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# FMEA

## Failure Mode Effects Analysis

# Failure Mode and Effects Analysis (FMEA)

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# Part 1 - Introduction - What Is FMEA?

Definition

Failure Mode and Effects Analysis (FMEA) is a system that is used to analyze a product, service, or design to identify any failures than may arise, and then taking steps to neutralize or at least curtail the exposures from those failures. FMEA can be considered as a process to determine why a failure occurs, or to even reverse-engineer a process or activity to pinpoint the different possibilities on how a design might fail. The FMEA process' principal output is a statement or statements that determine how a failure can be avoided through design or procedure improvement.

In breaking down the term FMEA, "Failure modes" relates to the modes, or ways, in which a process, system, or transaction might fail. Failures are any defects or errors that eventually affect an end user or customer. Failures can be both actual or potential. "Effects analysis" is the process of reviewing the consequences of a given failure or failures.

In this e-book, the subject will be failure and failure analysis in a service industry business setting.

Failure vs. Failure Mode

Essential to the FMEA process is the definition of what "failure" is. Failure is defined by The Merriam-Webster dictionary as:

"An omission of performance; a failing to perform an expected action or duty; the state of inability to perform a normal function."

Failure in a business setting is covered by this blanket dictionary meaning, but is expanded in many FMEA settings. In FMEA and business and general, failure is the loss or non-performance of a function under given conditions and situations. A failure can be a single event, while a FAILURE MODE is a wider description of a breakdown or error in the the FMEA process. Failure mode can also refer to the way that a failure happens and usually describes how it might have occurred. A failure mode will include the failure itself (A missed call or food returned by the customer in a restaurant) along with and how and why the failure occurred.

FMEA and the analysis of failures has been an integral part of United States industry for a long time and is known to have been instrumental in the revolutionizing of quality, standards, safety, and end-user and customer satisfaction.

History

FMEA isn't an entirely new concept. It was first developed in the United States back in the 1940's, during the Second World War. Like many developments in formal business practices, FMEA was developed in the demanding crucible of military operations. For example, if a helicopter falls from the sky because two wires to one of the major rotors is severed, FMEA's purpose is to disclose that the failure (crash) could have been avoided by the addition of another wire or two.

Before the development of FMEA, pioneers, so-called process experts, and inventors would attempt to predict what could go wrong with a process or underlying design even during the development or trial stage. Time-consuming and expensive trial and error would be conducted instead of a formalized review of how and why a failure occurred. Every repetition of an invention or process would be subject to some form of documentation but did not involve a fixed process so that ensuing failures could be subject to documented uniform and rigid form of analysis. Collective knowledge and discussion were then considered as sufficient to move forward from a failure.

To achieve a more coherent and logical approach, the U.S. military developed FMEA. It is referred to in military process manuals as "MIL-STD-1629" and provides the U.S. Department of Defense with a codified set of procedures for performing a failure mode, effects and criticality analysis. In military parlance, FMEA is also often referred to as Failure Mode and Effects Analysis and Criticality, or FMEAC analysis.

FMEA has also been heavily implemented at the National Aeronautics and Space Administration, or NASA. where failure prevention is given the utmost attention and criticality because even the smallest failure can cost billions of dollars in material loss and even worse, human life. Mission failures such as the Apollo and Challenger program disasters are exponentially more expensive than helicopters crashing, and NASA considers some form of failure analysis as a critical element of their operations.

In the corporate world, FMEA has been used in practically every type of manufacturing and service industry company. While it is very important in determining why and how things fail, it can also be used by companies to consider avoiding risky projects in the first place.

## Risk Management

FMEA can be an invaluable tool in risk management, although it should not be considered as a replacement of the overall risk management process. In an Enterprise Risk Management (ERM) program where risks are prevented, detected, and corrected, there are four ways where potential trouble can be addressed:

1. Avoid or eliminate risk;
2. Transfer risk;
3. Assume risk; and
4. Prevent or mitigate risk.

FMEA processes are used mainly as a tool in the avoidance and elimination of risk, but its results are also important when it comes to the prevention and mitigation of risk because failures are identified, isolated, and analyzed to help ensure their recurrence.

## Design FMEA vs. Process FMEA

Typical FMEA is carried out to evaluate failures that happen in existing businesses and can be termed Process Failure Mode and Effects Analysis (PFMEA). However, some companies may implement FMEA while they are in the process of starting or designing a system or project. FMEA is also used by other companies even BEFORE they officially open their business. This is called Design Failure Mode and Effects Analysis (DFMEA).

The approach used for both are essentially the same except for the fact that the "failures" considered in DFMEA are all hypothetical given that the business or system is not yet operational.

# Part 2 - Quick Overview and Example of the FMEA Process

FMEA starts with the identification of "failure modes," or the ways in which a process, service, or product could fail. This "list" is developed from company and industry experience and expertise. In practice, every element of business or process is evaluated from as early as determining what the product or service is through the delivery of the product or service to the customer. Failures will be ranked based on the repercussions of their occurrence, frequency, and detectability. The most important part, aside from addressing the failures, is to start to reduce, and eliminate failures after prioritizing them.

When FMEA is conducted

A business enterprise does not have to wait until a failure or disaster occurs. In practice, FMEA has been used during the following phases of a business, including specific projects:

1. Before developing control plans for a new or modified process;
2. Periodically during the existence of the process, product or service;
3. During the redesign or re-design of a product, service, or process;
4. The application of an existing product, service, or process in a new way;
5. When analyzing failures of an existing process, product or service;
6. When existing product, service, or process is being planned for enhancement and/or improvement.

Along every step of the way in any of the above situations, the FMEA analysis team asks, "what could go wrong here?"

Simple Example of the FMEA Process

A very common example is the analysis of failure modes in a service industry scenario is in determining what could wrong in serving a fresh cup of hot coffee at a gasoline station service stop.

In the gasoline stop, one of the most important primary inputs is to have a clean coffee pot. The result in this type of business is to make sure that a customer receives a hot cup of coffee. FMEA analysis assesses how failures in this service delivery can happen.

The primary input for this service is a "clean coffee pot." What failure mode can arise from this service?

- *First, the dishwater water's temperature may not be high enough, so the empty pot has not been thoroughly cleaned.*
- *Second, the coffeemaker or brewing machine needs to be filled with water. So what failure can arise from this the process? The water may not be hot enough or the kitchen person puts in either too little water or overfills the pot.*
- *Third, during the delivery process to the customer, the coffee may get a little cold before they receive it. In this situation, the customer may reject the coffee altogether and the company suffers a loss.*

Failure Classification

This illustration highlights what is true with an overwhelming number of failures: Some failure modes are worse than others. In this coffee case, providing a customer coffee at the wrong temperature is a failure; however, getting coffee that is colder would a "worse" failure than getting coffee that is a little less warm than expected. This is key to understanding FMEA results, which identifies three main attributes of failure:

1. Severity – How bad is the failure? In one of the Space Shuttle explosions, a misapplied or installed tile caused the entire shuttle to explode, killing all its astronauts. A lesser failure with a much more expensive part could have caused other problems, but may not have killed the astronauts or destroyed the shuttle.

2. Frequency – How often does the failure occur? Many occurrences of the same type of failure may identify a design flaw in the process.

3. Detectability – This is a key characteristic in failure identification, because undetected failures do not only mean that a company can rectify the failure but also means that the failure can lead to other subsequent, and maybe more damaging failures. Failures that are hard to detect are more likely to affect or reach a customer.

Failure Scoring

After identifying or classifying a failure, the FMEA team will assign a "score" to each failure following a standard formula, and taking all the failure characteristics into consideration. Often, a numerical score would be assigned to each failure. For example, assigning it a score from 1 to 10 as follows:

1. Severity – The higher the score, the more severe the impact of the failure. Most often this is expressed in dollar terms, with the most "expensive" failure being assigned a 10.

2. Frequency – The more times a failure is liable to occur, the higher the score assigned to it. Even if a failure is unlikely to happen, a business would still like to make sure that every possible failure is avoided.

3. Detectability – This is perhaps the most difficult and sometimes, subjective element which also requires the most amount of research and observation. The less detectable the failure is, the higher the score.

Upon an assessment of each failure, a Failure Assessment Number or FAN can be assigned with the following formula:

FAN = *(Severity) x (Frequency) x (Detectability)*

When the FAN is collected for each type of failure, these are ranked according to the highest score. These are the failures that happen more frequently, have more adverse impacts, and are not likely to be detected. These types of failures should be the focus of improvement or corrective processes. For each failure in the process, the company should also determine the effect of each failure customer satisfaction.

But some subjectivity is allowed in the scoring process, of course. For example, even if a failure scores less in total when compared to other failures but has a higher severity, they will still get first priority over other failures. In the service industry, if the severity measurement means that the company might affect its customer base, then whatever that failure is needs to be classified as a top priority item.

In many formal FMEA processes, the FAN is also widely known as the Risk Priority Number, or RPN.

Regardless of the FAN/RPN score, the business should always study the failure to find potential causes, search for alternatives to find and identify the problem, come up with a list of recommended solutions, and assign responsibilities for both process monitoring and wherever warranted, perform corrective action.

Going back to the service station coffee, let us look at how failure identification, scoring, and assessment is accomplished:

- PROCESS – Fill the coffee pot with water.
- Possible failure: Too much or too little water is poured in.
- Failure effect: The coffee will be either too weak (too much water) or too strong, and customer may become very irate or disappointed.

Severity score: 7

- Possible cause of failure: The water level marks on the coffee pot are faded or erased, making it difficult to determine the water level.

Frequency score: 5

- Typical method to control failure: Ocular inspection of the faded marks.

Detectability: 4

FAN = 7 x 5 x 4 = 140

- Recommended action: Consider replacing the coffee pot

Responsible party: Mike (Purchaser)

Discovering and assessing failures is an extremely important task for any business, but there are other important benefits for FMEA.

In Part 5, a more detailed description of each step is given which can be applied to any service industry situation.

# Part 3 - Benefits of Conducting FMEA

There are numerous benefits when it comes to maintaining a FMEA process in a business. The top 5 benefits are discussed in depth below, followed by a short description of other important advantages.

1. **FMEA enables early identification of single failure points and system interface problems that can hinder success and impact productivity.**

FMEA is all about identifying failure modes in specific processes. “Identification” not only means identifying and recording failure incidents, but it also means being able to relate the failure to other interrelated and cross-functional areas. In a service industry like a restaurant for example, a failure in serving of food in uneven portions could mean that the problem comes from a failure in buying produce and ingredients. The buying process failure in turn could be a result of failures in hiring and training.

2. **Enhances teamwork, understanding and cross-functional working relationships**

Because failure in one process affects the enterprise, it is in the interest of everyone in the organization to participate in FMEA together with the associated corrective actions as the failures are addressed. In the military and in the many businesses that have utilized FMEA, a corroborative group effort has been the norm as inter-disciplinary cooperation has been considered essential to success in evaluating failures. The review process is enhanced when different perspectives are presented in evaluating a breakdown.

3. **Improves product/process quality, reliability and safety**

The FMEA process inevitably assures that a company’s products and processes are improved and enhanced over time. Just as subjecting precious metals through several instances of intense heat and cleansing, FMEA helps to remove “impurities” in a business over time. The cross-functional and inter-disciplinary nature of a formal FMEA process helps leverage the improvements because FMEA users involve other departments, disciplines and expertise.

4. **Improved company competitiveness and image**

FMEA contributes towards the reduction of the impact of, and the elimination of failure and helps the company improve its revenues and profits, while helping decrease costs an avoid losses. By identifying and addressing failures, the company can work towards improving its products and burnishing its brand as it comes across as a flawless and quality-oriented organization. Image is important especially in the age of the internet and social media, as errors and faulty execution are reputation killers that can be quickly and widely disseminated.

5. **Customer satisfaction**

The end-all and be-all of businesses is making sure that the customers are happy and will come back to purchase products and services again. Repeated customer patronage means greater revenues, decreased expenses, and minimized loss because FMEA helps ensure that failures associated with customer dissatisfaction are limited and eliminated.

Other benefits:

1. **Promotes and Encourages Documentation**

FMEA demands that all analysis must be documented. This compels participating parties to thoroughly document processes and systems within their own functional areas. Whether they are conducting FMEA in the design process or as part of corrective action, end-users of a FMEA failure report will appreciate, and sometimes even demand that a visual representation of the process be included. This documentation will include lists, flowcharts, tables, and charts to "tell a story" about the failure that is being analyzed.

In many cases the documentation of failures from an FMEA process has encouraged an enterprise-wide effort to document ALL systems and process within that enterprise. This effort will only help to facilitate future FMEA activities.

2. **Lower cost and most efficient solutions**

Because there is a systematic and well-documented analysis of failures, the company is sometimes able to identify multiple solutions for a specific failure. Multiple solutions and approaches enables the company to have a menu of choices for not only fixing failures but also for mitigating future risk.

3. **For new companies and new processes, FMEA allows for the selection of alternative methods to address failure**.

A systematic approach to addressing failures allows for the shortening of development times for new processes, products, and services. Because the possible pitfalls for a process or business are identifiable and measurable, the time from the planning stage to implementation can also be significantly reduced. This can lead to greatly reduced development time, human resource allocation, and cost.

For companies rolling out a new product or service, this also means that the time needed to get everything into the market is greatly reduced. Less time in product incubation means higher revenues, profits, and the avoidance of losses.

# Part 4 - Risks of Not Conducting FMEA and Pitfalls

Most of the risk impact and pitfalls of not having a FMEA process mirror the benefits in the previous section. The absence of an FMEA process results in the following exposures:

1. **The causes of failures are not identified**

Merely talking about how and even why a failure happened means that the failure can very well happen again. This is because the root cause will not be extracted from just guessing and casual conversation, and any lack of documentation means that the details of the failures will be forgotten or unavailable for future reference.

For example, when a car rental customer complains about the fact that he or she did not get the car according to the specifications in the reservation, the manager might just scream at the counter agent and order him to rush to a nearby branch and get the needed car.

The immediate failure mode was that the desired car was not available in the lot during that very moment, but other deeper, root causes may be to blame as well. For example, insufficient inventory means that no car can be made available no matter what. Or the reason can be as simple as that the people responsible for cleaning and washing cars are not trained for the timely performance of their duties.

2. **The failure may occur again**

Because the failure was not properly identified and addressed, a solution cannot be developed as well. In the car rental example above, insufficient inventory for a popular car model can lead to the non-availability failure repeatedly.

3. **Employee and staff dissatisfaction**

Continuous failures in a company are not good for its employees. A company that is constantly failing to meet expectations will make it difficult for the company to retain and acquire good employees. Employee unhappiness is also often reflected in poor service delivery.

4. **Customer dissatisfaction and poor company image**

***Repeated failures in service delivery ultimately leads to customer losses***. If the car rental company insists on giving customers cars that they do not want, the customers will inevitably look for other companies that are able to. Constant failure and inefficiencies also inevitably lead to a tainted reputation.

While there are pitfalls from NOT having FMEA, there are also some limitations to the use of FMEA that should be kept in mind. FMEA is "merely" an assessment tool, and is not a panacea. It is not designed to eliminate problems, but serves as a mechanism to identify and isolate them instead.

For all the wonderful advantages and benefits that may come from a good FMEA program, businesses should also watch out for the following:

1. **FMEA is only as good as the group running it.**

This has two dimensions. First, the team must have the requisite knowledge and experience to be able to properly evaluate failures. No well-documented process can compensate for insufficient brainpower. The other dimension is that the performance of FMEA duties may not effective. It is quite easy to get distracted, and some members may be so preoccupied with their own day to day issues that they may not assess failure occurrences properly. They may omit a step in the FMEA analysis, or gloss over a key policy statement. With inadequate execution, the FMEA process is in danger of becoming a failure in itself.

2. **Identification and prioritization are not bulletproof**

A company may have an impressive FMEA program, but this does not ensure that locating and prioritizing failure modes will be perfect. Some failures do slip through the cracks, and it may take a while before these are discovered. The fact that FMEA itself is only an

assessment tool means that the failure cannot be fixed in the FMEA process. This will require intervention outside of the FMEA process and the FMEA process team.

### 3. **The FMEA scope could be too wide or too large**

In most cases, FMEA is a huge undertaking, and the analysis team can walk a fine line between taking on a scope that is too small or one that too large. A particular process or transaction can be comprised of many tiny details, and taking on a narrow scope may mean missing a few or even one of those details. This means that a failure mode will not be uncovered. On the other hand, taking on all of many details will make analysis seem to be a very daunting task. In any case, a good solution is to break down the FMEA process into smaller, more manageable segments.

### 4. **FMEA analysis is not static**

Just as a business in the service industry is a dynamic organism, the FMEA should also be treated as such. A FMEA plan should not be left in somebody's drawer forever and taken out only when a failure arises. The FMEA should be constantly and regularly updated to account for changes in the industry, products, and technology. Failure modes may need to be reviewed for relevancy and timeliness.

# Part 5 - The FMEA Process

Presented below is a recommended set or FMEA steps that can be applied universally to many service industry companies. It can be used as a guide to create a more comprehensive and detailed FMEA that suits individual needs.

1. **Establish responsibilities and accountability**

FMEA can be a critical function in any business organization, and the process needs higher management support. In a small business, the owner needs to take a leading role in the process. He may even conduct the failure analysis process himself with the help of others. In a larger organization, the Risk Management, Finance, and Operations functions at a minimum need to be involved in the process.

If personnel decisions or considerations are concerned, the Human Resources function may have to be involved. In failures where product, product delivery, and customer service are an issue, the Sales and Customer Service functions should be included.

The FMEA Analysis Team for a company in a service industry should therefore include representatives from all departments and disciplines. This should also be considered, not as a one-time effort, but as a "standing" committee that will convene at pre-determined times. These "times" can include regular and periodic (even when there are no instances of failure), and guidelines should specify when a failure event is severe enough to convene a formal inquiry.

A table of organization and list of members should be drawn up with leadership and reporting roles assigned and defined.

2. **Establish documentation requirements**

The conduct of all FMEA activity should be documented from beginning to end. This documentation should include the organization described in (1.) above, together with standards, scope and processes as described in detail in the subsequent steps.

It is useful to use chart templates provided for free by companies involved in risk management and process improvement. These templates can be tailored to fit most company types and situations. A sample of such a template is given at the end of this section.

3. **Establish the scope for failure analysis**

This step answers the question on when a uniform and well-documented method of assessing failures and failure modes will be subject to FMEA. Similar to a Risk Management process, general descriptions and classifications need to be identify and ranked based on their severity and impact on a company's revenues, profits, business image, and customer perception.

Common sense and perspective are essential when it comes to finishing this step. For example, finding a trashcan tipped over in the lunchroom while a customer is present, while an obvious HR or safety issue, is not a cause for a formal convening of an FMEA committee.

4. **Establish deadlines and reporting requirements**

The business must determine how long after a design or plan is completed, or when a failure occurs, does a formal FMEA report get generated. In most cases, the need for proper communication of findings is of the urgent, "I needed it yesterday" kind. Convenience must be balanced with the need to quickly communicate results especially if it involves processes that impact customer satisfaction.

5. **Identify possible failure points**

In this step, experience is valuable. It will be combined with analysis and some level of forecasting and even guessing.

When looking for failure modes, it is imperative to start with a good understanding and documentation of the underlying process. It should be clear as to what the objective, design, service or process of a system is. Its use or benefit to a customer should also be clearly stated, and should be described as much as possible as a VERB or ADJECTIVE followed by NOUN. For example, steaming cup of coffee, buzzing sports car,

For each process or function, every possible failure possibility should be identified. This step requires that each function and process is documented and defined with sufficient clarity and detail so that failure modes can be properly described. If needed, the functions should be rewritten with more detail. The system description should be broken down further into subsystems, assemblies, parts, and items for products.

6. **Identify consequences and severity of a failure**

Before identifying how a failure mode affects the company's profits and revenues, FMEA should determine the effect on customer experience arising from the failure, together with how the customer can to the failure, and how the company intends to respond

In this step, all the consequences on the system needs to be identified. This includes the effects on all of the related processes, the product itself, service delivery, and regulatory requirements.

For every failure, the consequences on the system, related systems, process, related processes, product, service, customer or regulations must be assessed and quantified to be able to measure the potential effects of the breakdown or error.

In the hot coffee example, does the inability to serve a hot cup of coffee correctly mean that the company violated some health regulation? Does it mean that the company needs to upgrade its equipment? Does it mean that further training is required?

After determining the effects, a severity rating (S) needs to be assigned on a scale of 1 -10 with 10 being the most catastrophic.

### 7. **Search for root causes**

Determine root causes for each failure mode. Root cause means the ultimate cause of a problem, and not just what appears on the surface. There are many professional tools available for root cause analysis, but tapping into the experience and knowledge of the FMEA team is very important. All possible root causes should be documented.

### 8. **Estimate occurrence**

The probability of each failure occurring again has to be estimated. This is the "O" or occurrence rating for the RPN or FAN. This will also be scored on a 1-10 scale where 1 means that failure extremely unlikely to occur, and 10 means that the failure in inevitable. The "O" score should be estimated using a pre-determined period, such as a calendar quarter or a year.

### 9. **Determine detectability**

The detectability, or "O" in the FAN/RPN rating needs to be determined after the failure has been identified and analyzed. This rating is an estimate of a how controls put in place can detect the failure before its impact reaches the customer.

Once again, detectability is rated on a 1-10 scale where 10 means that the failure will not be detected and 1 meaning that controls in place will be able to detect the failure.

## 10. **Calculate the FAN or RPN**

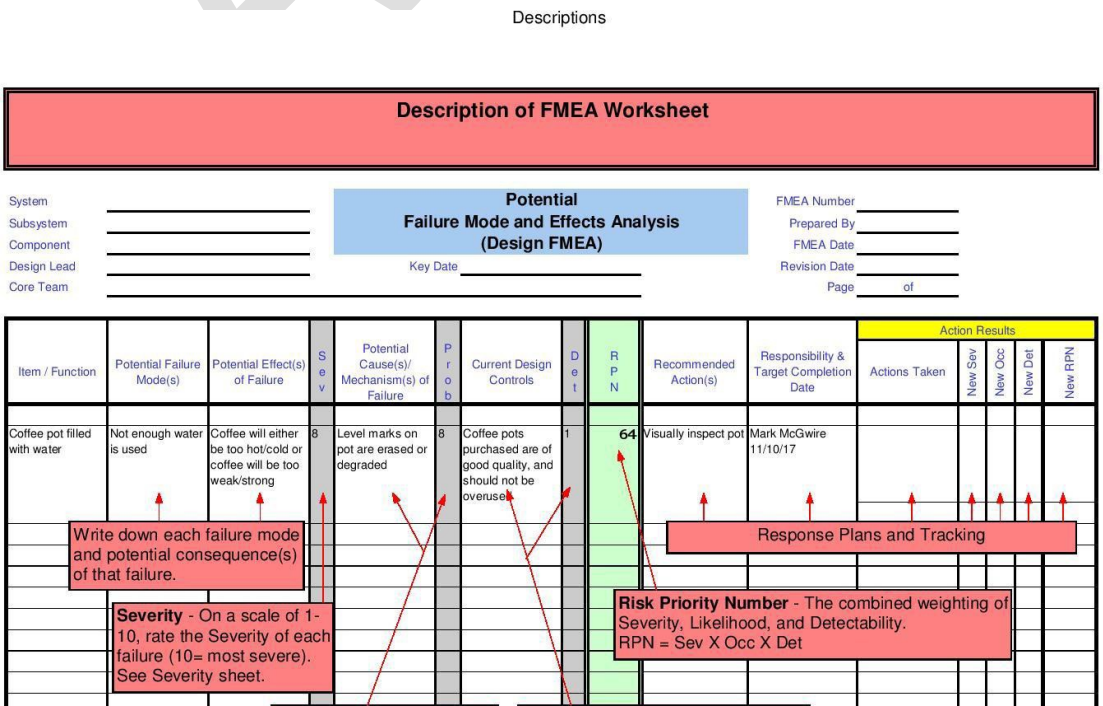
After the severity (S), occurrence (O), and detectability (D) factors have been estimated for each failure, the FAN/RPN can be calculated. This final number is the product of three factors: or S × O × D. The final number will be used to rank each failure possibility with special attention being give the severity factor as well as consideration being given to effects on customer satisfaction.

## 11. **Develop recommended actions**

The result of FMEA can, ultimately, help in identifying system and risk management controls to help ensure that process controls needed to mitigate or prevent failures can be put in place. These actions may include changes in the process, design, or system, or policies and procedures to help mitigate occurrence and severity in the future together with additional steps to improve failure detection. The controls can be also preventive (eliminating or reducing the likelihood of the failure occurring) or detective (detecting the failure after it has already happened BUT BEFORE the failure reaches the customer).

After the recommended actions are identified, FMEA should include documentation as to targeted dates of completion together with the assignment of responsibilities.

A sample FMEA worksheet is provided below.



# Part 6 - Other Disciplines that Complement FMEA

In Part 1, we touched briefly on the relationship of FMEA to Risk Management. This shows how FMEA is closely allied to the matter of correlating it to processes outside of regular operations.

Aside from Risk Management, FMEA can be used as an input, resource, or tool in other disciplines and functions. These include:

1. Project Management – Failures not only happen in regular operations but in projects that the companies undertake. Examples are development of new information systems or product launches. ***FMEA can be a tool in addressing breakdowns in these projects.***

2. Quality Management – Many companies are involved in enterprise quality efforts such as International Organization for Standardization (ISO), together with associated tools such as Six Sigma and Total Quality Management, or TQM. FMEA can be invaluable in identifying areas where quality is compromised.