# Chapter 2

# Theoretical Consideration and Literature Survey

## 2. Theoretical consideration

In this chapter, I have discussed about basic seven quality tools and the failure mode and effect analysis (FMEA) technique that applied for tinted products to develop standard process for color control in tinted products in paint manufacturing.

## 2.1 The seven basic quality tools for quality improvement

The seven basic quality tools is the one of common technique for assisting in the quality improvement. They provide a basis for understanding the problem, set up the priority for improvement and monitoring that action. Moreover, they also support user by enhancing the analysis of available data, translating them into valuable information on the problem under consideration.

The seven basic quality tools consist of :

| Technique | Function |
|---|---|
| 1. Process Flow Charting | 1. To be understand the overview of all steps in process. |
| 2. Check sheets/Tally Chart | 2. To evaluate the frequency of something or situation occurring. |
| 3. Histrogram | 3. To set up the overall pattern of variation |
| 4. Scatter diagrams | 4. To visualize relationship between two variations. |
| 5. Pareto Diagram | 5. To make decision for setting up the priority of problem |
| 6. Cause and Effect Diagram | 6. To sort out potential cause of problem. |
| 7. Control Chart | 7. To be enhance the understanding of variation within a process, and perform the process control |

**Table 2.1** : The seven basic quality tool

### 2.1.1 Process Flow Charting

This is the first step on of process of process improvement by allowing the team to understand the process in terms of picture. A beneficial technique is to map the ideal process and the actual process and identify the differences as targets for improvements. A good process flow chart can contribute to control of process back to area, which were previously slaves to that process. As such, it can act as a motivator and facilitat6e continuos improvement.

### 2.1.2 Check sheets/Tally Chart

Check sheets are designed for recording data about a process that need to transform the data into information. Decision-making and actions are taken from the data. The appropriate check sheet contributes the effective date for analysis and lead to problem resolution or process improvement. Check sheet normally uses in process distribution checks, defective items checks, defect cause checks etc.

### 2.1.3 Histrogram

The histrogram provides the method of representing the average and dispersion of data in terms of pictorial form. It can assist the user to make decision for appropriate action. It shows a bar chart of accumulated data and provides the easiest way to evaluate the distribution of data.

### 2.1.4 Scatter Diagram

A scatter diagram is a graphical diagram to show the relationship between two data variables. The basic diagram give the overview of the relationship whilst further steps may be taken to quantify it should the need arise. It is used to show the change of one variable when another changes. From a scatter diagram, user can find a mathematical equation that relates to the variables. To create a scatter diagram, these steps are followed:

- Collect data. This is the most essential step.
- Build a data sheet to show the information from the data.
- Define the variable axis of the graph.

    1. The horizontal axis (X axis) displays the variable's measurement values; most are cause variables.
    2. The vertical axis (Y axis) shows the measurement values of another variable; most are effect variables.

- Plot data on the graph.
- Construct a mathematical equation.

From a scatter diagram, curves are tentatively devised for linear and non-linear curves. With this, we can call two relationships between variables to linear and non-linear relationships.

### 2.1.5 Pareto Diagram

The "Pareto principle" states that 80% of problem will be due to 20% of causes. Hence, as a tool, it assists the user to decide upon the most important area for improvement on an analytical basis than relying on "gut feel" or less vigorous methods. It is used to define problems, to set their priority, to illustrate the problems detected, and determine their frequency in the process.

### 2.1.6 Cause and Effect Diagram

Cause and Effect Diagram or fish bone diagram was developed by Kaoru Ishikawa in 1943. This tool focuses on cause rather symptoms of problem, this leads to increased understanding of complex problems. It also emphasizes group communication and brainstorming. It is the most widely used and probably one of the most useful of the "QC seven tools". It is not based on statistics. This chart is simply a means of visualizing how the various factors associated with a process affect the process's output. The same data could be tabulated in a list, but the human mind would have a much more difficult time trying to associate the factors

with each other and with the total outcome of the process under investigation. The cause and effect diagram provides a graphic view of the entire process that easily interprets by team.

There are three types of diagram. These are :

- Dispersion Analysis

This type of diagram is the best characteristic by the question " What is causing the dispersion? "

- Process Classification

This type of diagram was originally referred to as the Production Process Classification type. This, however, tends to restrict the idea of potential users to production process. It is not popular because this technique is equally valid for any process and to limit it in this way to substantially reduce the chances for improvement for no good reason.

- Cause Enumeration

This is the most popular used of the three type of Cause and Effect Diagram. The potential causes are simply listed and then the diagram is created. Generally, the causes of problems can generate into 5 facets. They consist of man, material, machine, method, and environment.

The step for generating Cause and Effect Diagram :

1. Define the problem in a brief statement that all can agree upon.
2. Normally, the Man-Machine-Method-Material is used for organizing the possible solution into categories. However, it may want to devise own basic organizational scheme. These outgrowths become the main fishbone in diagram.
3. The next stage is an open brainstorming session in which any idea (a cause for the defined problem, for example), no matter how far-fetched, is allowed and is added to the diagram as another fishbone "leg" on one of the appropriate major categories. The idea is to generate as many ideas as possible that would explain why the problem exists or how the opportunity might be seized. No discussion as

to the merits of the idea and especially no negative comments are allowed. This absolutely must be strictly enforced! The only discussion might concern under which branch to place the idea, and the moderator should quickly step in to make a placement in case of disagreement, even if the placement is arbitrary.

4. After get many ideas, the next stage is discussion. It is most helpful if this takes the form of an explanation of the concept or thinking behind each idea by the one who proposed it, and even expansions on the idea. Number or letter each idea on the fishbone diagram and provide each person with a piece of paper. Each person is to select the five ideas he or she thinks have the most merit in defining the problem, causes, or opportunity and is to rank these five from most important to least important. The most important is given a numerical value of five, the next four, and so forth.

5. Ask team one by one for their ranking. Put a "5" on the board next to each person's highest ranked item, a "4" next to the second highest ranked item, and so forth until all five are on the board. Repeat this process with each person in the group.

6. Total the values next to each item on the fishbone diagram. The item with the highest total is the one the group has selected as having the most potential for defining or solving the problem or opportunity. It does not, of course, guarantee that this idea, or any of them for that matter, will actually work. It is instead a powerful tool for prioritizing problem or opportunity solving, for generating novel or innovative solutions, and for involving people intimately in the process. It is surprising how often this simple process generates good solutions and ideas.

It is simple to do, involves everyone in the solution process, and goes a long ways toward assuring strong support for solution implementation.

### 2.1.7 Control Chart

The control chart is tool that consists of a line chart with control limits. Normally, by mathematically constructing control limits at 3 standard deviations above and below the average, one can determine what variation is due to normal ongoing cause common causes) and what variation is produced by unique events (special causes). By eliminating the special causes first and then reducing common causes, quality can be improved.

## 2.2 The quality improvement process

Generally, the quality improvement process included as :

1. Identify and select problem
- Brainstorming
- Define the problem
- Prioritize
- Set boundaries
- Flow Chart

2. Analyze cause
- Cause and Effect Diagram
- Collect data
- Pareto
- Histrogram
- Process capability
- Re-prioritize

3. Potential solution
- Brainstorming
- Benchmarking
- Prioritize

4. Select and plan solution
- Select the top solutions
- Force field analysis
- Implement plan
- Ensure " buy-in "

5. Implement solution

- Project management
- Maintain commitment
- Ongoing review

6. Evaluation solution
- Monitor results
- Control
- Apply elsewhere

7. Learn from the process
- Document the process
- Summarize lessons
- Ensure recognition
- Start again

## 2.3 Failure Mode and Effect Analysis

### 2.3.1 Introduction

At the present, customers satisfactions is the most important that all of businesses try to achieve. Most of organizations try to prevent failure and reinforce reliability of products and services before reaching to customers. They focus on eliminating, controlling and/or reducing the risk in their operations. Failure Mode and Effect Analysis (FMEA) is the valuable technique to evaluate a system, design, process, or service for feasible paths in which failures can take place. FMEA was developed in the aerospace industry first. It is now broadly used automotive, medical devices, electronics and other leading industries. The main objective of FMEA can divides into 2 parts. They are long term and short term target. The long-term target is to eliminate their failure that occur, while short-term target is to minimize the failures if not eliminate them. Continual improvement intention is the main driving force for FMEA. It drives FMEA to dynamic process that intent to make a better system, process, design, products and/or services to satisfy customer or market needs. It is never-ending to eliminate, reduce failures, errors, cost, and mistake that impact to quality. It is continually revised as necessary.

### 2.3.2 Definition of FMEA

FMEA is an engineering technique used to define, identify, and eliminate known and/or potential failures, problems, errors, and so on from the system, design, process, and/or service before they reach to the customer (Omdahl : 1988).
Generally, source of data for analysis may take from 2 different ways. The first, it may receive from historical data such as quality record, non conformance product record, customer complaint, or any available data that are appropriate to define the failure. The second source may be consisting of inferent statistics data, mathematics equation modeling etc.

The FMEA is a preventive technique in system, design, process, and service, which enable to reduce the risk and prevent errors or failures before reaching the customers. It is quality tool for studying the potential cause and effect of failures, which can take place before system, design, process and service, is implemented. In each potential failure can estimate by its occurrence, severity, and detection is called " risk priority number" or " RPN". The RPN will be used for setting up the priorities of the identified failures. Finally, it provides for problem follow up and corrective actions required to preventive failure to reach customers. If the FMEA is performed well and appropriately, it enable provide the user with valuable information that can reduce or prevent the risk from their activities.

### 2.3.3 The four types of FMEA

Generally, there are four types of FMEA. It consists of system FMEA, design FMEA, process FMEA, and service FMEA. The figure below expresses with their respective focus and objective. The four types are (Stamatis 1995: 46-49)

**1. System FMEA** : It used to analyze systems and subsystems during concept and design stage to prevent the system-based failure. It focuses on potential failure modes between the functions of the system caused by system failures. It also includes the interactions between systems and elements of the systems.

The output of the system FMEA is :

- A potential list of failure modes ranked by the RPN
- A potential list of system functions that could detect potential failure modes

- A potential list of design actions to eliminate failure modes, safety issues, and reduce the occurrence

The benefits of the system FMEA are that it

- Helps select the optimum system design alternative
- Help in determining redundancy
- Help in defining the basis for system level diagnostic procedures
- Increase the likelihood that potential problems will considered
- Identifies potential system failures and their interaction with other systems or subsystems

**2. Design FMEA** : It used to analyze the part of design to prevent the design-based failure before they are released to manufacturing. A design FMEA concentrates on failure modes caused by design deficiency.

The output of the design FMEA is:

- A potential list of failure modes ranked by the RPN
- A potential list of critical and/or significant characteristic
- A potential list of design actions to eliminate failure modes, safety issues, and reduce the occurrence
- A potential list of parameters for appropriate testing, inspection ands/or detection methods.
- A potential list of recommended actions for the critical and/or significant characteristics

The benefits of the design FMEA are that it

- Establishes a priority for design improvement actions
- Documents the rationale for change
- Provides information to help through product design, verification and testing

- Helps identify the critical or significant characteristics
- Assists in evaluation of design requirements and alternatives
- Helps identify and eliminate potential safety concerns
- Helps identify product failure early in the product development phase

3. **Process FMEA** : It used to analyze the part of processes such as manufacturing, assembly to prevent the process-based failures before running in the production.

The output of the process FMEA is :

- A potential list of failure modes ranked by the RPN
- A potential list of critical and/or significant characteristic
- A potential list of recommended actions to address the critical and/or significant characteristics
- A potential list to eliminate the cause of failure modes, reduces their occurrence, and improves defect detection if CpK cannot be improved.

The benefits of the process FMEA are that it

- Identifies process deficiencies and offers a corrective action plan
- Identifies the critical and/or significant characteristics and helps in developing control plans
- Establish the priority of corrective actions
- Assists in the analysis of the manufacturing or assembly process
- Documents the rationale for changes

4. **Service FMEA** : It used to analyze the service before reaching to customers. It focuses on failures that caused by system or process deficiency.

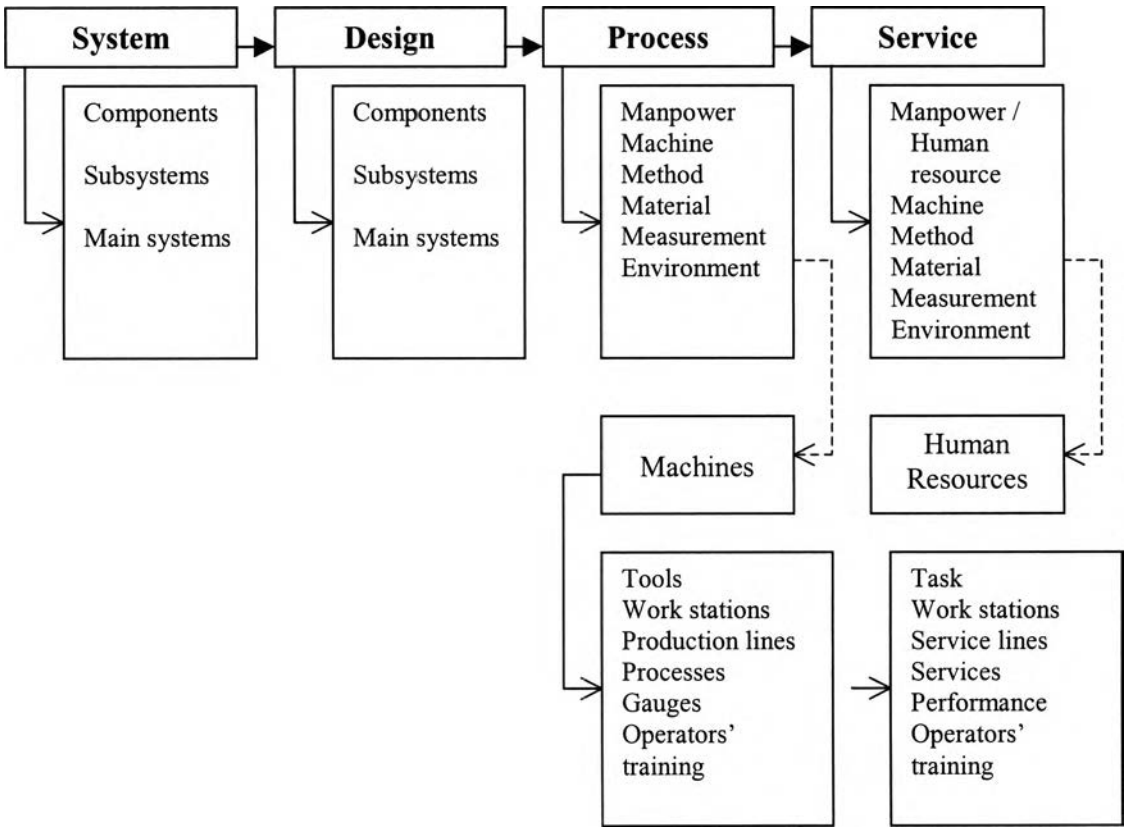
The output of the service FMEA is :

- A potential list of failure modes ranked by the RPN
- A potential list of critical and/or significant tasks, or processes
- A potential list of bottleneck processes or tasks
- A potential list to eliminate the errors
- A potential list of monitoring system/process functions

The benefits of the service FMEA are that it

- Assists in the analysis of job flow
- Assists in the analysis of the system and/or process
- Identifies task deficiencies
- Identifies critical or significant tasks and helps in the development of control plans
- Establishes a priority for improvement actions
- Documents the rationale for changes

## Type of FMEA




| | | | |
|---|---|---|---|
| **Focus :** Minimize Failure effects on the system **Objective/goal :** Maximize system quality, reliability, cost, and maintainability | **Focus :** Minimize Failure effects on the system **Objective/goal :** Maximize design quality, reliability, cost, and maintainability | **Focus :** Minimize Process failures on the total process (system) **Objective/goal :** Maximize the total process (system) quality, reliability, cost, maintainability and productivity | **Focus :** Minimize Service failures on the total organization **Objective/goal :** Maximize the customer satisfaction through quality reliability and service |

Source : D.H. Stamatis (1995) : " Failure Mode and Effect Analysis : FMEA from theory to Execution ", ASQC Quality Press, Milwaukee, Wisconsin, United State of America, Page 47

**Figure 2.1** : Type of FMEA

### 2.3.4 Key indicators for potential failure identification

There are many kinds of critical indicators that use for performing potential failure identification. Normally, it may be involve with government law and regulations, industrial standards, customer requisition, quality features of process or product that identified by customers and FMEA team etc.

### 2.3.5 Time to start the FMEA

FMEA can start whenever that you need, even though information are not complete yet. The FMEA is performed to continuous improvement to maximize the customer satisfaction.

Stamatis (1995 : 29) has identified the starting time for an FMEA program follows :

- "When new systems, designs, products, processes, or services are designed.
- When existing systems, designs, products, processes, or services are about to change regardless of reason
- When new applications are found for existing conditions of the systems, designs, products, process, or services
- When improvements are considered for the existing systems, designs products, processes, or services."

It is important to understand that, after FMEA implemented, FMEA become a living document. The FMEA should be continually conducted and the FMEA is considered finished on when the system, design, product, process, or service is considered complete, and/or discontinued.

### 2.3.6 Person who conduct the FMEA

The FMEA is a team orientation. It is rarely perfect to do the FMEA by individual because the result of FMEA may be biases. It caused by single individual perspective. So team must be set up as properly for a specific problem or project. This team can not serve as universal FMEA team. People in each team should be cross-functional and multi-disciplined. They can share their knowledge and experience in different point to identify potential failure and find out ways to prevent them from reaching to customer. If there is a limitation of time for full team discussion, it is possible to allow the leader of the FMEA team to present some of the failure in the meeting, and follow with a full discussion within the FMEA team.

### 2.3.7 The process of conducting an FMEA

The process for conducting the FMEA can conclude as following :

**1. Select the team and brainstorm**

Team approach is the heart of FMEA. Team should be four to six participant from cross-functional and multidiscipline areas such as manufacturing, quality engineering, maintenance etc. All of participates must be ensured that are suitable and willing to contribution. The team leader does not have to be the person most familiar with the process. After team is established, team members brainstorm to prioritize the chance to improvement.

**2. Define the process boundaries**

The FMEA on an entire process would be dramatically complex. Some of potential failure modes maybe overlook and misunderstand. So the process should be broken down into a series of sub processes and the FMEA conducted on each, for ease of analysis. Process flow diagram is applicable for process and

service, while functional block diagram is suitable for system and design. The objective of this stage is to contribute team understand the design, system, process, and/or service in the same direction.

**3. Brainstorming potential failure mode**

After define the process boundaries, team enable to understand the problem. The actual analysis starts. The brainstorming is the concept that uses for analysis. The brainstorming should focus on the process under study and on potential process failure modes that will affect the product. Remember that the product from this process will normally be the incoming material for the next process. The approach should be brainstorming on all potential failure modes or it could be a series of directed brainstorming on each specific area: man, machine and equipment, material, method, and measurement system.

The usage of cause and effect diagram can assist team in grouping the related failure modes.

**4. List all potential effect of each failure**

Next to each of the potential failure modes on the FMEA form, list the potential effects for each failure, describing what will result if this failure occurs. The failure could impact other components in the system, process, and leading to a domino effect. It also could obviously affect the customer, whether it be an internal customer (next process) or external customer (who pay the money). The description of the potential effects should be as specific as possible.

**5. List the potential causes of each failure**

The potential causes will also be listed next to the potential failure modes on the FMEA form. These are the potential root cause that led to failure. This information is imperative later in the FMEA process because they help directly the improvement effort.

**6. List the current control**

For each of the potential causes of failure, list the controls that are in place to prevent each cause from occurring, to detect the cause of failure, or to detect the failure mode.

**7. Estimate the frequency or probability of occurrence**

The frequency or probability of occurrence for each cause of failure is rated from 1 to 10. Table 2.2 and 2.3 shows an example ranking scale for probability and frequency. This table is only an example or guideline for general rankings. Team should develop their own ranking to suit with their failure. The ranking system that used must remain constant throughout the FMEA.

In estimating the occurrence probability, consideration must be given to those control designed to prevent the cause of effect failure from the occurring.

**8. Estimate the severity**

For each of the effect of failure, rank the seriousness of the failure, if it had occurred from 1 to 10. Table 2.4 and 2.5 shows a possible ranking scheme for severity. Again, each factory should establish their own standardized ranking scale and criteria, especially for quality problems that affect their final customers. Teams working on internal processes could establish their own ranking of the severity of quality problems on their internal customers.

**9. Estimate the detection ranking.**

The detection ranking is the probability of detecting a defect or quality problem before it is sent to the customer. Table 2.7 and 2.8 shows one ranking scheme. This again should be customized for each factory.

**10. Calculate the "risk"**

This is not a statistical risk calculation. It is a relative ranking method used to prioritize the items with the greatest risk to focus improvement efforts. The calculation for the "risk" is:

RISK = (OCCURRENCE) x (SEVERITY) x (DETECTION)

where the highest possible risk is 1000 and the lowest is 1.

**11. Determine recommended actions.**

The FMEA team should use the Pareto principle to identify those causes of failure with the highest risk. These will be the first items targeted for corrective actions, although the tear should also consider improving those causes of failure with very high occurrence rankings. Cutoff point may be set where all items with a risk grater than preset "dangers" level (such as 150 or 200) must be corrected before the process is put into operation.

To reduce the risk, the improvement effort can focus on:

- Reducing the probability or frequency of occurrence.
- Reducing the severity of failure occurring.
- Improving the detection methods.

The improvement efforts may focus on only one of these areas or the efforts may strive for some improvement in all three to reduce the overall risk. The team should establish responsible individuals and set a due data for each of the items slated for corrective measure or improvement.

**Table 2.2** : System and Design FMEA Ranking Scale for Probability and Frequency of Occurrence

| Occurrence | Rank | Criteria | CNF/1000 | Resolution |
|---|---|---|---|---|
| Almost impossible | 1 | Failure unlikely, History shows on failures. | <0.00058 | If the numerical value falls between tow numbers always select the higher number. |
| Remote | 2 | Rare number of failures likely. | 0.0068 | If the team has a disagreement in the ranking |
| Very slight | 3 | Very few failures likely. | 0.0036 | value the following may help. |
| Slight | 4 | Few failures likely. | 0.46 | 1. If the disagreement is an adjacent category, |
| Low | 5 | Occasional number of failures likely. | 2.7 | average out the difference. For example, if one member says 5 and someone else says 6, (5 and |
| Medium | 6 | Medium number of failures likely. | 12.4 | 6 are adjacent categories. Therefore 5 + 6 = 11, 11/2 = 5.5 ~ 6) |
| Moderately high | 7 | Moderately high number of failures likely. | 46 | 2. If the disagreement jumps one category, then consensus must be reached. Even with one |
| High | 8 | High number of failures likely. | 134 | person holding out, total consensus must be |
| Very high | 9 | Very high number of failures likely. | 316 | reached. No average, no majority. Everyone in that team must have ownership of the team |
| Almost certain | 10 | Failure almost certain. History of failures exists from previous or similar design. | >316 | must have ownership of the ranking. They may not agree 100 percent, but they can live with it. |

**Table 2.3** : Process and Service FMEA Ranking Scale for Probability and Frequency of Occurrence

| Rank | Criteria | Rank | Criteria | Resolution |
|---|---|---|---|---|
| 1 | Remote probability of occurrence. Capability shows at least X-bar ± 3σ within specifications (1/10000). | 1 | Failure is unlikely, CpK greater or equal to 1.67 (<1 in 10 6 or ~ ± 5σ) | If the numerical value falls between tow numbers always select the higher number. |
| 2 - 5 | Low probability of occurrence. Process in statistical control. Capability shows at least X-bar X-bar ± 3σ within specifications (1/5000 - 1/500) | 2 | Very low : Process is in statistical control, isolated failures exist. CpK is greater or equal to 1.33 (1 in 20000 or ~ ± 4σ). | If the team has a disagreement in the ranking value the following may help.<br>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 2 and someone else says 6, the ranking in this case should be 4 (2 and 6 are adjacent categories. Therefore 2 + 6 = 8, 8/2 = 4).<br>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority.<br><br>Everyone in that team must have ownership of the ranking.<br>They may not agree 100 percent, but they can live with it. |
| 6 - 7 | Moderate probability of occurrence. Process in statistical control with occasional failures, but not in major proportions. Capability shows more than X-bar ± 2.5σ within specifications (1/20 – 1/200). | 3 | Low : Process is in statistical control. Isolated failures occur sometimes. CpK is greater or equal to 1.00 (1 in 4000 or ~ ± 3.5σ) | |
| 8 - 9 | High probability of occurrence. Process in statistical control with failures often occurring. Capability shows X-bar ± 1.5σ (1/100 – 1/20). | 4 – 6 | Moderate : Process in statistical control with occasional failures but not in major proportions. CpK is less or equal to 1.00 (1 in 1000 to 1 in 80 or ~ ± 3σ). | |
| 10 | Very high probability of occurrence. Failure is almost certain. (1/10+). | 7 - 8 | High : Process not is statistical control. Have failures often (1/40 to 1/20). | |
| | | 9 - 10 | Very high : Failures are inevitable. | |

Note : to use a criteria scale such as this, one must have a substantial amount of data to support statistical control and CpK values. This is a very powerful scale if one has the data; if not, do not try to generate the data to support the scale. Use a theoretical scale, which is more qualitative but through the synergy of the team becomes just as powerful.

**Table 2.4** : System and Design FMEA Ranking Scale for Severity

| Effect | Rank | Criteria | Resolution |
|---|---|---|---|
| None | 1 | No effect | If the numerical value falls between two numbers always select the higher number.<br>If the team has a disagreement in the ranking value the following may help.<br>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, (5 and 6 are adjacent categories. Therefor 5 + 6 = 11, 11/2 = 5.5 ~ 6)<br>3. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority.<br>Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it. |
| Very slight | 2 | Customer not annoyed. Very slight effect on product or system performance. | |
| Slight | 3 | Customer slightly annoyed. Slight effect on product or system performance. | |
| Minor | 4 | Customer experiences minor nuisance. Minor effect on product or system performance. | |
| Moderate | 5 | Customer experiences some dissatisfaction. Moderate effect on product or system performance. | |
| Significant | 6 | Customer experiences discomfort. Product performance degraded, but operable and safe. Partial failure, but operable. | |
| Major | 7 | Customer dissatisfied. Product performance severely affected but functional and safe. System impaired. | |
| Extreme | 8 | Customer very dissatisfied. Product inoperable but safe. System inoperable. | |
| Serious | 9 | Potential hazardous effect. Able to stop product without mishap-time dependent failure. Compliance with government regulation is in jeopardy. | |
| Hazardous | 10 | Hazardous effect. Safety related-sudden failure. Noncompliance with government regulation. | |

**Table 2.5** : Process and Service FMEA Ranking Scale for Severity

| Rank | Criteria | Rank | Criteria | Resolution |
|---|---|---|---|---|
| 1 | Minor : Unreasonable to expect that the minor nature of this failure would cause any real effect on the product and / or service. Customer will probably not even notice the failure. | 1 | Minor : Unreasonable to expect that the minor nature of this failure would cause any noticeable effect on the product and / or service. Customer most likely will not be able to detect the failure. | If the numerical value falls between two numbers always select the higher number. If the team has a disagreement in the ranking value the following may help. |
| 2 - 3 | Low : Low severity ranking due to nature of failure causing only a slight customer annoyance. Customer probably will notice a slight deterioration of the product and / or service, a slight inconvenience in the next process, or minor rework action. | 2 – 3 | Low : Low severity ranking due to a slight annoyance of the failure. Customer probably will notice a very minor deterioration of the product and / or service. | 1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 2 and someone else says 6, the ranking in this case should be 4 (2 and 6 are adjacent categories. Therefore 2 + 6 = 8, 8/2 = 4). |
| 4 - 6 | Moderate : Moderate ranking because failure causes some customer dissatisfaction. Customer is made uncomfortable or is annoyed by the failure (e.g., engine misfire, compressor rumble, sunroof leak). May cause the use of unscheduled reworks / repairs and / or damage to equipment. | 4 – 6 | Moderate : Moderate failure causes customer dissatisfaction. Customer is made uncomfortable and / or is annoyed by the failure (e.g., engine misfire, compressor tumble, sunroof leak). Some degradation of performance is noticeable. | 2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it. |
| 7 - 8 | High : High degree of customer dissatisfaction due to the nature of the failure such as an inoperable product or inoperative convenience. Does not involve safety issues or government regulations. May cause serious disruption to subsequent processes and / or services. | 7 – 8 | High : High degree of customer dissatisfaction due to the failure. No safety or government regulations issues. | |
| 9 - 10 | Very High : Very high severity is when the failure mode affects safety and involves noncompliance with government regulations. | 9 - 10 | Very High : Very high severity ranking when safety issues are involved or compliance to government regulations is ignored. | |

**Table 2.6** : System and Design FMEA Ranking Scale for Detection

| Detection | Rank | Type | Criteria | Resolution |
|---|---|---|---|---|
| Almost certain | 1 | System FMEA | Proven detection methods available in concept stage. | If the numerical value falls between two numbers always select the higher number. If the team has a disagreement in the ranking value the following may help. 1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, (5 and 6 are adjacent categories. Therefore 5 + 6 = 11, 11/2 = 5.5 ~ 6). 2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it. |
| | | Design FMEA | Has the highest effectiveness in each applicable category. | |
| Very high | 2 | System FMEA | Proven computer analysis available in early design stage. | |
| | | Design FMEA | Has very high effectiveness. | |
| High | 3 | System FMEA | Simulation and / or modeling in early stage. | |
| | | Design FMEA | Has high effectiveness. | |
| Moderately high | 4 | System FMEA | Tests on early prototype system elements. | |
| | | Design FMEA | Has moderately high effectiveness. | |
| Medium | 5 | System FMEA | Tests on preproduction system components. | |
| | | Design FMEA | Has medium effectiveness. | |
| Low | 6 | System FMEA | Tests on similar system components. | |
| | | Design FMEA | Has low effectiveness. | |
| Slight | 7 | System FMEA | Tests on product with prototypes with system components installed. | |
| | | Design FMEA | Has very low effectiveness. | |
| Very slight | 8 | System FMEA | Proving durability tests on products with system component installed. | |
| | | Design FMEA | Has lowest effectiveness in each applicable category. | |
| Remote | 9 | System FMEA | Only unproved or unreliable technique(s) available. | |
| | | Design FMEA | Is unproved, or unreliable, or effectiveness is unknown. | |
| Almost impossible | 10 | System FMEA | No known techniques available. | |
| | | Design FMEA | No design technique available or known, and / or none is planned. | |

**Table 2.7** : Process and Service FMEA Ranking Scale for Detection

| Rank | Criteria | Rank | Criteria | Resolution |
|---|---|---|---|---|
| 1 | Very high : Controls almost certainly will detect the existence of a defect. | 1 | Remote likelihood that the product or service will be delivered (1/10000). The defect is functionally obvious and readily detected. Detection reliability at least 99.99%. | If the numerical value falls between two numbers always select the higher number. If the team has a disagreement in the ranking value the following may help. 1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 2 and someone else says 6, the ranking in this case should be 4 (2 and 6 are adjacent categories. Therefore 2 + 6 = 8, 8/2 = 4). 2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it. |
| 2 – 5 | High : Controls have a good chance of detecting the existence of a failure. | 2 – 5 | Low likelihood that the product would be delivered with the defect. The defect is obvious (1/5000 – 1/500). | |
| 6 – 8 | Moderate : Controls may detect the existence of a defect. | 6 – 8 | Moderate likelihood that the product will be delivered with the defect. The defect is easily identified (1/200 – 1/50). Detection reliability at least 98.00%. | |
| 9 | Low : Controls more likely will not detect the existence of a defect. | 9 | High likelihood that the product would be delivered with the defect. The defect is subtle (1/20). Detection reliability greater than 90%. | |
| 10 | Very low : Controls very likely will not detect the existence of a defect. | 10 | Very high likelihood that the product and / or service will be delivered with the defect. Item is usually not checked or not checkable. Quite often the defect is latent and would not appear during the process or service (1/10+). Detection reliability 90% or less. | |

**Table 2.8 :** The example of evaluation criteria for the Process FMEA in automotive industry that use for quality system requirement QS 9000

**Severity (s) Evaluation Criteria**

| Effect | Criteria | Score |
|---|---|---|
| Hazardous Effect | Hazardous Effect. Safety-related—sudden failure. Non compliance with government regulation. | 10 |
| Serious Effect | Potential hazardous effect. Able to stop product without mishap; safety-related ; time dependent failure. Disruption to subsequent process operations. Compliance with government regulation is in jeopardy. | 9 |
| Extreme Effect | Customer very dissatisfied. Extreme effect on process; equipment damaged. Product inoperable but safe. System inoperable. | 8 |
| Major Effect | Customer dissatisfied. Extreme effect on process; rework/repair on part necessary. Product/process performance severely affected but functionable and safe. Subsystem inoperable. | 7 |
| Significant Effect | Customer experience discomfort. Product/process performance degraded, but operable and safe. Non vital part inoperable. | 6 |
| Moderate Effect | Customer experiences some dissatisfaction. Moderate effect on product/process performance. Fault on nonvital part requires repair. | 5 |
| Minor Effect | Customer experiences minor nuisance. Minor effect on product/process performance. Fault does not require repair. Nonvital fault always noticed. | 4 |
| Slight Effect | Customer slightly annoyed. Slight effect on product or process performance. Nonvital fault noticed most of the time. | 3 |
| Very slightly effect | Customer more likely will not notice the failure. Very slightly effect on product/process performance. Nonvital fault noticed sometimes. | 2 |
| No Effect | No effect on product or subsequent processes. | 1 |

## Occurrence (O) Evaluation Criteria

| Effect | Criteria | Score |
|---|---|---|
| Almost certain | Failure almost certain. History of failures exists from previous or similar design | 10 |
| Very high | Very high number of failure likely | 9 |
| High | High number of failure likely. | 8 |
| Moderately high | Frequent high number of failure likely. | 7 |
| Medium | Moderate number of failure likely. | 6 |
| Low | Occasional number of failure likely. | 5 |
| Slight | Few failures likely. | 4 |
| Very slight | Very few failures likely | 3 |
| Remote | Rare number of failures likely. | 2 |
| Almost never | Failure unlikely. History shows no failures. | 1 |

## Detection (D) Evaluation Criteria

| Effect | Criteria | Score |
|---|---|---|
| Almost impossible | No known controls available to detect the failure. | 10 |
| Remote | Remote likelihood current controls will detect the failure. | 9 |
| Very slight | Very slight likelihood current controls will detect the failure. | 8 |
| Slight | Slight likelihood current controls will detect the failure. | 7 |
| Low | Low likelihood current controls will detect the failure. | 6 |
| Medium | Medium likelihood current controls will detect the failure. | 5 |
| Moderately high | Moderately high likelihood current controls will detect the failure. | 4 |
| High | Good likelihood current controls will detect the failure. | 3 |
| Very high | Very high likelihood current controls will detect the failure. | 2 |
| Almost Certain | Current controls almost always will detect the failure. Reliable detection controls are known and used in similar processes. | 1 |

**Source :** Chrysler Corporation, Ford Motor Company, and General Motor Corporation (1995) : " Potential Failure Mode and Effect Analysis (FMEA) Reference Manual " , 2nd Edition, United State of America.

**12. Follow-up on actions.**

The team should review the actions taken and then revise the occurrence, severity, and detection rankings. The new risk number can be calculated from the new rankings to determine if the actions were effective in reducing the risk to an acceptable level. When all the ratings are below the danger level, the team may elect to disband. Of course, they may also elect to continue the improvement process by working down their Pareto of risks that are unsatisfactory. It is recommended that each FMEA team reviews their progress with management before they disband.

After the FMEA procedures have been developed, it becomes a living document and is never really complete. It is a truly dynamic tool for improvement because regardless of the beginning phase, it will use information to improve the system, design, product, process, or service. It is continually updated as often as necessary. The longer step-by-step FMEA is shown in Appendix 2. Figure 2.2 below depicts the evolution of design of FMEA.

### 2.3.8 The process after FMEA completion

When FMEA is performed completely, there are seven stages that team must follow. The details show as below (Stamatis, 1995:45-46) :

1. Review the FMEA :

The objective is to ensure that all of problems that defined by team have been addressed and the properly actions are recommended and/or implemented.

2. Highlight the high-risk areas :

Generally, the high-risk area can inspect from RPN value in FMEA form. It was found that if RPN is higher or equal to 100, they are considered as the high risk.

3. Identify the critical, significant, and major characteristic :

After checking the RPN value and critical column in FMEA form, It should identify the critical, significant, and major characteristic in these failures. It is important to review that action should be needed or not.

4. Ensure that a control plan exists and is being followed :

After critical, significant, and major characteristic failures have been defined, the control plan in forms of document must be generated. It is used to ensure that products/services will be made under acceptable of customers.

5. Conduct capability studies :

When the statistic control is generated, the potential capability must be performed.

6. Work on processes which have a Cpk less than or equal to 1.33 :

To continual improve the process by eliminate variation to achieve minimum goal at Cpk =1.33.

7. Work on processes which have Cpk greater than or equal to 1.33 :

The FMEA concept is continual improvement. So team must to try to go beyond standard for further improvement to reduce variation of process.

POTENTIAL

FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA)

FMEA Doc Number_____

Page_____ of_____

Process_____ Process Responsibility_____ Prepared By_____

DCS System_____ Key Date_____ FMEA Date (Orig.)_____

Core Team_____ FMEA Date (Rev.)_____

| Process Function and Requirements | Potential Failure Mode | Potential Effect (s) of Failure | S e v | Potential caues (s) / Mechanism(s) of Failure | O c c u r | Current Process Controls | D e t e c | R. P. N. | Recommended Action(s) | Responsibility & Target Completion Date | Action Results | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | Action Results | S e v | O c c u r | D e t e c | R. P. N. |
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**Table 2.9** : Failure Mode and Effect Analysis form

The form of FMEA is not standardized. It depends on FMEA team that select form to suit with each task. Generally, the form mainly consists of :

1. Function

It is the proposal of system, design, process, and/or service under consideration. It is very important in understanding the totally FMEA process. It must be concise and clear.

2. Potential Failures Mode

Explain each possible failure mode that could take place. A failure mode may have more than one level. It depends on complexity of defined function.

3. Potential Effect of Failure

The outcome of the failure on the system, design, process, or service. Generally, team has to handle with questions of : What happen when failures take place? What is the outcome of that failure? It may be isolate affect or impact to other functions and/or components.

4. Severity of Effect

It is the numerical estimate of seriousness of the effect of potential failure mode. The severity frequently applies to the effect of a failure mode.

5. Potential Causes of Failure

It is the list of potential assigned to each failure mode. It may be said that it is the most important part of FMEA. If the root causes can define, it leads to be successful in eliminating failure.

6. Occurrence

It is the numerical estimate of frequencies of specific cause occurring, resulting in the failure mode observed.

7. Current Process controls

It is list of all current controls that are intended to prevent the cause of failure occurring, or detect the causes of failure or detect the outcome of failure mode in the design, process, or service.

8. Detection

It is the numerical estimate of the probability of detecting a failure mode arising from a specific cause such that the effect of failure is prevented.

9. Risk Priority Number (RPN)

It is outcome of severity, occurrence, and detection. It uses for defining the priority of the failure. The higher score should have priority for corrective action.

RPN = Severity*Occurrence*Detection

10. Recommended Actions
It may be specific actions or it may be further studying. The idea of recommended action is to reduce the severity, occurrence, detection, or all of them. Typical recommendations may be:

- No actions
- Some action may occur
- Definite actions will take place
- Definite actions will take place and extensive changes are required in the system, design, process, and/or service.

11. Responsibility and Target Completion Date
This part is designed for the responsible person/area and target completion date for the recommendation action.

12. Action Results
It uses for follow up the recommendation action to ensure that the recommendation to determine if it has been address properly, and/or if it is in need of updating.

### 2.3.9 Component of FMEA

The main important idea of the FMEA is to identify potential failures and find ways to prevent them from reaching customers. The concept of FMEA is that all of problems are not the same, and it also different in priority. So priority of each problem must be set first to make it easy to solve the most serious first.

There are three components helping us define the priority of failures and they are as below :

Occurrence (O) : the frequency of the failure
Severity (S) : the seriousness (effects) of the failure
Detection (D) : the ability to detect the failure before it reaches the customer

We can use numerical scales (called risk criteria guidelines) to represent the value of these above components. The guideline can be either "qualitative" or "quantitative".

If the guideline is qualitative, it must follow theoretical (expected) behavior of the component. The expected behavior for each component is as following.

- Occurrence : the expected behavior is normality.
- Severity : the expected behavior is lognormal.
- Detection : the expected behavior is that of a discrete distribution.

If the guideline is quantitative, it must be specific and it must follow real data, statistical process control data, and historical data. The table below illustrates some of the guidelines for the selection guideline ( Stamatis : 1995).

**Table 2.10** : Criteria for Selecting Ratings

| **If** | **Then use** | **Select** |
|---|---|---|
| The design is similar to others or historical data exist. | Statistical data from either historical or surrogate systems : Reliability data, actual distribution, mathematical modeling, and simulation. | Actual data and/or CpK. |
| Failure history is available with the design itself or similar, or surrogate parts. | Historical data based on reliability, design, actual distributions, mathematical modeling, simulation, cumulative data, and/or fraction defectives. | Actual data and/or cumulative number of failures. |
| The design is new and/or no quantification for any data is available. | Team Judgement. | Subjective criteria. Use team consensus and be conservative. |
| **If** | **Then use** | **Select** |
| The process is under statistical process control (SPC). | Statistical data; reliability data, process capability, actual distribution, mathematical modeling, simulation. | Actual data and/or CpK. |
| The process is similar to others or historical data exist. | Statistical data from either historical or surrogates systems: Reliability data, process capability, actual distribution, mathematical modeling, and simulation. | Actual data and/or CpK. |
| Failure history is available with the process itself or similar, or surrogate parts. | Historical data based on reliability, process, actual distributions, mathematical modeling, simulation, cumulative data, and/or fraction defectives. | Actual data and/or cumulative number of failures. |
| The process is new and/or no quantification for any data is available. | Team Judgement. | Subjective criteria. Use team consensus and be conservative. |

**Source** : D.H. Stamatis (1995) : " Failure Mode and Effect Analysis : FMEA from theory to Execution ", ASQC Quality Press, Milwaukee, Wisconsin, United State of America, Page 37-38

There is no standard of the ranking for the criteria of the "occurrence", "severity", and "detection". However the most widely used is the ranking based on 1 to 10 scale. This is because it provides ease of interpretation, accuracy, and precision in the quantification of the ranking.

The result of the "occurrence", "severity", and "detection" is called RPN (risk priority number). The purpose of this number is used for the ranking order of the identified failure modes. It is important to understand that not all the failure modes are solved. It depends on the "threshold of examining the failures". We have to check how critical of the system, design, product, process, and/or service is and set the percent of all failure must be addressed whereas the non-critical one may require 90 percent.

For example, we require that 90 percent of all failures must be prevented or solved for a system on a guideline scale of 1 to 10. The maximum number possible for the RPN is 10*10*10 (from occurrence, severity, and detection) or 1000 and 90 percent of 1000 is 900. Subtract 1000 – 900 = 100. Therefore the threshold of examining failures is an RPN equal to or greater than 100 based on a 90 percent confidence and a 1 to 10 guideline scale. In other words, if the potential failure mode has to RPN greater than or equal to 100, that failure mode must be addressed.

The team should classify all of risks before starting the evaluation process. They can be defined as minor, moderate, high, and critical risks. The level of actions taken is also different based on different risks. The example of action taken is shown below (Stamatis, 1995 : 39).

- Under minor risk : no action is taken.
- Under moderate risk : some action may take place.
- Under high risk, definite action will take place. (Selective validation and evaluation may be required).
- Under critical risk, definite actions will take place and extensive changes are required in the system, design, process, and/or service.

In case of the RPN show the same level, the problem that show high severity will be considered first, and following by detection. Because severity impact to failure directly.

After priority is set, the action of each problem will be addressed. The responsible person and due date are also implemented. Finally, actions result will be revised and indicate in terms of RPN. It is expected that RPN after action must be less than before actions. It depends on team that is it acceptable? If the RPN is still higher than 100, that means the action is not successful. So new solution will be addressed.

## 2.4 Literature surveys

**Charles Rooney (1990) :**
The author presents the way to become a world class paints maker. The concept covers as following :

1. World-class paint makers give their customer superb quality and service.
2. Quality and service will enable world class coating manufacturers to maintain price despite competition.
3. The world class paint makers will be low cost producers.
4. Inventory control is an essential aspect of modern manufacturing. The World-class paint makers will release capital by minimizing inventory.

**Chrysler Corporation, Ford Motor Company, General Motor Corporation (1995)**
This manual explains about potential Failure Mode and Effect Analysis (FMEA) and give general guidance in the application technique in automotive for quality planning and control plan.

**Dale H. Besterfield (1994) :**
The author proposes that each of failure has a root cause, and they are preventable. The prevention is cheaper than correction. He also recommends the quality improvement strategy as following :

- Reduce failure cost by problem solving

- Invest in the right prevention activities
- Reduce appraisal costs where appropriate and in a statically sound manner
- Continuously evaluate and redirect the prevention effort to gain further quality improvement

**D.H Stamatis (1995) :**
The author presented about the definition, concept and implementation of FMEA. He explains the process of conducting the system FMEA, design FMEA, process FMEA, and service FMEA. He also gives the rationale for doing as well as gives many of FMEA samples such as semiconductor industry, electromechanical industry etc.

**ISO/DC 8402-1 :**
Explain the quality assurance as " the prevention of quality problems through planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirement for quality.

**J.M. Juran and Frank M. Gryna (1988) and (1993) :**
The author explains the using FMEA and FMECA for a traveling lawn sprinkler and the analysis revealed that about 30 % of the expected failure were in the worm-and-bearing stem area and redesign that could be justified.

**John Wiley & Sons, Gary Born, (1994) :**
The author provides the example of error types of Failure Mode error. They also explain the case study of procedure for purchasing process.

**Kelvin Dushnisky and Steven G. Vick (1996) :**
The author presents the using Failure Mode and Effect Analysis (FMEA) in perform risk evaluation in environment. It is adept to natural systems by recognizing environment risk to incorporate both uncertainly about damaging

occurrences and their effect on key environmental attributes. It also helps to prioritize and reduce environmental risk from mining and similar complex projects having many features with the potential for a wide range of environmental effects.

**Michael R. Beauregard, Raymond J. Mikulak and Barbara A. Olson (1992) :**

This paper provided the general guideline and procedure for conducting an FMEA and the major process improvement techniques used for process start-up. These technique consist of brainstorming, failure mode and effect analysis (FMEA), and design of experimental (DOE)

**Shigeru Mizuno and Yoji Akao (1994) :**

The author described the improvement by FMEA for quality deployment system especially in the design and development phase. The FMEA is effective tools for failure prevention. It still uses for quality control in process chart.

**Sigmund Halpern (1979) :**

The author present the using FMEA as tool for solving the failures in integrated circuits in simple lead boning problem that should be detected by an alert QC inspector. Such analysis may include optical, metallurgical, chemical, electrical or X-ray analysis and may involve dissection of the failed items.

## 2.5 Other Relevant Researches

**Ben Sutarom (1995) :**

This thesis develops quality problem solving methods in metal parts production process for the house appliance industry. The author has used the cause and effect diagram to identify the root cause of each problem. Moreover, he also set up the system for quality assurance. Consequently, the percentage of defect is reduced around 81%.

**Chalermphon Lelapatikul (1997) :**
This research determines and controls the quality factors for tyre industry by using the failure mode and effect analysis (FMEA). The author has also used the quality tools such as the cause and effect diagram, relation diagram and tree diagram for his case study. This study lead to 50-90% reduction of the risk priority numbers (RPN) that compare with the prior to implement the FMEA.

**Saroach Buabucha (1998) :**
This research uses FMEA to study and analyze factors that affect to compound mixing quality and develop the appropriate process quality assurance as well as find out the way to reduce and prevent nonconforming compound in the tyre manufacturing industry.

**Sayom Suriyamongkol (1999) :**
This thesis use FMEA and the fault tree analysis (FTA) as quality tools for analyzing the potential failure modes and their effects in the DCS Project execution in a systematic way. The results of analysis using the FMEA technique have leaded to the establishment of quality assurance system for DCS project execution which include checklists, standard document and procedures, as well as the engineering database pool software.

**Somnuk Liabma (1997) :**
This thesis creates the quality assurance for the supplied parts in hard-disk drive manufacturing. The author has applied the statistical process control and Gage R&R study (Repeatability and Reproducibility) to control and review supplier process variation identified the potential product that related process failure modes by using the process FMEA. When FMEA is implemented, The corrective actions can reduce the major defect more than 50%.

**Tanasak Turian (2000) :**
This research uses FMEA as quality tool to study and analyze the potential failure mode and their effects in the rubber part industry. The results of analysis using the FMEA technique have leaded to the establishment of quality assurance system.

**Theerawadee Plienmolee (1997) :**
This thesis presented an application of FMEA to an integrated-circuit assembly factory. As most product failure in this type of assembly occur due to design and process problem, the factory's current procedures in design and process FMEAs are analyzed for improvements. Implementation of the improved design and process FMEA procedures resulted in increased process yield and reduce defect rates.