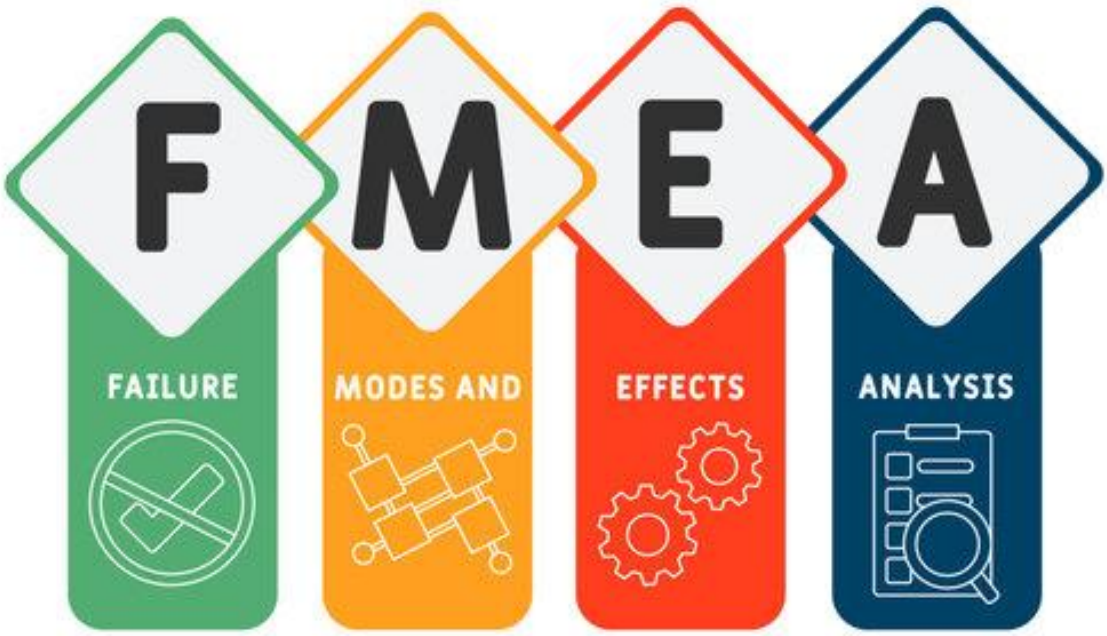
Study Guide: FMEA Study Guide



What is FMEA?

- Failure Mode and Effects Analysis (FMEA) is a systematic process that requires thoughtful consideration of all the potential failure modes associated with a new design or process
- In a perfect world, you would do an FMEA while you are designing the process because this is the time when you would be identifying and mitigating risk
- You can also do this process retroactively after you have designed your product or process in order to identify any weaknesses or failure modes and implement the appropriate corrective actions

FMEA risk management process

FMEA manages risk by systematically identifying potential failure modes, assessing their impact and likelihood, prioritizing them, and implementing control measures to reduce or mitigate their risks, thus improving product or process reliability and safety.

- **Risk Assessment**
  - Risk Identification: This initial step involves systematically identifying potential risks and their sources within a project, process, or system. It often relies on brainstorming sessions, historical data, and expert input to compile a comprehensive list of possible risks.
  - Risk Analysis: Once risks are identified, they must be analyzed in detail. This includes assessing the likelihood of each risk occurring and the severity of its potential impact.

Quantitative or qualitative analysis methods are employed to prioritize risks based on these factors.
    - Risk Evaluation: In this phase, prioritized risks are further evaluated to determine the level of risk exposure. This includes weighing the consequences of a risk against the organization's risk tolerance and strategic goals
- **Risk Control:** To mitigate or manage identified risks, appropriate control measures are put in place. These measures can include process changes, enhanced quality control, contingency plans, or the use of risk transfer mechanisms such as insurance
    - Risk Reduction: This step focuses on actively reducing the likelihood or severity of high-priority risks. Strategies may involve process improvements, technology upgrades, employee training, or other interventions aimed at minimizing risk exposure
    - Risk Acceptance: Some risks may be deemed acceptable, particularly when the cost of mitigation outweighs the potential impact. In such cases, organizations consciously choose to accept the risk, but this decision is typically documented and reviewed periodically.
- **Risk Review:** Regular reviews are crucial to monitor the effectiveness of risk management efforts. Risks evolve, and new ones may emerge, so ongoing assessment is essential to adapt strategies accordingly
    - Review Events: These events are scheduled checkpoints or milestones in the risk management process. They provide opportunities to assess progress, reassess risks, and ensure that risk management activities align with organizational objectives

DFMEA vs PFMEA

Issue	DFMEA	PFMEA
Customer	End-user plus related design teams & mfg	End-user plus downstream operations
Team Make-Up	Design Team	Process Team
Review	Blueprint or Schematic	Flowchart or Traveler
Intended Function(s)	Design Requirements	Operating parameters & product specs
Controls	Focus on product & design process	Manual, gages, & mistake- proofing
Ranking Criteria	Differs primarily in Severity & Detection Evaluation Criteria	

The DFMEA or Design FMEA, is focused on analyzing and improving the reliability and safety of your *new design*, with a heavy focus on design deficiencies and analysis of the different interactions, interfaces, and product features associated with your new design.

The PFMEA or Process FMEA, comes after the DFMEA and it is focused on analyzing your manufacturing or assembly process to identify all potential failure modes and then, subsequently assess the risk associated with those process deviations.

The 10 Steps of the FMEA process

Risk Identification

1. Define your system or process to be analyzed
2. Identify the potential failure modes for product or process

Risk Analysis

3. Determine the potential effects of the failure mode on the system or customer
4. Estimate the severity for each failure mode based on its effect
5. Determine the potential causes for each failure mode
6. Estimate the likelihood of occurrence for each failure mode and cause
7. Determine the control around those failure modes and the root cause
8. Estimate your detection level for each failure mode, cause, and effect
9. Calculate the Risk Priority Number (RPN) for each failure mode

Risk Evaluation and Risk Control

10. Take corrective action to reduce/mitigate or eliminate risk

Before you begin with the 10 steps, or step 0 in the process you must define the scales for Severity, Occurrence, and Detection. Also, document any assumptions, and define your acceptable risk level

Severity:

Effect	Criteria: Severity of Effect on Product (Customer Effect)	Rank	Effect	Criteria: Severity of Effect on Product (Manufacturing/Assembly Effect)
Failure to Meet Safety and/or Regulatory requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning	10	Failure to Meet Safety and/or Regulatory requirements	May endanger operator (machine or assembly) without warning.
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning	9		May endanger operator (machine or assembly) with warning.
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation)	8	Major Disruption	100% of product may have to be scrapped. Line shutdown or stop ship
	Degradation of primary function (vehicle operable, but at reduced level of performance)	7	Significant Disruption	A portion of the 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 the 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 by many customers (50%)	3		A portion of the 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 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:

Likelihood of Failure	Criteria: Occurrence of Cause - DFMEA (Design life/reliability of item/vehicle)	Criteria: Occurrence of Cause - PFMEA (Incidents per items/vehicles)		Rank
Very High	New technology/new design with no history.	≥ 100 per thousand ≥ 1 in 10		10
High	Failure is inevitable with new design, new application, or change in duty cycle/operating conditions.	50 per thousand 1 in 20		9
	Failure is likely with new design, new application, or change in duty cycle/operating conditions.	20 per thousand 1 in 50		8
	Failure is uncertain with new design, new application, or change in duty/operating conditions.	10 per thousand 1 in 100		7
Moderate	Frequent failures associated with similar designs or in design simulation and testing.	2 per thousand 1 in 500		6
	Occasional failures associated with similar designs or in design simulation and testing.	.5 per thousand 1 in 2,000		5
	Isolated failures associated with similar design or in design simulation and testing.	.1 per thousand 1 in 10,000		4
Low	Only isolated failures associated with almost identical design or in design simulation and testing.	.01 per thousand 1 in 100,000		3
	No observed failures associated with almost identical design or in design simulation and testing.	≤ .001 per thousand 1 in 1,000,000		2
Very Low	Failure is eliminated through preventative control.	Failure is eliminated through preventive control.		1

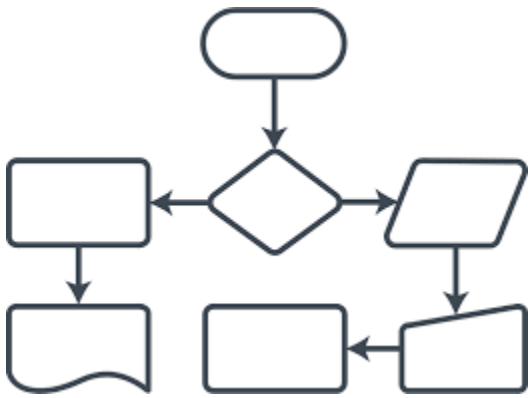
Detection:

Opportunity for Detection	Criteria: Likelihood of Detection by Design Control		Rank		Likelihood of Detection	Opportunity for Detection	Criteria: Likelihood of Detection by Process Control
No detection opportunity	No current design control; Cannot detect or is not analyzed.		10		Almost Impossible	No detection opportunity	No current process control; Cannot detect or is not analyzed
Not likely to detect at any stage	Design analysis/detection controls have a weak detection capability; Virtual Analysis (e.g., CAE, FEA, ect.) is **not correlated** to expected actual operating conditions.		9		Very Remote	Not likely to detect at any stage	Failure Mode and/or Error (Cause) is not easily detected (e.g. random audits)
Post Design Freeze and prior to launch	Product verification/validation after design freeze and prior to launch with **pass/fail** testing (Subsystem or system testing with acceptance criteria such as ride and handling, shipping evaluation, ect.).		8		Remote	Problem Detection Post Processing	Failure Mode detection post-processing by operator through visual/tactile/audible means
	Product verification/validation after design freeze and prior to launch with **test to failure** testing (Subsystem or system testing until failure occurs, testing of system interactions, etc.).		7		Very Low	Problem Detection at Source	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.)
	Product verification/validation after design freeze and prior to launch with **degradation** testing (Subsystem or system testing after durability test, e.g., function check).		6		Low	Problem Detection Post Processing	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)
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		Moderate	Problem Detection at Source	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 set-up causes only)
	Product validation (reliability testing, development or validation tests) prior to design freeze using **test to failure** (e.g., until leaks, yields, cracks, etc.)		4		Moderately High	Problem Detection Post Processing	Failure Mode detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing
	Product validation (reliability testing, development or validation tests) prior to design freeze using **degradation** testing (e.g., data trends, before/after values, etc.).		3		High	Problem Detection at Source	Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing.
Virtual Analysis Correlated	Design analysis/detection controls have a strong detection capability. Virtual analysis (e.g., CAE, FEA, etc.) **is highly correlated** with actual or expected operating conditions prior to design freeze		2		Very High	Error Detection and/or Problem Prevention	Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made.
Detection not applicable; Failure Prevention	Failure cause or failure mode can not occur because it is fully prevented through design solutions (e.g., proven design standard, best practice or common material, etc.)		1		Almost Certain	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 item has been error proofed by process/product design

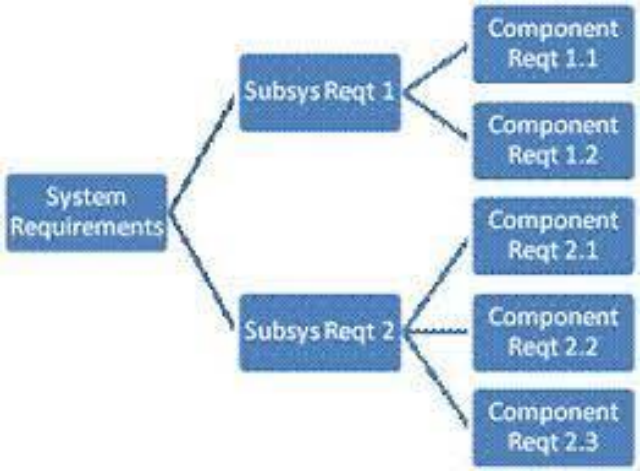
More on the FMEA steps:

- **Step 1.** Define your system or process to be analyzed

For a PFMEA, you can use a flow diagram to define your process and its various manufacturing steps that can contribute to failure

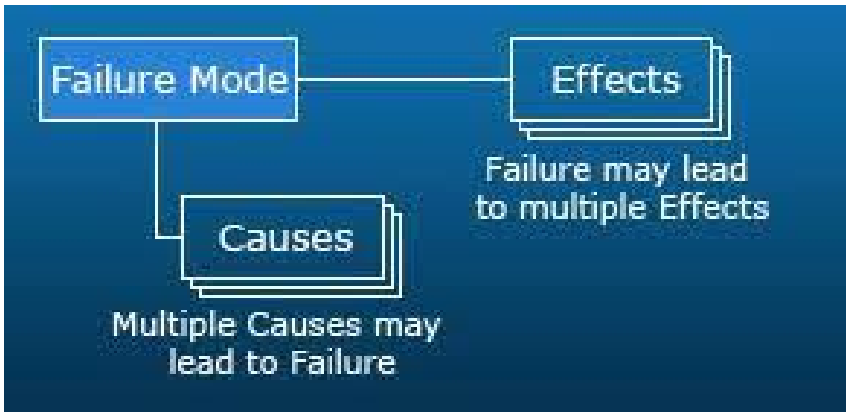


For a DFMEA, a system block diagram can be used to show the interfaces and relationships between the different aspects of your design



- **Step 2.** Identify potential failure modes
  - A failure is a non-conformance, error, or defect associated with your product
  - A failure mode is the mode, method, or way in which something might fail
  - For a DFMEA start with a design drawing to identify features, that if they were out of specification, would impact the functionality of the product
  - For a PFMEA your failure modes will be related to the various steps in the manufacturing process and how they might fail. The best way to find out how your process might fail is to walk your process with the subject matter experts.
  - Try not to talk only about the actual failure modes, but brainstorm potential failure modes as well, that way those risks can be mitigated and prevented from ever occurring in the first place.

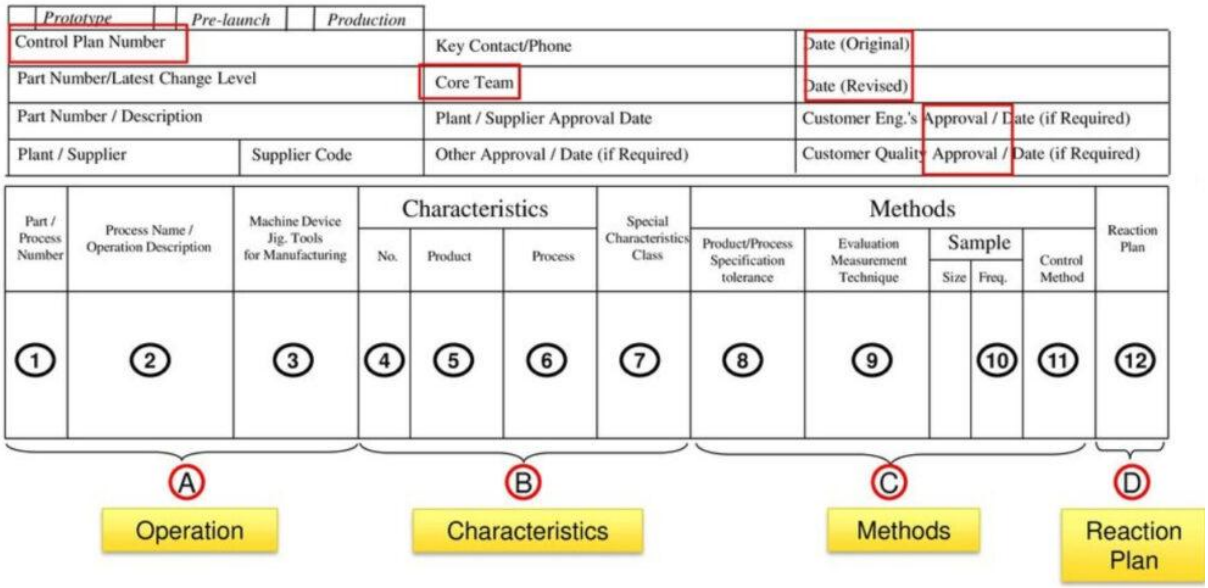
- **Step 3.** Determine the Effects
    - An effect is the impact on the end-user or customer. When the failure occurs what is the effect on the end user? This effect drives the severity score



- **Step 4:** Estimate the Severity
    - Severity is a measure of the degree to which the end user is affected or impacted by the potential failure mode being analyzed
- **Step 5:** Determine Potential Causes
    - Use the Root Cause Analysis tool that better serves you such as the 5 whys or the Fishbone Diagram.
    - In the Fishbone Diagram, you will find the 8Ms which are all potential causes of a failure mode:
        - Man: How do human interactions introduce potential failures
        - Machine: How can machines fail?
        - Method: What written procedures do you have in place and how might they result in failure
        - Materials: This is the one exception to most PFMEA and DFMEAs because this is a starting assumption where it is assumed that the materials are always conforming to all specifications

- Mother Nature: How might your production environment contribute to a failure mode
- Measurement: How might measuring techniques or equipment introduce failure
- Management: What are the attitudes and priorities of management that might result in a failure

- **Step 6:** Estimate the Occurrence
  - Once the root causes are identified, we can use them to estimate the occurrence.
  - The occurrence ranking is defined as the likelihood or possibility that a failure will occur
- **Step 7:** Determine the current controls
  - A control is anything in your process that might prevent or detect the failure mode that's being analyzed.



Advanced Product Quality Planning (APQP) Reference Manual, QS-9000

- **Step 8:** Estimate the Detection
  - Your detection is a reflection of the capability and effectiveness of your process control strategy to identify a failure mode once it has occurred, in other words, how likely are we to discover that failure
  - The detection score is based on the assumption that the failure mode has occurred
- **Step 9:** Calculate RPN
  - RPN gives us an objective prioritization tool to determine the "high-risk" failure modes that we should focus on
  - Risk Priority Number (RPN) = Severity * Occurrence * Detection
  - Focus your time on the highest RPNs and focus on corrective actions there

	S	x	O	x	D	=	RPN
FAILURE MODE 1	4		10		10		400
FAILURE MODE 2	10		10		4		400
FAILURE MODE 3	10		4		10		400

- **Step 10:** Take Corrective Actions
  - This is one of the most important steps in the process
  - During this step, you can recommend mitigation actions and follow the effect that action has in the process. This way we can determine what are the new Severity, Occurrence, and Detention scores, and finally the new RPN