FMEA
(Failure Mode and Effects Analysis)

Course

Course Contente

1. What is FMEA?
2. Why to use FMEA?
3. When to Use FMEA
4. How to use FMEA
5. FMEA benefits
6. Improvement through FMEA
7. FMEA Types
8. FMEA Examples
9. References

1. What is FMEA?

- In today global economy no failures are tolerated

1. What is FMEA?

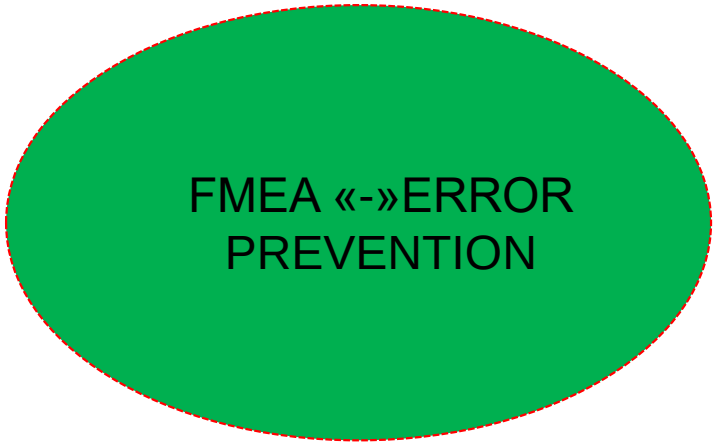
- Goal is to eliminate (or extremely reduce) any type of failure

1. What is FMEA?

- Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual

1. What is FMEA?

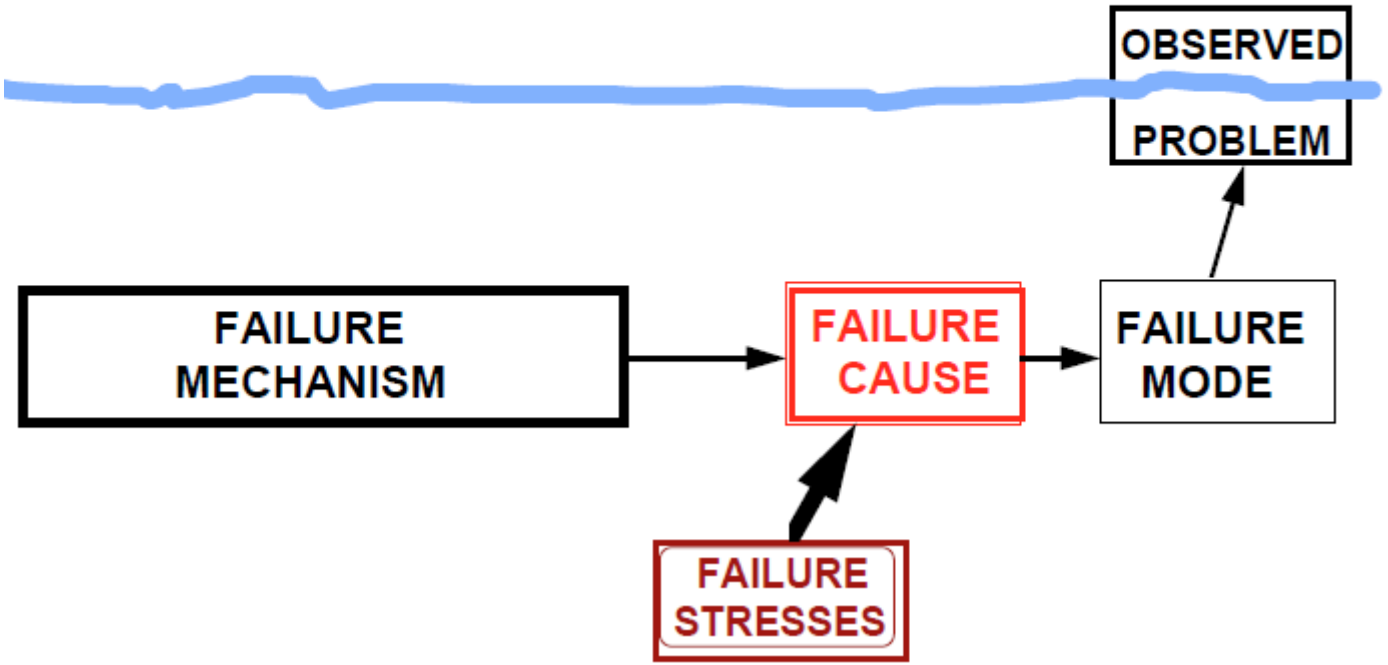
- Failure modes and effects analysis (FMEA) is a step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service



1. What is FMEA?

- “Failure modes” means the ways, or modes, in which something might fail
- “Effects analysis” refers to studying the consequences of those failures

FAILURE TERMS REVIEW: THE PROCESS OF FAILURE



1. What is FMEA?

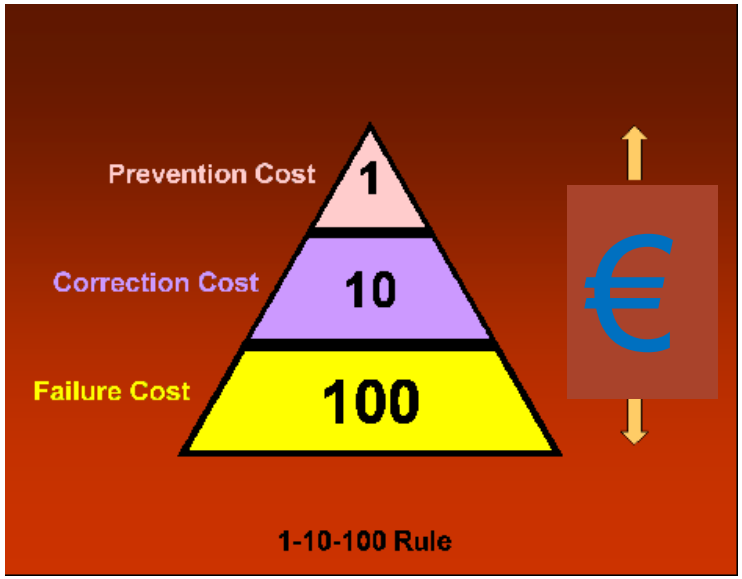
- Failures are prioritized according to how serious their consequences are, how frequently they occur and how easily they can be detected
- The purpose of the FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority ones

2. Why to use FMEA?

- FMEAs are used by organizations to manage the risks associated with the failures and its effects
- FMEAs should be used as a preventive action and be updated and redone regularly

2. Why to use FMEA?

- The costs associated with preventing failures are much less that the costs of correcting a failure after it has occurred



2. Why to use FMEA?

- FMEA also documents current knowledge and actions about the risks of failures, for use in continuous improvement

2. Why to use FMEA?

- FMEA started being used by the US Military in the 1940s.

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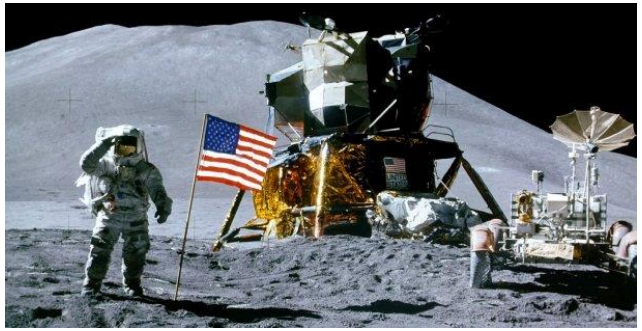
- Users of FMEA include NASA (since 1960s), Ford Motor Company (since 1980s), AIAG (Automotive Industry Action Group, since 1990s) and presently the Joint Commission for Accreditation of Healthcare Organizations



3. When to use FMEA?

- FMEA is used during design to prevent failures
- Later it’s used for control, before and during ongoing operation of the process
- Ideally, FMEA begins during the earliest conceptual stages of design and continues throughout the life of the product or service

3. When to use FMEA?

ASQ (www.asq.org) recommends using FMEA in the following situations :

1. When a process, product or service is being designed or redesigned, after quality function deployment

2. When an existing process, product or service is being applied in a new way

3. When to use FMEA?

3. Before developing control plans for a new or modified process

4. When improvement goals are planned for an existing process, product or service

3. When to use FMEA?

5. When analyzing failures of an existing process, product or service

6. Periodically throughout the life of the process, product or service

3. When to use FMEA?

- FMEA is also used in Six Sigma Methodology either for DMAIC (Define, Measure, Analyze, Improve and Control) or DFSS (Design for Six Sigma)
- Remark: Six Sigma is “a business improvement approach that seeks to eliminate causes of mistakes or defects in business processes by focusing on outputs that are of critical importance to customers” (Snee, 1999)

4. How to use FMEA

The following steps can used as a guideline to use FMEA (write the information on the FMEA table – there is no fixed model - as is produced):

1. Identify the scope of the FMEA: is it for a system, process or service? What are the boundaries and how detailed should it be?

2. Assemble a cross-functional team of people with diverse knowledge about the system, process or service (e.g., design, purchasing, manufacturing, engineering, quality, sales, marketing, customer service …)

3. Study the system, process or service and identify the several functions: What is the purpose? What are the expectations of the customers?

4. How to use FMEA

4. For each function identify all the ways the failure could happen, the potential Failure Modes

5. For each Failure determine how serious the failure effect can be. This is the Severity Rate, usually rated on a scale from 1 to 10, where 1 is insignificant and 10 is catastrophic

Example of Severity Rates

Effect	Criteria: Severity of the Effect	Ranking
Hazardous - without warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	10
Hazardous - with warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9
Very High	Vehicle / item inoperable, with loss of primary function.	8
High	Vehicle / item operable, but at reduced level of performance. Customer dissatisfied.	7
Moderate	Vehicle / item operable, but Comfort/Convenience item(s) inoperable. Customer experiences discomfort.	6
Low	Vehicle / item operable, but Comfort/Convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction.	5
Very Low	Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by most customers.	4
Minor	Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by average customer.	3
Very Minor	Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by discriminating customer.	2
None	No Effect.	1

6. For each Failure mode identify all the potential root causes and list them on the FMEA table

7. For each Failure mode rate the Occurrence Level (O) that estimates the probability of failure Occurring during the lifetime of the scope and that is usually rated from 1 (extremely unlikely) to 10 (inevitable)

4. How to use FMEA

Example of Occurrence Rates

Probability of Failure	Possible Failure Rates	Ranking
Very High: Failure is almost inevitable	>= 1 in 2	10
	1 in 3	9
High: Repeated failures	1 in 8	8
	1 in 20	7
Moderate: Occasional failures	1 in 80	6
	1 in 400	5
	1 in 2,000	4
Low: Relatively few failures	1 in 15,000	3
	1 in 150,000	2
Remote: Failure is unlikely	<= 1 in 1,500,000	1

8. For each cause, identify the present process controls (e.g., tests, controls and mechanisms in place to prevent that failures reach the customer)

9. For each control identify the detection level (or D) that estimates how well the controls can detect the cause or its failure mode after they have occurred but before the customer is affected. Usually this is rated on a scale from 1 (control will surely detect the problem) to 10 (control surely will not detect the problem)

Example of Detection Levels

Detection	Criteria: Likelihood of Detection by Design Control	Ranking
Absolute Uncertainty	Design Control will not and/or can not detect a potential cause/mechanism and subsequent failure mode; or there is no Design Control.	10
Very Remote	Very remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	9
Remote	Remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	8
Very Low	Very low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	7
Low	Low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	6
Moderate	Moderate chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	5
Moderately High	Moderately high chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	4
High	High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	3
Very High	Very high chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	2
Almost Certain	Design Control will almost certainly detect a potential cause/mechanism and subsequent failure mode.	1

9. Calculate the Risk Priority Number (RPN = S x O x D) and prioritize the order potential failures should be addressed

- Severity (S)
- Severity X Occurrence (S X O)
  - Criticality
- Severity X Occurrence X Detection (S X O X D) = RPN

11. Identify and implement improvement actions (e.g., design or process changes to lower severity or occurrence; additional controls to improve detection; also define responsible for the actions and completions dates). Re-evaluate the RPNs

12. Update the FMEA Table based on the actions completed and re-evaluation of the RPNs

Example of simplified FMEA Table (source: ASQ)

TABLE 1 Process Failure Mode Effects Analyses Example

Description: Specimen collection/processing
Year(s): 2004
Location: Detroit
Process responsiblity: Jane S.
Key date:
FMEA number: 2004-1
Prepared by: RDR Team
FMEA date: 10/23/2004
Revision date: 2/7/2005

Line No.	Process function/ requirements	Potential failure mode	Potential effect(s) of Failure	Severity	Class	Potential cause(s)/ mechanism(s) of failure	Occurrence	Current process controls	Detection	Risk priority number	Recommended action(s)	Responsibility and target completion date		Action Results				
														Actions taken	New severity	New occurrence	New detection	New risk priority number
1	1.0 Take specimen	1.1 Put in wrong tub	1.1.1 Run wrong test	8		Inadvertent error	3		8	192	Organize tubes by color, implement "pull" system of inventory mgmt.	Betty L.	12/2/2004	Recommended actions done	9	1	1	9
		1.2 Not refrigerated on time	1.2.1 Ruin specimen	6		Inadvertent error	6		8	288	Implement tracking log & use of alarms, audit chart daily for completion	Betty L.	11/25/2004	Recommended actions done	9	2	2	36
		1.3 Not centrifuged on time	1.3.1 Ruin specimen	6		Inadvertent error	6		8	288	Implement tracking log & use of alarms, audit chart daily for completion	Betty L.	11/15/2004	Recommended actions done	9	1	8	72
		1.4 Shortage of tubes	1.4.1 Rework another	4		Work load	7		7	196	Pull system of inventory management	Betty L.	12/02/2004		4	3	7	84
2	2.0 Centrifuge it	2.1 Equipment failure	2.1.1 Can't run test	4		Aged equipment	2		10	80	Add to PM log	Kaye P.	12/01/2004		4	2	6	48
		2.2 Insufficient run time	2.2.1 Specimen tainted	6		Inadvertent error	4		9	216	Set alarm to warm, provide process definition on RASIC chart, implement verification and audit daily	Kaye P.	10/30/2004	Recommended actions done	9	1	2	18
3	3.0 Store/ refrigerate it	3.1 No temperature log	3.1.1 Uncertainty of specimen	6		No thermometer	3	Acquire thermometer	10	180	Audit temperature log each shift	Kaye P.	11/07/2004		6	3	6	108
		3.2 Temperature wrong	3.2.1 Specimen tainted	6		Equipment failure	2		7	84	Add to PM log	Kaye P.	10/30/2004		6	2	6	72
		3.3 Drop it	3.3.1 Ruin specimen	6		Inadvertent error	1		3	18	Work instruction	Kaye P.	10/30/2004					

5. FMEA benefits

The benefits of a FMEA when used in the right way

Include (ASQ CSSGB Primer):

1. Improved product or service functions
2. Reduced manufacturing problems
3. Lower warranty and after service costs
4. Increased safety and reliability of products and processes
5. Improved customer satisfaction
6. Decreased business problems

6. Improvement through FMEA

Bongiorno (2000) proposes a 4-step process to improve organizations performance:

1. Measure the current FMEA performance for a baseline
2. Agree on a projected FMEA performance level (e.g., RPN level)
3. Develop a plan to close the gaps
4. Implement the recommended methods to achieve the target

7. FMEA types

According to Stamatis (1995) there are four types of FMEA:

1. System FMEA, applicable to systems, subsystems and components and the interactions between systems and elements of the system

2. Design FMEA, analyzing products prior to the release of production drawings for tooling and manufacturing, emphasis is on the failure modes caused by design deficiencies

7. FMEA types

3. Process FMEA: studying the manufacturing and assembly process, emphasis is on the failure modes caused by process or assembly operations

4. Service FMEA: studying the services before they reach the customer, focus on the tasks, errors, and mistakes, caused by process deficiencies that cover non manufacturing services

8. FMEA examples

An example of a Process FMEA on a Bank ATM machine is partially presented adapted from www.asq.org):

- Function: “Dispense cash”
- Failure Modes: Does note dispense cash, …
- According to RPN “machines jams” and “heavy computer network traffic” are the 1st and 2nd highest risks

8. FMEA examples

- The FMEA also shows criticality rating an approach that when used transform the FMEA into FMECA (Failure Mode Effect and Criticality Analysis)

- The Team should use their knowledge and experience to decide on the appropriate improvements actions and prioritization

8. FMEA examples

Function	Potential Failure Mode	Potential Effects(s) of Failure	S	Potential Cause(s) of Failure	O	Current Process Controls	D	RPN	CRIT	Recommended Action(s)	Responsibility and Target Completion Date	Action Results					
												Action Taken	S	O	D	RPN	CRIT
Dispense amount of cash requested by customer	Does not dispense cash	Customer very dissatisfied Incorrect entry to demand deposit system Discrepancy in cash balancing	8	Out of cash Machine jams Power failure during transaction	5 3 2	Internal low-cash alert Internal jam alert None	5 10 10	200 240 160	**40** 24 16								
	Dispenses too much cash	Bank loses money Discrepancy in cash balancing	6	Bills stuck together Denominations in wrong trays	2 3	Loading pro-cedure (riffle ends of stack) Two-person visual verification	7 4	84 72	12 18								
	Takes too long to dispense cash	Customer somewhat annoyed	3	Heavy computer network traffic Power interruption during transaction	7 2	None None	10 10	210 60	21 6								

8. FMEA examples

Another example of a Process FMEA on the possible failures of a toaster is partially presented adapted from www.asq.org).

An FMEA looks for all the ways a process or product can fail. For example, a toaster could fail in several ways:

- There is a short in the power cord
- The coils burn the bread no matter which setting is used
- The pop-up mechanism is too sensitive and flings toast onto the counter

8. FMEA examples

Failures can also occur when the user makes a mistake, and it is wise to include both types of failures in an FMEA. Anything that can be done to assure the product works correctly, regardless of how the user operates it, will move the product closer to 100% satisfaction.

A product/design FMEA can uncover problems that will result in safety hazards, product malfunctions or a shortened product life. They key question to ask here is, "How can the product fail?" A process FMEA uncovers process problems related to the manufacture of the product. The key question to ask here is, "How can process failure affect the product, processing efficiency or safety?"

8. FMEA examples

A short in the power cord of a toaster has a “hazardous effect without warning” so Severity is rated as 10.

The Team in charge of the FMEA has considered that the probability of occurrence of this failure is High, with repeated failures, leading to an Occurrence Raking of 7.

Concerning the likelihood of Detection, the Team has considered that it is very remote, so Detection Level 9 was chosen.

Final RPN is S x O x D = 10 x 7 x 9 = 630.

Because RPN is too high, the Team recommend the adoption of better packaging materials (heavy duty packaging foam) that will bring O to 2 (Low)and D to 5 (Moderate), with a final RPN of 100.

8. FMEA examples

FMEA Process for a Toaster

FMEA process											Action results				
Item and function	Potential failure mode	Potential effect(s) of failure	Severity	Potential cause(s) of failure	Occurrence	Current controls	Detection	RPN*	Recommended action	Responsibility and target completion date	Action taken	Severity	Occurrence	Detection	RPN
Power cord	Short	Fire	10	Rough handling during shipping process	7	None	9	630	Use better packaging materials	Paul: 2/25/02	Began using heavy duty packaging foam	10	2	5	100

* RPN–risk priority number Note: This is not a complete chart.

References

1. www.asq.org

2. Bongiorno, J. (2000), “Improving FMEAs: FMEAs can Transform Compliance into Competitive Advantage”, Quality Digest, 37-40

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3. CSSGB, Quality Council of Indiana, (2006,) ASQ

4. Nancy R.T., 2004, The Quality Toolbox, 2nd Ed., (2004), ASQ Quality Press

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5. Potential Failure Modes and Effects Analysis (FMEA) Reference Manual, 3rd. Ed.(2001) Southfield, MI, AIAG

6. Stamatis, D. (1995), Failure Mode and Effect Analysis: Failure From Theory to Execution, Milwaukee, ASQC Quality Press