Process Failure Modes and Effects Analysis (PFMEA)

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A Process FMEA is a risk assessment and continuous improvement tool used to identify potential process/manufacturing issues and mitigate them before the product (or service) is released to the customer.

**Assumptions:**
- Product is designed correctly
- Parts coming to a manufacturing process are made correctly, but not necessarily the correct part
- Manufacturing equipment is built correctly, but not necessarily working correctly
Process FMEA – what does it do?

- Identifies potential process/manufacturing issues that could cause:
  - Product Malfunctions
  - Shortened Product Life
  - Safety Hazards while using the product
  - Excessive scrap/rework
- Aids in designing/developing a robust manufacturing process
- Prioritizes process improvement activities
- Helps to analyze field complaints
- Allows for a full evaluation of proposed changes (process or product)
- Can drive design improvements if done early (improve ease of manufacturability)
- Increases product quality and reliability levels
- Helps identify potential key and/or critical characteristics

All failures impact product cost and decrease Customer satisfaction.
Process FMEA (PFMEA) – who is involved?

Cross-functional team of technical personnel:
– Design Engineering (R&D and Product)
– Quality
– Manufacturing (Mfg Engr and/or Process)
– Product Managers
– Other as appropriate (e.g. – Suppliers, Customers, etc)
Relationship To Other Tools

- Metrics Identification
- Process Map
- C & E Diagrams
- C & E Matrix/QFD

Design FMEA (Product or Service)
Process FMEA (Product or Service)

- Multivariate analysis
- Identification of vital few inputs
- Design reviews
- Quality Control Plan
An FMEA (design or process) may be performed at one of the following levels of analysis:

- **System** (e.g. - vehicle chassis)
- **Subsystem** (e.g. - front suspension subsystem)
- **Component** (e.g. - strut component)
Potential Failure Mode and Effects Analysis
(Types and Levels)

Design

- System
  - Sub-system
    - Component
      - Raw Material
    - Component
      - Raw Material

Process

- Final Assembly
  - Sub-assembly
    - Work Cell
      - Each Operation
  - Sub-assembly
    - Work Cell
      - Each Operation
FMEA Levels - Hierarchical Relationship

The cause identified at a higher level may become a failure mode at the next lower level.

<table>
<thead>
<tr>
<th>Level</th>
<th>Failure Mode</th>
<th>Effect</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>System</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Subsystem</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Component</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Diagram:
- A hierarchical diagram showing the relationship between system, subsystem, and component levels.
- Red arrows indicate the flow from cause to effect to cause.
Process FMEA – Sections

• The following slides describe each of the PFMEA sections
Process Step or Function

Enter the process step or function.

- Break each process step into single actions
- Identify resources for each action
- Identify interfaces between actions

If a process has more than one step, list all of the steps separately. Consider including all parts/sub-assemblies that are involved in each step.
Examples of Process Steps

- Material transformation step (i.e. injection mold, machine, heat treat, etc.)
  - For machining operations, each feature may need to be addressed independently unless made by a single tool/die
- Assemble
- Inspect/Test
- Package

- What other examples exist??????
Potential Failure Mode

A potential failure mode is the manner in which a process step can fail to meet the intended output.

- Do not ignore just because a Failure Mode or Cause is unlikely to occur
Examples of Failure Modes

- Missing part
- Wrong part used
- Over/Under-torque
- Wrong orientation
- Damage (including cosmetic where important)
- Skipped operation

What other Failure Modes exist with a process?
# Potential Effects of Failure Mode

Describe the effects of the failure in terms of what the customer would notice, perceive, or experience.

Consider all the effects in terms of the specific systems, subsystems, or components being analyzed. The customer may be internal or external.

- State clearly if the potential failure could affect safety or result in noncompliance to regulation (may affect the item’s classification).

<table>
<thead>
<tr>
<th>Potential Failure Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the impact on the Output Variables (Customer Requirements) or internal requirements?</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Examples of Potential Effects

- Noise
- Under-performance
- Leaks
- Inconsistent performance
- Safety
- Noncompliance of regulation

What other effects exist with products?
Severity Ranking

Severity is a relative rank associated with the most serious effect of each failure mode. Therefore, there should be one severity entry for each failure mode.

A reduction in severity ranking index can be effected only through a design change.
<table>
<thead>
<tr>
<th>Rank</th>
<th>Effect</th>
<th>Criteria External (Customer Effect)</th>
<th>Criteria Internal (Manufacturing Effect)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>None</td>
<td>No impact to Customer</td>
<td>No effect on product or subsequent process</td>
</tr>
</tbody>
</table>
| 2    | Very Minor                  | - No Discernible effect  
- Small deviation                                                                                   | Defect is contained, **no impact on downstream operations**  
- Rework inline (single lot)  
- Product/process parameter had only slight adverse shift and/or increase of variation          |
| 3    | Minor                       |                                                                                                     |                                                                                                         |
| 4    | Very Low                    |                                                                                                     |                                                                                                         |
| 5    | Low                         | Customer experiences discomfort  
- Delay of shipment to external customer  
- Detect that may cause concerns at customer incoming inspection although it is not stated in the customer specification, does not result in yield loss or product reliability problem. | Defect has **moderate impact on downstream operations**  
- Rework inline (single lot - many lots)  
- Scrap (single lot)  
- Moderate increase of variation on product or process parameter shift towards specification limits, internal yield slightly decreased |
| 6    | Moderate                    |                                                                                                     | Defect has **major impact on downstream operations, rework necessary**  
- Manufacturing significantly delayed in the subsequent steps.  
- Our line is disrupted, additional rework and inspection needed (5-10% of affected product)  
- Scrap lot (many lots)  
- Significant increase of variation on product or process; parameter, internal yield decreased |
| 7    | High                        | Customer slight dissatisfied  
- Slight disruption to product line at customer  
- Minor yield loss at customer                                                                   |                                                                                                         |
| 8    | Very High                   | Claim and Customer very dissatisfied  
- Reject at customer incoming  
- Minor Line Impact at customer                                                                  | Defect has **severe impact on all processes**  
- Our line is shut down, 100% sorting and rework needed.  
- Severe increase of variation on product or process in internal line, internal yield severely decreased |
| 9    | Hazardous -- with warning (Extremely Serious) | Claim and Customer extremely dissatisfied  
- Disruption to product line at customer  
- Major Line Impact at customer  
- Loss if yield creates concerns on product                                                          | Defect endangers **Environment, Health, Personnel's Safety**                                           |
| 10   | Hazardous -- without warning (Extremely Serious, Disaster) | Claim and Loss of business  
- Result in customer line shutdown  
- All assembled will be scrapped                                                                   |                                                                                                         |
Classification

Classification column may be used to classify a failure mode (e.g. - “critical”, “key”, etc.) so that it draws special attention downstream.

The purpose of classification in the PFMEA is to make sure that the process step associated with a crucial failure mode are subjected to stringent analysis and controls during manufacturing.

Links to other important analysis and controls (e.g. – MSA, Capability Studies, SPC, etc)
Classification (continued)

Used to classify component/subsystem/system characteristics that may require additional process controls:

- Safety and/or Government-Regulated characteristics
  - Safety Item
  - Critical Characteristic
  - Safety/Compliance Key Product Characteristic
- Important Performance, Fit, or Appearance Characteristics
  - Critical Characteristic
  - Critical Verification
  - Fit/Function Key Product Characteristic
  - Use your Customer’s methods
- Pass-through Characteristics
Potential Causes of Failure

Potential cause of failure is defined as the identification of a possible weakness, the consequence of which is the Failure Mode.

- Many Failure Modes have multiple Causes

For Process FMEA, the focus is on the manufacturing related causes, **not the design**!

For Design FMEA, the focus is on the design related causes, **not manufacturing**!
Examples of Causes

- Using the wrong material during the manufacturing process
  - Using white resin when the process/recipe called for gray
- Using the wrong recipe or process parameters
  - using “high altitude”, when cooking at “sea level”
- Missing a step or component
  - Not putting butter or grease in the pan prior to making fried eggs
- Mishandling
  - dropping a plate before delivering the order
- Over-processing (too long cure) or under-processing (too short cure)

What other causes are there related to processes?
Occurrence Ranking

Occurrence of a cause is the likelihood that the cause (listed in the previous column) will occur during the manufacturing process.

The Occurrence ranking number can be reduced only by preventing or controlling the cause of the failure mode through additional analysis or redesigning the process.

An Occurrence value is entered for each Cause
# FMEA (Process) – Occurrence

<table>
<thead>
<tr>
<th>Rank</th>
<th>Occurrence</th>
<th>Possible Failure Rate</th>
<th>Occurrence Per Period</th>
<th>Cpk</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Almost Never</td>
<td>(&lt;\sim 0.0001%))&lt;br&gt;0.001 in 1,000&lt;br&gt;1 in 1,000,000</td>
<td>Not yet</td>
<td>(&gt;1.7)</td>
</tr>
<tr>
<td>2</td>
<td>Remote</td>
<td>(\sim 0.001%)&lt;br&gt;0.01 in 1,000&lt;br&gt;1 in 100,000</td>
<td>So far only one lot or run or event</td>
<td>(&gt;1.5)</td>
</tr>
<tr>
<td>3</td>
<td>Very Slight</td>
<td>(\sim 0.01%)&lt;br&gt;0.1 in 1,000&lt;br&gt;1 in 10,000</td>
<td>(lot or run or event) Yearly</td>
<td>(&gt;1.3)</td>
</tr>
<tr>
<td>4</td>
<td>Slight</td>
<td>(\sim 0.1%)&lt;br&gt;1 in 1,000&lt;br&gt;1 in 1,000</td>
<td></td>
<td>(&gt;1.1)</td>
</tr>
<tr>
<td>5</td>
<td>Low</td>
<td>(\sim 0.2%)&lt;br&gt;2 in 1,000&lt;br&gt;1 in 500</td>
<td>(lot or run or event) Quarterly</td>
<td>(&gt;1.0)</td>
</tr>
<tr>
<td>6</td>
<td>Moderate</td>
<td>(\sim 0.5%)&lt;br&gt;5 in 1,000&lt;br&gt;1 in 200</td>
<td></td>
<td>(&gt;0.9)</td>
</tr>
<tr>
<td>7</td>
<td>Moderately High</td>
<td>(\sim 1%)&lt;br&gt;10 in 1,000&lt;br&gt;1 in 100</td>
<td>(lot or run or event) Monthly</td>
<td>(&gt;0.8)</td>
</tr>
<tr>
<td>8</td>
<td>High</td>
<td>(\sim 2%)&lt;br&gt;20 in 1,000&lt;br&gt;1 in 50</td>
<td></td>
<td>(&gt;0.7)</td>
</tr>
<tr>
<td>9</td>
<td>Very High</td>
<td>(\sim 5%)&lt;br&gt;50 in 1,000&lt;br&gt;1 in 20</td>
<td>(lot or run or event) Weekly</td>
<td>(&gt;0.6)</td>
</tr>
<tr>
<td>10</td>
<td>Almost Certain</td>
<td>(\geq \sim 10%)&lt;br&gt;(\geq 100) in 1,000&lt;br&gt;(\geq 1) in 10</td>
<td>(lot or run or event) Daily</td>
<td>(&lt;0.4)</td>
</tr>
</tbody>
</table>
Current Controls

Current Controls are methods that prevent and/or detect Causes or Failures of the product or service during (or after) production.

2 Types:
- Prevention
- Detection

<table>
<thead>
<tr>
<th>Current Controls</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention</td>
<td>Detection</td>
</tr>
<tr>
<td>What are the existing controls and procedures (inspection and test) that prevent/detect either the Cause or Failure Mode? Should include an SOP number.</td>
<td></td>
</tr>
</tbody>
</table>
Prevention Controls

Prevention Controls help to prevent a manufacturing problem from being present.

**Examples:**
- Work Instructions, Procedures, SOP’s, etc
- Training
- Assembly fixtures
- Poka-Yoke Methods (part presence sensors prior to cycle, color coding, etc)

What other types of Prevention Control exist?

Prevention controls directly impact the Occurrence Ranking
Detection Controls

Detection Controls are those that detect a manufacturing or product defect:

**Examples:**
- Contact Methods: measurement/detection through physical contact (e.g. – calipers, micrometers, surface roughness, etc)
- Non-Contact Methods: measurement/detection through optical methods (e.g. – vision system, eye sight, etc)
- Fixed-value Methods: Errors are detected through counting
- Motion-step Methods: Errors are detected by motion or lack of it

Detection controls only impact the Detection Ranking, not the Occurrence Ranking
# FMEA (Process) – Detection

<table>
<thead>
<tr>
<th>Rank</th>
<th>Detection</th>
<th>Measuring Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Almost Certain</td>
<td>100% automatic measurement and online control of the cause, very clear characteristic of cause. Discrepant parts cannot be made because item had been error-proofed by process/product design</td>
</tr>
<tr>
<td>2</td>
<td>Very High</td>
<td>Error causes detected at process step and be corrected before scrap is generated. Error causes detection in station by automated controls that will detect error and prevent discrepant part from being made.</td>
</tr>
<tr>
<td>3</td>
<td>High</td>
<td>100% automatic measurement and online control of hard to identify cause characteristic. Sample measurement of an easy to identify failure characteristic through an automatic measurement instrument. Failure Mode detection in station by automated control</td>
</tr>
<tr>
<td>4</td>
<td>Moderately High</td>
<td>Failure can be detected at end of process line Failure can be stopped at Final Inspection with 100% sorting Failure Mode detection post-processing by automated control</td>
</tr>
<tr>
<td>5</td>
<td>Moderate</td>
<td>100% visual control of an easy to identify failure characteristic Failure mode (or Error Cause) detection in station by operator through use of variable or automated controls in station that will detect discrepant parts and notify operator Gauging performed on setup and first piece check(for set-up causes only)</td>
</tr>
<tr>
<td>6</td>
<td>Low</td>
<td>Failure Mode detection post-processing by operator through use of variable or attribute gauging by operator</td>
</tr>
<tr>
<td>7</td>
<td>Very Low</td>
<td>100% visual control of a hard to identify failure characteristic Visual Sample control of an easy to identify failure characteristic</td>
</tr>
<tr>
<td>8</td>
<td>Remote</td>
<td>Random sample measurement Failure Mode detection post-processing by operator through visual/tactile/audible means</td>
</tr>
<tr>
<td>9</td>
<td>Very Remote</td>
<td>Not likely to detect at any stage Failure Mode and/or Error Cause are not easily detected</td>
</tr>
<tr>
<td>10</td>
<td>Almost Impossible</td>
<td>No detection opportunity (Current Action / Detection = None) No current process control Defective material will go to customer (detection by customer)</td>
</tr>
</tbody>
</table>
Detection Ranking

Detection is an assigned rank based on the detection controls from the previous column.

In order to achieve a lower ranking, the planned controls have to be improved:

- Improved effectiveness in detecting the failure mode or cause
- Implementation of additional controls
Risk Priority Number (RPN)

RPN = Severity × Occurrence × Detection

- Used as a guide to help rank design concerns
- Golf score concept (lower is better)
- There should not be a “threshold” value
- Special attention should be given when severity is high

\[ \text{RPN} = S \times O \times D \]
RPN Is a Relative Value

RPN’s indicate the relative importance (urgency to address) of the different failures within the context of a specific FMEA review.

- The absolute values of RPN’s from different FMEAs should never be compared, even if they relate to similar items or failure modes.
- Even within the same FMEA, there should not be a threshold value for RPN.
  - Specific customer requirements may force this to be in place
Recommended Actions

The outcome of a Process FMEA should be the following types of recommendations:

- Design change to reduce Severity ranking (e.g. – redundancy, change effect, etc)
- Design/Process change to remove a failure mode or cause from the process
- Implement additional prevention controls to reduce Occurrence ranking
- Improve effectiveness of detection method (e.g. – improve MSA, higher sensitivity, new method, etc) to reduce Detection Ranking

Goal is to reduce the RPN (reduce risk)
FMEA: Step-by-Step

1. Identify process step and resources that go into it
2. Determine all of the potential failure modes for individual process step
3. For each failure mode, determine the “worst case” effect on the customer (internal or external)
4. Identify all potential causes of each failure mode
5. List the current controls (Prevention/Detection) for each cause or failure mode
6. Repeat steps 1 – 5 above for each process step
7. Review Severity, Occurrence, and Detection ranking scales with the Team
8. Assign Severity, Occurrence and Detection ranking to each cause
9. Calculate the Risk Priority Number (RPN) for each cause and identify “high risk” items
10. Determine recommended actions to reduce RPN values on “high risk” items
11. Implement identified improvement actions and recalculate RPN’s
12. Repeat steps 10 -11 as appropriate to continually reduce risk
## The Process FMEA Steps

<table>
<thead>
<tr>
<th>Process/Function</th>
<th>Potential Failure Mode</th>
<th>Potential Failure Effect</th>
<th>Severity</th>
<th>Class</th>
<th>Potential Cause</th>
<th>Occurrence</th>
<th>Current Controls (Prevent/Detect)</th>
<th>Detection</th>
<th>RPN</th>
<th>Actions Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are process steps?</td>
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<tr>
<td>What are the Effect(s)?</td>
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<tr>
<td>What can go wrong? • Missing part • Wrong part • Over/Under torque • Damage • Extra part • Skipped step • Inspection error</td>
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<td>How bad is it?</td>
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<tr>
<td>What are the cause(s)?</td>
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<td>How often does it happen?</td>
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<td>How can this be prevented and detected?</td>
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<tr>
<td>How good is this method at detecting it?</td>
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<tr>
<td>What can be done? • Design change • Process change • Special controls • Changes to Standards, Procedures, or Guides</td>
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</tbody>
</table>
Alternatives

• Use 1-5 (or other scale) if more appropriate
  • 1- 10 scale can often be difficult to apply:
    • Low volume production
      • Occurrence Ranking
    • Design FMEA
      • Occurrence Ranking
      • Detection Ranking (based on tests/analysis performed)

• Modify Detection Ranking to be more analytical
  • Assign “Effectiveness Points” to each type of detection method
  • Sum “Effectiveness Points” to determine Detection Ranking
Alternatives (Detection Ranking)

- Effectiveness Points:
  - 100% Automated Inspection - 4 pts
  - 100% Manual Inspection (measurement) – 3 pts
  - 100% Visual Inspection (objective) – 3 pts
  - 100% Visual Inspection (subjective) – 2 pts
  - Sampling (statistically significant) – 2 pts
  - Sampling (random) – 1 pt
  - SPC (input variables) – 2 pts
  - SPC (output characteristics) – 1 pt
  - No Build Condition – 10 pts

<table>
<thead>
<tr>
<th>Eff Pts</th>
<th>Det Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 10</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>2</td>
</tr>
<tr>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>4</td>
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<tr>
<td>6</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Eff Pts</th>
<th>Det Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>≤1</td>
<td>10</td>
</tr>
</tbody>
</table>

Only take credit for Effectiveness Points if it is written in the PFMEA. If methods apply to multiple locations in process, identify each of them and take credit.
Final Thoughts

A thorough FMEA will be of limited value without positive and effective actions to prevent Failure Modes/Causes or mitigate their effects.

The FMEA team leader is responsible to implement a follow-up program to ensure all Recommended Actions have been adequately addressed.

It’s all about continuous improvement and reducing risk to the organization.