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Implementation of Failure Mode Effect Analysis in Indian Small & Medium Manufacturing Enterprises- A Review

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Abstract: FMEA methodology is a valuable tool at the hands of persons responsible with organizing the production in terms of reliability and quality management of products and processes. It is an inseparable part of risk management and it supports the continuous improvement. The main aim of the method consists in detecting effects and causes of failure modes that can affect the reliability, the quality and not least the safety of products, whether it is product, process, system or service analysis. It is widely used in manufacturing industries in various phases of the product life cycle and is now increasingly finding use in the service industry too. Although, initially developed by the military, FMEA methodology is now extensively used in a variety of industries including semiconductor processing, food service, plastics, software, and healthcare. Various approaches and applications of FMEA have been developed so far. This paper provides a survey and brief summary of the work on the FMEA till date.

Keywords: FMEA, Severity, Occurrence, Detection, Process FMEA and Design FMEA etc.

1. Introduction

FMEA analysis involves teamwork, management support, and deep knowledge of systems, products, processes, time and cost. Therefore, to be successful, this technique should be fully implemented quality management system both within the product development and processes. This will enable companies to rationalize their activities and thus reduce costs and increase efficiency.

A failure modes and effects analysis (FMEA) is a methodology in product development and operations management for analysis of potential failure modes within a system for classification by the severity and likelihood of the failures. A successful FMEA activity helps a team to identify potential failure modes, based on past experience with similar products or processes. Failure modes are any errors or defects in a process, design, or item, especially those that affect the customer, and can be potential or actual. Effects analysis refers to studying the consequences of those failures. An example of this is the Apollo Space program. It was also used as application for Hazard Analysis Critical Control Point (HACCP) for the Apollo Space Program, and later the food industry in general. The primary push came during the 1960s, while developing the means to put a man on the moon and return him safely to earth. In the late 1970s the Ford Motor Company introduced FMEA to the automotive industry for safety and regulatory consideration after the Pinto affair. They applied the same approach to processes (PFMEA) to consider potential process induced failures prior to launching production.

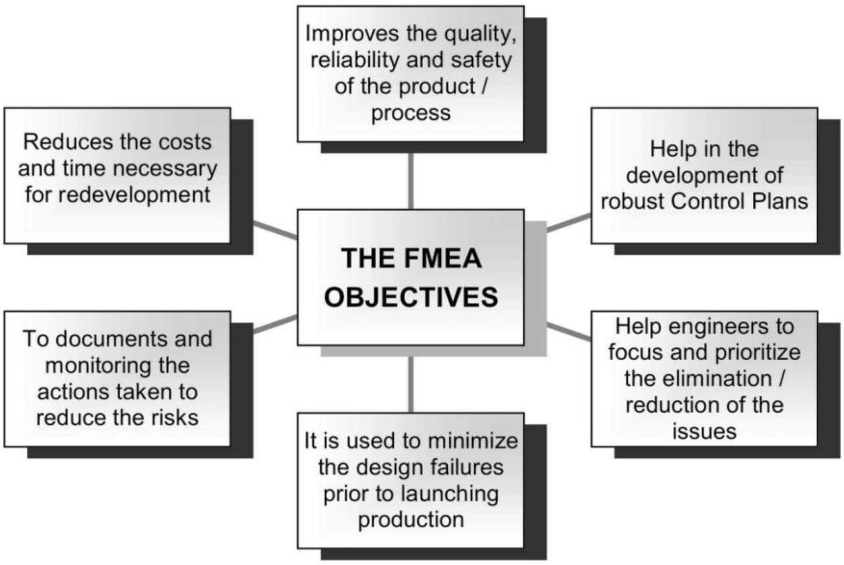
To be effective, the FMEA must be iterative to correspond with the nature of the design process itself. The extent of effort and sophistication of approach used in the FMEA will be dependent upon the nature and requirements of the individual program. FMEA can provide an analytical approach, when dealing with potential failure modes and their associated causes. When considering possible failures in a design – like safety, cost, performance, quality and reliability – an engineer can get a lot of information about how to alter the development/manufacturing process in order to avoid these failures. The process for conducting an FMEA developed in three main phases, in which appropriate actions need to be defined. But, before starting with an FMEA, it is important to complete some pre-work to confirm that robustness and past history are included in the analysis.

1.1 The Development Of FMEA

Year	Description
1963	FMEA was first proposed by aerospace industry
1965	The military of the US started to apply the FMEA technique
1974	The military of the US published the SOP of FMEA: MIL-STD-1629

1977	Ford Motor started to use FMEA
1980	The revised SOP of FMEA: MIL-STD-1629A
1985	The International Electro-technical Commission (IEC) published SOP of FMEA: IEC 812
1993	Ford, Chrysler, and General Motor established the 1st edition FMEA reference manual
1995	The 2nd edition of FMEA reference manual was revised by AIAG
2001	The 3rd edition FMEA reference manual was revised by AIAG
2008	The 4th edition FMEA reference manual was revised by AIAG
2008-now	FMEA is considered as an important examining item and analytic method by ISO-9000, ISO/TS 16949, CE, and QS-9000, and it has been widely used in risk assessment and quality improvement in many industries

1.2 FMEA Objectives



1.3 Classification Of FMEA

There are several types of FMEA's; some are used much more often than others. The types of FMEA‟s are shown in Figure 1.

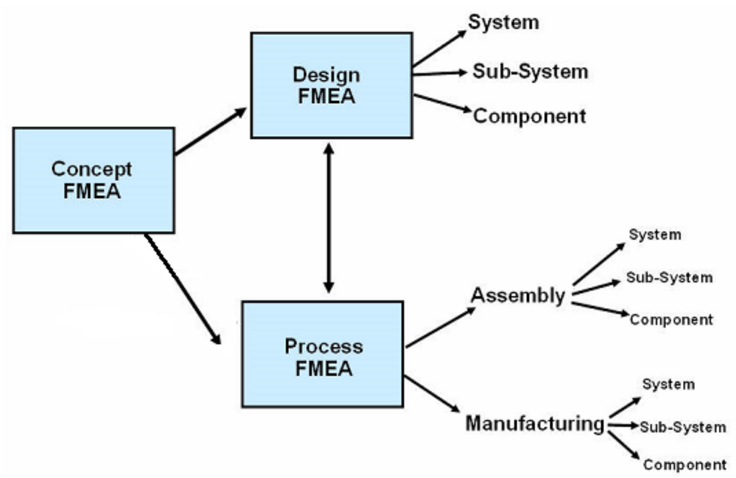


Fig. 1 Types of FMEA

Basically two types of FMEA‟s are used in manufacturing industries:

(i) The Design FMEA and
(ii) The Process FMEA.

The Design FMEA is used to analyze products before they are released to production and it focuses on potential failure modes of products, caused by design deficiencies. Design FMEA s are normally done at three levels – system, sub-system, and component levels. The Process FMEA is normally used to analyze manufacturing and assembly processes at the system, sub-system or component levels. This type of FMEA focuses on potential failure modes of the process that are caused by manufacturing or assembly process deficiencies. A robustness analysis can be obtained from interface matrices, boundary diagrams and parameter diagrams. A lot of failures are due to noise factors and shared interfaces with other parts and/or systems, because engineers tend to focus on what they control directly. To start, it is necessary to describe the system and its function. A good understanding of FMEA simplifies further analysis. This way an engineer can see which uses of the system are desirable and which are not. It is important to consider both intentional and unintentional uses. Unintentional uses are a form of hostile environment. It is useful to create a coding system to identify the different system elements. Before starting the actual FMEA, a worksheet needs to be created, which contains the important information about the system, such as the revision date or the names of the components. On this worksheet all the items or functions of the subject should be listed in a logical manner.

1.4 FMEA Procedure

Following steps are used to implement the FMEA:-

Severity (S):- Determine all failure modes, based on the functional requirements and their effects. Examples of failure modes are: electrical short-circuiting, corrosion or deformation. A failure mode in one component can lead to a failure mode in another component, therefore each failure mode should be listed in technical terms and for function. Thereafter the ultimate effect of each failure mode needs to be considered. A failure effect is defined as the result of a failure mode on the function of the system as perceived by the user. In this way it is convenient to write these effects down in terms of what the user might see or experience. Examples of failure effects are: degraded performance, noise or even injury to a user. Each effect is given a severity number (S) from 1 (no danger) to 10 (critical). These numbers help an engineer to prioritize the failure modes and their effects. If the severity of an effect has a number 9 or 10, actions are considered to change the design by eliminating the failure mode, if possible, or protecting the user from the effect. A severity rating of 9 or 10 is generally reserved for those effects which would cause injury to a user or otherwise result in litigation.

Occurrence (O):- In this step it is necessary to look at the cause of a failure mode and how many times it occurs. This can be done by looking at similar products or processes and the failure modes that have been documented for them. A failure cause is looked upon as a design weakness. All the potential causes for a failure mode should be identified and documented. Again this should be in technical terms. Examples of causes are: erroneous algorithms, excessive voltage or improper operating conditions. A failure mode is given an occurrence ranking (O), again 1–10. Actions need to be determined if the occurrence is high (meaning > 4 for non-safety failure modes and > 1 when the severity-number from step 1 is 9 or 10). This step is called the detailed development section of the FMEA process. Occurrence also can be expressed in percentage. If a non-safety issue happened less than 1%, one can give 1 to it. It is based on our product and customer specifications.

Detection (D):- When appropriate actions are determined, it is necessary to test their efficiency. In addition, design verification is needed. The proper inspection methods need to be chosen. First, an engineer should look at the current controls of the system, that prevent failure modes from occurring or which detect the failure before it reaches the customer. Thereafter one should identify testing, analysis, monitoring and other techniques that can be or have been used on similar systems to detect failures. From these controls an engineer can learn how likely it is for a failure to be identified or detected. Each combination from the previous two steps receives a detection number (D). This ranks the ability of planned tests and inspections to remove defects or detect failure modes in time. The assigned detection number measures the risk that the failure will escape detection. A high detection number indicates that the chances are high that the failure will escape detection, or in other words, that the chances of detection are low.

After these three basic steps, risk priority number (RPN) is calculated

Risk priority number (RPN):- Risk priority number (RPN) does not play an important part in the choice of an action against failure modes. They are more threshold values in the evaluation of these actions. After ranking the severity, occurrence and detectability, the RPN can be easily calculated by multiplying these three numbers:

$$RPN = S \times O \times D.$$

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

After these values are allocated, recommended actions with targets, responsibility and dates of implementation are noted. These actions can include specific inspection, testing or quality procedures, redesign (such as selection of new components), adding more redundancy and limiting environmental stresses or operating range. Once the actions have been implemented in the design/process, the new RPN should be checked to confirm the improvements. These tests are often put in graphs, for easy visualization. Whenever a design or a process changes, an FMEA should be updated.

Failure Modes and Effects Analysis (FMEA) is a tool widely used in the automotive, aerospace, and electronics industries to identify, prioritize, and eliminate known potential failures, problems, and errors from system under design before the product is released. FMEA proves to be one of the most important early preventive actions in system, design, process, or service which will prevent failure and errors from occurring and reaching customer. FMEA's are conducted in the product design or process development stages, although conducting an FMEA on existing products or processes may also yield benefits. A failure mode is defined as the manner in which component, sub system, system, process etc, could potentially fail to meet the design intent. FMEA used to solve problems due to manufacturing process. FMEA method is used to calculate RPN for each failure mode and then proposed recommended actions to reduce the RPN. The basic steps are to identify the root of the cause and potential problems that could occur, and then derive RPN which can direct improvement effort to the area of greatest concern. This work mainly includes application of proess Fmea in a manufacturing unit producing crank shaft. The case industry is situated in Kerala. Process FMEA is used to solve problems due to manufacturing process. It starts with a process flow chart that shows each manufacturing steps of a product. The potential failure modes at each work station are listed. Then the effect of each of failure is described in detail.

1.5 Shortcomings of FMEA

With all the advantages of this method, there are a number of limitations and shortcomings that are caused by the methodology itself. However, the conventional approach to obtain RPN has been considerably criticized for a variety of reasons. Significant criticisms include but are not limited to the following:-

Different sets of O, S and D ratings may produce exactly the same value of RPN, but their hidden risk implications may be totally different. For example, two different failure modes with values of 2, 3, 2 and 4, 1, 3 for O, S and D, respectively, will have the same RPN value of 12. However, the hidden risk implications of the two failure modes may be very. This may cause a waste of resources and time, or in some cases, a high risk failure mode being unnoticed.

The relative importance among O, S, and D is not taken into consideration. The three factors are assumed to have the same importance. This may not be the case when considering a practical application of FMEA. Some evaluators reason to believe that severity is the most important factor and therefore should be given more weight in the calculations of RPN.

The three risk factors are difficult to be precisely evaluated. Evaluation of a failure mode is more difficult if models for which no previous data are evaluated. The conversion of scores is different for the three factors. For example, a linear conversion is used for O, but a nonlinear transformation is employed for D. RPNs are not continuous distributed at the bottom of the scale from 1 to 1000. This causes problems in interpreting the meaning of the differences between different RPNs. For example, is the difference between the neighboring RPNs of 1 and 2 the same or less than the difference between 900 and 1000?

Low variations of the three parameters in a single evaluation can lead to very different RPN index values. For example, if the two parameters S and O have the same value 10 and the parameter D varies between 1 and 2 then the results for RPN are 100 and 200. The RPN considers only three factors mainly in terms of safety. Other important factors such as economical aspects are ignored. The RPN scale is not continuous and presents a series of "holes"; as the RPN values approaching 1000 the distances between values are increasing which may result the large intervals between consecutive values of RPN.

To overcome the above drawbacks, a number of approaches have been suggested in the literatures who try to resolve the subjective decision issues by using mathematical tools. From these the most common are: fuzzy logic methods, grey theory, Bayesian nets, Markov model, Dempster-Shafer theory, Analytic Hierarchy Process – AHP method.

2. Literature Review

Zhang and Chu (2011) proposed the fuzzy methods and linear programming method as an effective solution for fuzzy RPNs for resolving the vagueness and uncertainty existing in the evaluating process of the traditional FMEA. In this study, a fuzzy-RPNs-based method integrating weighted least square method, the method of imprecision and partial ranking method is proposed to generate more accurate fuzzy RPNs. With aid of a design example of new horizontal directional drilling machine, the proposed approach is illustrated.

Gargama and Chaturvedi (2011) proposed a fuzzy FMEA model for prioritizing failures modes based on the degree of match and fuzzy rule-base to overcome some limitations of traditional FMEA.The proposed model employed the belief structure for the assessment of risk factors, and then converted randomness in the assessed information into a convex normalized fuzzy number. The degree of match (DM) was used thereafter to estimate the matching between the assessed information and the fuzzy sets of risk factors. This computed DM then became the inputs to the fuzzy rule based systems where rules were processed resulting in failure classification with degree of certainty.

Geum *et al.* (2011) proposed a systematic approach for identifying and evaluating potential failures using a service-specific FMEA and grey relational analysis. Firstly, the service-specific FMEA was provided to reflect the service-specific characteristics, incorporating 3 dimensions and 19 sub-dimensions to represent the service characteristics. As the second step, under this framework of service-specific FMEA, the risk priority of each failure mode was calculated using grey relational analysis. In this paper, grey relational analysis was applied with a two-phase structure: one for calculating the risk score of each dimension: O, S and D, and the other for calculating the final risk priority.

Xiao *et al.*(2011) develop a FMEA method to combine multiple failure modes into single one, considering importance of failures and assessing their impact on system reliability. The proposed method was established upon the minimum cut sets (MCS) theory, which was incorporated into the traditional FMEA for assessing the system reliability in the presence of multiple failure modes. Additionally, they extended the definition of RPN by multiplying it with a weight parameter, which characterizes the importance of the failure causes within the system. Following the weighted RPN, the utility of corrective actions was improved.

Yang *et al.* (2011) also adopted evidence theory to aggregate the risk evaluation information of multiple experts. However, all individual and interval assessment grades were assumed to be crisp and independent of each other in the proposed model. It did not considerate the occasion in FMEA where an assessment grade may represent a vague concept or standard and there may be no clear cut between the meanings of two adjacent grades.

Zammori and Gabbrielli (2011) presented an advanced version of the FMECA, called analytic network process (ANP)/RPN, which enhances the capabilities of the standard FMECA taking into account possible interactions among the principal causes of failure in the criticality assessment. According to the ANP/RPN model, O, S and D were split into sub-criteria and arranged in a hybrid (hierarchy/ network) decision structure that, at the lowest level, contains the causes of failure. Starting from this decision-structure, the RPN was computed by making pairwise comparisons. In order to clarify and to make evident the rational of the final results a graphical tool was also presented in the paper.

Kutlu and Ekmekciog (2012) considered a fuzzy approach, allowing experts to use linguistic variables for determining O, S and D, for FMEA by applying fuzzy TOPSIS integrated with fuzzy AHP. Fuzzy AHP was utilized to determine the weight vector of the three risk factors. Then by using the linguistic scores of risk factors for each failure modes, and the weight vector of risk factors, fuzzy TOPSIS was utilized to get the scores of potential failure modes, which were ranked to prioritize the failure modes.

Sant'Anna (2012) proposed a method, derived from numerical evaluations on the criteria of security, frequency and detectability, of FMEA, a probabilistic priority measure for potential failures. The method proposed was based on treating the numerical initial measurements as estimates of location parameters of probability distributions, which allows for objectively taking into account the uncertainty inherent in such measurements and to compute probabilities of each potential failure being the most important according to each criterion. These probabilities were then combined into a global quality measure, which can be interpreted as a joint probability of choice of the potential failure.

Belu. *et al.* (2013) explained that FMEA methodology is a valuable tool at the hands of persons responsible with organizing the production in terms of reliability and quality management of products and processes. It is an inseparable part of risk management and it supports the continuous improvement. The main aim of the method consists in detecting effects and causes of failure modes that can affect the reliability, the quality and not least the safety of products, whether it is product, process, system or service analysis. FMEA analysis involves teamwork, management support, and deep knowledge of systems, products, processes, time and cost. Therefore, to be successful, this technique should be fully implemented quality management system both within the process of both product development and processes. This will enable companies to rationalize their activities and thus reduce costs and increase efficiency.

Carlson (2014) revealed everyone wants to support the accomplishment of safe and trouble-free products and processes while generating satisfied and loyal customers. When done correctly, FMEA can anticipate and prevent problems, reduce costs, shorten product development times, and achieve safe and highly reliable products and processes. Using the FMEA success factors will help ensure the success of FMEA projects. The author investigated that the quality of haemodialysis process is a prime concern in renal care. They surveyed at one of the leading hospitals in central India, providing kidney care and dialysis, aimed to identify areas in the haemodialysis unit needing special attention, to improve process quality and ensure better patient welfare. Their FMEA approach includes: deciding haemodialysis process requirements, identifying potential causes of process failure and quantifying associated risk with every cause. Suitable actions are then implemented to reduce the occurrence and improving the controls, thereby reducing risk. They suggested to adopt proper checklists for work monitoring, providing training to enhance patient and staff awareness; led to reduced process errors, mitigating overall risks, eventually resulting in effective patient care. Their research work provides a microscopic error proofing approach to haemodialysis process, using a proven engineering tool, FMEA, ensuring quality improvement. This approach could also be extended to cover other hospital activities.

A review of the human reliability literature is discussed to identify potential failure causes. Researchers have recommended the FMEA to evaluate the performance of the service industries. They implemented the FMEA to ward stock drug distribution system, health care organizations, passenger Transport Company etc. to improve the performance of the service industries.

3. Conclusions

Quality and reliability of products and manufacturing processes are critical to the performance of the final products. They are also important indices for meeting customer satisfaction. In order to fulfill customer's requirements for quality and reliability, some actions for assuring the quality and reliability of products or processes should be taken by all the persons involved. One of the most powerful methods available for measuring the reliability of products or process is FMEA. Probably the greatest criticism of the FMEA has been its limited use in improving designs. Customers are placing increased demands on companies for high quality and reliable products.

FMEA provides an easy tool to determine which risk has the greatest concern and therefore an action is needed to prevent a problem before it arises. The development of these specifications will ensure the product will meet the defined requirements. Before starting the actual FMEA, a worksheet needs to be created, which contains the important information about the system, such as the revision date or the names of the components. On this worksheet all the items or functions of the subject should be listed in a logical manner. The initial output of an FMEA is the prioritization of failure modes based on their risk priority numbers and this alone does not eliminate the failure mode. Additional action that might be outside the FMEA is needed. This paper will definitely enhance the knowledge of researchers who really want to carry their research in this area.

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