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REDUCING ERRORS IN THE SYSTEMS THROUGH FMEA

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Abstract: *There are numerous high-profile examples of product recalls resulting from poorly designed products and processes. These failures are debated in the public forum with producers, service providers and suppliers being depicted as incapable of providing a safe product. Failure Mode and Effects Analysis, or FMEA, is a methodology aimed at allowing organizations to anticipate failure during the design stage by identifying all of the possible failures in a design or production process. This article consists of three basic parts. First part deals with description of FMEA methodology and there are division of FMEA into the main categories. Second part is about FMEA procedure, while there is concretely defined seven steps that are important in FMEA methodology. In the third part you can find description of FMEA criticality matrix, while there are three critical coefficients, namely severity, detection, occurrence.*

Key words: FMEA methodology, FMEA procedure, FMEA criticality matrix, severity, detection, occurrence

1 INTRODUCTION

Nowadays, each production company tries to achieve the best results and deliver the highest quality products to its customers [1, 3, 13]. Of course, the better the product is, the greater quantity of pieces produced customer demands. If the company wants to achieve it, it needs clever people and the well-established processes in the production lines. Time goes forward and technology also [4, 5, 12]. Thus, in some cases, in companies, an automatic robot replaces the work of a person [6, 7, 14].

As in any activity, some errors occur in the production process that reduce the efficiency of the production process [10 ,11]. In order to identify these errors and subsequently remove these errors, FMEA is one of the most popular and most effective methods.

2 DESCRIPTION OF FMEA

"Failure Mode and Effects Analysis" (FMEA) is a system approach to detecting potential failures or errors that may arise in the design of a product or process.

It is a method, by which it is possible to prevent or reduce the risks that arise [2]:

- By building a management system.
- By product development and construction.
- By preparation of new technologies.
- By process development,
- By preparation of the production itself.

Error modes are ways, in which the process can fail. Effects are ways, in which these deficiencies can lead to waste, errors or harmful results for the customer. Analogue of faults and effects is designed to identify, prioritize and limit these failure modes.

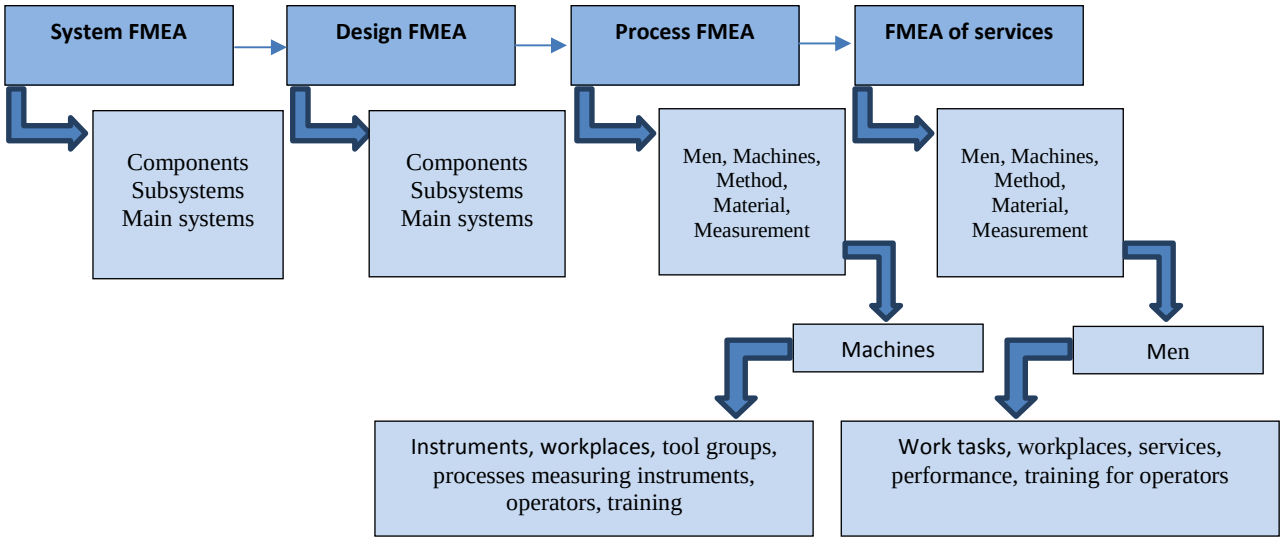

Figure 1 Basic FMEA groups [9]

FMEA is not a substitute for quality engineering. Rather, it improves high-quality engineering by using the knowledge and experience of the crisis functional team to review product development or process by evaluation its risk or failure. There are two broad categories of FMEA [8]:

1. Design FMEA (DFMEA) – explores the potential of product defects, reduction of product life, and safety and regulatory concerns arising from the:
   - Material properties.
   - Geometry.
   - Tolerance.
   - Interface with other components and/or systems.

2. Process FMEA (PFMEA) – identifies defects that affect product quality, process reliability, customer dissatisfaction, and safety or environmental hazards resulting from:
   - Human factors.
   - Used tools.
   - Process methods.
   - Measuring systems.

There are four basic FMEA groups (Fig. 1):

1. System FMEA.
2. Deign FMEA.
3. Process FMEA,
4. FMEA of services.

Historically, the sooner the failure occurs, the less funds will be necessary to eliminate the defect. If the error in the development or launch of the product is discovered late, the impact on production itself is more devastating. FMEA is one of many tools used to detect a failure at the earliest possible design stage of the product or process. This fact brings some benefits, such as:

- More options for reducing risk.
- Higher ability to verify changes,
- Cooperation between product design and process,
- Improved design for production and assembly,
- Lower cost of solution.

Ultimately, this methodology is effective in identifying and correcting process defects in a timely manner to avoid an unpleasant result of poor performance.

3 FMEA PROCEDURE

The FMEA performs in seven steps with key activities at every step of the process. Steps are separated to ensure that only the appropriate team members are present for each step. FMEA approach, which uses "Quality-One" company, has been developed to avoid typical traps that make analysis slow and inefficient.

There are seven steps to developing the FMEA [2, 8]:

1. FMEA is pre-working and assembling the FMEA team.
2. Development of path 1 (requirements according to severity assessment).
3. Development of path 2 (potential causes and control of prevention according to order of occurrence).
4. Development of path 3 (testing and detection controls through detection assessment).
5. Priority action and assignment (RPN).
6. Measures adopted/Design review.
7. Re-ranking RPN and closure.

1. FMEA is pre-working and assembling the FMEA team.
   Preparing for work involves collecting and creating of key documents. The FMEA works without problems during the development phases when an investigation of past failures and preparatory documents is carried out from the start of the survey. Preparatory documents may include:
   - Eight problem-solving disciplines (8D).
   - Boundary/Block Diagram (for DFMEA).
   - Parameter diagram.
   - Flow diagram of processes.
   - Matrix characteristics.

   A checklist is recommended for an effective FMEA event.

2. Development of path 1 (requirements according to severity assessment).
   Path 1 consists of insertion of functions, failure modes, consequences of failure, and severity assessments. The pre-work documents assist in this role by removing the information that were previously captured to fill in the first few columns (according to the selected worksheet) of the FMEA. Functions should be written in the context of a verb. Each feature may include:
   - Needs and desires.
   - Design specifications.
   - Government regulations.
   - Program-specific requirements.
   - The properties of the product that will be analysed.
   - Required process outputs.

3. Development of path 2 (potential causes and control of prevention according to order of occurrence).
   The causes are selected from design/process inputs or previous failures and are placed in the Case column when used for a particular fault mode. The columns in path 2 are:
   - Potential causes / mechanisms of failure.

- Current prevention checks (i.e. standard work, previously successful proposals, etc.).
- Occurrence, respectively ranking for each cause.
- classification of special properties, if indicated.
- Actions are developed to solve high-risk combinations of severity and occurrence defined in the critical quality matrix.

4. Development of path 3 (testing and detection controls through detection assessment).
   Path 3 development involves the addition of detection controls that verify whether the design meet the requirements (for FMEA Design) or fault mode. If unchecked, it can reach the customer (for the FMEA process). The columns in path 3 are:

   - Detection controls.
   - Detection order.
   - Measures are determined to improve controls if they are not sufficient for the risks identified in path 1 and path 2. The recommended activities should address the weaknesses in the testing and/or control strategy.
   - Examining and updating the design and management (R & D) verification plan or control plans are also possible outcomes of path 3.

5. Priority action and assignment (RPN).
   FMEA evaluates each process step and assigns scores on a scale of 1 to 10 for the following variables:

   - Severity – assesses the impact of the fault mode (process error), where 1 represents the smallest safety risk and 10 represents the highest safety risk. In most cases, processes with a degree of severity greater than 8 may require a fault tree analysis that estimates the probability of a failure mode by dividing it into other partial elements.
   - Occurrence – evaluates the possibility of occurrence of failure with 1 representing the lowest occurrence and 10 representing the highest occurrence. For example, a score of 1 may be attributed to a failure occurring once in 5 years, whereas a score of 10 may be attributed to a failure occurring once per hour, once per minute, etc.
   - Detection – evaluates the possibility of detecting a failure, where 1 represents the highest chance of detection and 10 represents the smallest chance of detection.

   RPN (risk priority number) = Severity x Occurrence x Detection (1).
   Regarding the rule, any RPN exceeding 80, requires a corrective action. The corrective action ideally leads to a lower RPN.

6. Measures adopted/Design review.
   FMEA shares are closed when counter measures have been taken and are successful in reducing risk. The purpose of the FMEA is to identify and reduce the risk. FMEAs that don´t find the risk are considered as weak and without added value. The team's effort didn´t produce improvement, so the time was wated in the analysis.

7. Re-ranking RPN and closure.
   After successful confirmation of risk reduction actions, the core team or team leader will re-rank the appropriate rating value (severity, occurrence, or detection). The new order will be multiplied to achieve a new RPN. The original RPN is compared to the revised RPN and the relative improvement of the design or process has been confirmed. Points associated with RPN reassignment may result in:

   - Re-ranked severity.
   - Re-ranked events.
   - Re-ranked detection.
   - Re-ranked RPN.
   - Created new actions, repeating step 5 until risk has been reduced.
   - Comparison of initial RPN and revised RPN.

4 FMEA CRITICALITY MATRIX

If the risk is considered as unacceptable, "Quality-One" company recommends that it is important to apply the priority of the action as follows [8]:

1. Error message (remove fault mode or address cause).
2. Fault mode (9 or 10 severity only).
3. Causes with high occurrence.
4. Improvement the potential of processes.
5. Increasing the tolerance (tolerance design).
6. Decreasing process deviations (statistical process control and process capability).
7. Improvement of controls.

FMEA relationship to problems solving

Fault modes in FMEA are equivalent to a statement about a problem or a description of a problem by solving problem. Causes in FMEA are equivalent to potential causes for problem solving. Failure effects in FMEA are problematic by problems solving. Other examples of this relationship are:

- Problem statements and descriptions are linked between both documents. Problem solving methods will be completed more quickly using localized, pre-brainstormed FMEA information.
- The possible causes in FMEA are immediately used to jump at the beginning of the Fishbone or Ishikawa diagrams.
- Data obtained from problems solving will be placed in the FMEA for future product or

process planning. This allows the FMEA to consider real failures, categorized as faults and causes, which will make the FMEA more efficient and complete.

- FMEA and problems solving combine each failure and cause cross-documentation of faults, problem reports, and possible causes.

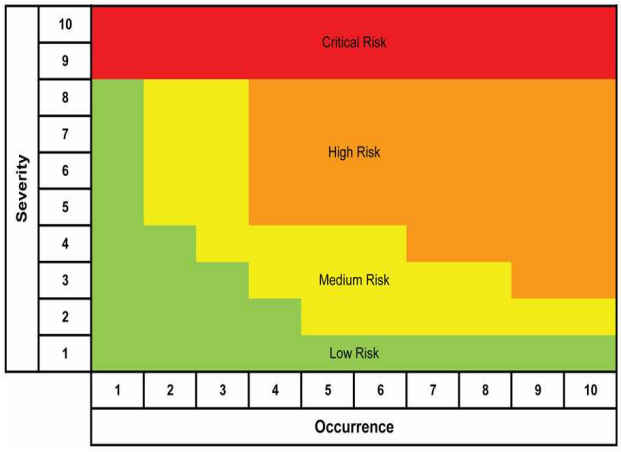

Figure 2 FMEA criticality matrix [8]

FMEA criticality matrix with the visualisation of individual zones (low risk, medium risk, high risk, critical risk) is shown in Fig. 2.

Table 1 shows the severity coefficients used in RPN calculations.

Table 2 describes detection coefficients used in RPN calculations.

Table 3 describes the severity or probability of a process failure and the possible occurrence of accidents.

Table 1 Severity coefficients [2, 8]

Effect	Criteria: Severity of effect on the product (Customer effect)	Value	Effect	Criteria: Severity of effect on the process (Product effect)
Failure to meet regulatory and safety requirements	Potential failure mode affects the safe operation of the vehicle and includes failure to comply with control unit without warning.	10	**Failure to meet regulatory and safety requirements**	It may endanger the operator (without warning).
	Potential failure mode affects the safe operation of the vehicle and includes failure to comply with control unit without warning.	9		It may endanger the operator (with warning).
Loss or degradation of primary function	Loss of primary function (immobile vehicle, not safe driving with the vehicle).	8	**Main disruption**	100% of the product becomes scrap. The line turns off or stops ship.
	Primary function degradation (mobile vehicle but reduced performance level).	7	**Significant disruption**	Part of production can be scrapped. Difference from the main process involves a reduction in line speed or manpower.
Loss or degradation of secondary function	Loss of secondary function (mobile vehicle, comfort zones not working).	6	**Moderate disruption**	100% of production must be reworked and returned back to production.
	Secondary function degradation (mobile vehicle, but reduced performance level of comfort zone).	5		Part of production must be reworked and re-released again into production.
Annoyance	Appearance or audible noise, mobile vehicle, not suitable for most customers (> 75%).	4	**Moderate disruption**	100% of production must be reworked at the pre-process station.
	Appearance or audible noise, mobile vehicle, not suitable for many customers (> 50%).	3		The part of the production must be reworked in the pre-process station.
	Appearance or audible noise, mobile vehicle, not suitable for minor group of customers (> 25%).	2	**Minor disruption**	Slight disruption of the process, operation, or operator.
No effect	No recognizable effect	1	**No effect**	No recognizable effect

Table 2 Detection coefficients [2, 8]

Opportunity for Detection	Criteria: Probability of detection by production control	Value	Probability of detection	Criteria: Severity of the effect on the process (effect on production)
No possibility of finding	No current control. It can´t be detected or analysed.	**10**	**Almost impossible**	It may endanger the operator (without warning).
Improbable to find out at any stage	The occurrence of errors or mistakes (causes) can´t be easily detected (e.g. random audits).	**9**	**Very slight**	It may endanger the operator (with warning).
Detection of production problem	Detection of errors by operators through visual, touch or audio means.	**8**	**Slight**	100% of the product becomes scrap. The line turns off or stops ship.
Detection of source problem	Detection of errors in the station by operators via visual, touch or audio means or measurement of attributes after the production process (manual torque check).	**7**	**Very low**	Part of production can be scrapped. Difference from the main process involves a reduction in line speed or human strength.
Detection of production problem	Detection of errors by operators by visual, touch or audio means or measurement of attributes in the station (manual torque check).	**6**	**Low**	100% of production must be reworked and released back to production process.
Detection of source problem	Detection the occurrence of errors (causes) in the operator station by using various measurements or automated checks at a station that detects an inoperable part and tells it the operator (light, signal, etc.) Measurements is made by setting and checking the first piece.	**5**	**Medium**	Part of production must be reworked and re-released back to production process.
Detection of production problem	Detection of errors in the station by automatic check where an inoperable part is detected and this part is then locked to prevent further production.	**4**	**Medium-high**	100% of production must be reworked at the pre-process station.
Detection of source problem	Occurrence detection of errors after the process by automatic check where an inoperable part is detected and this part is then locked to prevent further production.	**3**	**High**	The part of the production must be reworked in the pre-process station.
Wrong prevention or prevention problem	Detection of mistakes in the station by automatic checks that detect errors and prevent the production of an inoperable part.	**2**	**Very high**	Slightly disruption of the process, operation, or operator.
Detection not applicable Wrong Prevention	Prevention of errors (causes) as a result of the design of the clamping elements, design of the stand or the design of the parts. Inoperable parts can´t be produced because the item has been examined for the possibility of error through theproduction process.	**1**	**Almost certain**	No recognizable effect.

Table 3 Occurrence coefficient [2, 8]

Probability of failure	Criteria: Cause of occurrence - PFMEA (Accidents by item / vehicles)	Value
Very high	100 out of a thousand 1 out of 10	10
High	50 out of thousands 1 of 50	9
	20 out of thousands 1 of 50	8
	10 out of thousands 1 out of 100	7
Medium	2 out of thousands 1 out of 500	6
	0.5 out of thousands 1 of 2000	5
	0.1 out of thousands 1 out of 10 000	4
Low	0.01 out of thousands 1 out of 100 000	3
	0.001 of thousands 1 out of 1,000,000	2
Very low	Failure excluded by preventive control	1

From these tables (Table 1 – Table 3), RPN values are subtracted. In each table, the criterion given by the number is explained separately and how high risk it is for a given production or production line. Criteria are also determined from the customer's point of view, respectively what risk can occur when delivering the product to a customer.

As a result of the FMEA, effective corrective action is taken to reduce the risk of error.

5 CONCLUSION

FMEA method is very good, and in many companies, it still underestimates the preventive tool to identify potential problems and determine their level of risk.

FMEA is a very good basic for effective setup of control activities throughout the product implementation process.

FMEA also has a financial benefit. Costs to solve problems before they occur are often much lower than the costs of solving problems after their occurrence. Especially if the company produce large series of products, a major defect may occur.

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