Failure Mode and Effects Analysis
FMEA

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Agenda

- FMEA Defined
- FMEA Applications
- FMEA Terminology
- FMEA Core Elements
- Assessing Risk
- Step by Step Instructions

FMEA Defined

- Failure Mode and Effects Analysis implies that:
  - Every product or process has modes of failure
  - The effects represent the impact of the failures

- FMEA is a tool to:
  - Identify risks for a product or process
  - Initiate action plans
  - Track results of the action plan

FMEA Applications

- FMEA evaluates the impact of a potential failure of a product or process
- Design FMEA Application (DFMEA)
  - Applied to new designs and design improvements
- Process FMEA Application (PFMEA)
  - Applied to new and existing processes

FMEA Terminology

Failure Mode - a description of a “non-conformance” at a given process step.

Failure Effect - The effect of a particular failure mode on the customer. “What does the customer want?”

Failure Cause - How could the failure occur? It is best to describe this in terms of something that can be corrected or controlled.

FMEA Terminology

Severity - How severe was the failure? (core element #1)

Occurrence - This is an assessment of how often the problem occurs. (*core element #2*)

Detection- This is an assessment of the probability that your current controls will detect the defect. (*core element #3*)

FMEA Core Element #1

- Severity (S)
  - a qualitative assessment of the seriousness of a potential failure mode to the internal and external customers. **Severity** applies to the effect only.

- Severity
  - is estimated on a “1” to “10” scale

Severity : Likely Impact Of Failure

EFFECT	Criteria: Severity of Effect	Ranking
Hazardous – No Warning	Highest Level – Injury or Death	10
Hazardous – With Warning	Very High Level – Non-Compliance to government regulation	9
Very High	Process/Product/Item inoperable with loss of primary function. Customer very dissatisfied. (100% of product may have to be scrapped).	8
High	Process/Product/Item operable but at reduced level. Customer dissatisfied. (Product may have to be sorted, less than 100% scrap; the customer is dissatisfied).	7
Moderate	Process/Product/Item operable but may cause rework/repair and/or damage. A portion (less than 100 %) of the product may have to be scrapped	6
Low	Process/Product/Item operable but may cause slight inconvenience to operations. (100% of the product may have to be reworked.)	5
Very Low	Process/Product/Item operable but possesses some defects (aesthetic, etc.) noticeable to most customers. (The product may have to be sorted and a portion less than 100% reworked)	4
Minor	Process/Product/Item operable but possesses some defects (aesthetic, etc.) noticeable to average customers	3
Very Minor	Process/Product/Item operable but non-compliant to company policy. (Defect noticed by discriminating customers)	2
None	No Defect	1

FMEA Core Element #2

- Occurrence (O)
  - The likelihood that a specific failure cause/mechanism will occur and how frequent.
  - The “possible failure rates” are based on the historical data of similar processes or failures which may be anticipated during the execution of the process or design.
- Occurrence is estimated on a “1” to “10” scale

Effect & Analysis: Occurrence (O) Criteria

Probability of Failure	Possible Failure Rates	Ranking	Cpk
Very High: Failure is inevitable	≥1 in 2	10	Less than or = to a Cpk of 0.33
Very High	1 in 3	9	Greater than or = to a Cpk of 0.33
High: Repeated Failure	1 in 8	8	Less than or = to a Cpk of .51
High	1 in 20	7	Greater than or = to a Cpk of 0.51
Moderate: Occasional Failure	1 in 80	6	Greater than or = to a Cpk of 0.83
Moderate	1 in 400	5	Greater than or = to a Cpk of 1.00
Moderate	1 in 2,000	4	Greater than or = to a Cpk of 1.17
Low: Relatively Few Failures	1 in 15,000	3	Greater than or = to a Cpk of 1.33
Low	1 in 150,000	2	Greater than or = to a Cpk of 1.50
Remote	≤1 in 1,500,000	1	Greater than or = to a Cpk of 2.0

FMEA Core Element #3

- Detection (D)

  Type 1 or Prevention Controls are the strongest type of design control. Prevention controls include techniques such as mistake-proofing, predictive design validation, and reliability studies.

  Type 2 or Detection of Failure Mode Mechanisms are not as strong as type 1 controls. They include systems that self-alarm if a failure mechanism is triggered.

  Type 3 or Detection of Failure are the weakest form of design controls. They only detect the failure after it has occurred.

"Potential Failure Effect Mode and Analysis" Chrysler Corporation, Ford Motor Company, General Motors Corporation: 1995 pg 27

Effect & Analysis: Detection (D) Criteria

EFFECT	Criteria: Severity of Effect	Ranking
Absolute Uncertainty	No known controls available to detect failure mode	10
Very Remote	Very remote chance controls will detect failure	9
Remote	Remote chance controls will detect failure	8
Very Low	Very low chance controls will detect failure	7
Low	Low chance controls will detect failure	6
Moderate	Moderate chance controls will detect failure	5
Moderately High	Moderately high chance controls will detect failure	4
High	High chance controls will detect failure	3
Very High	Very high chance controls will detect failure	2
Almost Certain	Controls will almost certainly detect failure	1

Assessing The Risk Priority Number (RPN)

The Risk Priority Number(RPN) is the product of the Core Elements; Severity(S), Occurrence (O), and Detection (D) ranking values:

$$RPN = (S) \times (O) \times (D)$$

Step By Step FMEA Process

The development of a FMEA should begin with a flow chart, control plan or any other documentation available for the scope of the project.

Step By Step FMEA Process

- The FMEA consists of a minimum of 23 unique line items for processes and designs
- Considers that more than one potential failure mode may exist within a process or design
- Results in a clear assessment of a process or design

Step By Step FMEA Process

Steps 1-8 contain basic but very important information

FMEA NUMBER:	Do you have a unique identification system?
ITEM:	What is the part number?
PROCESS/DESIGN RESPONSIBILITY:	Who is responsible for the process or design?
PREPARED BY:	Who or what team prepared it?
PROCESS/DESIGN NAME:	What is the process or design?
KEY DATE:	What is the date of the original FMEA?
FMEA Date	What is the completion date of original FMEA? What revision is this?
CORE TEAM:	Who are the team members, their phone numbers and department(s)?

Step By Step FMEA Process

Step # 9

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (KPOVs)	SEV	Class	Potential Causes of Failure (KPIVs)	OCC	Current Process Controls	DET	RPN
1	Wash Components (Manifold, Generator)	Incomplete Cleaning	Internal Assembly Problems	4		Improper Chemical Concentration	3	Sample Titration	5	60
		Rust	Internal Assembly Problems	4		Parts in Stock Too Long	3	100% Visual Inspection, FIFO	4	48
2	Capacitance Discharge Weld Stud to Manifold	No Holes in Manifold	No Restraint, Eject Parts	10	*	Operator Error	2	100% Visual	4	80
		Wrong Hole Size	Decreased Performance	6		Wrong Parts on Line	2	AIMS Scan Bar Code Each Lot	2	24
				5		Line Not Purged	2	Verify Hole Diameter at Setup	5	50
		Wrong Number of Holes	Decreased Performance	6		Operator Error	3	100% Gage	3	54
		Stud Separation from Manifold during Deployment	Possible Ejection of Inflator during Function causing No Restraint, Cannot Assemble at Module Level	10	K	Worn Collet	2	Process Sampling Torque Test Control Chart	2	40

#2

#1

#3

Enter simple descriptions of your process.

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Step By Step FMEA Process

Step # 10

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (KPOVs)	SEV	Class	Potential Causes of Failure (KPIVs)	OCC	Current Process Controls	DET	RPN
1	Wash Components (Manifold, Generator)	Incomplete Cleaning	Internal Assembly Problems	4		Improper Chemical Concentration	3	Sample Titration	5	60
		Rust	Internal Assembly Problems	4		Parts in Stock Too Long	3	100% Visual Inspection, FIFO	4	48
2	Capacitance Discharge Weld Stud to Manifold	No Holes in Manifold	No Restraint, Eject Parts	10	*	Operator Error	2	100% Visual	4	80
		Wrong Hole Size	Decreased Performance	6		Wrong Parts on Line	2	AIMS Scan Bar Code Each Lot	2	24
				5		Line Not Purged	2	Verify Hole Diameter at Setup	5	50
		Wrong Number of Holes	Decreased Performance	6		Operator Error	3	100% Gage	3	54
		Stud Separation from Manifold during Deployment	Possible Ejection of Inflator during Function causing No Restraint, Cannot Assemble at Module Level	10	K	Worn Collet	2	Process Sampling Torque Test Control Chart	2	40

#2

#1

#3

The Potential Failure Mode: “Is defined as the manner in which the process could fail”

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Step By Step FMEA Process

Step # 11

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (KPOVs)	SEV	Class	Potential Causes of Failure (KPIVs)	OCC	Current Process Controls	DET	RPN
1	Wash Components (Manifold, Generator)	Incomplete Cleaning	Internal Assembly Problems	4		Improper Chemical Concentration	3	Sample Titration	5	60
		Rust	Internal Assembly Problems	4		Parts in Stock Too Long	3	100% Visual Inspection, FIFO	4	48
2	Capacitance Discharge Weld Stud to Manifold	No Holes in Manifold	No Restraint, Eject Parts	10	*	Operator Error	2	100% Visual	4	80
		Wrong Hole Size	Decreased Performance	6		Wrong Parts on Line	2	AIMS Scan Bar Code Each Lot	2	24
				5		Line Not Purged	2	Verify Hole Diameter at Setup	5	50
		Wrong Number of Holes	Decreased Performance	6		Operator Error	3	100% Gage	3	54
		Stud Separation from Manifold during Deployment	Possible Ejection of Inflator during Function causing No Restraint, Cannot Assemble at Module Level	10	K	Worn Collet	2	Process Sampling Torque Test Control Chart	2	40

#2

#1

#3

The Potential Effects of Failure: “Is defined as the effects of the failure on the customers”

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Step By Step FMEA Process

Step # 12

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (KPOVs)	SEV	Class	Potential Causes of Failure (KPIVs)	OCC	Current Process Controls	DET	RPN	
1	Wash Components (Manifold, Generator)	Incomplete Cleaning	Internal Assembly Problems	4		Improper Chemical Concentration	3	Sample Titration	5	60	#2
		Rust	Internal Assembly Problems	4		Parts in Stock Too Long	3	100% Visual Inspection, FIFO	4	48	
2	Capacitance Discharge Weld Stud to Manifold	No Holes in Manifold	No Restraint, Eject Parts	10	*	Operator Error	2	100% Visual	4	80	#1
		Wrong Hole Size	Decreased Performance	6		Wrong Parts on Line	2	AIMS Scan Bar Code Each Lot	2	24	
				5		Line Not Purged	2	Verify Hole Diameter at Setup	5	50	
		Wrong Number of Holes	Decreased Performance	6		Operator Error	3	100% Gage	3	54	#3
		Stud Separation from Manifold during Deployment	Possible Ejection of Inflator during Function causing No Restraint, Cannot Assemble at Module Level	10	K	Worn Collet	2	Process Sampling Torque Test Control Chart	2	40	

Severity Ranking: Use FDM(s) and Incident Reports

Step By Step FMEA Process

Step # 13

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (KPOVs)	SEV	Class	Potential Causes of Failure (KPIVs)	OCC	Current Process Controls	DET	RPN	
1	Wash Components (Manifold, Generator)	Incomplete Cleaning	Internal Assembly Problems	4		Improper Chemical Concentration	3	Sample Titration	5	60	#2
		Rust	Internal Assembly Problems	4		Parts in Stock Too Long	3	100% Visual Inspection, FIFO	4	48	
2	Capacitance Discharge Weld Stud to Manifold	No Holes in Manifold	No Restraint, Eject Parts	10	*	Operator Error	2	100% Visual	4	80	#1
		Wrong Hole Size	Decreased Performance	6		Wrong Parts on Line	2	AIMS Scan Bar Code Each Lot	2	24	
				5		Line Not Purged	2	Verify Hole Diameter at Setup	5	50	
		Wrong Number of Holes	Decreased Performance	6		Operator Error	3	100% Gage	3	54	#3
		Stud Separation from Manifold during Deployment	Possible Ejection of Inflator during Function causing No Restraint, Cannot Assemble at Module Level	10	K	Worn Collet	2	Process Sampling Torque Test Control Chart	2	40	

Class Ranking: Use to classify any special process characteristics

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Step By Step FMEA Process

Step # 14

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (KPOVs)	SEV	Class	Potential Causes of Failure (KPIVs)	OCC	Current Process Controls	DET	RPN
1	Wash Components (Manifold, Generator)	Incomplete Cleaning	Internal Assembly Problems	4		Improper Chemical Concentration	3	Sample Titration	5	60
		Rust	Internal Assembly Problems	4		Parts in Stock Too Long	3	100% Visual Inspection, FIFO	4	48
2	Capacitance Discharge Weld Stud to Manifold	No Holes in Manifold	No Restraint, Eject Parts	10	*	Operator Error	2	100% Visual	4	80
		Wrong Hole Size	Decreased Performance	6		Wrong Parts on Line	2	AIMS Scan Bar Code Each Lot	2	24
				5		Line Not Purged	2	Verify Hole Diameter at Setup	5	50
		Wrong Number of Holes	Decreased Performance	6		Operator Error	3	100% Gage	3	54
		Stud Separation from Manifold during Deployment	Possible Ejection of Inflator during Function causing No Restraint, Cannot Assemble at Module Level	10	K	Worn Collet	2	Process Sampling Torque Test Control Chart	2	40

#2

#1

#3

Potential Causes of Failures (KPIVS) List all of the potential causes of failure for each potential failure mode.

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Step By Step FMEA Process

Step # 15

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (KPOVs)	SEV	Class	Potential Causes of Failure (KPIVs)	OCC	Current Process Controls	DET	RPN	
1	Wash Components (Manifold, Generator)	Incomplete Cleaning	Internal Assembly Problems	4		Improper Chemical Concentration	3	Sample Titration	5	60	#2
		Rust	Internal Assembly Problems	4		Parts in Stock Too Long	3	100% Visual Inspection, FIFO	4	48	
2	Capacitance Discharge Weld Stud to Manifold	No Holes in Manifold	No Restraint, Eject Parts	10	*	Operator Error	2	100% Visual	4	80	#1
		Wrong Hole Size	Decreased Performance	6		Wrong Parts on Line	2	AIMS Scan Bar Code Each Lot	2	24	
				5		Line Not Purged	2	Verify Hole Diameter at Setup	5	50	
		Wrong Number of Holes	Decreased Performance	6		Operator Error	3	100% Gage	3	54	#3
		Stud Separation from Manifold during Deployment	Possible Ejection of Inflator during Function causing No Restraint, Cannot Assemble at Module Level	10	K	Worn Collet	2	Process Sampling Torque Test Control Chart	2	40	

Occurrence Rating: How often does it occur?

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Step By Step FMEA Process

Step # 16

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (KPOVs)	SEV	Class	Potential Causes of Failure (KPIVs)	OCC	Current Process Controls	DET	RPN
1	Wash Components (Manifold, Generator)	Incomplete Cleaning	Internal Assembly Problems	4		Improper Chemical Concentration	3	Sample Titration	5	60
		Rust	Internal Assembly Problems	4		Parts in Stock Too Long	3	100% Visual Inspection, FIFO	4	48
2	Capacitance Discharge Weld Stud to Manifold	No Holes in Manifold	No Restraint, Eject Parts	10	*	Operator Error	2	100% Visual	4	80
		Wrong Hole Size	Decreased Performance	6		Wrong Parts on Line	2	AIMS Scan Bar Code Each Lot	2	24
				5		Line Not Purged	2	Verify Hole Diameter at Setup	5	50
		Wrong Number of Holes	Decreased Performance	6		Operator Error	3	100% Gage	3	54
		Stud Separation from Manifold during Deployment	Possible Ejection of Inflator during Function causing No Restraint, Cannot Assemble at Module Level	10	K	Worn Collet	2	Process Sampling Torque Test Control Chart	2	40

#2

#1

#3

Current Process Controls: Consists of implementation actions taken by the company to either detect or prevent an event from happening.

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Step By Step FMEA Process

Step 17

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (KPOVs)	SEV	Class	Potential Causes of Failure (KPIVs)	OCC	Current Process Controls	DET	RPN
1	Wash Components (Manifold, Generator)	Incomplete Cleaning	Internal Assembly Problems	4		Improper Chemical Concentration	3	Sample Titration	5	60
		Rust	Internal Assembly Problems	4		Parts in Stock Too Long	3	100% Visual Inspection, FIFO	4	48
2	Capacitance Discharge Weld Stud to Manifold	No Holes in Manifold	No Restraint, Eject Parts	10	*	Operator Error	2	100% Visual	4	80
		Wrong Hole Size	Decreased Performance	6		Wrong Parts on Line	2	AIMS Scan Bar Code Each Lot	2	24
				5		Line Not Purged	2	Verify Hole Diameter at Setup	5	50
		Wrong Number of Holes	Decreased Performance	6		Operator Error	3	100% Gage	3	54
		Stud Separation from Manifold during Deployment	Possible Ejection of Inflator during Function causing No Restraint, Cannot Assemble at Module Level	10	K	Worn Collet	2	Process Sampling Torque Test Control Chart	2	40

#2

#1

#3

Detection Rating: an assessment of the probability that the process controls in place will detect a process weakness or failure mode.

Step By Step FMEA Process

Step 18

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (KPOVs)	SEV	Class	Potential Causes of Failure (KPIVs)	OCC	Current Process Controls	DET	RPN	
1	Wash Components (Manifold, Generator)	Incomplete Cleaning	Internal Assembly Problems	4		Improper Chemical Concentration	3	Sample Titration	5	60	#2
		Rust	Internal Assembly Problems	4		Parts in Stock Too Long	3	100% Visual Inspection, FIFO	4	48	
2	Capacitance Discharge Weld Stud to Manifold	No Holes in Manifold	No Restraint, Eject Parts	10	*	Operator Error	2	100% Visual	4	80	#1
		Wrong Hole Size	Decreased Performance	6		Wrong Parts on Line	2	AIMS Scan Bar Code Each Lot	2	24	
				5		Line Not Purged	2	Verify Hole Diameter at Setup	5	50	
		Wrong Number of Holes	Decreased Performance	6		Operator Error	3	100% Gage	3	54	#3
		Stud Separation from Manifold during Deployment	Possible Ejection of Inflator during Function causing No Restraint, Cannot Assemble at Module Level	10	K	Worn Collet	2	Process Sampling Torque Test Control Chart	2	40	

RPN#: RPN = S*O*D rank your RPN #'s

Step By Step FMEA Process

Step 19-23: Closing the loop

19	RECOMMENDED ACTIONS:	Start with the highest number and implement permanent corrective actions to reduce the severity, occurrence and detection.
20	PERSON RESPONSIBLE:	Name a person; not a group of people. Use teams, but ultimately one person is in charge.
21	ACTIONS TAKEN:	Document changes to the process or design.
22	RESULTING RPN:	Re-evaluate the process or design. Can it be improved?
23	FOLLOW-UP:	Is everything documented, revised, communicated and up to date? Are you measuring the process or design results? How did we do?
	CORE TEAM:	Who are the team members, their phone numbers and department(s)?

Thank You

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8.24.11

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9.14.11

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9.20.11

CICC: Continuous Improvement Champion Certification Program

10.5.11

TLFT: Team Leader & Facilitator Training

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