



Failure Mode & Effects Analysis

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LEARNING OBJECTIVES:

- To understand Failure Mode & Effects Analysis (FMEA) concepts and terms
- To know when to use FMEA
- To be able to lead a process improvement team through successful FMEA completion
- To know how to analyze FMEA results
- To be able to craft risk mitigation plans informed by FMEA results

WHY COMPLETE AN FMEA?

“First reckon, then risk.”

Field Marshal Helmuth Graf von Moltke, 1800-1891

Risk is unavoidable in business. Every product we design and manufacture, every process we perform, every action we undertake carries with it some risk of failure, no matter how remote. Despite the dire consequences product or process failure may bring, we often do not take the time to evaluate and mitigate risk prior to launching a product or process.

Benefits of a Properly-Executed FMEA:

- **Improved product/process functionality & robustness**
- **Reduced warranty/liability costs**
- **Fewer manufacturing problems**
- **Improved products and processes**
- **Reduced business process issues**
- **Greater customer satisfaction**

FMEAs PROVIDE A COMPLETE PICTURE OF RISK EXPOSURE

WHEN DO WE COMPLETE AN FMEA?

Define

Review 1

Project Charter*

Measurable Y

Business CTQs

Project 4-Blocker*

Updated Storyboard*

Updated Database

Accept Champion Review 1
Signed:

(Champion)

(Process Owner)

(BB/MBB)

Measure

Review 2

Process Description
(SIPOC, etc.)

Customer CTQs

Initial Performance of
Y (in Zst)

Confidence level &
interval of above

Performance target for
Y (in Zst)

Updated Storyboard*

Updated Database

Accept Champion Review 2
Signed:

(Champion)

(Process Owner)

(BB/MBB)

Analyze

Review 3

Potential Xs

Critical Xs

Performance Targets
for Xs

Financial model*

Updated Storyboard*

Updated Database

Accept Champion Review 3
Signed:

(Champion)

(Process Owner)

(BB/MBB)

Improve

Review 4

Improvement strategy
(mean shift and/or
spread reduction)

Improvement model

Implementation plan

Risk analysis

Risk mitigation plan

New Process Description
(SIPOC, etc.)

Updated Storyboard*

Updated Database

Accept Champion Review 4
Signed:

(Champion)

(Process Owner)

(BB/MBB)

Control

Review 5

Post-project
Performance of Y (in Zst)

Transition plan

Control plan

Lessons learned*

Project documentation
(E-file, etc.)

Updated Storyboard*

Updated Database

Accept Champion Review 5
Signed:

(Champion)

(Process Owner)

(BB/MBB)

(Finance Owner)

* indicates template exists for deliverable which must be used

TYPES OF FMEA

There are two main types of FMEA: **Design FMEAs**, which are used to evaluate products, and **Process FMEAs**, which are used to evaluate processes.

DESIGN FMEA

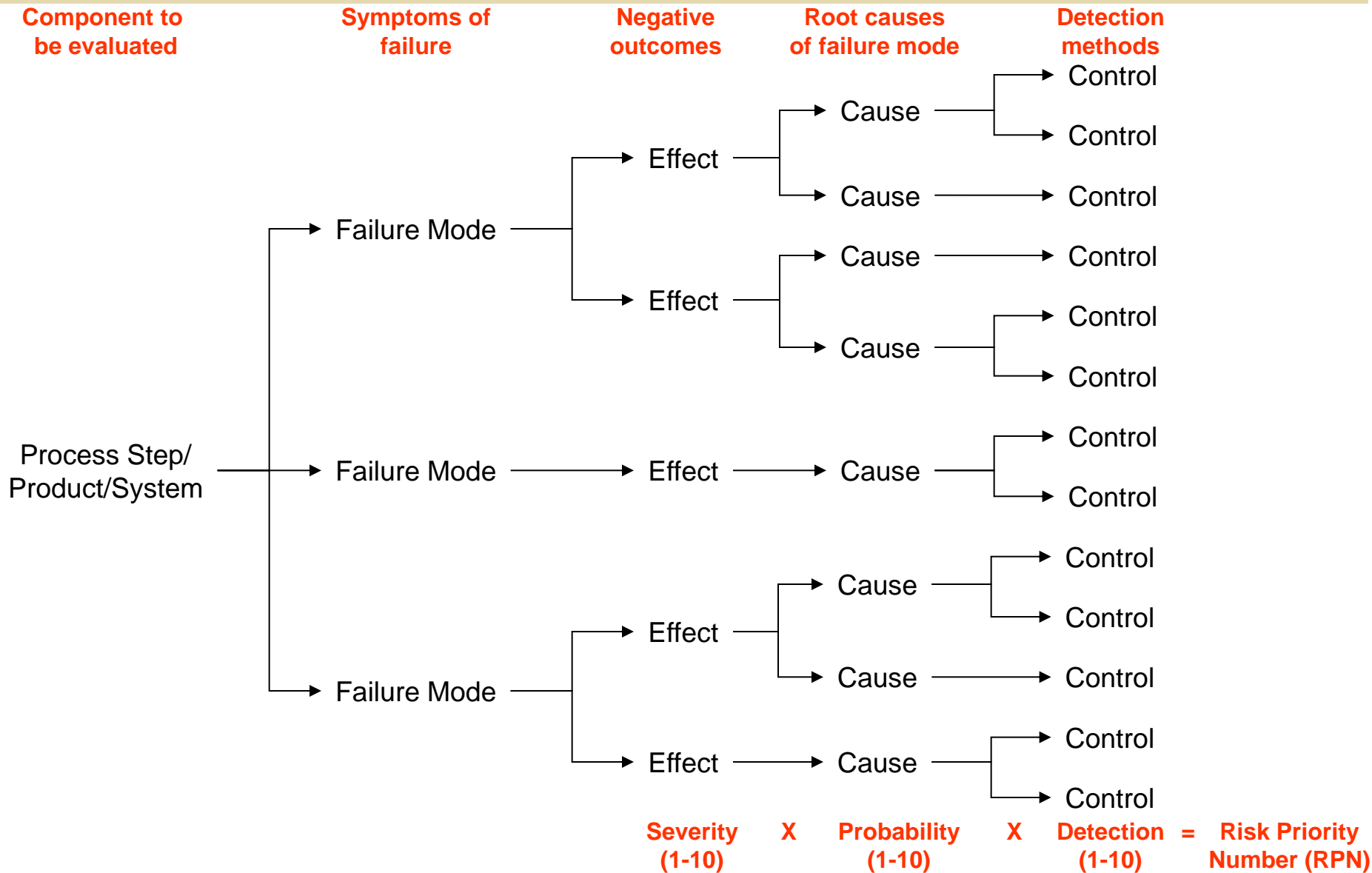
- Focuses on product risk
- Breaks product down into subsystems for risk analysis
- More technical in nature
- Failure modes tied to external customer/end user CTQs
- Does not rely on process controls to reduce risk
- Does consider manufacturability issues
- Relies upon clear definition of design intent

PROCESS FMEA

- Focuses on process risk
- Breaks process down into steps for analysis
- More transactional in nature
- Failure modes tied to internal and external customer CTQs
- Relies upon process controls to reduce risk
- Does not contemplate product design issues
- Requires clear definition of process flow

MAJOR DIFFERENCE IS WHETHER PRODUCT OR PROCESS IS STUDIED

ELEMENTS OF FMEA



Gather Team of Experts

- Should represent all subsystems/ components in design
- Should have detailed knowledge of design

Determine Effects of Failure

- For each failure mode
- List one or more possible impacts upon customer
- Rank occurrence

Determine Failure Modes

- List every subsystem in Item/Process Column
- For each subsystem, list 2-3 ways it can fail
- Rank severity according to provided scale

Analyze & Improve

- Calculate RPN
- Action plan
- Implement plan
- Recalculate RPN

Determine Causes of Failure

- List one or more root causes
- Identify Controls allowing for detection or prevention of root cause
- Rank detection

Gather Team of Experts

- Should represent all process steps
- Should have detailed knowledge of process

Determine Effects of Failure

- For each failure mode
- List one or more possible impacts upon customer
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Determine Failure Modes

- List every process step in Item/Process Column
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Analyze & Improve

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Determine Causes of Failure

- List one or more root causes
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FMEA OBJECTIVE SCALES--SEVERITY

Without objective scales, FMEAs can become exercises in frustration as the team tries to rank severity, occurrence, and detection to calculate RPN. The scales below can be used to objectively rank these areas:

Effect	SEVERITY of Effect	Ranking
Hazardous without warning	Potential failure mode impacts safety of product without prior warning.	10
Hazardous with warning	Potential failure mode impacts safety of product with prior warning.	9
Very High	Potential failure mode renders product inoperative and irreparable without impact on safety.	8
High	Potential failure mode renders product inoperative but repairable without impact on safety.	7
Moderate	Product inoperative with minor damage	6
Low	Product inoperative without damage	5
Very Low	Product operative with significant degradation of performance (>50%)	4
Minor	Product operative with some degradation of performance (>10%)	3
Very Minor	Product operable with minimal interference (10% or less)	2
None	No effect	1

FMEA OBJECTIVE SCALES--OCCURRENCE

Occurrence is based upon the probability of failure. To use, one must calculate the failure rate for a given element, then convert that failure rate to DPMO (defects per million opportunities) and apply the scale below.

PROBABILITY of Failure	Failure Prob	Ranking
Very High: Failure is almost inevitable	500,000 in 1,000,000 (1.5 Sigma)	10
	308,538 in 1,000,000 (2.0 Sigma)	9
High: Repeated failures	158,655 in 1,000,000 (2.5 Sigma)	8
	66,807 in 1,000,000 (3.0 Sigma)	7
Moderate: Occasional failures	22,750 in 1,000,000 (3.5 Sigma)	6
	6,210 in 1,000,000 (4.0 Sigma)	5
	1,350 in 1,000,000 (4.5 Sigma)	4
Low: Relatively few failures	233 in 1,000,000 (5.0 Sigma)	3
	32 in 1,000,000 (5.5 Sigma)	2
Remote: Failure is unlikely	3.4 in 1,000,000 (6.0 Sigma)	1

FMEA OBJECTIVE SCALES--DETECTION

Detection is based on the effectiveness of the process controls and the probability that they will adequately detect potential root causes of failure. Once this effectiveness is known, simply apply the scale below to rate detection.

Detection	Likelihood of DETECTION by Design Control	Ranking
Absolute Uncertainty	Design control cannot detect potential cause/mechanism and subsequent failure mode	10
Very Remote	<10% chance design control will detect potential cause/mechanism and subsequent failure mode.	9
Remote	25% chance design control will detect potential cause/mechanism and subsequent failure mode.	8
Very Low	33% chance design control will detect potential cause/mechanism and subsequent failure mode.	7
Low	50% chance design control will detect potential cause/mechanism and subsequent failure mode.	6
Moderate	60% chance design control will detect potential cause/mechanism and subsequent failure mode.	5
Moderately High	75% chance design control will detect potential cause/mechanism and subsequent failure mode.	4
High	90% chance design control will detect potential cause/mechanism and subsequent failure mode.	3
Very High	95% chance design control will detect potential cause/mechanism and subsequent failure mode.	2
Almost Certain	100% chance design control will detect potential cause/mechanism and subsequent failure mode.	1

How do we address the risk of a bad PMI-Metrolina Chapter meeting?

SUMMARY

Failure Mode and Effects Analysis can be a powerful tool for analyzing and reducing risk; however, it must be properly employed. Follow the tips below to ensure a successful application of the tool:

- DO** include all product/process experts on FMEA development team
- DO** review the FMEA tool, development process, and scales with team
- DO** begin by drawing a high-level system or process map
- DO** determine RPN rankings through consensus
- DO** challenge any rankings > 8 or < 3 ---there is a tendency to exaggerate
- DO** use complementary tools such as Pareto analysis to inform results
- DO** review RPN rankings at end to “sanity check” results
- DO** use FMEA to follow up on required improvement actions

FOLLOW THESE TIPS TO MAXIMIZE CHANCE OF SUCCESS