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FMEA METHOD IN PROCESS QUALITY MANAGEMENT

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Abstract

In this paper, the subject of analysis is the FMEA method in quality management. Quality management enables companies to continuously improve their products, processes and systems. The FMEA tool enables organizations to identify potential problems in a system, product or process before they occur. By proactively assessing the potential consequences and severity of these issues, mitigation strategies can be developed to reduce risk and improve overall business efficiency. In order to show the importance of the method, an example of a concrete application of this method will be presented.

Keywords: FMEA method, RPN, quality management, errors, process improvement.

INTRODUCTION

Failure mode and effects analysis (FMEA) is a powerful risk management tool. It originated in the aerospace industry in the 1960s and since then it has been used in various industries. The FMEA tool enables organizations to identify potential system, product or process failures before they occur. By proactively assessing the potential consequences and severity of these failures, mitigation strategies can be developed to reduce risk and improve overall business efficiency [1, 2]. FMEA is very important in the early phase of the project life cycle. By systematically predicting potential errors at each stage of product development or project execution, FMEA provides a clear framework for identifying vulnerabilities before they manifest as costly errors.

FMEA AREAS

FMEA is divided into different areas depending on the time of application and the affected object [3, 4].

FMEA design. Construction or design FMEA (construction mode and effects analysis) is a sub-area of FMEA that examines a specific product. It is used as part of the development, design and planning of new products and takes place especially in the early stages of product planning.

The goal of the FMEA project is to develop measures that contribute to reliability, safety and availability. An interdisciplinary team with participants from all involved departments conducts the FMEA. The basic points of the analysis are: reliability, functionality, geometry, material selection, manufacturability, testability and usability.

The FMEA process. Process FMEA is a subfield of FMEA that deals with the investigation of a specific process. Process FMEA triggers can be, for example, new designs, technologies or processes, a change in an existing process or also the application of a process in a new area. It especially applies to the areas of production, assembly and testing. The FMEA process is performed as part of the production planning phase and aims to create a smooth process. For this purpose, all factors that could prevent or complicate such a flawless flow of the process are identified. In the FMEA process, the entire chain of actions with all impacts is considered. It takes into account the production process with suitability and safety factors, as well as the quality capability and stability of the process and

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the determination of process control characteristics.

The FMEA system. System FMEA (also: system analysis) is intended to examine the system as a whole and verify that all individual components within it are operating in a functionally correct manner. From the analysis, measures can be derived, the implementation of which aims to increase the security, reliability and availability of the system. So-called error sequences describe how the system behaves when an error condition occurs. This requires initial information that can be taken, for example, from the requirements specification or from quality planning via the application of the quality function.

THE PROCEDURE OF FMEA

FMEA has two parts [5,6]:

1) failure modes or problems or errors that occur within processes, products or services,
2) analysis of effects refers to the part where the effects or consequences of failures are determined and analyzed.

The steps in performing the FMEA method are given in folowing text [7, 8].

Step 1: *Determine what needs to be solved.* Is there a new process that has yet to be implemented and needs to be reviewed to proactively prevent problems that may arise? Which business segment is problematic? Determine which process, system, metric, or aspect of the business to focus on.

Step 2: *Create a cross-functional FMEA team.* Build a team composed of members who are familiar with the aspect of the business to be worked on. FMEA team members, led by a coordinator, can work together to identify issues that need to be addressed.

Step 3: *Establish a process, system or steps.* Outline the entire process, system, or steps involved in the problematic aspect of the business that needs to be worked on. Create a flowchart that clearly shows and describes the entire process to all team members.

Step 4: *Analyze each step and identify problem areas.* Check each step in the process and identify areas where problems occur or could occur (failure modes). Make a list of all the problems from the failure analysis and clearly describe each of them.

Step 5: *Choose which issues to give priority.* From the list of problems or failure modes, determine which problems should be prioritized by calculating the FMEA Risk Priority Number (RPN). Determine a score of 1-5 for severity, occurrence and detection and multiply them by each other. Do this risk analysis for all items on the list. The top RPN should help decide which problem to prioritize.

Step 6: *Apply changes.* After we determine which problem should be prioritized based on the RPN, implement changes that would eliminate or reduce the occurrence or impact of those problems.

Step 7: *Track implementation of changes and measure their effectiveness.* It is necessary to make sure that the changes were really implemented and that they had a positive impact on the business. Measure their impact by tracking the process, system or steps where the changes have taken place and check if the desired result has been achieved.

In general, FMEA the process typically follows the following steps [9, 10].

Preparation and Planning: Define the scope and objectives of the FMEA. Assemble a multi-functional team with diverse expertise.

Structure analysis: Break down the production process into individual steps or components. Create a detailed process flow diagram.

Failure Mode Identification: Identify potential failure modes for each process step. Consider what could go wrong, and the potential causes of these failures.

Risk assessment: Assess the severity (S) of the impact of each failure mode. Determine the probability of occurrence (O) for each failure mode. Assess the ability of detection (D) to detect a defect before it reaches the customer. Calculate the Risk Priority Number (RPN) for each failure mode (RPN = S × O × D).

Risk Mitigation: Prioritize failure modes based on their RPN. Determine responsibility and deadlines for corrective actions.

Monitoring and review: Monitoring the effectiveness of implemented actions. Periodically re-evaluate the FMEA to ensure continued relevance and accuracy. Table 1 shows a typical format/table of the method. The remaining steps include the information that will go into the form columns.

In the following practical example, FMEA is focused on occupational safety, environmental protection and quality management risk assessment in construction, which is based on three aspects, including "failure occurrence" (indicating the risk/probability that a failure mode will occur as a result of a particular cause) , "severity" (refers to the assessment of the severity of the effect of a potential failure in the process when it has occurred), and "detection" (refers to the probability that the potential failure will be detected). An explanation of failure occurrence, severity and detection of occupational health, quality and environmental risks is given in Table 2 [16]. It is necessary for FMEA experts to specify potential risks according to the characteristics of the specified construction phase and the studied construction site. Eight potential risks category were identified, with their risk factors including falls from roofs and roof structures, electric shock, holes in floors, accidents with construction debris, elevator accidents, fires and explosions (Table 3).

To assess the risk of OHS, environment and quality, a five-point Likert-type scale is used, in which "5" represents the greatest possible occurrence (the most serious in terms of severity and the most noticeable), and 1 the least. FMEA team members were asked to submit their scales for assessing the occurrence, severity and detection of potential risks, which were averaged to calculate the RPN. The results are shown in table 2. Based on the RPN calculated based on the occurrence, severity and detection of potential risks, a certain risk is evaluated and its acceptability determined. Risk acceptability is classified into four scenarios, including acceptable, moderate, undesirable and unacceptable (Table 4).

In the identification of factors that are at risk of product failures, an analysis is performed based on the risk priority number (RPN) obtained by multiplying three risk factors, namely: Occurrence (O) or probability of failure, Severity (S) or severity of failure and detection (D) or the capacity to detect failure before failure occurs (RPN = O x S x D). In order to calculate the RPN, these three factors should be assessed using predefined scales. FMEA prioritizes failure modes based on the assumption that the higher the RPN of the failure mode, the greater the risk of product failure as well as poor quality. With highest results of RPN are risk factors received roof related falls (RPN = 46.62), hits by falling objects (RPN = 39.2) and holes in the floors at the construction site (RPN = 33.32), and so on. This clearly indicates the fact which problem should be given priority.

Table 1. FMEA table [12]

List of improvement plans	List of Failure Mode	Likelihood of Occurrence (1-5)	Likelihood of Detection (1-5)	Severity (1-5)	Risk Priority Number (RPN)
1	Failure Mode #1	3	2	4	
2	Failure Mode #2	1	5	3	
3	Failure Mode #3	2	2	4	
4	Failure Mode #4	4	1	3	
					Total RPN = (n)

Table 2. Explanation of the occurrence, severity and detection of potential risks [16]

Failure occurrence	OHS risk	Environmental risks	Quality risks
Occurrence	Probability of accidents and dangerous events on OHS	Probability of hazardous events for the environment	Probability of failure in quality
Severity	Severity of impact of accidents and hazardous events on OHS	The severity of the impact of hazardous events on the environment	The severity of the failure's impact on quality
Detection	The likelihood that accidents and hazardous events at OHS will be detected	Probability that environmentally hazardous events will be detected	The likelihood that a quality defect will be detected

Table 3. Risk assessment for OHS, environment and quality in construction

Risk category	Risk factors	The source of the risk	Occurrence (O)	Severity (S)	Detection (D)	RPN
Electricity	Risk of electric shock.	Defective electrical equipment and electrical connections	1.5	2.6	1.7	6.63
Environmental damage	Dust, noise, vibrations	The lack of personal protective equipment	3.5	0.4	4.3	6.02
	Waste	The lack of a technical guide.	3.5	0.4	4.0	5.6
	Toxins and suffocation	Use of materials that are not environmentally acceptable or lack of personal protective equipment.	2.2	0.8	3.6	6.34
Fall of part of the object/load	Roof related falls	Skylight falls, falls from roof structures, falls through existing openings and other hazards.	3.7	4.2	3.0	46.62
	The crane falls on the construction site	Operators can fall from great heights from their cranes, and cranes can lose their balance and overturn, resulting in many injuries.	1.8	4.3	2.1	16.25
	Unsafe scaffolding	Scaffolding falls can occur due to the lack of necessary protective measures	2.3	3.5	2.1	16.9
	The elevator shaft falls	The elevators in the floors are not properly marked.	1.8	4.5	3.0	24.3
	Holes in the floors at the construction site	The holes in the floors are not properly marked.	3.5	2.8	3.4	33.32
Falling objects	Hit by falling objects	The result of workers' poor safety awareness.	3.3	3.6	3.3	39.2
Fires and explosions	An explosion of compressed gas	Improper operation	0.8	3.9	1.1	3.43
	Welding accidents	It can be caused by welding fumes, UV light, sparks, etc.	1.3	1.5	1.7	3.32
The structure	Failure of the structure	The structure breaks because it cannot carry as much load as it could before the failure.	0.6	4.5	2.5	6.75
	Structure collapse	Poor design, faulty construction, foundation failure, extreme loading, unexpected failure or any combination of these causes.	0.5	3.5	3.7	6.48
Use of equipment	Crane related accidents	Lightning, strong winds, faulty cranes, falls and electric shock.	0.5	3.2	3.6	5.76

Risk category	Risk factors	The source of the risk	Occurrence (O)	Severity (S)	Detection (D)	RPN
	Accidents related to scaffolding	Improper placement of planks or loosening of supports or workers slipping or being struck by falling objects.	1.2	3.5	2.8	11.76
	Trampled by work equipment	Lack of rigorous application of safety regulations.	1.9	4.3	3.4	27.78
	Accidents due to excavation	Lack of rigorous application of safety regulations or	2.2	4.1	3.2	28.86
Engine use	Accidents related to cutting and nail gun	The result of reckless operations.	3.8	1.5	2.6	14.82
	Accidents on the compressor	Inadequate training, faulty safety practices and poor compressor quality.	1.7	2.9	2.2	10.85

Table 4. Degree of risk for OHS, environment and quality in construction

Degree of risk	Consequence	RPN	Acceptability
V	Disastrous	25< RPN	Unacceptable
IV	Critical	6<RPN≤25	Undesirable
III	Significantly	2.5<RPN≤6	Moderate
II	Little importance	1<RPN≤2.5	Acceptable
I	Insignificant	1	

CONCLUSION

Failures are prioritized according to how serious their consequences are, how often they occur, and how easily they can be detected. The purpose of FMEA is to take actions to eliminate or reduce failures, starting with those with the highest priority. Failure mode and effect analysis also documents current knowledge and actions on failure risks, for use in continuous improvement. FMEA is used during design to prevent failures. Later it is used for control, before and during the ongoing operation of the process. Ideally, FMEA begins during the earliest conceptual stages of design and continues throughout the life of the product or service.

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REFERENCE

[1] Cahyono, A., Titisari, M. A., & Rusdiyantoro. (2023). Aplication of the FMEA method in determining improvement priorities in the product quality system at Company X , Scientia, 12(02), 1218-1224.

[2] Chin-Keng, T. (2011). Study of Quality Management in Construction Projects, Chinese Business Review, 10(7).

[3] Claxton, K., & Campbell-Allen, N. M. (2017). Failure modes effects analysis (FMEA) for review of a diagnostic genetic laboratory process. International journal of quality & reliability management, 34(2), 265-277.

[4] Dudek-Burlikowska, M. (2011). Application of FMEA method in enterprise focused on quality. Journal of achievements in Materials and Manufacturing Engineering, 45(1), 89-102.

[5] Hellingsworth, B., Hall, P., Anderson, H. (2020). Quality management principles, Higher National Computing.

[6] Ivkovic, B., Popovic, Z. (2005). Project management in construction, Construction book.

[7] Kania, A., Cesarz-Andraczke, K., & Odrobiński, J. (2018). Application of

FMEA method for an analysis of selected production process. Journal of Achievements in materials and manufacturing Engineering, 91(1), 34-40.
[8] Mosadeghrad, A. M. (2012). Towards a theory of quality management: an integration of strategic management, quality management and project management, International Journal of Modelling in Operations Management, 2(1).
[9] Paciarotti, C., Mazzuto, G., & D’ettorre, D. (2014). A revised FMEA application to the quality control management. International Journal of Quality & Reliability Management, 31(7), 788-810.
[10] Pop C., Frunză, G., Ciobanu, M.M. (2019). STUDY REGARDING APPLICATION OF THE FMEA METHOD WITHIN A FOOD SAFETY MANAGEMENT SYSTEM, Scientific Papers-Animal Science Series: Lucrări Ştiinţifice - Seria Zootehnie, vol. 71.
[11] Rose, K. (2005). Project quality management: why, what and how. J. Ross Pub.
[12] Sai X. Zeng, Chun M. Tam, Vivian W. Y. Tam. (2010). Integrating Safety, Environmental and Quality Risks for Project Management Using a FMEA Method, Inzinerine Ekonomika-Engineering Economics 21(1).
[13] Sharma, K. D., & Srivastava, S. (2018). Failure mode and effect analysis (FMEA) implementation: a literature review. J Adv Res Aeronaut Space Sci, 5(1-2), 1-17.
[14] Wolniak, R. (2019). Problems of use of FMEA method in industrial enterprise. Production engineering archives, 23(23), 12-17.
[15] Wu, Z., Liu, W., & Nie, W. (2021). Literature review and prospect of the development and application of FMEA in manufacturing industry. The International Journal of Advanced Manufacturing Technology, 112, 1409-1436.
[16] Zeng, S. X., Tam, C. M., & Tam, V. W. (2010). Integrating safety, environmental and quality risks for project management using a FMEA method. Engineering Economics, 66(1).