Module III Product Quality Improvement

Lecture 3-What is Design FMEA?

Continually measuring the reliability of a product is an essential part of Quality. When creating a new product, or even modifying an existing product, it is always necessary to improve the reliability of the product. One of the most powerful methods available for improving the reliability of product is design FMEA. FMEA is an approach that combines the technology and experience of people in identifying foreseeable failure modes of a product and planning for its elimination. FMEA attempts to detect the potential product-related failure modes. The approach is used to anticipate causes of failure and prevent them from happening. It is like eliminating/preventing potential causes of failure in a cause and effect diagram. This method can be implemented in both the product design and process design and involves effect on both internal and the external customer.

FMEA uses an occurrence and detection probability criteria in conjunction with severity criteria to develop a risk prioritization numbers for prioritization the corrective action. It is to be noted that for FMEA to be successful, it is extremely important to treat the FMEA as a living record, and continually changing as per new problem(s) and being updated to ensure that the most critical problems are identified and addressed to prevent recurring.

A design (product) FMEA or process FMEA can provide the following benefits:

(i)Having a systematic review approach of component failure modes can ensure that any failure produces minimal damage to the product or process.

(ii) Determining the effects that any failure will have on product or process and their functions.

(iii) Determining those critical parts of a product or a process whose failure will have critical effects on product or process operation.

(iv) Eliminating or minimizing the adverse effects that failures could generate and indicating safeguards to be incorporated if the product or the process cannot be made fail-safe or brought within acceptable failure limits.

(v) Help uncover oversights, misjudgments, and errors that may have been made.

It is to be noted that a FMEA document, however, cannot solve all design and process problems and failures. The document, by itself, will not fix the identified problems or define the action that needs to be taken. FMEA cannot also replace the basic root cause analysis approach.

FMEA Team

The FMEA approach is a team effort where the responsible engineer involves design, manufacturing, materials, quality, service, supplier, and even the next customer (whether internal or external). The team leader has certain responsibilities, which include coordinating corrective action assignments and follow-up, keeping files and records of FMEA forms, leading the team through completion of the forms, keeping the process moving, and finally, drawing everyone into participation.

Details on FMEA Documentation

The concept of FMEA is nothing new to engineers. Engineers designing and building a product have always incorporated the concepts of FMEA in their thinking process. However, FMEA does help keep those ideas available for future use and for the use of others. One engineer may find a potential problem elementary and not worth extra attention; a second engineer may not realize the problem altogether. The purpose of the FMEA document (Please see **Figure 3-12**) is to allow all involved engineers to have access to others' thoughts and to design and manufacture using this collective group of thoughts. In this document, on the top right corner (see **Figure 3-12**) is the FMEA Number. This number is only for record. There is also an item space to clarify which exact component or process is being analyzed. The name and number of the system or sub-system being analyzed is also mentioned in this space. Some of the critical headings mentioned in FMEA document is discussed below.

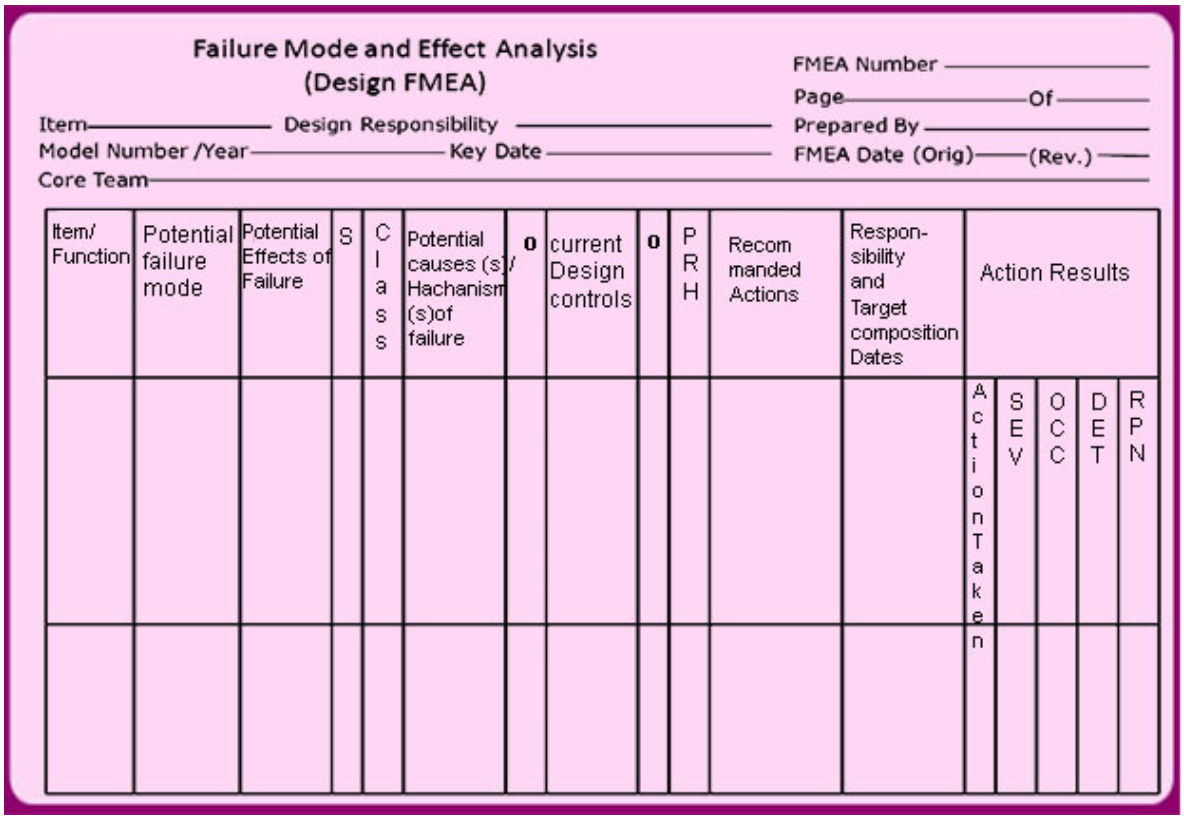

Figure 3-12 Design FMEA Document

Design Responsibility

The team in charge of the design or process is identified in the space designated as Design Responsibility. The name and department of the person or group responsible for preparing the documentation is included here.

Prepared By

The name, telephone number, and address of the concerned persons (group) are included here so as to contact them in case a part of the document needs further explanation.

FMEA Date

The date the FMEA was compiled and the latest revision date is included in this FMEA Date space.

Item/Function

In this section, the name and part number of the item being analyzed is recorded. This information avoids confusion involving similar items. Next, the function of the item is to be entered below the description of the item. No specifics should be left out in giving the function of the item. If the item has more than one function, they should be listed here. The function of the item including the environment in which the system operates (say temperature, pressure, and humidity) is also recorded here.

Potential Failure Mode

The Potential Failure Mode information may be one of two things. First, it may be the way in which the item may fail to meet the design criteria. Second, it may be a potential failure in a higher-level system or may be the result of failure of a lower-level system. It is important to consider and list each and every potential failure mode. A possible starting point when listing potential failure modes is to consider past failures. Also, the potential failure modes must be described in technical terms. Some typical failure modes may include ‘cracked or deformed, loosened joints, leakage from welding, short circuit in water heater, and fractured.'

Potential Effect(s) of Failure

The potential effects of failure are the effects of the failure as perceived by the internal or external customer. The effects of failure must be described in terms of what the customer will notice or experience. It is also stated whether the failure will impact personal safety or violate any product regulations. This section of the document must also forecast what effects the particular failure may have on other subsystems in immediate contact. Some typical effects of failure may include engine noise and poor appearance.

Severity (S)

Severity is the assessment of the seriousness of the effect of the potential failure mode to the subsequent component, sub-system, or customer. It is to be emphasized that the severity applies only to the effect of the failure, not the potential failure mode. Severity rating must not change from any reasoning except change in the product design. Severity is rated on a 1-to-10 scale, with a 1 being least severe and a 10 being the most severe. Rating criteria is given in **Table 3-1**. Readers may also refer QS 9000 (http://en.wikipedia.org/wiki/QS9000), which provides further details on severity rating.

Classification (Class)

This column is used to classify any special characteristics for components that may require additional controls.

Potential Cause(s)/Mechanism(s) of Failure

Every potential failure cause is to be listed completely and concisely. Some failure modes may have more than one cause and/or mechanism of failure. Typical failure causes may include incorrect product specification, inadequate design, over-stress, poor environment protection. Typical failure mechanisms may be creep, fatigue, wear, and corrosion.

Occurrence (0)

Occurrence is the possible chance that one of the specific causes/mechanisms will occur. This is done for every cause and mechanism listed. Reduction or removal in occurrence ranking must not come from any reasoning except for a direct change in the design or process. Change is the only way a reduction in the occurrence ranking can be affected. The likelihood of occurrence is based on a 1-to-10 scale, with 1 being the least chance of occurrence and 10 being the highest chance of occurrence. A reference on occurrence rating is given in **Table 3-2**.

Table 3-1 Severity Rating Reference

Effect	Criteria: Severity of Effect	Ranking
Hazardous Without warning	Very high ranking when potential failure mode affects safe operation and/or regulation noncompliance. Failure occurs without warning.	10
Hazardous With warning	Very high ranking when potential failure mode affects safe operation and/or regulation noncompliance. Failure occurs with warning.	9
Very High	Item or product is inoperable, with loss of function. Customer very dissatisfied.	8
High	Item or product is operable, but with loss of performance. Customer dissatisfied.	7
Moderate	Item or product is operable, but with loss to comfort/convenience items inoperable. Customer experiences discomfort.	6
Low	Item or product is operable, but with loss of performance of comfort/convenience items. Customer has some dissatisfaction.	5
Very Low	Certain item characteristics do not conform. Noticed by most customers.	4
Minor	Certain item characteristics do not conform. Noticed by average customer.	3
Very Minor	Certain item characteristics do not conform. Noticed by discriminating customers.	2
None	No Effect.	1

Table 3-2 Occurance Rating Reference

Probability of Failure	Possible Failure Rates	Ranking
Very High: Failure is Almost Inevitable.	>1 in 2	10
	1 in 3	9
High: Repeated Failures	1 in 8	8
	1 in 20	7
	1 in 80	6
	1 in 400	5
	1 in 2000	4
Low: Relatively Few Failures	1 in 15,000	3
	1 in 150,000	2
Remote: Failure is Unlikely	<1 in 1,500,000	1

Current Design Controls

In order to improve the occurrence rating for the particular failure mode, the design control must be employed. Current Design control indicates the state of control that will be able to detect the occurance of a failure or minimize the failure chances.

Detection (D)

This is a relative measure of assessment of the ability of the design control to detect either a potential cause/mechanism or the subsequent failure mode before the component goes to end/next user. Typically, in order to achieve a lower detection rating, design control must be improved. A reference for rating in detection phase is given in **Table 3-3**.

Table 3-3 Rating of Likelihood of Detection in Design FMEA

Rankings of likelihood of detection by Design Control for Design FMEA

Effect	Criteria : severity of Effect	Ranking
Absolutely Impossible	Design control will not and / or cannot detected a potential cause / mechanism and subsequent failure mode : or there is no design control	10
Very remote	Very remote chance the design control will detected a potential cause /mechanism subsequent failure mode	9
Remote	Remote chance the design control will detect a potential cause / mechanism and subsequent failure mode.	8
Very low	Very low chance the design control will detect a potential cause /mechanism and subsequent and failure mode	7
Low	Low chance the design control will detected a potential cause / mechanism and subsequent failure mode	6
Moderate	Moderate chance the design control will detect a potential cause / mechanism and subsequent failure mode	5
Moderate highly	Moderately high chance the design control will detect a potential cause / mechanism and subsequent failure mode	4
High	High chance the design control will detect a potential cause / mechanism and subsequent failure mode	3
Very High	Very high chance the design control will detect a potential cause /mechanism and subsequent failure mode	2
Almost certain	Design control will almost certainly detect a potential cause / mechanism and subsequent failure mode	1

Risk Priority Number (RPN)

The Risk Priority Number is the product of the severity (S), occurrence *(0),* and detection *(P)* rankings. This product may be viewed as a relative measure of the design risk. Values for the *RPN* can range from 1 to 1000, with 1 being the smallest design risk possible. This value is then used to rank order the various causes of failure in the design. For causes with a relatively high *RPN,* the engineering team must make efforts to take corrective action to reduce the *RPN.* Any score above 50 may be considered as cutoff to eliminate/minimize the impact of a particular cause. However, because a certain concern has a relatively low *RPN* (<50), the FMEA team

should not overlook the concern and neglect an effort to reduce the *RPN*. This is especially true when the severity of a concern is high. In such case(s), a low *RPN* may be extremely misleading, not placing enough importance on a concern where the level of severity may be disastrous. In general, the purpose of the *RPN* is to rank the various causes on the record. However, every cause should be given full priority by the team, and the team should look for every method available to reduce the *RPN*.

Recommended Actions

After every concern has been examined and given a risk priority number, the team should begin to examine the corrective action(s) that may be employed, beginning with the concern with the greatest *RPN* and working in descending order according to *RPN*. Also, concerns with high severity should be examined. The purpose of the recommended actions is to reduce one or more of the rating that constitute the risk priority number. An increase in design validation actions will result in a reduction in only the detection ranking. Only removing or controlling one or more of the causes/mechanisms of the failure mode through design revision can effect a reduction in the occurrence ranking. And only a design revision can bring about a reduction in the severity ranking. Some actions that should be considered when attempting to reduce the three rankings include, but are not limited to: design of experiment (DOE), revised test plan, and revised design.

Responsibility and Target Completion Dates

Here the individual or group responsible for the recommended actions and the target completion date should be entered as reference for future record.

Actions Taken

After a corrective action has been implemented, a brief description of the action and its effective date is entered. This is done after the action has been implemented so future users can track the progress of the plan.

Resulting RPN

After the corrective actions have been identified, the resulting severity, occurrence, and detection rankings should be re-estimated. Then the resulting *RPN* should be reo calculated and recorded. If no actions are taken, this section should be left blank. If no actions are taken and the prior rankings and *RPN* are simply repeated, future users may reason that there were recommended actions taken, but that they had no effect. After this section is completed, the resulting *RPNs* should be evaluated, and if further action is deemed necessary, steps from the recommended actions section can be repeated.

The overall objective of Design FMEA is to improve the design, improve product reliability, and reduce the chances of occurrence of failures. Design of Experiment (DOE) is recommended by various researchers to improve the quality of design. One of the DOE approach is so-called '*Robust Design*', originally proposed by Genechi Taguchi in 1980. A bried detail on his concept is discussed below.