



At a crossroads?



Failure Modes Effect Analysis (FMEA)





Failure Modes Effect Analysis (FMEA) is a structured approach to:

- Predict failures and prevent their occurrence in manufacturing and other functional areas that generate defects.
- Identify the ways in which a process can fail to meet critical customer requirements (Y).
- Estimate the Severity, Occurrence and Detection (SOD) of defects
- Evaluate the current Control Plan for preventing these failures from occurring and escaping to the customer.
- Prioritize the actions that should be taken to improve and control the process using a Risk Priority Number (RPN).



Give me an “F”, give me an “M”



History of FMEA:

- First used in the 1960's in the Aerospace industry during the Apollo missions
- In 1974 the Navy developed MIL-STD-1629 regarding the use of FMEA
- In the late 1970's automotive applications driven by liability costs began to incorporate FMEA into the management of their processes
- Automotive Industry Action Group (AIAG) now maintains the FMEA standard for both Design and Process FMEA's



- **System FMEA:** Performed on a product or service product at the early concept/design level when various modules all tie together. All the module level FMEA's tie together to form a system. As you go lower into a system more failure modes are considered.
 - Example: Electrical system of a car, consists of the following modules: battery, wiring harness, lighting control module and alternator/regulator.
 - System FMEA focuses on potential failure modes associated with the modules of a system caused by design
- **Design DFMEA:** Performed early in the design phase to analyze product fail modes before they are released to production. The purpose is to analyze how fail modes affect the system and minimize them. The severity rating of a fail mode MUST be carried into the Process PFMEA.
- **Process PFMEA:** Performed in the early quality planning phase of manufacturing to analyze fail modes in manufacturing and transactional processes that may escape to the customer. The failure modes and the potential sources of defects are rated and corrective action taken based on a Pareto analysis ranking.
- **Equipment FMEA:** used to analyze failure modes in the equipment used in a process to detect or make the part.
 - Example: Test Equipment fail modes to detect open and short circuits.



FMEA's:

- Improve the quality, reliability and safety of products.
- Increase customer satisfaction.
- Reduce product development time and cost.
- Document and track actions taken to reduce risk and improve the process.
- Focus on continuous problem prevention not problem solving.



Who

- The focused team working on a breakthrough project.
- ANYONE who had or has a role in defining, executing, or changing the process.
- This includes:
 - Associates
 - Technical Experts
 - Supervisors
 - Managers
 - Etc.

When

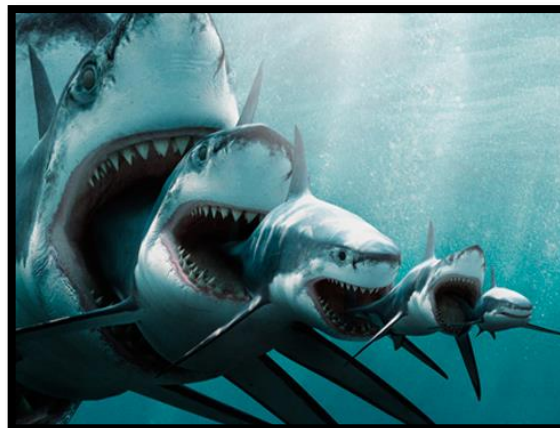
- Process FMEA's should be started:
 - At the conceptual design phase.
- Process FMEA's should be updated:
 - When an existing design or process is being changed.
 - When carry-over designs or processes will be used in new applications and environments.
 - When a problem solving study is completed and needs to be documented.
- System FMEA's should be created after system functions are defined but before specific hardware is selected.
- Design FMEA's should be created when new systems, products and processes are being designed.



As a means to manage...

RISK!!!

We want to avoid causing failures in the Process as well as the Primary & Secondary Metrics .





#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (Y's)	S E V	C l a s s	Potential Causes of Failure (X's)	O C C	Current Process Controls	D E T	R P N	Recommend Actions	Responsible Person & Target Date	Taken Actions	S E V	O C C	D E T	R P N
1																	
2																	
3																	
4																	
5																	
6																	
7																	
8																	
9																	



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The first column is the Process Step Number.

1

2

3

4

5

Etc.



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Enter the Name of the Process Function here. The FMEA should sequentially follow the steps documented in your Process Map.

Phone
Dial Number
Listen for Ring
Say Hello
Introduce Yourself
Etc.





#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (Y's)	Severity	Occurrence	Potential Causes of Failure (X's)	Occurrence	Current Process Controls	Detection	Retention	Recommend Actions	Responsible Person & Target Date	Taken Actions	Severity	Occurrence	Detection	Retention
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Potential Failure Modes refers to the mode in which the process could potentially fail. These are the defects caused by a C,P or N factor that could occur in the Process.

This information is obtained from Historical Defect Data.

FYI...A failure mode is a fancy name for a defect.



At a crossroads?





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Potential Failure Effects is simply the effect of realizing the potential failure mode on the overall process. It focuses on the outputs of each step.

This information can be obtained in the Process Map.



#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (Y's)	Severity	Causes	Potential Causes of Failure (X's)	Occurrence	Current Process Controls	Detection	Retention	Recommend Actions	Responsible Person & Target Date	Taken Actions	Severity	Occurrence	Detection	Retention
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This ranking should be developed based on the team's knowledge of the process in conjunction with the predetermined scale.

The measure of **Severity** is a financial measure of the impact to the business of realizing a failure in the output.





Effect	Criteria: Severity of Effect Defined	Ranking
Hazardous: Without Warning	May endanger the operator. Failure mode affects safe vehicle operation and/or involves non-compliance with government regulation. Failure will occur WITHOUT warning.	10
Hazardous: With Warning	May endanger the operator. Failure mode affects safe vehicle operation and/or involves non-compliance with government regulation. Failure will occur WITH warning.	9
Very High	Major disruption to the production line. 100% of the product may have to be scrapped. Vehicle/item inoperable, loss of primary function. Customers will be very dissatisfied.	8
High	Minor disruption to the production line. The product may have to be sorted and a portion (less than 100%) scrapped. Vehicle operable, but at a reduced level of performance. Customers will be dissatisfied.	7
Moderate	Minor disruption to the production line. A portion (less than 100%) may have to be scrapped (no sorting). Vehicle/item operable, but some comfort/convenience item(s) inoperable. Customers will experience discomfort.	6
Low	Minor disruption to the production line. 100% of product may have to be re-worked. Vehicle/item operable, but some comfort/convenience item(s) operable at a reduced level of performance. Customers will experience some dissatisfaction.	5
Very Low	Minor disruption to the production line. The product may have to be sorted and a portion (less than 100%) re-worked. Fit/finish/squeak/rattle item does not conform. Most customers will notice the defect.	4
Minor	Minor disruption to the production line. A portion (less than 100%) of the product may have to be re-worked online but out-of-station. Fit/finish/squeak/rattle item does not conform. Average customers will notice the defect.	3
Very Minor	Minor disruption to the production line. A portion (less than 100%) of the product may have to be re-worked online but in-station. Fit/finish/squeak/rattle item does not conform. Discriminating customers will notice the defect.	2
None	No effect.	1

* *Potential Failure Mode and Effects Analysis (FMEA), Reference Manual, 2002. Pgs 29-45. Chrysler Corporation, Ford Motor Company, General Motors Corporation.*

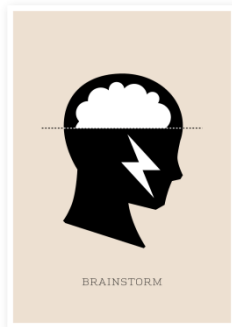


- The guidelines presented on the previous slide were developed for the auto industry.
- This was included only as a guideline....”actual results may vary” for your project.
- Your severity may be linked to impact on the business or impact on the next customer, etc.

***You will need to define your own criteria...
and be consistent throughout your FMEA***

Let's brainstorm how we might define the following **SEVERITY** levels in our own projects:

1, 5, 10





Effect	Criteria: Impact of Effect Defined	Ranking
Critical Business Unit-wide	May endanger company's ability to do business. Failure mode affects process operation and / or involves noncompliance with government regulation.	10
Critical Loss - Customer Specific	May endanger relationship with customer. Failure mode affects product delivered and/or customer relationship due to process failure and/or noncompliance with government regulation.	9
High	Major disruption to process/production down situation. Results in near 100% rework or an inability to process. Customer very dissatisfied.	7
Moderate	Moderate disruption to process. Results in some rework or an inability to process. Process is operable, but some work arounds are required. Customers experience dissatisfaction.	5
Low	Minor disruption to process. Process can be completed with workarounds or rework at the back end. Results in reduced level of performance. Defect is noticed and commented upon by customers.	3
Minor	Minor disruption to process. Process can be completed with workarounds or rework at the back end. Results in reduced level of performance. Defect noticed internally but not externally.	2
None	No effect.	1



#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (Y's)	Severity	Class	Potential Causes of Failure (X's)	Occurrence	Current Process Controls	Detectability	Repeatability	Recommend Actions	Responsible Person & Target Date	Taken Actions	Severity	Occurrence	Detectability	Repeatability
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Class should categorize each step as a...

- Controllable (C)
- Procedural (P)
- Noise (N)

This information can be obtained in the Process Map.

Controllable – A factor that can be dialed into a specific setting/value. For example Temperature or Flow.

Procedures – A standardized set of activities leading to readiness of a step. For example Safety Compliance, “Lock-Out Tag-Out.”

Noise - A factor that can not be dialed in to a specific setting/value. For example rain in a mine.



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Potential Causes of the Failure refers to how the failure could occur. This information should be obtained from the Fishbone Diagram.

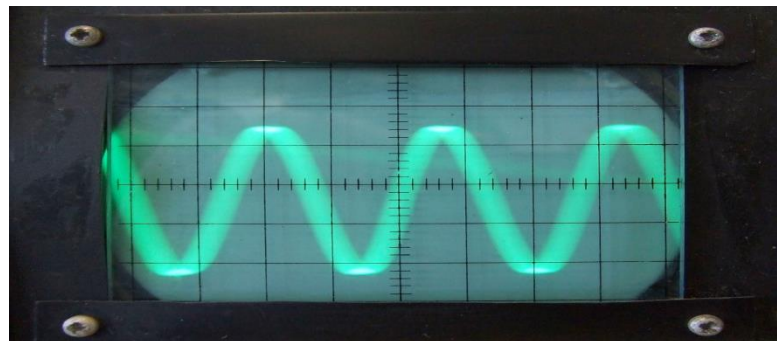




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Occurrence refers to how frequently the specified failure is projected to occur.

This information should be obtained from Capability Studies or Historical Defect Data - in conjunction with the predetermined scale.





Probability of Failure	Possible Failure Rates	Cpk	Ranking
Very High: Failure is almost inevitable.	≥ 1 in 2	< 0.33	10
	1 in 3	$^3 0.33$	9
High: Generally associated with processes similar to previous processes that have often failed.	1 in 8	$^3 0.51$	8
	1 in 20	$^3 0.67$	7
Moderate: Generally associated with processes similar to previous processes that have experienced occasional failures but not in major proportions.	1 in 80	$^3 0.83$	6
	1 in 400	$^3 1.00$	5
	1 in 2,000	$^3 1.17$	4
Low: Isolated failures associated with similar processes.	1 in 15,000	$^3 1.33$	3
Very Low: Only isolated failures associated with almost identical processes.	1 in 150,000	$^3 1.5$	2
Remote: Failure is unlikely. No failures ever associated with almost identical processes.	≤ 1 in 1,500,000	$^3 1.67$	1

Potential Failure Mode and Effects Analysis (FMEA), Reference Manual, 2002. Pg. 35.. Chrysler Corporation, Ford Motor Company, General Motors Corporation.



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Current Process Controls refers to the three types of controls that are in place to prevent a failure in with the X's. The 3 types of controls are:

- SPC - (Statistical Process Control)
- Poke-Yoke – (Mistake Proofing)
- Detection after Failure – (Inspection)

Ask yourself “How do we control this defect?”



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Detection is an assessment of the probability that the proposed type of control will detect a subsequent Failure Mode.

This information should be obtained from your Measurement System Analysis Studies and the Process Map. A rating should be assign in conjunction with the predetermined scale.



Detection	Criteria: The likelihood that the existence of a defect will be detected by the test content before the product advances to the next or subsequent process	Ranking
Almost Impossible	Test content must detect < 80% of failures	10
Very Remote	Test content must detect 80% of failures	9
Remote	Test content must detect 82.5% of failures	8
Very Low	Test content must detect 85% of failures	7
Low	Test content must detect 87.5% of failures	6
Moderate	Test content must detect 90% of failures	5
Moderately High	Test content must detect 92.5% of failures	4
High	Test content must detect 95% of failures	3
Very High	Test content must detect 97.5% of failures	2
Almost Certain	Test content must detect 99.5% of failures	1

Potential Failure Mode and Effects Analysis (FMEA), AIAG Reference Manual, 2002 Pg. 35. Chrysler Corporation, Ford Motor Company, General Motors Corporation.



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The Risk Priority Number is a value that will be used to rank order the concerns from the process.

The RPN is the product of Severity, Occurrence and Detect ability as represented here...

$$\text{RPN} = (\text{SEV}) * (\text{OCC}) * (\text{DET})$$



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Recommended Actions refers to the activity for the prevention of a defect.

Responsible Person & Date refers to the name of the group or person responsible for completing the activity and when they will complete it.

Taken Action refers to the action and effective date after it has been completed.



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Once the Recommended Actions, Responsible Person & Date, Taken Action have been completed the Severity, Occurrence and Detection should be adjusted. This will result in a new RPN rating.