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

TARDEC Systems Engineering Risk Management Team

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Report Documentation Page

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For TARDEC Failure Mode and Effects Analysis (FEMA) Training Classes

14. 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

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Training Objectives

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.

A Note on FMECA

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 Standards

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 J-1739 Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Process (Process FMEA).
- SAE ARP-5580: “Recommended failure mode and effects analysis (FMEA) practices for non-automobile applications”. Aerospace Recommended Practice
- Automotive Industry Action Group FMEA reference manual: Automotive applications of SAE J-1739

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.

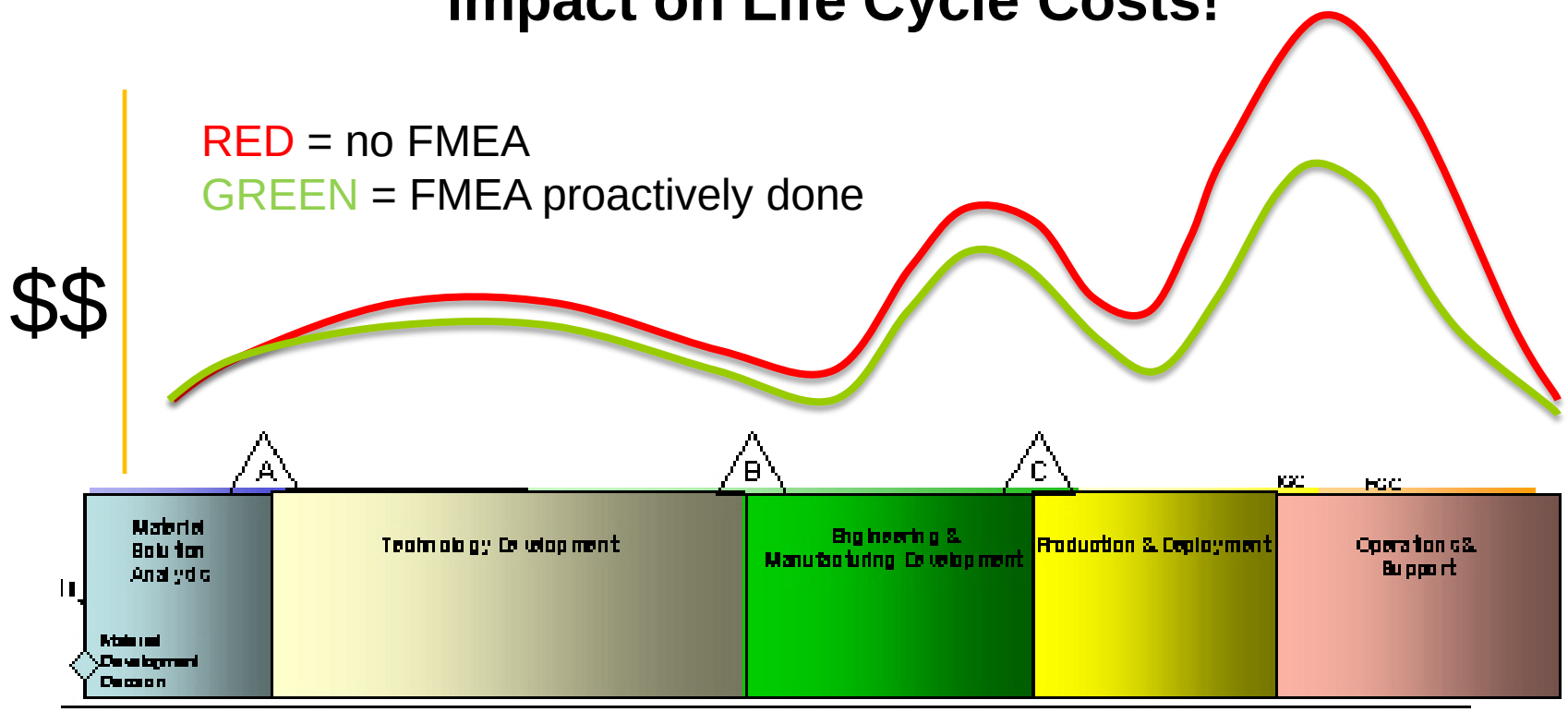
7. Increase Reliability and Maintainability:

FMEA improves reliability and maintainability through risk mitigation.

8. High Reuse for Next Program.

Why Should You Care?

Failure Mode and Effects Analysis can have SIGNIFICANT impact on Life Cycle Costs!



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.

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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.

Updating the FMEA

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.

FMEA and the Risk Management Process

The risk management process includes the following key activities, performed on a continuous basis:

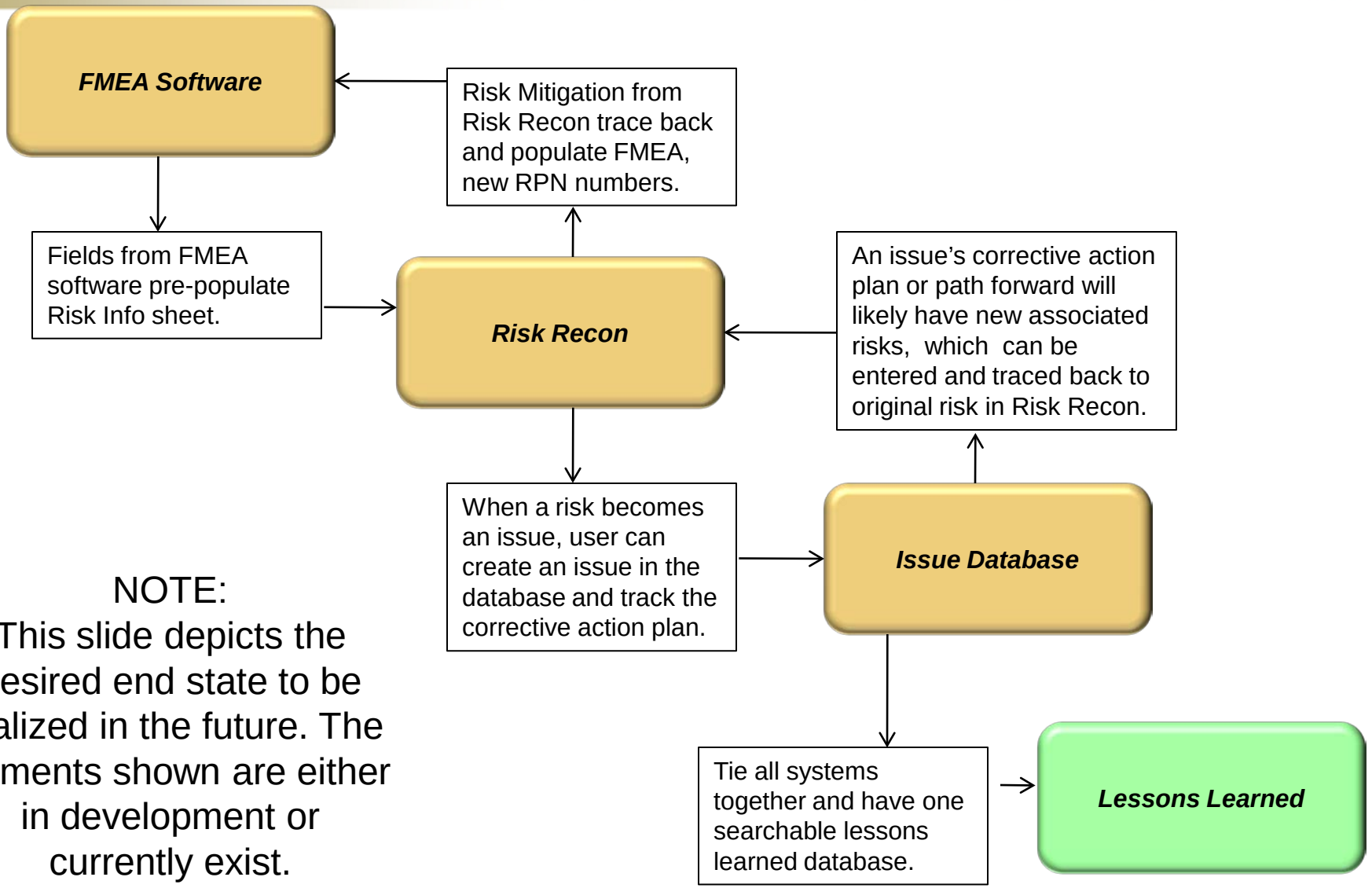
- Risk Identification
- Risk Analysis
- Risk Prioritization and Mitigation Planning
- Mitigation Plan Implementation
- Risk Tracking and Reporting

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.

Risk Management Cycle



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 Thought Process

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.

FMEA Template Structure

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

Who Should Contribute?

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

Input Material for FMEA

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.

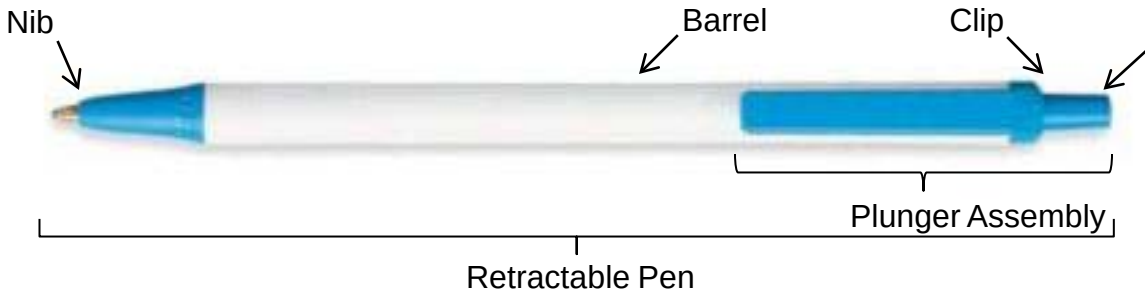
Use proven, thorough approaches to describe all the elements of the product/process:

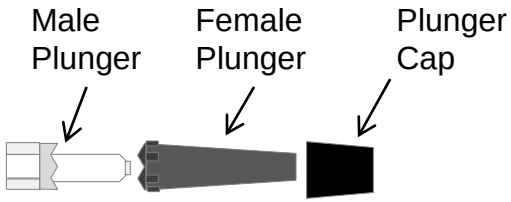
- Parameter Diagram (P diagram)
- Block Diagram
- Work/product Breakdown Structure (WBS)
- Process Map (PMAP)
- Process Flow Diagram

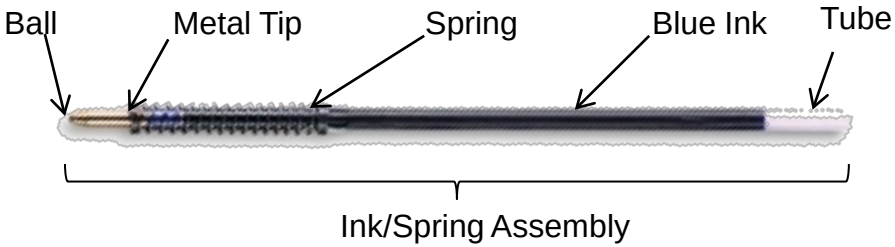
All these tools contain elements which can help populate certain fields within the FMEA. In some form or another, they provide information about the item/process step, function, failure mode, or causes of failure.

The following slides explain each tool, and how it applies to the retractable pen.

The Retractable Pen Example



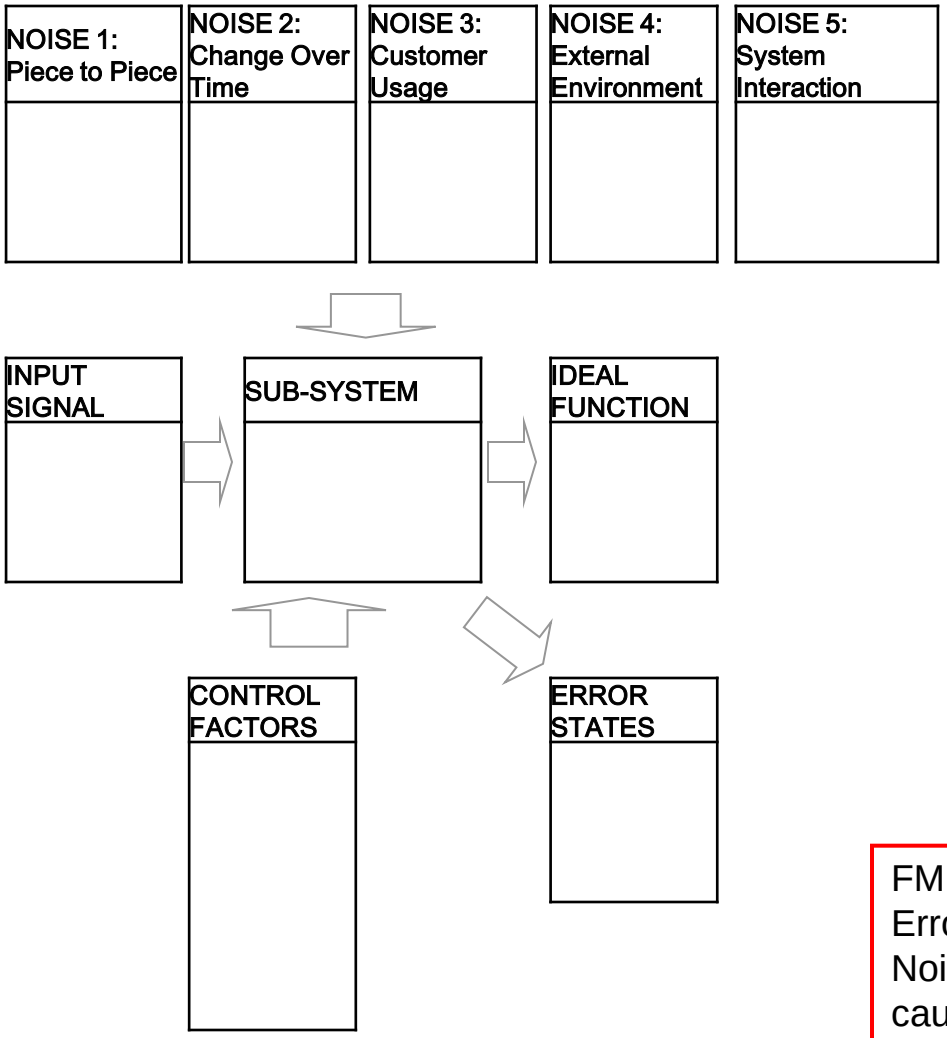




This pen will be used as an example throughout the remainder of the class to illustrate concepts and conduct exercises.

Components		Material	Qty
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	ABS/PP	1
1.1.1.1.2	Male Plunger	ABS/PP	1
1.1.1.1.3	Female Plunger	ABS/PP	1
1.1.1.1.4	Plunger Cap	ABS/PP	1
1.1.1.2	Barrel	ABS/PP	1
1.1.2	Ink/Spring Assembly		
1.1.2.1	Ink Tube		
1.1.2.1.1	Tube	ABS/PP	1
1.1.2.1.2	Metal Tip	Brass	1
1.1.2.1.3	Ball	Tungsten Carbide	1
1.1.2.1.4	Blue Ink	Ink	.1 grams
1.1.2.2	Spring	Steel	1
1.1.3	Nib	ABS/PP	1

Parameter (P) Diagram Template



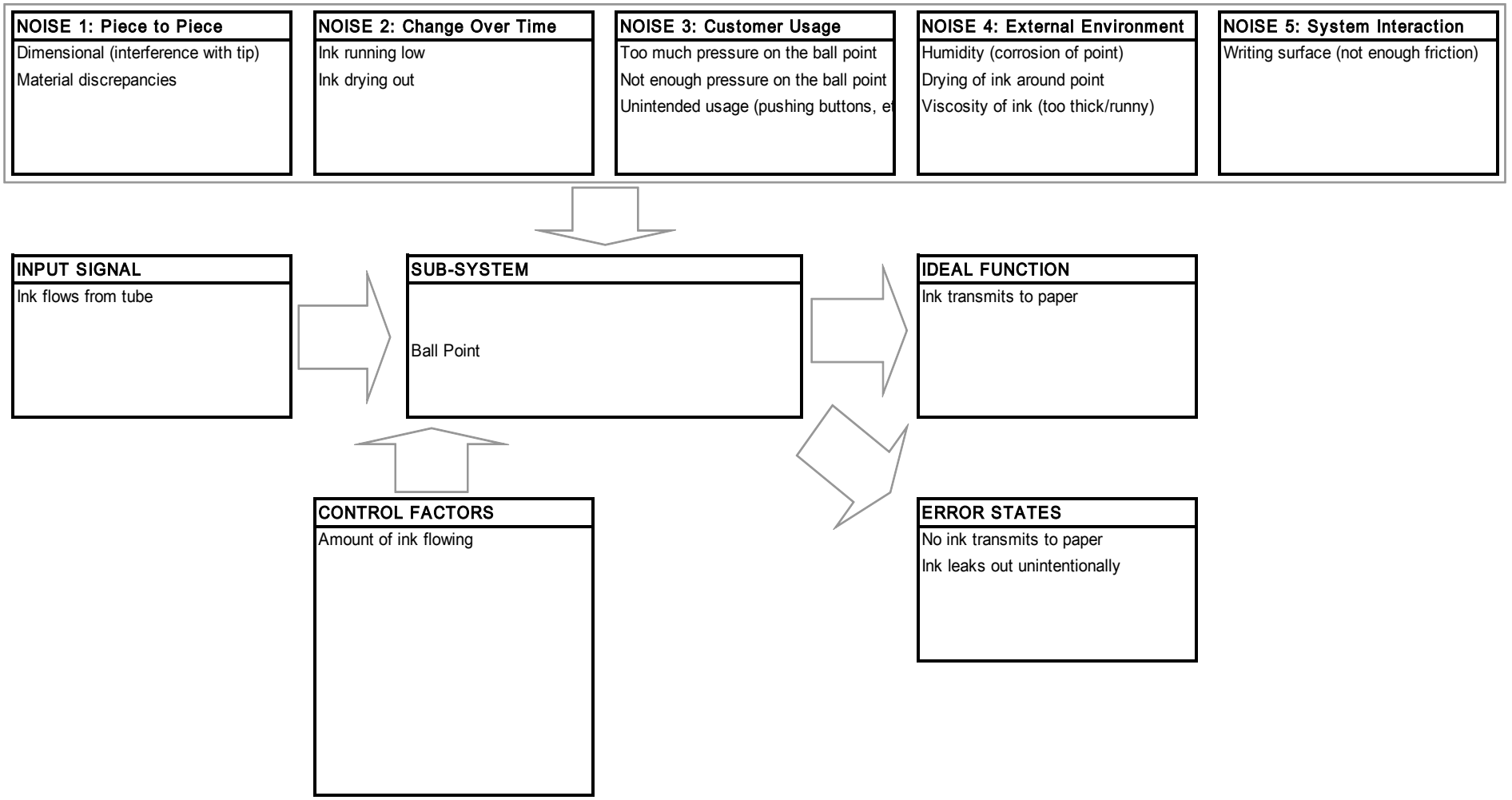
A P-Diagram helps a team to understand the physics related to the functions of the design. The team analyzes the intended inputs and outputs for the design as well as those controlled and uncontrolled factors which can impact performance. The inputs to the product and outputs from the product are useful 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

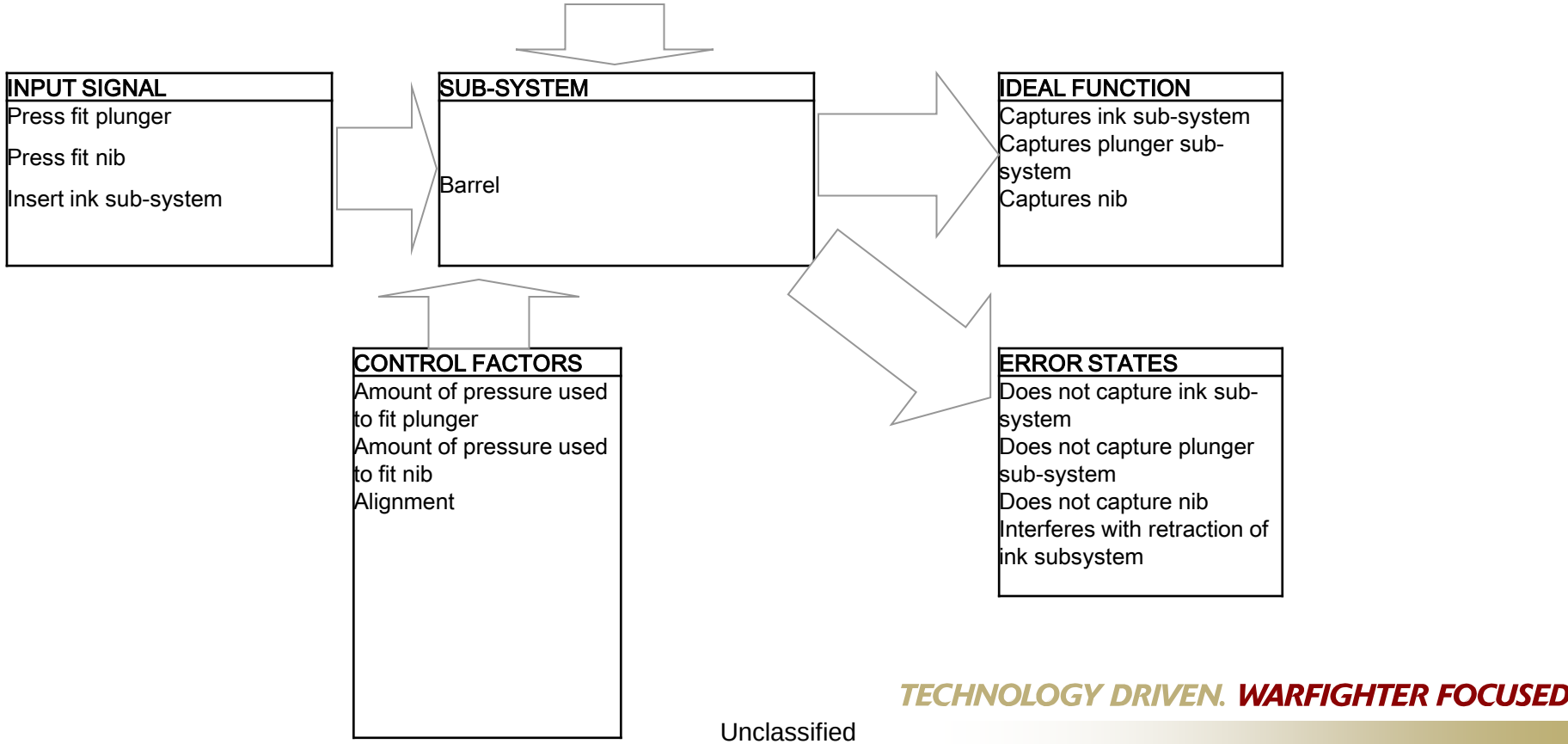
FMEA translations:
Error states = Failure modes
Noise, Control Factor, and Input Signal = Potential causes of failure
Ideal function = Function or Step
Sub system = Item or step name

Ball Point Parameter (P) Diagram



Pen Barrel Parameter (P) Diagram

NOISE 1: Piece to Piece	NOISE 2: Change Over Time	NOISE 3: Customer Usage	NOISE 4: External Environment	NOISE 5: System Interaction
Dimensional (interference with nib) Dimensional (interference with plunger) Dimensional (interference with ink) Material discrepancies	Warping of barrel	Unintended usage (removal/reinsertion of nib) Unintended usage (removal/reinsertion of plunger)	Humidity (material changes) Temperature (expansion/contraction)	Too much force from plunger Too much force from nib



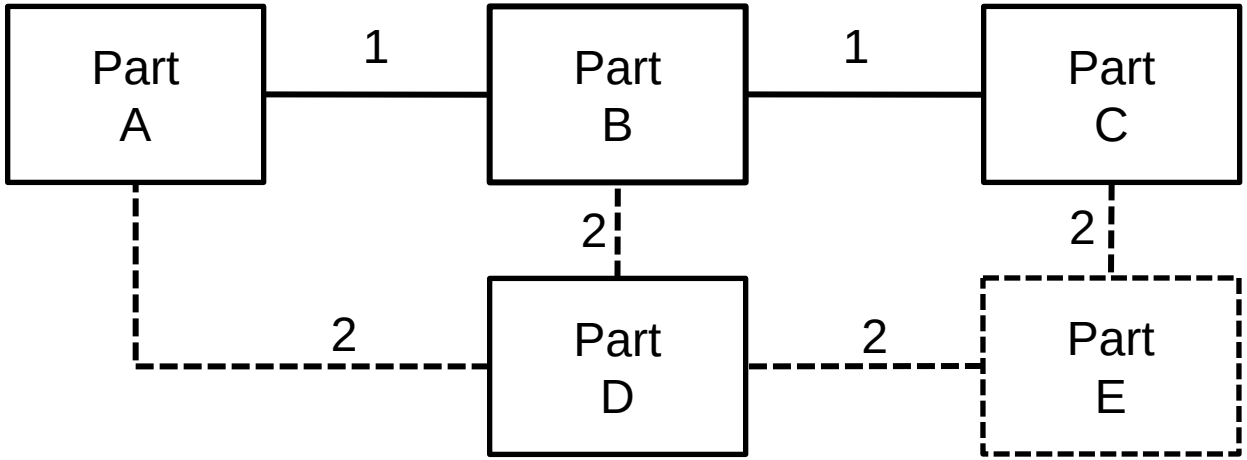
Block Diagram Template

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

Block Diagram:



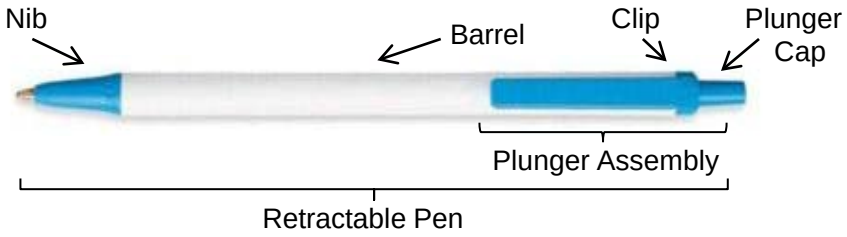
Components:
A. <Component 1>
B. <Component 2>
Etc…

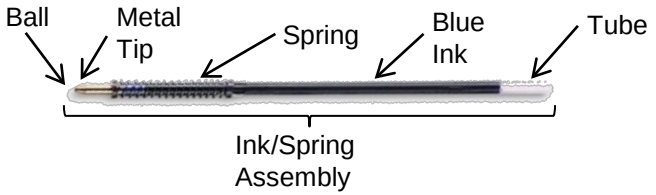
Attaching Methods:
1. <Method 1>
2. <Method 2>

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

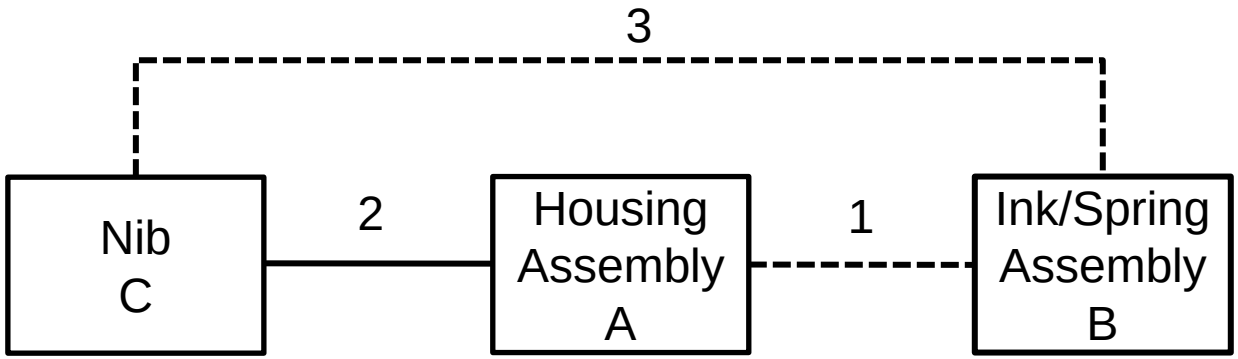
FMEA translations:
Part = Item name and number
Attaching method = Function
"Bad" Attaching method = Failure mode

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

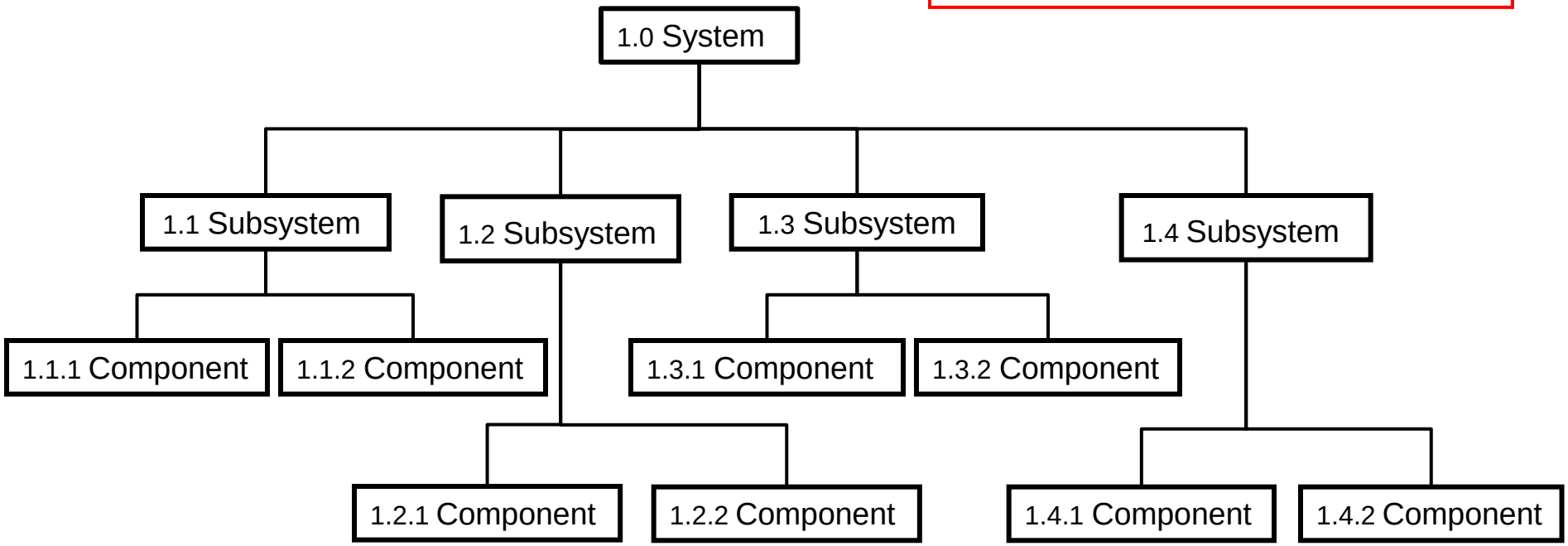
Work Breakdown Structure (WBS) Template

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.

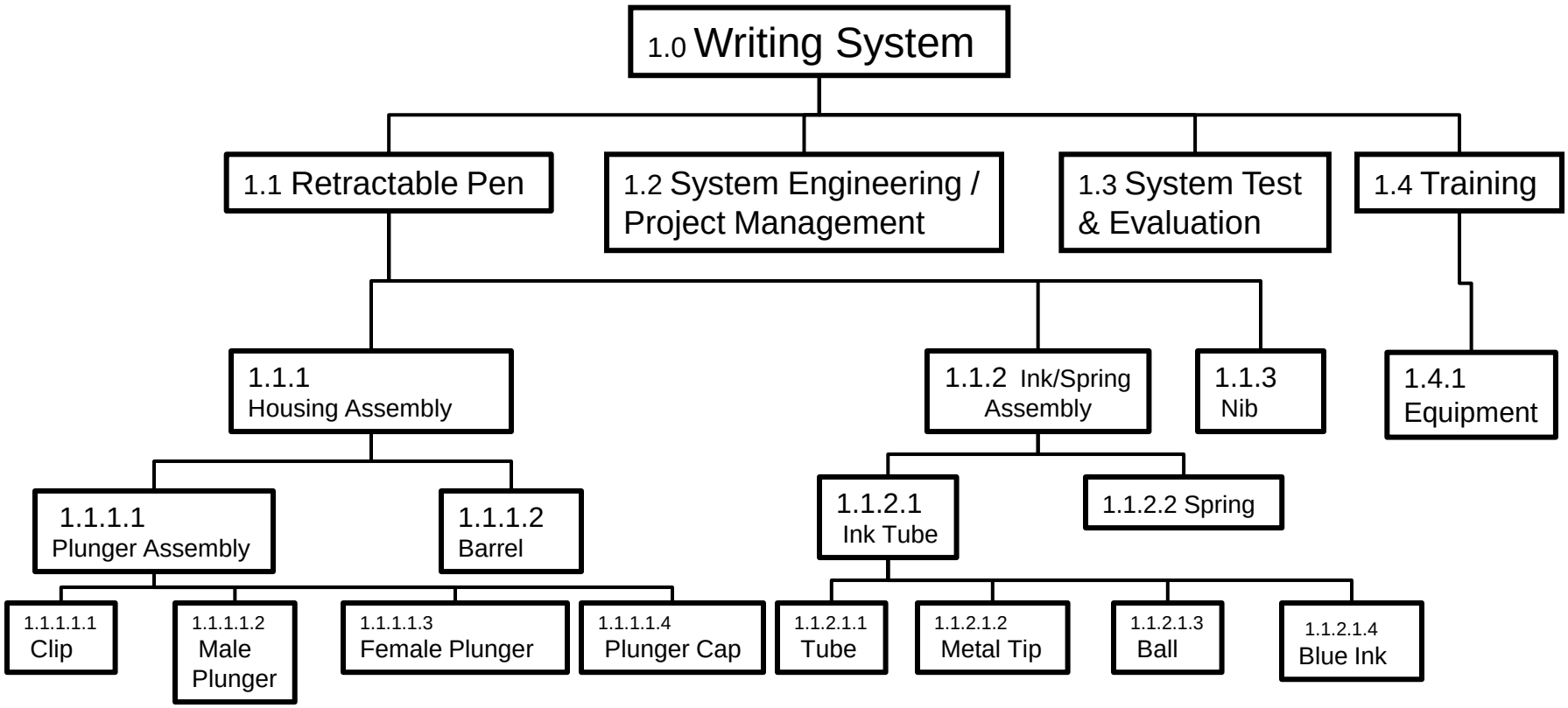
Objective: To understand the scope of the project, and to see the process/product in smaller, more manageable pieces

May be applicable to: Design FMEA

FMEA translations:
WBS element = Item name & number



WBS for a Retractable Pen

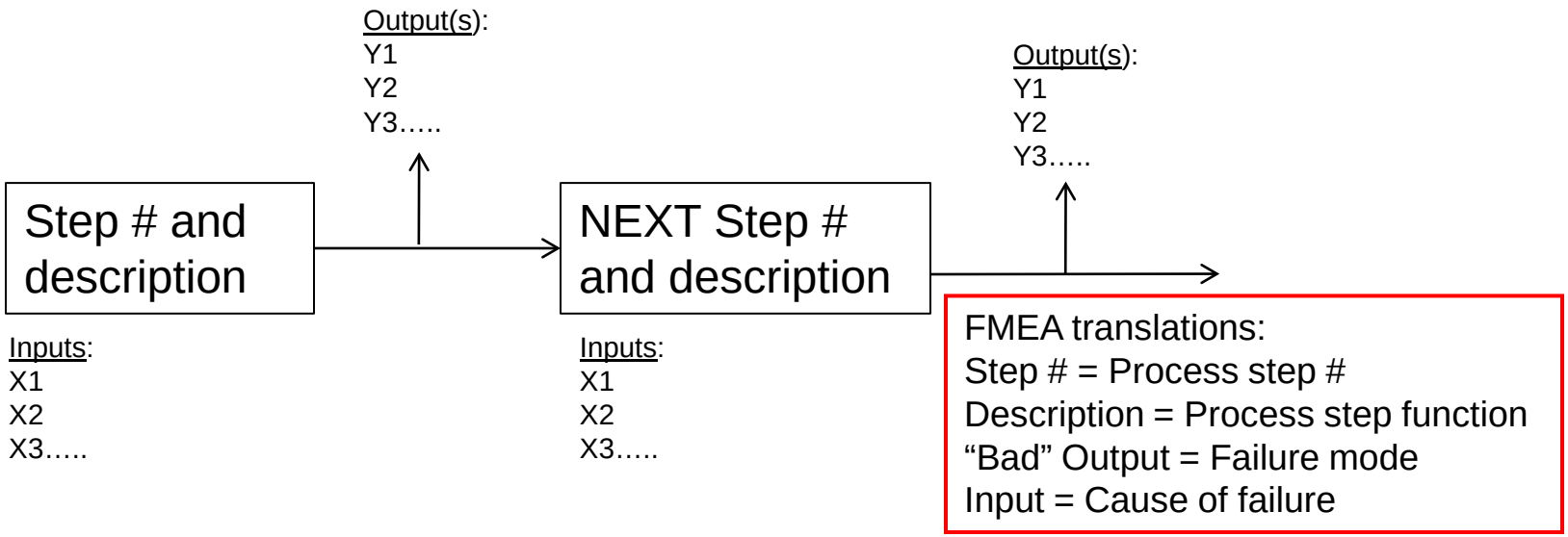


Process Map Template

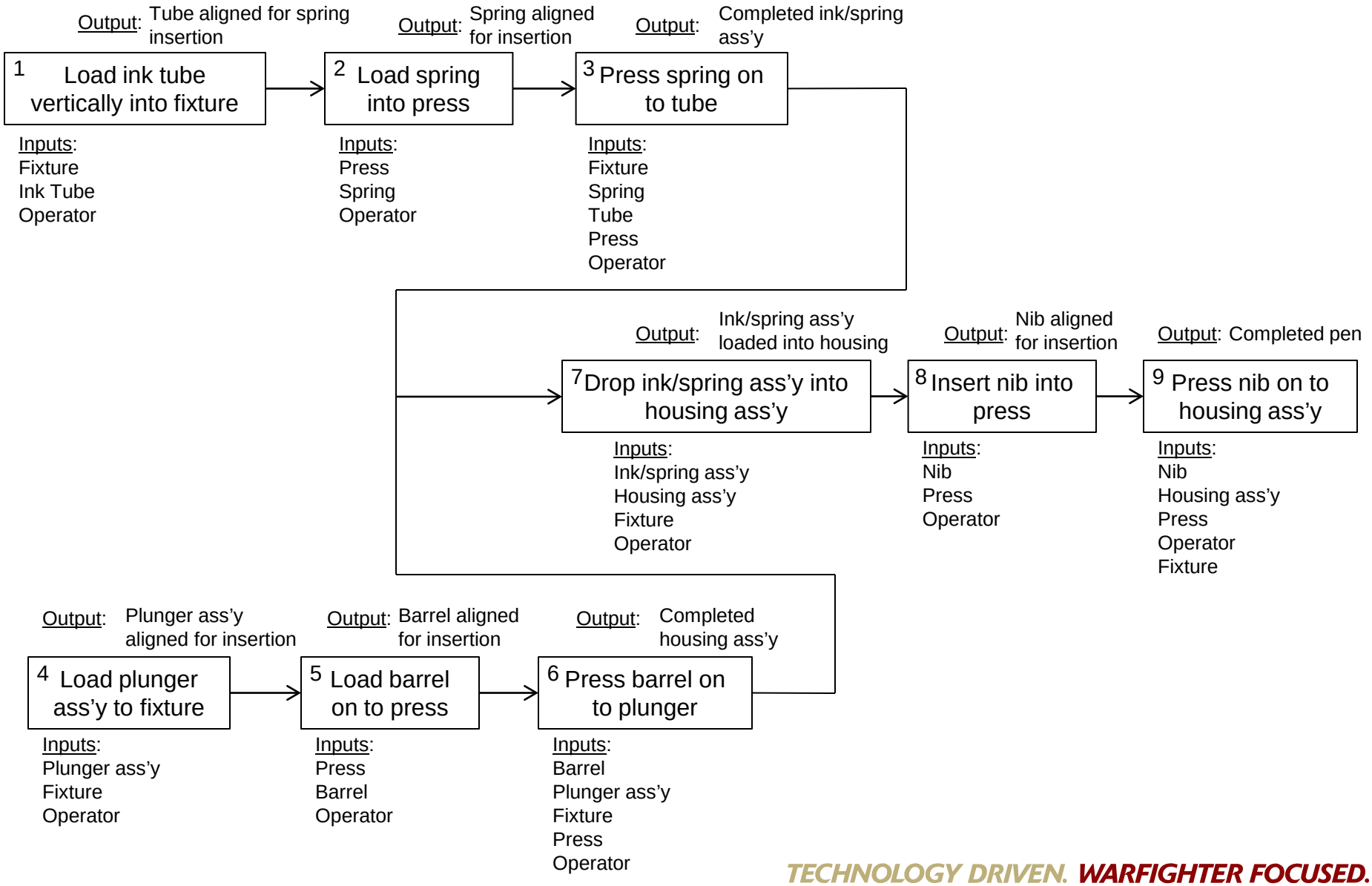
A process map is a depiction of how a process flows. Assembly, Manufacturing, and Transactional process maps describe the actionable steps taken to build or make something, or to achieve some business related output. In all cases process maps include inputs and the various tasks involved in turning those 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)

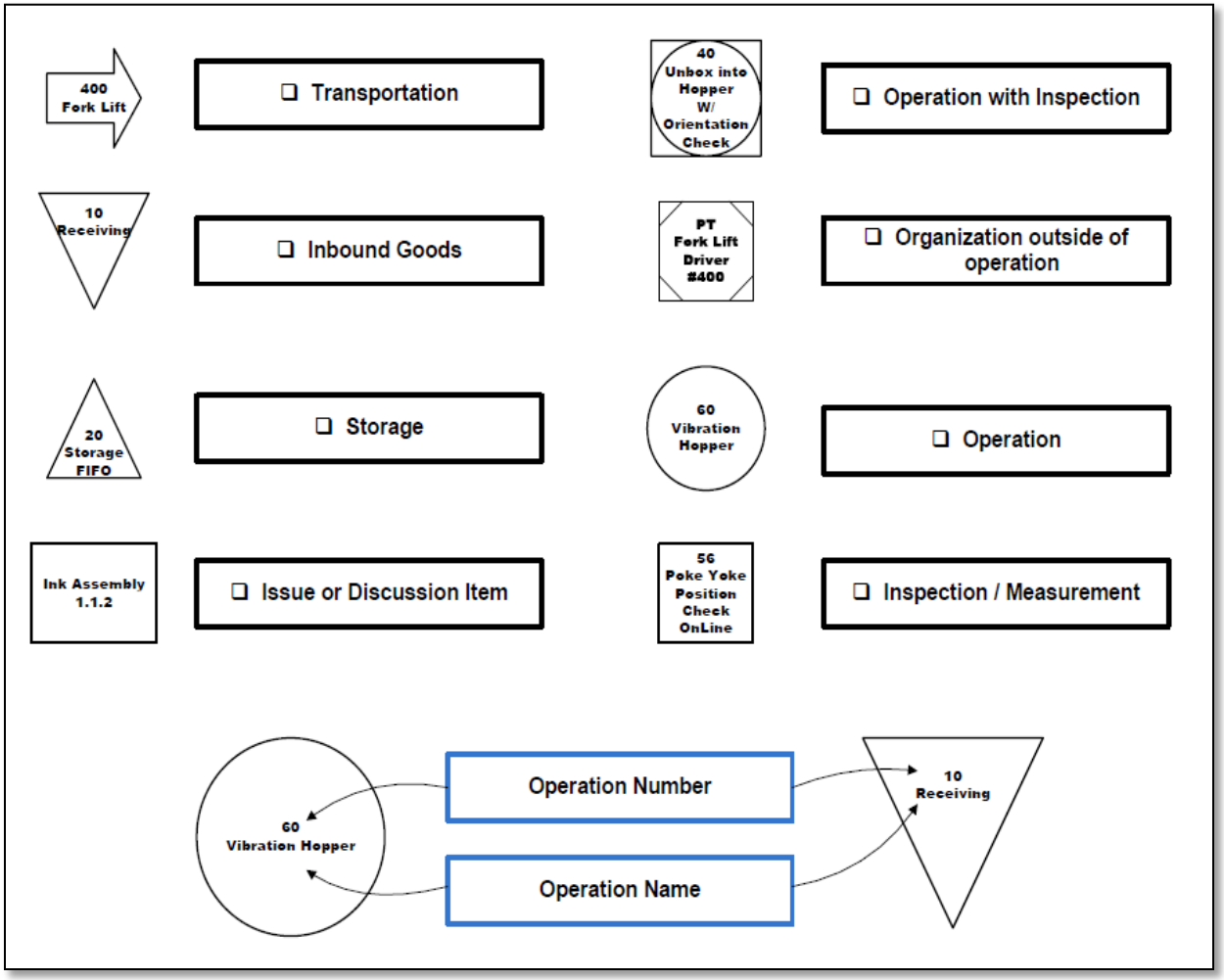


Pen Assembly Process Map



Process Flow Diagram Template

Standard Manufacturing Process Flow Symbols



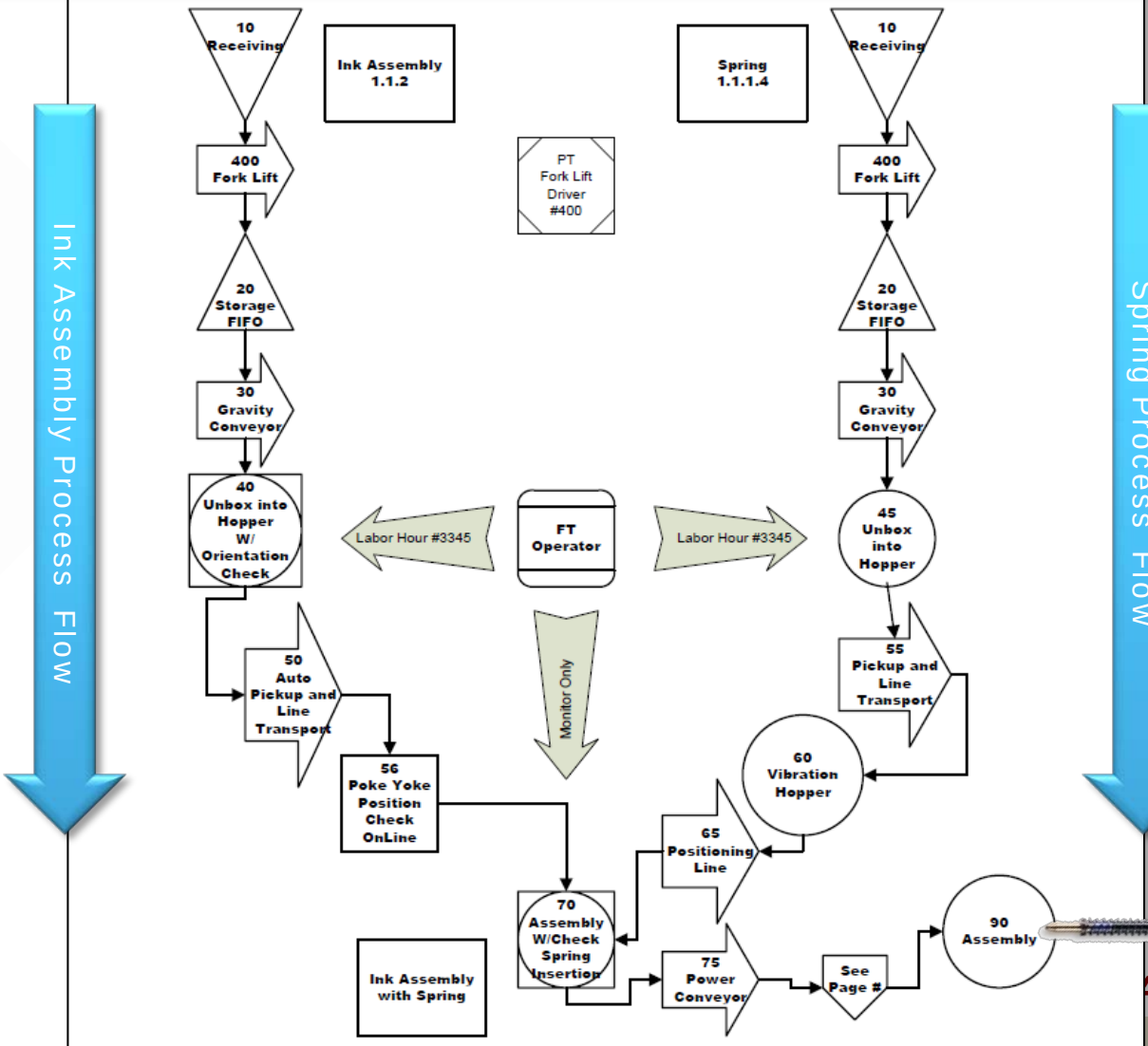
A process flow diagram describes the flow of the product through the process from incoming to outgoing. This should include each step In a manufacturing or assembly process as well as their related outputs (product characteristics, requirements, deliverables, etc.) and inputs (process characteristics, sources of variation, etc.). The details of the process flow depends on the stage of process development discussion.

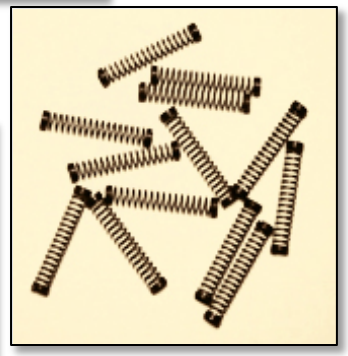
Objective: To understand the work flow of a process and the operations required

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

	Design FMEA	Process FMEA	Transactional FMEA
Block Diagram	X		
Process Map		X	X
WBS	X		
Parameter (P) Diagram	X	X	X
Process Flow Diagram		X	

Section C

How to Do FMEA

Bottom Line Up Front

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 x O x 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.

Item

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.
1											

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 it's support documents. A WBS example might look like “1.1.2.3” or some similar format.

Item name / Function

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.

2

An item can have more than one function, and therefore more than one failure mode.

Enter the name and function of the item being analyzed.

Examples of functions include:

- **Torque Converter - Transmit torque**
- **Corrosion Coating - Resist corrosion**
- **Bearing Retainer - Retain bearing**

Ball Design FMEA Exercise

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.
1.1.2.3	Ball / deliver ink to paper										

Potential Failure Mode

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.

3

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

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.

4

Describe what the customer might notice or experience

Examples of effects:
- **Vehicle cannot move**
- **Shortened material life span**
- **Excessive vibration and noise**

Ball Design FMEA Exercise

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.
1.1.2.3	Ball / deliver ink to paper										

Ball Design FMEA Exercise

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1.1.2.3	Ball / deliver ink to paper	Not enough ink delivered to paper	Intermittent line / skipping								
		No ink delivered to paper	Pen discarded								
		Too much ink delivered to paper	Document ruined								

Potential Causes

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.

List all potential causes of the failure

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

Current Design Controls - Prevention

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.

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

Examples of prevention actions:

- **Use hardened material**
- **Exceed minimum coating thickness**
- **Stay within specifications**

Current Design Controls – Detection

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.

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

Examples of detection actions:

- **Batch hardness testing**
- **Corrosion testing (salt / humidity)**
- **Validation testing**

Ball Design FMEA Exercise

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.
1.1.2.3	Ball / deliver ink to paper	Not enough ink delivered to paper	Intermittent line / skipping								
		No ink delivered to paper	Pen discarded								
		Too much ink delivered to paper	Document ruined								

Ball Design FMEA Exercise

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.
1.1.2.3	**Ball / deliver ink to paper**	**Not enough ink delivered to paper**	**Intermittent line / skipping**			Ball diameter variations	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		
						Paper surface finsh variation; too rough or too smooth	Paper surface finish range specification		No control		
						Ball surface finsh variation	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		
						Ball diameter too big; blocking flow of ink	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		
						User does not exert sufficient pressure	Force study done on users		Test: pressure vs ink delivery; 6 parts per month 0-6 psi		
						User holds pen at extreme angle	Grip angle study done on users		Test: angle vs ink delivery; 6 parts per month 0 - 90 degrees		
		No ink delivered to paper	**Ripped paper**			Ball diameter too big; blocking flow of ink	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		
		Too much ink delivered to paper	**Document ruined**			Ball diameter too small	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		
						User exerts excessive pressure	Force study done on users		Test: pressure vs ink delivery; 6 parts per month 0-6 psi		
						Improper hardness of ball material	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		

Ranking Failure Modes

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:

- RPN = Severity (S) x Occurrence (O) x 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

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.
				8							

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

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.
								9			

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

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.

10

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.

Risk Priority Number

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.

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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 = (Severity x Occurrence x Detection)
= S x O x 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.

Hrii-FMEA

Ball Design FMEA Exercise

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.
1.1.2.3	**Ball / deliver ink to paper**	**Not enough ink delivered to paper**	**Intermittent line / skipping**			Ball diameter variations	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		
						Paper surface finsh variation; too rough or too smooth	Paper surface finish range specification		No control		
						Ball surface finsh variation	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		
						Ball diameter too big; blocking flow of ink	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		
						User does not exert sufficient pressure	Force study done on users		Test: pressure vs ink delivery; 6 parts per month 0-6 psi		
						User holds pen at extreme angle	Grip angle study done on users		Test: angle vs ink delivery; 6 parts per month 0 - 90 degrees		
		No ink delivered to paper	**Ripped paper**			Ball diameter too big; blocking flow of ink	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		
		Too much ink delivered to paper	**Document ruined**			Ball diameter too small	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		
						User exerts excessive pressure	Force study done on users		Test: pressure vs ink delivery; 6 parts per month 0-6 psi		
						Improper hardness of ball material	Tolerance specification		Supplier self certification and incoming inspection 10 of every lot		

Ball Design FMEA Exercise

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.
1.1.2.3	**Ball / deliver ink to paper**	**Not enough ink delivered to paper**	**Intermittent line / skipping**	7		Ball diameter variations	Tolerance specification	1	Supplier self certification and incoming inspection 10 of every lot	2	**14**
				7		Paper surface finsh variation; too rough or too smooth	Paper surface finish range specification	6	No control	10	**420**
				7		Ball surface finsh variation	Tolerance specification	2	Supplier self certification and incoming inspection 10 of every lot	2	**28**
				7		Ball diameter too big; blocking flow of ink	Tolerance specification	1	Supplier self certification and incoming inspection 10 of every lot	2	**14**
				7		User does not exert sufficient pressure	Force study done on users	5	Test: pressure vs ink delivery; 6 parts per month 0-6 psi	4	**140**
				7		User holds pen at extreme angle	Grip angle study done on users	5	Test: angle vs ink delivery; 6 parts per month 0 - 90 degrees	4	**140**
		No ink delivered to paper	**Ripped paper**	5		Ball diameter too big; blocking flow of ink	Tolerance specification	1	Supplier self certification and incoming inspection 10 of every lot	2	**10**
		Too much ink delivered to paper	**Document ruined**	9		Ball diameter too small	Tolerance specification	1	Supplier self certification and incoming inspection 10 of every lot	2	**18**
				9		User exerts excessive pressure	Force study done on users	5	Test: pressure vs ink delivery; 6 parts per month 0-6 psi	4	**180**
				9		Improper hardness of ball material	Tolerance specification	2	Supplier self certification and incoming inspection 10 of every lot	2	**36**

Barrel Design FMEA Example

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.	Recommended Actions
1.1.1.2	Barrel/Captures ink sub-system	Does not capture ink sub-system	Lose ink sub-system	7		Wrong ink sub-system	Incoming inspection (100 every lot)	6	Material specification on detail drawing and BOM, validated during testing	2	84	
				7		No plunger to capture ink sub-system	Visual inspection	6	Automated Assembly check	4	168	
		Interferes with retraction of ink sub-system	Prevents retraction	7		Warping of barrel (wrong material selection)	Material specification	2	Function check testing	6	84	
				7		Warping of ink sub-system (wrong material selection)	Material specification	2	Material specification on detail drawing and BOM, validated during testing	2	28	
	Barrel/Captures plunger sub-system	Does not capture plunger sub-system	Unfinished pen assembly	7		Barrel inside diameter too big	Tolerance specification	2	Verification testing	4	56	
				7		Barrel inside diameter too small	Tolerance specification	2	Verification testing	4	56	
				7		Wrong plunger diameter	Tolerance specification	2	Verification testing	4	56	
				7		Improper press fit (wrong GD&T)	GD&T	2	Verification testing	4	28	
			Lose ink sub-system	7		No plunger to capture ink sub-system	Visual inspection	6	Requires visual signoff by engineering team prior to testing	4	168	
	Barrel/captures nib	Does not capture nib	Unfinished pen assembly	7		Barrel inside diameter too big	Tolerance specification	2	Verification testing	4	56	
				7		Barrel inside diameter too small	Tolerance specification	1	Verification testing	4	28	
				7		Warping of barrel (wrong material)	Material specification	**2**	Material specification on detail drawing and BOM, validated during testing	6	84	
				7		Wrong nib diameter	Tolerance specification	1	Verification testing	4	28	
				7		Improper press fit (wrong GD&T)	GD&T	2	Verification testing	4	56	

PFMEA (differences from DFMEA)

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) **<u>Design</u> failures**	**Process FMEA (PFMEA)** **<u>Manufacturing</u> failures**	**Process FMEA (PFMEA)** **<u>Assembly</u> failures**
• Generates heat • Slow acceleration • Cannot track target	• Porous casting • Poorly machined finish • Injection molding short shot	• 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.

PFMEA (differences from DFMEA)

DESIGN FMEA

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.
9	10	11	12	16		13	14	17	15	18	19

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.

PROCESS FMEA

Process step #	Process step function / requirements	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Process Controls Prevention	Occurrence	Current Process Controls Detection	Detect	R.P.N.
9	10	11	12	16		13	17	14	15	18	19

PFMEA Exercise

PLEASE DO NOT LOOK BEYOND THIS SLIDE!

The next three slides contain the completed PFMEA

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.

Pen Assembly PFMEA

Process step #	Process step function / requirements	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Process Controls Prevention	Occurrence	Current Process Controls Detection	Detect	R.P.N.
1	Load ink tube vertically into fixture	Tube mis-aligned	Spring cannot be inserted	5		Fixture features/dimensions incorrect	Fixture drawings	3	In line sensor	2	30
1				5		Operator not trained	Work instructions	5	Visual inspection	7	175
1		Tube missing	Spring cannot be inserted	5		Fixture features/dimensions incorrect (tube fell out)	Fixture drawings	3	In line sensor	2	30
1				5		Operator forgot to load tube	Visual inspection	6	No detection control	10	300
2	Load spring into press	Spring mis-aligned	Spring cannot be inserted	5		Press features/dimensions incorrect	Fixture drawings	3	In line sensor	2	30
2				5		Operator not trained	Work instructions	5	Visual inspection	7	175
2		Spring missing	Spring cannot be inserted	5		Press features/dimensions incorrect (spring fell out)	Fixture drawings	3	In line sensor	2	30
2			Spring cannot be inserted	5		Operator forgot to load spring	Visual inspection	6	No detection control	10	300
3	Press spring on to tube	Spring not fully pressed on to tube	Spring may fall off in a later step	7		Press does not move far enough down	Position sensors	1	Visual inspection	8	56
3				7		Operator did not activate press	Visual reminder (green light)	6	No detection control	10	420
3		Spring pressed on to tube too far	Ink/tube may not retract/extend	10	KPP	Press travel incorrect	Hard stop on press	1	Optical sensor	4	40
3		Spring not on tube at all	Rework needed	8		Spring fell off of press while moving downward	Part orientation	4	Visual inspection	8	256
3		Spring pressed on incorrectly (crooked)	Ink/tube may not retract/extend	10	KPP	Fixture/press alignment issue	Verify alignment at each shift	2	Hourly audits	6	120
3		Spring pressed on incorrectly (crooked)	Ink/tube cannot be inserted into housing	5		Fixture/press alignment issue	Verify alignment at each shift	2	Hourly audits	6	60

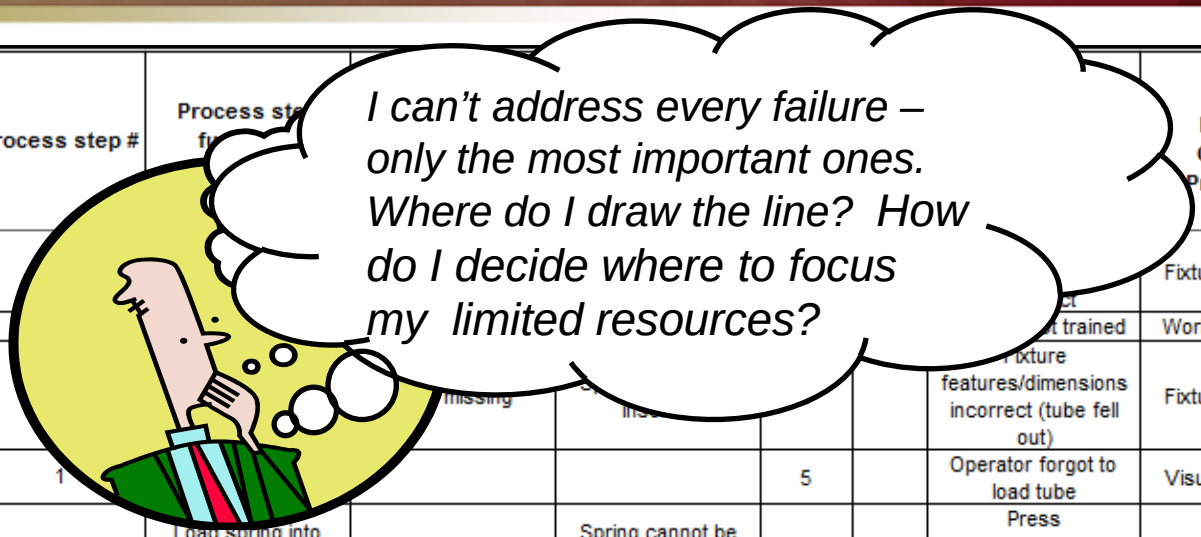
Pen Assembly PFMEA

Process step #	Process step function / requirements	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Process Controls Prevention	Occurrence	Current Process Controls Detection	Detect	R.P.N.
4	Load plunger ass'y to fixture	Plunger ass'y misaligned	Housing cannot be added	5		Fixture features/dimensions incorrect	Fixture drawings	3	In line sensor	2	30
4				5		Operator not trained	Work instructions	5	No detection control	10	250
4		Plunger ass'y missing	Housing cannot be added	5		Fixture features/dimensions incorrect (plunger ass'y fell out)	Fixture drawings	3	In line sensor	2	30
4				5		Operator forgot to load plunger ass'y	Visual inspection	6	No detection control	10	300
5	Load barrel on to press	Barrel mis-aligned	Housing cannot be added	5		Press features/dimensions incorrect	Press drawings	3	In line sensor	2	30
5				5		Operator not trained	Work instructions	5	No detection control	10	250
5				5		Press features/dimensions incorrect (barrel fell out)	Press drawings	3	In line sensor	2	30
5				5		Operator forgot to load barrel	Visual inspection	6	No detection control	10	300
6	Press barrel on to plunger	Barrel not fully pressed on to plunger	Barrel may fall off in a later step	7		Press does not move far enough down	Position sensors	1	No detection control	10	70
6				7		Operator did not activate press fully	Visual reminder (blue light)	6	No detection control	10	420
6		Barrel pressed on to plunger too far	Damaged parts/Scrap	8		Press travel incorrect	Position sensors	1	No detection control	10	80
6		Barrel not on plunger at all	Rework needed	8		Barrel fell off of tube	Part orientation	4	No detection control	10	320
6		Barrel pressed on incorrectly	Damaged parts/Scrap	8		Fixture/press alignment issue	Verify alignment at each shift	2	Hourly audits	6	96

Pen Assembly PFMEA

Process step #	Process step function / requirements	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Process Controls Prevention	Occurrence	Current Process Controls Detection	Detect	R.P.N.
7	Drop ink/spring ass'y into housing ass'y	Ink/spring ass'y missing from housing ass'y	Pen could be assembled without writing mechanism	10	KPP	Operator poorly placed component	Visual inspection	6	No detection control	10	600
8	Insert nib into press	Nib mis-aligned	Nib cannot be inserted	5		Press features/dimensions incorrect	Press drawings	3	In line sensor	2	30
9	Press nib on to housing ass'y	Nib not fully pressed on to housing	Nib may fall off and ink/spring ass'y fall out later	7		Press does not move far enough down	Position sensors	1	No detection control	10	70
9				7		Operator did not activate press fully	Visual reminder (blue light)	6	No detection control	10	420
9		Nib pressed on to housing too far	Damaged parts/Scrap	8		Press travel incorrect	Position sensors	1	No detection control	10	80
9		Nib not on housing at all	Rework needed	8		Barrel fell off of tube	Part orientation	4	No detection control	10	320
9		Nib pressed on incorrectly	Damaged parts/Scrap	8		Fixture/press alignment issue	Verify alignment at each shift	2	Hourly audits	6	96

Take Action Where Needed



Process step #	Process step function	Potential Failure Mode	Potential Failure Effects	Severity	Classification	Potential Cause(s) / Mechanism(s) of Failure	Current Process Controls Prevention	Occurrence	Current Process Controls Detection	Detect	R.P.N.
							Fixture drawings	3	In line sensor	2	30
						t trained	Work instructions	5	Visual inspection	7	175
		missing	Ins			Fixture features/dimensions incorrect (tube fell out)	Fixture drawings	3	In line sensor	2	30
1				5		Operator forgot to load tube	Visual inspection	6	No detection control	10	300
2	Load spring into press	Spring mis-aligned	Spring cannot be inserted	5		Press features/dimensions incorrect	Fixture drawings	3	In line sensor	2	30
2				5		Operator not trained	Work instructions	5	Visual inspection	7	175
2		Spring missing	Spring cannot be inserted	5		Press features/dimensions incorrect (spring fell out)	Fixture drawings	3	In line sensor	2	30
2			Spring cannot be inserted	5		Operator forgot to load spring	Visual inspection	6	No detection control	10	300
3	Press spring on to tube	Spring not fully pressed on to tube	Spring may fall off in a later step	7		Press does not move far enough down	Position sensors	1	Visual inspection	8	56
3				7		Operator did not activate press	Visual reminder (green light)	6	No detection control	10	420
3		Spring pressed on to tube too far	Ink/tube may not retract/extend	10	KPP	Press travel incorrect	Hard stop on press	1	Optical sensor	4	40
3		Spring not on tube at all	Rework needed	8		Spring fell off of press while moving downward	Part orientation	4	Visual inspection	8	256
3		Spring pressed on incorrectly (crooked)	Ink/tube may not retract/extend	10	KPP	Fixture/press alignment issue	Verify alignment at each shift	2	Hourly audits	6	120
3		Spring pressed on incorrectly (crooked)	Ink/tube cannot be inserted into housing	5		Fixture/press alignment issue	Verify alignment at each shift	2	Hourly audits	6	60

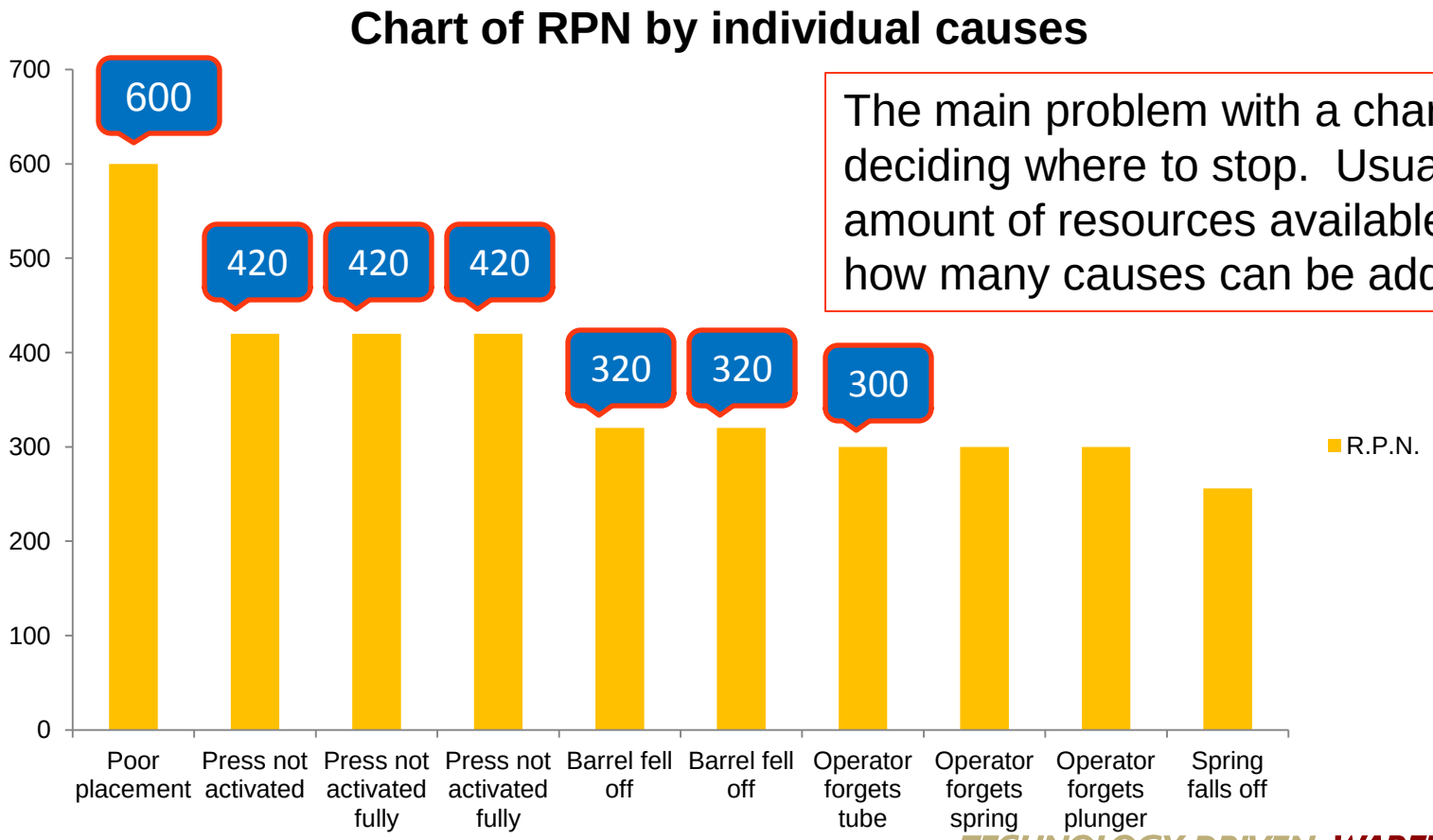
Prioritizing Failure Modes/ Mitigation Actions

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 straight forward 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.

Take Action Where Needed

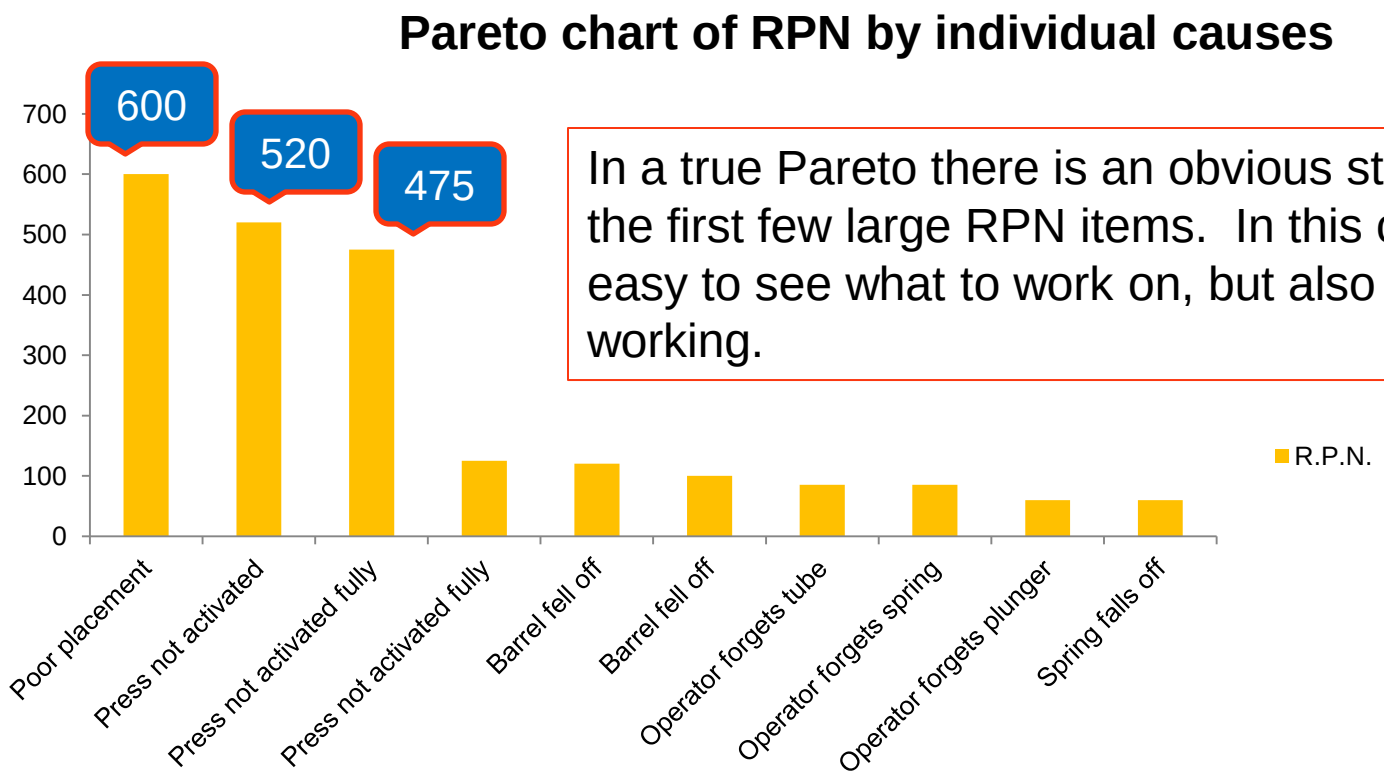
A chart can be made of RPN versus cause. Without a Pareto, the easiest way to decide what to work on is to simply sort by RPN and address the highest items. In a simple rank order chart the RPN falls (descends) by even, somewhat linear steps.



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.

Take Action Where Needed

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.

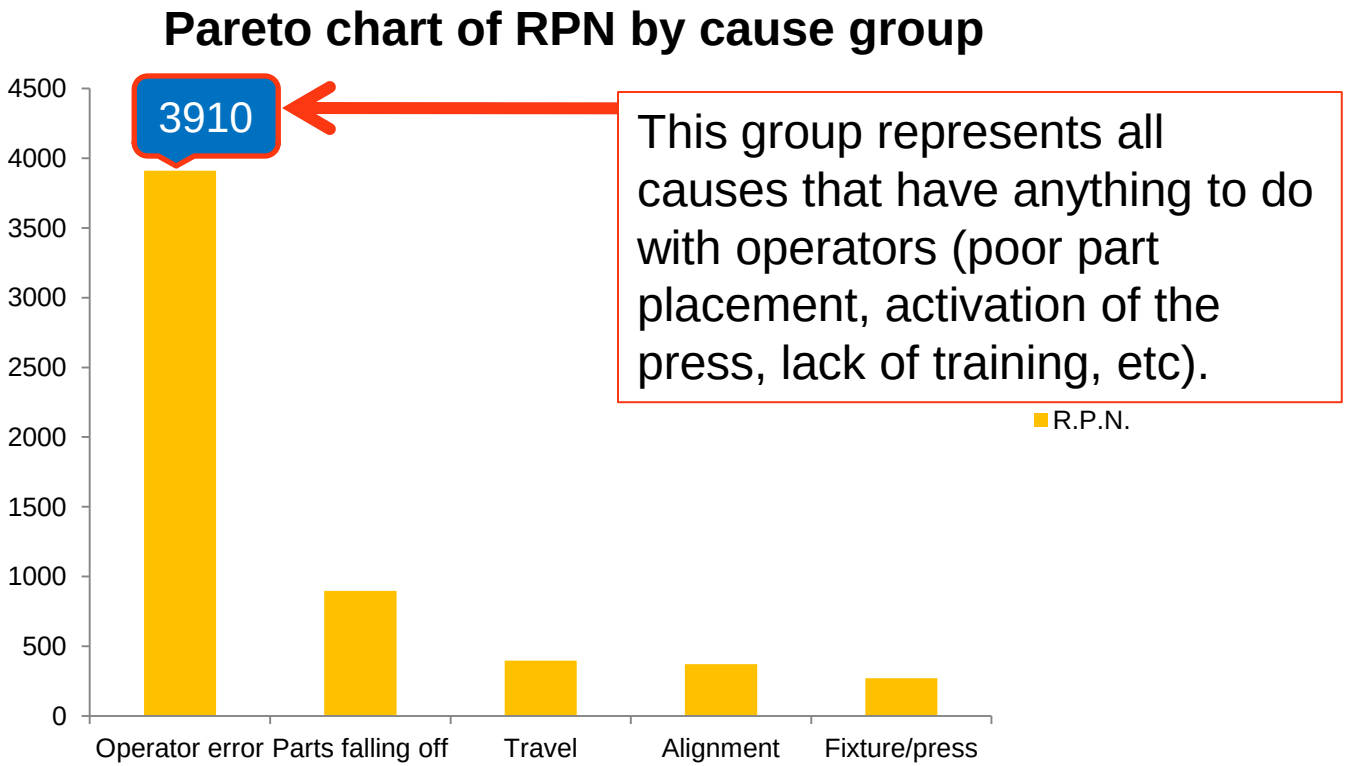


In a true Pareto there is an obvious step down after the first few large RPN items. In this case it is not only easy to see what to work on, but also where to stop working.

Take Action Where Needed

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!



Recommended Action

Recommended Actions Plan	Responsibility & Target Completion Date	Action Results				
		Actions Taken	Severity	Occur	Detection	R.P.N.

12

Describe what actions are needed to reduce the overall RPN

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

Recommended Action

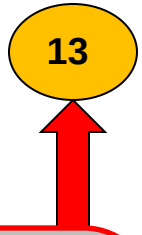
The primary objective of the recommended action is to reduce risk thereby reducing the possibility of failure. This in turn increases customer satisfaction and lowers cost.

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.

Responsibility & Target Completion Date

Recommended Actions Plan	Responsibility & Target Completion Date	Action Results				
		Actions Taken	Severity	Occur	Detection	R.P.N.



Name who will take action and when

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**

Target Completion Date

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

Recommended Actions Plan	Responsibility & Target Completion Date	Action Results				
		Actions Taken	Severity	Occur	Detection	R.P.N.

14

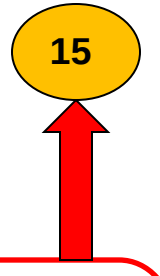
Describe ACTUAL actions taken

Actions taken:

- **Are not always identical to the recommendations (time and resources limited)**
- **May not get done when expected**

Action Results & New RPN

Recommended Actions Plan	Responsibility & Target Completion Date	Action Results				
		Actions Taken	Severity	Occur	Detection	R.P.N.



Recalculate New RPN

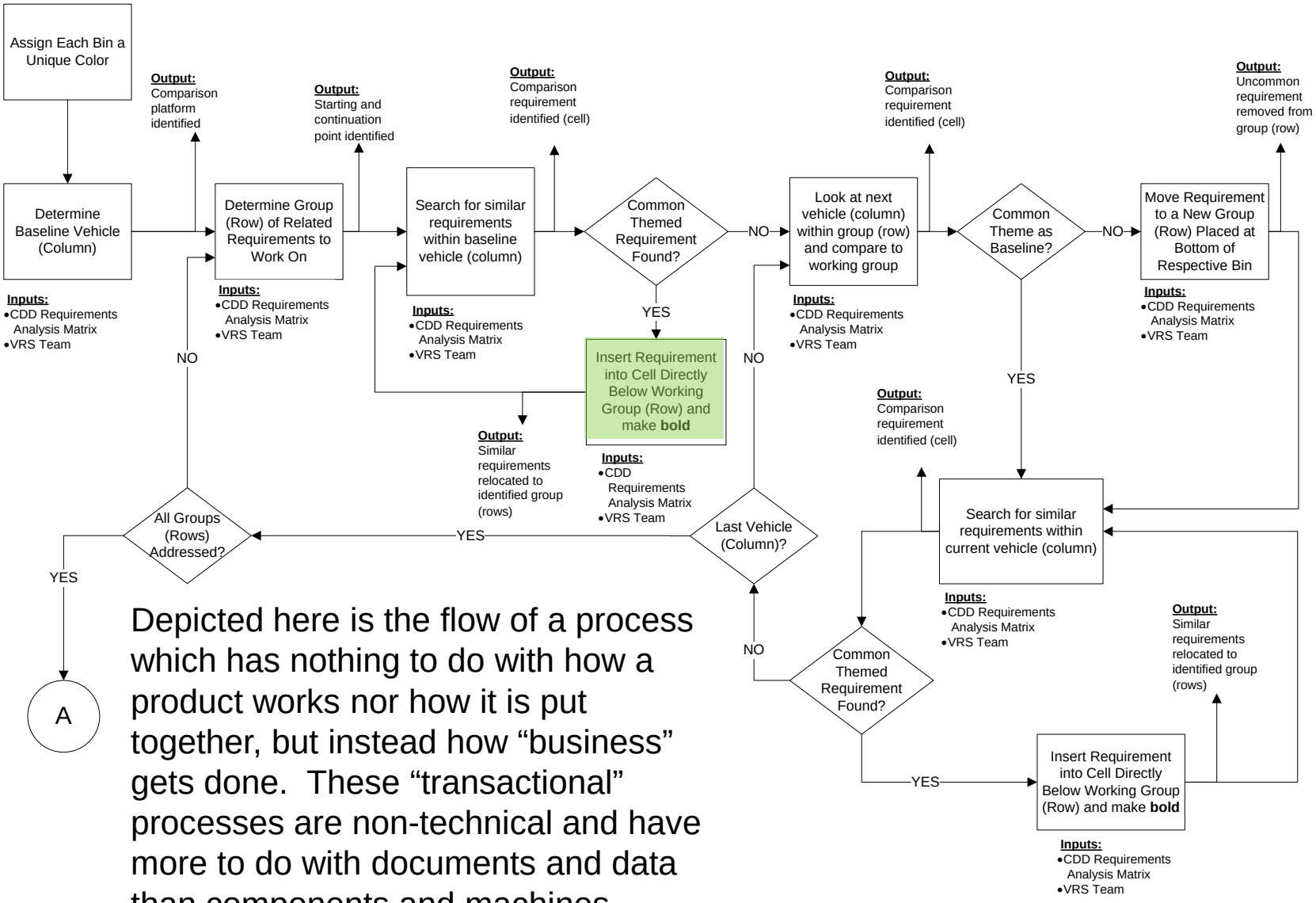
- **Once the action has been executed the team must indicate new severity, occurrence, and detection rankings where applicable**
- **Recalculate the RPN after re-ranking**

Ball Design FMEA Exercise

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.	Recommended Actions	Responsibility & Completion Date	Action Results: Actions Taken	Severity	Occur	Detection	R.P.N.
1.1.2.3	Ball / deliver ink to paper	Not enough ink delivered to paper	Intermittent line / skipping	7		Ball diameter variations	Tolerance specification	1	Supplier self certification and incoming inspection 10 of every lot	2	14							
				7		Paper surface finsh variation; too rough or too smooth	Paper surface finish range specification	6	No control	10	420	Study coefficient of friction vs ink delivery amount	G. Ratajczak 11 Nov 2011	Study complete - must control ball surface finish	7	1	10	70
				7		Ball surface finsh variation	Tolerance specification	2	Supplier self certification and incoming inspection 10 of every lot	2	28							
				7		Ball diameter too big; blocking flow of ink	Tolerance specification	1	Supplier self certification and incoming inspection 10 of every lot	2								
				7		User does not exert sufficient pressure	Force study done on users	5	Test: pressure vs ink delivery; 6 parts per month 0-6 psi	4								
				7		User holds pen at extreme angle	Grip angle study done on users	5	Test: angle vs ink delivery; 6 parts per month 0 - 90 degrees	4								
		No ink delivered to paper	Ripped paper	5		Ball diameter too big; blocking flow of ink	Tolerance specification	1	Supplier self certification and incoming inspection 10 of every lot									
		Too much ink delivered to paper	Document ruined	9		Ball diameter too small	Tolerance specification	1	Supplier self certification and incoming inspection 10 of every lot		18							
				9		User exerts excessive pressure	Force study done on users	5	Test: pressure vs delivery; 6 parts month 0-6 p		180							
				9		Improper hardness of ball material	Tolerance specification	2	Suppl certifica incoming in 10 of ev	2	36							

Recommended Actions	Responsibility & Target Completion Date	Action Results: Actions Taken	Severity	Occur	Detection	R.P.N.
Study coefficient of friction vs ink delivery amount	G. Ratajczak 11 Nov 2011	Study complete - must control ball surface finish	7	1	10	70

Transactional FMEA Example



Depicted here is the flow of a process which has nothing to do with how a product works nor how it is put together, but instead how “business” gets done. These “transactional” processes are non-technical and have more to do with documents and data than components and machines.

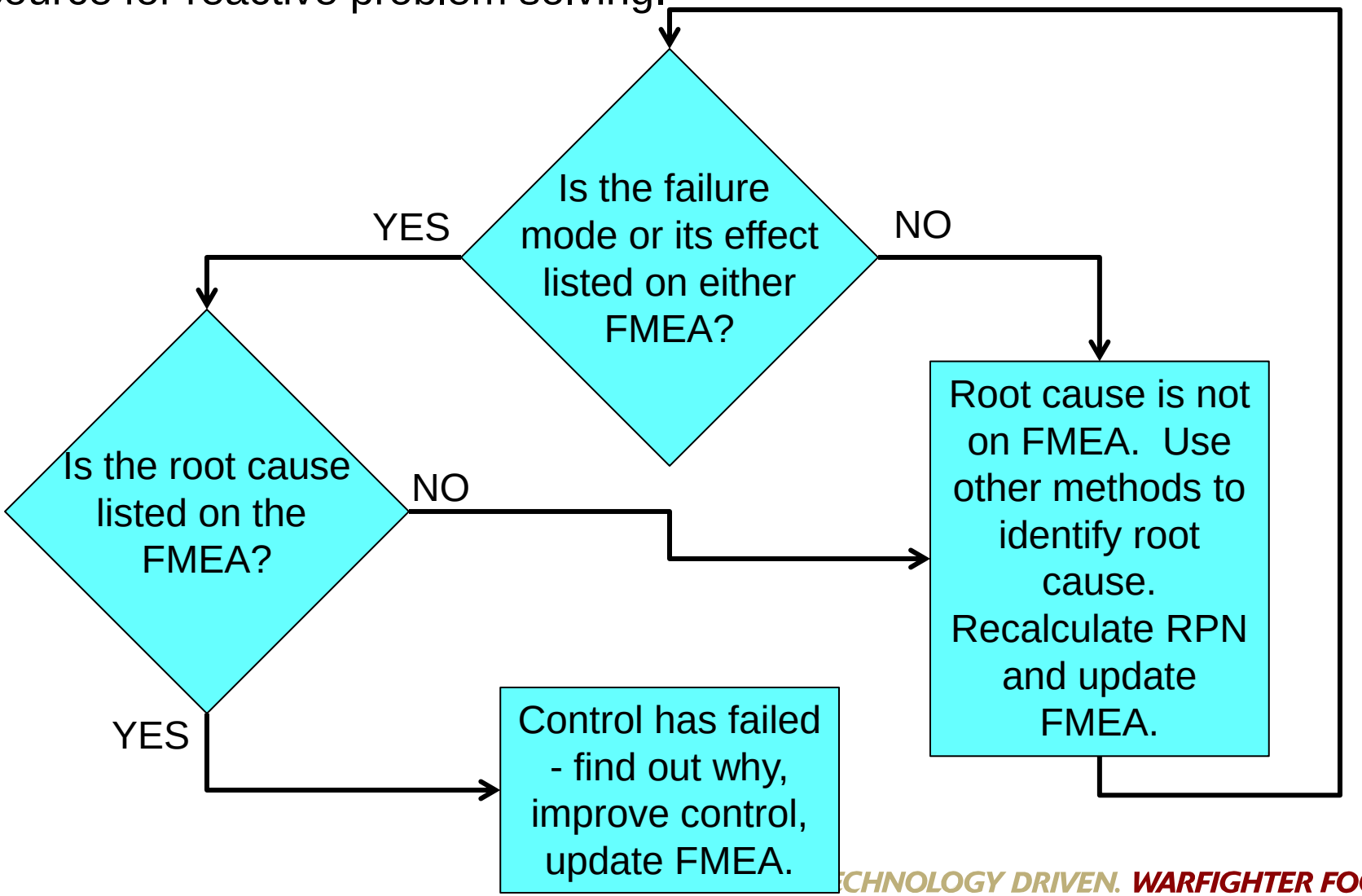
Transactional FMEA Example

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.

Process step function / requirements	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Process Controls Prevention	Occurrence	Current Process Controls Detection	Detect	R.P.N.	Recommended Actions
Insert Requirement into Cell Directly Below Working Group (Row) and Make **Bold**	Similar req't placed in incorrect row, but did not overwrite anything	Duplication of superset requirements, resulting in additional work / schedule delay	7		VRS Team human error	None	10	Deconfliction process forces reconsideration of stand alone req'ts	1	**70**	
Insert Requirement into Cell Directly Below Working Group (Row) and Make **Bold**	Similar req't placed directly below working group row, but overwrites an existing req't	Incorrect superset requirement generated (overwritten req't present in other platforms, but was the driving req't for a superset req't)	8		VRS Team human error	None	10	None	10	**800**	Count number of req'ts for each platform before commonizing req'ts within that platform. Check req't count after commonizing req'ts to ensure that the number does not change.
Insert Requirement into Cell Directly Below Working Group (Row) and Make **Bold**	Similar req't placed directly below working group row, but overwrites an existing req't	SIL lacks capability in question (overwritten req't not present in other platforms, so entire capability is lost)	10		VRS Team human error	None	10	None	10	**1000**	Count number of req'ts for each platform before commonizing req'ts within that platform. Check req't count after commonizing req'ts to ensure that the number does not change.
Insert Requirement into Cell Directly Below Working Group (Row) and Make **Bold**	Similar req't not moved at all	Incorrect superset requirement generated	8		VRS Team human error	None	10	Continued req't commonization will ensure the non-moved req't is assessed for commonality (which would catch the duplicate req't)	1	**80**	
Insert Requirement into Cell Directly Below Working Group (Row) and Make **Bold**	Similar req't not moved at all	Duplication of superset requirements, resulting in additional work / schedule delay	7		VRS Team human error	None	10	Continued req't commonization will ensure the non-moved req't is assessed for commonality (which would catch the duplicate req't)	1	**70**	
Insert Requirement into Cell Directly Below Working Group (Row) and Make **Bold**	Partial move of similar req't (failure to move comments, rationale, and traceability when relocating a similar req't)	Difficulty creating superset requirement due to missing details	5		VRS Team human error	None	10	None	10	**500**	Upon completion of requirement commonization for a platform, expand the collapsed column and look for rows that have comments, rationale, and/or traceability without an associated req't
Insert Requirement into Cell Directly Below Working Group (Row) and Make **Bold**	Req't copied and pasted, instead of cut and pasted	Duplication of superset requirements, resulting in additional work / schedule delay	7		VRS Team human error	None	10	Continued req't commonization will ensure the duplicate req't is assessed for commonality (which would catch the	1	**70**	Count number of req'ts for each platform before commonizing req'ts within that platform. Check req't count after commonizing req'ts to ensure that the number does not change.

Using FMEA for Root Cause Analysis

In the event that a failure mode is encountered, the FMEA can be the first source for reactive problem solving.



Using FMEA for Root Cause Analysis - Example

<u>Situation:</u> 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.

Ground Vehicle (GV) - Example

- **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:

Design Responsibility :
Kick off Date :

Item / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Potential Causes / Mechanisms of Failure	Occurrence	Current Controls: Prevention Controls	Current Controls: Detection Controls
[1] The fan subsystem shall meet airflow requirements (6 in. WCΔP 1500 CFM for XXXX)	**[1.1]** The fan subsystem **does not** meet airflow requirements (6 in. WCΔP 1500 CFM for XXXX)	Complete loss of airflow (8)	8	**[1.1.1]** Loss of source current / voltage - Blown fuse - Broken wire	4	- 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	- **Yuma** - Test vehicle - **New Yuma** - test vehicle
		Partial loss of airflow (6)		**[1.1.2]** Over-voltage / Transients	3		- **FW 3** - Electrical Requirements and characterization - **FW 4** - Body Fan Requirement validation - **Yuma** - Test vehicle - **New Yuma** - test vehicle
				[1.1.3] Control circuit malfunction	5		- **FW 3** - Electrical Requirements and characterization - **FW 4** - Body Fan Requirement validation - **Yuma** - Test vehicle - **New Yuma** - test vehicle
				[1.1.4] Mechanical impedence/obstruction that either slows or stops the rotation of the impeller (internal/external contamination)	6		- **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**

Using FMEA for Root Cause Analysis - Exercise

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

FMEA and Risk Management

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.

Transferring Risks from FMEA to Risk Management/Risk Recon

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.

Government Contracts and FMEA

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 sub-contractor 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.

Suggested Government Contracts' Language for FMEA

- **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.

Evaluating/Managing FMEAs

Preparing:

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.

Evaluating/Managing FMEAs

Managing:

Work with FMEA owners to address and close identified action items

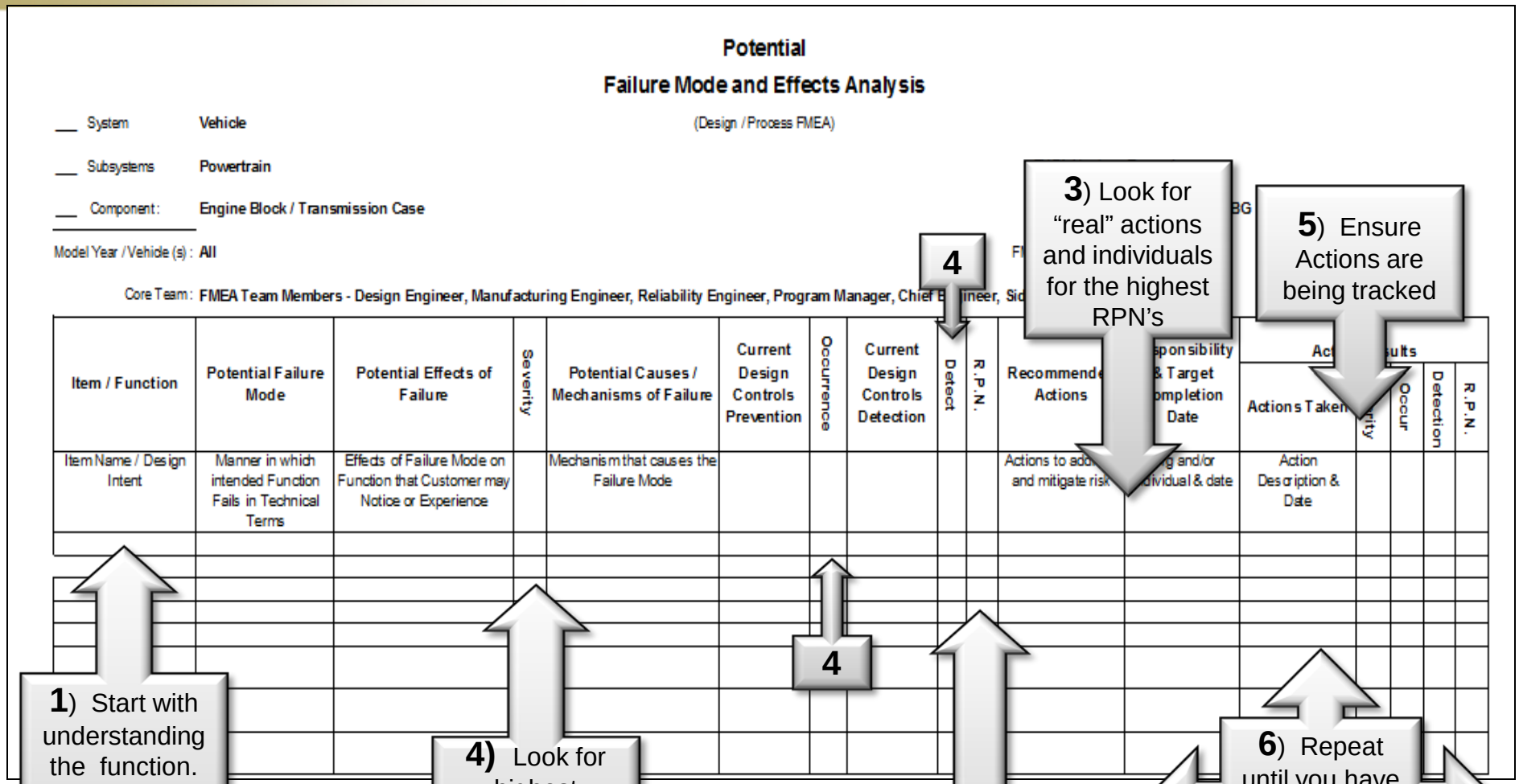
Ensure FMEAs are reviewed at appropriate times throughout contract execution

- 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

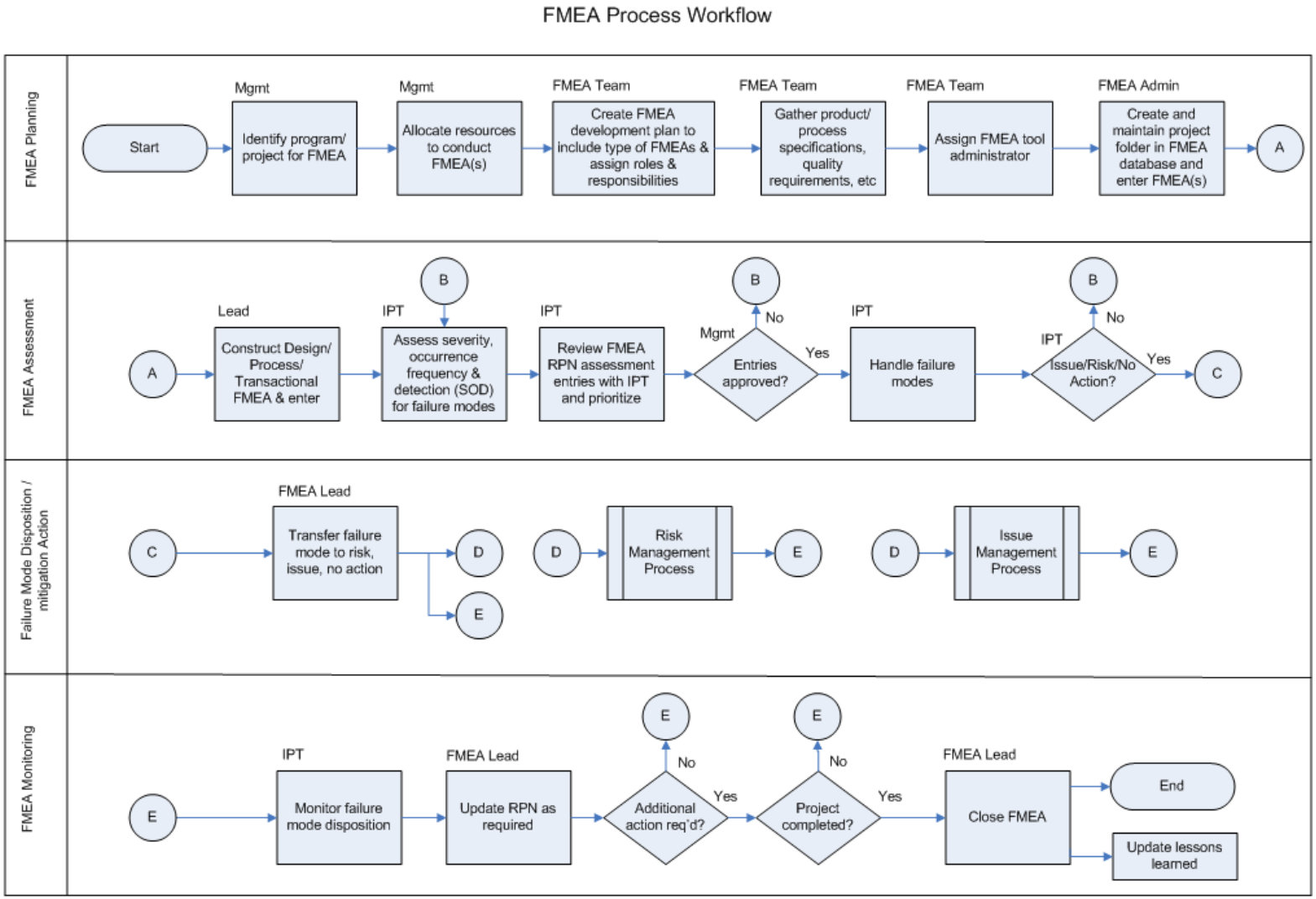
Quick FMEA Review Technique



Section E

Summary and Appendix

Summary of all FMEA Activities



DFMEA Severity Table

Category (Product)	Severity of Effect on Product (DFMEA)	FMEA Rank	Risk Conseq-uence Rank
Safety and/or Regulatory Compliance	Failure could injure the user or an employee	10	5
	Failure would create noncompliance with federal regulations	9	
Primary Function (Essential)	Failure renders the unit inoperable or unfit for use	8	
	Failure causes a high degree of user dissatisfaction	7	4
Secondary Function (Convenient)	Failure results in a subsystem or partial malfunction of the product	6	
	Failure creates enough of a performance loss to cause the user to complain	5	3
Annoyance	Failure can be overcome with modifications to the user's process or product, but there is minor performance loss	4	
	Failure would create a minor nuisance to the user, but the user can overcome it without performance loss	3	2
	Failure may not be readily apparent to the user, but would have minor effects on the user's process or product	2	
No Effect	Failure would not be noticeable to the user and would not affect the user's process or product	1	1

DFMEA Occurrence Table

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

DFMEA Detection Table

Category (Product)	Detection of Cause (DFMEA)	FMEA Rank
Absolute Uncertainty	No current design control; cannot detect or is not analyzed	10
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	9
Post Design Freeze and Prior to Launch	Product verification/validation after design freeze and prior to launch with **pass/fail** testing (sub-system or system testing with acceptance criteria e.g. ride and handling, shipping evaluation, etc.)	8
	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
	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)	6
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.)	5
	Product validation (reliability testing, development or validation tests) prior to design freeze using **test to failure** (e.g. until leaks, yields, cracks, etc.)	4
	Product validation (reliability testing, development or validation tests) prior to design freeze using **degradation** testing (e.g. data trends, before/after values, etc.)	3
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	2
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.)	1

PFMEA Severity Table

Category (Process)	Severity of Effect on Process (PFMEA)	FMEA Rank	Risk Conseq-uence Rank
Safety and/or Regulatory Compliance	May endanger operator (machine or assembly) without warning	10	5
	May endanger operator (machine or assembly) with warning	9	
Major Disruption; Major Effect on Throughput	100% of product may have to be scrapped and/or line shutdown or stop ship	8	4
Significant Disruption; Significant Effect on Throughput	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	7	
Rework out-of-station; Moderate Effect on Throughput	100% of production run may have to be reworked off line and accepted	6	3
	A portion of the production run may have to be reworked off line and accepted	5	
Rework in-station; Minor Effect on Throughput	100% of production run may have to be reworked in station before it is processed	4	2
	A portion of the production run may have to be reworked in station before it is processed	3	
Minor Disruption	Slight inconvenience to process, operation, or operator	2	1
No Effect	No discernable effect	1	

PFMEA Occurrence Table

Likelihood of Failure	Occurrence of Cause (PFMEA)	Ppk	FMEA Rank	Risk Likelihood Rank
Very High	≥ 100 per thousand pieces	< 0.55	10	5
High	50 per thousand pieces	≥ 0.55	9	
	20 per thousand pieces	≥ 0.78	8	4
	10 per thousand pieces	≥ 0.86	7	
Moderate	5 per thousand pieces	≥ 0.94	6	3
	2 per thousand pieces	≥ 1.00	5	
	1 per thousand pieces	≥ 1.10	4	2
Low	0.5 per thousand pieces	≥ 1.20	3	
	0.1 per thousand pieces	≥ 1.30	2	1
Very Low	≤ 0.01 per thousand pieces	≥ 1.67	1	

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

Category (Process)	Detection of Cause (PFMEA)	FMEA Rank
Absolute Uncertainty	No current process control; cannot detect or is not analyzed	10
Difficult to Detect	Defect (failure mode) and/or error (cause) is not easily detected (e.g. random audits)	9
Defect Detection Post Processing	Defect (failure mode) detection post-processing by operator through visual/tactile/audible means	8
Defect Detection at Source	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.)	7
Defect Detection Post Processing	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.)	6
Defect Detection at Source	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)	5
Defect Detection Post Processing	Defect (failure mode) detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing	4
Defect Detection at Source	Defect (failure mode) detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing	3
Error Detection and/or Defect Prevention	Error (cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made	2
Detection not applicable; Error Prevention	Error (cause) prevention as a result of fixture design, machine design or part design	1

DFMEA Template and Definitions

Potential
Failure Mode and Effects Analysis
(Design FMEA)

(1) FMEA # :_____
Contract # :_____
Supplier :_____

(2) ___ System
___ Subsystems
___ Component :_____

(3) Design Responsibility:_____
Government POC:_____

(4) Prepared by :_____

(5) Program name :_____

(6) FMEA key date:_____

(7) FMEA date (Orig.) :_____ Revision date :_____

(8) Core Team :

Item #	Item name / Function	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detect	R.P.N.	Recommended Actions	Responsibility & Target Completion Date	Action Results				
														Actions Taken	Severity	Occur	Detection	R.P.N.
(9)	(10)	(11)	(12)	(16)		(13)	(14)	(17)	(15)	(18)	(19)	(20)	(21)	(22)		(23)		

DFMEA Template and Definitions

Item #	Name	Description	Further comments
1	FMEA Number Contract # Supplier/DPRP	Enter an appropriate FMEA document number, which may be used for tracking. Fill in as many fields as information allows.	FMEA numbers should follow a sequence as dictated by the existing reccomendations or practices of the OEM, Vendor, Supplier, Department and/or Group who has design responsibility.
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. - 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.
3	Design responsibility	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.	

DFMEA Template and Definitions

4	Prepared by	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.
5	Program name	Enter the name of the program.	
6	FMEA Key date	Enter the date the design FMEA is to be completed by and specify its relevance.	FMEA is a proactive tool meant to be a "before the event" action, not an "after the fact" 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.
7	FMEA date(Orig) and Revision date	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.

DFMEA Template and Definitions

8	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.
9	Item #	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 it's support documents. An example might look like 1.1.2.3 or similar format for a WBS element.
10	Item name/Function	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 "transmit data" or "support load" are easy to turn around into potential failure descriptions.

DFMEA Template and Definitions

11	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 uniquness. 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).
12	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.

DFMEA Template and Definitions

13	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 usualy 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 straight forward. Potential causes should be "root" causes and may require problem solving to discover.
14	Current Design Controls - Prevention	List the controls/feature that prevent the cause (and in turn the failure mode) from occuring, 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.

DFMEA Template and Definitions

15	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.
16	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 negligble.

DFMEA Template and Definitions

17	Occurrence (O)	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.	Do not confuse failure mode with occurrence of cause. Rank the possibility of the cause happening, not the possibility of the failure mode happening.
18	Detection(D)	Detection is an assessment of the likelihood that the Current Controls (items 14 & 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.	
19	RPN	The Risk Priority Number is the product of the Severity (S), Occurrence (O), and Detection (D) ranking. RPN=(S) x (O) x (D).	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 "high" RPN and what deserves action to be taken.
20	Recommended Actions	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, serverity, 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.	Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.
21	Responsibility & Target Completion Date	Enter the organization and individual responsible for the recommended action and the target completion date.	Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.
22	Actions Taken	After an action has been implemented, enter a brief description of the actual action and effective date.	Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.
23	Action Results	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 "Action Results" and related ranking columns blank.	Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.

PFMEA Template and Definitions

Potential
Failure Mode and Effects Analysis
(Process FMEA)

(1) FMEA # :_____
Contract # :_____
Supplier :_____

(2) ___ System
___ Subsystems
___ Component :_____

(3) Process Responsibility:_____
Government POC:_____

(4) Prepared by :_____

(5) Program name :_____

(6) FMEA key date:_____

(7) FMEA date (Orig.) :_____ Revision date :_____

(8) Core Team :

Process step #	Process step function / requirements	Potential Failure Mode	Potential Effects of Failure	Severity	Classification	Potential Causes / Mechanisms of Failure	Current Process Controls Prevention	Occurrence	Current Process Controls Detection	Detect	R.P.N.	Recommended Actions	Responsibility & Target Completion Date	Action Results				
														Actions Taken	Severity	Occur	Detection	R.P.N.
(9)	(10)	(11)	(12)	(16)		(13)	(14)	(17)	(15)	(18)	(19)	(20)	(21)	(22)		(23)		

PFMEA Template and Definitions

Item #	Name	Description	Further comments
1	FMEA Number Contract # Supplier/DPRP	Enter an appropriate FMEA document number, which may be used for tracking. Fill in as many fields as information allows.	FMEA numbers should follow a sequence as dictated by the existing reccomendations or practices of the OEM, Vendor, Supplier, Department and/or Group who has design responsibility.
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.
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.	

PFMEA Template and Definitions

4	Prepared by	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.
5	Program name	Enter the name of the program/process.	
6	FMEA Key date	Enter the date the process FMEA is to be completed by and specify its relevance.	FMEA is a proactive tool meant to be a "before the event" action, not an "after the fact" 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.
7	FMEA date(Orig) and Revision date	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.

PFMEA Template and Definitions

8	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.
9	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.
10	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 measureable metrics or to refer back to the source while creating the FMEA.

PFMEA Template and Definitions

11	Potential Failure Mode	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.	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 "bent", "cracked", "burred", "short circuted", "open circuited", 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 uniquness. For instance, if the function is "drill hole" the team may have to consider whether the potential failures "hole too small" and "hole too large" 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). Examples of failure modes in business and transactional processes are "approval not received" or "invoice is paid late".
12	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, the ultimate end user, or even the next process step.	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 "unit leaks", "high effort", "part will be scrapped", etc. Typical descriptions that affect downstream operation are "cannot fasten", "will not fit", "causes excessive tool wear", "will prompt PLC error codes", etc.

PFMEA Template and Definitions

13	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 process or operation. This field should contain phrases that accurately describe the reason for the failure to happen. These descriptions usualy include words like "incorrect" or "insufficient" or "excessive" followed by some noun. Examples: "incorrect setting", "insufficient welding current", "excessive drill speed". Other examples: "debris present", "worn tool", "improper setup", etc. Choosing to describe causes in this fashion makes identifying their solutions straight forward. Potential causes should be "root" causes and may require problem solving to discover.
14	Current Process Controls - Prevention	List the controls/feature that prevent the cause (and in turn the failure mode) from occuring, 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, 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.

PFMEA Template and Definitions

15	Current Process Controls - Detection	List the controls/feature that allow the cause or the failure mode to be detected as early as possible, leading to corrective actions.	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.
16	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 negligble.

PFMEA Template and Definitions

17	Occurrence (O)	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.	Do not confuse failure mode with occurrence of cause. Rank the possibility of the cause happening, not the possibility of the failure mode happening.
18	Detection(D)	Detection is an assessment of the likelihood that the Current Controls (items 14 & 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.	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.
19	RPN	The Risk Priority Number is the product of the Severity (S), Occurrence (O), and Detection (D) ranking. RPN=(S) x (O) x (D).	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 "high" RPN and what deserves action to be taken.
20	Recommended Actions	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, serverity, 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.	Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.
21	Responsibility & Target Completion Date	Enter the organization and individual responsible for the recommended action and the target completion date.	Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.
22	Actions Taken	After an action has been implemented, enter a brief description of the actual action and effective date.	Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.
23	Action Results	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 "Action Results" and related ranking columns blank.	Risks identified by FMEA that warrant action should be managed through the Risk Recon tool.

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: _____

Accept. Consistent Adherence to FMEA Criteria

Revision Required.

		Yes	No	Comments
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

8	**Occurrence Column**			
8a	Each cause is rated separately			
8b	Each cause has at least 1 Prevention Design Control. (If there are no Prevention Controls, then Occurrence is automatically rated as a "10")			
8c	Occurrence ranks the effectiveness of Prevention Controls in eliminating the Root Cause from the Design Release			
8d	Occurrence ranking considers the likelihood of the cause occurring over the entire design life of the product			
9	**Current Design Controls - Detection**			
9a	Design Controls refer to specific tests, analyses, actions, etc. that take place during TD and EMD phases			
9b	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")			
9c	Design Controls do not include production process controls			
9d	Detection Controls are applied in a timely manner, in order to avoid the inclusion of the cause/failure mode in a Customer Built product			
10	**Detection Column**			
10a	Detection ranks the likelihood that the cause / failure mode would be detected			
10b	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).			
11	**Risk Priority Number**			
11a	RPN appears realistic & not artificially low. Ranking values can be substantiated.			
11b	RPN was calculated correctly			

DFMEA Evaluation Checklist

12	**Recommended Actions & Responsibility**			
12a	Highest RPNs and Severity Rankings comprising a rolling top 20%, or top issues as determined by DFMEA Review Team, are addressed with needed actions			
12b	Severity Ratings of 8, 9 or 10 are given special consideration			
12c	Recommended Actions are assigned to a named person w/ target dates			
12d	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			
12e	Recommended Actions may not be left blank. If actions are not needed, "None" and a statement such as " Risk to customer is very low due to experience with surrogate products" or "Currently there are no earlier detection controls which would reduce risk to the program," " Risk to customer is very low due to high likelihood that TD phase testing is very likely to detect a potential Failure Mode.			
12f	Predicted RPN are effected by Occurrence and/or Detection, unless a design change mitigates the Failure Mode and Effect of Failure			
12g	Predicted RPNs are stated in the Recommended Actions column, not in the Action Results column			
13	**Actions taken**			
13a	Actions taken and Target Completion Dates are shown			
13b	Completion of Recommended Actions is timely, RPN's have been updated and level of risk is acceptable			
14	**Analysis of Findings**			
14a	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			

DFMEA Evaluation Checklist

	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

Name of Component, Sub-System or System: _____

Responsible Engineer & Facility Name _____

Quality Auditor: _____

Date Reviewed: _____

Accept. Consistent Adherence to FMEA Criteria

Revision Required.

		Yes	No	Comments
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

3	**Potential Failure Modes Column Adequate?**			
3a	Failure modes logically match process steps			
3b	Each process step has at least 1 potential failure mode			
4	**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			
5	**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			

USED.

PFMEA Evaluation Checklist

10	**Additional Guidelines**			Comments
10a	PFMEA seems to be a decision making tool			
10b	Document appears to be a living document			
10c	Current Controls operationalized in Process Control Plan & SOPs			
10d	Key characteristics noted in DFMEA are conveyed to PFMEA			
10e	PFMEA has been updated as experience is gained			
10f	Response to high risk failures is a priority			
10g	Detailed Process Flow Chart is attached			
10h	"Operator Error" is not the only (catch all) potential cause			
10i	"Supplier" & out of spec components are not catch all causes			
10j	"Visual inspection" rated high because it's ineffective			
10k	"No build" assy. (in-station) rated low because it's very effective			
10l	In-station, aided inspection rated better than end of line inspection			
10m	Detection in subsequent station better than end of the line			
10n	Incoming inspection of components, is rated high			
10o	Line start-up procedure & thorough workstation review is rated moderately			
10p	If equipment failure is cause, preventive maintenance is good control			

Questions? Contact us

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

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