# Basics of Failure Mode Effects Analysis (FMEAs) Implementing in A Manufacturing Organization to Focus on Quailty

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***Abstract*: The goal of the FMEAs (Failure Mode, Effects and Analysis) process is to determine the consequences that failures may have on the function of a complex system. In manufacturing industries, this process is very important with in international standards. Today, most of the process is performed manually. This can be problematic, since, although the basic process is not difficult, taking into account all behaviors and all the interactions between the behaviors of several components of a system can be very complex, error prone and costly. In this paper, we discuss only the basic concepts implements for design and process FMEAs in manufacturing Sector.**

***Keywords: FMEAs; DFMEAs; PFMEAs; Severity; Occurance; Detetication; RPN.***

## I. HISTORY

The automotive industry began to use FMEA by the mid-1970s. The Ford motor company introduced FMEA to the automotive industry for safety and regulatory consideration after the Pinto affair. Ford applied the same approach to processes (PFMEA) to consider potential process induced failures prior to launching production. In 1993 the Automotive Industry Action Group (AIAG) first published an FMEA standard for the automotive industry. The SAE first published related standard J1739 in 1994. This standard is also now in its fourth edition. In 2019 both method descriptions were replaced by the new AIAG / VDA FMEA handbook. It is a harmonization of the former FMEA standards of AIAG, VDA, SAE and other method descriptions.

Although initially developed by the military, FMEA methodology is now extensively used in a variety of industries including semiconductor processing, food service, plastics, software, and healthcare. Toyota has taken this one step further with its Design Review Based on Failure Mode (DRBFM) approach. The method is now supported by the American Society for Quality which provides detailed guides on applying the method. The standard Failure Modes and Effects Analysis (FMEA) and Failure Modes, Effects and Criticality Analysis (FMECA) procedures identify the product failure mechanisms, but may not model them without specialized software. This limits their applicability to provide a meaningful input to critical procedures such as virtual qualification, root cause analysis, accelerated test programs, and to remaining life assessment. To overcome the shortcomings of FMEA and FMECA a Failure Modes, Mechanisms and Effect Analysis (FMMEA) has often been used.

## II. INTRODUCTION

Failure mode and effects analysis (FMEA) is the process of reviewing many components, assemblies, and subsystems as possible to identify potential failure modes in a system and their causes and effects. For each component, the failure modes and their resulting effects on the rest of the system are recorded in a specific FMEA worksheet. There are numerous variations of such worksheets. An FMEA can be a qualitative analysis, but may be put on a quantitative basis when mathematical failure rate models are combined with a statistical failure mode ratio database. It was one of the first highly structured, systematic techniques for failure analysis. It was developed by reliability engineers in the late 1950s to study problems that might arise from malfunctions of military systems. An FMEA is often the first step of a system reliability study.

The two most common types of FMEAs are Design - FMEAs (or) DFMEAs and Process-FMEAs (or) PFMEAs.

### *A. Design - FMEAs*

The primary objective of a Design-FMEA is to uncover potential failures associated with the product design that could cause:

- Product malfunctions
- Shortened product life
- Safety hazards while using the product

Design-FMEAs should be used throughout the design process – from preliminary design until the product goes into production.

### *B. Process - FMEAs*

Process-FMEAs uncover potential failures that can:

- Impact product quality
- Reduce process reliability
- Cause customer dissatisfaction
- Create safety or environmental hazards

Ideally, Process-FMEAs should be conducted prior to start-up of a new process, but they can be conducted on existing processes as well.

Similar principles and steps are followed for both Design and Process FMEAs.

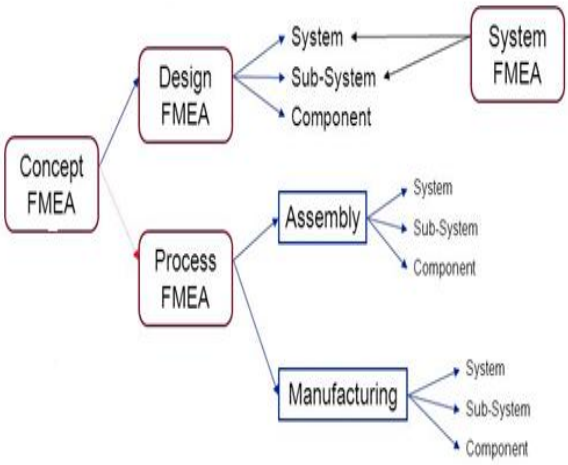


Figure.1: Types of FMEAs flowchart

Sometimes FMEA is extended to FMECA (failure mode, effects, and criticality analysis) to indicate that criticality analysis is performed too. FMEA is an inductive reasoning single point of failure analysis and is a core task in reliability engineering, safety engineering and quality engineering.

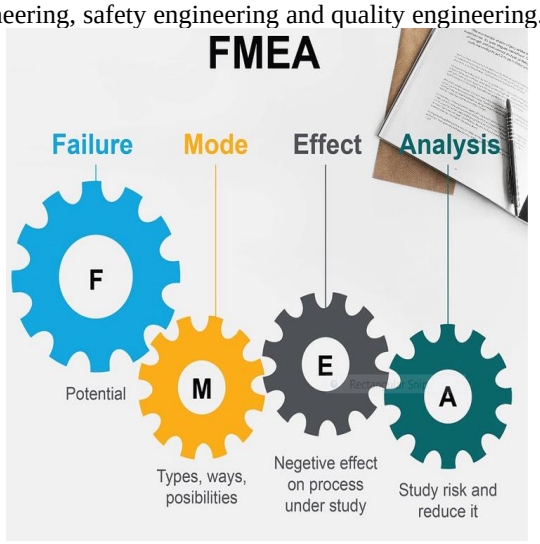


Figure.2: FMEA terms Expansions

A successful FMEA activity helps identify potential failure modes based on experience with similar products and processes or based on common physics of failure logic.It is widely used in development and manufacturing industries in various phases of the product life cycle. Effects analysis refers to studying the consequences of those failures on different system levels.

## III. BASIC TERMs USED IN FMEAs

The following are some of basic FMEAs terminology.

### A. *Failure*

The loss of a function under stated conditions.

### B. *Failure Mode*

The specific manner or way by which a failure occurs in terms of failure of the part, component, function, equipment, subsystem, or system under investigation.

Depending on the type of FMEA performed, failure mode may be described at various levels of detail.

### C. *Action Priority*

It makes a statement about the need for additional improvement measures

### D. *Failure Cause and Mechanism*

Defects in requirements, design, process, quality control, handling or part application, which are the underlying cause or sequence of causes that initiate a process (mechanism) that leads to a failure mode over a certain time.

A failure mode may have more causes.

***For Example:*** "Fatigue or corrosion of a structural beam" or "fretting corrosion in an electrical contact" is a failure mechanism and in itself not a failure mode. The related failure mode is a "full fracture of structural beam" or "an open electrical contact". The initial cause might have been "Improper application of corrosion protection layer" and /or "vibration input from another system".

### E. *Failure Effect*

Immediate consequences of a failure on operation, or more generally on the needs for the customer / user that should be fulfilled by the function but now is not, or not fully, fulfilled.

### F. *Local Effect*

The failure effect as it applies to the item under analysis

### G. *Next Higher Level Effect*

The failure effect as it applies at the next higher indenture level.

### H. *End Effect*

The failure effect at the highest indenture level or total system.

### I. *Detection*

The means of detection of the failure mode by maintainer, operator or built in detection system, including estimated dormancy period.

**Table.1:** Detection score guideline

| Detection | Criteria: Like hood the Existence of Defect will be detected by process controls before next (or) Subsequent process (or) Before Part (or) Component leaves the manufacturing (or) Assembly Location | Ranking |
|---|---|---|
| Almost Impossible | No known control available to detect cause / mechanism of failure. | 10 |
| Very Remote | Very remote likelihood current control will detect cause / mechanism of failure. | 9 |
| Remote | Remote likelihood current control will detect cause / mechanism of failure. | 8 |
| Very Low | Very low likelihood current control will detect cause / mechanism of failure. | 7 |
| Low | Low likelihood current control will detect cause / mechanism of failure. | 6 |
| Moderate | Moderate likelihood current control will detect cause / mechanism of failure. | 5 |
| Moderately High | Moderately likelihood current control will detect cause / mechanism of failure. | 4 |
| High | High likelihood current control will detect cause / mechanism of failure. | 3 |
| Very High | Very High likelihood current control will detect cause / mechanism of failure. | 2 |
| Almost Certain | Current control almost certain to detect cause / mechanism of failure. | 1 |

### J. *Probability*

The likelihood of the failure occurring.

Table.2: Probability score guideline

| Probability of Failure | Possible Failure Rates | Ranking |
|---|---|---|
| **Very High:** Failure Almost Inevitable | ≥1 in 2 | 10 |
| | 1 in 3 | 9 |
| **High:** Generally associated with process similar to previous processes that have often failed. | 1 in 8 | 8 |
| | 1 in 20 | 7 |
| **Moderate:** Generally Associated with processes similar to previous processes which have experienced occasional failures, but not in major proportions. | 1 in 80 | 6 |
| | 1 in 400 | 5 |
| | 1 in 2,000 | 4 |
| **Low:** Isolated failures associated with similar processes | 1 in 15,000 | 3 |
| **Very Low:** Only Isolated Failures associated with almost Identical Processes. | 1 in 150,000 | 2 |
| **Remote:** Failure is unlikely. No failures ever associated with almost Identical process. | 1 in 1,500,000 | 1 |

### K. *Severity*

The consequences of a failure mode. Severity considers the worst potential consequence of a failure, determined by the degree of injury, property damage, system damage and/or time lost to repair the failure.

**Table.3:** Severity score guideline

| Effect | Criteria: Severity of Effect | Ranking |
|---|---|---|
| Hazardous without warning | May endanger machine (or) operator. Very high severity ranking when a potential failure mode effects safe vehicle operation and/or involves noncompliance with government regulation. Failure will occur without warming. | 10 |
| Hazardous with warning | May endanger machine (or) operator. Very high severity ranking when a potential failure mode effects safe vehicle operation and/or involves noncompliance with government regulation. Failure will occur with warming. | 9 |
| Very High | Major disruption to production line. 100% of Product may have to be scrapped. Vehicle / Item inoperable. Loss of primary function. Customer very dissatisfied. | 8 |
| High | Minor disruption to production line. Product may have to be sorted and a portion (less than 100%) scrapped. Vehicle operable, but a reduced level of performance. Customer dissatisfied. | 7 |
| Moderate | Minor disruption to production line. A portion (<100%) of the product may have to be scrapped (no Sorting). Vehicle / Item operable, but some comfort / convenience items inoperable. Customer experience discomfort. | 6 |
| Low | Minor disruption to production line.100% of the product may have to be reworked. Vehicle/ item operable, but some comport / convenience items operable at reduced level of performance. Customer experiences some dissatisfaction. | 5 |
| Very Low | Minor disruption to production line. The product may have to be sorted and a portion (<100%) reworked. Fit and Finish / squeak & Rattle item does not conform. Defect noticed by most customers. | 4 |
| Minor | Minor disruption to production line. The product may have to be sorted and a portion (<100%) reworked. Fit and Finish / squeak & Rattle item does not conform. Defect noticed by average customers. | 3 |
| Very Minor | Minor disruption to production line. The product may have to be sorted and a portion (<100%) reworked. Fit and Finish / squeak & Rattle item does not conform. Defect noticed by discriminating customers | 2 |
| Low | No Effect | 1 |

### L. *Risk Priority Number (RPN)*

Severity (of the event) × Probability (of the event occurring) × Detection (Probability that the event would not be detected before the user was aware of it).

### M. *Remarks / Mitigation / Actions*

Additional info, including the proposed mitigation or actions used to lower a risk or justify a risk level or scenario.

## IV. FMEAs REPORT AND RISK CHART

### A. *FMEAs REPORT*

The purpose of the FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority ones. Failure modes and effects analysis also documents current knowledge and actions about the risks of failures, for use in continuous improvement. FMEA is used during design to prevent failures.

**Table.4:** Design and Process FMEAs Report

| No | Part Name Part No (Process / Function Name) | Function | Failure Mode | Mechanism (s) & cause(s) of Failure | Effect(s) of Failure | Current Control | Ranking | | | | Recommended Corrective Action(s) | Action(s) taken | Ranking | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | S | O | D | RPN | | | S | O | D | RPN |
| 1 | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | | | | |

### B. *Risk Chart*

A risk matrix visualizes risks in a diagram. In the diagram, the risks are divided depending on their likelihood and their effects or the extent of damage, so that the worst case scenario can be determined at a glance.

Significance of Colors in Risk Chart (or) Diagram

**Red:** Fire protection, Danger, high risk of injury or death.

**Yellow:** Caution statements, Minor risk of injury.

**Green:** Safety equipment (or) Information.

**Table.5:** Design and Process Risk Chart

| | Severity--> | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | None | Very Slight | Slight | Minor | Moderate | Significant | Major | Extreme | Serious | Hazardous |
| occurrence | 10 | Almost certain. | | | | | | | | | |
| | 9 | Very high | | | | | | | | | |
| | 8 | High | | | | | | | | | |
| | 7 | Moderately high | | | | | | | | | |
| | 6 | Medium | | | | | | | | | |
| | 5 | Low | | | | | | | | | |
| | 4 | Slight | | | | | | | | | |
| | 3 | Very slight | | | | | | | | | |
| | 2 | Remote | | | | | | | | | |
| | 1 | Almost impossible | | | | | | | | | |

**Table.6:** Example of FMEAs Report and Risk Chart

FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

Product Name: Prepared by:

Version No./ Year / Product(s): Reviewed by: FMEA Date: (Rev.)

| No | Part Name Part No (Process / Function Name) | Function | Failure Mode | Mechanism (s) & cause(s) of Failure | Effect(s) of Failure | Current Control | Ranking | | | | Recommended Corrective Action(s) | Action(s) taken | Ranking | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | S | O | D | RPN | | | S | O | D | RPN |
| 1 | Material Inspection. | Checking of materials as per specifications / Quality plan or Test report | a)Transit Damage | i) Improper packing by supplier. | i) Not fit for further / remaining process. | i) Packing Instruction mentioned in PO to supplier. ii) Inward inspection as per the Quality plan | 5 | 3 | 1 | 15 | | | | | | |
| | | | b) Visual Defects - bend, dents, cracks. | i) Improper Material Handling. | i) Not fit for further / remaining process. | i) Inspection as per work Instructions. ii) Training provided for material handling. | 6 | 3 | 2 | 36 | | | | | | |

| | Severity--> | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | None | Very Slight | Slight | Minor | Moderate | Significant | Major | Extreme | Serious | Hazardous |
| occurrence | 10 | Almost certain. | | | | | | | | | |
| | 9 | Very high | | | | | | | | | |
| | 8 | High | | | | | | | | | |
| | 7 | Moderately high | | | | | | | | | |
| | 6 | Medium | | | | | | | | | |
| | 5 | Low | | | | | | | | | |
| | 4 | Slight | | | | | | | | | |
| | 3 | Very slight | | | | 16(i) | 15(i) | 16(i) | | | |
| | 2 | Remote | | 6.5d(iv),17b(i) 18c(i) | | | | | | | |
| | 1 | Almost impossible | | | | | 17b(ii) | | | | |

## V. ADVANTAGES, DISADVANTAGES AND USES OF FMEAs

### A. *Advantages*

- FMEAs can track product failure modes, their causes and effects which provides very valuable knowledge for future product and process design.
- FMEAs provide the designer with an Indication of the predominant failures that should receive considerable attention while the product is being designed.
- Actions can be taken to Eliminate or reduce failures in order of quantitatively RPN.

### B. *Disadvantages*

- FMEAs is time consuming and tedious to trace failure through FMEA Chart.
- FMEAs is applied too late and does not affect decision making of design and process.
- FMEAs depends on subjective analysis and engineers experience that are known by a small group individuals, but fairly unknown and unmanaged at the enterprise level.
- The relationship between different failure components is disregarded.

### C. *Uses*

- Development of system requirements that minimize the likelihood of failures.
- Development of designs and test systems to ensure that the failures have been eliminated or the risk is reduced to acceptable level.
- Development and evaluation of diagnostic systems
- To help with design choices.

## VI. CONCULSIONS

- FMEAs is to take actions to eliminate or reduce failures, starting with the highest-priority ones.
- FMEAs also documents current knowledge and actions about the risks of failures, for use in continuous improvement.
- FMEAs is used during design to prevent failures.
- By taking effectively counter measure we will bring the risk only up to tolerable limit and acceptable limit in all areas of activities but cannot eliminate the hazards and risk completely from the workplace because in manufacturing industry many machinery, substances and activities are in use so there is always have possibility to cause some injury to operators.
- Thus, there is always some residual risk in process industry. Each of the hazards that remain poses some risk to the workers and the community in the operation of the plant.
- These risks need to be identified specifically and evaluated. Risks are controlled in several ways and these indicate other source of risk.
- For any manufacturing industry to be successful it should have to meet not only the production requirements, but also have to sustain the highest safety standards for all concerned.

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