions’ column

example:
incorrect seam design – occurrence 3
Developing a FMEA …

Current Design Controls
- Preventive controls are those that help reduce the likelihood that a failure mode or cause will occur – affects occurrence value
- Detective controls are those that find problems that have been designed into the product – assigned detection value
- Clearly identify preventive and detective controls
- Ensure that the methods listed detect the causes or failure modes
  example:
  - engineering specifications – preventive control; historical data – preventive control; functional testing – detective control

Detection (Rating)
- Detection is the value assigned to each of the detective controls
- Detection values of 1 must eliminate the potential for failures due to design deficiency
  example:
  - engineering specifications – detection 1
  - historical data – detection 1
  - functional testing – detection 4
  - general vehicle durability – detection 5

RPN (Risk Priority Number)
- Risk Priority Number is a multiplication of the severity, occurrence and detection ratings
- Lowest detection rating is used to determine RPN
- RPN threshold should not be used as the primary trigger for definition of recommended actions
  example:
  - occupant injury caused by fragments – severity 9, incorrect seam design – occurrence 3
  - functional testing – detection 4, RPN = 9 x 3 x 4 = 108

Action Results
- Remedial actions taken must detail what actions occurred, and the results of those actions
- Unless the failure mode has been eliminated, severity should not change
- Occurrence may or may not be lowered based upon the results of actions
- Detection may or may not be lowered based upon the results of actions
- If severity, occurrence or detection ratings are not improved, additional recommended actions must be defined
- Ensure special manufacturing/assembly controls for Special Characteristics
## Rating Chart

<table>
<thead>
<tr>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous Without Warning</td>
<td>Very High persistent failures ≥100 per thousand vehicles / items</td>
<td>Absolute uncertainty design control will not and/or cannot detect a potential cause/mechanism and subsequent failure mode, or there is no design control.</td>
<td>10</td>
</tr>
<tr>
<td>Hazardous With Warning</td>
<td>Very High 50 per thousand vehicles / items</td>
<td>Very Remote chance the design control will detect a potential cause/mechanism and subsequent failure mode.</td>
<td>9</td>
</tr>
<tr>
<td>Very High vehicle/item inoperable (loss of primary function)</td>
<td>High: Frequent Failures 20 per thousand vehicles/items</td>
<td>Remote chance the design control will detect a potential cause / mechanism and subsequent failure mode.</td>
<td>8</td>
</tr>
<tr>
<td>High</td>
<td>High: Frequent Failures 10 per thousand vehicles/items</td>
<td>Very Low chance the design control will detect a potential cause / mechanism and subsequent failure mode.</td>
<td>7</td>
</tr>
<tr>
<td>Moderate vehicle / item operable but at a reduced level of performance. Customer very dissatisfied.</td>
<td>Moderate: Occasional Failures 5 per thousand vehicles / items</td>
<td>Low moderate chance the design control will detect a potential cause / mechanism and subsequent failure mode.</td>
<td>6</td>
</tr>
<tr>
<td>Low</td>
<td>Moderate: Occasional Failures 2 per thousand vehicles / items</td>
<td>Moderate chance the design control will detect a potential cause / mechanism and subsequent failure mode.</td>
<td>5</td>
</tr>
<tr>
<td>Very low fit &amp; finish / squeak &amp; rattle item does not conform. Defect noticed by most customers (&gt; 75%).</td>
<td>Moderate: Occasional Failures 1 per thousand vehicles / items</td>
<td>Moderately High moderately high chance the design control will detect a potential cause / mechanism and subsequent failure mode.</td>
<td>4</td>
</tr>
<tr>
<td>Minor fit &amp; finish / squeak &amp; rattle item does not conform. Defect noticed by 50 % of customers.</td>
<td>Low: Relatively Few failures 0.5 per thousand vehicles / items</td>
<td>High high chance the design control will detect a potential cause / mechanism and subsequent failure mode.</td>
<td>3</td>
</tr>
<tr>
<td>Very Minor fit &amp; finish / squeak &amp; rattle item does not conform. Defect noticed by discriminating customers (&lt; 25 %).</td>
<td>Low: Relatively Few 0.1 per thousand vehicles / items</td>
<td>Very High high chance the design control will detect a potential cause / mechanism and subsequent failure mode.</td>
<td>2</td>
</tr>
<tr>
<td>None no discernible effect.</td>
<td>Remote: Failure is Unlikely ≤ 0.01 per thousand vehicles / items</td>
<td>Almost Certain design control will almost certainly detect a potential cause / mechanism and subsequent failure mode.</td>
<td>1</td>
</tr>
</tbody>
</table>