**Report Title:** TARDEC FMEA TRAINING: Understanding and Evaluating Failure Mode and Effects Analyses (FMEA)  

**Authors:** Kadry Rizk; Gregor Ratajczak  

**Abstract:** By the end of this training, the participant should be able to -Identify and prioritize risks of failure -Identify the function(s) of parts/processes, their inputs, and associated outputs -Understand how supporting tools are used to help create a FMEA -Understand the FMEA fields and line items -Evaluate and manage contractors' FMEAs

**DISTRIBUTION/AVAILABILITY STATEMENT:** Approved for public release; distribution unlimited

**SUPPLEMENTARY NOTES:** For TARDEC Failure Mode and Effects Analysis (FEMA) Training Classes

**ABSTRACT**
By the end of this training, the participant should be able to -Identify and prioritize risks of failure -Identify the function(s) of parts/processes, their inputs, and associated outputs -Understand how supporting tools are used to help create a FMEA -Understand the FMEA fields and line items -Evaluate and manage contractors' FMEAs
By the end of this training, the participant should be able to:

- Identify and prioritize risks of failure
- Identify the function(s) of parts/processes, their inputs, and associated outputs
- Understand how supporting tools are used to help create a FMEA
- Understand the FMEA fields and line items
- Evaluate and manage contractors’ FMEAs
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Section A

Overview
What is a Failure Mode and Effect Analysis (FMEA)?

Failure mode and effect analysis (FMEA) is an analysis of all potential failure modes within a system. It provides an organized, critical analysis of potential failure modes and identifies associated causes and effects.

FMEA.....

• can be performed on systems, subsystems, components, functions, interfaces, software, and any process that has the potential to fail.

• is a risk assessment tool where possible failure modes, their effects, and possible causes are identified and ranked according to their level of risk. FMEA is the most complete way to do risk management.

• is a widely accepted analysis procedure which should be used at the initial stages of development as well as throughout the life cycle.

• is used as a foundation for root cause analysis.
FMEA Defined

Failure: the inability to produce the desired output, which may occur at any point within the function of a product.

Failure Mode: The manner by which a failure is observed; it generally describes the way the failure occurs.

Effects: the consequences of failure. The power of the effect will dictate the level of action. Not every failure needs to be addressed.

Analysis: the investigation of how a product or process can fail. This identification of the potential failures then serves to rate:
  • how severe the effects are.
  • how often the cause might occur.
  • how easily we can prevent, or at least detect failure.
  • What actions can be taken to prevent the failure in the future.
Types of FMEA

Design FMEA – *also known as DFMEA*
• Identifies how a product fails to perform its intended function.

Process FMEA – *also known as PFMEA*
• Identifies the possibilities of incorrectly manufacturing or assembling a product, or incorrectly performing a set of tasks.

Program/Transactional FMEA
• Identifies potential failure modes in non-technical processes (business systems, procurement processes, hiring practices, etc.) or any process that is not describing a product or the manufacturing or assembly of that product.

Other
• FMEA has been adapted over the years to address failures in very specific areas such as machinery, services, etc.
Failure Mode Effects and Criticality Analysis (FMECA) is similar in method to FMEA but with an added factor called Criticality. The use of Criticality to influence a FMEA is explained in MIL-STD 1629A, which was canceled on 4 August 1998 with no superseding document.

In light of the cancellation of MIL-STD 1629A, the TARDEC FMEA IPT and the ARDEC SE AD agree that FMEA should be taught as it is taught in industry and without the particular emphasis on Criticality. Criticality is addressed by the RPN in FMEA. Therefore this material will present multiple ways to prioritize risk beyond that single criteria.
FMEA is a widespread practice used by various industries. Different industries have different standards:

- All are very similar in philosophy and procedures
- They vary mostly in product specific details

Different standards include:

- SAE ARP-5580: “Recommended failure mode and effects analysis (FMEA) practices for non-automobile applications”. Aerospace Recommended Practice
How Can FMEA Help My Program?

• A DFMEA provides robustness of design.

• A PFMEA provides robustness of process.

• A FMEA reused from a previous program reduces the design time for the system.

• Potential failure modes are identified early in the program and can be dealt with up front, rather than detected later.

• FMEAs can be used to determine the root cause of system or part failures, once fielded!!!
Benefits of FMEA

FMEA is a proactive approach which should start early in program life, and be maintained throughout the life cycle. FMEA provides benefits in the following areas:

1. **More Robust Design/Process:**
   It can identify the need to alter the development of the design and/or the manufacturing process to prevent major risks, reduce failure, minimize cost, or reduce development time.

2. **Upfront Risk Identification and prioritization:**
   FMEA feeds the larger risk management process. The analysis prioritizes the actions that should be taken to reduce risk. It also highlights where further actions would result in further risk reduction.

3. **Effective Risk Mitigation:**
   Failures can be identified and mitigated before they happen. FMEA helps a program “do it right the first time”, saving time and money.
Benefits of FMEA

4. Improved Control Plans:
   Design and process FMEAs can help to identify what design and process controls that need to be put in place.

5. Foundation for Root Cause Analysis:
   Root cause analysis, failure investigation, and corrective action planning time can be greatly reduced using FMEA. This includes diagnosing failures in theatre.

6. Provide Repository for Lessons Learned:
   A FMEA is a living document and provides basis for lessons learned and best practices which can be shared for use in other programs.

7. Increase Reliability and Maintainability:
   FMEA improves reliability and maintainability through risk mitigation.

8. High Reuse for Next Program.
Failure Mode and Effects Analysis can have SIGNIFICANT impact on Life Cycle Costs!

RED = no FMEA
GREEN = FMEA proactively done

When correctly executed FMEA reduces costs by reducing the possibility of failure.

Doing it **right the first time** is always less expensive than the alternative.
When to Conduct FMEA?

Design FMEA is a living document and should be initiated before or at design concept finalization, be continually updated as changes occur, and be fundamentally completed before production drawings are released for tooling.

Process FMEA (for manufacturing and assembly) is also a living document and should be initiated at the beginning of the design stage, and take into account all manufacturing operations of components and assemblies.

Design and Process FMEA are similar. Each identifies different sets of risks which need to be addressed in different ways. It is not sufficient to do one without the other.
As a living document, the FMEA should be updated at every opportunity. It’s value increases with each new piece of knowledge.

- FMEA should be updated at every design/process change or after improvements/upgrades.

- FMEA should be reviewed when performing failure analysis/root cause analysis to resolve a field/theater problem. It helps in identifying root cause(s) of failure.

- The FMEA should be updated when any new failure mode or root cause is identified at any point during the life cycle that is not in the FMEA. This allows for reusability on next program.

- When a FMEA is used for a similar new design/process, it should be reviewed and revised to reflect changes in the new design/process from the existing one.
The risk management process includes the following key activities, performed on a continuous basis:

- Risk Identification
- Risk Analysis
- Risk Prioritization and Mitigation Planning
- Mitigation Plan Implementation
- Risk Tracking and Reporting

FMEA feeds identified and prioritized risks to Risk Recon for mitigation planning, implementation, and tracking.

Once a risk is realized, it becomes an issue and is tracked separately in the issues tracking database with corrective action(s) if necessary.

Risk Recon is an effective tool for risk mitigation planning, mitigation plan implementation, risk tracking and reporting.
Fields from FMEA software pre-populate Risk Info sheet. 

Risk Mitigation from Risk Recon trace back and populate FMEA, new RPN numbers.

An issue’s corrective action plan or path forward will likely have new associated risks, which can be entered and traced back to original risk in Risk Recon.

When a risk becomes an issue, user can create an issue in the database and track the corrective action plan.

Tie all systems together and have one searchable lessons learned database.

NOTE: This slide depicts the desired end state to be realized in the future. The elements shown are either in development or currently exist.
FMEA development, either design or process, uses a common approach to address:
• Potential product or process failure to meet expectations
• Potential effects/consequences of the failure
• Potential causes of the failure mode
• Application of current controls
• Level of risk
• Risk reduction

Before the FMEA document is started, the team must define the scope of the project and collect existing information which is necessary for an efficient and effective FMEA development process.
The purpose of the FMEA template used is to organize the collection and display of relevant FMEA information. The template address:

• Functions, requirements, and deliverables of the product or process being analyzed,
• Failure modes when functional requirements are not met,
• Effects and consequences of the failure mode,
• Potential causes of the failure mode,
• Actions and controls to address the causes of the failure mode,
• Actions to prevent recurrence of the failure mode.
Section B

How to Prepare for FMEA
A cross functional team should be formed to perform a FMEA. Members should include, but not be limited to, representatives from the following areas:

- Design
- Validation
- Assembly
- Warranty
- Manufacturing
- Quality
- Testing
- Logistic
- Maintenance
- Safety

- Reliability
- Craftsmanship
- Service
- Materials
- Supplier(s)
- Contractor(s)
- RAM
- Sustainment
- Human Factors
- Environmental
Many sources can provide a head start to a new FMEA:
• Current/past Manufacturing/Assembly issues related to the design
• Customer contract statement of requirements
• Assumptions from quote package
• FMEAs from similar products
• Engineering specifications and standards
• Development test data
• Manufacturing, assembly, service, recycle requirements
• Warranty data
• Prior/similar customer requests for corrective action
• Lessons learned
• Best practices
• Benchmarking
Preparing for FMEA

Understanding how something works is imperative to finding out how it can fail.

Use proven, thorough approaches to describe all the elements of the product/process:

- Parameter Diagram (P diagram)
- Block Diagram
- Work/product Breakdown Structure (WBS)
- Process Map (PMAP)
- Process Flow Diagram

All these tools contain elements which can help populate certain fields within the FMEA. In some form or another, they provide information about the item/process step, function, failure mode, or causes of failure.

The following slides explain each tool, and how it applies to the retractable pen.
This pen will be used as an example throughout the remainder of the class to illustrate concepts and conduct exercises.
A P-Diagram helps a team to understand the physics related to the functions of the design. The team analyzes the intended inputs and outputs for the design as well as those controlled and uncontrolled factors which can impact performance. The inputs to the product and outputs from the product are useful in identifying error states, noise factors, and control factors. **Objective:** To convert the entirety of input energy into desirable outputs **May be applicable to:** All FMEA

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FMEA translations:
- Error states = Failure modes
- Noise, Control Factor, and Input Signal = Potential causes of failure
- Ideal function = Function or Step
- Sub system = Item or step name
**NOISE 1: Piece to Piece**
- Dimensional (interference with nib)
- Dimensional (interference with plunger)
- Dimensional (interference with ink)
- Material discrepancies

**NOISE 2: Change Over Time**
- Warping of barrel

**NOISE 3: Customer Usage**
- Unintended usage (removal/reinsertion of nib)
- Unintended usage (removal/reinsertion of plunger)

**NOISE 4: External Environment**
- Humidity (material changes)
- Temperature (expansion/contraction)

**NOISE 5: System Interaction**
- Too much force from plunger
- Too much force from nib

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**INPUT SIGNAL**
- Press fit plunger
- Press fit nib
- Insert ink sub-system

**SUB-SYSTEM**
- Barrel

**DEAL FUNCTION**
- Captures ink sub-system
- Captures plunger sub-system
- Captures nib

**CONTROL FACTORS**
- Amount of pressure used to fit plunger
- Amount of pressure used to fit nib
- Alignment

**ERROR STATES**
- Does not capture ink sub-system
- Does not capture plunger sub-system
- Does not capture nib
- Interferes with retraction of ink subsystem
A block diagram is an illustration of a system that shows the physical and logical relationships between the components of the product. Each block contains a component of a product, and the lines show how each of the components interface with each other.

**Objective:** To understand requirements/inputs to the system, the activities acting on the inputs, and the deliverables/outputs

**May be applicable to:** Design FMEA

### Components:

A. <Component 1>
B. <Component 2>
Etc…

### Attaching Methods:

1. <Method 1>
2. <Method 2>

### Key:

- Letters = Components
- Numbers = Attaching Methods
- = Attached/Joined
- = Interfacing, Not Joined
- = Not included in this Diagram

### FMEA translations:

Part = Item name and number
Attaching method = Function
“Bad” Attaching method = Failure mode
FMEA Block Diagram Example

System Name: WRITING SYSTEM (1.0)
RETRACTABLE PEN (1.1)

COMPONENTS
A. Housing Assembly
B. Ink/Spring Assembly
C. Nib

ATTACHING METHODS
1. Captured
2. Compressive Fit
3. Captured

KEY
Letters = Components
Numbers = Attaching Methods
= Attached/Joined
= Interfaced, Not Joined
= Not included in this FMEA
A Work Breakdown Structure is a hierarchical tool used to make a process/product more manageable. It divides the process/product into smaller tasks. It relates all of these tasks with each other and with the final output.

**Objective:** To understand the scope of the project, and to see the process/product in smaller, more manageable pieces

**May be applicable to:** Design FMEA

FMEA translations:
WBS element = Item name & number
WBS for a Retractable Pen

1.0 Writing System

1.1 Retractable Pen

1.1.1 Housing Assembly

1.1.1.1 Plunger Assembly

1.1.1.1.1 Clip

1.1.1.1.2 Male Plunger

1.1.1.1.3 Female Plunger

1.1.1.4 Plunger Cap

1.1.1.2 Barrel

1.1.2 Ink/Spring Assembly

1.1.2.1 Ink Tube

1.1.2.1.1 Tube

1.1.2.1.2 Metal Tip

1.1.2.1.3 Ball

1.1.2.1.4 Blue Ink

1.1.2.2 Spring

1.1.3 Nib

1.2 System Engineering / Project Management

1.3 System Test & Evaluation

1.4 Training

1.4.1 Equipment
A process map is a depiction of how a process flows. Assembly, Manufacturing, and Transactional process maps describe the actionable steps taken to build or make something, or to achieve some business related output. In all cases process maps include inputs and the various tasks involved in turning those inputs into outputs. (Advanced use of Functional process maps can describe the sequential purposes of components working together to achieve a desired output. This information would help populate a Design FMEA.)

**Objective:** To understand the work flow of a process and the actions required to turn inputs into desirable outputs

**May be applicable to:** Process FMEA, Transactional FMEA (and possibly Design FMEA)

**FMEA translations:**
- **Step # = Process step #**
- **Description = Process step function**
- “Bad” **Output = Failure mode**
- **Input = Cause of failure**
Pen Assembly Process Map

1. Load ink tube vertically into fixture
   - Inputs: Fixture, Ink Tube, Operator

2. Load spring into press
   - Inputs: Press, Spring, Operator

3. Press spring on to tube
   - Inputs: Fixture, Spring, Tube, Press, Operator

4. Load plunger ass'y to fixture
   - Inputs: Plunger ass'y, Fixture, Operator

5. Load barrel on to press
   - Inputs: Press, Barrel, Operator

6. Press barrel on to plunger
   - Inputs: Barrel, Plunger ass'y, Fixture, Press, Operator

7. Drop ink/spring ass'y into housing ass'y
   - Inputs: Ink/spring ass'y, Housing ass'y, Fixture, Operator

8. Insert nib into press
   - Inputs: Nib, Press, Operator

9. Press nib on to housing ass'y
   - Inputs: Nib, Housing ass'y, Press, Operator, Fixture

Outputs:
- Tube aligned for spring insertion
- Spring aligned for insertion
- Completed ink/spring ass'y
- Ink/spring ass'y loaded into housing
- Nib aligned for insertion
- Completed pen
- Plunger ass'y aligned for insertion
- Barrel aligned for insertion
- Completed housing ass'y
- Output
A process flow diagram describes the flow of the product through the process from incoming to outgoing. This should include each step in a manufacturing or assembly process as well as their related outputs (product characteristics, requirements, deliverables, etc.) and inputs (process characteristics, sources of variation, etc.). The details of the process flow depends on the stage of process development discussion.

**Objective:** To understand the work flow of a process and the operations required

**May be applicable to:** Process FMEA
Pen Assembly Process Flow Diagram

Sample - Manufacturing Process Flow Diagram
Pen – Adding Spring to Ink Assembly
## Suggested Application of Tools to Populate a FMEA

<table>
<thead>
<tr>
<th></th>
<th>Design FMEA</th>
<th>Process FMEA</th>
<th>Transactional FMEA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Block Diagram</strong></td>
<td>X</td>
<td></td>
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<tr>
<td><strong>Process Map</strong></td>
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<tr>
<td><strong>WBS</strong></td>
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<tr>
<td><strong>Parameter (P) Diagram</strong></td>
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<tr>
<td><strong>Process Flow Diagram</strong></td>
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Section C

How to Do FMEA
Steps to complete a FMEA

1. For each subsystem, component, or process determine the ways in which the item functions or process steps can go wrong (these are the potential failure modes).

2. For each failure mode, determine the effect(s) of the failure.

3. Identify potential cause(s) of each failure mode.

4. List the current controls to prevent or detect each cause.

5. Assign a severity (S) rating to the effect, and occurrence (O), and detection (D) ratings to each cause.

6. Calculate the risk priority number (RPN). \( RPN = S \times O \times D \)

7. Using RPN as the measure, develop mitigation recommendations for high RPN failures.

8. Take appropriate mitigation actions and document responsible persons and completion date(s).

9. Re-evaluate RPN after mitigation action is complete.

10. Repeat 1-10 until all RPN represent accepted risk and whenever the process or product undergoes change, revision, or unidentified failure.
Enter the number of the item as it appears on the WBS or any other document which describes the breakdown of the system, sub-system, or component in question.

This field is useful to tie the FMEA back to its support documents. A WBS example might look like “1.1.2.3” or some similar format.
Examples of functions include:
- Torque Converter - Transmit torque
- Corrosion Coating - Resist corrosion
- Bearing Retainer - Retain bearing

An item can have more than one function, and therefore more than one failure mode.
<table>
<thead>
<tr>
<th>Item #</th>
<th>Item name / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Severity</th>
<th>Classification</th>
<th>Potential Causes / Mechanisms of Failure</th>
<th>Current Design Controls Prevention</th>
<th>Occurrence</th>
<th>Current Design Controls Detection</th>
<th>Defect</th>
<th>R.P.M.</th>
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</table>
### Potential Failure Mode

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<th>Current Design Controls Detection</th>
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#### Describe how an item can fail to meet its intended function

Examples of failure modes:
- No torque transmitted
- Rust forms
- Bearing falls out
### Potential Effect(s) of Failure

<table>
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<tr>
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### Describe what the customer might notice or experience

- Vehicle cannot move
- Shortened material life span
- Excessive vibration and noise
## Ball Design FMEA Exercise

<table>
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<tr>
<th>Item #</th>
<th>Item Name / Function</th>
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<th>Detect</th>
<th>R.P.M.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.2.3</td>
<td>Ball / deliver ink to paper</td>
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## Ball Design FMEA Exercise

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<tbody>
<tr>
<td>1.1.2.3</td>
<td>Ball / deliver ink to paper</td>
<td>Not enough ink delivered to paper</td>
<td>Intermittent line / skipping</td>
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### Potential Causes

#### Examples of causes:
- Broken coupling
- Improper material composition
- Bearing retainer too large

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<td>46</td>
</tr>
</tbody>
</table>
### Current Design Controls - Prevention

#### Examples of prevention actions:
- Use hardened material
- Exceed minimum coating thickness
- Stay within specifications

#### List the controls/features that prevent the cause (and in turn the failure mode) from occurring, or reduce its rate of occurrence.

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</table>
Examples of detection actions:
- Batch hardness testing
- Corrosion testing (salt / humidity)
- Validation testing

List the controls/feature that allow the cause or the failure mode to be detected as early as possible, preferably before effecting function.
### Ball Design FMEA Exercise

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<td>Not enough ink delivered to paper</td>
<td>Intermittent line / skipping</td>
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<td></td>
<td>No ink delivered to paper</td>
<td>Pen discarded</td>
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<tr>
<td></td>
<td>Too much ink delivered to paper</td>
<td>Document ruined</td>
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</tbody>
</table>
## Ball Design FMEA Exercise

<table>
<thead>
<tr>
<th>Item #</th>
<th>Item name / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Severity</th>
<th>Classification</th>
<th>Potential Causes / Mechanisms of Failure</th>
<th>Current Design Controls Prevention</th>
<th>Occurrence</th>
<th>Detect</th>
<th>R.P.M.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.2.3</td>
<td>Ball / deliver ink to paper</td>
<td>Not enough ink delivered to paper</td>
<td>Intermittent line / skipping</td>
<td>Ball diameter variations</td>
<td>Tolerance specification</td>
<td>Paper surface finish variation; too rough or too smooth</td>
<td>Paper surface finish range specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ball surface finish variation</td>
<td>Tolerance specification</td>
<td></td>
<td></td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
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<td></td>
<td></td>
<td>Ball diameter too big; blocking flow of ink</td>
<td>Tolerance specification</td>
<td></td>
<td></td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
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<td></td>
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<td></td>
<td></td>
<td>User does not exert sufficient pressure</td>
<td>Force study done on users</td>
<td></td>
<td>Test: pressure vs ink delivery; 6 parts per month 0-6 psi</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>User holds pen at extreme angle</td>
<td>Grip angle study done on users</td>
<td></td>
<td>Test: angle vs ink delivery; 5 parts per month 0-90 degrees</td>
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<td></td>
<td>Too much ink delivered to paper</td>
<td>Document ruined</td>
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<td></td>
<td></td>
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<td>Tolerance specification</td>
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<td>Supplier self certification and incoming inspection 10 of every lot</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Improper hardness of ball material</td>
<td>Tolerance specification</td>
<td></td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
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</tbody>
</table>
For each potential failure, severity, occurrence, and detection are evaluated based on a scale of 1 to 10.

The Risk Priority Number (RPN) characterizes a failure mode’s overall level of risk and is calculated as:

- \[ \text{RPN} = \text{Severity (S)} \times \text{Occurrence (O)} \times \text{Detection (D)} \]

The product of the RPN equation ranges between 1 and 1000 and is used to prioritize the potential failure modes by their level of risk and need for mitigation action.

Guidance for ranking severity, occurrence, and detection is included in the appendix.
Severity Ranking

<table>
<thead>
<tr>
<th>Item #</th>
<th>Item name / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Severity Classification</th>
<th>Potential Causes / Mechanisms of Failure</th>
<th>Current Design Controls Prevention</th>
<th>Occurrence</th>
<th>Current Design Controls Detection</th>
<th>Detect</th>
<th>R.P.N.</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

**Severity** is associated with the effect of a given failure mode.
- Each potential effect receives a severity ranking.
- Severity is described in relation to how it affects the customer.
- Severity is the most difficult ranking to later attempt reducing. In most cases only changing the mode of failure can change the effect of the failure.

**Classification** refers to any special characteristics of the design or to high priority failure modes like SAFETY or REGULATORY items. Key requirements or important product characteristics can also be noted here (i.e. KPP, KCC, KPC, KSA, etc).
**Occurrence Ranking**

<table>
<thead>
<tr>
<th>Item #</th>
<th>Item name / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
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<th>Classification</th>
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<th>Current Design Controls Prevention</th>
<th>Occurrence</th>
<th>Current Design Controls Detection</th>
<th>Detect</th>
<th>R.P.N.</th>
</tr>
</thead>
</table>

Occurrence is the likelihood that a specific cause will occur, generating a failure mode.

- Remember that occurrence relates to how often the CAUSE will happen, not the failure mode. Therefore similar causes, even in different applications, might be a resource for estimating occurrence.
- In determining the occurrence ranking ask the following questions:
  - Are there any issues with the previous design or a current like design?
  - Is this a carryover part, same application, or same function as in the past? If so apply historical knowledge.
  - Is there new content or is this a completely new design? Similar causes in other applications may help estimate occurrence.
  - Are any prevention controls already in place?
  - Are there any known quality, reliability, or durability issues related to this product?
- Reducing the occurrence level is done by preventing or controlling the cause of the failure mode.
- If there is no prevention control, Occurrence is automatically scored as 10.
Detection Ranking

Detection is associated with the best control that can detect the cause of a failure mode or the failure mode itself. Although this control does not prevent the failure from happening it should identify it before it can get to the field or the user.

- Each detection control receives a Detection ranking.
- If multiple controls are in place, list all, but use the best control to rank Detect.
- If there is no detection control Detect is automatically scored as 10.
- In order to achieve a lower ranking, the planned design control (validation, and/or verification activities) has to be improved.

<table>
<thead>
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<th>Item #</th>
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<th>Potential Effects of Failure</th>
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<th>Occurrence</th>
<th>Current Design Controls Detection</th>
<th>Detect</th>
<th>R.P.N.</th>
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</thead>
<tbody>
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<td>10</td>
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</table>

Detection | 10
Risk Priority Number (RPN)
This number characterizes the overall risk of the failure mode in question. The higher the RPN is the more the need for action to mitigate or reduce the risk. RPN is the product of severity, occurrence and detection.

The RPN ranges between 1 and 1000 for the purposes of prioritizing mitigation activity.

\[
RPN = (\text{Severity} \times \text{Occurrence} \times \text{Detection})
= S \times O \times D
\]

Not all potential failure modes and/or causes of failure will require mitigation action. The higher RPN items will demand action while the lower ones may go unanswered due to time and resources constraints.
<table>
<thead>
<tr>
<th>Item #</th>
<th>Item name / Function</th>
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<th>Classification</th>
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<th>Current Design Controls Prevention</th>
<th>Occurrence</th>
<th>Current Design Controls Detection</th>
<th>Detect</th>
<th>R.P.N.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.2.3</td>
<td>Ball / deliver ink to paper</td>
<td>Not enough ink delivered to paper</td>
<td>Intermittent line / skipping</td>
<td></td>
<td></td>
<td>Ball diameter variations</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paper surface finish variation; too rough or too smooth</td>
<td>Paper surface finish range specification</td>
<td>No control</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Ball surface finish variation</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
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<td>Ball diameter too big; blocking flow of ink</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
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<td></td>
<td></td>
<td>User does not exert sufficient pressure</td>
<td>Force study done on users</td>
<td>Test: pressure vs ink delivery; 6 parts per month 0-6 psi</td>
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<td></td>
<td></td>
<td></td>
<td>User holds pen at extreme angle</td>
<td>Grip angle study done on users</td>
<td>Test: angle vs ink delivery; 6 parts per month 0 - 90 degrees</td>
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<tr>
<td></td>
<td>No ink delivered to paper</td>
<td>Ripped paper</td>
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<td></td>
<td></td>
<td>Ball diameter too big; blocking flow of ink</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Too much ink delivered to paper</td>
<td>Document ruined</td>
<td></td>
<td></td>
<td></td>
<td>Ball diameter too small</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
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<td></td>
<td></td>
<td></td>
<td>User exerts excessive pressure</td>
<td>Force study done on users</td>
<td>Test: pressure vs ink delivery; 6 parts per month 0-6 psi</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Improper hardness of ball material</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
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</table>
# Ball Design FMEA Exercise

<table>
<thead>
<tr>
<th>Item #</th>
<th>Item name / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Severity</th>
<th>Classification</th>
<th>Potential Causes / Mechanisms of Failure</th>
<th>Current Design Controls Prevention</th>
<th>Occurrence</th>
<th>Current Design Controls Detection</th>
<th>Dated</th>
<th>RPM</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.2.3</td>
<td>Ball / deliver ink to paper</td>
<td>Not enough ink delivered to paper</td>
<td>Intermittent line / skipping</td>
<td>7</td>
<td>Ball diameter variations</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
<td>2</td>
<td>14</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7</td>
<td>Paper surface finish variation; too rough or too smooth</td>
<td>Paper surface finish range specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
<td>10</td>
<td>420</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7</td>
<td>Ball surface finish variation</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
<td>2</td>
<td>28</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7</td>
<td>Ball diameter too big; blocking flow of ink</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
<td>2</td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7</td>
<td>User does not exert sufficient pressure</td>
<td>Force study done on users</td>
<td>Test: pressure vs ink delivery; 5 parts per month 0-6 psi</td>
<td>4</td>
<td>140</td>
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</tr>
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<td></td>
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<td></td>
<td>7</td>
<td>User holds pen at extreme angle</td>
<td>Grip angle study done on users</td>
<td>Test: angle vs ink delivery; 6 parts per month 0-90 degrees</td>
<td>4</td>
<td>140</td>
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<tr>
<td></td>
<td>No ink delivered to paper</td>
<td>Ripped paper</td>
<td></td>
<td>5</td>
<td>Ball diameter too big; blocking flow of ink</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
<td>2</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Too much ink delivered to paper</td>
<td>Document ruined</td>
<td></td>
<td>9</td>
<td>Ball diameter too small</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
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<td>18</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9</td>
<td>User exerts excessive pressure</td>
<td>Force study done on users</td>
<td>Test: pressure vs ink delivery; 5 parts per month 0-6 psi</td>
<td>4</td>
<td>180</td>
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</tr>
<tr>
<td></td>
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<td></td>
<td>9</td>
<td>Improper hardness of ball material</td>
<td>Tolerance specification</td>
<td>Supplier self certification and incoming inspection 10 of every lot</td>
<td>2</td>
<td>36</td>
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</tbody>
</table>
## Barrel Design FMEA Example

<table>
<thead>
<tr>
<th>Item #</th>
<th>Item name / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Severity</th>
<th>Classification</th>
<th>Potential Causes / Mechanisms of Failure</th>
<th>Current Design Controls Prevention</th>
<th>Occurrence</th>
<th>Current Design Controls Detection</th>
<th>Defect</th>
<th>FPM</th>
<th>Recommended Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.1.2</td>
<td>Barrel/Captures ink sub-system</td>
<td>Does not capture ink sub-system</td>
<td>Lose ink sub-system</td>
<td>7</td>
<td></td>
<td>Wrong ink sub-system</td>
<td>Incoming inspection (100 every lot)</td>
<td>0</td>
<td>Material specification on detail drawing and BOM, validated during testing</td>
<td>2</td>
<td>84</td>
<td></td>
</tr>
<tr>
<td>1.1.1.2</td>
<td>Interferes with retraction of ink sub-system</td>
<td>Prevents retraction</td>
<td>Warping of barrel (wrong material selection)</td>
<td>7</td>
<td></td>
<td>Material specification</td>
<td>2</td>
<td>Function check testing</td>
<td>6</td>
<td>84</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1.1.2</td>
<td>Barrel/Captures plunger sub-system</td>
<td>Does not capture plunger sub-system</td>
<td>Unfinished pen assembly</td>
<td>7</td>
<td></td>
<td>Barrel inside diameter too big</td>
<td>Tolerance specification</td>
<td>2</td>
<td>Verification testing</td>
<td>4</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>1.1.1.2</td>
<td>Barrel inside diameter too small</td>
<td>2</td>
<td>Verification testing</td>
<td>4</td>
<td>56</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1.1.2</td>
<td>Wrong plunger diameter</td>
<td>2</td>
<td>Verification testing</td>
<td>4</td>
<td>56</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1.1.2</td>
<td>Improper press fit (wrong GD&amp;T)</td>
<td>GD&amp;T</td>
<td>2</td>
<td>Verification testing</td>
<td>4</td>
<td>28</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1.1.2</td>
<td>Lose ink sub-system</td>
<td>No plunger to capture ink sub-system</td>
<td>Visual inspection</td>
<td>8</td>
<td></td>
<td>Requires visual signoff by engineering team prior to testing</td>
<td>4</td>
<td>168</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1.1.2</td>
<td>Barrel/captures nib</td>
<td>Does not capture nib</td>
<td>Unfinished pen assembly</td>
<td>7</td>
<td></td>
<td>Barrel inside diameter too big</td>
<td>Tolerance specification</td>
<td>2</td>
<td>Verification testing</td>
<td>4</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>1.1.1.2</td>
<td>Barrel inside diameter too small</td>
<td>2</td>
<td>Verification testing</td>
<td>4</td>
<td>28</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1.1.1.2</td>
<td>Warping of barrel (wrong material)</td>
<td>Material specification</td>
<td>2</td>
<td>Material specification on detail drawing and BOM, validated during testing</td>
<td>6</td>
<td>84</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1.1.2</td>
<td>Wrong nib diameter</td>
<td>Tolerance specification</td>
<td>1</td>
<td>Verification testing</td>
<td>4</td>
<td>28</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1.1.1.2</td>
<td>Improper press fit (wrong GD&amp;T)</td>
<td>GD&amp;T</td>
<td>2</td>
<td>Verification testing</td>
<td>4</td>
<td>50</td>
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</tbody>
</table>
What we have just learned pertains to the risk involved with the DESIGN of a product. We have seen how to identify how things can fail to meet their intended functions and how those failures were driven by causes inherent to the design.

However, just because something is designed well does not mean it cannot still fail if it is manufactured or assembled incorrectly.

Similar to how the Design FMEA showed us the failure to function, the Process FMEA can show us the failures in manufacturing and assembly.

**Design FMEA (DFMEA)**  
**Design failures**
- Generates heat
- Slow acceleration
- Cannot track target

**Process FMEA (PFMEA)**
- Manufacturing failures
  - Porous casting
  - Poorly machined finish
  - Injection molding short shot
- Assembly failures
  - Parts missing
  - Parts damaged
  - Wrong parts used

When creating the PFMEA it is general practice to assume that the DESIGN is correct. This will insure that you do not accidentally associate design failures with manufacturing or assembly failures.
The differences between the PFMEA and the DFMEA are minimal. The descriptions of the item in the design become descriptions of the steps in the process. The control section changes in name but the intent does not. Controls for prevention and detection are still applicable.
In this exercise each table will be a team. Each team will be responsible for performing a Process FMEA on three steps of the retractable pen assembly process. The instructor will assign the steps to each team. Take no longer than 30 minutes.

1. Choose a space on the nearby wall where your team can display your work or use a flip chart if need be.
2. Using the Post-it notes and markers re-create a PFMEA form (write the title of each PFMEA field on a Post-it and put it on the wall). Refer to slide 59.
3. Refer to slide 36 to determine which tools will be helpful to create a PFMEA.
4. Refer to slide 24 to familiarize yourself with the parts of the retractable pen.
5. From slides 25-35 decide what information describes the PROCESS (do not use the design related information).
6. Following the instructions on slide 38, complete all steps until and including the calculation of the RPN (step 6).
7. Choose a representative and be prepared to discuss your results with the class.
<table>
<thead>
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<tbody>
<tr>
<td>1</td>
<td>Load ink tube vertically into fixture</td>
<td>Tube mis-aligned</td>
<td>Spring cannot be inserted</td>
<td>5</td>
<td>Failure features/dimensions incorrect</td>
<td>Fixture drawings</td>
<td>3</td>
<td>In line sensor</td>
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<td>Load spring into press</td>
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<td>Spring cannot be inserted</td>
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<td>Failure features/dimensions incorrect</td>
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<td>In line sensor</td>
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<td>Press spring on to tube</td>
<td>Spring not fully pressed on to tube</td>
<td>Spring may fall off in a later step</td>
<td>7</td>
<td>Press does not move far enough down</td>
<td>Position sensors</td>
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</tr>
<tr>
<td>3</td>
<td>Press spring on to tube</td>
<td>Ink/tube may not retract/extend</td>
<td>10</td>
<td>KPP</td>
<td>Press travel incorrect</td>
<td>Hard stop on press</td>
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</tr>
<tr>
<td>3</td>
<td>Spring pressed on to tube too far</td>
<td>Ink/tube may not retract/extend</td>
<td>10</td>
<td>KPP</td>
<td>Fixture/press alignment issue</td>
<td>Verify alignment at each shift</td>
<td>2</td>
<td>Hourly audits</td>
<td>6</td>
<td>120</td>
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<tr>
<td>3</td>
<td>Spring pressed on to tube incorrectly (crooked)</td>
<td>Ink/tube cannot be inserted into housing</td>
<td>5</td>
<td>Fixture/press alignment issue</td>
<td>Verify alignment at each shift</td>
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<td>Hourly audits</td>
<td>6</td>
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## Pen Assembly PFMEA

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<td>Load plunger ass’y to fixture</td>
<td>Plunger ass’y misaligned</td>
<td>Housing cannot be added</td>
<td>5</td>
<td></td>
<td>Fixture features/dimensions incorrect</td>
<td>Fixture drawings</td>
<td>3</td>
<td>In line sensor</td>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>4</td>
<td>Plunger ass’y missing</td>
<td>Housing cannot be added</td>
<td>5</td>
<td>Operator not trained</td>
<td>Work instructions</td>
<td>5</td>
<td>No detection control</td>
<td>10</td>
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<tr>
<td>4</td>
<td>Plunger ass’y missing</td>
<td>Housing cannot be added</td>
<td>5</td>
<td>Operator not trained</td>
<td>Work instructions</td>
<td>5</td>
<td>No detection control</td>
<td>10</td>
<td>300</td>
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<td>5</td>
<td>Load barrel on to press</td>
<td>Barrel mis-aligned</td>
<td>Housing cannot be added</td>
<td>5</td>
<td></td>
<td>Press features/dimensions incorrect</td>
<td>Press drawings</td>
<td>3</td>
<td>In line sensor</td>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>5</td>
<td>Press barrel on to plunger</td>
<td>Barrel not fully pressed on to plunger</td>
<td>Barrel may fall off in a later step</td>
<td>7</td>
<td>Press does not move far enough down</td>
<td>Position sensors</td>
<td>1</td>
<td>No detection control</td>
<td>10</td>
<td>70</td>
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<td>6</td>
<td>Press barrel on to plunger</td>
<td>Barrel not fully pressed on to plunger</td>
<td>Barrel may fall off in a later step</td>
<td>7</td>
<td>Operator did not activate press fully</td>
<td>Visual reminder (blue light)</td>
<td>6</td>
<td>No detection control</td>
<td>10</td>
<td>420</td>
<td></td>
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<tr>
<td>6</td>
<td>Barrel pressed on to plunger too far</td>
<td>Damaged parts/Scrap</td>
<td>8</td>
<td>Press travel incorrect</td>
<td>Position sensors</td>
<td>1</td>
<td>No detection control</td>
<td>10</td>
<td>80</td>
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<tr>
<td>6</td>
<td>Barrel not on plunger at all</td>
<td>Rework needed</td>
<td>8</td>
<td>Barrel fell off of tube</td>
<td>Part orientation</td>
<td>4</td>
<td>No detection control</td>
<td>10</td>
<td>320</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Barrel pressed on incorrectly</td>
<td>Damaged parts/Scrap</td>
<td>8</td>
<td>Fixture/press alignment issue</td>
<td>Verify alignment at each shift</td>
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Unclassified
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<tr>
<td>7</td>
<td>Drop ink/spring ass'y into housing ass'y</td>
<td>Ink/spring ass'y missing from housing ass'y</td>
<td>Pen could be assembled without writing mechanism</td>
<td>10</td>
<td>KPP</td>
<td>Operator poorly placed component</td>
<td>Visual inspection</td>
<td>6</td>
<td>No detection control</td>
<td>10</td>
<td>600</td>
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<tr>
<td>8</td>
<td>Insert nib into press</td>
<td>Nib mis-aligned</td>
<td>Nib cannot be inserted</td>
<td>5</td>
<td></td>
<td>Press features/dimensions incorrect</td>
<td>Press drawings</td>
<td>3</td>
<td>In line sensor</td>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>9</td>
<td>Press nib on to housing ass'y</td>
<td>Nib not fully pressed on to housing</td>
<td>Nib may fall off and ink/spring ass'y fall out later</td>
<td>7</td>
<td></td>
<td>Press does not move far enough down</td>
<td>Position sensors</td>
<td>1</td>
<td>No detection control</td>
<td>10</td>
<td>70</td>
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<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td>7</td>
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<td>Operator did not activate press fully</td>
<td>Visual reminder (blue light)</td>
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<td>No detection control</td>
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<td>10</td>
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<td>9</td>
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<td>8</td>
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<td>Part orientation</td>
<td>No detection control</td>
<td>10</td>
<td>320</td>
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<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td>8</td>
<td></td>
<td>Rework needed</td>
<td>No detection control</td>
<td>10</td>
<td>320</td>
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</tbody>
</table>

**Pen Assembly PFMEA**
Take Action Where Needed

I can’t address every failure – only the most important ones. Where do I draw the line? How do I decide where to focus my limited resources?
How does one decide where to focus resources?

• Rank order all failures by descending RPN and work on the highest RPNs. This most simple approach is straightforward but does not always indicate where to stop working.

• Identify if a Pareto exists within the rank order. Unlike a simple rank order, a Pareto has a natural boundary between higher and lower RPNs. This suggests a goal to work to.

• Create a chart of RPN by grouped causes and again look for the Pareto. Multiple similar causes might be mitigated using the same action. This approach is usually the most economical.

• Prioritize using severity only, or severity with occurrence together. If severity (or severity + occurrence) alone was of great concern it could be used to dictate the focus of mitigation actions.
A chart can be made of RPN versus cause. Without a Pareto, the easiest way to decide what to work on is to simply sort by RPN and address the highest items. In a simple rank order chart the RPN falls (descends) by even, somewhat linear steps.

**Chart of RPN by individual causes**

The main problem with a chart like this is deciding where to stop. Usually the amount of resources available will dictate how many causes can be addressed.
If a Pareto exists then the 80/20 rule starts to apply, meaning that the majority of our concern can be eliminated by addressing the relatively few but very potent top items.

Pareto chart of RPN by individual causes

In a true Pareto there is an obvious step down after the first few large RPN items. In this case it is not only easy to see what to work on, but also where to stop working.
If another way is desired to identify a Pareto and get the most risk mitigation for the money, causes that are similar and that might receive the same controls can be grouped. This is a “kill many birds with the same stone” approach. Cause groups are comprised of many similar causes found throughout the entire FMEA. Individually their RPN rankings might be low, but when combined into a group they can add up substantially.

Addressing anything that has to do with “operator error” has a HUGE impact!

This group represents all causes that have anything to do with operators (poor part placement, activation of the press, lack of training, etc).
### Recommended Action

Reducing RPN can be done by:
- Decreasing the severity
- Reducing the likelihood of occurrence
- Improving detection methods

**Describe what actions are needed to reduce the overall RPN**
The primary objective of the recommended action is to reduce risk thereby reducing the possibility of failure. This in turn increases customer satisfaction and lowers cost.

The actual intent of any recommended action is to reduce the rankings of any of the following: severity, occurrence, and detection.

If the RPN value is below the agreed to threshold, then the team can enter “none” for the recommended action.
<table>
<thead>
<tr>
<th>Recommended Actions Plan</th>
<th>Responsibility &amp; Target Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name who will take action and when</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Recommended actions:**
- need completion dates
- can be taken by FMEA team members, or..
- can be taken by other parties with a FMEA team member being responsible

**Action Results**
- Actions Taken
- Severity
- Occur
- Detection
- R.P.N.
As simple as it seems the Target Completion Date should be paid careful attention to:

- This is the estimated date when the team agrees the recommended action should be completed. If it looks like the date will be missed, then the team should revise the date.

Traceability:

- If the person responsible leaves the core team prior to the completion of the recommended action, then another core team member should be assigned.
- If the person responsible leaves the core team after completion of the recommended action, then that persons name stays on the document.
## Action Taken and Effective Date

<table>
<thead>
<tr>
<th>Recommended Actions Plan</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Actions Taken</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severity</td>
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<tr>
<td></td>
<td></td>
<td>Occur</td>
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<tr>
<td></td>
<td></td>
<td>Detection</td>
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<tr>
<td></td>
<td></td>
<td>R.P.N.</td>
</tr>
</tbody>
</table>

### Describe ACTUAL actions taken

Actions taken:
- Are not always identical to the recommendations (time and resources limited)
- May not get done when expected
Once the action has been executed the team must indicate new severity, occurrence, and detection rankings where applicable.

- Recalculate the RPN after re-ranking.
<table>
<thead>
<tr>
<th>Item</th>
<th>Item name &amp; Functions</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Severity</th>
<th>Causes of Failure</th>
<th>Current Design Controls Prevention</th>
<th>Detection</th>
<th>Recommended Actions</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Action Results</th>
<th>R.P.N.</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Ball delivers ink to paper</td>
<td>Intermittent line skipping</td>
<td>Ball diameter deviation</td>
<td>7</td>
<td>Tolerance specification</td>
<td>1</td>
<td>Supplier self certification and incoming inspection of every lot</td>
<td>2</td>
<td>G. Ratajczak</td>
<td>Study coefficient of friction vs ink delivery amount</td>
<td>7 1 10 70</td>
</tr>
<tr>
<td>7</td>
<td>Ball surface roughness</td>
<td></td>
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<tr>
<td>7</td>
<td>Ball diameter too big blocking flow of ink</td>
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<td></td>
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<tr>
<td>7</td>
<td>User does not exert sufficient pressure for study done on users</td>
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</tr>
<tr>
<td>7</td>
<td>User holds pen at extreme angle</td>
<td></td>
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</tr>
<tr>
<td>6</td>
<td>No ink delivered to paper</td>
<td>Ripped paper</td>
<td>Ball diameter too big blocking flow of ink</td>
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<td>Tolerance specification</td>
<td>1</td>
<td>Supplier self certification and incoming inspection of every lot</td>
<td>2</td>
<td>G. Ratajczak</td>
<td>Study complete - must control ball surface finish</td>
<td>7 1 10 70</td>
</tr>
<tr>
<td>5</td>
<td>Too much ink delivered to paper</td>
<td>Document ruined</td>
<td>Ball diameter too big small</td>
<td>5</td>
<td>Tolerance specification</td>
<td>1</td>
<td>Supplier self certification and incoming inspection of every lot</td>
<td>10</td>
<td>G. Ratajczak</td>
<td>Study complete - must control ball surface finish</td>
<td>7 1 10 70</td>
</tr>
<tr>
<td>5</td>
<td>User exerts excessive pressure for study done on users</td>
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<tr>
<td>5</td>
<td>Improper hardness of ball material</td>
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**Study coefficient of friction vs ink delivery amount**

G. Ratajczak 11 Nov 2011

Study complete - must control ball surface finish

<table>
<thead>
<tr>
<th>Severity</th>
<th>Occur</th>
<th>Detection</th>
<th>R.P.N.</th>
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<tbody>
<tr>
<td>7</td>
<td>1</td>
<td>10</td>
<td>70</td>
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</tbody>
</table>
Transactional FMEA Example

Assign Each Bin a Unique Color

Determine Baseline Vehicle (Column)

Determine Group (Row) of Related Requirements to Work On

Search for similar requirements within baseline vehicle (column)

Common Themed Requirement Found?

NO

NO

Search for similar requirements within current vehicle (column)

Common Themed Requirement Found?

NO

NO

Last Vehicle (Column)?

NO

NO

Common Themed Requirement Found?

YES

YES

Inputs:
- CDD Requirements Analysis Matrix
- VRS Team

Output: Comparison requirement identified (cell)

Insert Requirement into Cell Directly Below Working Group (Row) and make bold

Common Theme as Baseline?

NO

NO

NO

Output: Comparison requirement identified (cell)

Insert Requirement into Cell Directly Below Working Group (Row) and make bold

Move Requirement to a New Group (Row) Placed at Bottom of Respective Bin

All Groups (Rows) Addressed?

NO

YES

NO

NO

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Transactional FMEA Example

Using the PFMEA form is most appropriate when risk reducing transactional processes because like assembly processes they are typically a combination of STEPS. Transactional processes are often overlooked in risk reduction although the consequences of their failure still equate to cost and time. Whether new or already in use, transactional processes should be understood and risk reduced using all the tools you have just learned.

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Insert Requirement into cell directly below working group (row) and make bold</td>
<td>Similar req placed in incorrect row, but did not overwrite anything</td>
<td>Duplication of superset requirements, resulting in additional work / schedule delay</td>
<td>7</td>
<td>VRS Team human error</td>
<td>None</td>
<td>10</td>
<td>Deconfliction process forces reconfiguration of stand alone reqts</td>
<td>70</td>
<td>Count number of reqts for each platform before uncommonizing reqts within that platform. Check req count after uncommonizing reqts to ensure that the number does not change</td>
</tr>
<tr>
<td>Insert Requirement into cell directly below working group (row) and make bold</td>
<td>Similar req placed directly below working group row, but overwrites an existing req</td>
<td>Incorrect superset requirement generated (overwritten req not present in other platforms, but was the driving req for a superset req)</td>
<td>6</td>
<td>VRS Team human error</td>
<td>None</td>
<td>10</td>
<td>None</td>
<td>10</td>
<td>Count number of reqts for each platform before uncommonizing reqts within that platform. Check req count after uncommonizing reqts to ensure that the number does not change</td>
</tr>
<tr>
<td>Insert Requirement into cell directly below working group (row) and make bold</td>
<td>Similar req placed directly below working group row, but overwrites an existing req</td>
<td>SIL lacks capability in question (overwritten req not present in other platforms, so entire capability is lost)</td>
<td>10</td>
<td>VRS Team human error</td>
<td>None</td>
<td>10</td>
<td>None</td>
<td>10</td>
<td>Count number of reqts for each platform before uncommonizing reqts within that platform. Check req count after uncommonizing reqts to ensure that the number does not change</td>
</tr>
<tr>
<td>Insert Requirement into cell directly below working group (row) and make bold</td>
<td>Similar req not moved at all</td>
<td>Incorrect superset requirement generated</td>
<td>6</td>
<td>VRS Team human error</td>
<td>None</td>
<td>10</td>
<td>Continued reqt uncommonization will ensure the non-moved reqt is assessed for commonality (which would catch the duplicate reqt)</td>
<td>80</td>
<td>Count number of reqts for each platform before uncommonizing reqts within that platform. Check req count after uncommonizing reqts to ensure that the number does not change</td>
</tr>
<tr>
<td>Insert Requirement into cell directly below working group (row) and make bold</td>
<td>Similar req not moved at all</td>
<td>Duplication of superset requirements, resulting in additional work / schedule delay</td>
<td>7</td>
<td>VRS Team human error</td>
<td>None</td>
<td>10</td>
<td>Continued reqt uncommonization will ensure the non-moved reqt is assessed for commonality (which would catch the duplicate reqt)</td>
<td>70</td>
<td>Count number of reqts for each platform before uncommonizing reqts within that platform. Check req count after uncommonizing reqts to ensure that the number does not change</td>
</tr>
<tr>
<td>Insert Requirement into cell directly below working group (row) and make bold</td>
<td>Partial move of similar req (failure to move comments, rationale, and traceability when relocating a similar req?)</td>
<td>Difficulty creating superset requirement due to missing details</td>
<td>5</td>
<td>VRS Team human error</td>
<td>None</td>
<td>10</td>
<td>None</td>
<td>10</td>
<td>Count number of reqts for each platform before uncommonizing reqts within that platform. Check req count after uncommonizing reqts to ensure that the number does not change</td>
</tr>
<tr>
<td>Insert Requirement into cell directly below working group (row) and make bold</td>
<td>Req copied and pasted, instead of cut and pasted</td>
<td>Duplication of superset requirements, resulting in additional work / schedule delay</td>
<td>7</td>
<td>VRS Team human error</td>
<td>None</td>
<td>10</td>
<td>Continued reqt uncommonization will ensure the duplicate reqt is assessed for commonality (which would catch the duplicate reqt)</td>
<td>70</td>
<td>Count number of reqts for each platform before uncommonizing reqts within that platform. Check req count after uncommonizing reqts to ensure that the number does not change</td>
</tr>
</tbody>
</table>
In the event that a failure mode is encountered, the FMEA can be the first source for reactive problem solving.

1. Is the failure mode or its effect listed on either FMEA?
   - YES: Control has failed - find out why, improve control, update FMEA.
   - NO: Is the root cause listed on the FMEA?
     - YES: Root cause is not on FMEA. Use other methods to identify root cause. Recalculate RPN and update FMEA.
     - NO: NO
Situation: Retractable pen field failure: returned pen with loose/falling out nib

Suggested approach -
• Examine both DFMEA and PFMEA for possible design, manufacturing or assembly causes for the loose nib.
• If the failure mode or its effect are not present on FMEA -
  • Use P-diagram, block diagram, process map and similar tools to identify this failure mode and then its cause. Execute formal problem solving.
• If the failure mode or its effect are present on FMEA look in the cause column -
  • Possible design causes that could cause loose nib are: wrong barrel or nib diameter, wrong GD &T (geometric dimensioning and tolerance) between barrel and nib, warping of material due to wrong material selection.
  • Investigate unintended usage (removal and reinsertion of nib) which may wear material out.
  • Possible process causes that could cause loose nib are: not enough pressure for insertion (nib not fully seated), misalignment between barrel and nib.
• Verify your findings by testing and/or re-creating the failure.
• If the root cause you found is not in the FMEA, update the FMEA, issues, and lessons learned databases.
• **Failure:** A GV Air Conditioning (A/C) condenser fan motor was failing in OIF. When it failed, the vehicles had no A/C and were unusable in high ambient conditions. Power to the motors was confirmed to be present, they just would not function.
  
  • Parts were shipped back to the US from Iraq and torn down. Upon inspection, the PC board showed damage and charring due to over-current situation.
  
  • A probable failure was determined but could not be verified as the root cause since the supplier did not have a FMEA for the part. Duplication of failure testing commenced and took three months to complete before the root cause was acknowledged. This could have been shortened to days if a FMEA existed.

• **Lesson Learned** – For critical subsystems, a FMEA should be contractually required from the tier 1, who should enlist the lower tier suppliers to create and maintain to shorten the duration of root cause analysis and corrective action.

• **Corrective Action** – For this part, a FMEA was created to ensure the corrective action would not create additional problems. Generic FMEA contractual language has been developed for future use.
## Root Cause Analysis – Partial Design FMEA Shown

### System: A/C Condenser Fan System
### Subsystem: A/C Condenser Fan
### Component: -
### Model Year / Vehicle (s): -
### Core Team: -
### Support: -

<table>
<thead>
<tr>
<th>Item</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Potential Causes / Mechanisms of Failure</th>
<th>Occurrence</th>
<th>Current Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>[1.1] The fan subsystem shall meet airflow requirements (6 in. WCaP 1500 CFM for XXXX)</td>
<td>Complete loss of airflow (8)</td>
<td>[1.1.1] Loss of source current / voltage - Blown fuse - Broken wire</td>
<td>4</td>
<td>- Conduct a worst case circuit analysis of vehicle control circuit - Compare fuse capacity to in-rush current and stall current during high ambient temperature conditions - Review wire routing, attachment and shielding</td>
</tr>
<tr>
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<td></td>
<td>- Yuma - Test vehicle - New Yuma - test vehicle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[1.2] Over-voltage / Transients</td>
<td>Partial loss of airflow (8)</td>
<td></td>
<td>3</td>
<td>- FW 3 - Electrical Requirements and characterization - FW 4 - Body Fan Requirement validation - Yuma - Test vehicle - New Yuma - test vehicle</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>- FW 3 - Electrical Requirements and characterization - FW 4 - Body Fan Requirement validation - Yuma - Test vehicle - New Yuma - test vehicle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[1.3] Control circuit malfunction</td>
<td></td>
<td></td>
<td>5</td>
<td>- FW 3 - Electrical Requirements and characterization - FW 4 - Body Fan Requirement validation - Yuma - Test vehicle - New Yuma - test vehicle</td>
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<td>- FW 3 - Electrical Requirements and characterization - FW 4 - Body Fan Requirement validation - Yuma - Test vehicle - New Yuma - test vehicle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[1.4] Mechanical impedance/obstruction that either slows or stops the rotation of the impeller (internal/external contamination)</td>
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<td>6</td>
<td>- DTL 1 - Hot Clean - DTL 2 - Hot + Dust - DTL 3 - Hot + Imbalance - DTL 4 - Hot + Dust + Road load / Resonance - FW 1 - Fan imbalance cycling - FW 2 - Dust - Yuma - Test vehicle - New Yuma - test vehicle - Airflow verification</td>
</tr>
</tbody>
</table>
Situation: A group of retractable pens were returned to your company with complaints of malfunction (not clicking and ink tube not staying out in the writing position)

Your team is given one good pen (for reference) and one malfunctioning pen

Instructions – spend no more than 30 minutes to:

• Use the pen assembly PFMEA to perform Root Cause Analysis (for this example the DFMEA is not used; in reality you should always look at both). Follow the flowchart on slide 78.
• Try to verify the root cause by re-creating the failure
• Recommend any changes to the assembly PFMEA if necessary to clarify this failure mode
• Choose a representative to present your findings
Section D

Transitioning to Risk Recon & Managing Contractors’ FMEAs
Although FMEA is often used in industry to manage the actions that will mitigate failure, it does not allow enough room for detailed mitigation planning. The Government has a process for managing risks and mitigation plans and documents using the Army owned risk management tool called Risk Recon.

- Risk Recon is for implementing, tracking, and reporting the progress of the recommended mitigation plans/actions created in the FMEA. In this way FMEA is a necessary input to Risk Recon.
- Information from the FMEA fields can be transferred to populate the risk info sheet and mitigation plans in Risk Recon.
- Periodic reports can be generated by Risk Recon for management notification on mitigation plan implementation, progress, and status.
- Risk Recon is capable of electronic tracking and providing notifications to team members and persons responsible for executing mitigation actions.
- Successful risk mitigation reduces the RPN. Once a risk is mitigated, or an issue corrected, this information gets documented in the FMEA and the RPN is rescored.
In risk management Risk Recon ranks risk by using two parameters only:
- consequence (correlates to severity)
- likelihood (correlates occurrence)

Similar to FMEA high risk is associated to failures with high scores on consequence and likelihood.

To transfer rankings from FMEA to Risk Management/Risk Recon, we translate the FMEA 1-10 severity and occurrence scales to the Risk Recon 1-5 consequence and likelihood scales. This translation is provided on the ranking tables in the appendix.

Risk Recon is a two dimensional view of risk since detection is not transferred from the FMEA. However, failures which were significant due to the inclusion of poor detection rankings on the FMEA cannot be ignored in Risk Recon. To manage risk completely transfer ALL high risk failures and their mitigation actions to Risk Recon.
Many government products are designed, manufactured, and assembled by contractors through written contracts.

We have learned that without some structured approach to reducing risk, such as FMEA, failures with various levels of effect can and will result. This is unacceptable to the Warfighter.

Therefore the Government should expect contractors to complete any and all appropriate FMEAs needed to risk reduce a product.

Government contracts need to be written such that the FMEA and its supporting documents will be able to be utilized, shared, and audited by the Government. This will insure that failures are minimized, and costs stay within expectations.

Recommend using TARDEC FMEA Templates, Ranking Tables with two scales, and FMEA evaluation Check Lists for DFMEA & PFMEA customized to DoD systems.
Suggested Government Contracts’ Language for FMEA

• Example: Design FMEA Language

The contractor shall conduct and provide Design Failure Mode and Effects Analysis (DFMEA) on all critical items and key subsystems. For subcontractor-sourced critical items or key subsystems, the contractor shall contract subcontractor to complete and deliver applicable DFMEA. The information used to create this Contract Data Requirement List (CDRL) shall be available to the Government and discussed at IPT meetings as well as major reviews in accordance with the Government provided Integrated Master Plan (IMP). The contractor and their suppliers shall use the AIAG FMEA manual (latest edition) as a guide to create the DFMEAs and use the government provided TARDEC DFMEA Severity, Consequence and Likelihood guides for ranking.

Design FMEAs for other items (non-critical items, non-key subsystems) shall be made available upon Government request. The DFMEA and related documents (e.g. block diagram, WBS, FTA, P-diagram) are living documents. The contractor shall update these documents to reflect lessons learned, updated reliability predictions, and corrective actions.
• Example: Process FMEA Language (for manufacturing and/or assembly process)

The contractor shall create PFMEA’s for all processes (manufacturing and assembly) necessary to build the specific Government product/vehicle. The contractor shall provide all key subsystem PFMEAs to the Government. The information used to create this Contract Data Requirement List (CDRL) shall be available to the Government and discussed at IPT meetings as well as major reviews in accordance with the Government provided IMP. The contractor and their suppliers shall use AIAG FMEA manual (latest edition) as a guide to create the PFMEAs and use the government provided TARDEC PFMEA Severity, Consequence and Likelihood guides for ranking. The PFMEA’s are living documents and shall be traceable to the engineering change level & process changes, and shall be included in the configuration management change process.

Process FMEAs for other items (non-critical items, non-key subsystems) shall be made available upon Government request. The PFMEA and related documents (e.g. process map, process flow diagram, FTA) are living documents. The contractor shall update these documents to reflect lessons learned, updated reliability predictions, and corrective actions.
Preparation:

Ensure appropriate contracting language is crafted and understood by parties involved

Construct internal reference documents as appropriate
  • P-Diagram
  • Functional Diagram
  • WBS
  • Etc

Determine the “key subsystems” for which FMEA has to be delivered to the Government for review, and are documented in the contract.
  • The contractors are required to complete FMEA on all systems, and they should be visible to the Government.
  • Key subsystems are determined using lessons learned in the TD phase or using engineering judgment.

Assemble appropriate cross-functional teams
  • Depending on area of DFMEA or PFMEA being reviewed, the teams will include different sets of participants
Evaluating/Managing FMEAs

Evaluating:

Cross-check reference documents against internal documents for concurrence

Use the checklists in the appendix of this material to ensure content and quality of FMEAs

Identify gaps

• Establish action item lists detailing activities necessary to improve quality and/or content of FMEA
• Ensure appropriate participants are notified of action items via appropriate contracting channels
• Confirm that the design-in process parameters meet user requirements if specifically spelled out as a requirement.
Managing:

Work with FMEA owners to address and close identified action items

Ensure FMEAs are reviewed at appropriate times throughout contract execution
  • Technical Reviews
  • Appropriate IPT Meetings

Ensure FMEAs are treated as living documents and updated throughout the lifecycle of the product
  • Feedback from reviews
  • Risk mitigation activities
  • Root cause analysis/Issue resolution
  • Whenever a change is made to the system
### Quick FMEA Review Technique

1. Start with understanding the function. Make sure the team really understands what it is really supposed to do.

2. Look for the highest RPN numbers.

3. Look for "real" actions and individuals for the highest RPN’s.

4. Look for highest Severity, Occurrence, & Detection #'s. Cross check with rating charts.

5. Ensure Actions are being tracked.

6. Repeat until you have tracked down to lower RPN #'s.

---

**Potential Failure Mode and Effects Analysis**

(Design/ Process FMEA)

<table>
<thead>
<tr>
<th>Item / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Potential Causes / Mechanisms of Failure</th>
<th>Current Design Controls Prevention</th>
<th>Current Design Controls Detection</th>
<th>RPN</th>
<th>Detect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item Name / Design Intent</td>
<td>Manner in which intended Function Fails in Technical Terms</td>
<td>Effects of Failure on Function that Customer may Notice or Experience</td>
<td>Mechanism that causes the Failure Mode</td>
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</tbody>
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**Model Year/ Vehicle:**

- **System:** Vehicle
- **Subsystems:** Powertrain
- **Component:** Engine Block / Transmission Case

---

**Core Team:** FMEA Team Members - Design Engineer, Manufacturing Engineer, Reliability Engineer, Program Manager, Chief Engineer, Supplier Engineer, Supplier Engineer, Supplier Engineer, Supplier Engineer.

---

**TECHNOLOGY DRIVEN. WARFIGHTER FOCUSED.**
Section E

Summary and Appendix
Summary of all FMEA Activities

FMEA Process Workflow

<table>
<thead>
<tr>
<th>FMEA Planning</th>
<th>Mgmt</th>
<th>Mgmt</th>
<th>FMEA Team</th>
<th>FMEA Team</th>
<th>FMEA Team</th>
<th>FMEA Admin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start</td>
<td>Identify program/project for FMEA</td>
<td>Allocate resources to conduct FMEA(s)</td>
<td>Create FMEA development plan to include type of FMEAs &amp; assign roles &amp; responsibilities</td>
<td>Gather product/process specifications, quality requirements, etc</td>
<td>Assign FMEA tool administrator</td>
<td>Create and maintain project folder in FMEA database and enter FMEA(s)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>FMEA Assessment</th>
<th>Lead</th>
<th>IPT</th>
<th>IPT</th>
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<th>IPT</th>
<th>IPT</th>
<th>IPT</th>
<th>IPT</th>
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</thead>
<tbody>
<tr>
<td>A</td>
<td>Construct Design/Process/Transaction FMEA &amp; enter</td>
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<td>B</td>
<td>B</td>
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<td>B</td>
<td>B</td>
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<tr>
<td>B</td>
<td>Assess severity, occurrence frequency &amp; detection (SOD) for failure modes</td>
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<td>IPT</td>
<td>IPT</td>
<td>IPT</td>
<td>IPT</td>
<td>IPT</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>FMEA Lead</td>
<td>Transfer failure mode to risk, issue, no action</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>D</td>
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<td>D</td>
<td>Risk Management Process</td>
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<td>Issue Management Process</td>
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<td>Close FMEA</td>
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</table>

<table>
<thead>
<tr>
<th>Failure Mode Disposition / Mitigation Action</th>
<th>FMEA Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>Transfer failure mode to risk, issue, no action</td>
</tr>
<tr>
<td>D</td>
<td>Risk Management Process</td>
</tr>
<tr>
<td>E</td>
<td>Issue Management Process</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IPT</th>
<th>E</th>
<th>FMEA Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPT</td>
<td>E</td>
<td>Update RPN as required</td>
</tr>
<tr>
<td>E</td>
<td>No</td>
<td>Additional action req'd?</td>
</tr>
<tr>
<td>E</td>
<td>No</td>
<td>Project completed?</td>
</tr>
<tr>
<td>E</td>
<td>Yes</td>
<td>Close FMEA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E</th>
<th>FMEA Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPT</td>
<td>Monitor failure mode disposition</td>
</tr>
<tr>
<td>E</td>
<td>Update RPN as required</td>
</tr>
<tr>
<td>E</td>
<td>Additional action req'd?</td>
</tr>
<tr>
<td>E</td>
<td>Project completed?</td>
</tr>
<tr>
<td>E</td>
<td>Close FMEA</td>
</tr>
<tr>
<td>End</td>
<td>Update lessons learned</td>
</tr>
<tr>
<td>Category (Product)</td>
<td>Severity of Effect on Product (DFMEA)</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Safety and/or Regulatory Compliance</td>
<td>Failure could injure the user or an employee</td>
</tr>
<tr>
<td></td>
<td>Failure would create noncompliance with federal regulations</td>
</tr>
<tr>
<td>Primary Function (Essential)</td>
<td>Failure renders the unit inoperable or unfit for use</td>
</tr>
<tr>
<td></td>
<td>Failure causes a high degree of user dissatisfaction</td>
</tr>
<tr>
<td>Secondary Function (Convenient)</td>
<td>Failure results in a subsystem or partial malfunction of the product</td>
</tr>
<tr>
<td></td>
<td>Failure creates enough of a performance loss to cause the user to complain</td>
</tr>
<tr>
<td>Annoyance</td>
<td>Failure can be overcome with modifications to the user's process or product, but there is minor performance loss</td>
</tr>
<tr>
<td></td>
<td>Failure would create a minor nuisance to the user, but the user can overcome it without performance loss</td>
</tr>
<tr>
<td></td>
<td>Failure may not be readily apparent to the user, but would have minor effects on the user's process or product</td>
</tr>
<tr>
<td>No Effect</td>
<td>Failure would not be noticeable to the user and would not affect the user's process or product</td>
</tr>
</tbody>
</table>
## DFMEA Occurrence Table

<table>
<thead>
<tr>
<th>Likelihood of Failure</th>
<th>Occurrence of Cause (DFMEA)</th>
<th>FMEA Rank</th>
<th>Risk Likelihood Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High</td>
<td>New technology/new design with no history</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Failure is inevitable with new design, new application, or change in duty cycle/operating conditions</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td><em>line</em></td>
<td>Failure is likely with new design, new application, or change in duty cycle/operating conditions</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td><em>line</em></td>
<td>Failure is uncertain with new design, new application, or change in duty cycle/operating conditions</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Frequent failures associated with similar designs or in design simulation and testing</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td><em>line</em></td>
<td>Occasional failures associated with similar designs or in design simulation and testing</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><em>line</em></td>
<td>Isolated failures associated with similar design or in design simulation and testing</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Low</td>
<td>Only isolated failures associate with almost identical design or in design simulation and testing</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><em>line</em></td>
<td>No observed failures associated with almost identical design or in design simulation and testing</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Very Low</td>
<td>Failure is eliminated through preventative control</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
## DFMEA Detection Table

<table>
<thead>
<tr>
<th>Category (Product)</th>
<th>Detection of Cause (DFMEA)</th>
<th>FMEA Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Absolute Uncertainty</strong></td>
<td>No current design control; cannot detect or is not analyzed</td>
<td>10</td>
</tr>
<tr>
<td><strong>Difficult to Detect</strong></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>
</tr>
<tr>
<td><strong>Post Design Freeze and Prior to Launch</strong></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 and handling, shipping evaluation, etc.)</td>
<td>8</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>
</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>
</tr>
<tr>
<td><strong>Prior to Design Freeze</strong></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>
</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>
</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>
</tr>
<tr>
<td><strong>Virtual Analysis - Correlated</strong></td>
<td>Design analysis/detection controls have a strong detection capability. Virtual analysis (e.g. CAE, FEA, etc.) is highly correlated with actual and/or expected operating conditions prior to design freeze</td>
<td>2</td>
</tr>
<tr>
<td><strong>Detection not applicable; Failure Prevention</strong></td>
<td>Failure cause or failure mode cannot occur because it is fully prevented through design solutions (e.g. proven design standard/best practice or common material, etc.)</td>
<td>1</td>
</tr>
</tbody>
</table>

1 - **Detection not applicable; Failure Prevention**: Failure cause or failure mode cannot occur because it is fully prevented through design solutions (e.g. proven design standard/best practice or common material, etc.).

2 - **Virtual Analysis - Correlated**: Design analysis/detection controls have a strong detection capability. Virtual analysis (e.g. CAE, FEA, etc.) is highly correlated with actual and/or expected operating conditions prior to design freeze.

3 - **Degradation Testing**: Product verification/validation after design freeze and prior to launch with degradation testing (sub-system or system testing after durability test e.g. function check).

4 - **Test to Failure**: Product verification/validation after design freeze and prior to launch with test to failure testing (sub-system or system testing until failure occurs, testing of system interactions, etc.).

5 - **Pass/Fail Testing**: Product validation (reliability testing, development or validation tests) prior to design freeze using pass/fail testing (e.g. acceptance criteria for performance, function checks, etc.).

6 - **Post Design Freeze and Prior to Launch**: Product verification/validation after design freeze and prior to launch with test to failure testing (sub-system or system testing until failure occurs, testing of system interactions, etc.).

7 - **Post Design Freeze and Prior to Launch**: Product verification/validation after design freeze and prior to launch with degradation testing (sub-system or system testing after durability test e.g. function check).

8 - **Prior to Design Freeze**: Product validation (reliability testing, development or validation tests) prior to design freeze using pass/fail testing (e.g. acceptance criteria for performance, function checks, etc.).

9 - **Difficult to Detect**: Design analysis/detection controls have a weak detection capability; virtual analysis (e.g. CAE, FEA, etc.) is not correlated to expected actual operating conditions.

10 - **Absolute Uncertainty**: No current design control; cannot detect or is not analyzed.
## PFMEA Severity Table

<table>
<thead>
<tr>
<th>Category (Process)</th>
<th>Severity of Effect on Process (PFMEA)</th>
<th>FMEA Rank</th>
<th>Risk Consequence Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety and/or Regulatory Compliance</td>
<td>May endanger operator (machine or assembly) without warning</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>May endanger operator (machine or assembly) with warning</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Major Disruption; Major Effect on Throughput</td>
<td>100% of product may have to be scrapped and/or line shutdown or stop ship</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Significant Disruption; Significant Effect on Throughput</td>
<td>A portion of the production run may have to be scrapped, and/or deviation from primary process, and/or decreased line speed or added manpower</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Rework out-of-station; Moderate Effect on Throughput</td>
<td>100% of production run may have to be reworked off line and accepted</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>A portion of the production run may have to be reworked off line and accepted</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Rework in-station; Minor Effect on Throughput</td>
<td>100% of production run may have to be reworked in station before it is processed</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>A portion of the production run may have to be reworked in station before it is processed</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Minor Disruption</td>
<td>Slight inconvenience to process, operation, or operator</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>No Effect</td>
<td>No discernable effect</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
## PFMEA Occurrence Table

<table>
<thead>
<tr>
<th>Likelihood of Failure</th>
<th>Occurrence of Cause (PFMEA)</th>
<th>Ppk</th>
<th>FMEA Rank</th>
<th>Risk Likelihood Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High</td>
<td>&gt; 100 per thousand pieces</td>
<td>&lt; 0.55</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>High</td>
<td>50 per thousand pieces</td>
<td>≥ 0.55</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20 per thousand pieces</td>
<td>≥ 0.78</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>10 per thousand pieces</td>
<td>≥ 0.86</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>5 per thousand pieces</td>
<td>≥ 0.94</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2 per thousand pieces</td>
<td>≥ 1.00</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 per thousand pieces</td>
<td>≥ 1.10</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Low</td>
<td>0.5 per thousand pieces</td>
<td>≥ 1.20</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.1 per thousand pieces</td>
<td>≥ 1.30</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Very Low</td>
<td>≤ 0.01 per thousand pieces</td>
<td>≥ 1.67</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Note: The Ppk values are to be used by the FMEA team as guidance to assist in determining an occurrence ranking when valid statistical data is available. No other use of the Ppk values is intended.
### PFMEA Detection Table

<table>
<thead>
<tr>
<th>Category (Process)</th>
<th>Detection of Cause (PFMEA)</th>
<th>FMEA Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute Uncertainty</td>
<td>No current process control; cannot detect or is not analyzed</td>
<td>10</td>
</tr>
<tr>
<td>Difficult to Detect</td>
<td>Defect (failure mode) and/or error (cause) is not easily detected (e.g. random audits)</td>
<td>9</td>
</tr>
<tr>
<td>Defect Detection Post Processing</td>
<td>Defect (failure mode) detection post-processing by operator through visual/tactile/audible means</td>
<td>8</td>
</tr>
<tr>
<td>Defect Detection at Source</td>
<td>Defect (failure mode) detection in-station by operator through visual/tactile/audible means or post-processing through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.)</td>
<td>7</td>
</tr>
<tr>
<td>Defect Detection Post Processing</td>
<td>Defect (failure mode) detection post-processing by operator through use of variable gauging or in-station by operator through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.)</td>
<td>6</td>
</tr>
<tr>
<td>Defect Detection at Source</td>
<td>Defect (failure mode) or error (cause) detection in-station by operator through use of variable gauging or by automated controls in-station that will detect discrepant part and notify operator (light, buzzer, etc.); gauging performed on setup and first-piece check (for setup causes only)</td>
<td>5</td>
</tr>
<tr>
<td>Defect Detection Post Processing</td>
<td>Defect (failure mode) detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing</td>
<td>4</td>
</tr>
<tr>
<td>Defect Detection at Source</td>
<td>Defect (failure mode) detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing</td>
<td>3</td>
</tr>
<tr>
<td>Error Detection and/or Defect Prevention</td>
<td>Error (cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made</td>
<td>2</td>
</tr>
<tr>
<td>Detection not applicable; Error Prevention</td>
<td>Error (cause) prevention as a result of fixture design, machine design or part design</td>
<td>1</td>
</tr>
</tbody>
</table>
### DFMEA Template and Definitions

<table>
<thead>
<tr>
<th>Item #</th>
<th>Item name / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Severity</th>
<th>Classification</th>
<th>Potential Causes / Mechanisms of Failure</th>
<th>Current Design Controls Prevention</th>
<th>Controls</th>
<th>Design</th>
<th>Effect</th>
<th>RFM</th>
<th>Recommended Actions</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Potential Failure Mode and Effects Analysis** (Design DFMEA)

1. **Contract #:**
2. **Supplier:**
3. **Program Name:**
4. **Component:**
5. **Design Responsibility:**
6. **Government POC:**
7. **FMEA date (Orig.):**
8. **FMEA key date:**
9. **Prepared by:**
10. **Revision date:**

**Item #**

1. Actions Taken
2. Severity
3. Occur
4. Detection
5. RPL

**TECHNOLOGY DRIVEN. WARFIGHTER FOCUSED.**
<table>
<thead>
<tr>
<th>Item #</th>
<th>Name</th>
<th>Description</th>
<th>Further comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>FMEA Number</td>
<td>Enter an appropriate FMEA document number, which may be used for tracking. Fill in as many fields as information allows.</td>
<td>FMEA numbers should follow a sequence as dictated by the existing recommendations or practices of the OEM, Vendor, Supplier, Department and/or Group who has design responsibility.</td>
</tr>
<tr>
<td>2</td>
<td>System, Subsystem, or Component</td>
<td>Check or mark the appropriate level of analysis and enter the name of the system, subsystem or component being analyzed.</td>
<td>- A System is a set of interacting or interdependent components forming an integrated whole. A vehicle is an example of a system.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- A Sub-System is a set of elements, which is a system itself, and a component of a larger system. The HVAC in a vehicle is an example of a sub-system.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- A component is an element which, in conjunction with other components, come together in an integrated fashion to create a sub-system or system. The compressor in a HVAC sub-system is an example of a component.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Components are themselves made up of any number of elements, and/or sub-components, but refrain from this as a justification to label certain components as sub-systems.</td>
</tr>
<tr>
<td>3</td>
<td>Design responsibility</td>
<td>Enter the OEM, Vendor, Supplier, Department, and/or Group who is responsible for the design of the System, Subsystem, or Component described in item 2. Enter the name and contact information for the Government Point of Contact.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Prepared by</td>
<td>Enter the name, telephone number, e-mail address, (and company name where applicable) of the POC responsible for preparing the FMEA.</td>
<td>Use best judgement as to how much information is needed. Non-Government FMEA forms should specify company names while Government FMEA forms may contain branch or group names. In most cases the FMEA is prepared by a member of the group holding Design Responsibility, but there may be exceptions. In all cases provide enough information for the reader to understand the origination point of the FMEA.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>5</td>
<td>Program name</td>
<td>Enter the name of the program.</td>
<td>FMEA is a proactive tool meant to be a &quot;before the event&quot; action, not an &quot;after the fact&quot; exercise. Therefore the FMEA should be completed BEFORE significant events so that actions can be taken to mitigate risk BEFORE failure happens. Examples of relevant dates might be Full or Low Rate Production (FRP or LRP), Milestones, Design Reviews, etc.</td>
</tr>
<tr>
<td>6</td>
<td>FMEA Key date</td>
<td>Enter the date the design FMEA is to be completed by and specify its relevance.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>FMEA date(Orig) and Revision date</td>
<td>Enter the date the original FMEA was compiled and date of the latest revision.</td>
<td>Since the FMEA is a living document it is important to update the revision date ANY time changes are made to the FMEA.</td>
</tr>
<tr>
<td>Item</td>
<td>Description</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Core team</td>
<td>List the names of the responsible individuals and departments which have the authority to identify and or perform tasks. The core team is also the group of individuals who, along with the person indicated in item 4 as the person responsible for the preparation, will create the FMEA before the key date. It is strongly recommended that complete contact information be maintained either on the FMEA in this field, as an attachment to the form, or as a separate tab in the excel file. The life of an FMEA can sometimes outlast that of phone numbers, addresses, and current employees. Therefore all attempts to be current and complete are helpful if original team members need to be contacted. Updating contact information is a legitimate revision reason and the date of such an action should be recorded in Item 7. Core team members should be labelled with the following identifiers: (G) Government, (O) OEM or Prime, (SC) service contractor.</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Item #</td>
<td>Enter the number of the item as it appears on the WBS or any other document which describes the breakdown of the system, sub-system, or component in question. This field is useful to tie the FMEA back to its support documents. An example might look like 1.1.2.3 or similar format for a WBS element.</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Item name/Function</td>
<td>Enter the name of the item being analyzed. Use the nomenclature and show the design level as indicated on the engineering drawing. Below the name, enter the function of the item. Be concise but limit the description to verb/noun phrases when possible. If the item has multiple functions list each as a separate function as they may have their own unique failure modes and effects. When describing functions keep in mind that the way they are worded can sometimes make it easier to describe how they can fail. Functions like &quot;transmit data&quot; or &quot;support load&quot; are easy to turn around into potential failure descriptions.</td>
<td></td>
</tr>
</tbody>
</table>
### Potential Failure Mode

Potential Failure Mode is defined as the manner in which a component, subsystem, or system could potentially fail to meet its intended function. The most obvious potential failure mode is the opposite of the intended function. Enter a short description that characterizes the failure.

Remember that although the opposite of the intended function is one obvious failure mode it may not be the only failure mode. All of the potential failure modes should be listed, but the FMEA team should be careful not to identify multiple failure modes unless they are sure of their uniqueness. For instance, if the function is "inject fuel" the team may have to consider whether the potential failures "no fuel injected" and "too little fuel injected" are really unique and have different consequences and solutions, or if they are just two levels of the same failure mode. Do not forget the less obvious failures such as "fit" (describing tolerance stack ups), "interface" (a sub-set of fit meaning that this item must mate with another item), and "form" (the ability to maintain shape).

### Potential Effect(s) of Failure

Enter the Potential Effect of Failure in terms of what the customer might notice or experience, remembering that the customer may be an internal customer or the ultimate end user.

The effect of the failure mode is described by envisioning the effect it will have on the user. Typical descriptions of design failure effects are "rough operation", "excessive noise", "intermittent operation", etc.
### Potential Causes / Mechanisms of Failure

Enter the Potential Cause or Mechanism of the failure. Potential cause of Failure is defined as how the failure could occur, described in terms of something that can be corrected or can be controlled.

Potential causes are often requirements or specifications that have not been met in the execution of the function. This field should contain phrases that accurately describe the reason for the failure to happen. These descriptions usually include words like "incorrect" or "insufficient" or "excessive" followed by some noun. Examples: "incorrect gap", "insufficient lubrication", "excessive heat". Choosing to describe causes in this fashion makes identifying their solutions straightforward. Potential causes should be "root" causes and may require problem solving to discover.

### Current Design Controls - Prevention

List the controls/feature that prevent the cause (and in turn the failure mode) from occurring, or reduce its rate of occurrence.

Prevention controls are preferable over detection controls as they actually PREVENT the cause from happening. This type of control suggests that the cause (item 13) cannot happen because it is not possible. Error proofing is often considered a form of prevention. For example, the spout of a diesel fuel dispenser is designed to be too large to fit into the gas tank opening of a conventional "gas" vehicle, thereby greatly reducing the potential failure of engine damage. Note the distinction of where to place control; by controlling the ROOT CAUSES failures are avoided. Failure modes are not controlled - their causes are controlled.
### Current Design Controls - Detection

List the controls/feature that allow the cause or the failure mode to be detected as early as possible, preferably before effecting function.

Detection controls are different from prevention controls in that they do not control the cause, but instead give warning as to its presence. Sometimes causes cannot be prevented and the alternative is to simply be aware of them before they can generate a failure. Regular inspections or preventative maintenance can "find" causes before they can result in failure. Statistical process control (SPC), training, and written procedures are also means of raising awareness and making causes more detectable. Sometimes causes cannot be prevented and detection is the highest level of control available.

### Severity(s) and Classification

Severity is an assessment or ranking of the seriousness of the effect (item 12) of the potential failure mode to the next component, subsystem, system or customer if it occurs. Severity applies to the effect only.

Classification refers to any special characteristics of the design or high priority failure modes. Key requirements or important product characteristics can be noted here (i.e. KPP, KCC, KPC, KSA, etc). Entering something in the classification column indicates that the effect of this failure mode requires mitigation action regardless of its associated Occurrence and Detection ratings. In addition, Safety and Regulatory classifications imply higher severity ratings (i.e. 9 or 10) and similarly demand mitigation action. When entering a classification use or recognize the accepted abbreviations or symbols which may be company or industry specific (note: Safety is popularly classified with an S, Regulatory with and R). Remember that entering any classification at all means mitigation action needs to be taken.

Do not confuse failure mode with effect. Rank the effect, not the failure mode. Some failure modes have very severe effects while others are negligible.
<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>17</td>
<td>Occurrence (O)</td>
<td>Occurrence is an assessment of the likelihood that a specific cause/mechanism (item 13) will occur or present itself. The likelihood of occurrence ranking number has a meaning rather than a value. Removing or controlling one or more of the causes/mechanisms of the failure mode through a design change is the only way a reduction in the occurrence ranking can be affected.</td>
<td>Do not confuse failure mode with occurrence of cause. Rank the possibility of the cause happening, not the possibility of the failure mode happening.</td>
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<td>Detection(D)</td>
<td>Detection is an assessment of the likelihood that the Current Controls (items 14 &amp; 15) will detect the Cause of the failure mode, thereby preventing it, or that the subsequent failure mode will be detected before it reaches the customer.</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>RPN</td>
<td>The Risk Priority Number is the product of the Severity (S), Occurrence (O), and Detection (D) ranking. RPN=(S)×(O)×(D).</td>
<td>For higher RPNs the team must undertake efforts to reduce this calculated risk through mitigative action. It is the team's discretion as to what constitutes &quot;high&quot; RPN and what deserves action to be taken.</td>
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<tr>
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<td>Recommended Actions</td>
<td>When the failure modes have been ranked ordered by RPN, mitigative action should be first directed at the highest ranked concerns and critical items. The intent of any recommended action is to reduce any or all of the occurrence, severity, and or detection rankings. After using RPN as an indicator of mitigation action, next look for any failure mode that had something entered into the Classification column. Create mitigation actions for any failure mode which has a classification, no matter what the classification is.</td>
<td>Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.</td>
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<td>21</td>
<td>Responsibility &amp; Target Completion Date</td>
<td>Enter the organization and individual responsible for the recommended action and the target completion date.</td>
<td>Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.</td>
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<tr>
<td>22</td>
<td>Actions Taken</td>
<td>After an action has been implemented, enter a brief description of the actual action and effective date.</td>
<td>Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.</td>
</tr>
<tr>
<td>23</td>
<td>Action Results</td>
<td>After action has been completed, re-assess and record the new severity, occurrence, and detection rankings. Calculate and record the resulting RPN. If no actions are taken, leave the &quot;Action Results&quot; and related ranking columns blank.</td>
<td>Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.</td>
</tr>
</tbody>
</table>
## PFMEA Template and Definitions

### Potential Failure Mode and Effects Analysis

<table>
<thead>
<tr>
<th>Process step #</th>
<th>Process step function / requirements</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Severity</th>
<th>Classification</th>
<th>Potential Causes / Mechanisms of Failure</th>
<th>Current Process Controls Prevention</th>
<th>Customer Controls</th>
<th>Detect</th>
<th>R.P.A.</th>
<th>Recommended Actions</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>1</td>
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</tr>
</tbody>
</table>

### FMEA Details

- **FMEA #:**
- **Contract #:**
- **Supplier:**
- **Prepared by:**
- **FMEA key date:**
- **FMEA date (Orig.)**
- **Revision date:**

---

**Government POC:**

**Core Team:**

**Process Responsibility:**

**Process step:**

**Function:**

**Mechanisms of ..**

**Target Mode of Failure .**

**Controls Controls**

**Recommended Actions:**

**Action Results:**

---

**Actions Taken**

**Severity**

**Occur**

**Detection**

**R.P.A.**

---

**Unclassified**

---

**Technology Driven. Warfighter Focused.**
# PFMEA Template and Definitions

<table>
<thead>
<tr>
<th>Item #</th>
<th>Name</th>
<th>Description</th>
<th>Further comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>FMEA Number</td>
<td>Enter an appropriate FMEA document number, which may be used for tracking. Fill in as many fields as information allows.</td>
<td>FMEA numbers should follow a sequence as dictated by the existing recommendations or practices of the OEM, Vendor, Supplier, Department and/or Group who has design responsibility.</td>
</tr>
<tr>
<td></td>
<td>Contract #</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Supplier/DPRP</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 2      | System, Subsystem, or Component            | Check or mark the appropriate level of analysis and enter the name of the system, subsystem or component being analyzed. | - A System is a set of interacting or interdependent components forming an integrated whole. A vehicle is an example of a system. Business or transactional processes may be considered systems, but there is no further breakdown into sub-systems or components.  
- A Sub-System is a set of elements, which is a system itself, and a component of a larger system. The HVAC in a vehicle is an example of a sub-system.  
- A component is an element which, in conjunction with other components, come together in an integrated fashion to create a sub-system or system. The compressor in a HVAC sub-system is an example of a component.  
Components are themselves made up of any number of elements, and/or sub-components, but refrain from this as a justification to label certain components as sub-systems. |
<p>| 3      | Process responsibility                     | Enter the OEM, Vendor, Supplier, Department, and/or Group who is responsible for the process described in item 2. Enter the name and contact information for the Government Point of Contact. |                                                                                  |</p>
<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Prepared by</td>
<td>Enter the name, telephone number, e-mail address, (and company name where applicable) of the POC responsible for preparing the FMEA. Use best judgement as to how much information is needed. Non-Government FMEA forms should specify company names while Government FMEA forms may contain branch or group names. In most cases the FMEA is prepared by a member of the group holding Design Responsibility, but there may be exceptions. In all cases provide enough information for the reader to understand the origination point of the FMEA.</td>
</tr>
<tr>
<td>5</td>
<td>Program name</td>
<td>Enter the name of the program/process.</td>
</tr>
<tr>
<td>6</td>
<td>FMEA Key date</td>
<td>Enter the date the process FMEA is to be completed by and specify its relevance. FMEA is a proactive tool meant to be a &quot;before the event&quot; action, not an &quot;after the fact&quot; exercise. Therefore the FMEA should be completed BEFORE significant events so that actions can be taken to mitigate risk BEFORE failure happens. Examples of relevant dates might be Full or Low Rate Production (FRP or LRP), Milestones, Design Reviews, etc.</td>
</tr>
<tr>
<td>7</td>
<td>FMEA date (Orig) and Revision date</td>
<td>Enter the date the original FMEA was compiled and date of the latest revision. Since the FMEA is a living document it is important to update the revision date ANY time changes are made to the FMEA.</td>
</tr>
</tbody>
</table>
### Core Team

List the names of the responsible individuals and departments which have the authority to identify and or perform tasks.

The core team is also the group of individuals who, along with the person indicated in Item 4 as the person responsible for the preparation, will create the FMEA before the key date. It is strongly recommended that complete contact information be maintained either on the FMEA in this field, as an attachment to the form, or as a separate tab in the excel file. The life of an FMEA can sometimes outlast that of phone numbers, addresses, and current employees. Therefore all attempts to be current and complete are helpful if original team members need to be contacted. Updating contact information is a legitimate revision reason and the date of such an action should be recorded in Item 7.

Core team members should be labelled with the following identifiers: (G) Government, (O) OEM or Prime, (SC) service contractor.

### Process Step #

Enter the number of the item as it appears on the Process Map, Process Flow Diagram, or any other document which describes the flow and the order of the process.

This field is useful to tie the FMEA back to it’s support documents. An example might be STEP 1 for a Process Map block.

### Process Step Function / Requirements

Enter a simple description of the process or operation being analyzed which indicates the purpose of the process or operation. If the process or operation has multiple steps list each separately as they may have their own unique failure modes and effects.

When describing process steps keep in mind that the way they are worded can sometimes make it easier to describe how they can fail. Use verb noun phrases. Descriptions like "drill hole" or "solder wire to contact" are easy to turn around into potential failure descriptions. For business and transactional processes examples are "perform design review" or "create master schedule".

Depending on the source of the information it may be appropriate to enter requirements in the form of measurable metrics or to refer back to the source while creating the FMEA.
<table>
<thead>
<tr>
<th></th>
<th>11 Potential Failure Mode</th>
<th>Potential Failure Mode is defined as the manner in which the process could potentially fail to meet the process requirements and/or design intent as described in the Process Step Function / Requirements column (Item 10). The most obvious potential failure mode is the opposite of the intended output. Enter a short description that characterizes the failure.</th>
<th>Remember that although the opposite of the intended output is one obvious failure mode it may not be the only failure mode. Be sure to consider failure modes that can result when process settings are incorrect such as &quot;bent&quot;, &quot;cracked&quot;, &quot;burried&quot;, &quot;short circuited&quot;, &quot;open circuited&quot;, etc. All of the potential failure modes should be listed, but the FMEA team should be careful not to identify multiple failure modes unless they are sure of their uniqueness. For instance, if the function is &quot;drill hole&quot; the team may have to consider whether the potential failures &quot;hole too small&quot; and &quot;hole too large&quot; are really unique and have different consequences and solutions, or if they are just two levels of the same failure mode. Do not forget the less obvious failures such as &quot;fit&quot; (describing tolerance stack ups), &quot;interface&quot; (a sub-set of fit meaning that this item must mate with another item), and &quot;form&quot; (the ability to maintain shape). Examples of failure modes in business and transactional processes are &quot;approval not received&quot; or &quot;invoice is paid late&quot;.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12 Potential Effect(s) of Failure</td>
<td>Enter the Potential Effect of Failure in terms of what the customer might notice or experience, remembering that the customer may be an internal customer, the ultimate end user, or even the next process step.</td>
<td>The effect of the failure mode is described by envisioning the effect it will have on the user or the next operation. Typical descriptions of process failure effects are &quot;unit leaks&quot;, &quot;high effort&quot;, &quot;part will be scrapped&quot;, etc. Typical descriptions that affect downstream operation are &quot;cannot fasten&quot;, &quot;will not fit&quot;, &quot;causes excessive tool wear&quot;, &quot;will prompt PLC error codes&quot;, etc.</td>
</tr>
<tr>
<td></td>
<td>Potential Causes / Mechanisms of Failure</td>
<td>Enter the Potential Cause or Mechanism of the failure. Potential cause of Failure is defined as how the failure could occur, described in terms of something that can be corrected or can be controlled.</td>
<td>Potential causes are often requirements or specifications that have not been met in the execution of the process or operation. This field should contain phrases that accurately describe the reason for the failure to happen. These descriptions usually include words like &quot;incorrect&quot; or &quot;insufficient&quot; or &quot;excessive&quot; followed by some noun. Examples: &quot;incorrect setting&quot;, &quot;insufficient welding current&quot;, &quot;excessive drill speed&quot;. Other examples: &quot;debris present&quot;, &quot;worn tool&quot;, &quot;improper setup&quot;, etc. Choosing to describe causes in this fashion makes identifying their solutions straightforward. Potential causes should be &quot;root&quot; causes and may require problem solving to discover.</td>
</tr>
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<tr>
<td>13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Current Process Controls - Prevention</td>
<td>List the controls/feature that prevent the cause (and in turn the failure mode) from occurring, or reduce its rate of occurrence.</td>
<td>Prevention controls are preferable over detection controls as they actually PREVENT the cause from happening. This type of control suggests that the cause (item 13) cannot happen because it is not possible. Error proofing is often considered a form of prevention. For example, commonization of fasteners eliminates the possibility of using the wrong fastener in any given location. Note the distinction of where to place control; by controlling the ROOT CAUSES failures are avoided. Failure modes are not controlled - their causes are controlled.</td>
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<tr>
<td>15</td>
<td>Current Process Controls - Detection</td>
<td>List the controls/feature that allow the cause or the failure mode to be detected as early as possible, leading to corrective actions.</td>
<td>Detection controls are different from prevention controls in that they do not control the cause, but instead give warning as to its presence. Sometimes causes cannot be prevented and the alternative is to simply be aware of them before they can generate a failure. Regular inspections or preventative maintenance can &quot;find&quot; causes before they can result in failure. Statistical process control (SPC), training, and written procedures are also means of raising awareness and making causes more detectable. Sometimes causes cannot be prevented and detection is the highest level of control available.</td>
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<td>16</td>
<td>Severity(S) and Classification</td>
<td>Severity is an assessment or ranking of the seriousness of the effect (item 12) of the potential failure mode to the next component, subsystem, system or customer if it occurs. Severity applies to the effect only. Classification refers to any special characteristics of the design or high priority failure modes. Key requirements or important product characteristics can be noted here (i.e. KPP, KCC, KPC, KSA, etc). Entering something in the classification column indicates that the effect of this failure mode requires mitigation action regardless of its associated Occurrence and Detection ratings. In addition, Safety and Regulatory classifications imply higher severity ratings (i.e. 9 or 10) and similarly demand mitigation action. When entering a classification use or recognize the accepted abbreviations or symbols which may be company or industry specific (note: Safety is popularly classified with an S, Regulatory with and R). Remember that entering any classification at all means mitigation action needs to be taken.</td>
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<td>Occurrence (O)</td>
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<td>18</td>
<td>Detection (D)</td>
<td>Detection is an assessment of the likelihood that the Current Controls (items 14 &amp; 15) will detect the cause of the failure mode, thereby preventing it, or that the subsequent failure mode will be detected before it reaches the end user.</td>
<td>Random quality checks are not likely to detect low frequency failure modes and are therefore poor detection techniques relative to statistical sampling used in SPC and control charting.</td>
</tr>
<tr>
<td>19</td>
<td>RPN</td>
<td>The Risk Priority Number is the product of the Severity (S), Occurrence (O), and Detection (D) ranking. RPN = (S) x (O) x (D).</td>
<td>For higher RPNs the team must undertake efforts to reduce this calculated risk through corrective action. It is the team’s discretion as to what constitutes &quot;high&quot; RPN and what deserves action to be taken.</td>
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<tr>
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<td>Recommended Actions</td>
<td>When the failure modes have been rank ordered by RPN, mitigative action should be first directed at the highest ranked concerns and critical items. The intent of any recommended action is to reduce any or all of the occurrence, severity, and or detection rankings. After using RPN as an indicator of mitigation action, next look for any failure mode that had something entered into the Classification column. Create mitigation actions for any failure mode which has a classification, no matter what the classification is.</td>
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<td>Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.</td>
</tr>
</tbody>
</table>
# DFMEA Evaluation Checklist

## Design FMEA Development & Audit Summary

**Name of Component, Sub-System, System:**  

**Internal or Contractor (Specify Contractor):**  

**Responsible person & date reviewed against this checklist:**  

<table>
<thead>
<tr>
<th>Accept</th>
<th>Consistent Adherence to FMEA Criteria</th>
<th>Revision Required.</th>
<th>Comments</th>
</tr>
</thead>
</table>

### 1 Preparation Steps for DFMEA Lead and Team members:

1a Obtain & review DFMEA. Review relevant background materials, including: Engineering Specifications, DFMEAs, TEMP, PFMEAs and Customer feedback to identify required functions & historical performance of predecessor products.

1b Construct a Boundary or P-Diagram to define the Component, Module or System for which the DFMEA is being developed.

1c Create a Function Model (or equivalent) for the component, module or system.

### 2 Header Information: Required Fields

2a Name(s) and Year(s) of Program(s)

2b Correct Component/ System for program is addressed

2c Name of Responsible Engineer

2d Name of Supplier (Components), if Applicable

2e Name of Component Team (Systems)

2f Team Members are identified and the team is cross functional

2g Key Date Shown

2h Date of original FMEA is shown

2i Revision levels & dates are shown

### 3 Function / Parts Column

3a All functions are identified, including manufacturability, serviceability, regulatory, legal including all functions identified in the Function Model.

3b All identified functions have measurable requirements per specification.
### DFMEA Evaluation Checklist

#### 4 Potential Failure Modes Column
- **4a** Failure modes match functions
- **4b** Failure modes for each function have been identified. (For Example, "Inoperable," "Degraded Function," "Intermittent Function," "Unintended/Inadvertent Function" have been addressed)

#### 5 Potential Failure Effects Column & Severity
- **5a** Potential effects of failure describe the customers experience
- **5b** Severity index rating is appropriate for the most severe potential effects
- **5c** Safety and regulatory concerns are rated with a severity of "9" or "10"
- **5d** Potential Safety items with causes that are susceptible to mfg. variation, are identified with an "S"; Regulatory items are identified with an "R"; KPPs, KSAs, KCCs, KPCs, etc are identified accordingly in the Classification column
- **5e** Descriptions of effect include impact on intermediate "customers" like Assemblers, Service Techs
- **5f** Potential Effects are sufficiently detailed (not "doesn't work")

#### 6 Potential Causes
- **6a** All failure modes have at least 1 cause
- **6b** Indicates root cause(s) of the identified failure mode

#### 7 Current Design Controls - Prevention
- **7a** Prevention Controls refer to specific simulations, GD&T studies, analyses, TD testing actions, etc.
- **7b** Prevention Controls include specific requirements from Engineering Standards, use of best practice design guidelines, analysis of surrogate data, lessons learned and prior product history.
- **7c** Prevention Controls impact the Design Release
- **7d** Prevention Controls include Error/Mistake proofing, Design for Manufacturability / Assembly of product, process capability data, as applicable.
DFMEA Evaluation Checklist

<table>
<thead>
<tr>
<th></th>
<th>Occurrence Column</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Each cause is rated separately</td>
<td></td>
</tr>
<tr>
<td>8a</td>
<td>Each cause has at least 1 Prevention Design Control. (If there are no Prevention Controls, then Occurrence is automatically rated as a “10”)</td>
<td></td>
</tr>
<tr>
<td>8b</td>
<td>Occurrence ranks the effectiveness of Prevention Controls in eliminating the Root Cause from the Design Release</td>
<td></td>
</tr>
<tr>
<td>8c</td>
<td>Occurrence ranking considers the likelihood of the cause occurring over the entire design life of the product</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Current Design Controls - Detection</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>9a</td>
<td>Design Controls refer to specific tests, analyses, actions, etc. that take place during TD and EMD phases</td>
<td></td>
</tr>
<tr>
<td>9b</td>
<td>Each cause has at least 1 Detection Design Control. (If there are no Detection Controls for a Potential cause, then Detection is automatically rated as a “10”)</td>
<td></td>
</tr>
<tr>
<td>9c</td>
<td>Design Controls do not include production process controls</td>
<td></td>
</tr>
<tr>
<td>9d</td>
<td>Detection Controls are applied in a timely manner, in order to avoid the inclusion of the cause/failure mode in a Customer Built product</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Detection Column</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10a</td>
<td>Detection ranks the likelihood that the cause / failure mode would be detected</td>
<td></td>
</tr>
<tr>
<td>10b</td>
<td>Detection ranking reflects the timeliness of the application of the Detection Control. (The detection will result in a revised design prior to the EMD build).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Risk Priority Number</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>11a</td>
<td>RPN appears realistic &amp; not artificially low. Ranking values can be substantiated.</td>
<td></td>
</tr>
<tr>
<td>11b</td>
<td>RPN was calculated correctly</td>
<td></td>
</tr>
</tbody>
</table>
### DFMEA Evaluation Checklist

#### 12 Recommended Actions & Responsibility

<table>
<thead>
<tr>
<th>Recommended Actions &amp; Responsibility</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>12a</strong></td>
<td>Highest RPNs and Severity Rankings comprising a rolling top 20%, or top issues as determined by DFMEA Review Team, are addressed with needed actions</td>
</tr>
<tr>
<td><strong>12b</strong></td>
<td>Severity Ratings of 8, 9 or 10 are given special consideration</td>
</tr>
<tr>
<td><strong>12c</strong></td>
<td>Recommended Actions are assigned to a named person w/ target dates</td>
</tr>
<tr>
<td><strong>12d</strong></td>
<td>Key characteristics have a Current Design Control or a Recommended Action to ensure or verify that they are addressed, for example, in a PFMEA, Engineering drawings, Standard Work Instruction</td>
</tr>
<tr>
<td><strong>12e</strong></td>
<td>Recommended Actions may not be left blank. If actions are not needed, &quot;None&quot; and a statement such as &quot;Risk to customer is very low due to experience with surrogate products&quot; or &quot;Currently there are no earlier detection controls which would reduce risk to the program,&quot; &quot;Risk to customer is very low due to high likelihood that TD phase testing is very likely to detect a potential Failure Mode.</td>
</tr>
<tr>
<td><strong>12f</strong></td>
<td>Predicted RPN are effected by Occurrence and/or Detection, unless a design change mitigates the Failure Mode and Effect of Failure</td>
</tr>
<tr>
<td><strong>12g</strong></td>
<td>Predicted RPNs are stated in the Recommended Actions column, not in the Action Results column</td>
</tr>
</tbody>
</table>

#### 13 Actions taken

<table>
<thead>
<tr>
<th>Actions taken</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>13a</strong></td>
<td>Actions taken and Target Completion Dates are shown</td>
</tr>
<tr>
<td><strong>13b</strong></td>
<td>Completion of Recommended Actions is timely, RPN's have been updated and level of risk is acceptable</td>
</tr>
</tbody>
</table>

#### 14 Analysis of Findings

<table>
<thead>
<tr>
<th>Analysis of Findings</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>14a</strong></td>
<td>Highest Risk Potential Causes of Failure Modes are identified in a Pareto Analysis/chart, which is created and attached as the summary cover page of the DFMEA</td>
</tr>
</tbody>
</table>
**Additional DFMEA Information for Lead Engineer and Team members:**

- Requires the use of standard DFMEA format, ranking scale definitions (which have been tailored by the FMEA IPT for DoD application and can be further tailored by the specific FMEA teams) and reference materials, provided in the Automotive Industry Action Group (AIAG) FMEA Manual.
- Team should review this form while developing the DFMEA & evaluate DFMEA prior to submission for approval.
- When there is an "S" in the Class column, the DFMEA team should communicate the significance of the characteristic to Manufacturing (e.g., through the drawing and/or that it is addressed in the PFMEA).
- The approved DFMEA should be updated with the latest TEMP results (i.e., new Failure Modes, Causes, Design Controls identified, etc.) and any Actions Taken.
- DFMEA's should be reviewed at: Technical Reviews and Milestones to ensure the inclusion of the latest test results & completed Recommended Actions before product launch and whenever changes are written for the component or system.

**Design FMEA Review Log:** Comments & Program Phase / Date Reviewed / Reviewer
PFMEA Evaluation Checklist

"Program Name" Process FMEA Basics: Audit Summary

<table>
<thead>
<tr>
<th>Name of Component, Sub-System or System:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsible Engineer &amp; Facility Name</td>
<td></td>
</tr>
<tr>
<td>Quality Auditor:</td>
<td></td>
</tr>
<tr>
<td>Date Reviewed:</td>
<td></td>
</tr>
</tbody>
</table>

Accept. Consistent Adherence to FMEA Criteria
Revision Required.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Does the Header Contain Adequate Information?
   1a Name of Program(s)
   1b Year of Program(s)
   1c Component/System is included in Program
   1d Name of Contractor
   1e Name of Contractor Team & Plant (Assembly)
   1f Key Date Shown
   1g Date of original FMEA is shown
   1h Revision levels & dates are shown.

2. Is the Process Steps Column Adequate?
   2a Process steps/work stations are clearly identified
   2b Tests and inspections are indicated in process flow chart
   2c Each operation is (briefly) described, rather than just numbered
   2d Separate in-line inspection stations are shown as process steps
### PFMEA Evaluation Checklist

#### Potential Failure Modes Column Adequate?
- 3a Failure modes logically match process steps
- 3b Each process step has at least 1 potential failure mode

#### Potential Failure Effects Column Adequate?
- 4a Effects include those impacting warfighter, employees, equipment
- 4b Severity index is appropriate for potential effects
- 4c Safety, Regulatory characteristics are rated with a 9 or 10

#### Potential Causes Column Adequate?
- 5a All Safety items are addressed
- 5b Each Failure mode must have at least 1 cause
- 5c Each cause is rated separately
- 5d Occurrence index logically rates causes
- 5e Assembly & processing concerns are evaluated
- 5f Potential equipment malfunction is included
- 5g Selection of wrong parts, # of parts, machine settings, etc included
- 5h Specific deficiencies are indicated, i.e. widget installed upside down
- 5i Failure mechanisms for Safety, Regulatory, KPP, KSA, KCC, KPC are indicated
### PFMEA Evaluation Checklist

#### 6 Current Controls Column Adequate?
- **6a** Current Controls are evaluated separately by cause
- **6b** Each cause has at least 1 process or design for assy. control
- **6c** Detection index logically rates adequacy of process controls
- **6d** Controls include part fixturing, visual aids, limit switches, etc.
- **6e** Process Controls do not just include "operator training".
- **6f** Process Controls include Mistakeproofing
- **6g** Controls evaluated per experience w/similar production lines/equip.

#### 7 Risk Priority Number Logical?
- **7a** RPN is realistic
- **7b** RPN is not kept artificially low
- **7c** RPN is correctly calculated.

#### 8 Recommended Actions & Responsibility Columns Reasonable?
- **8a** High RPNS are addressed with needed actions
- **8b** Severity Ratings of 9 or 10 are addressed
- **8c** Recommended Actions are assigned to a specific person
- **8d** Target Completion dates are shown

#### 9 Action Results Effectively Executed?
- **9a** All actions taken are shown
- **9b** Actions were completed in a timely manner
- **9c** Actions include additional tests, inspections, mistakeproofing, etc
- **9d** Re-ratings were completed and reasonable
- **9e** Re-calculated RPN number now indicates low-medium risk
- **9f** High risk failures are taken seriously
<table>
<thead>
<tr>
<th></th>
<th>Additional Guidelines</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td><strong>Additional Guidelines</strong></td>
<td></td>
</tr>
<tr>
<td>10a</td>
<td>PFMEA seems to be a decision making tool</td>
<td></td>
</tr>
<tr>
<td>10b</td>
<td>Document appears to be a living document</td>
<td></td>
</tr>
<tr>
<td>10c</td>
<td>Current Controls operationalized in Process Control Plan &amp; SOPs</td>
<td></td>
</tr>
<tr>
<td>10d</td>
<td>Key characteristics noted in DFMEA are conveyed to PFMEA</td>
<td></td>
</tr>
<tr>
<td>10e</td>
<td>PFMEA has been updated as experience is gained</td>
<td></td>
</tr>
<tr>
<td>10f</td>
<td>Response to high risk failures is a priority</td>
<td></td>
</tr>
<tr>
<td>10g</td>
<td>Detailed Process Flow Chart is attached</td>
<td></td>
</tr>
<tr>
<td>10h</td>
<td>&quot;Operator Error&quot; is not the only (catch all) potential cause</td>
<td></td>
</tr>
<tr>
<td>10i</td>
<td>&quot;Supplier&quot; &amp; out of spec components are not catch all causes</td>
<td></td>
</tr>
<tr>
<td>10j</td>
<td>&quot;Visual inspection&quot; rated high because it's ineffective</td>
<td></td>
</tr>
<tr>
<td>10k</td>
<td>&quot;No build&quot; assy. (in-station) rated low because it's very effective</td>
<td></td>
</tr>
<tr>
<td>10l</td>
<td>In-station, aided inspection rated better than end of line inspection</td>
<td></td>
</tr>
<tr>
<td>10m</td>
<td>Detection in subsequent station better than end of the line</td>
<td></td>
</tr>
<tr>
<td>10n</td>
<td>Incoming inspection of components, is rated high</td>
<td></td>
</tr>
<tr>
<td>10o</td>
<td>Line start-up procedure &amp; thorough workstation review is rated moderately</td>
<td></td>
</tr>
<tr>
<td>10p</td>
<td>If equipment failure is cause, preventive maintenance is good control</td>
<td></td>
</tr>
</tbody>
</table>
Questions? Contact us

The following TARDEC representatives can answer your questions concerning the use of FMEA:

Kadry.W.Rizk.civ@mail.mil
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Lisa.J.Graf2.civ@mail.mil

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RISK RECON HELP DESK PHONE: 586-219-6096