CHAPTER II

REVIEW OF LITERATURE AND RELATED STUDIES

2.1 Definitions of Failure Mode and Effects Analysis (FMEA)

Failure Mode and Effects Analysis (FMEA) is one of well-known risk-assessment methodologies. FMEA, first used in 1960's in the Aerospace industry, is now recognized as a fundamental tool in the Reliability Engineering field. The purpose of FMEA is to examine possible failure modes and determine the impact of these failures on design and process. It is a living document and never ends. The FMEA used can be categorized into three types as follows:

- Design FMEA: is a systematic method to identify and correct any known or potential failure modes before the first production run. It focuses on potential failure modes associated with the functions of product and caused by the design deficiencies
- Process FMEA: is used to analyze the already developed or existing processes. The focus of the process FMEA is to minimize production failure effects on the system by identifying the key variables.
- Service FMEA: is used to analyze the product serviceability, i.e. it is focused on the potential problems associated with both maintenance issues and field failures of the manufactured products.

R.R. Mohr (1994) defines the definition of term used in FMEA as follows:

- Fault: Inability to function in a desired manner, or operation in an undesired manner, regardless of cause.
- Failure: A fault owing to breakage, wear out, compromised structural integrity, etc. FMEA does not limit itself strictly to failures, but includes faults.
- Failure Mode: The manner in which a fault occurs, i.e. the way in which the element faults.

- <u>Element</u> | <u>Failure Mode Examples</u>

Element	Failure Mode Examples
Switch	open, partially open, closed, partially closed, chatter
Valve	open, partially open, closed, partially closed, wobble
Spring	stretch, compress/collapse, fracture
Cable	stretch, break, kink, fray
Relay	contacts closed, contacts open, coil burnout, coil short
Operator	wrong operation to proper item, wrong operation to wrong item proper operation to wrong item, perform too early perform too late, fail to perform

- Failure Effect: The consequence(s) of a failure mode on an operation, function, status of a system/process/activity/environment. The undesirable outcome of a fault of a system element in a particular mode. The effect may range from relatively harmless impairment of performance to multiple fatalities, major equipment loss, and environmental damage, for example.

  All failures are faults; not all faults are failures. Faults can be caused by actions that are not strictly failures.

  A system that has been shut down by safety features responding properly has NOT faulted (e.g., over temperature cutoff).

  A protective device which functions as intended (e.g., a blown fuse) has NOT failed.

- Failed/Faulted SAFE: Proper function is compromised, but no further threat of harm exists (e.g., a smoke detector alarms in the absence of smoke).

- Failed/Faulted DANGEROUS: Proper function is impaired or lost in a way which poses threat of harm (e.g., a smoke detector does not alarm in the presence of smoke).

2.2 FMEA Methodology

The process of conducting a Failure Mode and Effects Analysis (FMEA) is systematic. There are ten basic steps to follow by Robin E. Medermott, Raymondy J. Mikulak and Michael Beauregard (2002):

- Step 1: Define the FMEA Boundaries

Most teams will want to utilize the FMEA start-up worksheet (included in the worksheet file) to organize and document the FMEA process in addition to Performance Improvement model to document the improvement actions taken. The FMEA start-up worksheet will give a clear understanding of the boundaries of the team project and team members responsibilities. The boundaries or scope of the FMEA will need to be clearly defined, including a description of the process under review. The FMEA leadership sponsors and the team leader must work together to determine which aspects of the FMEA the team is responsible for- the FMEA analysis, recommendations for improvement, and implementation of improvements. The process also needs to be clarified if the team needs to expand beyond these boundaries.

- Step 2: Assemble the FMEA Team

FMEA which is a team function is not done on an individual basis. Teams are specifically defined for an individual FMEA project, are cross-functional and multi-disciplinary, and may disband after the FMEA is completed. The purpose of the FMEA team is to bring a variety of perspectives and experiences to the project.

  - There will be a person assigned to coordinate the team, the team leader, who understand FMEA.
  - A mission or purpose statement regarding the scope is to be written.
  - Team membership must include people who know the process best.
  - Just-in-time training will be needed for the team members.
  - The FMEA team process will need to be documented for monitoring and use in the quality program.

- Step 3: Review the Process

To ensure everyone on the FMEA team has the same understanding of the process that is being worked on, review the process by creating a detailed flowchart of the process or service. Develop the flowchart as team, for example using Post-It type self-sticking notes, until the process is agreed upon (then transfer into a permanent document). Consecutively number each process step identified in the process flow diagram to help identify the step with the work done on the FMEA worksheet. Identify all sub-processes under each block on the diagram and consecutively letter these sub-steps. This flowchart will be used for the life of the FMEA so create a permanent document on a chart pad or as a computer document.

- Step 4: Brainstorm Potential Failure Modes

Once the team has an understanding of the process, determine all the ways the process step could fail (failure modes). For each failure mode, it is worthwhile at this point to also describe possible causes (Step 5). This will later provide insight on the likelihood (probability of failure). The team brainstorms to determine failure modes for each process step. Focusing on each of the elements will result in a more thorough list of potential failure modes. An affinity diagram can be used to organize brainstorm ideas or a fishbone diagram (cause and effect diagram) may be helpful to diagram categories and potential causes for each category. When this work is final, place the findings on the FMEA worksheet under potential failure modes corresponding to the applicable process section. More than one potential failure mode may be identified for each process or sub-process step. The team should list all failure modes.

- Step 5: Identify the Potential Cause(s) of Each Failure Mode

One of the most important sections of a FMEA is determining the potential causes of the failure mode as it provides insight into the probability of failure and points the team toward prevention and/or corrective actions. The more focused the FMEA is on the causes, the more successful the team will be in eliminating failures. Record the potential causes on the FMEA Worksheet.

- Step 6: List the Potential Effects

For each failure listed on the FMEA Worksheet, the FMEA team identifies the potential effects of the failure should occur. The effect is the outcome-try to answer the question “what happens when a failure occurs” or “what is(are) the consequence(s)”. The effects can be localized or isolated (doesn’t affect anything else) or global (affects other functions or components). Generally, global effects are more serious than local effects. For some of the failure modes, there may be only one effect, while there may be several effects for other failure modes. Record the potential effects on the FMEA Worksheet.

- Step 7: Assign Risk Codes

Now the team will evaluate the severity, occurrence and ability to detect the failure of each mode. This step of the FMEA attempts to assign risk codes to each potential failure mode-effect combination so they can be prioritized for actions (or countermeasures) to reduce or eliminate them. Risk is an expression of the degree of threat posed by a hazard.

- Step 8: Develop and Prioritize Actions or Countermeasures to Reduce Risks

Using an organized problem solving process identify feasible actions (controls or countermeasures) to eliminate or reduce the high risk failure modes. Record the recommended actions on the FMEA Worksheet and the FMEA Action Worksheet.

- Step 9: Assign Action Responsibility

From the FMEA team charter, determine if the FMEA team or another group will be responsible for implementation of the proposed actions or countermeasures. It is important to make an assignment of responsibility and project the completion date.

- Step 10: Monitor the Action Results and Risk Reduction

Once the actions have been implemented, the team or group assigned accountability for the actions should continue to document the FMEA actions as part of the FMEA documentation. Sometimes it takes a long lead-time to detect a change after the action is taken, while others will be immediately apparent.

2.3 Advantages and Disadvantages of FMEA

2.3.1 Advantages of FMEA

There are many studies and literatures supporting FMEA as the useful and effective technique. Examples of these studies are:

Debbie Vermilion (2002) explained that service companies who frequently conduct FMEA's and evaluate their success typically experience:

- Minimized customer defection/increased customer satisfaction
- Increased consistency in service quality
- Reduction of costly design changes
- Reduced transaction costs/increased profits
- Reduced liability

FMEA is differentiated over other types of failure analysis methods in that it is particularly adept at:

- Identifying *cause* and *effect* of known and potential failures *before* they occur
- Providing documentation of failures which can be tracked over time
- Making accountability easier to pinpoint
- Facilitating continuous improvement
- Creating a common language that can be easily understood by both technical and non-technical people in the organization

Hayet Mouss, Djamel Mouss, Nadia Mouss and Samia Chebira (2000) explained that the FMEA is a method of critical analysis which consists of identifying an inductive and systematic way the risks of abnormal operations of a system then to seek the origins and their consequences. More generally, it allows:

- Identification of the failure modes of all the components of a system
- The possible investigation into the failure causes, for each mode of failure

- The evaluation of the effects on the system and the user for each combination cause-mode of failure
- The search of possible detections, for each combination cause-mode of failure

FMEA was always used for the studies of the diagnosis prepared within the framework of the plant maintenance. The diagnosis uses the links between the effects of a failure, perceived like a addition of detection test (visual or sound alarms, measurement of signals, etc.) allotted to each combination cause-mode of failure(as figure 2.1 shown below).

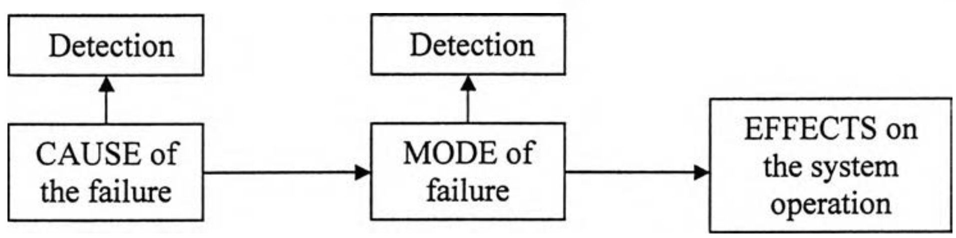

Figure 2.1: Failure Mechanism

The realization of an FMEA first of all requires the determination of the level of decomposition. A system could be the subject of a hierarchical decomposition in as much of level of decomposition must be compatible with the knowledge of all the modes of failure, and their effects. The results of these analyses are then presented in the form of a table with columns gathering the main analyzed criteria.

John H. Casper (1999) explained that FMEA is a reliability engineering tool that the system safety community has adopted as a safety tool for analyzing system failures that could cause a hazard. To put it another way, a FMEA is an analytical tool to identify all the ways that a component can fail, and what are the effects of the failure on the system. The company should use FMEA for analyzing systems at the lowest level to determine the hazard associated with component failure, and how the failures affect the overall mission performance of the safety critical system. He further recommended that FMEA should be used after other hazard analysis techniques have identified safety-critical systems that need further analysis. The process for performing a FMEA is accomplished in steps. The quality of FMEA is determined by how these steps are performed. The steps are as follows:

- Define the system and the scope and boundaries of the analysis, i.e. identify the lowest level that the company wants to analyze.
- Construct a functional block diagram showing the relationship between the different system levels.
- Assess each functional block and determine if its failure would affect the rest of the system.
- Use a bottom-up type approach to determine the effects of failure of each component. List the modes or ways that the component can fail.
- For each failure mode determine the worst credible effect and determine a severity and probability of occurrence.
- Identify whether the failure is a single-point failure. (A single-point failure is a failure of a single component that could cause complete failure of the mission or loss of the system.)
- Determine corrective actions. (These can prevent the failure or mitigate the effects of the failure.)
- Document the failure on the worksheet.

The advantages of FMEA are explained as follow:

- FMEA is good for specific, critical or hazardous subsystems to know what can fail and what the result of the failure will be.
- FMEA is very systematic approach
- FMEA technique looks at every component to determine failure effects

Doug Bonacum, Diane Brown (2002) explained that Failure Mode and Effects Analysis (FMEA) is one of over one hundred analytical tools that is part of the broad management practice of "system safety." System safety aims to identify, assess, and control risks or hazards before they cause harm. FMEA has been part of the system safety toolbox for decades. It has received increased attention as we focus more on preventive of problems and trying to proactively understand "what could go wrong" before it actually does.

Dorothy Lueck (1996) explained that the best time to start the FMEA is before a failure is designed into a product or manufacturing process. The advantages of FMEA are as follows:

- FMEAs help reduce crises during product development and launch and thus reduce costs, since early, upfront changes tend to cost less than late, downstream ones. The corrective action review and evaluation can avoid creating new concerns, and the cost impact of changes can be evaluated during development.
- FMEAs can also be used to develop new equipment or to evaluate the operations of existing equipment and systems. FMEAs are an interactive process of continuous improvement that involves team effort. Functional areas involved include design, materials, manufacturing, assembly, packaging, shipping, service, recycling, quality, reliability, vendors, and customers. Customers include, but are not limited to, downstream engineering functions, downstream manufacturing functions, end users, service functions, and recycling or reuse functions.

Yiannis Papadopoulos & David Parker (2004) explained that the FMEA can help analysts in two ways:

- FMEA helps to locate problems in the design
- FMEA also determines the level of fault tolerance in the system, i.e. determine whether the system can tolerance any single or any combination of two, three or more component failures.

D.H. Stamatis (1997) explained that the propensity of managers and engineers to minimize the risk in a particular design and/or process has forced the company to look at reliability engineering to not only minimize but also to define the risk. Obviously the risk is a multifaceted issue, but, from a generic perspective one may define it based on: management emphasis, market pressures, customer requirements, safety, legal and statutory requirements, public liability, development technical risks, warranty and service costs, competition, and so on. These risks can be measured by reliability engineering and/or statistical analyses. However, because of their complexity, the FMEA has extracted the basic principles without the technical mathematics and has provided us with a tool that anybody committed to continual improvement can utilize. Other benefits of the FMEA include:

- Improving the quality, reliability and safety of the products
- Improving the company's image and competitiveness
- Helping increase customer satisfaction
- Reducing product development time and costs
- Helping select the optimum system design
- Helping determine the redundancy of the system
- Helping identify diagnostic procedures
- Establishing a priority for design improvement actions
- Helping identify critical and/or significant characteristics
- Helping in the analysis of new manufacturing and/or assembly processes

Even though all these reasons are well worth the effort of conducting an FMEA, the most important reason for writing an FMEA is the need to improve. Unless this need is part of the culture of the organization, the FMEA program is not going to be successful.

In addition, in order to carry out FMEA to its highest advantage, the following prerequisites are necessary. **(D.H. Stamatis (1997))**

- Not all problems are important. We must recognize that some problems are more important than others for whatever the reason.
- We must know the customer. A customer may also be defined as a subsequent or downstream operation as well as a service operation. When using the term customer from an FMEA perspective, the definition plays a very major role in addressing problems. Once you define your customer (internal, intermediate, or external) you may not change it-at least not for the problem at hand-unless you recognize that by changing it you may indeed have changed your problem and/or consequences.
- You must know the function. It is imperative to know the function, purpose, or objective of what you are trying to accomplish, otherwise you are going to waste time and effort in redefining your problem based on situations.

- You must be prevention oriented. Unless you recognize that continual improvement is in your best interest, the FMEA is going to be "static" document to satisfy your customer. The push for this continual improvement makes the FMEA a "dynamic" document changing as the design and/or process changes with the intent always to make a better design and/or process.

2.3.2 Disadvantages of FMEA

Although FMEA has lots of advantages, there are some researches explaining the disadvantages of FMEA as follows:

Cherrill M. Spencer and Seung J. Rhee (2003) explained about problems with traditional FMEA. A team of engineers following the traditional FMEA process consider all the possible failures modes of a system component, from design through operation, identify all their causes, and rank their severity, expected frequency and likelihood of detection. A multidisciplinary team carried out a FMEA and identified 10 design changes that would improve its reliability. A prototype NLC quadrupled that incorporated most of these changes was fabricated in 2000 and has been run for about 10,000 hours since without any failures. The degree of risk of each failure is represented by the product of these 3 ranked indices, called the Risk Priority Number (RPN). However, the problems with FMEA are found as follows:

- Inconsistent definitions result in questionable risk priorities, and the use of failure modes rather than cause and effect fault chains inhibits ones understanding of the true causes of failures.
- Traditional FMEA ends with the calculation of RPNs, the team does not consider the consequences of the failures in terms of costs. They do not check that their design changes for avoiding failures cost less than the failures.

LT Robb Wilcox, P.E. (1996) explained that while FMEA is a useful tool for risk management, it also has qualities that limit its application as a complete system safety approach. This technique provides risk analysis for comparison of single component failures only; avoiding such concerns as common cause failures.

Hayet Mouss, Djamel Mouss, Nadia Mouss and Samia Chebira (2002) explained about FMEA that the problem of the diagnosis is the deductive step which consists in analyzing the table and to determine all the possible causes of an observed failure. The disadvantage is its extreme heaviness of use. For complex industrial systems, an FMEA can lead to the realization of thousands of tables. Under these conditions, the use of the FMEA for diagnosis imposes the use of a deductive procedure which makes it possible to automatically generate knowledge necessary to the design of a diagnosis tool.

John H. Casper (1999) explained that even though FMEA is excellent for analyzing what on the systems can fail as a single-point failure, the FMEA does not consider procedures; only hardware. Disadvantages of FMEA are as follow:

- Only looks at hardware and not at operations
- Too laborious and time-consuming to use on an entire building
- Only looks at hazards associated with failures, not those associated with normal operations
- Only looks at the hardware failures, not the interaction between personnel, equipment or environment
- Does not identify all hazards associated with a system, even if it identifies all single point failures

C.J. Price, I.S. Pegler, M.B. Ratcliffe, A. McManus (1997) explained that Process FMEAs are intended to be 'live' documents, i.e. continually referenced and updated. In practice these documents are produced to satisfy customer requirements and are rarely utilized to their full potential.

Jenny Waller, Derek Allen, Andrew Burns (1995) explained that even though FMEA can be used at the planning stage of products or processes to avoid problems in manufacturing and service industries, the companies should not use it if they need a quality improvement. This is because FMEA is about avoidance, not active improvement. Like all predictive tools, it is possible that companies can spend a lot of time predicting things that won't happen, and missing the things that will.

R.R. Mohr (1994) explain about limitations and abuses of FMEA that

- Frequently, human errors and hostile environments are overlooked.
- Because the technique examines individual faults of system elements taken singly, the combined effects of coexisting failures are not considered.
- If the system is at all complex and if the analysis extends to the assembly level or lower, the process can be extraordinarily tedious and time consuming.
- Failure probabilities can be hard to obtain; obtaining, interpreting, and applying those data to unique or high-stress systems introduces uncertainty which itself may be hard to evaluate.

Cayman Business Systems (2004) explained that

- FMEA is not a problem solver. It is used in combination with other problem solving tools. "The FMEA presents the opportunity but does not solve the problem."
- The team developing the FMEA turns out to be one individual.
- The FMEA is created to satisfy a customer or third party requirement, not to improve the process.
- The FMEA is developed too late in the process and does not improve the product/process development cycle.
- The FMEA is not reviewed and revised during the life of the product. It is not treated as a dynamic tool.
- The FMEA is perceived either as too complicated or as taking too much time.

2.4 FMEA Applications

FMEA has been used successfully within many different industries as illustrated by numerous studies including:

LT Robb Wilcox, P.E. (1996) explained that the marine industry is recognizing the powerful techniques including Failure Mode and Effects Analysis (FMEA) that can be used to perform risk analysis of marine systems. The safety of a ship design is often questioned when relatively new technologies or complex systems are used that have not had a successful history of safe operation or an established engineering system. The need for better understanding of the safety performance of new marine designs has prompted the application of established risk analysis techniques to develop an improved assessment of design safety. FMEA is one of the reliability/safety analysis tools adopted by the marine community for system safety analysis. Recently FMEA technique has been applied in maritime regulations to address safety concerns with relatively new designs.

Roberto Gilioli Rotondaro and Claudio Lopez de Oliveira (2001) show that FMEA is a useful tool for service companies to prevent any failure during the services operation because the service companies must be able to develop and error-free services to the customers. According to Service definition, the customer is always present during the process and delivery of the service. If something goes wrong, it will happen in the presence of the customer. This study shows the use of FMEA as a prevention tool in the services offered by a Medical Clinic restaurant. FMEA is proved to be effective in preventing error or any failure during the service operation. To achieve this, a group of employees was trained in prevention tools; they designed the process map, identified the critical points and applied the FMEA method.

Mario Villacourt (1992) provides the guideline for use of FMEA in the semiconductor industry. Steps of FMEA were taken during the design phase of the equipment life cycle to ensure that reliability requirements have been properly implemented. He ensures that FMEA is a proactive approach to solving potential failure modes and using FMEA can help cut down cost and avoid the embarrassment of discovering problems such as defects, failures, downtime, scrap loss in the field.

According to his study, there are many companies in semiconductor industry successfully use FMEA in designs and process. For instance, Ford Motor Company requires their suppliers to perform detailed FMEAs on all designs and process. Texas Instruments and Intel Corporation have implemented extensive training on FMEA as part of their total quality educational programs. At Nippon Electronics Corporation (NEC), the FMEA process became the most important factor for improving equipment reliability during the design of new systems.

Anker Neilsen (2002) provides a guideline on the use of FMEA as a method for better quality for buildings. The FMEA will typically begin with a number of block diagrams. The purpose is to understand the logic in the system. A FMEA analysis is a good help in finding better solution for moisture proofs buildings. Using this systematic approach gives better understanding of building failures, their effects and remediation method. Finding and preventing hidden failures is a very important task. Using the right solution in the constructions can also reduce the risk of serious damage from water leakage. The analysis is important in the building phase but must include the influence of the user and the lifetime of the building. The analysis results as checklists and information on critical points should be structured for the different parties in the building process as architects, engineers and craftsmen. Selecting, building and keeping moisture-proof constructions are important for preventing health problems in buildings.

Antonio Scipioni, Giovanni Saccarola, Angela Centazzo, Francesca Arena (2002) reports the usefulness of FMEA methodology and its implementation in a food company. FMEA, known as "Hazard Analysis and Critical Control Points (HACCP), can be used to assure product quality and improve operational performance of the production cycle by identifying, monitoring, and controlling areas of food production process which may be critical in terms of the likelihood of problems or contamination. The work was developed in an Italian confectionery industry in cooperation with part of the internal staff, chosen as FMEA team member, and was focused on the study of wafer biscuit production line. There are two main tasks completed by the FMEA team in two complementary operations: the control of exterior qualitative aspects and the implementation and integration of the obtained results in the food control system built in the company on the basis of HACCP.

P.G. Hawkins & D.J. Woollons (1998) explained that there are five basic failure modes in associated with mechanical equipment. The failure modes are categorized according to the type of equipment and energy:

1. fluid flow equipment (leakage and distorted flow)
2. structural systems (fracture and excessive deflection)
3. thermodynamic systems (bearing seizure and reduced accuracy of relative movement)
4. kinematics systems (bearing seizure and reduced accuracy of relative movement)
5. material properties (incorrect material or geometry)

These failure modes originate at the lowest level of aggregation where faults are considered on individual parts. Failure modes are not normally considered below this level. Instead the cause of the failure mode may be identified such as environmental effects including temperature, contamination and fatigue.