FAILURE MODE AND EFFECTS ANALYSIS

FMEA

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1. BASIC TERMS

FMEA:
Failure mode effect analysis.

Failure mode:
The manner by which a failure is observed; it generally describes the way the failure occurs.

Failure effect:
The immediate consequences a failure has on the operation, function or functionality, or status of some item.

Indenture levels:
An identifier for item complexity. Complexity increases as the levels get closer to one.

Local effect:
The Failure effect as it applies to the item under analysis.

Next higher level effect:
The Failure effect as it applies at the next higher indenture level.

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

Failure cause:
Defects in design, process, quality, or part application, which are the underlying cause of the failure or which initiate a process which leads to failure.

Severity:
The consequences of a failure mode. Severity considers the worst potential consequence of a failure, determined by the degree of injury, property damage, or system damage that could ultimately occur.

2. TYPES & HISTORY

2.1 Definition
2.2 History
2.3 Types

2.1 Definition

A **Failure mode and effects analysis (FMEA)** is a **procedure** for analysis of potential failure modes within a system for the classification by severity or determination of the failures' effect upon the system.
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.

It is widely used in the manufacturing industries in various phases of the product life cycle and is now increasingly finding use in the service industry as well.

Failure causes are any errors or defects in process, design, or item especially ones that affect the customer, and can be potential or actual.

"Failure modes" means the ways, or modes, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual.

Effects analysis refers to studying the consequences of those failures.

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.

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. 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.

2.2 History

FMEA is quite old, with the oldest form being trial and error. However, learning from each failure is both costly and time consuming. As such, it is considered better to first conduct some thought experiments.

FMEA was formally introduced in the late 1940's, with military purposes, by the US Armed Forces.

Later it was used for aerospace / rocket development to avoid errors in small sample sizes of costly rocket technology. An example of this is the Apollo Space program. The primary push came during the 1960's, while developing the means to put a man on the moon and safely get him back.

In the late 1970's the Ford Motor Company introduced FMEA to the automotive industry for safety and regulatory consideration after the Pinto affair. They also used it to improve production and design.

Although initially developed by the military, the FMEA methodology is now extensively used in a variety of industries including semiconductor processing, foodservice, plastics, software, and healthcare.

It is integrated into Advanced Product Quality planning (APQP) to provide primary risk mitigation tools and timing in the preventing strategy, in both design and process formats. Each potential cause must be considered for its effect on the product or process and, based on the risk, actions are determined and risks revisited after actions are complete.

Toyota has taken this one step further with its Design Review Based on Failure Modes (DRBFM) approach.

2.3 Types

1. Process:
   Analysis of manufacturing and assembly processes

2. Design:
   Analysis of products and their use, prior to production

3. Concept:
   Analysis of systems or subsystems in the early design concept stages

4. Equipment:
   Analysis of machinery and equipment design before purchase

5. Service:
   Analysis of service industry processes before they are released to impact the customer

6. System:
   Analysis of the global system functions

7. Software:
   Analysis of the software functions

3. IMPLEMENTATION PURPOSE

In FMEA, Failures are prioritized according to how serious their consequences are, how frequently they occur and how easily they can be detected.

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

When apply the FMEA?

It is used:

1. during the design or redesign stage of a process, product or service (after quality function deployment) with an aim to avoid future failures.

2. if an existing process is being applied in a new way.

3. before developing control plans for a new or modified process for process control, before and during ongoing operation of the process.

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

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

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

Ideally, FMEA begins during the earliest conceptual stages of design and continues throughout the life of the product or service.

The purpose of the FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority ones.

It may be used to evaluate risk management priorities for mitigating known threat-vulnerabilities.

FMEA helps select remedial actions that reduce cumulative impacts of life-cycle consequences (risks) from a systems failure (fault).

It is used in many formal quality systems such as QS-9000 or ISO/TS 16949.

4. FMEA IMPLEMENTATION, PROCEDURE

4.1 General description
4.2 Procedure

4.1 General description

FMEA can provide an analytical approach, when dealing with potential failure modes and their associated causes.

When considering possible failures in a design – like safety, cost, performance, quality and reliability – an engineer can get a lot of information about how to alter the development/manufacturing process, in order to avoid these failures as best as possible.

FMEA provides an easy tool to determine which risk has the greatest concern, and therefore an action is needed to prevent a problem before it arises. The development of these specifications will ensure the product will meet the defined requirements.

4.1.1 The pre-work

The process for conducting an FMEA is straightforward. It is developed in 3 main phases, in which appropriate actions need to be defined. But before starting with an FMEA, it is important to do some pre-work to make sure the robustness and past history are included in the analysis.

Therefore a robustness analysis can be obtained from Interface Matrices, Boundary Diagrams and Parameter Diagrams.
A lot of failures are due to noise factors and shared interfaces with other parts and / or systems, because engineers tend to focus on what they control directly.

To start it is necessary to describe the system and its function. A good understanding simplifies the further analysis. This way an engineer can see which uses of the system are desirable and which are not.

It is important to consider both intentional and unintentional uses! Unintentional uses are a form of hostile environment.

Next a block diagram of the system needs to be created. This diagram gives an overview of the major components or process steps and how they are related.

These are called logical relations around which the FMEA can be developed. It is useful to create a coding system to identify the different system elements. The block diagram should always be included with the FMEA.

Before starting the actual FMEA, a worksheet needs to be created, which contains the important information about the system, such as the revision date or the names of the components. On this worksheet all the items or functions of the subject should be listed in a logical manner, based on the block diagram.

Example FMEA Worksheet

Function	Failure mode	Effects	S (severity rating)	Cause(s)	O (occurrence rating)	Current controls	D (detection rating)	CRIT (critical characteristic	RPN (risk priority number)	Recommended actions	Responsibility and target completion date	Action taken
Fill tub	High pressure sensor never trips	Liquid spills on customer floor	8	Pressure sensor failed Pressure sensor disconnected	2	Fill timeout based on time to fill to low pressure sensor	5	N	80	Perform cost analysis of adding additional sensor halfway between low and high pressure sensors	Jane Doe 10-Oct-2010	

4.1.2 Step 1: Severity

Determine all failure modes based on the functional requirements and their effects.

Examples of failure modes are: Electrical short-circuiting, corrosion or deformation.

It is important to note that a failure mode in one component can lead to a failure mode in another component.

Therefore each failure mode should be listed in technical terms and for function. Hereafter the ultimate effect of each failure mode needs to be considered.

A failure effect is defined as the result of a failure mode on the function of the system as perceived by the user. In this way it is convenient to write these effects down in terms of what the user might see or experience.

Examples of failure effects are: degraded performance, noise or even injury to a user. Each effect is given a **severity number**(S) from 1(no danger) to 10(important).

These numbers help an engineer to prioritize. If the severity of an effect has a number 9 or 10, actions are considered to change the design by eliminating the failure mode, if possible, or protecting the user from the effect. A severity rating of 9 or 10 is generally reserved for those effects which would cause injury to a user or otherwise result in litigation.

4.1.3 Step 2: Occurrence

In this step it is necessary to look at the cause of a failure and how many times it occurs.

This can be done by looking at similar products or processes and the failures that have been documented for them.

A failure cause is looked upon as a design weakness. All the potential causes for a failure mode should be identified and documented. Again this should be in technical terms.

Examples of causes are: erroneous algorithms, excessive voltage or improper operating conditions.

A failure mode is given a **probability number**(O),again 1-10. Actions need to be determined if the occurrence is high (meaning >4 for non safety failure modes and >1 when the severity-number from step 1 is 9 or 10). This step is called the detailed development section of the FMEA process.

4.1.4 Step 3: Detection

When appropriate actions are determined, it is necessary to test their efficiency. Also a design verification is needed. The proper inspection methods need to be chosen.

First, an engineer should look at the current controls of the system, that prevent failure modes from occurring or which detect the failure before it reaches the customer.

Hereafter one should identify testing, analysis, monitoring and other techniques that can be or have been used on similar systems to detect failures.

From these controls an engineer can learn how likely it is for a failure to be identified or detected.

Each combination from the previous 2 steps, receives a **detection number**(D). This number represents the ability of planned tests and inspections at removing defects or detecting failure modes.

4.1.5 Step 4: Risk Priority Numbers

After these 3 basic steps, Risk Priority Numbers (RPN) are calculated.

RPN do not play an important part in the choice of an action against failure modes. They are more threshold values in the evaluation of these actions.

After ranking the severity, occurrence and detectability the RPN can be easily calculated by multiplying these 3 numbers: RPN = S x O x D

This has to be done for the entire process and / or design.

Once this it is done it is easy to determine the areas of greatest concern. The failure modes that have the highest RPN should be given the highest priority for corrective action. This means it is not always the failure modes with the highest severity numbers that should be treated first. There could be less severe failures, but which occur more often and are less detectable.

After these values are allocated, recommended actions with targets, responsibility and dates of implementation are noted. These actions can include specific inspection, testing or quality procedures, redesign (such as selection of new components), adding more redundancy and limiting environmental stresses or operating range.

Once the actions have been implemented in the design / process, the new RPN should be checked, to confirm the improvements. These tests are often put in graphs, for easy visualization. Whenever a design or a process changes, an FMEA should be updated.

A few logical but important thoughts come in mind:

* Try to eliminate the failure mode (some failures are more preventable than others)
* Minimize the severity of the failure
* Reduce the occurrence of the failure mode
* Improve the detection

4.2 Procedure

The following steps have to be taken:

1. Assemble a cross-functional team of people with diverse knowledge about the process, product or service and customer needs. Functions often included are: design, manufacturing, quality, testing, reliability, maintenance, purchasing (and suppliers), sales, marketing (and customers) and customer service.

2. Identify the scope of the FMEA. Is it for concept, system, design, process or service? What are the boundaries? How detailed should we be? Use **flowcharts** to identify the scope and to make sure every team member understands it in detail. (From here on, we'll use the word "scope" to mean the system, design, process or service that is the subject of your FMEA.)

3. Fill in the identifying information at the top of your FMEA form. Figure on page 10 shows a typical format. The remaining steps ask for information that will go into the columns of the form.

4. Identify the functions of your scope. Ask, "What is the purpose of this system, design, process or service? What do our customers expect it to do?" Name it with a verb followed by a noun. Usually you will break the scope into separate subsystems, items, parts, assemblies or process steps and identify the function of each.

5. For each function, identify all the ways failure could happen, which influences are playing a role. The influences come form outside and should be monitored with limits (see Process Control). These are potential failure modes. If necessary, go back and rewrite the function with more detail to be sure the failure modes show a loss of that function.

6. For each failure mode, identify all the consequences on the system, related systems, process, related processes, product, service, customer or regulations. These are potential effects of failure. Ask, "What does the customer experience because of this failure? What happens when this failure occurs?" Set up a matrix for estimating the effects.

7. Determine how serious each effect is. This is the severity rating, or S. Severity is usually rated on a scale from 1 to 10, where 1 is insignificant and 10 is catastrophic. If a failure mode has more than one effect, write on the FMEA table only the highest severity rating for that failure mode.

8. For each failure mode, determine all the potential root causes. Use tools classified as **cause analysis tool** (amongst them Ishikawa-diagram), as well

as the best knowledge and experience of the team. List all possible causes for each failure mode on the FMEA form.

9. For each cause, determine the occurrence rating, or O. This rating estimates the probability of failure occurring for that reason during the lifetime of your scope. Occurrence is usually rated on a scale from 1 to 10, where 1 is extremely unlikely and 10 is inevitable. On the FMEA table, list the occurrence rating for each cause.

10. For each cause, identify current process controls. These are tests, procedures or mechanisms that you now have in place to keep failures from reaching the customer. These controls might prevent the cause from happening, reduce the likelihood that it will happen or detect failure after the cause has already happened but before the customer is affected.

11. For each control, determine the detection rating, or D. This rating estimates how well the controls can detect either the cause or its failure mode after they have happened but before the customer is affected. Detection is usually rated on a scale from 1 to 10, where 1 means the control is absolutely certain to detect the problem and 10 means the control is certain not to detect the problem (or no control exists). On the FMEA table, list the detection rating for each cause.

12. (Optional for most industries) Is this failure mode associated with a critical characteristic? (Critical characteristics are measurements or indicators that reflect safety or compliance with government regulations and need special controls.) If so, a column labelled “Classification” receives a Y or N to show whether special controls are needed. Usually, critical characteristics have a severity of 9 or 10 and occurrence and detection ratings above 3.

13. Calculate the risk priority number, or RPN, which equals S × O × D. Also calculate Criticality by multiplying severity by occurrence, S × O. These numbers provide guidance for ranking potential failures in the order they should be addressed.

14. Identify recommended actions. These actions may be design or process changes to lower severity or occurrence. They may be additional controls to improve detection. Also note who is responsible for the actions and target completion dates.

15. As actions are completed, note results and the date on the FMEA form. Also, note new S, O or D ratings and new RPNs.

5. USE & TIMING OF FMEA

5.1 Use
5.2 Timing

5.1 Use

The following items are listed, not pretending to be complete and in the ranking of importance:

1. Ensuring that any failure that could occur will not injure the company, its employees or seriously impact on a system.

2. Ensuring that any failure that could occur will not injure the customer or seriously impact on a system.

3. Development of system requirements that minimize the likelihood of failures at the start of a new process, product.

4. Development of methods to design and test systems to ensure that the failures have been eliminated.

5. Evaluation of the requirements of the customer to ensure that those do not give rise to potential failures.

6. Identification of certain design characteristics that contribute to failures, and minimize or eliminate those effects.

7. Tracking and managing potential risks in the design. This helps avoid the same failures in future projects.

5.2 Timing

The FMEA should be set up / updated whenever:

1. At the beginning of a cycle (new product / process)
2. Changes are made to any operating conditions
3. A change is made in the product design
4. New regulations are instituted by law, authorities, customer, company
5. Customer (or any other) feedback indicates a problem.

6. EVALUATION OF FMEA

6.1 Advantages
6.2 Disadvantages

6.1 Advantages

1. Improve the quality, reliability and safety of a product / process
2. Improve company image and market competiveness
3. Increase employee & user satisfaction
4. Collect information to reduce future failures, capture engineering knowledge
5. Early identification and elimination of potential failure modes
6. Emphasis problem prevention
7. Catalyst for teamwork and idea exchange between functions
8. Reduce the potential for warranty concerns
9. Minimize late changes and associated cost
10. Reduce system development timing and cost

6.2 Disadvantages

1. If used as a **“top-down”** tool, FMEA may only identify major failure modes in a system. Fault tree analysis (**FTA**) is better suited for "top-down" analysis.

   When used as a **"bottom-up"** tool FMEA can augment or complement FTA and identify many more causes and failure modes resulting in top-level symptoms.

2. It is not able to discover complex failure modes involving multiple failures within a subsystem, or to report expected failure intervals of particular failure modes up to the upper level subsystem or system.

3. The multiplication of the severity, occurrence and detection rankings may result in rank reversals, where a less serious failure mode receives a higher RPN than a more serious failure mode. The reason for this is that the rankings are ordinal scale numbers, and multiplication is not a valid operation on them. The ordinal rankings only say that one ranking is better or worse than another, but not by how much. For instance, a ranking of "2" may not be twice as bad as a ranking of "1," or an "8" may not be twice as bad as a "4," but multiplication treats them as though they are.

4. It needs a software for keeping the system up to date and easy working with it. When selecting the software package which best suits your company's needs, it is important to choose one that is easy to learn and promotes consistent updating of your documentation.

7. OTHER SIMILAR SYSTEMS

7.1 FMECA
7.2 PDPC
7.3 Risk assessment
7.4 Failure rate

7.1 Failure Mode, Effects, and Criticality Analysis (FMECA)

This is an **extension** of Failure Mode and Effects Analysis (FMEA).

In addition to the basic FMEA, it includes a **"criticality analysis"**, which is used to chart the probability of failure modes against the severity of their consequences. The result highlights failure modes with relatively high probability and severity of consequences, allowing remedial effort to be directed where it will produce the greatest value.

The typical goal, when FMECA is performed as part of a design project, is to eliminate failure modes with high severity *and* probability, and to reduce as much as possible those with high severity or high probability.

If the Criticality Analysis is performed iteratively during the design process, the charted failure modes should be seen to migrate to the left and bottom (typically) of the chart.

This enables priority ranking by means of the so called Risk Priority Number (RPN). The **RPN** is a result of a multiplication of:

detectability (*D*) x severity (*S*) x occurrence (*O*).

Each on a scale from 0 to 10.

The highest *RPN* is 10x10x10 = 1000. This means that this failure is not detectable by inspection, very severe and the occurrence is almost sure.
If the occurrence is very sparse, this would be 1 and the *RPN* would decrease to 100. So, criticality analysis enables to focus on the highest risks.

7.2 Process Decision Program Chart (PDPC)

This is a technique designed to help prepare **contingency plans**.

The emphasis of the PDPC is to identify the consequential impact of failure on activity plans, and create appropriate contingency plans to limit risks.

Process diagrams and planning tree diagrams are extended by a couple of levels when the PDPC is applied to the bottom level tasks on those diagrams.

Methodology:

From the bottom level of some activity box, the PDPC adds levels for:

1. identifying what can go wrong (failure mode or risks)
2. consequences of that failure (effect or consequence)
3. possible countermeasures (risk mitigation action plan).

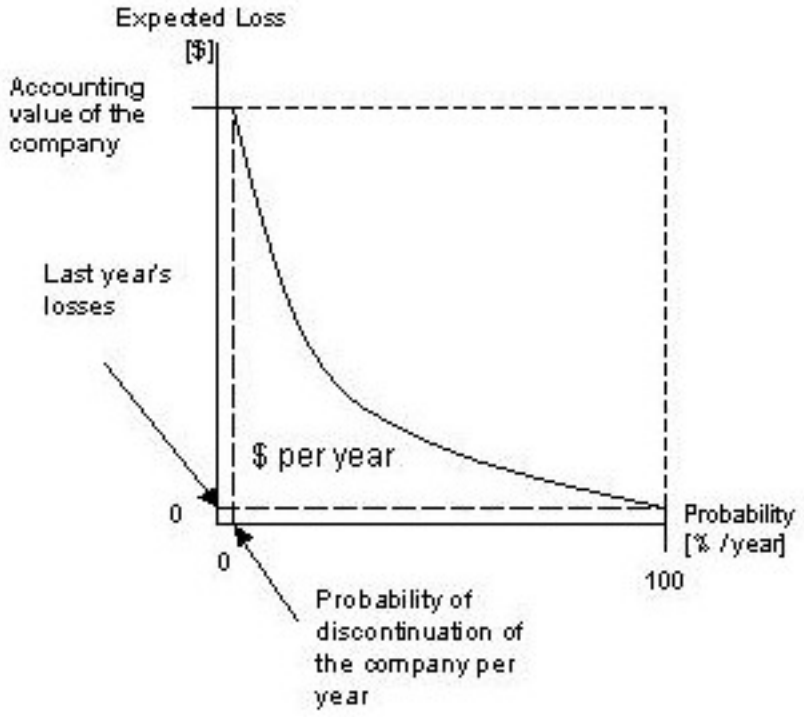
The PDPC is similar to the failure mode and effects analysis (FMEA) in that both identify risks, consequences of failure, and contingency actions.
The FMEA adds prioritized risk levels through rating relative risk for each potential failure point.

7.3 Risk Assessment

Risk assessment is a common first step in a **risk management** process.

Risk assessment is the determination of quantitative or qualitative value of risk related to a concrete situation and a recognized threat.

Quantitative risk assessment requires calculations of two components of risk R, the magnitude of the potential loss L, and the probability p that the loss will occur.



Risk assessment is an important, yet difficult, step in the risk management process.

Once risks have been identified and assessed, the steps to properly deal with these risks are more formulaic.

Part of the difficulty of risk management is that measurement of both of the quantities in which risk assessment is concerned- potential loss and probability of occurrence- can be very difficult to measure.
The chance of error in the measurement of these two concepts is large. A certain risk with a large potential loss and a low probability of occurring must be treated differently than one with a low potential loss and a high likelihood of occurring.
In theory, both are of nearly equal priority in dealing with first, but in practice it can be very difficult to manage when faced with the scarcity of resources, especially time, in which to conduct the risk management process.

If the risk estimate takes into account information on the number of individuals exposed, it is termed a **"population risk"** and is in units of expected increased cases per a time period.

If the risk estimate does not take into account the number of individuals exposed, it is termed an "individual risk" and is in units of incidence rate per a time period.

Population risks are of more use for cost / benefit analysis; individual risks are of more use for evaluating whether risks to individuals are "acceptable".

7.4 Failure rate

Failure rate is the frequency with which an engineered system or component fails, expressed for example in failures per hour. It is important in reliability theory.

In practice, the reciprocal rate “MTBF” (Mean Time Between Failure) is more commonly expressed and used for high quality components or systems.

Failure rate is usually time dependent, and an intuitive corollary is that both rates change over time versus the expected life cycle of a system.

For example, as an automobile grows older, the failure rate in its fifth year of service may be many times greater than its failure rate during its first year of service; one simply does not expect to replace an exhaust pipe, overhaul the brakes, or have major power plant-transmission problems in a new vehicle.

So in the special case when the likelihood of failure remains constant with respect to time (for example, in some product like a brick or protected steel beam), failure rate is simply the inverse of the mean time between failure (MTBF), expressed for example in hours per failure. MTBF is an important specification parameter in all aspects of high importance engineering design such as naval architecture, aerospace engineering, automotive design, etc. and in short, any task where failure in a key part or of the whole of a system needs be minimized and severely curtailed, particularly where lives might be lost if such factors are not taken into account. These factors account for many safety and maintenance practices in engineering and industry practices and government regulations, such as how often certain inspections and overhauls are required on an aircraft.

A similar ratio used in the transport industries, especially in railways and trucking is '**Mean Distance Between Failure' (MDBF)**, a variation which attempts to correlate actual loaded distances to similar reliability needs and practices.

Failure rates and their projective manifestations are important factors in insurance, business, and regulation practices as well as fundamental to design of safe systems throughout a national or international economy.