

Supplier Quality Management

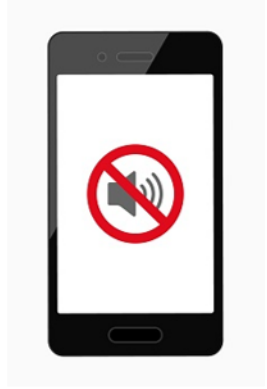
Continuous Improvement Training

Process Failure Mode & Effects Analysis

Advanced Quality Team



GROUND RULES



Silence cell phones



**Mute your
microphone**



No Multitasking



**All Questions are
welcome**

Supplier Quality Management

Continuous Improvement Training

Process Failure Mode & Effects Analysis

Advanced Quality Team



Agenda

Part 1 – Intro to PFMEA

- Background
- Objectives
- Concepts
- Intro to PFMEA template

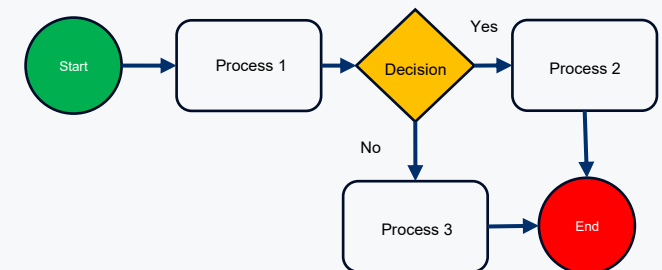
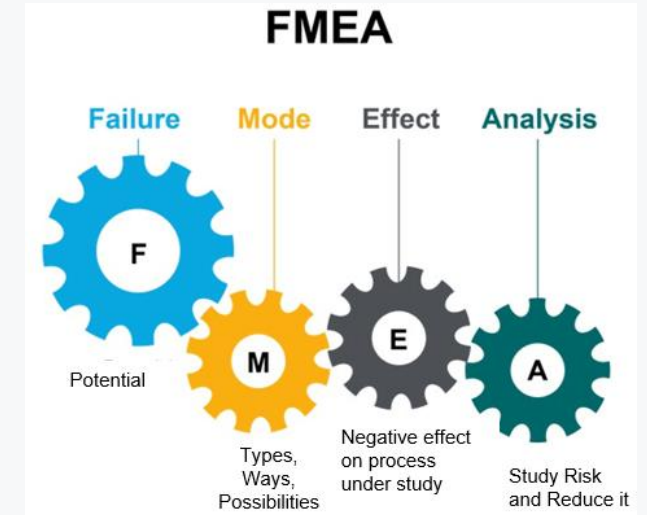
Part 2 – PFMEA

- Case Study
- How tools fit together



Training Objectives

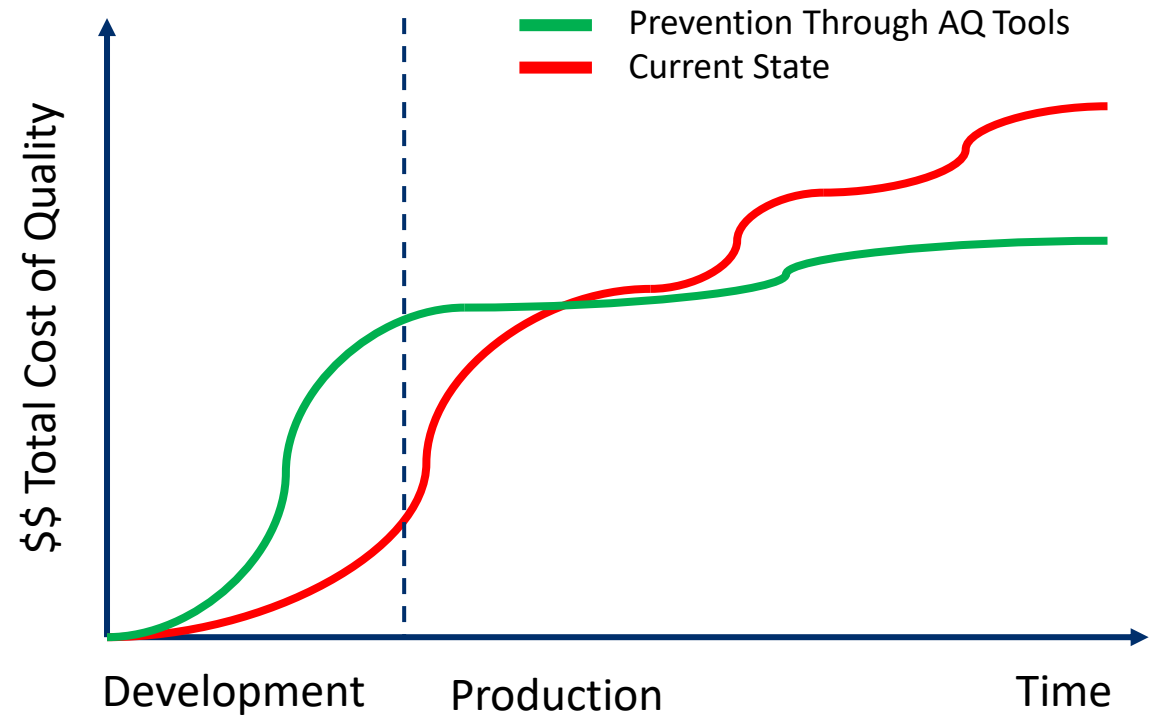
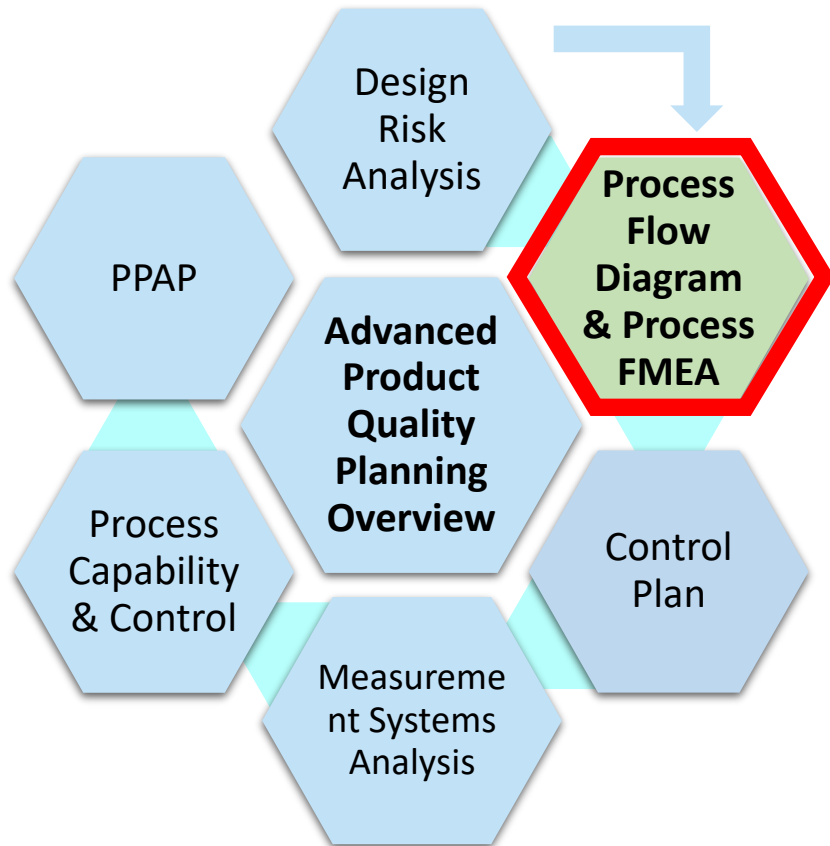
- Enable participants to understand and effectively assess advanced quality tools to help suppliers transition from a reactive to a preventive mindset
- Introduce the key concepts of Process Failure Mode & Effects Analysis (PFMEA)
- Understand the benefits of element usage
- Be acquainted with the relationship between PFD / PFMEA



Part 1

Introduction to Process FMEA

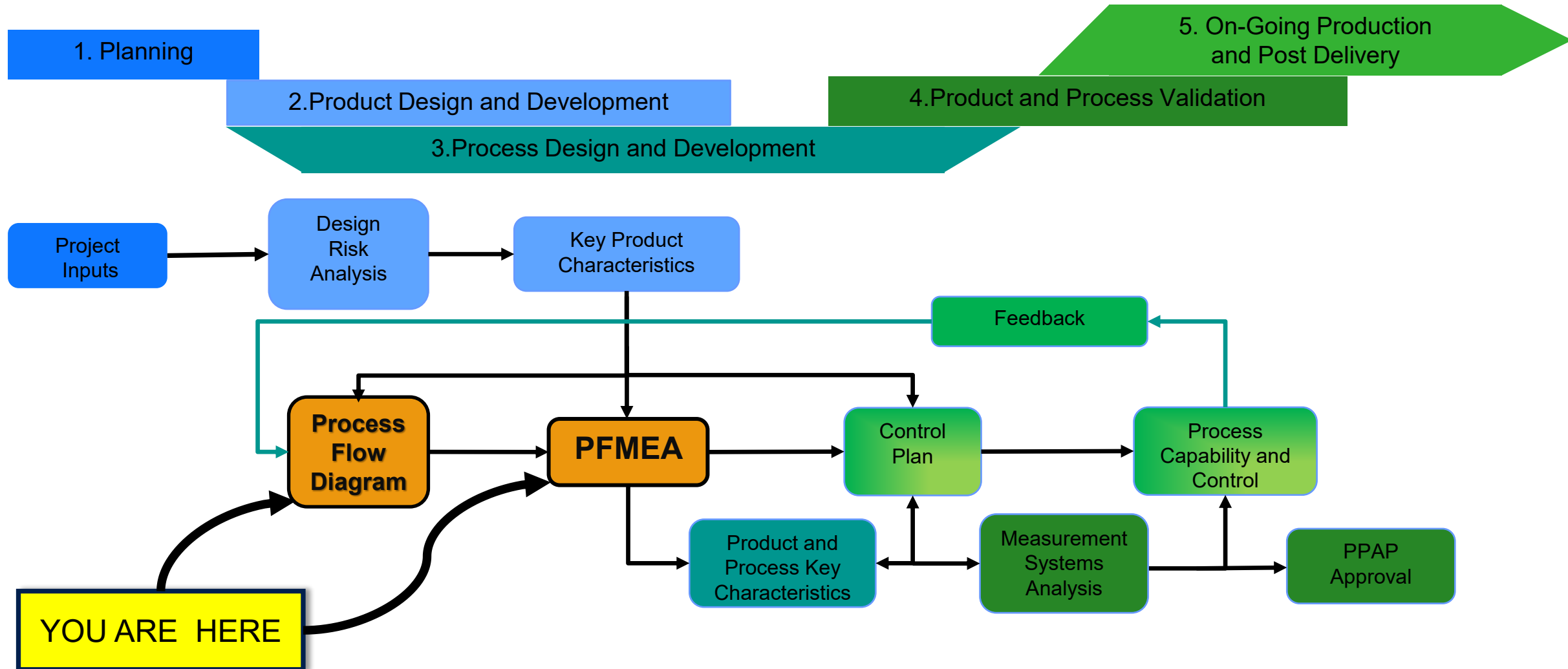
Background



Value Proposition

Invest more in upfront planning to significantly reduce cost later in the product lifecycle!

APQP Relationship



* Reference AS9145 Table 2 – Production part approval process file contents

Process Failure Mode & Effects Analysis (PFMEA)

Process Step	Potential Failure Mode	Potential Failure Effect	Severity (SV)	Potential Causes	Occurrence (OC)	Current Process Controls	Detection (DET)	Risk Priority Number (RPN)	Action Recommended	Responsibility and Target Completion Date	Action Taken	How Sev. New	How OC New	How Det New	How RPN New
What is the step?	In what ways can the step go wrong?	What is the impact on the customer if the failure mode is not prevented or corrected?	How severe is the effect on the customer?	What causes the step to go wrong (i.e., how could the failure mode occur)?	How frequently is the cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is detection of the failure mode or its cause?	Risk priority number calculated as SV x OC x DET	What are the actions for reducing the occurrence of the cause or for improving its detection? Provide actions on all high RPNs and on severity ratings of 9 or 10.						
Updating Medication Reconciliation at Discharge (specific focus on cardiac medications following AMI)	Wrong dose listed	Permanent Harm	8	Lack of clear accountability on who completes medication reconciliation at discharge	10	Pharmacy staff have been assigned to review every record prior to discharge to validate accuracy. This is an interim measure implemented immediately after the concern was identified	1	80	Discharging physician is accountable for a correct med rec at discharge. Pharmacy staff will validate prior to discharge. Patterns of non-compliance will be brought to the attention of the CMO	Dr. Gray (CNO) 4/21/2021	All rec. actions	8	1	1	8
	Wrong frequency	Permanent Harm	9	Medical residents do not have access to this section in EMR	10	See above	1	90	Educate medical residents on medication reconciliation documentation and provide necessary access within the EMR	Bill (IT) 4/19/2021	All rec. actions	9	1	1	9
	Incorrect medication listed	Permanent Harm/Death	10	Nursing staff do not feel comfortable stopping a discharge if the medication reconciliation hasn't been completed	10	See above	1	100	Empower nursing staff to hold a discharge based upon medication reconciliation concerns. Immediate steps should be to notify pharmacy staff and attending physician for clarification.	Betty (CNO) and Dr. Gray (CNO) 4/9/2021	All rec. actions	10	1	1	10

IMPORTANT!!

A cross-functional team is
REQUIRED
to complete a robust PFMEA

What is it?

- A structured method for identifying all possible failures & impacts of the process under review
- Prevention controls emphasized over detection, where feasible
- Failure modes are prioritized according to how serious the consequences,
how frequently they occur, and how easily they can be detected
- Reaction plan to eliminate or reduce failure modes with high severity, reduce occurrence, and improve detection

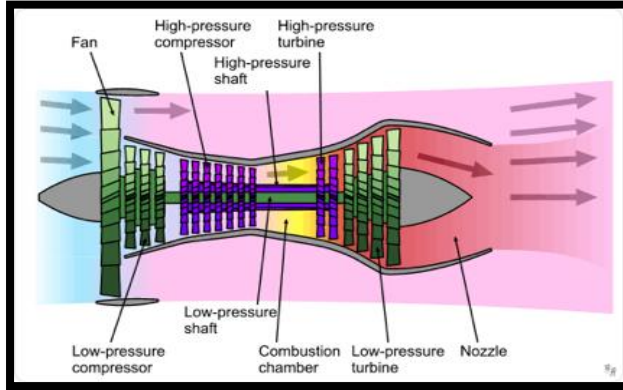
When to Use It

- Launching a new product or service
- Design and development of new manufacturing process
- To improve an existing process and/or significant changes to product
- Work transfers

Objective or Purpose

- Identify potential product related process failure modes
- Assess potential effect of the failures
- Identify potential causes(s)
- Plan for the prevention, mitigation and control of failures
- Repository for Lessons Learned

Different Types of FMEA



System FMEA



Design FMEA



Process FMEA

All FMEA's have the same primary objective, Improve the Design:

- a) For System FMEAs, the objective is to improve the design of the system.
- b) For Design FMEAs, the objective is to improve the design of the subsystem or component.
- c) For Process FMEAs, the objective is to improve the design of the manufacturing & assembly process.

Process FMEA Requirements

Must be Created & Maintained by
a **CROSS FUNCTIONAL TEAM**

PFMEA must be done at the
RIGHT TIME

Is **PART NUMBER** Specific

Include **ALL** Process Steps



EVERY Design Characteristic
included in the PFMEA

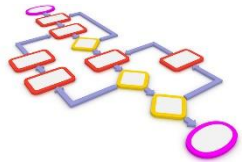
PFMEA Failure Modes must
describe **PRODUCT DEFECTS**

PFMEAs must **DRIVE ACTIONS**
to reduce risk

Keep up to date – They are **LIVE**
documents

Overview

1



Operations, Steps &
Requirements

2



Potential Failure
Modes, Potential
Effects & Severity
Rating

3



Potential Causes,
Prevention Controls &
Occurrence Rating

4



Detection Controls
& Detection Rating

5



Calculating the
Risk Priority Number
(RPN)

6



Improvement
Actions

Linkages between PFD and PFMEA

PFD	Operation #/ Process Step	Operation Description	Incoming sources of variation (ISV)	PFD	Product KC	Process KC
		Description of operation 	Input material variation affects the outcome of Process  Product Characteristic or previous operation	Symbol	What is expected out of the process 	Characteristics which affect the outcome  Characteristics which change with time only need to be mentioned

PFMEA	Operation #/Process Step	Process Function/ Description	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Occurrence	Current Process Controls			Detection	RPN	Recommended Actions
		Description of operation 	Negative of product characteristics 	Symbol	How bad is it?	Key Characteristics	From ISV and process characteristics  	How often? From in-process rejection from similar process	1. Prevent cause 2. Detect cause 3. Detect failure mode					

The Process FMEA Template

Section 1		Section 2			Section 3			Section 4		Section 5	Section 6
Operation / Step	Requirements	Potential Failure Modes	Potential Effects of Failure	Severity Score	Potential Causes of Failure	Prevention Controls	Occ Score	Detection Controls	Detection Score	RPN	Improvement Actions
What is the process that you are focusing on (Process Step)? What are you trying to achieve (Product Requirements)? Defined by Engineering Drawings & Specifications Or Assembly Instructions PFMEA must include ALL Design Requirements	50mm Diameter +/- 0.1mm CNC Drilling	Fuel Leaks leading to a How could you get the Requirements wrong (Failure Modes)? What could happen if it did go wrong (Potential Effects)? How bad would it be if it did go wrong (Severity Score)?	Scrap Part	9	Drill Oversize	Drill Tool pre-setting check	4	Bore micrometer at OP 50	7	252	List of Improvement Actions required to mitigate the key Risks Identified
					What would need to fail in the process to cause the Failure Mode to occur (Potential Causes)?	Asset Care & machine calibration schedule		How will you check if the Cause and/or Failure Mode occur (Detection Controls)?		189	
					How could this be prevented (Prevention Controls)?	Part Loose In Fixture	1	How likely are you to detect the Cause or Failure Mode if it was defective (Detection Score)?			
					How likely is it to go wrong (Occurrence Score)?	Swarf on tool	4				
Product Focused					Process Focused					Risk Mitigation	

Process FMEA Information Flow

OP / Step	Requirement	Failure Mode	Potential Effect	Severity	Class.	Potential Cause	Prevention Control	Occurrence	Detection Controls	Detection	RPN
OP10 CNC Drilling	50mm +/- 0.1 mm Diameter	Hole Too Big	Engine Vibration	9							
			Scrap Part	7							
						Oversize Drill Used	Tool Pre-setter Check	2			108
						Part Loose in Fixture	Fixture Check pre-machining	3			162
						Spindle Alignment not to Spec	6 Monthly Preventative Maintenance	4			216
									Bore Mic at OP50	6	
									Spindle Ball Bar Check	8	

Process FMEA Information Flow

OP / Step	Requirement	Failure Mode	Potential Effect	Severity	Class.	Potential Cause	Prevention Control	Occurrence	Detection Controls	Detection	RPN
OP10 CNC Drilling	50mm +/- 0.1 mm Diameter	Hole Too Big	Engine Vibration	9		Oversize Drill Used	Tool Pre-setter Check	2	Bore Mic at OP50	6	108
			Scrap Part	7		Part Loose in Fixture	Fixture Check pre-machining	3	Bore Mic at OP50	6	162
						Spindle Alignment not to Spec	6 Monthly Preventative Maintenance	4	Bore Mic at OP50	6	216
									Spindle Ball Bar Check	8	288
		Hole Too Small									

Process FMEA Data Sources

Process Flow
Diagram

Designer informed by
the Product DFMEA
and/or similar part history &
Manufacturing Engineer for Process Knowledge

Quality Metrics
(Cpk, Scrap, Rework, Escapes, Maintenance
Records, etc. from Similar Parts)

Operation / Step	Requirements	Potential Failure Modes	Potential Effects of Failure	Severity Score	Potential Causes of Failure	Prevention Controls	Occ Score	Detection Controls	Detection Score	RPN

Characteristics
Matrix

Drawings, Assembly
Instructions &
Engineering Specifications

Reference
PFMEAs or Similar Part
PFMEAs
(or team knowledge)

Process Flow Diagram,
Characteristics Matrix,
Inspection Plan,
Similar Part Control Plans

Part 2

Process FMEA

Case Study

Preparing the PFMEA



Team Effort:

1. Establish Team Leader to organize team
 - Define goals, scope, roles, and schedule
2. Include Cross-Functional membership
 - Design
 - Engineering
 - Manufacturing
 - Quality
 - Operations
3. Include Subject Matter Experts
4. Include a FMEA facilitator as needed

Rules:

- Product design will meet product intent
- The product coming into the process is conforming
- Severity **score** can only be impacted by a change in design
- A ranking system for severity, occurrence and detection is defined

Necessary PFMEA Inputs:

- Process Flow Diagram
- Quality Performance Data (similar parts & processes)
- PFMEA (similar parts & processes)
- Design Risk Analysis (e.g. DFMEA)
- Key Characteristics
- Control Plan (similar parts & processes)
- **Characteristics Matrix**

Characteristics Matrix Example

Feature Details ↓			Operations Sequence →				
Feature Number	Description	Specification	OP100 Drill	OP150 Deburr	OP200 Clean	OP250 CMM	etc. →
1	Fuel Port Inner Diameter 1	10.50 mm +/- 0.1 mm	X	A		I	
2	Fuel Port Location	1450 (x), 761 (y), 600 (z)	X				
3	Oil Port Inner Diameter 1	18.50 mm +/- 0.3 mm	X	A		I	
4	Oil Port Location	1150 (x), 200 (y), 45 (z)	X				
etc. ↓							

Key: **X** = Feature Created, **A** = Feature Affected, **I** = Inspected

FMEA Section 1

Operation / Step & Requirements

Defining the Scope of the PFMEA

Section 1		Section 2			Section 3			Section 4		Section 5	Section 6
Operation / Step	Requirements	Potential Failure Modes	Potential Effects of Failure	Severity Score	Potential Causes of Failure	Prevention Controls	Occ Score	Detection Controls	Detection Score	RPN	Improvement Actions
What is the process that you are focusing on (Process Step)? What are you trying to achieve (Product Requirements)? Defined by Engineering Drawings & Specifications Or Assembly Instructions PFMEA must include ALL Design Requirements		How could you get the Requirements wrong (Failure Modes)? What could happen if it did go wrong (Potential Effects)? How bad would it be if it did go wrong (Severity Score)?			What would need to fail in the process to cause the Failure Mode to occur (Potential Causes)? How could this be prevented (Prevention Controls)? How likely is it to go wrong (Occurrence Score)?			How will you check if the Cause and/or Failure Mode occur (Detection Controls)? How likely are you to detect the Cause or Failure Mode if it was defective (Detection Score)?		Risk Priority Number (RPN)	List of Improvement Actions required to mitigate the key Risks Identified
Product Focused					Process Focused				Risk Mitigation		

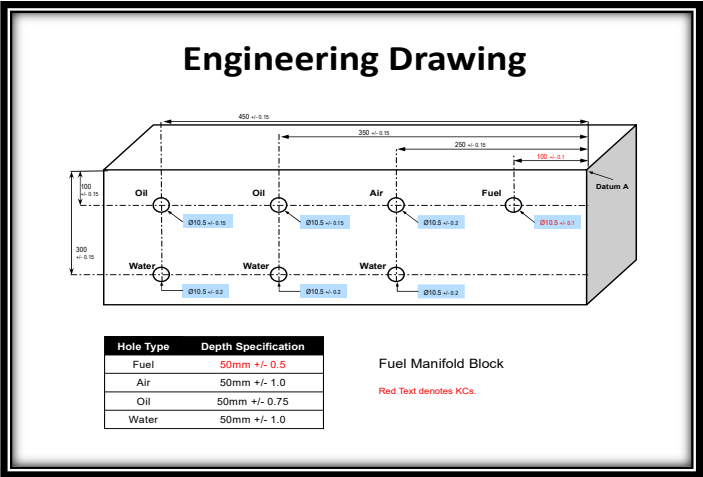
Identifying the In-Scope Operations / Steps

Operation	Step	Function	Requirement	Failure Mode	Potential Effect	Severity	Class.	Potential Cause
10	1	Mazak CNC Machining Hole Drilling	10 mm +/- 0.1 mm Diameter					
1. Operation / Step should be derived from the Process Flow Diagram and/or the Characteristics Matrix. 2. It must consider all Process Steps. 3. It should consider only those Operations / Steps that can transform the product, even if inadvertently. 4. The focus of the PFMEA is on product non-conformance.			Location X,Y					
			50 mm +/- 1.0mm Depth					

Process FMEA Operations and Steps: Other Examples

Deliberate Transformations	Inadvertent Transformation	No Transformation
Drill Holes	Damage	Load CNC program
Cut to length	FOD	Load CNC Tooling
Assemble part x to y	Contamination	Load Fixture to Machine
Weld joints	Corrosion	Download work instructions
Torque bolts	Store parts in warehouse	Complete work traveler / Batch card
Apply Coating	Transport parts to assembly line	
Harden		

Defining Requirements



**Geometric
Tolerances**



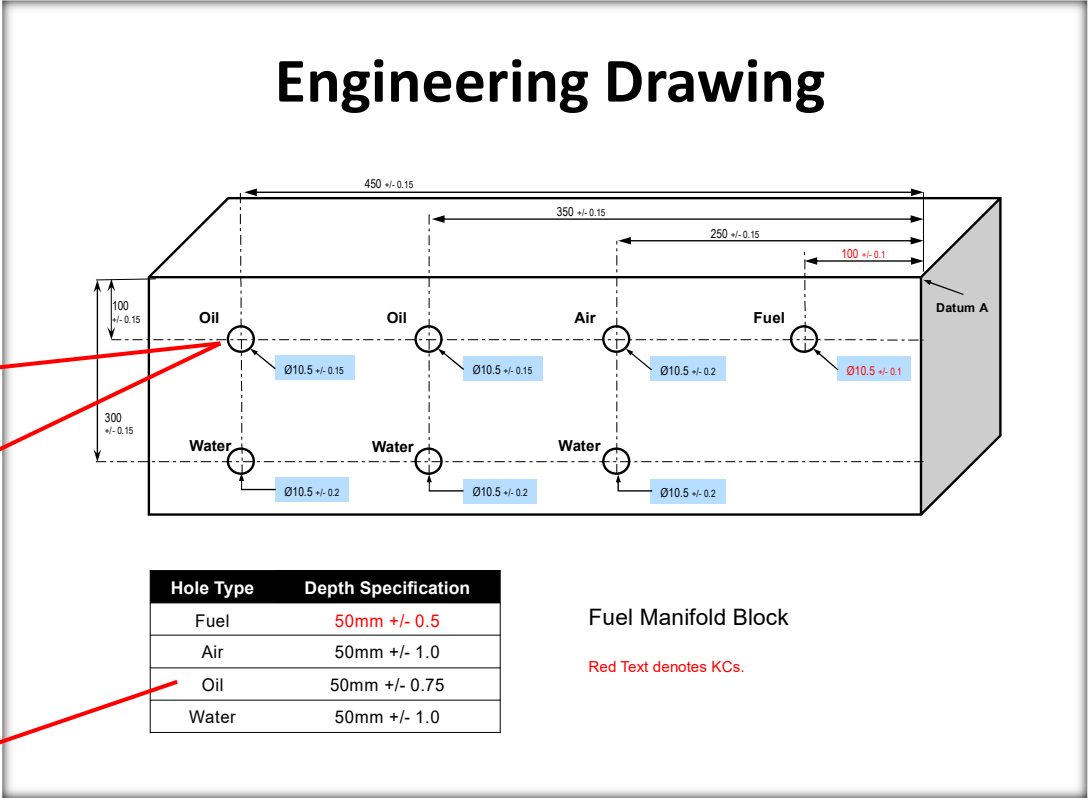
**Material
Processing**



**Assembly
Operations**

Identifying Requirements from a Geometric Drawing

Function	Requirement	Failure Mode
Mazak CNC Machining Hole Drilling	10.5 mm +/- 0.15 mm Diameter	
	Location X,Y	
	50 mm +/- 0.75 mm Depth	



All characteristics must be listed in the PFMEA at the appropriate Operation / Step where it is created.

The Characteristics Matrix is another good source of this information

Poor Requirements Definition – Heat Treat Example



Work Instruction - Example

1. Soak parts at 350C for 2 hours (minimum)

Does this requirement describe a Product Characteristic or a Process Parameter?

Poor Requirements Definition – Heat Treat Example

Requirement	Failure Mode	Potential Effect	Severity	Class.	Potential Cause
1. Soak parts at 350C for 2 hours (minimum)	Temperature too high / too low	Parts too hard / not hard enough			Furnace not calibrated / out of calibration
	Parts left in furnace for too long / not long enough	Parts too hard / not hard enough			
Describes Process Parameters	Describes Process Parameters	Difficult to identify customer effects directly			

Improved Requirements Definition – Heat Treat Example



Work Instruction

~~1. Soak parts at 350C for 2 hours
(minimum)~~

1. Harden material to 45 HRC +/- 3 HRC

NOTE:

The requirements must define the physical **PRODUCT** characteristics / condition that is to be achieved.

Improved Requirements Definition – Heat Treat Example

Requirement	Failure Mode	Potential Effect	Severity	Class.	Potential Cause
1. Material to be hardened to 45 HRC +/- 3	Material is too soft	Excessive wear leads to engine vibration & noise			Parts removed from furnace too soon
		Excessive wear reduces engine service intervals			Furnace temperature too low
	Material is too hard	Potential cracks in material could lead to engine failure without warning (safety concern)			Furnace temperature too high

Describes Product Characteristics

Describes Product Characteristics

Easy to identify customer effects

Describes Process Issues

FMEA Section 2

Potential Failure Modes.

Effects & Severity Rating

Section 1		Section 2			Section 3			Section 4		Section 5	Section 6
Operation / Step	Requirements	Potential Failure Modes	Potential Effects of Failure	Severity Score	Potential Causes of Failure	Prevention Controls	Occ Score	Detection Controls	Detection Score	RPN	Improvement Actions
What is the process that you are focusing on (Process Step)? What are you trying to achieve (Product Requirements)? Defined by Engineering Drawings & Specifications Or Assembly Instructions PFMEA must include ALL Design Requirements		How could you get the Requirements wrong (Failure Modes)? What could happen if it did go wrong (Potential Effects)? How bad would it be if it did go wrong (Severity Score)?			What would need to fail in the process to cause the Failure Mode to occur (Potential Causes)? How could this be prevented (Prevention Controls)? How likely is it to go wrong (Occurrence Score)?			How will you check if the Cause and/or Failure Mode occur (Detection Controls)? How likely are you to detect the Cause or Failure Mode if it was defective (Detection Score)?		Risk Priority Number (RPN)	List of Improvement Actions required to mitigate the key Risks Identified
Product Focused					Process Focused				Risk Mitigation		

Identifying Failure Modes – CNC Hole Drilling

Identify all of the Characteristics that are specified by the drawing and related specifications for the feature.

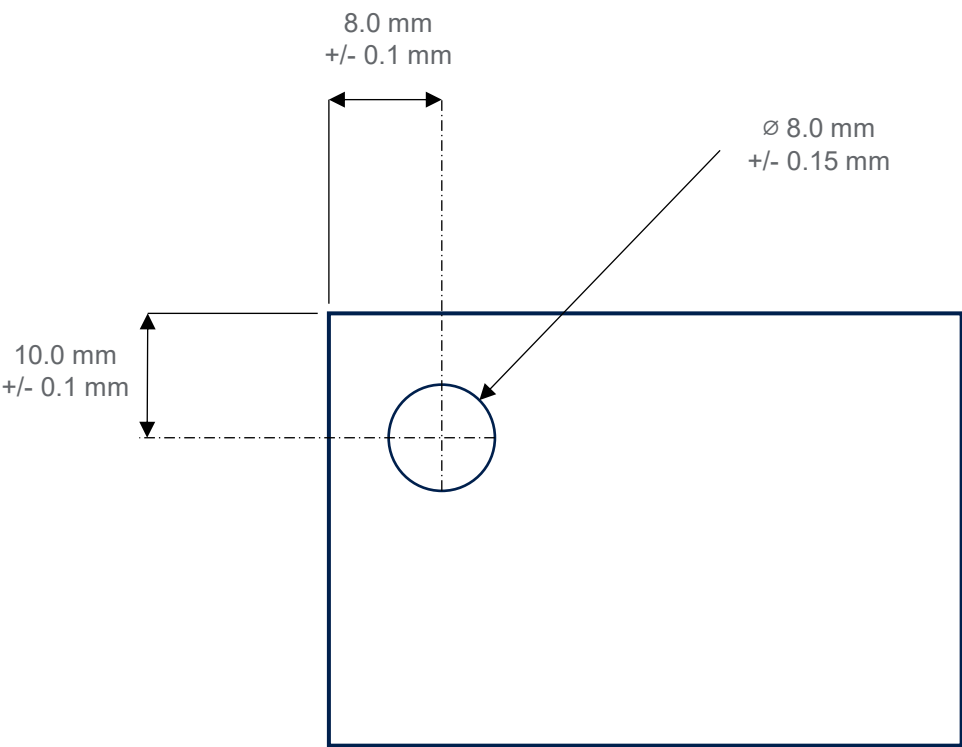
Use the Characteristics Matrix & related specifications.

Requirement	Failure Modes	
Location X, Y	Wrong Location	
Diameter	Too Big	Too Small
Roundness	Out of Round	
Depth	Too Shallow	Too Deep
Straightness	Not Straight	
No Burrs present	Burrs present (above specification)	
No FOD present	FOD present	
No Damage (beyond limits)	Damage present (beyond limits)	

For Each Characteristic identify the ways in which the part could fail to meet the defined Requirements

Failure Modes are Finite!

Don't Create Failure Modes that are not linked to a Requirement



Specification xyz states no burrs / sharp edges on drilled holes are allowed

Operation / Step	Requirement	Failure Modes
OP10 CNC Drilling Drill Fuel Hole	Diameter 8.0 mm +/- 0.15 mm	Hole diameter too big
		Hole diameter too small
	Location 8.00 mm +/- 0.1 mm (x), 10.0 +/- 0.1 mm (y)	Out of Location
	No burrs or sharp edges	Burrs / sharp edges present
		Hole not round
		FOD present

Failure Modes must be linked to defined requirements only.
If it is believed to be a missing requirement get Design Engineering to change the requirements.

Identifying Failure Modes – Manual Assembly

Requirement	Failure Modes		
Correct orientation	Wrong orientation		
Fit part X to part Y	Incorrect part fitted	No part fitted	
Torque all bolts to specified value	Over tightened	Under tightened	Not tightened
Apply X quantity of Sealant uniformly to Zone A	Excessive sealant applied	Insufficient sealant applied	Sealant applied to wrong location / no sealant applied
No FOD	FOD present		
No Damage	Damage present (beyond limits)		

PFMEA Potential Failure Modes Library - Examples

Failure Modes describe a physical property of the **PRODUCT**

Type	Characteristic	Typical Failure Modes
Geometry	Length	Too long
		Too short
	Depth	Too deep
		Too shallow
	Width	Too wide
		Too narrow
	Diameter	Too big
		Too small
	Radii	Too big
		Too small
	Angle	Too big
		Too small
	Position / Location	Out of position / location error
	Flatness	Not flat
	Surface Finish	Too rough
		Too smooth
	Thickness	Too thick
		Too thin
	Parallelism	Not parallel
	Circularity	Not circular
	Squareness	Not square

Type	Characteristic	Typical Failure Modes
Geometry	Profile of a line	Not to profile
	Profile of a surface	Not to profile
	True position	Out of true position
	Concentricity	Out of concentricity
	Thread pitch	Pitch too large
		Pitch too small
Material	Porosity within limits	Porosity outside of limits
	Splatter free	Splatter above allowable limits
	Pitting	Pitting above allowable limits
	Damage	Damage above allowable limits
	Clean part	Contaminated part
	No sharp edges	Sharp edges present above limits
	Fit Part	Part not fitted
Assembly	Correct orientation	Incorrect orientation
	Torque to value	Not tightened
		Over tightened
		Under tightened
	Apply Sealant	Too much
		Too little / None

Source: RM13004 App A

SUMMARY: Failure Modes

1. To ensure that the right **Failure Modes** are captured the **REQUIREMENTS** description must be precise.

This is of particular concern for Assembly PFMEAs where Assembly Instructions may not describe the product characteristics / condition clearly.

Requirements must always describe product characteristics.

2. **Failure Modes** must describe a physical property of the **PRODUCT**.
3. Do not specify different increments of Failure. This will be considered when discussing **Effects** later.
4. Do not add **Failure Modes** where there is no Design Requirement.
5. **Failure Modes** are finite. Once established they can be captured in a Failure Mode Library and reused.

Keep updated if new knowledge comes to light.

Potential Effects of the Failure Mode

Requirement	Failure Mode	Potential Effect	Severity
Hole Diameter 10.0 mm +/- 0.1mm	Hole Diameter Too Big	Engine Vibration can be caused if the structure is able to move due to the oversize hole feature, may lead to reduced component life. Engine performance not affected.	
		Rework is not an option for this feature and therefore the part will need to be scrapped if it cannot be conceded.	
		If the oversize condition is less than 10% or the tolerance band then it may be possible to apply for an Engineering Concession	

1. Potential Effects describe the way in which the Failure Mode will impact the Customer.
2. The Customer may be the End User or the next Manufacturing Operation.
3. The Effects will consider different levels of Failure
4. We would expect to see several Potential Effects per Failure Mode in a good PFMEA including Effects to the Customer / User of the product as well as Effects on the business (scrap / rework etc.)
5. When identifying Potential Effects we should have the Designer, informed by the DFMEA (if it exists) to help determine the Effects and the Impact (Severity Score)
6. This is the stage where the DFMEA links to the PFMEA (Potential Effects and Severity) – but it is not a simple ‘look up’ guide.

SEVERITY RANKING

References	Modified from J1739 / AS13004			
Effect	Severity of Effect on Product (Customer Effect)	Ranking	Category	Severity of Effect on Process (Manufacturing / Assembly Effect)
Failure to meet safety and/or regulatory requirements	Potential failure mode affects safe operation and/or involves noncompliance with regulations without warning	10	Failure to meet safety and/or regulatory requirements	May endanger operator, machine or assembly without warning.
	Potential failure mode affects safe operation and/or involves noncompliance with regulations with warning	9		May endanger operator, machine or assembly with warning.
Loss or degradation of primary function	Loss of primary function (product inoperable, does not affect safe operation)	8	Major disruption	100% of product may have to be scrapped. Line shutdown or stop ship.
	Degradation of primary function (product operable, but at a reduced level of performance)	7	Significant disruption	A portion of the production run may have to be scrapped. Deviation from primary process; decreased line speed or added manpower).
Loss or degradation of secondary function	Loss of secondary function (product operable but service life greatly reduced, convenience item(s) inoperable, customer dissatisfied)	6	Moderate disruption	100% of production run may have to be reworked off line and accepted
	Degradation of secondary function (product operable but appearance affected, convenience item(s) operable at a reduced level, customer dissatisfied.	5		A proportion of the production run may have to be reworked off line and accepted
Annoyance	Appearance, fit and finish type items do not conform, defect noticed by most of the customers (>75%)	4	Moderate disruption	100% of production run may have to be reworked in station before it is processed.
	Appearance, fit and finish type items do not conform, defect noticed by about half of the customers (50%)	3		A proportion of the production run may have to be reworked in station before it is processed.
	Appearance, fit and finish type items do not conform, defect noticed by discriminating customers (<25%)	2	Minor disruption	Slight inconvenience to process, operation or operator.
No effect	No discernible effect	1	No effect	No discernible effect

Severity Scoring

Requirement	Failure Mode	Potential Effect	Severity	Modified from J1739 / AS13004			SEVERITY RANKING
				Ranking	Category	Severity of Effect on Process (Manufacturing / Assembly Effect)	
Hole Diameter 10.0 mm +/- 0.1mm	Hole Diameter Too Big	Engine Vibration can be caused if the structure is able to move due to the oversize hole feature, may lead to reduced component life. Engine performance not affected.	6	10	Failure to meet safety and/or regulatory requirements	May endanger operator, machine or assembly without warning.	
				9		May endanger operator, machine or assembly with warning.	
		Rework is not an option for this feature and therefore the part will need to be scrapped if it cannot be conceded.	7	8	Major disruption	100% of product may have to be scrapped. Line shutdown or stop ship.	
				7	Significant disruption	A portion of the production run may have to be scrapped. Deviation from primary process; decreased line speed or added manpower).	
				6	Moderate disruption	100% of production run may have to be reworked off line and accepted	
		If the oversize condition is less than 10% or the tolerance band then it may be possible to apply for an Engineering Concession	2	5		A proportion of the production run may have to be reworked off line and accepted	
				4	Moderate disruption	100% of production run may have to be reworked in station before it is processed.	
				3		A proportion of the production run may have to be reworked in station before it is processed.	
				2	Minor disruption	Slight inconvenience to process, operation or operator.	
				1	No effect	No discernible effect	

Effects & Severity Score Summary

1. There should be **multiple** **Effects per Failure Mode**.
2. The **Potential Effects** should include the Impact on the Customer including the End User and Subsequent Operations.
3. The Designer can help to identify the Impact on the Product.
4. The **Design FMEA** will not provide a 'look up' guide – It will need the Designer to Interpret it to inform the PFMEA.
5. The **PFMEA** can be completed when there is no Design FMEA – the designer or the organization's own previous knowledge can help identify Effects and Severity.
6. The **Effects** description must be clear and concise – It will be read by other teams and will need to make sense to them.
7. Effects should be described in terms that will help to determine the **Severity Score**.
8. If the **Severity Score is 1** then there is not need to do any further analysis for that Failure Mode.

FMEA Section 3

Potential Causes, Prevention Controls and Occurrence Rating

Section 1		Section 2			Section 3			Section 4		Section 5	Section 6
Operation / Step	Requirements	Potential Failure Modes	Potential Effects of Failure	Severity Score	Potential Causes of Failure	Prevention Controls	Occ Score	Detection Controls	Detection Score	RPN	Improvement Actions
What is the process that you are focusing on (Process Step)? What are you trying to achieve (Product Requirements)? Defined by Engineering Drawings & Specifications Or Assembly Instructions PFMEA must include ALL Design Requirements		How could you get the Requirements wrong (Failure Modes)? What could happen if it did go wrong (Potential Effects)? How bad would it be if it did go wrong (Severity Score)?			What would need to fail in the process to cause the Failure Mode to occur (Potential Causes)? How could this be prevented (Prevention Controls)? How likely is it to go wrong (Occurrence Score)?			How will you check if the Cause and/or Failure Mode occur (Detection Controls)? How likely are you to detect the Cause or Failure Mode if it was defective (Detection Score)?		Risk Priority Number (RPN)	List of Improvement Actions required to mitigate the key Risks Identified
Product Focused					Process Focused				Risk Mitigation		

Identifying Potential Causes

Requirement	Failure Mode	Potential Effect	Severity	Class.	Potential Cause	Prevention Control	Occurrence
Hole Diameter 10.0 mm +/- 0.1mm	Hole Diameter Too Big	Engine Vibration	6				
		Scrap Part	7				
		Concession	2				

1. The Potential Cause describes what could happen in the process to cause the Failure Mode to occur
2. There should be more than 1 Potential Cause per Failure Mode
3. They should describe a 'direct' cause i.e. if the Potential Cause occurs then the Failure Mode will occur
4. Avoid loose descriptions such as;
 - Operator error
 - Poor maintenance
 - Incorrect work instructions

Identifying Potential Causes : Avoid too much Detail

1. Typically you should expect 4 – 6 Potential Causes per Failure Mode
2. A typical problem is where teams over specify Potential Causes by listing examples of the same thing



EXAMPLE:

- In our Heat Treatment example, the Failure Mode of 'material too hard' can be caused by leaving the material in the furnace for too long.
- Therefore, one of the Potential Causes of this Failure Mode can be as simple as 'Material left in furnace too long (over 2 hours)'.
- A common mistake however is to list all of the reasons here for why it may be left in the furnace for too long, e.g.:
 - a) Material left in Furnace too long due to Alarm failure
 - b) Material left in Furnace too long due to Operator distracted
 - c) Material left in Furnace too long due to the incorrect program being used

Prevention Controls

Requirement	Failure Mode	Potential Effect	Severity	Class.	Potential Cause	Prevention Control	Occurrence
Hole Diameter 10.0 mm +/- 0.1mm	Hole Diameter Too Big	Engine Vibration	6		Wrong Drill Used (oversize)		
		Scrap Part	7		Spindle Alignment Error		
		Concession	2		Part Loose in Fixture		

1. Prevention Controls identify the things we can do to prevent the Potential Cause from occurring
2. They should be TRULY preventative and have a direct effect on the Potential Cause i.e. they are not a detection activity 'after the event'
3. Best form of Prevention Control is error proofing i.e. where the Potential cause cannot happen
4. Maintenance & calibration activities are allowable
5. Avoid loose controls such as 'training' or 'defined work instructions' as these are not preventative although necessary activities
6. If there is no Prevention Control, then write 'NONE' in the cell and move on. These can be a good improvement opportunity later on.

Prevention Controls: Examples

Requirement	Failure Mode	Potential Effect	Severity	Class.	Potential Cause	Prevention Control	Occurrence
Hole Diameter 10.0 mm +/- 0.1mm	Hole Diameter Too Big	Engine Vibration	6		Wrong Drill Used (oversize)	Tool Pre-setting	
		Scrap Part	7		Spindle Alignment Error	Preventive Maintenance Schedule – laser alignment check every 6 months	
		Concession	2		Part Loose in Fixture	Air Detection System used in Fixture	
					Swarf 'pick up' on drill	NONE	

Occurrence Scoring Introduction

Requirement	Failure Mode	Potential Effect	Severity	Class.	Potential Cause	Prevention Control	Occurrence Score
Hole Diameter 10.0 mm +/- 0.1mm	Hole Diameter Too Big				Wrong Drill Used (oversize)	Tool Pre-setting	6
					Spindle Alignment Error	Preventive Maintenance Schedule – laser alignment check every 6 months	
					Part Loose in Fixture	Operator fixture check before machining	

The Occurrence Scoring is an estimate of the likelihood of the Failure Mode and / or the Potential Cause happening

The Occurrence Rating Table in AS13004 defines a set of criteria for determining the Occurrence Score

There should be an occurrence score for each Potential Cause

References	J1739	AS13004				AIAG FMEA - 4th Edition	J1739
Ranking	Likelihood of Failure	Low volume production		Process PPM	Time-Based Example	High volume production	
		Likelihood of Cause	Time-Based Example			Likelihood of Cause	Incidents per item/unit
10	Very High	100% of production	≥1 per occurrence per shift	500,000	≥ 1 per occurrence per shift	1 in 10	≥ 100 per thousand
9	High	50% of production	≥1 per occurrence per day	50,000	≥ 1 per occurrence per day	1 in 20	50 per thousand
8		20% of production	≥1 per 2-3 days	20,000	≥1 per 2-3 days	1 in 50	20 per thousand
7		10% of production	≥1 per week	10,000	≥ 1 per week	1 in 100	10 per thousand
6		5% of production	1 per month	5,000	≥1 per 2 weeks	1 in 500	2 per thousand
5	Moderate	0.5% of production	2 per year	1,000	≥1 per quarter	1 in 2,000	.5 per thousand
4		0.1% of production	1 per year	100	≥1 per half year	1 in 10,000	.1 per thousand
3		0.05% of production	1 per 5 years	10	≥1 per year	1 in 100,000	.01 per thousand
2	Low	0.01% of production	1 per 10 years	1	<1 per year	1 in 1,000,000	≤.001 per thousand
1		Less than 0.01% of production	<1 per 10 years	zero	Never	eliminated thru preventive controls	eliminated thru preventive controls

FMEA Section 4

Detection Controls and Detection Rating

Section 1		Section 2			Section 3			Section 4		Section 5	Section 6
Operation / Step	Requirements	Potential Failure Modes	Potential Effects of Failure	Severity Score	Potential Causes of Failure	Prevention Controls	Occ Score	Detection Controls	Detection Score	RPN	Improvement Actions
What is the process that you are focusing on (Process Step)? What are you trying to achieve (Product Requirements)? Defined by Engineering Drawings & Specifications Or Assembly Instructions PFMEA must include ALL Design Requirements		How could you get the Requirements wrong (Failure Modes)? What could happen if it did go wrong (Potential Effects)? How bad would it be if it did go wrong (Severity Score)?			What would need to fail in the process to cause the Failure Mode to occur (Potential Causes)? How could this be prevented (Prevention Controls)? How likely is it to go wrong (Occurrence Score)?			How will you check if the Cause and/or Failure Mode occur (Detection Controls)? How likely are you to detect the Cause or Failure Mode if it was defective (Detection Score)?		Risk Priority Number (RPN)	List of Improvement Actions required to mitigate the key Risks Identified
Product Focused					Process Focused				Risk Mitigation		

Detection Controls

(Detection of the Failure Mode and/or the Potential Cause)

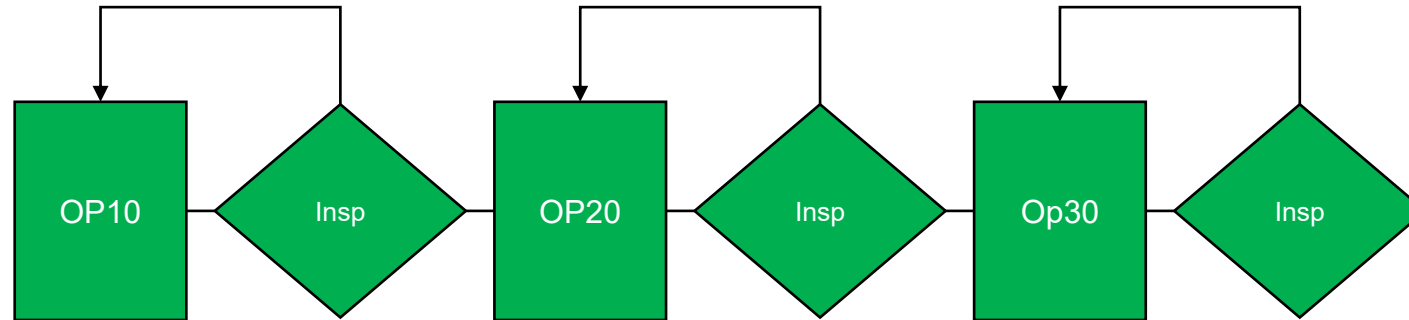
Requirement	Failure Mode	Potential Effect	Severity	Class.	Potential Cause	Prevention Control	Occurrence	Detection Controls	Detection	RPN
Hole Diameter 10.0 mm +/- 0.1mm	Hole Diameter Too Big	Engine Vibration	6		Wrong Drill Used (oversize)	Tool Pre-setting	6	CMM Check at Op450		
		Scrap Part	7		Spindle Alignment Error	Preventive Maintenance Schedule – laser alignment check every 6 months	3	CMM Check at Op450		
								CNC Ball Bar Check weekly		
		Concession	2		Part Loose in Fixture	Operator fixture check before machining	2	CMM Check at Op450		

DETECTION RANKING	References	Modified from J1739 / AS13004		Mistake-proofed	Gauged	Manual Inspection
	Ranking	Likelihood of Detection by Process Control - Category	Likelihood of Detection by Process Control - Criteria			
	10	Absolute Uncertainty	No current process control; Cannot detect or compliance analysis is not performed.		Manual gauging is used on every part	100% Human Inspection
	9	Difficult to Detect	Defect (Failure Mode) and/or Error (Cause) in not easily detected (e.g. Random audits).			
	8	Defect Detection Post Processing	Defect (Failure Mode) detection post-processing by operator through visual/tactile/audible means with no boundary samples.			
	7	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.) with no boundary samples.			
	6	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.) with boundary samples.			
	5	Defect Detection at Source	Defect (Failure Mode) or Error (Cause) detection in-station by operator through use of variable gauging or by automated controls that will detect discrepant part and notify operator (light, busser, etc.). Gauging performed on setup and first-piece check (for set-up causes only).			
	4	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.	Controls in place for mistake proofing the assembly	Automatic gauging or controls to detect discrepant part	
	3	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.			
	2	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.			
	1	Detection not applicable	Error (Cause) prevention as a result of fixture design, machine design or part design.			

What's the Score? Detection Controls Example

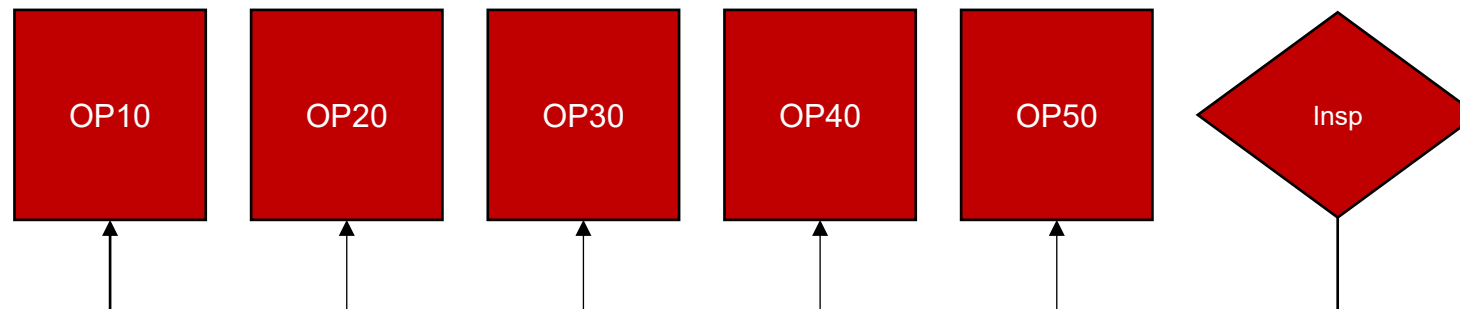
References	Modified from J1739 / AS13004		Mistake-proofed	Gauged	Manual Inspection	Detection Controls	Detection	RPN
Ranking	Likelihood of Detection by Process Control - Category	Likelihood of Detection by Process Control - Criteria						
10	Absolute Uncertainty	No current process control; Cannot detect or compliance analysis is not performed.			100% Human Inspection			
9	Difficult to Detect	Defect (Failure Mode) and/or Error (Cause) in not easily detected (e.g. Random audits).						
8	Defect Detection Post Processing	Defect (Failure Mode) detection post-processing by operator through visual/tactile/audible means with no boundary samples.						
7	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.) with no boundary samples.						
6	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.) with boundary samples.						
5	Defect Detection at Source	Defect (Failure Mode) or Error (Cause) detection in-station by operator through use of variable gauging or by automated controls that will detect discrepant part and notify operator (light, busser, etc.). Gauging performed on setup and first-piece check (for set-up causes only).	Controls in place for mistake proofing the assembly	Manual gauging is used on every part		CMM Check at Op450 (Post processing)	6	
4	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.		Automatic gauging or controls to detect discrepant part		Vernier check by Operator in cell at OP 100	5	
3	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.				CNC Ball Bar Check weekly	9	
2	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.				CNC in-cycle probing of diameter	3	
1	Detection not applicable	Error (Cause) prevention as a result of fixture design, machine design or part design.						

Why is 'In-Station/Process' Inspection better than 'Post Processing'?



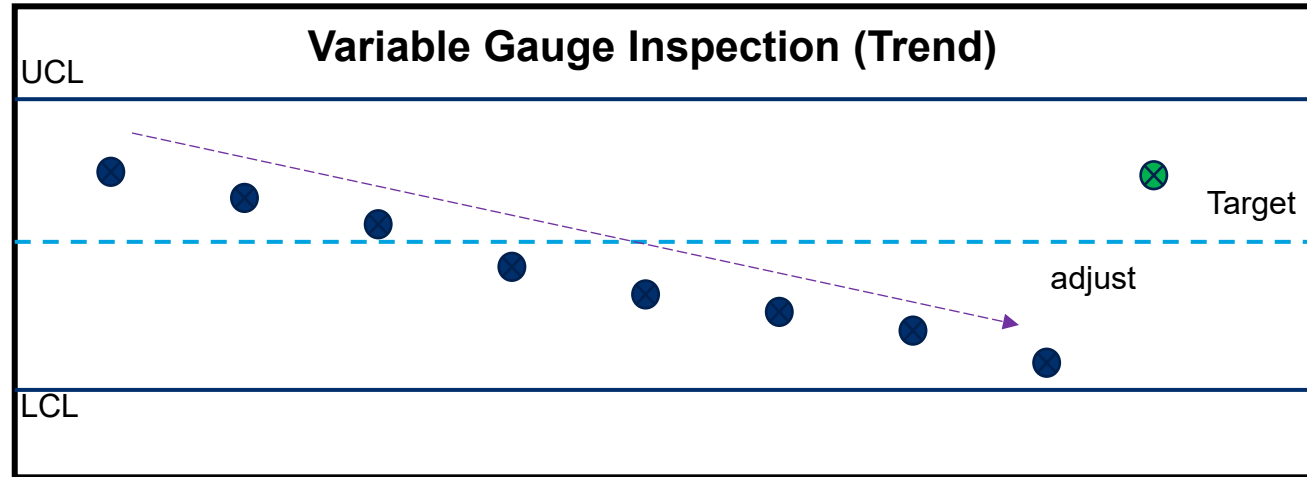
Inspection of Failure Mode and /or Error Cause in-station

Is less Risk than

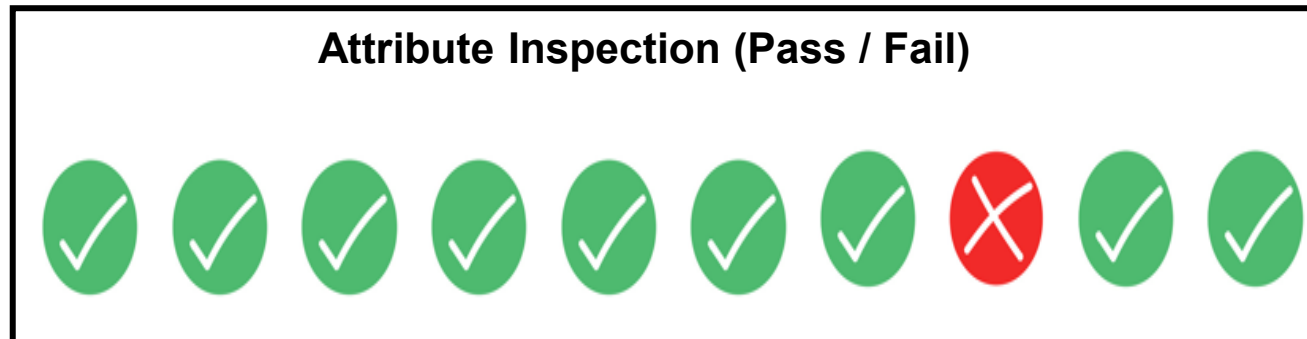


Inspection of Failure Mode at subsequent Operation or 'end of line' (post processing)

Why is Variable Gauging better than Attribute?



is more useful than



Ways to lower the Detection Score

1. **Mistake Proofing** the process (error cause prevention) is always the best option.
2. Second best is to Mistake Proof the inspection / detection process.

You Cannot Score Lower than a 5 without Automation!

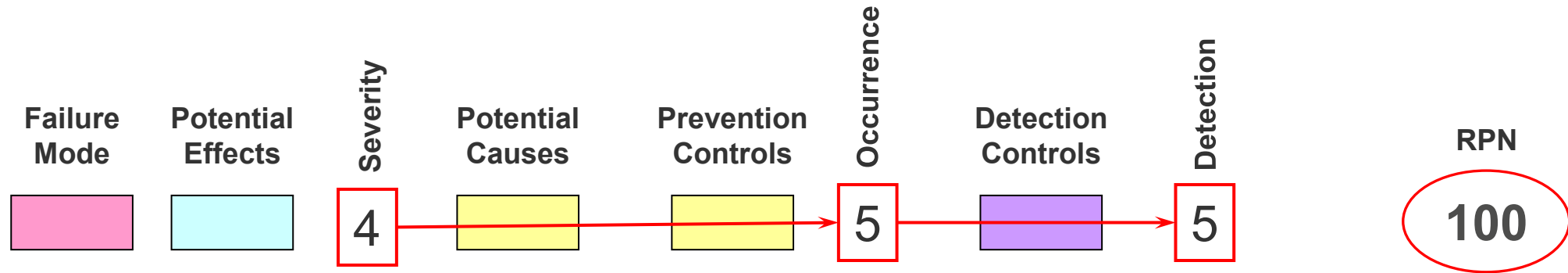
3. **In-process Inspection** (at source) is always preferred to 'end of line' inspection (post processing).
4. **Variable Gauging** is better than Attribute Gauging.
5. **Visual Inspection with Boundary Samples** is better than without 'Boundary Samples.'
6. Inspection that has **not passed MSA** is almost as bad as not inspecting it at all (includes measurement and visual inspection).

FMEA Section 5

Calculating the Risk Priority Number (RPN)

Section 1		Section 2			Section 3			Section 4		Section 5	Section 6
Operation / Step	Requirements	Potential Failure Modes	Potential Effects of Failure	Severity Score	Potential Causes of Failure	Prevention Controls	Occ Score	Detection Controls	Detection Score	RPN	Improvement Actions
What is the process that you are focusing on (Process Step)? What are you trying to achieve (Product Requirements)? Defined by Engineering Drawings & Specifications Or Assembly Instructions PFMEA must include ALL Design Requirements		How could you get the Requirements wrong (Failure Modes)? What could happen if it did go wrong (Potential Effects)? How bad would it be if it did go wrong (Severity Score)?			What would need to fail in the process to cause the Failure Mode to occur (Potential Causes)? How could this be prevented (Prevention Controls)? How likely is it to go wrong (Occurrence Score)?			How will you check if the Cause and/or Failure Mode occur (Detection Controls)? How likely are you to detect the Cause or Failure Mode if it was defective (Detection Score)?		Risk Priority Number (RPN)	List of Improvement Actions required to mitigate the key Risks Identified
Product Focused					Process Focused					Risk Mitigation	

FMEA Risk Priority Number Scoring



Severity x Occurrence x Detection = RPN

$$4 \times 5 \times 5 = 100$$

FMEA Risk Priority Number Scoring

Failure Mode	Potential Effects	Severity	Potential Causes	Prevention Controls	Detection Controls	Detection	RPN
		4				5	200
		6				5	128
		8				2	
		3				5	72
						3	
						6	

The **Highest** Severity Score

Every Occurrence Score of Each Potential Cause

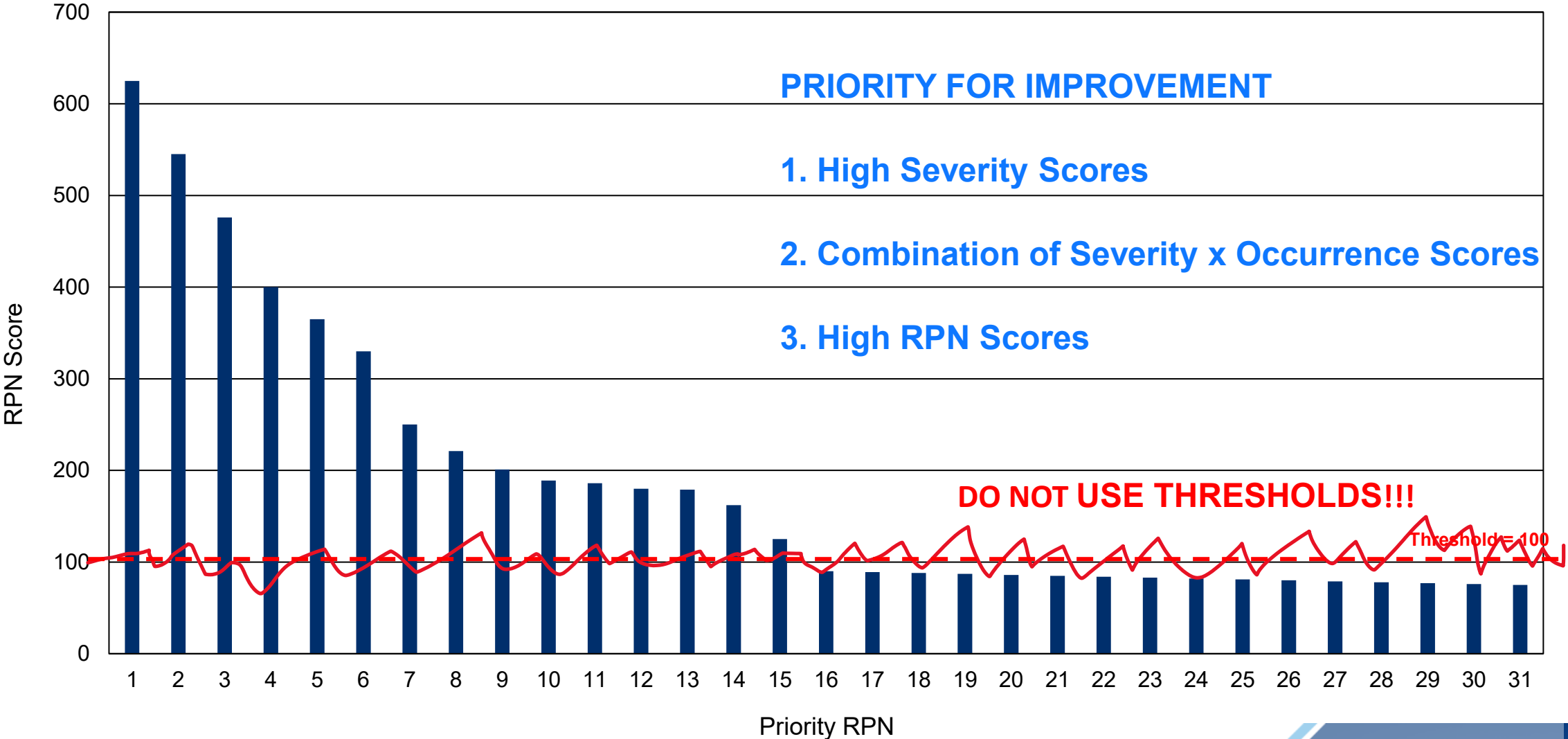
The **Lowest** Detection Score

An RPN Score For every Potential Cause & Failure Mode Combination

FMEA Section 6 Improved Actions

Section 1		Section 2			Section 3			Section 4		Section 5	Section 6
Operation / Step	Requirements	Potential Failure Modes	Potential Effects of Failure	Severity Score	Potential Causes of Failure	Prevention Controls	Occ Score	Detection Controls	Detection Score	RPN	Improvement Actions
What is the process that you are focusing on (Process Step)? What are you trying to achieve (Product Requirements)? Defined by Engineering Drawings & Specifications Or Assembly Instructions PFMEA must include ALL Design Requirements		How could you get the Requirements wrong (Failure Modes)? What could happen if it did go wrong (Potential Effects)? How bad would it be if it did go wrong (Severity Score)?			What would need to fail in the process to cause the Failure Mode to occur (Potential Causes)? How could this be prevented (Prevention Controls)? How likely is it to go wrong (Occurrence Score)?			How will you check if the Cause and/or Failure Mode occur (Detection Controls)? How likely are you to detect the Cause or Failure Mode if it was defective (Detection Score)?		Risk Priority Number (RPN)	List of Improvement Actions required to mitigate the key Risks Identified
Product Focused					Process Focused					Risk Mitigation	

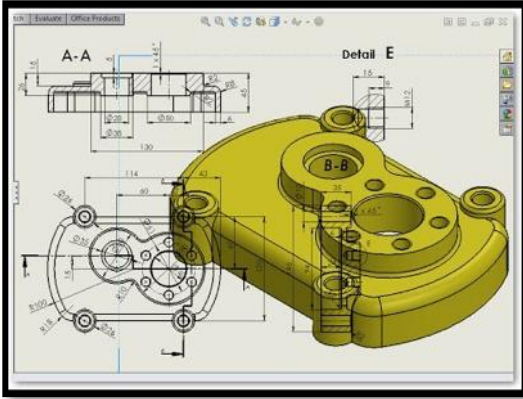
FMEA Action Prioritization RPN PARETO



FMEA Action Prioritization Occurrence x Severity GRID

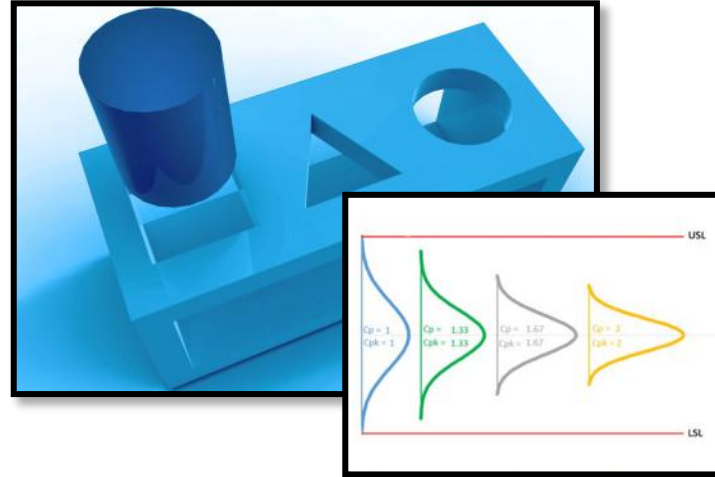
Occurrence Score	Severity Score									
	1	2	3	4	5	6	7	8	9	10
1	Green	Green	Green	Green	Green	Green	Green	Yellow	Red	Red
2	Green	LOW Risk Action Not Required		Green	Green	Green	Yellow	Yellow	Red	Red
3	Green			Green	Green	Yellow	Yellow	Yellow	Red	Red
4	Green	Green	Green	Green	MEDIUM Risk Action Maybe Required		Yellow	Yellow	Red	Red
5	Green	Green	Green	Yellow			Yellow	Yellow	Red	Red
6	Green	Green	Yellow	Yellow	Yellow	Red	Red	Red	Red	Red
7	Green	Yellow	Yellow	Yellow	Red	Red	Red	Red	HIGH Risk Action Required	
8	Green	Yellow	Yellow	Red	Red	Red	Red	Red		
9	Green	Yellow	Red	Red	Red	Red	Red	Red	Red	Red
10	Green	Red	Red	Red	Red	Red	Red	Red	Red	Red

Risk Mitigation Strategies



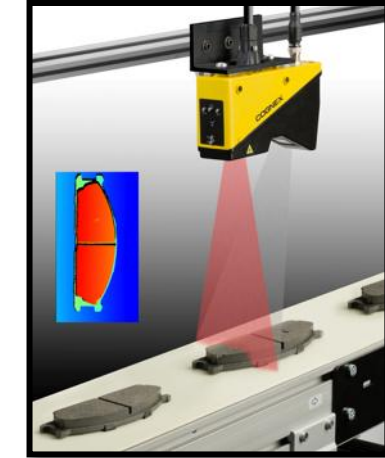
Severity Scores

Can only be reduced through Product Redesign
e.g. removing the need for a function or providing a 'fail safe' solution.



Occurrence Scores

Can be reduced through mistake proofing or enhanced process control leading to improved process capability.



Detection Scores

Can be reduced through finding error proof solutions for inspection (remove the reliance on human inspection) or using variable inspection at the point of feature creation.

Process FMEA Improvement Actions

Hole Diameter Too Big				
Sev	Potential Cause	Occ	Det	Risk Priority Number
9	CNC Spindle alignment error	4	6	216

IMPROVEMENT ACTIONS							
Recommended Actions	Responsibility	Target Date	Action Taken	Sev	Occ	Det	RPN
Move Bore Mic Inspection from OP50 to Op10 for Hole Diameter measurement (Improved DETECTION Score)	Sarah Seaward	June 1 st	Introduced May 29 th	9	4	5	180

Improved Detection Score from 6 to 5 by moving Variable Gauge check from 'post processing' to 'in-process'

Increase Frequency of Laser Alignment Check from 6 Monthly to Every Month (Improved OCCURRENCE Score)	Daryl Jackman	July 7 th	Introduced June 25 th	9	3	5	135
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Improved Occurrence Score from 4 to 3 by increasing the frequency of machine calibration and spindle alignment, hence minimizing the machine drift between calibrations.

Evaluating Your Process FMEA

Are all Operations & Steps where the product can be transformed included in the scope of the PFMEA?

Do the Effects include a description of how it impacts the customer / user as well as the internal impacts?

Are the Prevention Controls truly preventative to stop the Potential Cause from Occurring?

Operation / Step	Requirements	Potential Failure Modes	Potential Effects of Failure	Severity Score	Potential Causes of Failure	Prevention Controls	Occ Score	Detection Controls	Detection Score	RPN
				Does the Severity Score align to the AS13004 Guide?			Does the Occ Score align to the AS13004 Guide?		Does the detection Score align to the AS13004 Guide?	Has the RPN been scored properly ?

Do the Requirements describe the desired physical properties of the product that need to be achieved?

Do the Failure Modes describe the physical properties of the product and how they fail to meet the defined Requirements?

Are the list of Potential Causes clear on how they could cause the Failure Mode?

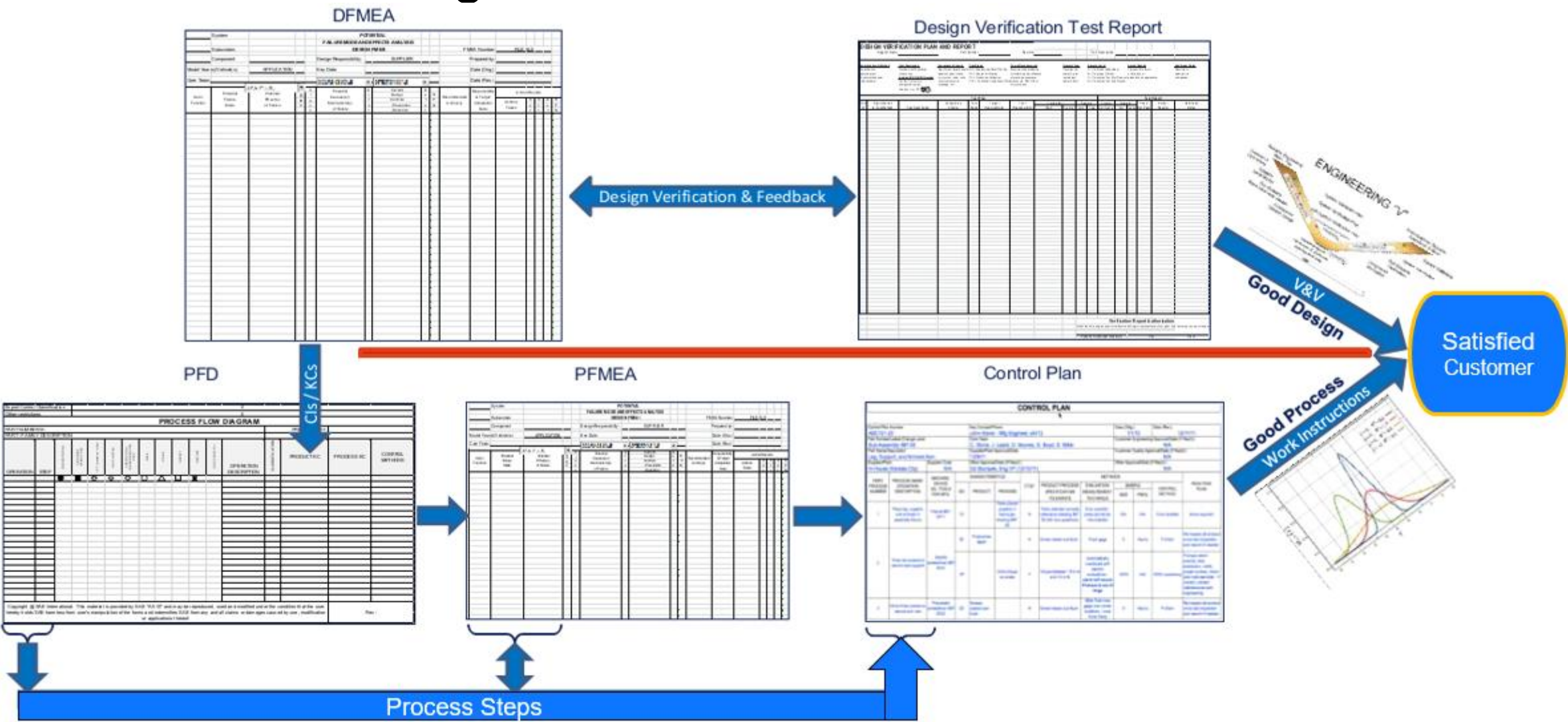
Do the Detection Controls include how the Failure Mode could be found as well as the Potential Cause?

The Underlying Message

- Don't correct a weak **product** design by focusing on a super robust process
- Don't correct a weak **process** design by focusing on design changes to the product

How does it fit all together?

How It All Fits Together



Questions



LOCKHEED MARTIN 