Quality Journey

FMEA

What is Failure Mode and Effects Analysis

Failure Mode and Effects Analysis, or FMEA, is a methodology aimed at allowing organizations to anticipate failure during the design stage by identifying all of the possible failures in a design or manufacturing process.
Is a structured approach to discovering potential failures that may exist within the design of a product or process.

Failure modes are the ways in which a process can fail
Effects are the ways that these failures can lead to waste, defects or harmful outcomes for the customer

Failure Mode and Effects Analysis is designed to identify, prioritize and limit these failure modes

There are two broad categories of FMEA, Design FMEA (DFMEA) and Process FMEA (PFMEA)

Design FMEA
Material Properties
Geometry
Tolerances
Interfaces with other components and/or systems
Engineering Noise

Process FMEA
Human Factors
Methods followed while processing
Materials used
Measurement systems impact on acceptance
Environment Factors on process performance

Why Perform Failure Mode and Effects Analysis (FMEA)

Risk is the substitute for failure on new processes. It is a good practice to identify risks for each process step as early as possible.

Risks are identified on new technology and processes, which if left unattended, could result in failure. The PFMEA is applied when:

- There is a new technology or new process introduced
- There is a current process with modifications, which may include changes due to updated processes, continuous Improvement, Kaizen or Cost of Quality (COQ).
- There is a current process exposed to a new environment or change in location (no physical change made to process)

FMEA Operating Definition

Failure Mode and Effects Analysis is a structured and systematic process to identify potential design and process failures before they have a chance to occur with the ultimate objective of eliminating these failures or at least minimizing their occurrence or severity. FMEA helps in

- Identifying the areas and ways in which a process or system can fail (failure mode)
- Estimating risk associated with specific causes
- Identifying and prioritizing the actions that should be taken to reduce those risks
- Evaluating and documenting proposed process plans or current control plans

What does Risk Analysis include?

Risk analysis includes

- Identification of risks
- Estimation of their likelihood of occurrence
- Estimation of their causes and the magnitude of their potential impact
- Risk evaluation and Development of risk mitigation plan

Full Failure	*Partial Failure*	*Intermittent Failure*	*Degraded Failure*	*Unintentional Failure*

Risk in the process can be defined and prioritized basis the **RPN number (Risk Priority Number)**

RPN = Severity * Occurrence * Detection

Severity

Effect	Criteria : Severity of effect on Product (Customer Effect)	Rank	Effect	Criteria : Severity of effect on Process (Manufacturing /Assembly Effect)
Failure to meet safety and or/ regulatory requirements	Potential failure affects safe vehicle operation and/ or involves noncompliance with government regulation without warning	10	Failure to meet safety and or/ regulatory requirements	May endanger the operator (machine or assembly) without warning
	Potential failure affects safe vehicle operation and/ or involves noncompliance with government regulation with a warning	9		May endanger the operator (machine or assembly) with a warning
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable , does not effect safe vehicle operation)	8	Major Disruption	100% of the product may have to be scrapped. Line shut down or stop the ship.
	Degradation of primary function (vehicle operable, but at reduced level of performance)	7	Significant Disruption	A portion of production run may have to be scrapped. Deviation from
				primary process including decreased line speed or added manpower.
Loss or Degradation of Secondary Function	Loss of Secondary Function (vehicle operable , but comfort/ convenience functions inoperable)	6	Moderate Disruption	100% of production run may have to be reworked off line and accepted.
	Degradation of Secondary Function (vehicle operable, but comfort/convenience functions at reduced level of performance)	5		A portion of production run may have to be reworked off line and accepted.
Annoyance	Appearance or Audible Noise, Vehicle operable, item does not conform and noticed by most customers (>75%)	4	Moderate Disruption	100% of production run may have to be reworked in station before it is processed.
	Appearance or Audible Noise, Vehicle operable, item does not conform and noticed	3		A portion of production run may have to be reworked in station before it is
	by many customers (50%)			processed.
	Appearance or Audible Noise, Vehicle operable, item does not conform and 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

Occurrence

Occurrence: A measure of probability that a particular failure will actually happen.

The degree of occurrence is measured on a scale of 1 to 10, where 10 signifies the highest probability of occurrence

Likelihood of Failure	Criteria: Occurrence of Cause – PFMEA (Incidents per items/vehicles)	Rank
Very High	≥ 100 per thousand	10
	≥ 1 in 10	
High	50 per thousand	9
	1 in 20	
	20 per thousand	8
	1 in 50	
	10 per thousand	7
	1 in 100	
Moderate	2 per thousand	6
	1 in 500	
	.5 per thousand	5
	1 in 2,000	
	.1 per thousand	4
	1 in 10,000	
Low	.01 per thousand	3
	1 in 100,000	
	≤ .001 per thousand	2
	1 in 1,000,000	
Very Low	Failure is eliminated through preventive control	1

Detection

A measure of probability that a particular failure or the cause in our operation shall be detected in current operation and shall not pass on to the next operation. (Would not affect the internal/ external customer

Opportunity for Detection	Criteria: Likelihood of Detection by Process Control	Rank	Likelihood of Detection
No detection Opportunity	No process control; cannot detect or is not analyzed	10	Almost Impossible
Not likely to detect at any stage	Failure Mode and or/ Error (Cause) is not easily detected (e.g. Random Audits).	9	Very Remote
Problem Detection Post Processing	Failure Mode Detection Post Processing by operator through visual/tactile/audible means.	8	Remote
Problem Detection at Source	Failure Mode detection in station by the operator through visual/tactile/audible means or post processing through the use of attribute gauging (go/no-go, manual torque check/clicker wrench etc.).	7	Very Low
Problem Detection Post Processing	Failure Mode post processing by the operator through the use of variable gauging or in station by the operator through the use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.).	6	Low
Problem Detection at Source	Failure Mode or Error (Cause) detection in -station by the operator through the use of variable gauging or by automated controls in-station that will detect discrepant part and notify the operator (light, buzzer, etc.). Gauging performed on setup and first-piece check (for set-up causes only).	5	Moderate
Problem Detection Post Processing	Failure Mode detection post-processing by automated controls that will detect discrepant part and lock parts to prevent further processing.	4	Moderately High
Problem Detection at Source	Failure Mode Detection in station by automated controls that will detect discrepant part and automatically lock parts in station to prevent further processing.	3	High
Error Detection and/or Problem Prevention	Error (Cause) detection in-station by automated controls that will detect the error and prevent the discrepant part from being made.	2	Very High
Detection not applicable; Error Prevention	Error (Cause) prevention as a result of fixture design, machine design or part design. Discrepant parts cannot be made because the item has been error proofed by process/product Design.	1	Almost Certain

FMEA Template

Item No.	Process Function/Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Potential Failure Cause	Current Process Controls				RPN	Recommended Action	R & D		Action Results				
						Prevention Controls	Occ	Detection Controls	Det			Responsible	Target Completion Date	Actions Taken	Sev	Occ	Det	RPN

When to do FMEA

The FMEA is a living document. Throughout the product development cycle change and updates are made to the product and process. These changes can and often do introduce new failure modes. It is therefore important to review and/or update the FMEA when:

- A new product or process is being initiated (at the beginning of the cycle).
- Changes are made to the operating conditions the product or process is expected to function in.
- A change is made to either the product or process design. The product and process are inter-related. When the product design is changed the process is impacted and vice-versa.
- New regulations are instituted.
- Customer feedback indicates problems in the product or process.

Steps to do a process FMEA

STEP 1: Review the process	• Use a process flowchart to identify each process component • List each process component in the FMEA table • If it starts feeling like the scope is too big, it probably is. This is a good time to break the Process Failure Mode and Effects Analysis into more manageable chunks
STEP2: Brain storm potential failure modes	• Review existing documentation and data for clues about all of the ways each component can failure. • The list should be exhaustive – it can be paired down and items can be combined after this initial list is generated. • There will likely be several potential failures for each component.
STEP 3: List potential effects of each failure	• The effect is the impact the failure has on the end product or on subsequent steps in the process. • There will likely be more than one effect for each failure.
STEP 4: Assign Severity rankings	• Based on the severity of the consequences of failure.
STEP 5: Assign Occurrence rankings	• Rate the severity of each effect using customized ranking scales as a guide.

Steps to do a process FMEA

STEP 6: Assign Detection rankings	• What are the chances the failure will be detected prior to it occurring.
STEP 7: Calculate the RPN	• Severity X Occurrence X Detection
STEP 8: Develop the action plan	• Decide which failures will be worked on based on the Risk Priority Numbers. Focus on the highest RPNs. • Define who will do what by when.
STEP 9: Take action	• Implement the improvements identified by your Process Failure Mode and Effects Analysis team
STEP 10: Calculate the resulting RPN	• Re-evaluate each of the potential failures once improvements have been made and determine the impact of the improvements

Thank You