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Failure Mode and Effect Analysis

Key Learning Points

1. Describe the importance of Failure Mode and Effect Analysis.
2. Explain how to develop and interpret Failure Mode and Effect Analysis.
3. Utilize Failure Mode and Effect Analysis in improvement projects.

What is Failure Mode and Effect Analysis?

Failure Mode and Effect Analysis (FMEA) is a systematic method for identifying possible failures that pose the greatest overall risk for the process, product, or service. It depends on identifying a failure mode, the effect of a failure, the cause of a failure, and analysis of the failure mode.

Structured

FMEA provides a structured approach to identifying and prioritizing potential failure modes, taking action to prevent and detect failure modes and making sure mechanisms are in place to ensure ongoing process control.

Identifies

FMEA helps to document and identify where in a process lies the source of the failure that impacts a customer's CTQ's.

Failure Mode and Effect Analysis Example

Process Step or Variable or Key Input	Potential Failure Mode	Potential Effect on Customer Because of Defect	SEV	Potential Causes	OCC	Current Process Controls	DET	RPN
1. Customer Application	Application being filled out incorrectly	Application has to be resubmitted	8	Difficult to understand instructions	6	Check of application form for correct information by data entry operator	2	96
2. Data Entry	Data entered incorrectly	Customer receives checks with printing errors	4	Data entry error within a single field	6	None in place	10	240
3. Data Entry	Data entered incorrectly	Customer receives checks with printing errors	4	Information entered in wrong field	4	Self inspection	5	80

How FMEA Works

Once each failure mode is identified, the data is analyzed, and three factors are quantified:

- Severity (SEV): The severity of the effect of the failure as felt by the customer (internal or external). The question may be asked, "How significant is the impact of the effect to the customer?"
- Occurrence (OCC): The frequency which each failure or potential cause of the failure occurs. The question may be asked, "How likely is the cause of the failure mode to occur?"
- Detection (DET): The chance that the failure will be detected before it affects the customer (internal or external). The question may be asked, "How likely will the current system detect the failure mode if it occurs, or when the cause is present?"

Each of the three factors is scored on a 1 (Best) to 10 (Worst) scale. The combined impact of these three factors is the Risk Priority Number (RPN). This is the calculation of risk of a particular failure mode, and is determined by the following calculation: RPN = SEV x OCC x DET

The RPN is used to place priority on which items need additional quality planning.

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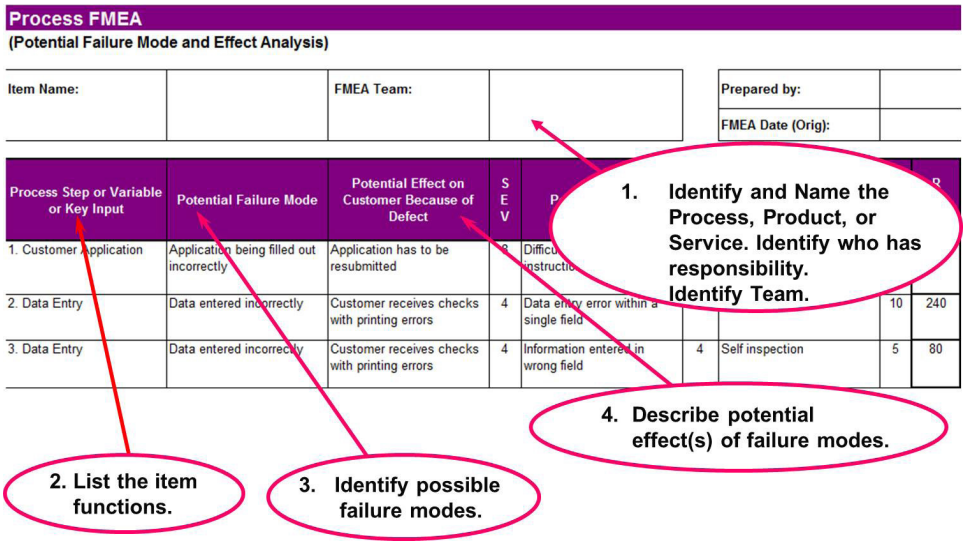
FMEA Factors

Process Step or Variable or Key Input	Potential Failure Mode	Potential Effect on Customer Because of Defect	SEV	Potential Causes	OCC	Current Process Controls	DET	RPN
What is the process step?	In what ways can the Process Step, Variable, or Key Input go wrong? (Chance of not meeting requirements)	What is the impact on the Key Output Variable (Customer Requirements) or internal requirements)	How Severe is the effect to the customer?	What causes the Key Input to go wrong? (How could the failure mode occur)	How frequent is cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or defect it should occur?	How probable is Detection of cause?	Risk Priority Number to rank order concerns

Steps in Conducting FMEA



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Process FMEA
(Potential Failure Mode and Effect Analysis)

Item Name:		FMEA Team:		Prepared by:	
				FMEA Date (Orig):	

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5. Use table to identify severity.

Process FMEA
(Potential Failure Mode and Effect Analysis)

7. Rate the likelihood of the identified failure cause occurring.

Item Name:		FMEA Team:		Prepared by:	
				FMEA Date (Orig):	

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6. Identify Potential Cause(s) of failure….
"How the failure could occur"
Hint:
Describe in terms of something that can be corrected or can be controlled.

8. Describe the current process controls to prevent the failure mode.

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Process FMEA

(Potential Failure Mode and Effect Analysis)

Item Name:		FMEA Team:		Prepared by:	
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9. Use table to determine the likelihood that the failure cause will be detected.

10. Multiply the three ratings to calculate the Risk Priority Number (RPN).

RPN	Actions Recommended	Resp.& Target Date	Actions Taken
96			
240			
80			

11. Use the RPN to identify further actions. Once action is taken, recalculate the RPN.

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Rating Factors

Severity

RATING	DEGREE OF SEVERITY
1	Customer will not notice the adverse effect or it is insignificant
2	Customer will probably experience slight annoyance
3	Customer will experience annoyance due to the slight degradation of performance
4	Customer dissatisfaction due to reduced performance
5	Customer is made uncomfortable or their productivity is reduced by the continued degradation of the effect
6	Warranty repair or significant manufacturing or assembly complaint
7	High degree of customer dissatisfaction due to component failure without complete loss of function. Productivity impacted by high scrap or rework levels.
8	Very high degree of dissatisfaction due to the loss of function without a negative impact on safety or governmental regulations
9	Customer endangered due to the adverse effect on safe system performance with warning before failure or violation of governmental regulations
10	Customer endangered due to the adverse effect on safe system performance without warning before failure or violation of governmental regulations

Probability

RATING	PROBABILITY OF OCCURRENCE	
		FREQUENCY (1 in ...)
1	Likelihood of occurrence is remote	1,000,000
2	Low failure rate with supporting documentation	20,000
3	Low failure rate without supporting documentation	5,000
4	Occasional failures	2,000
5	Relatively moderate failure rate with supporting documentation	500
6	Moderate failure rate without supporting documentation	100
7	Relatively high failure rate with supporting documentation	50
8	High failure rate without supporting documentation	20
9	Failure is almost certain based on warranty data or significant Design Verification* testing	10
10	Assured of failure based on warranty data or significant Design Verification* testing	2

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Detection

RATING	ABILITY TO DETECT	
		Detection Certainty
1	Sure that the potential failure will be found or prevented before reaching the next customer	100%
2	Almost certain that the potential failure will be found or prevented before reaching the next customer	99%
3	Low likelihood that the potential failure will reach the next customer undetected	95
4	Controls may detect or prevent the potential failure from reaching the next customer	90
5	Moderate likelihood that the potential failure will reach the next customer	85
6	Controls are unlikely to detect or prevent the potential failure from reaching the next customer	80
7	Poor likelihood that the potential failure will be detected or prevented before reaching the next customer	70
8	Very poor likelihood that the potential failure will be detected or prevented before reaching the next customer	60
9	Current controls probably will not even detect the potential failure	50
10	Absolute certainty that the current controls will not detect the potential failure	< 50

When Should FMEA Be Used?

FMEA is used to help rank potential Xs when creating theories of potential cause. It also used when evaluating alternative solutions or improvements.

Pitfalls to Avoid

Using only the RPN to select where to focus the action might lead you to the wrong conclusion. How could this happen? How would you avoid the pitfall?

Look at the example below.

Failure C has by far the highest severity, but occurs only rarely and is invariably discovered before affecting the customer.

Failure B has minor impact each time it occurs, but it happens often, although it is almost always discovered before affecting the customer.

Failure A has even smaller impact and occurs less often than B. When the failure does occur, it almost always escapes detection. The RPNs suggest that, as a result, failure mode A is the failure mode to work on first. This choice might not be the best if you have not defined and assigned your ratings correctly. Because C has

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such a large effect when it does occur, be sure that both its frequency of occurrence and chance of detection are small enough to be the least important to work on now.

The result above would not be unusual, because the very large impact could have led to improvements in the past that reduced the defect rate and improved detection and control. The team needs to review the results and ask whether the individual interpretations and relative RPNs are consistent with their understanding of the process.

If the results do not seem to make sense, the team should review both the values assigned to each ranking and the rankings assigned to each failure mode, and change them if appropriate. However, FMEA analysis, by forcing systematic thinking about three different dimensions of risk, may in fact give the team new insights that do not conform with their prior understanding.

Failure Mode	Sev (1-10)	Occ (1-10)	Det (1-10)	RPN
A	2	4	10	80
B	3	8	2	48
C	9	2	1	18

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