Failure Modes and Effects Analysis

- ✓ Understanding Where the High-Leverage Opportunities Are
- ✓ What Are the Potential Risks

By

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Learning Objectives

◆ Understand the use of Failure Modes and Effects Analysis (FMEA)

◆ Learn the steps to developing FMEAs

◆ Summarize the different types of FMEAs

◆ Learn how to link the FMEA to other Blackbelt tools

When to Use FMEA

◆ FMEAs can be used in every Lean Six Sigma Phase:

- **Define and Measure**
  - To understand the risks of a project

- **Analyze**
  - To understand how process steps or KPIVs relate to risk
  - To prioritize KPIVs

- **Improve**
  - To understand the improvement implementation risks

- **Control**
  - To assess the effectiveness of a Control Plan

Application Examples

◆ A manager is responsible for moving a manufacturing operation to a new facility. He wants to be sure the move goes as smoothly as possible and that there are no surprises.

◆ A design engineer wants to think of all the possible ways a product he is designing could fail so that he can build robustness into the product.

◆ A Black Belt wants to use FMEA so that he can focus on the key improvement opportunities for a process.

◆ A maintenance engineer wants to analyze the possible failures of a piece of equipment for Reliability Centered Maintenance (RCM)

FMEA different types

According to the target there is a differentiation between:

- The **Design (Construction)-FMEA**, sometime named R&D-FMEA
- The **Process-FMEA**
- The **Systems-FMEA**.
- The **Equipment-FMEA**

◆ Basic procedure of the FMEAs is similar. Differentiation comes up with the planning phase associated with, the development of the FMEA and the target setting for the process.

◆ The Design-FMEA is linked with the blueprint. It is used to disclose potential errors of the blueprint, to quantify the relevance of the findings and to propose counter measures.

◆ The Process-FMEA analyzes the potential errors in the process. Aim is here to quantify the potential errors and the weak points of the process and to develop adequate counter measures to avoid the weaknesses.

Note: There is FMECA Failure Mode Effect Criticality Analyzes also mentioned in literature

Analyze Phase

◆ The team develops an understanding of the greatest sources of variation within the process and pinpoints the critical few key process input variables that must be addressed to improve the key process output variables.
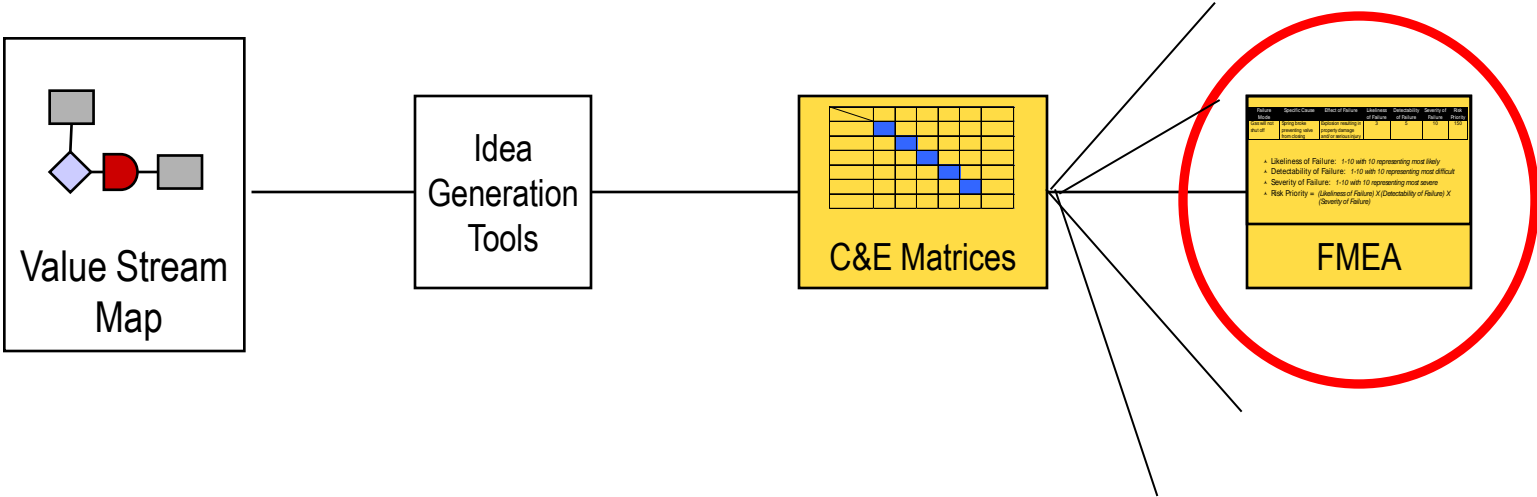
What Is a Failure Mode?

◆ The way in which the component, subassembly, product, input, or process could fail to perform its intended function. Failure modes may be the result of upstream operations or may cause downstream operations to fail.

◆ Things that could go wrong.

FMEA

◆ **What**

■ Failure Modes and Effects Analysis is a methodology to evaluate failure modes and their effects in designs and in processes.

Process Step/ Input	Potential Failure Mode	Potential Failure Effects	S E V E R I T Y	Potential Causes	O C C U R A N C E	Current Controls	D E T E C T I O N	R P N	Actions Recommended	Resp.	Actions Taken	S E V E R I T Y	O C C U R A N C E	D E T E C T I O N	R P N
What is the process step and input under investiga-tion?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements)?		What causes the Key Input to go wrong?		What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode?			What are the actions for reducing the occurrence of the cause, or improving detection?		What are the completed actions taken with the recalculated RPN?				

- Severity of Failure: *1-10 with 10 representing most severe*
- Occurrence of Failure: *1-10 with 10 representing highest rate of occurrences*
- Detection of Failure: *1-10 with 10 representing most difficult to detect*
- Risk Priority Number (RPN) = *Severity x Occurrence x Detection*

FMEA

◆ **Why**

- Facilitates process improvement

- Identifies and eliminates concerns early in the development of a process or design

- Improves internal and external customer satisfaction

- Focuses on prevention

- FMEA may be a customer requirement

- FMEA may be required by an applicable Quality System Standard

FMEA

◆ **How**

- ■ Team identifies potential failure modes for design functions or process requirements.
  - ● They assign severity to the effect of this failure mode
  - ● They assign frequency of occurrence to the potential cause of failure
  - ● Probability of detection of failure
- ■ Team calculates a Risk Priority Number by multiplying severity times frequency of occurrence times likelihood of detection
- ■ Team uses ranking to focus process improvement efforts.

When to Conduct an FMEA

◆ Early in the process improvement investigation

◆ When new systems, products, and processes are being designed

◆ When existing designs or processes are being changed

◆ When carry-over designs are used in new applications

◆ After system, product, or process functions are defined, but before specific hardware is selected or released to manufacturing

◆ To analyze potential failures of equipment to determine a Reliability Centered Maintenance Program

FMEA

◆ A structured approach to:

- ■ Identifying the ways in which a product or process can fail

- ■ Estimating risk associated with specific causes

- ■ Prioritizing the actions that should be taken to reduce risk

- ■ Evaluating design validation plan (product) or current control plan (process)

The FMEA Form

Process/Product FMEA Form

| Process or Product Name: | | | Prepared by: | | Page ___ of ___ | | | |
| FMEA Date (Orig) _____ (Rev) _____ |

Process Step/ Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Causes	OCCURANCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURANCE	DETECTION	RPN
What is the process step and input under investiga-tion?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements)?		What causes the Key Input to go wrong?		What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode?			What are the actions for reducing the occurrence of the cause, or improving detection?		What are the completed actions taken with the recalculated RPN?				

Identify failure modes and their effects

Identify causes of the failure modes and controls

Prioritize

Determine and assess actions

FMEA:
A Team Tool

◆ A team approach is necessary.

◆ Team should be led by the Blackbelt, a responsible manufacturing engineer or technical person, or other similar individual familiar with FMEA.

◆ The following should be considered for team members:

- ■ Design
- ■ Manufacturing
- ■ Quality
- ■ Reliability
- ■ Materials
- ■ Suppliers
- ■ Customers

FMEA Procedure

1. For each process input (start with high value inputs), determine the ways in which the input can go wrong (failure mode).

2. For each failure mode, determine effects.
   - Select a severity level for each effect.

3. Identify potential causes of each failure mode.
   - Select an occurrence level for each cause.

4. List current controls for each cause.
   - Select a detection level for each cause.

5. Calculate the Risk Priority Number (RPN).

FMEA Procedure (Cont.)

6. Develop Recommended Actions, Assign Responsible Persons, and Take Actions.

   - Give priority to high RPNs
   - MUST look at severities rated a 10.

7. Assign the Predicted Severity, Occurrence, and Detection Levels and Compare RPNs

FMEA Inputs and Outputs

Inputs

Brainstorming
C&E Matrix
Value Stream Map
Process History
Procedures
Knowledge
Experience

FMEA

Outputs

List of actions to prevent causes or detect failure modes

History of actions taken

Failure Modes and Effects

◆ The relationship between failure modes and effects is not always 1 to 1.
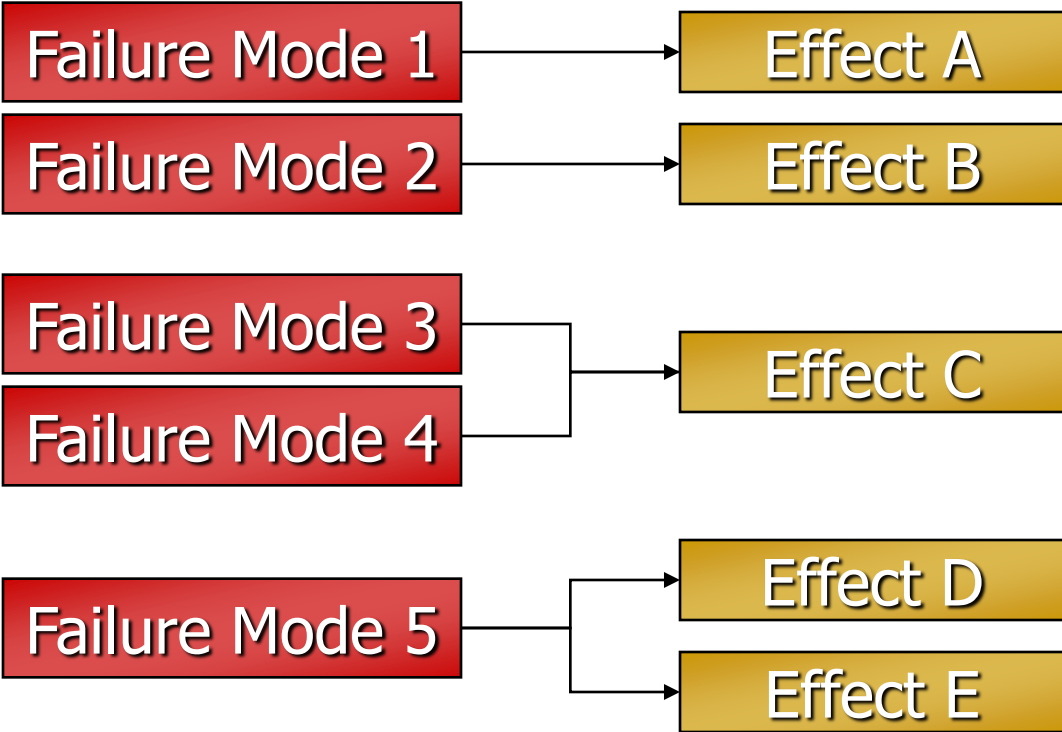
Severity, Occurrence, and Detection

◆ **Severity**

- Importance of the effect on customer requirements.
  - Often can't do anything about this.
  - 1=Not Severe, 10=Very Severe

◆ **Occurrence**

- Frequency with which a given cause occurs and creates failure modes.
- 1=Not Likely, 10=Very Likely

◆ **Detection**

- The ability of the current control scheme to detect or prevent a given cause.
- 1=Likely to Detect, 10=Not Likely to Detect

Rating Scales

◆ There are a wide variety of scoring "anchors", both quantitative or qualitative.

◆ Two types of scales are 1-5 or 1-10.

◆ The 1-5 scale makes it easier for the teams to decide on scores.

◆ The 1-10 scale allows for better precision in estimates and a wide variation in scores (most common).

FMEA Example

◆ We will conduct an FMEA on the truck stop example we used to create a C&E Matrix.

◆ A Black Belt wants to improve customer satisfaction with the coffee served at the truck stop.

◆ The value stream map and completed C&E matrix follow.

Truck Stop Coffee Process Stream Map

Inputs

Hot Water
Soap
Scrubber

Clean Carafe
Cold Water
Measuring Mark

Full Carafe

Filter

Maker w/Filter
Fresh Coffee
Dosing Scoop

Maker w/Filter &
Coffee

Brewing Coffee

Process Steps:

- Clean Carafe
- Fill Carafe w/Water
- Pour Water into Maker
- Place Filter in Maker
- Put Coffee in Filter
- Turn Maker On
- Select Temperature Setting
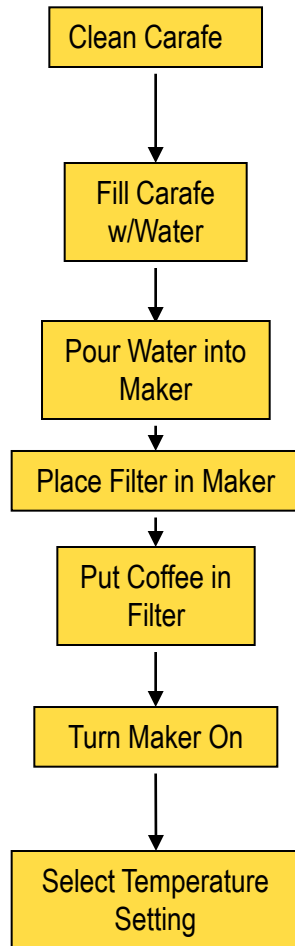
Outputs

Cleaned Carafe
Dirty Water
Wet Scrubber

Full Carafe

Filled Maker
Empty Carafe

Maker w/Filter

Maker w/Filter &
Coffee

Operating Maker
Heat
Brewed Coffee

Hot Coffee

Inputs

Customer
Order
Size Specification

Complete Order
Hot Coffee
Cup

Filled Cup
Customer
Cream
Sugar
Amount Desired

Complete Order
Money

Coffee Delivery

Process Steps:

- Receive Coffee Order
- Pour Coffee into Cup
- Offer Cream & Sugar
- Complete Transaction
- Say Thank You
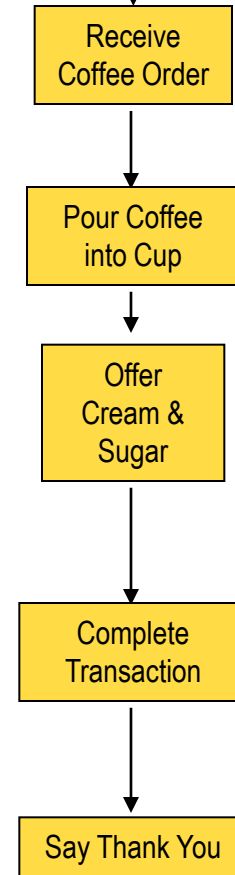
Outputs

Complete Order

Filled Cup

Customer Reply
Amount Specified
Complete Order

Make Change
Temperature
Taste
Strength

Smile
Happy Customer

Truck Stop Coffee C&E Matrix

		Temp of Coffee	Taste	Strength		Process Outputs
		8	10	6		
Process Steps	**Process Inputs**	**Correlation of Input to Output**				**Total**
Clean carafe			3	1		36
Fill carafe with water			9			**144**
Pour water into maker			1			16
Place filter in maker			3			36
Put coffee in filter			9			**144**
Turn maker on		3	1			34
Select temperature setting		9	3	3		120
Receive coffee order				1		6
Pour coffee into cup		3	1	3		52
Offer cream and sugar		3	9	3		132
Complete transaction		1	1	1		24
Say thank you				0		

> We will focus on one of the two steps with the highest scores

Step 1. For Each Input, Determine the Potential Failure Modes

Process/Product FMEA Form

Process or Product Name:			Prepared by:		Page ___ of ___	
			FMEA Date (Orig) _____ (Rev) _____			
Responsible:						

Process Step/ Input	Potential Failure Mode	Potential Failure Effects	S E V E R I T Y	Potential Causes	O C C U R A N C E	Current Controls	D E T E C T I O N	R P N	Actions Recommended	Resp.	Actions Taken	S E V E R I T Y	O C C U R A N C E	D E T E C T I O N	R P N
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Fill carafe with water	Wrong amount of water														
	Water too warm														
	Carafe not clean														

Step 2. For Each Failure Mode, Identify Effects and Assign Severity

3. ANALYZE

Process/Product FMEA Form

Process or Product Name:		Prepared by:		Page ___ of ___
Responsible:		FMEA Date (Orig) _____ (Rev) _____		

Process Step/ Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Causes	OCCURANCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURANCE	DETECTION	RPN
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Fill carafe with water	Wrong amount of water	Coffee too strong or too weak													
	Water too warm	Coffee too strong													
	Carafe not clean	Foreign objects in coffee													
		Bad taste													

Step 3. Identify Potential Causes of Each Failure Mode and Assign Score

Process/Product FMEA Form

Process or Product Name:		
Responsible:		

Prepared by:	Page ___ of ___
FMEA Date (Orig) _____ (Rev) _____	

Process Step/ Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Causes	OCCURANCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURANCE	DETECTION	RPN
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Fill carafe with water	Wrong amount of water	Coffee too strong or too weak	8	Faded level marks on carafe	4										
			8	Water spilled from carafe	5										
	Water too warm	Coffee too strong	8	Faucet not allowed to run and cool	8										
			8	Employee not aware of new need for cool water	7										
	Carafe not clean	Foreign objects in coffee	10	Carafe not washed	4										
		Bad taste	10	Carafe stored improperly	7										

Step 4. List Current Detection Controls for Each Cause and Assign Score

Process/Product FMEA Form

Process or Product Name:						
		Prepared by:		Page ___ of ___		
Responsible:		FMEA Date (Orig) _____ (Rev) _____				

Process Step/ Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Causes	OCCURANCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURANCE	DETECTION	RPN
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Fill carafe with water	Wrong amount of water	Coffee too strong or too weak	8	Faded level marks on carafe	4	Visual inspection	4								
			8	Water spilled from carafe	5	None	9								
	Water too warm	Coffee too strong	8	Faucet not allowed to run and cool	8	Finger	4								
			8	Employee not aware of new need for cool water	7	None	10								
	Carafe not clean	Foreign objects in coffee	10	Carafe not washed	4	Visual inspection	4								
		Bad taste	10	Carafe stored improperly	7	Training	5								

Step 5. Calculate RPNs

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**Process/Product
FMEA Form**

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Process or Product Name:		Prepared by:		Page ___ of ___	
		FMEA Date (Orig) _____ (Rev) _____			
Responsible:					

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Fill carafe with water	Wrong amount of water	Coffee too strong or too weak	8	Faded level marks on carafe	4	Visual inspection	4	128							
			8	Water spilled from carafe	5	None	9	360							
	Water too warm	Coffee too strong	8	Faucet not allowed to run and cool	8	Finger	4	256							
			8	Employee not aware of new need for cool water	7	None	10	560							
	Carafe not clean	Foreign objects in coffee	10	Carafe not washed	4	Visual inspection	4	160							
		Bad taste	10	Carafe stored improperly	7	Training	5	350							

Step 6. Develop Recommended Actions, Assign Responsible Persons, and Note Actions Taken

Process/Product FMEA Form

Process or Product Name:		Prepared by:		Page ___ of ___
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Fill carafe with water	Wrong amount of water	Coffee too strong or too weak	8	Faded level marks on carafe	4	Visual inspection	4	128	Replace carafe	Mel	Carafe replaced				
			8	Water spilled from carafe	5	None	9	360	Train employees	Flo	Employees trained				
	Water too warm	Coffee too strong	8	Faucet not allowed to run and cool	8	Finger	4	256	Train employees	Flo	Employees trained				
			8	Employee not aware of new need for cool water	7	None	10	560	Train employees	Flo	Employees trained				
	Carafe not clean	Foreign objects in coffee	10	Carafe not washed	4	Visual inspection	4	160	Appoint inspector before storage	Alice	Vera is the new inspector				
		Bad taste	10	Carafe stored improperly	7	Training	5	350	Create storage bin & train employees	Alice	New storage bin & employees trained				

Step 7. Compare RPNs, Prioritize and Implement Solutions

Process/Product FMEA Form

Process or Product Name:							Prepared by:		Page ___ of ___					
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Responsible:														

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			8	Water spilled from carafe	5	None	9	360	Train employees	Flo	Employees trained	8	2	7	112
	Water too warm	Coffee too strong	8	Faucet not allowed to run and cool	8	Finger	4	256	Train employees	Flo	Employees trained	8	2	6	96
			8	Employee not aware of new need for cool water	7	None	10	560	Train employees	Flo	Employees trained	8	1	8	64
	Carafe not clean	Foreign objects in coffee	10	Carafe not washed	4	Visual inspection	4	160	Appoint inspector before storage	Alice	Vera is the new inspector	10	1	4	40
		Bad taste	10	Carafe stored improperly	7	Training	5	350	Create storage bin & train employees	Alice	New storage bin & employees trained	10	2	3	60