

THE USE OF QUALITY MANAGEMENT METHODS AND TECHNIQUES

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Abstract

This research aims to present various methods and techniques for improving business processes through proactive management. The contemporary approach to process management requires a rapid response to enhance or halt the production process, with quality control emerging as an operational activity primarily focused on process improvement, rather than merely an activity that monitors the current state. For manufacturers to meet consumer expectations, they must adjust the design of the production process, the performance of machines, acquire necessary equipment and technology, use appropriate materials, ensure skilled workers with continuous training and supervision, all while applying Total Quality Management (TQM). Process management, as a key factor in customer acquisition, involves a continuous search for the best technical, technological, marketing, and other improvements. To achieve this, all phases of the process—from the input elements of production and the production process to the creation of the new product—are controlled.

The central question addressed in this paper is: How can methods such as Failure Mode and Effect Analysis (FMEA) and other approaches be optimally applied to eliminate errors in industrial processes to improve quality and productivity?

The aim of this paper is not only to analyze the application of FMEA but also to identify the most effective strategies for implementation, best practices, and possible improvements in business processes.

Key words: management, quality, optimization, business processes, improvement.

JEL Classification: O32 Management of Technological Innovation and R&D

INTRODUCTION

Organizations are constantly faced with changes in the market, ownership changes, and societal changes. Due to the process of globalization and regionalization of the market, companies must think more urgently about strengthening their competitiveness. Macedonian enterprises have yet to realize that a competitive position is achieved only through continuous improvement of product/service quality to meet the needs of customers. The path to the advancement of domestic enterprises must be sought in embracing new philosophies, appropriately utilizing new strategies, concepts, and knowledge. Changes in the environment and within the organizations, on one hand, and the growth and development of the organization, on the other, can be complementary factors if a dynamic process of internal changes is established within the organization, providing responses to external changes and ensuring market competitiveness for the organization. This process of internal changes, which provides effective responses to external changes, is embedded in the new Total Quality Management (TQM) strategy. To adopt the new TQM philosophy, it is necessary to change the existing culture, a process that sometimes occurs very successfully (although it requires significant energy and time), and sometimes only leads to the adjustment of the existing culture (Mitreva, 2011).

The movement for Total Quality Management (TQM) is based on the understanding that quality is not created where the product is controlled but is created within business processes, in all organizational units of the enterprise, and therefore must be controlled

everywhere. In this way, the quality of the product is the responsibility of not only the Production Department but also the Procurement Department for raw materials and spare parts, energy, machines, machine maintenance, the Commercial Department for concluding sales contracts, the Development Department, Marketing, Sales, Packaging, etc. With this strategy, control goes beyond the production department and expands throughout all areas of the organization, and quality takes on new dimensions—not only product quality but also the quality of operations and the organization of operations (Dervitsiotis, 2000).

The message of this strategy is: “Do not control quality to remove the error, but to remove the cause so the error does not repeat. A repeated error is shameful.” Control deals with consequences, while management deals with causes (Campanella, 1999).

Proactive work begins with the analysis of business organization, then continues through the analysis of internal and external customer requirements, and ends with a detailed definition of the process. The everyday practice of each employee should not only be control in their work but employees must be trained to act preventively and not be preoccupied with detection; they must be empowered to correct their own mistakes and to report any quality-related problems they discover (Sasaoka, 1995).

Designing a Total Quality Management system in its development sets the following requirements (Mitрева, et al., 2019):

- Achieving the highest quality.
- Involving the greatest number of employees in achieving quality.
- More efficient, more rational, and more economical control.

In this way, a comprehensive approach to quality is created, but this process is a long-term effort, an obligation of top management, and a self-reliance to fulfill these obligations. One of the first steps for the implementation of this strategy is the reengineering of business processes. Organizations reengineer business processes to improve quality, productivity, and efficiency. When vital business processes are reengineered, new ways of managing and controlling are required. Similar to quality management, the essence of reengineering is the improvement of business processes through radical redesign, the use of new technologies, and motivating all employees to apply them. This paper presents methods and techniques for process management within the industry and provides examples for evaluating them in real conditions. A review of literature on methods for error elimination in industry follows.

LITERATURE REVIEW

The role and significance of methods and techniques for quality, as well as activities for quality improvement, are emphasized in the ISO 9004-4 standard, noting that the application of any of these methods will lead to significant improvements in business processes, products/services quality (Mitрева, et al., 2008; Kratsu, 1995; Fahy, 2002).

The evolution of defect removal methods in the industry has been shaped by the need for increased efficiency, reduced costs, and improved quality. Historically, manufacturers relied on inspection-based approaches, but over time, various methodologies were developed, each designed to identify, analyze, and eliminate defects in the production process. These techniques are typically classified into two categories: proactive and reactive methods. While proactive methods focus on preventing defects before they arise, reactive methods address defects once they occur. The management team in an enterprise, with their persistence and goodwill, should involve all human resources, forming teams from different profiles and integrating their knowledge, in order to fully master quality in all business processes at the lowest operating costs. This will enable the timely prevention of possible defects, prompt resolution of problems, and elimination of root causes. The usual resistance and fear of

change are quickly overcome, and a strong desire for change in the existing situation is born, with a new approach to quality and full commitment to the client, employees, the environment, and the state (Mitreva, et al., 2019; Luburić, 2014; Heleta, 2010).

An analysis conducted in enterprises engaged in the metalworking industry in the United Kingdom shows that the main reasons why companies do not apply quality methods and techniques are ignorance and lack of experience in their application. However, the most common issue lies in the definition and proper application of these methods (Parashar and Singh, 2005; Ojwaka, 1999).

Stoiljković and others (2009) emphasize that the development of quality methods and techniques began with the emergence of the first elements of statistical theory in inspection. They cite the example of the well-known company Lucas Engineering & Systems, where three out of thirteen key principles for the development, application, and success of the total quality management strategy are related to quality methods and techniques, confirming their significant role. According to the authors, the benefits of applying these methods in organizations include:

- Raising the quality of all business processes in the organization;
- Reducing all types of costs;
- Lowering the price of products;
- Building trust with customers/users;
- Raising employee knowledge.

According to these authors, applying these methods and techniques results in increased motivation among employees, higher productivity, market expansion, and other positive effects.

An analysis of the application of quality methods and techniques in automotive parts manufacturers by Sugiyama (1996) reveals the following benefits:

- Achieving competitive products that meet the quality required by customers/users;
- Reducing costs;
- Improving the skills and knowledge of employees;
- Possibility to transfer knowledge and experience to contractors and suppliers in applying quality tools;
- Increasing process efficiency.

Jayaram and others (1997) conducted research in Brock and Brock with about 50 quality methods and techniques, proposing 26 methods for application. They cite the view of Modaress and Ansari, based on empirical research into causes of errors, omissions, and defects in American companies, where quality methods and techniques are considered a necessity in all business processes within the quality system (Jayaram, et al., 1997).

Lascelles and Dale (1991), in their research based on data from the UK motor industry, emphasize that the application of quality methods and techniques is a key tool for implementing quality improvement activities and creating competitive advantages for the enterprise.

Groenendijk and Dopheide (2003) distinguish 98 methods and techniques for quality that can be applied in the global industry for quality improvement, but many of them do not have practical application.

Analyzing the methods and techniques for quality represented in the series of ISO standards, as well as those analyzed by various authors, an optimal number (about 30) has been reached that have a wide range of applications in industrial practice.

APPLICATION OF SIGNIFICANT QUALITY METHODS AND TECHNIQUES

The process-oriented organization places the greatest emphasis on organizing processes to increase efficiency, which also leads to improved business results. Proper management of business processes provides the best picture of the quality of the company's operations, as it accelerates the process of implementing the business strategy and enables the achievement of business goals at the highest level of satisfaction for the organization's top management.

Processes are described through Standard Operating Procedures (SOP) and guidelines, which can be presented through Flowcharts or block diagrams, in which the Deming Circle, based on a circular flow, is integrated: Plan-Do-Check-Act, and the CE (Cause and Effect) approach, or the QC-CE model. When writing documents, changes in form and content lead to changes in the organizational structure, reengineering of business processes, all to adapt the company to new requirements. These changes primarily relate to new ways of grouping organizational units, delegating tasks and responsibilities, coordination, and communication.

What does applying the QC-CE model in designing business processes mean?

For effective use of the quality system, it is essential to build and use appropriate methods. A starting methodology for designing the quality system is the combination of the QC concept (Quality Circle) and the CE approach (Cause and Effect). The foundation of the QC concept is Deming's Circle, whose philosophy is based on the circular flow: Plan-Do-Check-Act (Чепујноска, 2009).

Each of the four steps in the PDCA cycle includes:

- Plan
 - = setting goals and intentions;
 - = determining methods to achieve the goals;
 - = utilizing resources.
- Do
 - = education and ability to implement the plan;
 - = implementation of the plan.
- Check
 - = comparison of the realized with the planned.
- Improve - Act
 - = reassessment of the results of the check;
 - = proposing measures for improvement.

Each activity must be carefully planned. The activity should be carried out in this manner, and the results should be checked to see if they match expectations. If not, corrective actions must be taken and incorporated into the first activity—planning. The cycle then starts again.

The basis of the QC concept is *Deming's Circle*, and the CE approach (Cause and Effect) is best suited to encompass all elements and factors essential for performing each task in the system. The CE diagram (Cause-Effect) allows consideration of all influences on task execution, including: What? Who? When? How? Where? To whom? (Чепујноска, et al. 2008; Mitreva, 2011).

Methods for quality improvement include: concepts, techniques, methods, studies, tools, or all efforts directed toward improving quality (Pareto Diagram, Regression Analysis, 5 Whys, Control Charts, Cause and Effect Methods, Studies of Precision, Accuracy, and

Process Stability as integral parts of quality management), according to the company's defined policies, goals, and responsibilities.

The classification of quality methods and techniques according to their place of application in the business system is crucial, as it provides guidance on which methods should be included in the implementation of specific business systems.

The methodology for improving quality involves applying corrective and preventive measures, so, according to the nature of their action, quality methods and techniques can be divided into corrective and preventive (Mitrevva and Filiposki, 2012).

Corrective action methods and techniques include: data collection forms, control charts, Cause and Effect methods, data analysis and processing, studies of precision, accuracy, and stability, cumulative value methods, input, process, and output control, while other relevant quality methods and techniques have a preventive effect.

The basic quality methods and techniques are easy to use in the direction of their successful application, unlike complex ones, for whose application prior experience with basic methods is necessary. An example is the application of the QFD (Quality Function Deployment) method, or Quality Function Development as a complex quality tool. The implementation of this method requires knowledge of data collection forms, brainstorming methods, benchmarking strategies, Pareto analysis, matrix diagrams, control charts, etc.

Companies first introduce basic quality methods and techniques, which lead to the improvement of business processes, but at the same time, the need arises for the introduction of methods that support decision-making processes in the business system, known as management methods. Management methods and techniques serve to collect and process numerical data. These are tools, methods, and techniques for supporting company management, aimed at improving business processes, products/services.

Why the application of Statistical Process Control (SPC) is necessary

A quality system that does not have the concept of Statistical Process Control (SPC) developed and applied will not provide sufficient guarantee for its survival. On the other hand, applying SPC without a developed system for data recording and SOP (Standard Operating Procedures) has no logic, and the application will be reduced to error documentation. For all of this, well-trained teams are necessary. The use of SPC is one of the requirements of ISO 9001:2015.

The essence of Statistical Process Control is to ensure the stability of processes and predictability in production with deviations of three standard deviations (SD) from the average value of a given property. All variations can move within defined intervals, known as tolerance limits. If the process is a series of cases and conditions and a series of phases where the input value is expected to provide the desired output with minimal variations, we can say that the process is stable. Prevention and reduction of property variations should begin much earlier in the "life" of the product.

For other authors, Statistical Process Control is a methodology for reducing variability as part of the Total Quality Management (TQM) strategy for permanent quality improvement. It helps in deciding which data is important and how to extract maximum insights from them to avoid nonconformities, analyze ongoing issues, and so on (Taskov and Mitrevva, 2015).

Although many statistical methods and techniques are used in manufacturing enterprises, they have broad applications in service industries, according to Xiao and others (2011). The statistical concept of quality management is based on four fundamental principles:

- The results of any process are variable, they scatter, and follow one of the laws of distribution;

- Errors are always possible and always present;
- Data is always collected, and corrective action is taken based on it;
- Data must be presented with defined origin, the method of obtaining them, so that they can be used in the right direction.

In today's highly competitive industrial environment, maintaining high-quality standards and operational efficiency is essential for businesses aiming for long-term success (Westcott, 2014). The presence of defects in manufacturing processes can lead to increased costs, production delays, customer dissatisfaction, and damage to the company's reputation. As a result, industrial organizations must apply systematic methods to identify, analyze, and eliminate potential failures before they affect the quality of the final product. One of the most effective methodologies for achieving this goal is Failure Mode and Effects Analysis (FMEA), a structured approach to risk assessment and defect prevention.

ANALYSIS OF THE METHOD AND IMPACT OF ERRORS (FMEA)

FMEA (Failure Mode and Effects Analysis) represents a proactive tool used in various industries such as automotive, pharmaceutical, aerospace, and electronics. The methodology enables a systematic assessment of potential failure modes, their impact on production, and the implementation of corrective actions to reduce risks. When FMEA is integrated with continuous improvement frameworks, such as the DMAIC model (Define, Measure, Analyze, Improve, Control) from Six Sigma, it significantly improves process reliability, reduces defects, and increases overall efficiency of production systems.

This paper explores the application of error elimination methods in industrial conditions, with a particular focus on FMEA as a key strategy for improving quality and efficiency. Through an analysis of relevant techniques for identifying and eliminating defects, as well as a comparative review of various methodologies, the most effective approaches for minimizing risks in production processes will be evaluated. Additionally, the real effectiveness of FMEA and the most common challenges in its implementation will be investigated.

FMEA is a systematic method for assessing potential failure modes in a product or process and determining their impact on quality and efficiency. By identifying risks early in the design and production phases, FMEA helps prioritize corrective actions to prevent failures before they occur (Vusić, 2007).

During the 1980s, FMEA analysis became a tool for implementing the philosophy of Total Quality Management (TQM), and by the 1990s, it was also used in the Six Sigma strategy. The automotive industry (AIAG - Automotive Industry Action Group) and the American Society for Quality Control (ASQC - American Society for Quality Control) protected the copyright for the application of FMEA standards in February 1993.

The application of this method, when considered in the short term, provides an overview of potential risks, identifies the criticality of their consequences, and determines the priority for corrective actions. However, if considered in the long term, it develops a criterion for planning the testing process of the system, ensures documentation for future feasibility analysis in case of design changes, provides a foundation for planning preventive maintenance, and creates a basis for qualitative and quantitative analysis for system security. Furthermore, FMEA allows for risk evaluation of systems, processes, and products.

From another perspective, if FMEA is more precisely defined, it can be said that it is a procedural methodology for the creation of the product design, the production process, and the system in such a way that (Sharma and Srivastava, 2018):

- It identifies and evaluates failure modes, the potential causes of failure, and the effects of that failure;

- It defines actions that eliminate or reduce the likelihood of a cause that would lead to a failure;
- It calculates the risk of the failure occurrence;
- It documents the entire process.

Typically, this methodology is used in the development phase for defining the product, the production process, and the system, but its use is not excluded even in the serial production phase, due to the probability that possible indicators and causes for failure may arise during serial production.

Today, FMEA is part of:

- Advanced Product Quality Planning (APQP);
- Production Part Approval Process (PPAP);
- Quality System QS 9001 and ISO/TS 16949 and other management systems (MS);
- FMEA is integrated into the quality system (VDA) applicable for companies that are part of the German automotive industry.

It can easily be said that today, the application of this method is often a customer requirement.

What does the FMEA method represent?

The FMEA method answers two main questions: What could go wrong in a business process, i.e., what potential errors might arise, what is the likelihood of their occurrence, and what are the consequences that might result from these errors. By definition, this method ensures customer satisfaction at the highest level by fully or partially eliminating potential errors (Nouri and Soltani, 2017).

This method is based on teamwork, where all team members have equal rights in decision-making. FMEA is used to analytically evaluate the design of a new or modified product. The goal of applying this method is to avoid errors before they occur.

Through this method, the following are detected early:

- Potential errors in each operation;
- Potential consequences of these errors;
- Potential causes of the errors.

By calculating the Risk Priority Number (RPN), effective corrective measures are proposed to improve quality (using the Pareto approach). After implementing corrective activities, the new status is checked.

Conditions for implementing FMEA in business processes:

- A procedure for implementing the FMEA method and all necessary forms must be created;
- A flow chart of the production process for a specific product must be available;
- Modular Quality Circles (MQC) must be recognized, and their members must be identified;
- A decision must be made regarding the selection of the FMEA team and guidelines for each team member regarding the activities they need to complete;
- A coordinator for the team must be appointed, usually the head of the Testing Department;
- The team members should be introduced to the work process.

Before implementing the FMEA method, it is essential to define what the customer requires, which in this case might not necessarily be the end consumer but can be an employee in the next step of the process.

Types of FMEA analysis for the mode and impact of errors

FMEA is a universal and flexible method that can be used to analyze different types of problems an organization might face. It can be applied in any organization, regardless of its size or business profile. Literature lists several types of FMEA analysis, which are categorized based on the area of application or, more simply, the type of system the FMEA method applies to.

The following types of FMEA analysis are mentioned in literature:

Design FMEA (Design Failure Mode and Effects Analysis): This is applied during the design process of specific systems or products. Its purpose is to predict and eliminate potential errors during the design process and during the use of equipment throughout its lifecycle until it is completely decommissioned.

Process FMEA (Process Failure Mode and Effects Analysis): Focuses on the manufacturing process, the functioning of production equipment, maintenance, and the defects that arise from the functioning of this equipment. Process FMEA is used to analyze the process itself, where input and output requirements, control measures, and necessary resources are defined for each step of the process.

System FMEA (System Failure Mode and Effects Analysis): Deals with research, prediction, and prevention of defects and potential problems in relatively large processes, such as entire production lines. System FMEA is used to analyze the system and subsystems during the early stages of design concept development.

Service FMEA: Applied to services provided to users, such as in hotels, hospitals, etc.

Software FMEA (Software Failure Mode and Effects Analysis): Focuses on identifying potential errors in information technology systems. Software FMEA is used to analyze services before they are offered to the customer. This method highlights the different understandings of the concept of quality from the customer's perspective, expressed through their subjective feelings of satisfaction or dissatisfaction with the provided service.

Environmental FMEA (Environmental Failure Mode and Effects Analysis): Focuses on identifying potential environmental impacts.

The most commonly used FMEA types in companies are product, process, and system FMEA. System FMEA also covers service and software.

Costs of Implementing FMEA

To define the basic settings for the application of this method, the following key questions need to be answered:

- What is the goal of conducting the mode and impact analysis of errors?
- What are the short-term and long-term goals that need to be achieved through preventive and improvement measures?
- What is the task of the FMEA team, and what are the boundaries of their actions?
- Will the results be applied in practice, or will they serve as projections for potential unnecessary costs?
- Are there archival data on how to implement the analysis?

Primarily, the FMEA method provides a list of potential errors in the system and environment. By applying this method, it ensures that all potential errors are considered during system design.

Application of the FMEA Method in Product Development Process

The application of the FMEA (Failure Modes and Effects Analysis) method is beneficial right from the design phase of a system and all its subsystems. Once the analysis is

completed, a hierarchical ranking of the system and the components that comprise it is obtained. The analysis is compared before making specific technical decisions, allowing the user of the method to assess the probability of errors occurring in individual components. This way, the user is less likely to find themselves in a situation where individual subsystems or components need to be modified after the entire system is completed, as corrections are made during the design and testing stages. An even greater issue is the need to incorporate a safety element that could have been anticipated earlier.

Applying the method through an analysis of error modes and their impacts is crucial, though not the only condition for reducing costs in production and product sales. It is a fact that the FMEA method always reduces production and sales costs, but not completely, as in practice, it is not always possible to predict a complete or zero probability of errors occurring.

From the individual definitions, it can be concluded that the primary characteristic that distinguishes the FMEA method is its focus on preventing all potential errors, completely eliminating them, or reducing these problems to the lowest level possible.

The analysis of error modes and their effects, in addition to the benefits it brings, also entails costs categorized as quality costs. If a company's policy is to reduce the possibility of errors, it is essential to completely or partially eliminate the root causes of these errors. This is particularly important, as the later an error is detected, the greater its consequences and, consequently, the costs involved (Bouti and Kadi, 1994; Dighe and Bezold, 1996; Foster, 2001).

By applying statistical process control for defect-free production, analyzing quality costs, and introducing continuous employee education, high-quality production can be achieved with the lowest operational costs.

Steps of the FMEA Analysis

FMEA analysis is conducted through the following steps:

- Defining and tabulating potential errors, their criticality, as well as the likelihood and probability of detection.
- Setting the objective of the study, which should involve the interaction between components or individual processes throughout the entire production flow, followed by a detailed analysis.
- Identifying potential errors in the product, process, or system (including issues, corresponding corrective actions, and opportunities for continuous improvement).
- Identifying the consequences of errors on other components within the system, sequential processes, operations, customers, and legal regulations.
- Identifying the root causes of errors.
- Defining the method/procedure/system.
- Quantitative ranking of the significance/criticality of the potential errors' effects.
- Estimating the frequency of occurrence of potential errors.
- Assessing the likelihood of detection of potential problems.
- Calculating the risk priority number (RPN).
- Taking corrective actions.

Due to its relative simplicity and clarity, FMEA analysis is suitable for a quick preliminary assessment, after which a more detailed evaluation can follow.

Composition of the FMEA Analysis Team

FMEA analysis produces the best results when performed as a team effort, with members having diverse profiles yet possessing relevant knowledge about the system under

analysis. Although it is beneficial for all team members to have at least a basic understanding of the analysis method itself, the most important factors are knowledge and experience in solving issues within the system being analyzed.

In addition to knowledge and experience, it is crucial that team members collaborate in the development of the analysis by offering suggestions and ideas. The team should have a leader, who will oversee the entire FMEA analysis process. The leader must have a good understanding of the analysis method and practical experience in its application. It is also important to note that the motivation of team members is a key factor influencing the success of the analysis.

The team leader's goal is to engage individuals with specific profiles who possess a degree of patience, precision, motivation, and a desire to improve the system they are working on. Additionally, the team leader should maintain a high level of interest among team members throughout the analysis.

FMEA analysis is applicable in various industrial sectors. While the method itself remains consistent, there are requirements that may differ depending on the industry.

General Information about Process FMEA (P-FMEA) Analysis

As mentioned earlier, P-FMEA encompasses all the production steps of the manufacturing process. The more potential failure causes are identified in the process, the more errors are made. This results in defining more actions to eliminate or prevent errors. Ultimately, it can be concluded that the deeper the exploration into the manufacturing process, the better the full understanding of it.

P-FMEA covers the following areas:

- Focuses on potential failure modes in the manufacturing processes caused by deficiencies that affect the execution of the business or manufacturing process.
- Assumes that the product design is finalized.
- The product-related errors are already defined in the Design/Product FMEA analysis.
- Assumes that errors may occur but are not necessarily guaranteed.
- Analyzes manufacturing and other business processes within the entire system, subsystems, or levels for the assembly of individual components.
- Defines actions aimed at eliminating the main causes of errors.

Input and Output Information for Process FMEA (P-FMEA) Analysis

Just like any process that needs to be functional, P-FMEA requires defined input information that, when processed, results in appropriate output information.

The input information for P-FMEA analysis includes:

- Process Flow Diagram (PFD).
- Design/Product FMEA analysis.
- Technical procedures (technical drawings, work procedures, and instructions).
- Cause-and-effect analysis or Ishikawa Diagram.
- Customer requirements.
- Quality standards requirements.

Processing the input information results in the creation of the P-FMEA analysis. The output information derived from this analysis includes:

- A list of potential failure modes.
- A list of confirmed specific and critical characteristics that must be added to the process control plan.
- The foundation for creating the process control plan.

- Preventive actions that will prevent the occurrence of potential failure causes.
- Detection actions that will detect the occurrence of failure modes.
- Archiving and access to the data that is part of P-FMEA.

General Goals of Process FMEA (P-FMEA) Method

P-FMEA aims to achieve the following general goals:

- Improve the quality, reliability, and safety of the process.
- Create potential for reducing process risk and the costs of assembly or manufacturing processes.
- Help engineers prioritize, i.e., focus on eliminating or reducing failure modes.
- Evaluate the process from a different perspective.
- Continuously improve customer satisfaction with the use of the product/service.

Eliminating process risk should be a responsibility for all employees within an organization.

In order to achieve the required quality in manufacturing a product, risk analyses of the manufacturing process are crucial. In the automotive industry, P-FMEA, as one of the core risk analysis methods, is part of two standards: TS16949 and VDA. The implementation of P-FMEA must be performed in line with the design and implementation of the integrated part of the ISO standard intended for the automotive industry – TS16949.

Preventive Maintenance of the Manufacturing Process

Preventive maintenance of the manufacturing process is in the interest of any organization, whether the production process is stable or not. There is always a risk in the manufacturing process, and for that reason, every organization strives to minimize it. When planning annual production, planning for preventive maintenance of the manufacturing process is also done using the P-FMEA methodology. The number of regular FMEA sessions to be held annually is planned. This does not mean that strict adherence to the annual planning is necessary, as if needed, an FMEA session can be held outside the planned schedule with timely notification to all involved participants. The organization of these FMEA sessions is in the hands of the FMEA leader (moderator). Their task is to design the content of the FMEA session based on the process risk statistics and inform all participants in time so that they can come prepared. The purpose of these FMEA sessions is to define new preventive and detection actions, after which a 100% effective recalculation of the process risk can be performed, minimizing the risk.

On Customer Request

Each customer requires a guarantee of the established quality of the manufacturing process and product from their supplier. To maintain consistent quality in the manufacturing process, preventive actions need to be taken to eliminate potential indicators and causes of errors. Almost every visit or official audit by the customer includes discussing the P-FMEA analysis for the specific manufacturing process. The customer wants to have knowledge or an overview of the process risk. In special situations (increased number of complaints), the customer may request the mandatory use of the P-FMEA methodology to stabilize the manufacturing process to a certain extent. To avoid such unpleasant situations with the customer, most organizations define the use of the P-FMEA methodology, as mentioned in these situations.

In Case of Internal or Customer Complaints

Regardless of whether the complaints are internal or from the customer, it is necessary to define corrective actions first. After the error has been corrected, preventive and detection actions must be defined to eliminate the potential indicator or cause of the complaint. This

refers to preventive maintenance of the manufacturing process to prevent recurring defects. By using P-FMEA in such situations, process risk and recurrence of complaints can be minimized. Although the purpose of the P-FMEA methodology is to prevent defects from occurring, it is also used to completely eliminate the repetition of the same type of defect.

Conclusion

The application of cost optimization methodologies has shown to be very significant for management, as they allow the achievement of defined quality with minimal defects and cost losses. These methods and techniques for defect-free operation in various industries have enabled the achievement of defined quality, protection of customers/users from defective products, and an increase in the company's competitiveness, profitability, quality improvement, reduced defects, and operational costs, as well as increased satisfaction and employee participation in decision-making. This indicates the universal application of these methodologies in practice, regardless of the industry the companies belong to. By applying these methods, effective process control can be established while achieving defined quality with minimal operating costs. For many companies, the implementation of these methodologies means quality improvement through examining organizational processes not only in terms of process definition, improvement, and design but also improving productivity and optimizing costs. Competitive advantages are often decisive for the development and use of the quality assurance system (Hammer, 1990)

Employees' daily practices should not only involve self-control but they must also be trained to act preventively. They should be responsible, correct their mistakes, and raise any issues regarding quality that they discover. The decision to develop a quality assurance system can go hand in hand with the company's growth and the mature concept of Total Quality Management (TQM). Therefore, Total Quality Management implies the existence of a formal quality assurance system that controls and constantly improves the processes. The application of the TQM strategy means: the company identifies the problems, as opposed to the previous case with the design and implementation of ISO 9001:2015, where external institutions and experts were used.

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