FMEA - BASIC CONCEPT IN PRODUCT QUALITY

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Abstract: *Failure modes and effects analysis (FMEA) is a systematic procedure for analyzing a system (the entire system or just an assembly, subassembly or component) to identify potential failure modes, causes and effects of each failure on system operation. A somewhat different definition was formulated by Goddard Space Flight Center (USA) : FMEA is a procedure whereby every credible way of defeating each item from the lower decomposition level to the highest level is analyzed to determine effects on the system and classify each potential way of failure according to the severity of its effect.*

Key words: errors, manufacturing process, defects, failure risks

1. INTRODUCTION

Product development and operations managers can run a failure modes and effects analysis (FMEA) to analyze potential failure risks within systems, classifying them according to severity and likelihood, based on past experience with similar products or processes. The object of FMEA is to help design identified failures out of the system with the least cost in terms of time and money.

Failure Mode and Effects Analysis (FMEA) is one of the most popular methods for the systematic prevention of errors. The problem of early defect detection has become so important to result in developing a method for identifying errors in the design phase of the product.

The analysis can be carried out for the whole product, a single component or a structural component of the product and for the whole technological process or any operation

Murphy's law and the main reason behind the FMEA: "Everything that can fail, will fail". or "If something goes wrong, surely it will ruin at the worst possible time".[1]

So, the FMEA is trying to answer the questions:

- What can go wrong in a system or process?
- What's the worst thing that can happen?
- What to do to prevent defects?

The costs for correcting an undetected fault in a previous step increase 10 times from one implementation stage to another!

2. METHODOLOGY OF FMEA

FMEA is one of design tools used in the product design process. The environmental application of FMEA takes into account the environmental impacts caused by technical problems, deficiencies or irregularity errors or processes.

This analysis can be used to make constructional, process and system improvements. E-FMEA method allows for a systematic summary of potential environmental problems associated with a product or process, before their consequences appear.

The notion of “environmental impact” is “evaluation free”, while the notion “environmental load” describes the negative consequences of influences and it can be used to evaluate the importance or the importance of environmental impact (S).

The second criterion involves potential technical causes used to estimate the probability of impact risk occurrence (O). Finally, one can estimate the possibility of influence of the causes and the related risk. For the criteria used to evaluate the importance of environmental impact (S), the probability of cause occurrence (O) and for the causes of influence (D), like in the quality area, values in the range of 1 (small risk) to 10 (high risk) are assigned.

This is the way the product of these three values RPN (Risk Priority Number) is obtained.

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FMEA defines the term “failure mode” to identify defects or errors, potential or actual, in a product design or process, with emphasis on those affecting the customer or end user. A “failure effect” is the result of a failure mode on the product or system function as perceived by the user.

Failure effects can be described in terms of what the end user may see or experience. The study of consequences of identified failures is called effects analysis.

FMEA prioritizes failures according to severity, frequency and detectability. Severity describes the seriousness of failure consequences. Frequency describes how often failures can occur.

Detectability refers to degree of difficulty in detecting failures. FMEA also involves documenting current knowledge about failure risks.

FMEA seeks to mitigate risk at all levels with resulting prioritized actions that prevent failures or at least reduce their severity and/or probability of occurrence. It also defines and aids in selecting remedial activities that mitigate the impact and consequences of failures.

FMEA can be employed from the earliest design and conceptual stages onward through development and testing processes, into process control during ongoing operations throughout the life of the product or system.[3]

Process steps in FMEA

Step 1: Identify potential failures and effects

Step 2: Determine severity

Step 3: Gauge likelihood of occurrence

Step 4: Failure detection

• Risk priority number (RPN)

Step 1: Identify potential failures and effects

The first FMEA step is to analyze functional requirements and their effects to identify all failure modes.

Examples: warping, electrical short circuit, oxidation, fracture.

Failure modes in one component can induce them in others.

List all failure modes per function in technical terms, considering the ultimate effect(s) of ach failure mode and noting the failure effect(s).

Examples of failure effects include: overheating, noise, abnormal shutdown, user injury.

Step 2: Determine severity

Severity is the seriousness of failure consequences of failure effects. Usual practice rates failure effect severity (S) on a scale of one to 10 where one is lowest severity and 10 is highest.

The following table shows typical FMEA severity ratings and their meanings:

Table 1

Rating	Meaning
1	No effect, no danger
2	Very minor – usually noticed only by discriminating or very observant users
3	Minor – only minor part of the system affected; noticed by average users
4-6	Moderate – most users are inconvenienced and/or annoyed
7-8	High – loss of primary function; users are dissatisfied
9-10	Very high – hazardous. Product becomes inoperative, customers angered. Failure constitutes a safety hazard and can cause injury or death.

Step 3: Gauge likelihood of occurrence

Examine cause(s) of each failure mode and how often failure occurs. Look at similar processes or products and their documented failure modes. All potential failure causes should be identified and documented in technical terms. Failure causes are often indicative of weaknesses in the design.

Examples of causes include: incorrect algorithm, insufficient or excess voltage, operating environment too hot, cold, humid, etc. Failure modes are assigned an occurrence ranking (O), again from one to 10, as shown in the following table.

Table 2

Rating	Meaning
1	No documented failures on similar products/processes
2-3	Low – relatively few failures
4-6	Moderate – some occasional failures
7-8	High – repeated failures
9-10	Very high – failure is almost certain
9-10	Very high – hazardous. Product becomes inoperative, customers angered. Failure constitutes a safety hazard and can cause injury or death.

Step 4: Failure detection

After remedial actions are determined, they should be tested for efficacy and efficiency. Also, the design should be verified and inspections procedures specified.

1. Engineers inspect current system controls that prevent failure mode occurrence, or detect failures before they impact the user/customer.

2. Identify techniques used with similar products/systems to detect failures.

These steps enable engineers to determine the likelihood of identifying or detecting failures. Then, each combination from steps one and two is assigned a detection value (D), which indicates how likely it is that failures will be detected, and ranks the ability of identified actions to remedy or remove defects or detect failures. The higher the value of D, the more likely the failure will not be detected.[3]

Table 3

Rating	Meaning
1	Fault is certain to be caught by testing
2	Fault almost certain to be caught by testing
3	High probability that tests will catch fault
4-6	Moderate probability that tests will catch fault
7-8	Low probability that tests will catch fault
9-10	Fault will be passed undetected to user/customer

Risk priority number (RPN)

After the foregoing basic steps, risk assessors calculate Risk Priority Numbers (RPNs). These influence the choice of action against failure modes. RPN is calculated from the values of S, O and D as follows:

$$RPN = S * O * D \text{ (or } RPN = S \times O \times D)$$

RPN should be calculated for the entire design and/or process and documented in the FMEA. Results should reveal the most problematic areas, and the highest RPNs should get highest priority for corrective measures. These measures can include a variety of actions: new inspections, tests or procedures, design changes, different components, added redundancy, modified limits, etc. Goals of corrective measures include, in order of desirability:

- Eliminate failure modes (some are more preventable than others);
- Minimize the severity of failure modes;
- Reduce the occurrence of failure modes;
- Improve detection of failure modes.

When corrective measures are implemented, RPN is calculated again and the results documented in the FMEA.

The analysis assumed that the existing defects were also a burden for the environment - it is associated with the second treatment or disposal of the defect, which affects the assessment of the process eco-efficiency. Table 4 sets out general criteria of the E-FMEA analysis developed.

Table 4- *General criteria used in the particular parts of the E-FMEA analysis*

Occurrence, O	Significance, S	Detection, D
Standards and environmental ranges	Standards and environmental ranges	The use of systems and supervising measures with regard to machinery and equipment
Stability and failure of machines and equipment	Stability and failure of machines and equipment	The use of systems and supervising measures with regard to the standards and scope of environmental processes

The result of the E-FMEA analysis is the risk assessment of the process impacts on the environment. The result in the form of numerical values constituting the product of three adopted values based on the description provided in Tables 5 – 7.[1]

Table 5 - *Directions to adopt the O indicator*

Possible risks for the risks of the process impact on the environment, including the exceeding of standards and scopes, the law established for the process and machine failures and technological equipment used in the process - that aff ect the environment.			
O	Occurrence		Characteristics
1	Improbale	Does not occur.	The violation of established standards and environmental ranges in a process is excluded. Stable, without the emergency operation of machinery and technological equipment.
2	Almost unbelievable	Providing an incompatible product (lack of) is almost impossible. Very high quality of the process and the ability of the machine.	Almost impossible violation of established environmental standards and ranges for the implemented process. Very high assurance that no failure of machinery and technological equipment will occur.
3	Rarely	There are shortcomings, but rarely. The high quality of the process and the capacity of the machine.	There are short duration violations of established environmental standards and scopes for implemented processes. High assurance of the absence of machinery and technological equipment failure.
4 5 6	Average	The appearance is very likely. The process has good qualitative ability, but is unstable.	The implementation of processes with established standards and environmental ranges, but there are temporary violations. A failure of machinery and technological equipment is probable or very probable.
7 8	Frequently	Frequent gaps are expected. The process is characterized by a low quality and is unstable.	The process is characterized by frequent violations of standards and environmental ranges. Frequently occurring failures of machinery and technological equipment with impact on the environment.
9 10	Very common	Error is almost unavoidable. The process is characterized by a very low capacity and the quality is unstable.	The process is often carried out at a level violating established standards and environmental ranges. Very frequently occurring breakdowns of machinery and technological equipment with impact on the environment.

Table 6 - *Directions to adopt the S indicator*

The importance of the impact of machinery and equipment failure on the environment, the continuity of the process, exceeded environmental standards and ranges of the process			
S	Significance		Characteristics
1	Extremely small	The defect of the roduct will not aff ect	Failures of machinery and equipment in the process have no impact on the

		the conditions of use. The disadvantage of the process will not aff ect in any way the quality of the product / service.	environment. No violation of environmental standards occurs.
2 3	Small	The importance of defects is small and leads only to a slight deterioration of the product. The disadvantage of the process slightly affects the quality of the product / service.	Failures of machinery and equipment are rare and have little impact on the environment, they require taking the standard methods for stabilizing the process. Shut down process is short, and does not signifi cantly aff ect the continuity of production. Violations of the environmental standards do not occur often.
4 5 6	Average	The defect of the product provides a clear dissatisfaction. The disadvantage of the process signifi cantly aff ects the quality of the product.	The increasing number of machinery and equipment breakdowns have a clear impact on the environment, and require adopting standard methods to improve stabilization. The shut down process is short, slightly aff ecting the continuity of production. Violations of the environmental standards are rare, and their impact on the environment is local (for the area of machinery, equipment).
7 8	Large	It is impossible to use the product as intended. The disadvantage of the process results in a product incompatibility.	The occurring breakdowns of machinery and equipment have a signifi cant impact on the environment, and require the use of more than just the standard methods of stabilization processes. The interrupted process seriously aff ects the continuity of production. Exceeding the environmental standards aff ects the environment around the production hall - workplace.
9 10	Very large - critical	The defect of the product endangers the safety of the user or violates the law. The disadvantage of the process can lead to the need of product repair.	The breakdowns of machinery and equipment have a large impact on the environment and people, and require the use of specialized methods to stabilize the process, including the intervention of specialized services unavailable to the company. The interruption process has a strategic level impact on the production continuity. Exceeding environmental standards aff ects the environment with an area larger than just the production hall / workplace.

__Table 7 -__ Directions to adopt the D indicator

The detection of machinery and equipment failure having an impact on the environment, as well as exceeding standards and environmental ranges in the process			
D	Detection		Characteristics
1 2	Very high	Control measures used and supervision provided make us almost certain that the product defect or disturbance of the process that the defect may cause will be detected.	The system and surveillance measures used provide almost full assurance and: • Predict the failure of machinery and equipment and its protection against the occurrence of environmental risk; • The stability of the process remains within the limits of accepted standards and environmental ranges.
3 4	High	The control measures used and supervision provide a good opportunity to detect defects in the product or a process interference .	The system and surveillance measures used provide a good opportunity to: • Predict the failure of machinery and equipment and its protection against the occurrence of environmental risk; • Detect the absence of process stability within accepted standards and environmental ranges.
5 6	Average	The control measures used and supervision provide a good opportunity to detect a fault or process interference, but they have limited ability to control it in 100% .	The system and surveillance measures used provide an opportunity to predict the failure of machinery and equipment and its protection against the occurrence of environmental risk.
7 8	Low	It is very likely that the measures of control and supervision do not detect a fault or process interference.	The system and surveillance measures used are not capable of predicting machinery and equipment failure and its protection against the occurrence of environmental risk.
9	Very low	It can be assumed with great certainty that the control measures adopted do not detect defects in the product or process interference.	The system and surveillance measures used allow for predicting the failure of machinery and equipment and its protection against the occurrence of environmental risk to a very small extent.
10	Impossible	There are no known means of control and supervision of detecting the product defect or process interference.	There are no system and surveillance measures available to predict the failures of machines and equipment and its protection against the occurrence of environmental risk.

3. Conclusions

The methodology of FMEA suggested in the paper is part of the scope of eco-management methods dedicated to manufacturing processes.

The purpose of the suggested method of FMEA is to improve both projects and the implemented manufacturing processes. It allows us to assess the environmental risk of productive processes in terms of individual operations, both involving manufacturing and transportation processes.

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