Chapter

Perspective Chapter: Defining and Applying the FMEA Process Method in the Field of Industrial Engineering

Cristina-Ileana Pascu, Raluca Malciu and Ilie Dumitru

Abstract

The analysis of failure modes and effects (FMEA) is a method of analyzing the potential failure of a product or process and developing an action plan aimed at their prevention and increased quality of products, processes, and job production environments. As a method of critical analysis, FMEA has very clear objectives: determination of the weaknesses of a technical system; initiating causes of failure-seeking components; analysis of the environmental impacts, safety of operation, the product value; provision of corrective actions to remove the causes of the occurrence of defects; provision of a plan to improve product quality and maintenance; determining the needs of technology and modernization of production; increasing the level of communication between departments of working people at hierarchical levels. FMEA should be used before taking the product. Subsequently, there is no point, only because the customer demands it, to achieve FMEA. Therefore, FMEA must be within organizational conduct. This chapter describes the FMEA method and presents studies about the improvement of the quality process for some products from industrial engineering by using FMEA, such as: axis for packaging, assembly "stator Housing," composite parts used in the railway field. The potential causes of the defects were studied, and improvement measures were proposed.

Keywords: FMEA, process, quality, occurrence, improving, RPN

1. Introduction

1.1 Method definition

Worldwide, due to customer expectations coupled with the continuing increase in the complexity of products, declining design and launch periods have necessitated systematic quality planning [1]. In the last decade, quality control and improvement have become a priority in the development strategy of companies in all fields: industry, distribution, transport companies, health, government agencies, financial organizations, etc. Achieving and maintaining a high level of quality of products or services offer a competitive advantage that allows a company to dominate its competitors in the field in which it operates. Thus, a company can dominate its competitors by continuously improving processes and applying quality control [2]. The application of quality control at all stages of product process fabrication is considered a zero priority in the automotive field [3]. The premise of traditional quality assurance, based on the detection and elimination of defective products, is no longer relevant, the argument being extremely simple and intuitive: defects that can be avoided before launching the product do not need to be corrected later [4]. Modern methods of systemic quality design are the answer to new quality requirements. They must allow the analysis and elimination of potential defects from the design and implementation stage [5], so that more and more often the notion of "quality design" is encountered [6]. One of these methods that has become increasingly used in recent decades is the failure modes, effects, and analysis (FMEA) [7, 8].

One of the most widely used methods in the field of quality engineering is failure modes, effects, and analysis (FMEA), with applicability from the manufacturing design stage to the prototyping and zero series production stage [9].

The FMEA is a systematic method of determining and preventing errors, defects and risks that may occur, applicable to a process, product or equipment used in the process. This method consists of detecting possible defects, inventorying the causes that could produce these defects, the effects of defects on users, in order to plan the necessary measures to prevent their occurrence [10]. The English name of the method has a correspondent both in Romanian and in French, where it is called L'Analise des Modes de Defaillance, de leur Effet et de leur Criticite (AMDEC), or in German DAMUK [11]. This method consists of detecting possible defects, inventorying the causes that could cause these failures, demerits effects on users, in order to plan the necessary measures to prevent their occurrence.

The method was originally developed by the US military, as evidenced by the 1949 MIL-P-1829 military procedure entitled "Procedures for Failure, Effects and Critical Analysis" applicable to projects aimed at ensuring the maximum availability of strategic military equipment [12, 13].

The first notable applications of AMDEC techniques are related to NASA (1960s), and later, in the 1990s, by the top three US automakers: GM, Ford, and Chrysler by including them in the prescriptions of the QS 9000 quality standard [14], **Figure 1**.

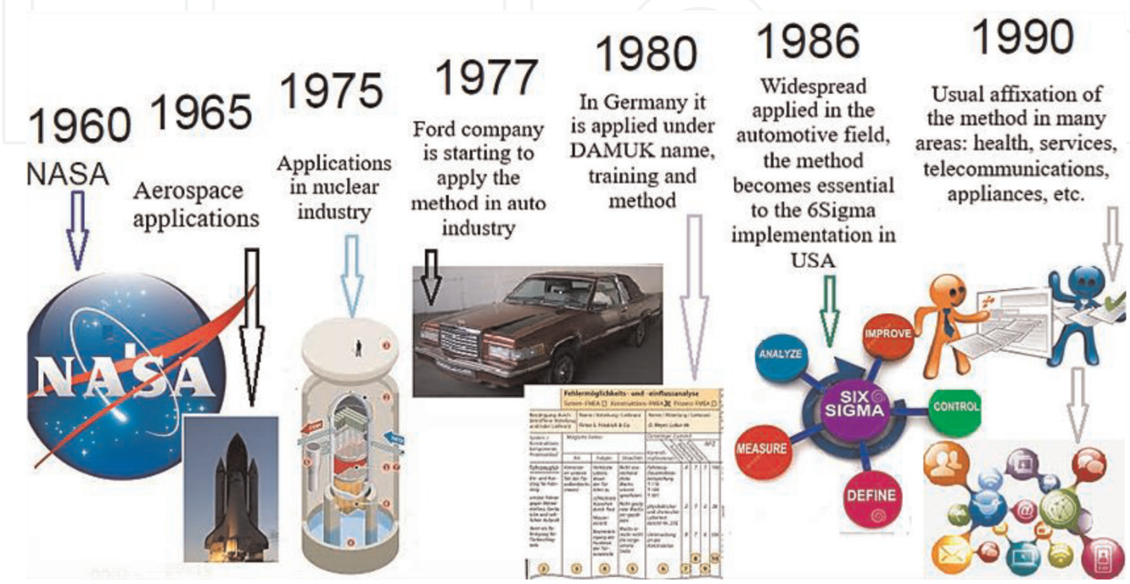


Figure 1.
Time evolution of the FMEA workability.

From **Figure 1** it can be seen that since the 1970s, the FMEA method has been used in the aerospace and nuclear industry. Since 1977, the American company Ford has been widely applying the FMEA method for solving car projects, and since 1986, with the launch of 6Sigma (6σ) technique, the method has become one of the basic tools used in the US automotive industry [14].

According to ref. [15], the French claim the discovery of this method in 1995, by applying a previous AMDEC method to shorten the production time of the prototypes for the mirage fight planes.

In 1980, Renault adopted the AMDEC method to make the Clio car, which became the first feasible project obtained by applying the method to both the process and the assembly, and since 1984, the French car manufacturer has adapted and improved the method using various other names: AMDEC CONNECTIQUE, DELTA 2, etc.

The correct use of the method allows the analysis and minimization of potential risks. By applying it, all types of defects and/or potential defects in terms of causation and effects are predicted.

Once the appropriate and correct actions have been implemented, the causes of the defects can be hampered or even avoided. The FMEA is considered to be an effective tool for quality assurance prevention.

1.2 The purpose and objectives of FMEA

The purpose of the FMEA is to ensure the development of high-quality products from the design and prototyping phases, before the transition to series production.

The FMEA provides the necessary preconditions for early detection of quality problems and the prevention of their occurrence through appropriate measures.

This makes it possible to meet product quality requirements and, at the same time, reduce the costs of errors and the consequences of errors. The objectives of the FMEA are shown in **Figure 2**.

Fault analysis and effects analysis (FMEA) is a systemic analysis of potential failures of a product, process, or machine used during the process, with the goal of developing an action plan to prevent their occurrence and to improve the quality of the products, work processes, and production environments.

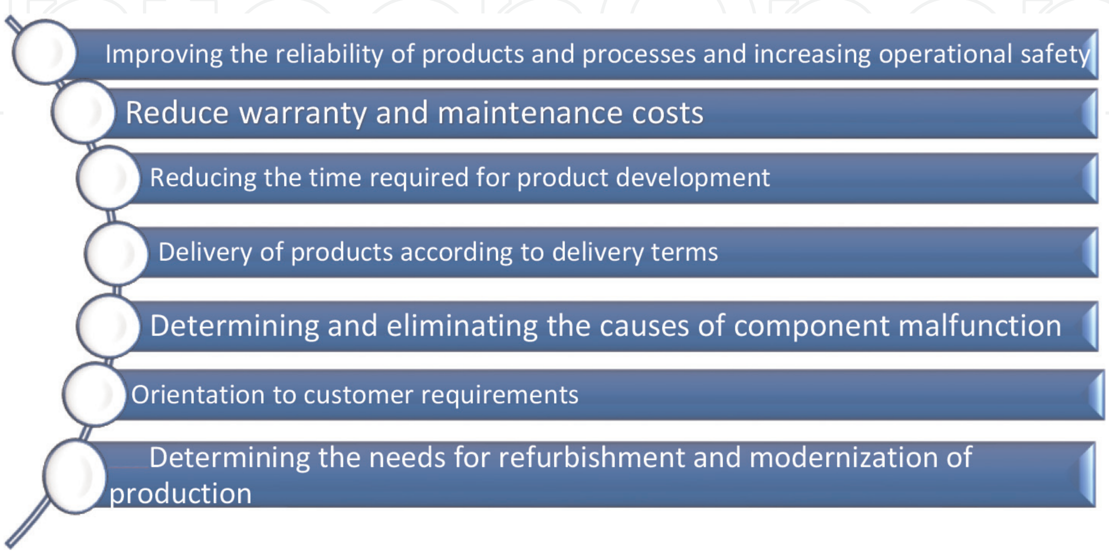


Figure 2.
FMEA objectives.

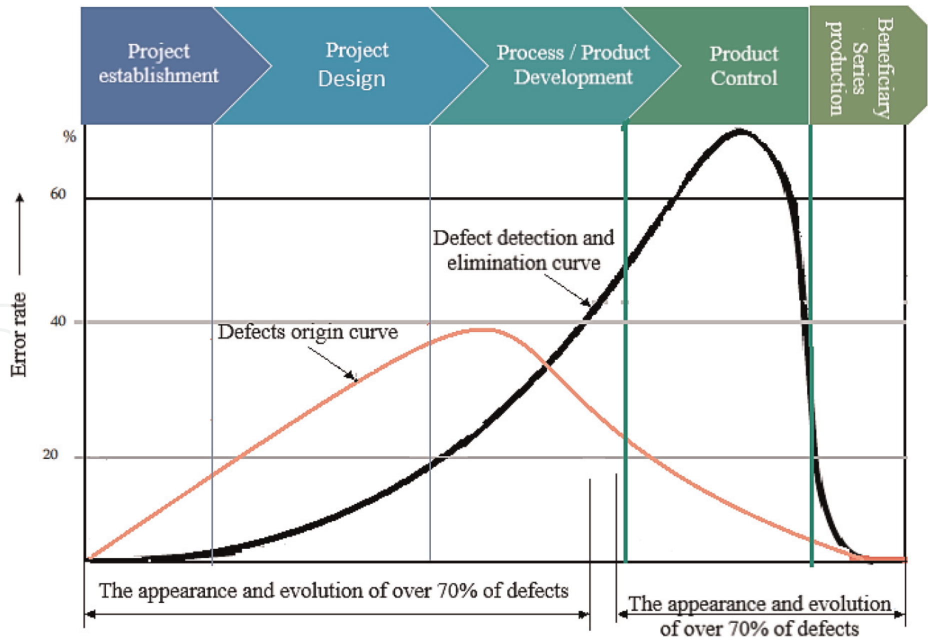


Figure 3.
The relationship between the origin of defects and their detection during the manufacturing cycle of a product.

We start from the elements to determine the triplet Cause – Mode – Effect. **Figure 3** shows the relationship between the origin of the defects occurring and their detection during the manufacturing process of a product [16].

It is mentioned that the FMEA method highlights possible risks, but does not solve the problem. However, the correct approach of the FMEA can result in "zero defects" but not "zero errors."

1.3 FMEA types

There are two main types of FMEA [17]: product design, DFMEA, and process development, PFMEA, **Figure 4**.

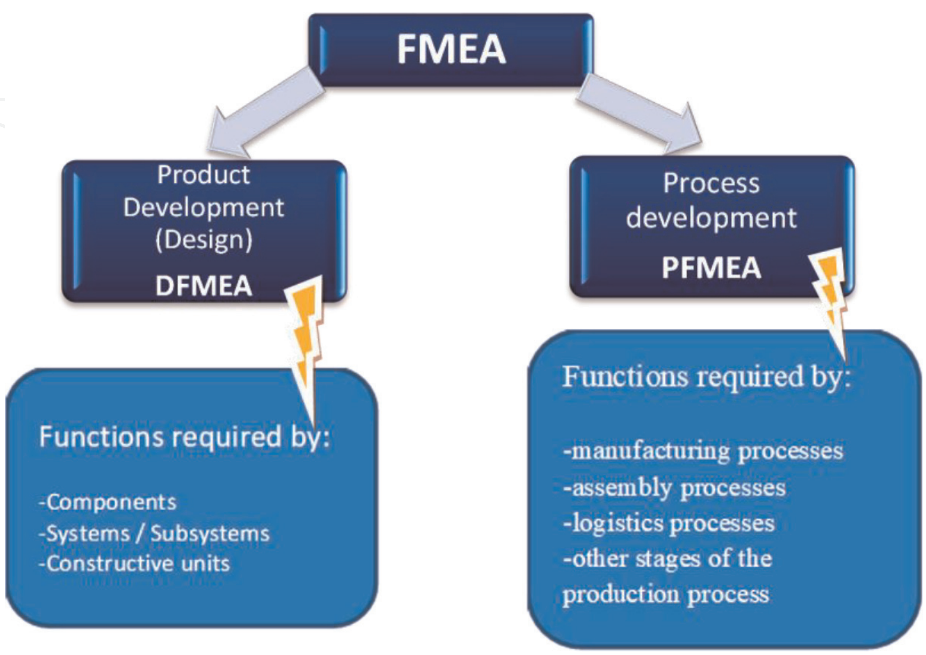


Figure 4.
Main types of the FMEA method.

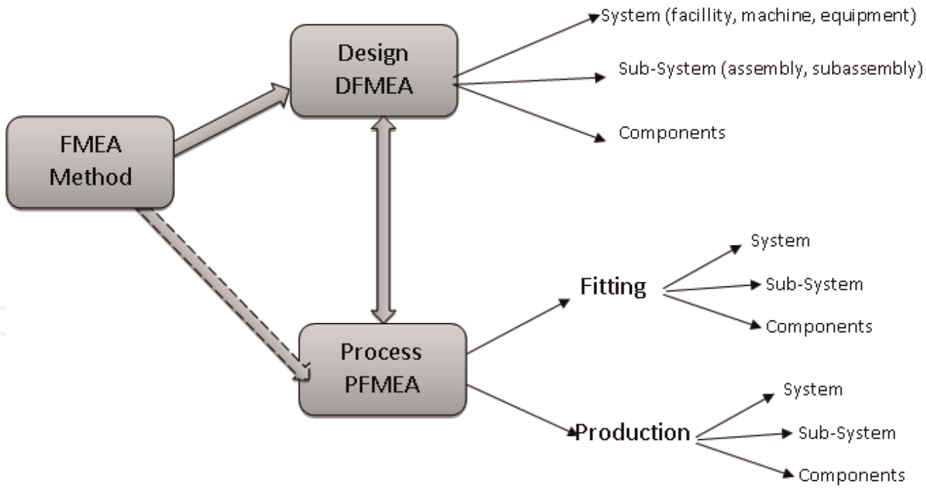


Figure 5.
DFMEA and PFMEA.

Accordingly to the AIAG, VDA manuals [18, 19], in addition to the two types of FMEA listed above (DFMEA and PFMEA), explained in **Figure 5**, the following are also known and used:

- FMEA system focused on the study of the functions of the components of the subsystem, machine, machinery, or technological equipment;
- FMEA service that is used to analyze the functions of the service;
- FMEA software focused on studying the functions of software and computer components.

However, the FMEA method must be performed whenever errors or malfunctions may occur that could cause potential harm to the user (customer) for whom the product is intended.

The scope of the FMEA method is wide and diverse. This method can be implemented not only in industry but also in the field of services.

The FMEA is aimed at [13, 18]:

- product-project;
- product-process;
- machine/work equipment or system.

The product-design FMEA is applied immediately after the elaboration of the constructive design documentation (design) in order to follow and analyze the products from the conception and design stage.

The product-process FMEA is performed after the preparation of the technological documentation of the process necessary to make the product. It also allows the validation of the technological process of making a product in accordance with the desired quality and efficiency expectations.

FMEA machine/work equipment is executed after the system of machines, machines, and technological equipment is established. Based on that, the technological process consists of the analysis of the means of production aiming to reduce the number of scrap, failure rate and increase availability and reliability of the product. The development of the FMEA lies in the inventory of the way of detecting errors, component problems, analyzing the causes of occurrence, and evaluating their effects on the set of functions of the system.

1.4 Fields of application of the FMEA method

In the current context, the need to apply the FMEA method derives from the quality requirements, with the emphasis shifting from detecting noncompliant products to preventing errors and defects before prototyping the final product or switching to series production.

As can be seen in **Figure 6**, FMEA is a method of preventive quality recommended in the IATF16949: 2016 standard, AIAG, VDA, norms and regulations manuals, being a basic tool for 6Sigma.

The FMEA method is applicable to, **Figure 7**:

- products, parts, with quality problems;
- processes with non-conformities;
- modernization of an existing technology or implementation of a new technology;
- products that require a high level of security;
- launching a new type of product or process;
- evaluation of the probability of occurrence of errors and/or failures, at important components from the point of view of the safety of the whole;

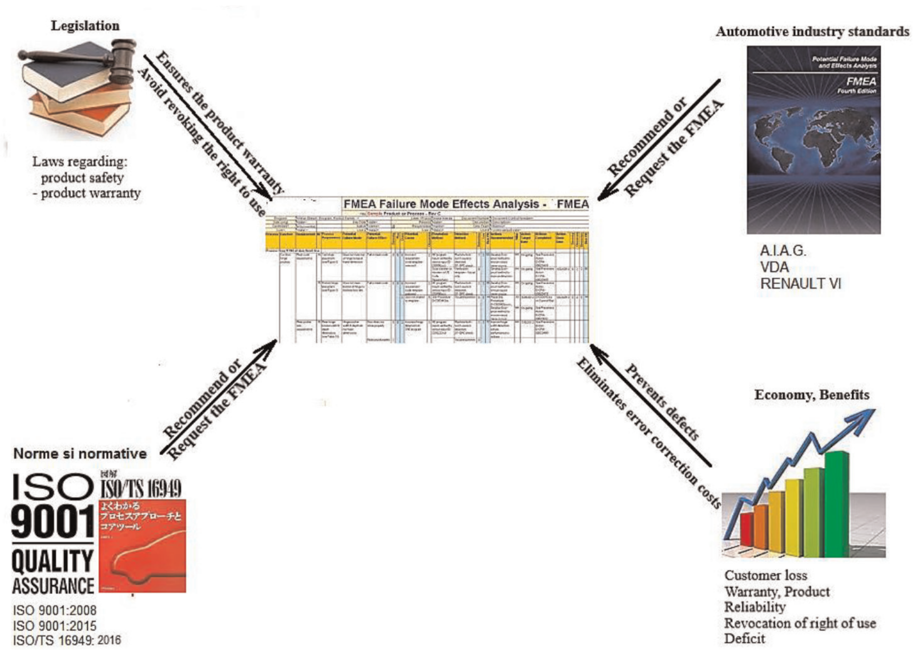


Figure 6.
The requirement to apply the FMEA method.

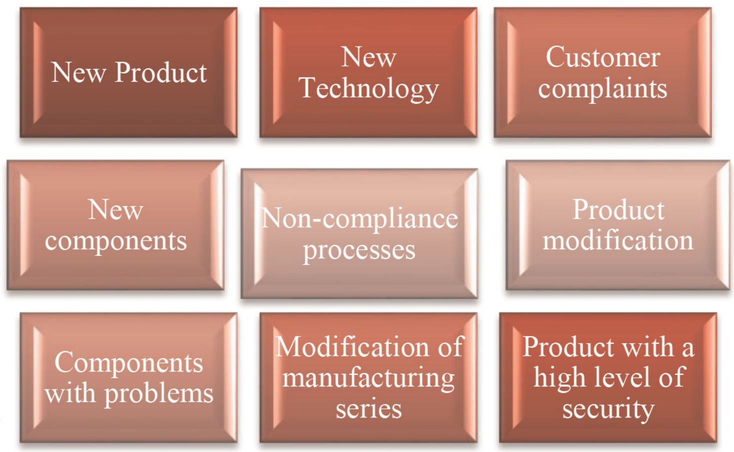


Figure 7.
The area of FMEA applicability.

- adapting products to new operating conditions;
- modification of manufacturing series.

By applying the FMEA method, the risk of non-conformities in the design and manufacture of products is reduced. The implementation of the method allows to reduce costs in all stages of the quality spiral, **Figure 8**: in design, by better reflecting customer expectations in design quality; in supply, by avoiding difficulties due to improper selection of suppliers; in manufacturing, by preventing the occurrence errors and defects and avoidance of critical points in the field of service, by reducing customer grievances and complaints, etc.

1.5 Methodology for FMEA analysis implementation

FMEA must be performed before the product prototype is made, **Figure 9**. No sense in applying FMEA afterward, upon the request of the client.

Figure 8.
The spiral of quality.

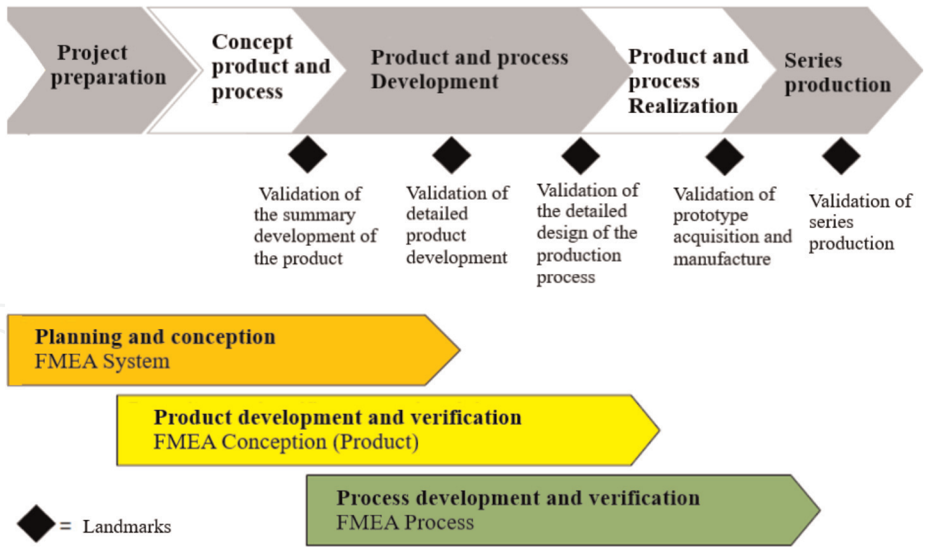


Figure 9.
Validation of FMEA analysis.

The FMEA must be performed before the product is prototyped as it is a living, dynamic organism that must be updated throughout the life of the product or process.

This is the reason why the approach and implementation of the FMEA must be part of the organizational development of the product manufacturing, starting before prototyping and ending before the launch of series production.

In carrying out the FMEA method, the main "5 steps" must be completed.

These important "5 steps" in the development and implementation of the FMEA are, **Figure 10**:

Step 1—The elaboration of the structure of the system consists in the description of the system, with the definition of its component elements and the structural determination of the whole.

Step 2—The introduction of functions in the system structure involves the functional description, the structural determination of the system with functions, the correlation of functions, which will lead to obtaining a network of functions, respectively, the formation of a functional structure.

Step 3—Defects and faults analysis consists of the introduction of the "failure" functions in the system structure and correlating these functions, obtaining a "network of failures," respectively, the functional structure of the faults.

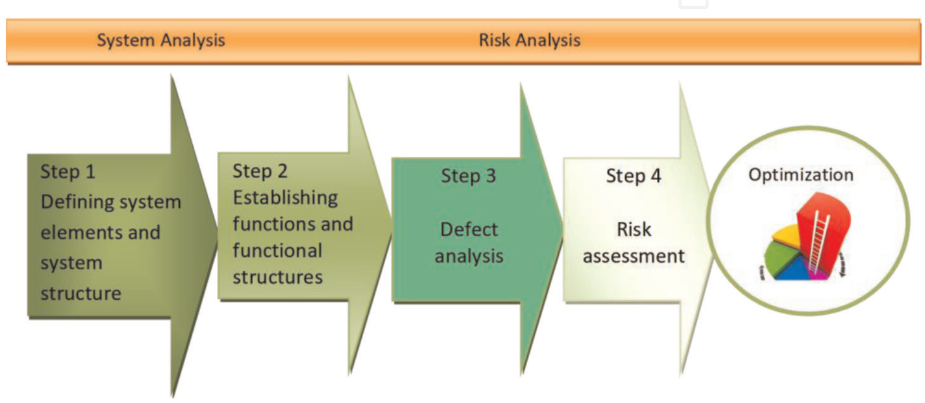


Figure 10.
Stages of FMEA application.

Step 4—The risk assessment lies in the FMEA form through avoidance and detection measures, with the assessment form being completed.
Step 5—Optimization is the stage in which changes are processed in the FMEA form, the risks of errors and defects are reduced by new measures, the persons responsible and the deadlines in which the recommended measures must be organized and carried out are designated, and the optimization form is made.

1.6 The FMEA team

The FMEA research is carried out in interdisciplinary groups in which the departments involved in the realization of the product participate under the leadership of a moderator.

The FMEA moderator is usually a person from outside the company or from the Quality Assurance department.

Tasks of the FMEA moderator:

- Participate in FMEA planning.
- FMEA preparation/organization.
- Moderation of the work team.
- Documentation of the analysis.
- Evaluation and presentation of FMEA results.
- Ensuring methodological correctness.
- Participate in improving the efficiency of the FMEA.
- Exchange of FMEA experience.

Employees of the design-development, manufacturing process planning, manufacturing, control, customer service, and quality assurance departments generally participate in the implementation of the FMEA, and their number will not exceed 6–8 people.

This ensures that all departments involved in the manufacturing of their products bring their experience in the analysis. The success of the FMEA largely depends on the creativity of the team.

The product is systematically broken down by a “top-down” process into components or functions and subsequently researched to meet the constructive requirements and to maintain these requirements during manufacture. The systematic analysis procedure is supported by using an appropriate form.

In order to perform an FMEA analysis, the operation of the analyzed system must be very well known, or the appropriate means must be available to obtain the necessary information from the owners.

The FMEA team consists of, **Figure 11**:

- The project coordinator (decision-maker) is the person with responsibility in the company who has the power to exercise a final choice. They will make the final decisions regarding cost, quality, and deadlines:

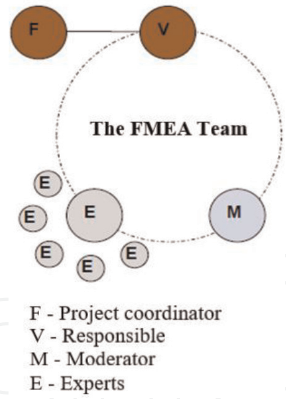


Figure 11.
The FMEA team.

- Enforcement decisions
- Information collection support
- FMEA approval

Team members should, as required, provide the following:

- The person in charge (Initiator) with the FMEA analysis is the person or service that has the initiative to start the study and to choose the subject of the analysis. In general, it has the following tasks:
- Co-participation in FMEA training
- Contributing information based on experience gained from already known processes
- Co-participation in the selection of measures

The moderator (animator) is the guarantor of the method, the organizer of the group activity. He specifies the agenda of the meetings, conducts the meetings, provides the secretariat, and monitors the progress of the study.

Often, it is a person outside the company, or at least outside the department, to animate the members of the group.

These first three people generally do not have precise technical skills.

Experts (analysis group) in number of 2–5 people will be people responsible and competent, with good knowledge of the studied system and who could bring the necessary information for the analysis (one can only discuss what is well known).

Depending on the study, the following will be:

- maintenance service staff;
- staff of the quality assurance department;
- production operators;

- members of the design offices;
- experts in the field studied.

Their tasks are:

- Presentation within the team of the project/development stage
- Contributing with information based on experience gained from already known processes
- Introduction of optimization measures established in the project stage

The FMEA designated design team consists of 5–8 people.

Figure 12 shows the phases necessary for the preparation and planning stage of the FMEA analysis session.

1.7 Stages of FMEA application

The necessary steps for the development and implementation of the FMEA method are presented in **Figure 13** [13].

Identification of the functions of the product/process subject to FMEA analysis

When applying the FMEA to the product, identify the functions of the product, part, or component considered for the study.

In relation to these functions, potential failures are determined, assessing their severity (criticality).

The causes of errors and malfunctions are then determined, and measures are taken to prevent them from occurring. The Ishikawa Diagram or the “5 Why” technique is usually used to identify the causes of errors or malfunctions.

The application of the FMEA process involves, in a first stage, the description of the process functions. Starting from these functions, the potential faults are identified, and the critical stages of the process are highlighted. The necessary corrective measures shall be taken to prevent damage.

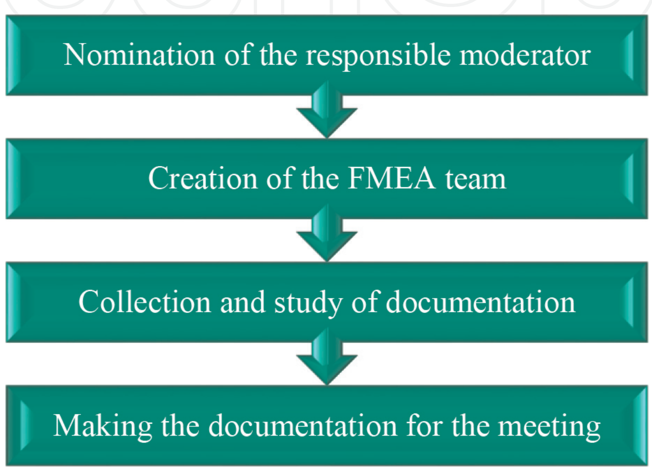


Figure 12.
The necessary steps for the preparation and planning phase of the FMEA analysis session.

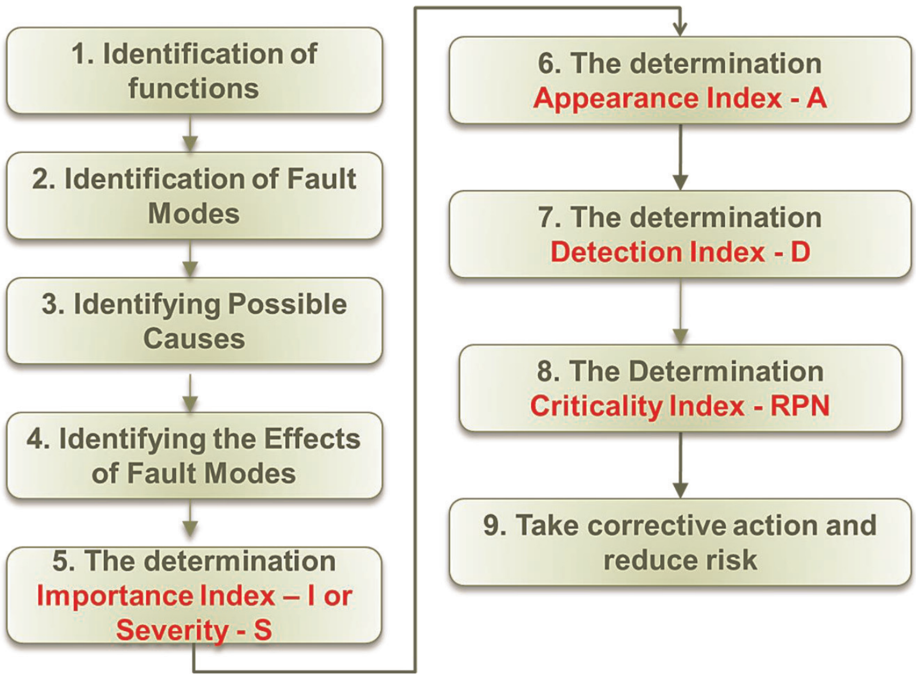


Figure 13.
Steps required to develop and implement the FMEA method.

Identifying fault modes consists of inventorying all possible faults of the product, part, component (DFMEA), or process (PFMEA) and establishing fault modes. This is usually done by specialists, but in some cases it is possible to use working groups, capitalizing on the experience gained in the field by the group members (company workers, workers serving the equipment used during the technological process). The modes of failure can be multiple: wear, deformation, corrosion, rupture, buckling, crushing, etc.

1.8 Assessing the effects and importance (criticality) of failures

Defects are usually assessed depending on two criteria: probability of occurrence (A) and probability of detection (D), which are expressed using the same notation scale.

The quantification of these probabilities depends on the type of product or process analyzed.

Severity (importance) means the value that characterizes how serious the established effect is for the failure mode and how it affects the customer, in terms of product/process failure/failure, their effects, and notation being presented in **Table 1**.

In assessing the significance (severity) of the faults, the following general rules must be observed:

- the importance of a failure is that for all potential causes of failure;
- defects that generate the same effects will be of equal importance;
- for different causes of a failure, the probabilities A and D may be different;
- the defect that has the highest probability of being identified by the customer will be marked with the maximum score (10 points)

The assessment of the significance of the defects is done using the notation scale. Based on probabilities A and D, and importance I, the RPN risk coefficient is determined using the relationship:

$$RPN = A \cdot D \cdot I \tag{1}$$

This coefficient has values between 0 and 1000. It is generally considered that measures are needed to prevent potential damage when the RPN risk coefficient is greater than 100.

In **Table 1**, the evaluation of the significance (severity, seriousness) of the defects ("I") when FMEA of the product or process is applied is presented.

The appearance index (A) estimates the probability of occurrence of the defect as a product of the probability of occurrence of the cause and the probability that this cause will provoke the considered defect [13].

Table 2 shows how to score the occurrence index according to its probability of occurrence.

The detection index (D) estimates the probability of detecting noncompliance before it reaches the customer.

Table 3 shows the scoring values of the detection index.

After evaluating and scoring each of the three indices, in the next stage, indications are given regarding the need for improvement measures, depending on the values of indices A, D, and I.

The assessment of the need for improvement measures (general guidance) is presented in **Table 4**.

The results of the analysis are written in tabular form, similar to that described in **Figure 14**

Advantages of applying FMEA:

- Improving the quality, reliability, and safety of a product/process
- Early identification and avoidance of possible defects in the various phases of product planning and manufacturing, as well as at the structural level of the process.
- Reducing the costs of development times;

I (S)	Criteria for Assessing the Importance of Failure Mode
1	Minimal deficiency, the client does not notice it
2–3	Minor deficiency, which the customer can detect and which can cause him a slight dissatisfaction, but without any degradation of product performance.
4–5	Defect of medium severity that bothers or disturbs the customer
6–7	Serious defect, which causes a significant degradation of product performance, causing customer dissatisfaction
8	Serious defect that causes great dissatisfaction to the customer and requires high repair costs
9–10	Particularly serious defects that involve customer security issues and affect product or process safety
10	Deficiency involving safety issues, possible accident

Table 1.
Ways to assess the importance index (I).

A	Probability of occurrence		
1	From 0	to 3/100000	The defect is unlikely to occur
2	3/100000	1/10000	
3	1/10000	3/10000	
4	3/10000	1/1000	
5	1/1000	3 /1000	
6	3/1000	1/100	
7	1/100	3/100	
8	3/100	10/100	
9	10/100	30/100	
10	30/100	100/100	The defect is inevitable

Table 2.
Evaluation of the Occurrence Index (A).

D	Probability of error detection		The probability of the defect reaching the customer	
1	100%	Errors are detected	From 0%	to 2%
2	Very high	The probability of error detection is very high	2%	12%
3	High	The probability of error detection is very high. Checks are safe.	12%	22%
4			22%	32%
5	Moderate	The probability of error detection is medium. Checks are relatively secure.	32%	42%
6			42%	52%
7	Low	The probability of error detection is low. Checks are inaccurate.	52%	62%
8			62%	72%
9	Improbable	The probability of error detection is almost impossible. No checks are possible.	72%	82%
10			82%	100%

Table 3.
Scoring the detection index.

- Collecting information in order to reduce future failures and defects;
- Increasing problem prevention;
- Minimizing late changes that could be made to the product/process, as well as the related costs, etc.;
- Quickly carrying out of the necessary changes and avoiding the unnecessary ones, thus reducing manufacturing times, respectively reducing quality costs in all areas

DOI: http://dx.doi.org/10.5772/intechopen.107401

A	D	I	Description	Measures
1	1	1	The ideal case (goal)	Not required
1	1	10	The situation is certainly under control	Not required
1	10	1	The defect does not affect the customer	Not required
1	10	10	The defect may affect the customer	Required
10	1	1	The defect is more common; it will definitely be detected by the customer	Required
10	1	10	The defect is more common; it may affect the customer	Required
10	10	1	More frequent defect, of great importance	Required
10	10	10	Totally inappropriate situation	Required

Table 4.
The need for improvement.

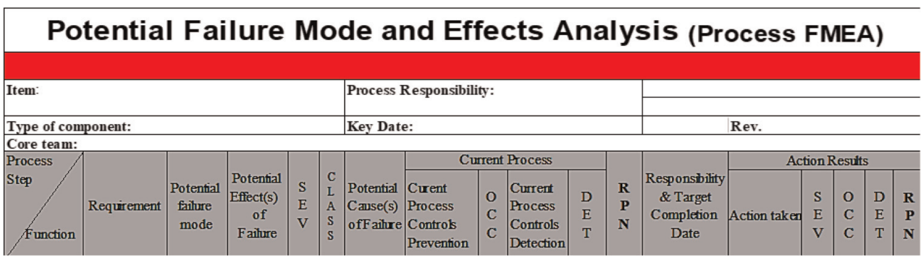


Figure 14.
FMEA spreadsheet example.

- Extremely simple use and neutral application in all industries, both for technical and organizational issues and for services;
- Successful completion of new, verified work techniques, such as Quality Function Deployment value analysis;
- Correct use of existing expert knowledge;
- Improving the company's image and competitiveness;
- Improving communication, cooperation, and collaboration between customers, suppliers, and various internal departments of an organization;
- Increasing consumer satisfaction.

The main advantages of applying the FMEA are shown in **Figure 15**.

2. Studies about the implementation of the FMEA Process

2.1 Study about implementing the FMEA Process for a steel structures components assembly

In **Figure 16**, the technical details of the components of the "Stator Housing" assembly are shown, which were considered for the FMEA Process research,

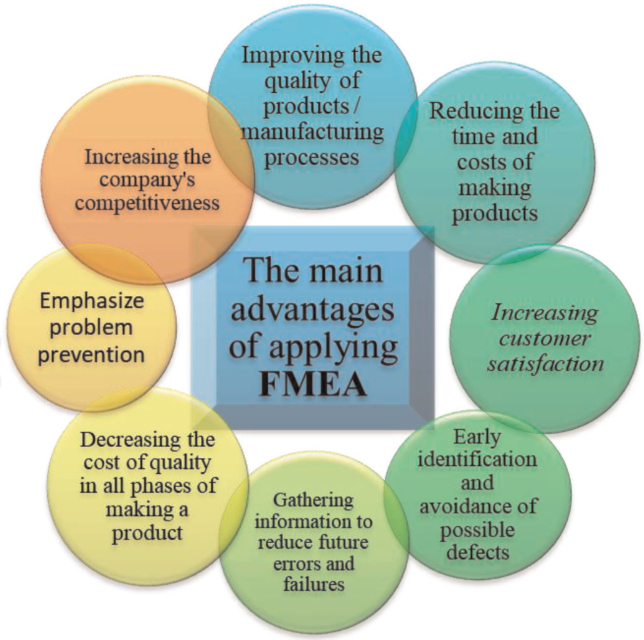


Figure 15.
The main advantages of applying FMEA for a company.

respectively the welds used to make the housing are shown [20]. It is specified that the welds used to make the housing were considered very important.

The components of the "Stator housing" assembly shown in **Figure 16** are: 1 – support plate, 2 – flat bar, 3 – stiffening plate, 4 – flat bar, 5 – housing base, 6 – ring segment, 7 – front wall, 8.9 – ribs, 10 – shell, 11 – shell segment, 12 – intermediate wall, 13 – front wall, 14 – cable guide, 15 – reinforcement, 16 – pipe, and 17 – supporting bush.

Figure 17 shows details of the elements of the assembly that will be considered in the FMEA study, respectively the welds used to make the housing.

Figure 18 shows the positioning of the welded elements along the stator housing.

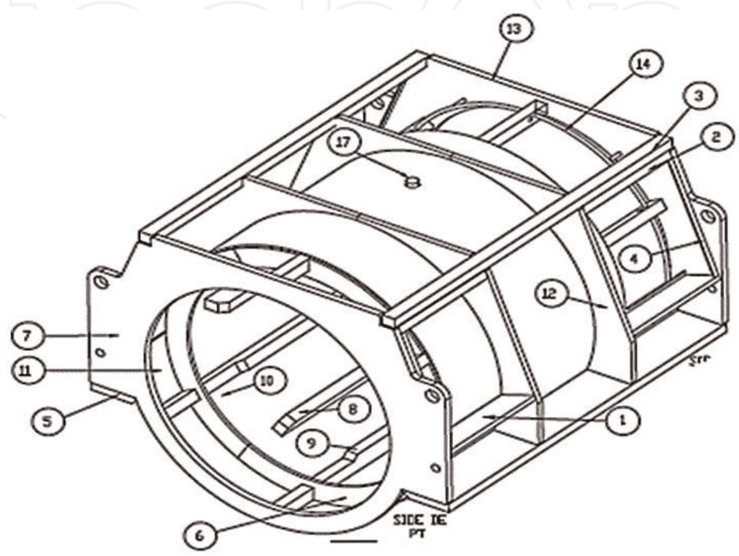


Figure 16.
Elements of assembly "Stator Housing" considered for the FMEA study.

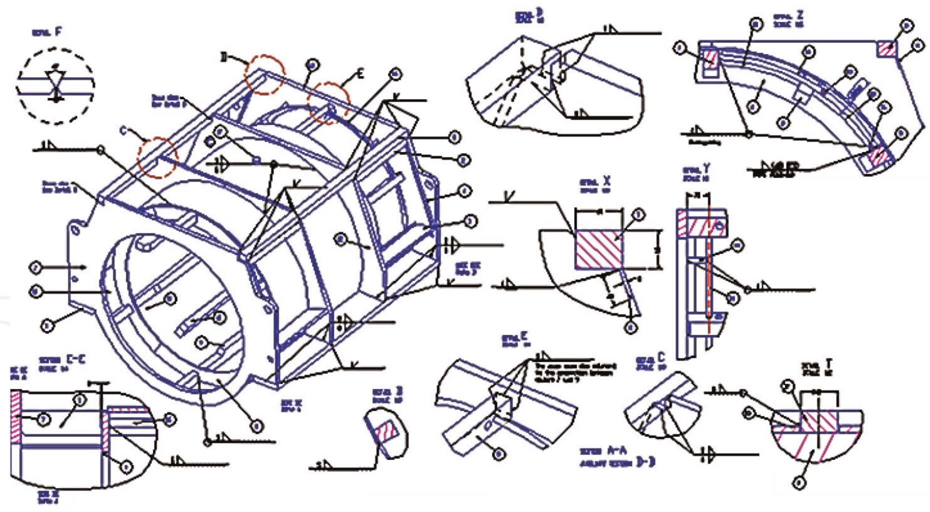


Figure 17.
Elements of the ensemble considered for the FMEA study.

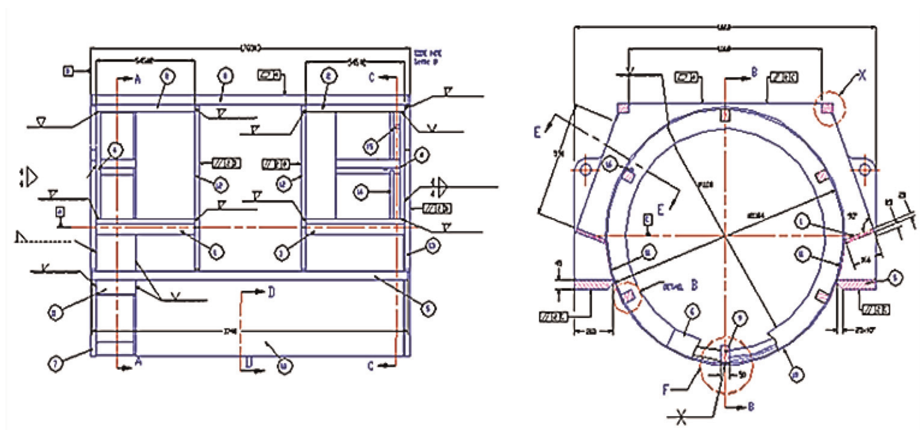


Figure 18.
Positioning the welded elements on the stator housing assembly.

Regardless of the product/manufacturing process to which the FMEA method is applied, the steps required to perform an FMEA Process analysis in order to obtain a "zero defect" production are those shown in **Figure 19**.

FMEA-Process analysis includes several stages: process/product analysis, process diagram determination, FMEA preparation, control plan development, statistical data analysis, document package update, FMEA team information, use of documentation made by FMEA application.

In general, the steps required to prepare an FMEA-Process analysis are as follows: planning and preparation, risk analysis, assessment and, subsequently, risk minimization. These steps are shown in **Figure 20**.

Figure 21 shows the stages of the technological process of manufacturing the "Stator housing" assembly. The necessary operations and stages in the chronological order of their development are: qualitative inspection—material reception, CNC cutting, saw cutting, adjustment, semiautomatic cutting, saw cutting, parting off on guillotine, components adjustment, shell rolling and spot welding, rings rolling and spot welding, assembly and sharpening, ribs assembling and welding, welding and assembling, manual marking out and parting-off, final welding, final assembling, first sandblast cleaning, final adjustment, final sandblast cleaning, priming.

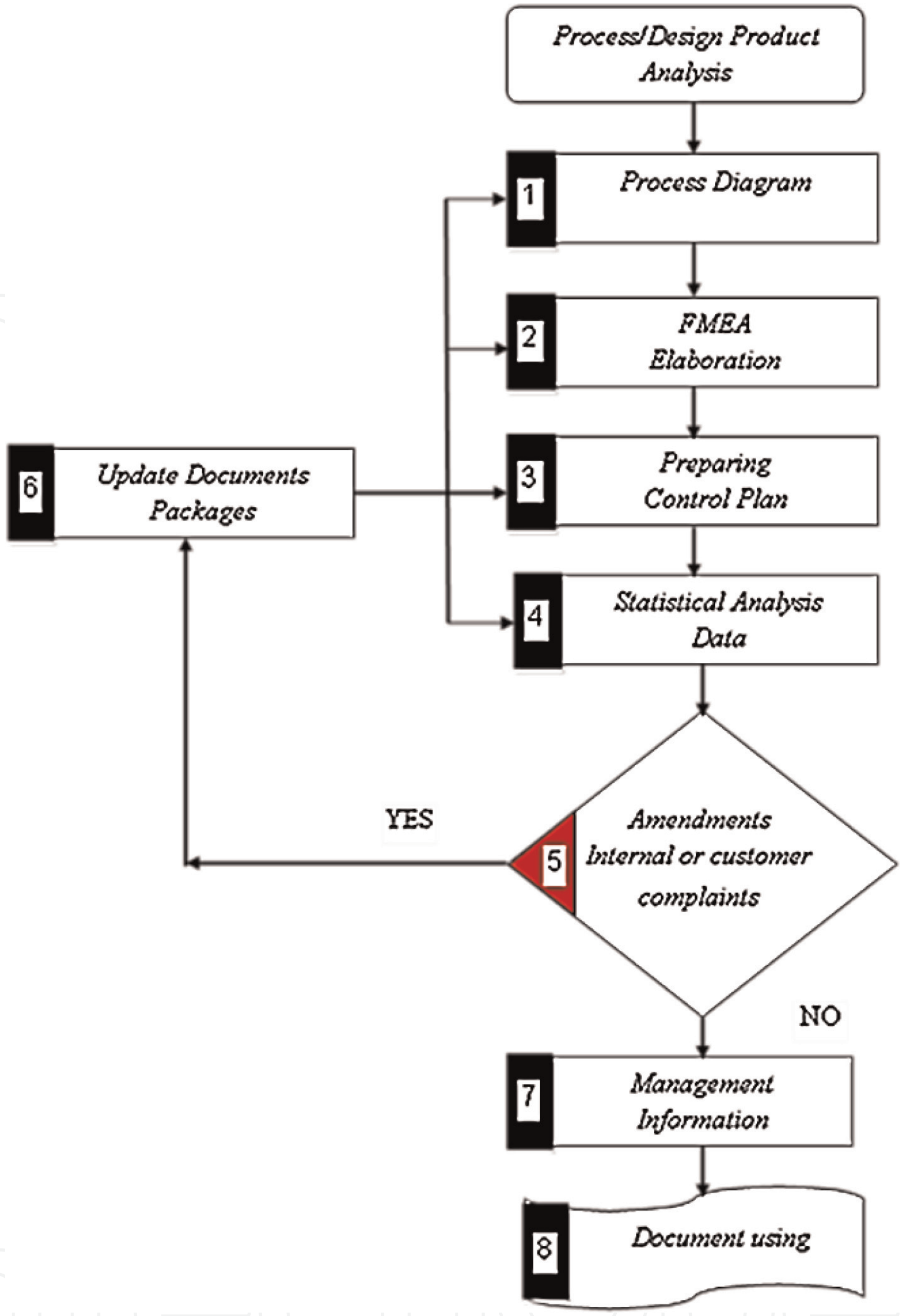


Figure 19.
FMEA roadmap [19].

From **Figure 21** it can be observed on the left side of the figure the presence of the 6M: Man, Machine, Method, Measure, Mother Nature (Environment), Material.

The influence of each factor of the 6M on the quality of the product, as a result of a process (output) is shown in **Figure 22** [13].

The influence of the equipment on which the manufacturing process takes place is minimal, because the initial settings remain unchanged for a long time.

The influence of the human factor is remarkable, being on a higher class. Employees can be trained and motivated to perform, manage, and verify manufacturing processes and products; however, the mental factor related to their health or family problems cannot be quantified, producing inattention, lack of interest, etc.

DOI: http://dx.doi.org/10.5772/intechopen.107401

Figure 20.
The stages of preparing the FMEA analysis.

The most significant and uncontrollable influence has the environment (M Nature) in which the manufacturing processes take place, being included here is both the internal working environment of the company and the external business environment, the domestic and international economic market.

Figure 23 shows the technological flow used to build the "Stator Housing" assembly.

The FMEA-process analysis was performed in order to improve the quality of the welded elements of the "Stator housing" assembly, this being partially shown in **Table 5**.

As it can be seen in **Table 5**, there are several operations that have a cumulative score for Severity, Occurrence, and Detection, respectively RPN major, of over 60 points. But the operations that could cause serious disruptions to the technological process are those with a high RPN of over 100 points (cells colored red as in **Table 5**), these being the following:

- when chamfering small surfaces, due to the low weld mechanical strength over time (Severity—point 8, Appearance—point 3, Detection—point 5), RPN is 120; it is recommended to purchase a chamfering machine;

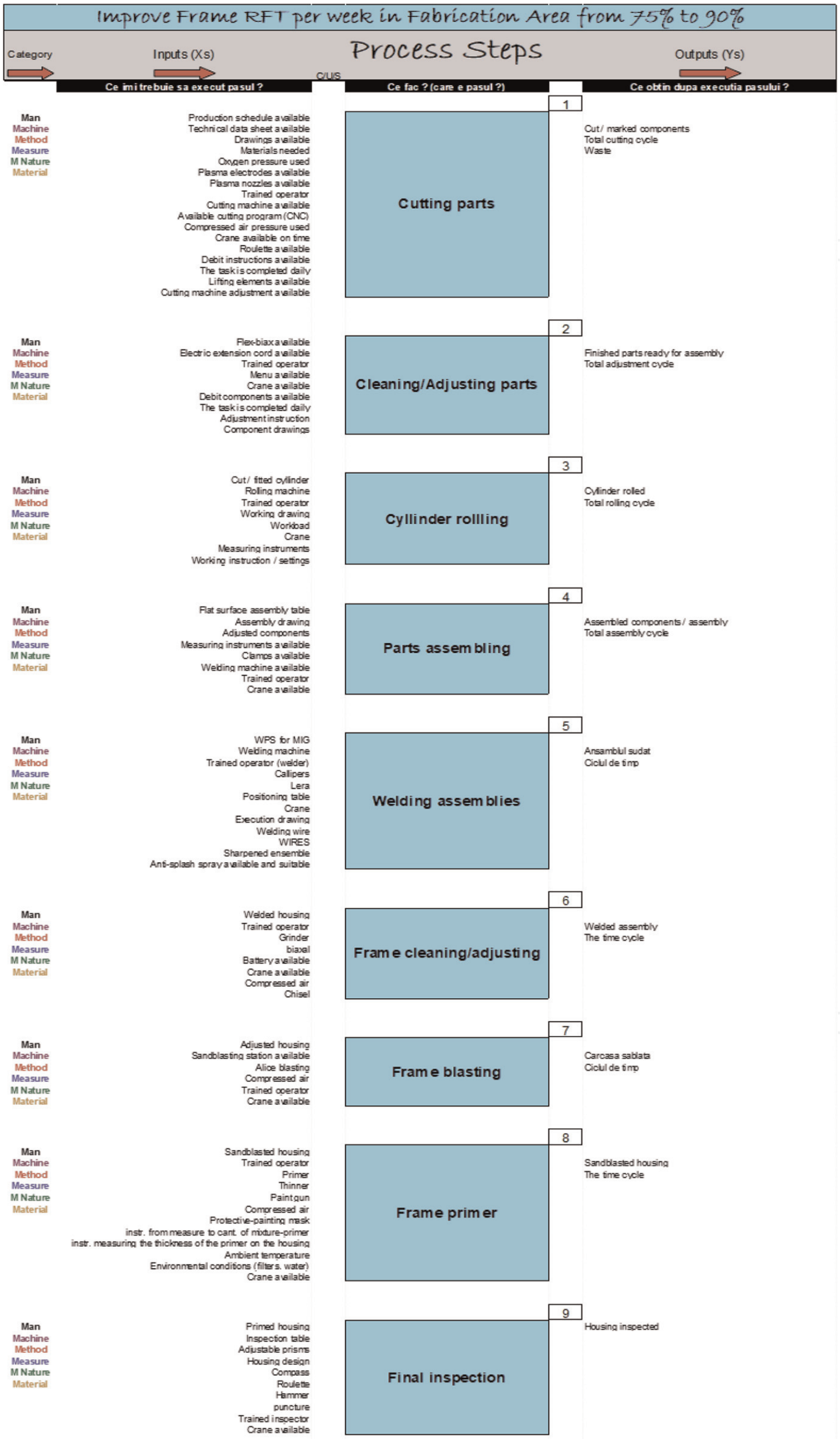


Figure 21.
The stages of the technological process of making the ensemble.

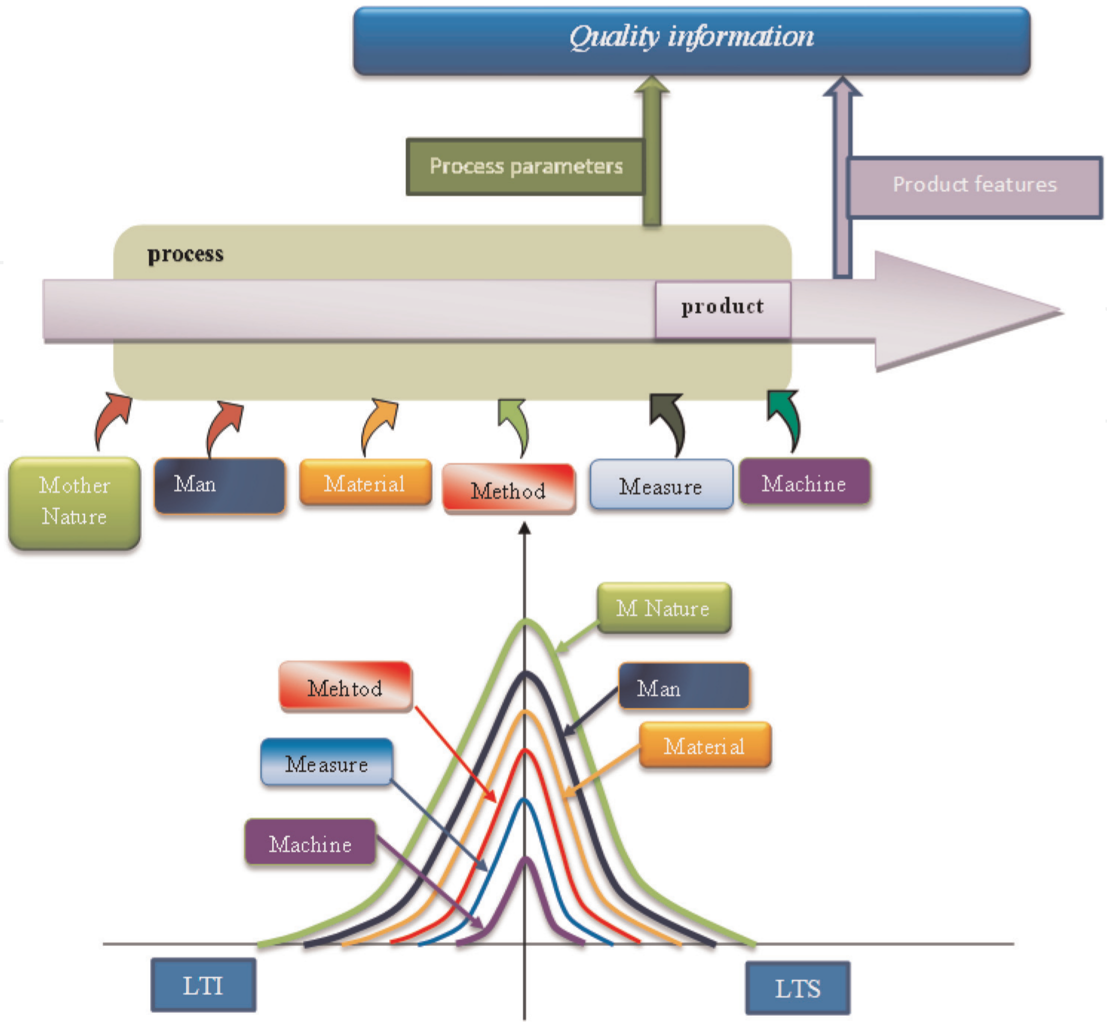


Figure 22.
Process model and influencing factors.

- when chamfering along the entire length of the part, due to the irregular shape of the chamfer, having the effect of low mechanical resistance of welding over time (Severity – score 8, Appearance – score 4, Detection – score 5), RPN is 160, or due to the quality of the welding bead, (Severity – score 5, Appearance – score 4, Detection – score 5), RPN is 100; when chamfering smaller surfaces, due to the small size of the chamfer, the effect is the low mechanical resistance of the weld over time (Severity – score 8, Appearance – score 3, Detection – score 5), RPN is 120; for all this it is recommended to buy a chamfering machine;

- in the case of the operation of assembling reinforcements/stiffeners and frameworks/terminal box console, due to geometric deviations (flatness, parallelism, perpendicularity) there is an angle of less than 90^0 having as result the impossibility of mounting blinds/grids/other parts or subassemblies (Severity – score 8, Appearance – score 5, Detection – score 3), RPN is 120, EMM/SDV replacement is recommended.

It was found that RPN decreased to zero and therefore achieved finished products with "zero defects," after taking the necessary steps to implement the recommendations for each operation with a high RPN.

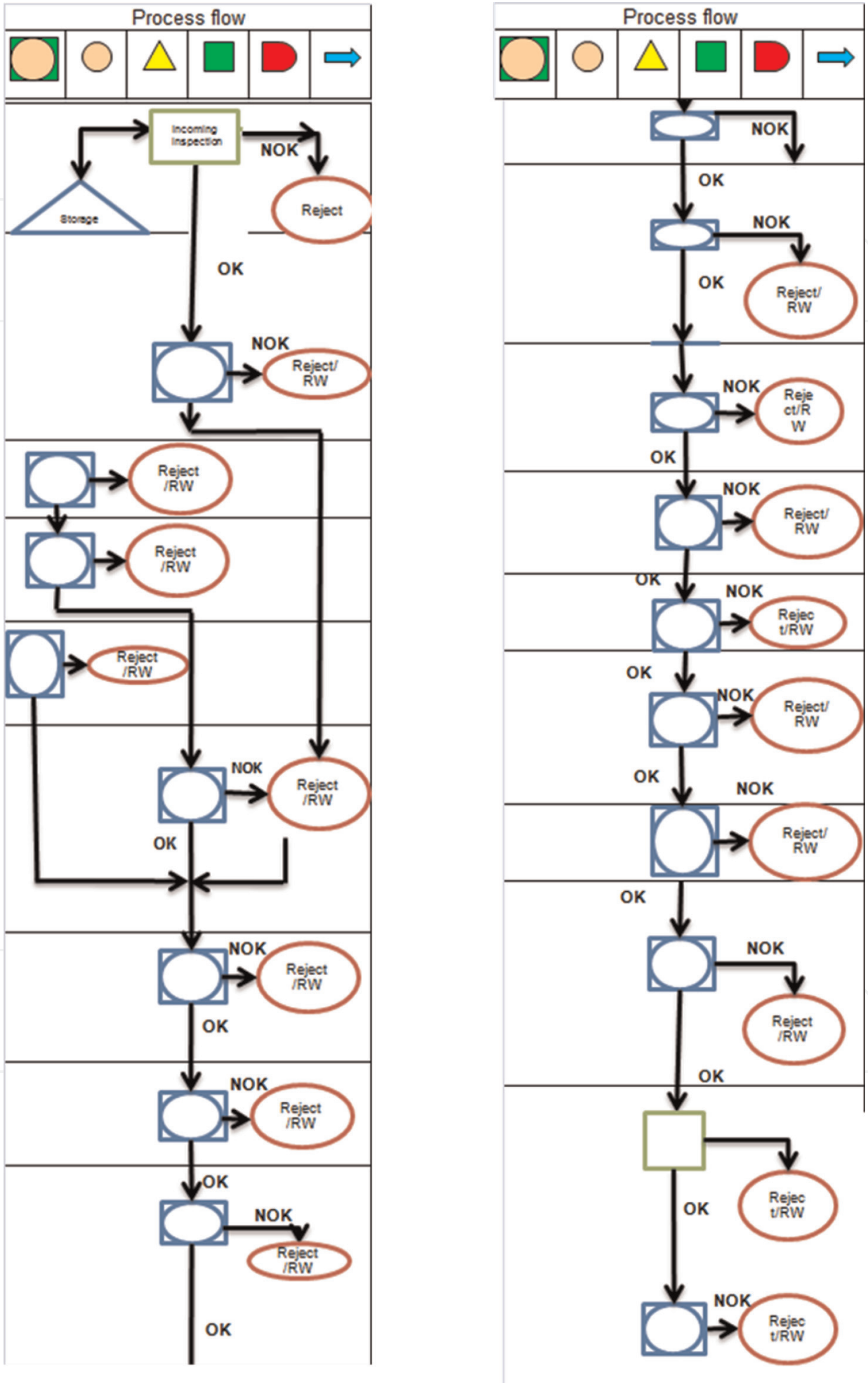


Figure 23.
Process flow for the realization of the "Stator Housing."

Potential failure mode and effects analysis (Process FMEA)

Process step / Function	Potential failure mode	Potential Effect(s) of Failure	Severity "S"	Potential Cause(s)/ Mechanism(s) of Failure	Occurrence "P"	Detection "D"	R.P.N.	Recommended Action(s)
Cutting parts on saw	sloping surfaces	additional consumption of labor (additional technological operations)	4	incorrect positioning of the semi-finished product on the machine table	5	3	60	purchase of a specialized table for the placement and taking over of the semi-finished product
Chamfering	larger chamfered surface dimensions (inclination angles, chamfering dimensions)	weld bead appearance and quality	5	skill of the operator	3	5	75	purchase of chamfering machine
	smaller chamfered surface dimensions (inclination angles, chamfer dimensions)	appearance of welding defects (non-penetration at the weld root)	6	skill of the operator	3	5	90	purchase of chamfering machine
	smaller chamfered surface dimensions (inclination angles, chamfer dimensions)	low mechanical strength of the weld over time	8	skill of the operator	3	5	120	purchase of chamfering machine
	irregular shape of the chamfer	weld bead appearance and quality	5	skill of the operator	4	5	100	purchase of chamfering machine
	irregular shape of the chamfer	low mechanical strength of the weld over time	8	skill of the operator	4	5	160	purchase of chamfering machine
	large unevenness on chamfered surfaces	additional labor (for removal by polishing)	3	skill of the operator	4	5	60	purchase of chamfering machine
Ribs assembling	small number of provisional welds	breaking of temporary welding and displacement of the rib	3	incomplete work instruction	10	2	60	

Potential failure mode and effects analysis (Process FMEA)

Process step / Function	Potential failure mode	Potential Effect(s) of Failure	Severity "S"	Potential Cause(s)/ Mechanism(s) of Failure	Occurrence "P"	Detection "D"	R.P.N.	Recommended Action(s)
Ribs welding	excesive convexity (cod 503/ISO6520-1:2007)	low mechanical strength of the assembling over time	8	Too small current	2	4	64	automatic system welding
	excesive convexity (cod 503/ISO6520-1:2007)	low mechanical strength of the assembling over time	8	Too small voltage	2	4	64	
Bases assembling	the bases are not in the same plane	no machining allowance	6	front wall assembly error	3	3	54	grinding and checking the assembly table
	the bases are not in the same plane	no machining allowance	6	cutting parts error	6	2	72	Purchase of material cutting software (Fast Cam)
	the bases are not in the same plane	too large machining allowance	6	cutting parts error	6	2	72	Purchase of material cutting software (Fast Cam)
	smaller distance from the horizontal axis to the base surface	the overall dimension is not achieved	8	front walls cutting error	3	3	72	
Assembling of intermediate walls / gussets	the intermediate walls are not in the same plane	deviation from linearity between the four walls	8	cutting parts error	3	3	72	
	the intermediate walls are not in the same plane	no machining allowance for the top milling	8	cutting parts error	3	3	72	
	the intermediate walls are not in the same plane	too large machining allowance for the top processing	8	cutting parts error	3	3	72	
	the intermediate walls are not in the same plane	unequal dimensions of the walls after machining	8	cutting parts error	3	3	72	
	the intermediate walls are not in the same plane	large gap when assembling the intermediate walls with the bases	8	cutting parts error	3	3	72	

DOI: http://dx.doi.org/10.5772/intechopen.107401

Potential failure mode and effects analysis (Process FMEA)								
Process step / Function	**Potential failure mode**	**Potential Effect(s) of Failure**	**Severity "S"**	**Potential Cause(s)/ Mechanism(s) of Failure**	**Occurrence "P"**	**Detection "D"**	**R.P.N.**	**Recommended Action(s)**
Assembling reinforcements / stiffeners and frameworks/ terminal box console	geometric deviations (flatness, perpendicularity, parallelism): angle less than 90 degrees	impossibility of mounting blinds / protection grilles / other parts or subassemblies	8	defective / worn EMM	5	3	120	EMM replacement – action in progress
	no machining allowance to the upper part of the housing	additional remediation operations	5	cutting parts error	3	4	60	Purchase of material cutting software (Fast Cam)
Sandblasting before final welding	incorrectly sandblasted areas	possible welding faults	5	skill of the operator	3	4	60	
Final welding	too thin welding beads	low mechanical strength of the weld over time	8	non-compliance with WPS	3	3	72	specific WPS develop-ment
Final welding	shape of the weld: excessive convexity (cod 503/ ISO6520-1:2007)	low mechanical strength of the assembling over time	8	Too small current	2	4	64	
			8	Too small voltage	2	4	64	
Adjustment	surfaces with welding spatter	unsightly product	6	hard to reach areas	3	3	54	purchase of special chisels for cleaning welding spatter
Final Innspection	the appearance of the weld beads outside the documentation tolerances	correction	8	skill of the operator	4	2	64	Operators monitoring

Table 5.
Aspects of FMEA-process analysis for "Stator Housing".

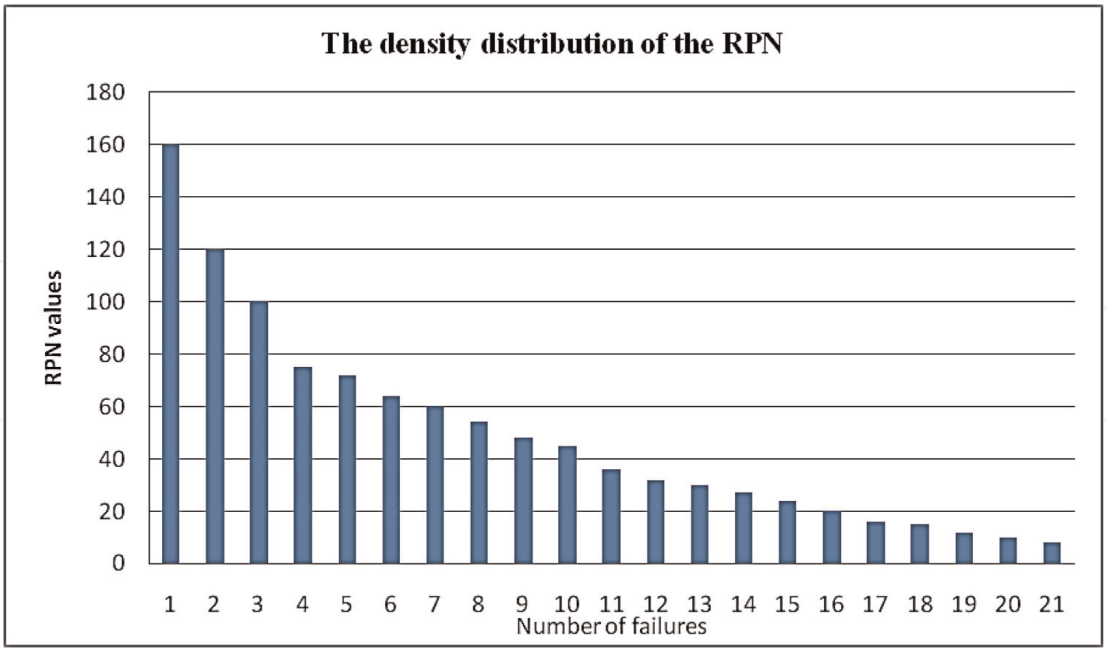


Figure 24.
Diagram of RPN distribution.

The RPN values in descending order for the assembly subjected to the FMEA analysis are represented in the diagram shown in **Figure 24**.

The risk prioritization figure (RPN) is obtained by multiplying the assessment factors established for Severity, Probability of Occurrence and Detection.

The maximum RPN value for the product in question was:

$$RPN = 8x4x5 = 160 \tag{2}$$

This maximal value for RPN was obtained when chamfering on the entire length of the workpiece due to irregular shape of chamfering.

The solution that has been proposed for the correction of this defect was purchasing a chamfering machine, which significantly reduced the RPN value.

From the diagram shown in **Figure 24**, it may be noticed that measures are required for the defects that have RPN values greater than 120. Thus, for the "Stator housing" assembly, for the chamfering operation along the entire length of the part, due to the irregular shape of the chamfer, a low mechanical resistance of welding over time results (Severity – score 8, Appearance – score 4, Detection – score 5), RPN is 160 or, due to the quality of the weld bead, (Severity – score 5, Appearance – score 4, Detection – score 5), RPN is 100. For smaller dimensions and surfaces chamfering, the effect is low weld mechanical strength over time due to the small size of the chamfer (Severity – score 8, Appearance – score 3, Detection – score 5), RPN is 120.

The recommended improvement measure is the purchase of a chamfering machine, with the setting of the responsible department and the deadline for application. Following the application of the last measure, a risk assessment is carried out again. The main potential defects analyzed are: low mechanical strength of the weld; deformations; welding lines; large unevenness on chamfered surfaces; excessive weld convexity; high values of geometric deviations in excess of the prescribed tolerances; assembling errors; non-uniformity of the color of the part surface; cracks; air gaps; welding spatter, scratches.

The potential causes of the defects have been studied and improvement measures have been proposed. These include:

- implementation and monitoring of preventive maintenance program;
- preparation and compliance with specific welding rules;
- purchase of a specialized table for placing and taking over the semi-finished product;
- purchase of a chamfering machine;
- changing the welding installation with an automatic welding installation;
- purchase of a device for measuring humidity and its use;
- grinding and checking the assembly table;
- purchase of special chisels for cleaning welding spatter;
- monitoring operators through actions to monitor operator non-compliance and their regular training.

Figure 25 shows a comparison between the actual process RFT (Right First Time) index for the number of landmarks inspected weekly, after applying the FMEA analysis, and the waiting level.

Figure 25 shows that, after applying the FMEA Process for the Stator Housing assembly, at the weekly check, for Monday, from January to August 2014, the RFT index was always over 80%, and starting from week 21, it was located at 100%, far exceeding the proposed level of expectation of 50%.

In conclusion, by proper use of the analysis of FMEA Process expensive amendments of the assembly "Stator Housing" technological process could be avoided by

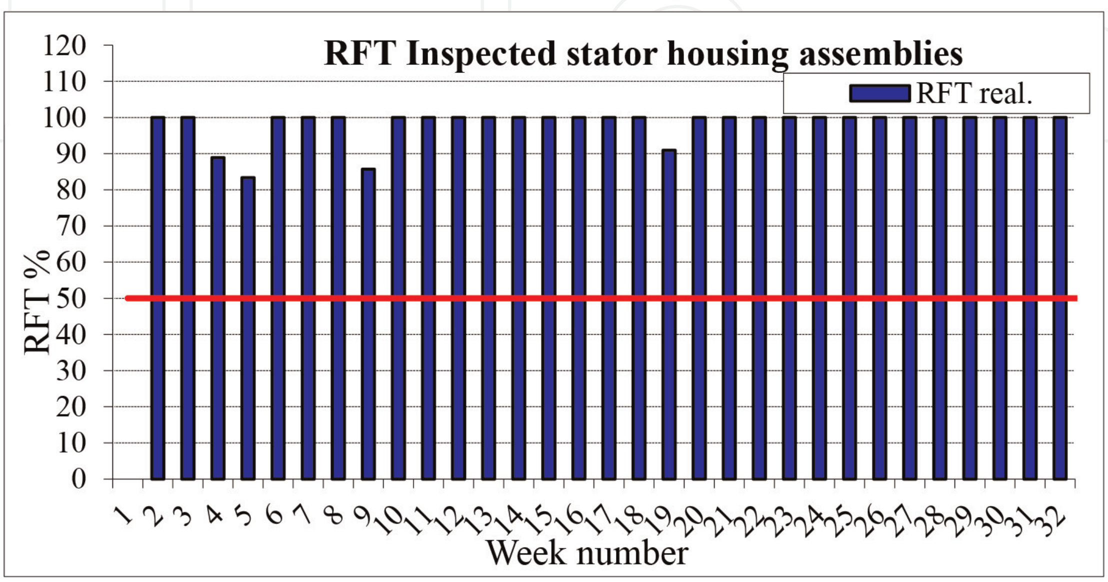


Figure 25.
Actual process RFT index for the number of assemblies inspected.

identifying potential defects, to avoid them, and also, by assessing risks and potential consequences of failures/defects [19].

The main potential defects that were analyzed were: low mechanical strength of the weld; deformations; weld line; large irregularities on the tapered surface; excessive convexity of the weld; high values of the geometric deviations exceeding the tolerances specified values; assembly errors; irregularity of the part surface nuance; cracks; bubbles; weld spatter, scratches.

Potential causes of defects were studied and, after that, improvements were proposed. These include: implementation and tracking preventive maintenance program; preparation and specific compliance for welding; purchase of specialized setting and reception table for workpieces; buying a chamfering machine; changing welding system with automatic welding system purchasing a humidity measuring device and its uses rectification and verification of table assembly; purchase of special chisels for cleaning weld splashes; operators monitoring by monitoring nonconformities operators and their regular training

2.2 Research about implementing FMEA Process for a Packing Shaft

A study on the application of FMEA Process analysis was performed for the packing axis shown in **Figure 26** [21].

Figure 27 shows the execution drawing of the packing shaft, where there also appear the sections with risk factors prone to.

Figure 28 presents the process flow of the shaft, with the operations and stages necessary to achieve the benchmark, in chronological order of their development.

In **Figure 29**, the method of estimating the effects of each process and the influences on the final product is presented [20].

The FMEA Process analysis for the packing shaft was performed by a team of experts from the company.

Table 6 shows the beginning of the table completed after the accomplishment of the analysis.

It was found that there are several operations that have a cumulative score for Severity, Occurrence and Detection, respectively the major RPN risk coefficient of over 90 points.

There are operations that lead to serious disruptions of the technological process, with a high RPN, of more than 100 points (cells colored red, as in **Table 6**), these being the following:

Figure 26.
Packing shaft.

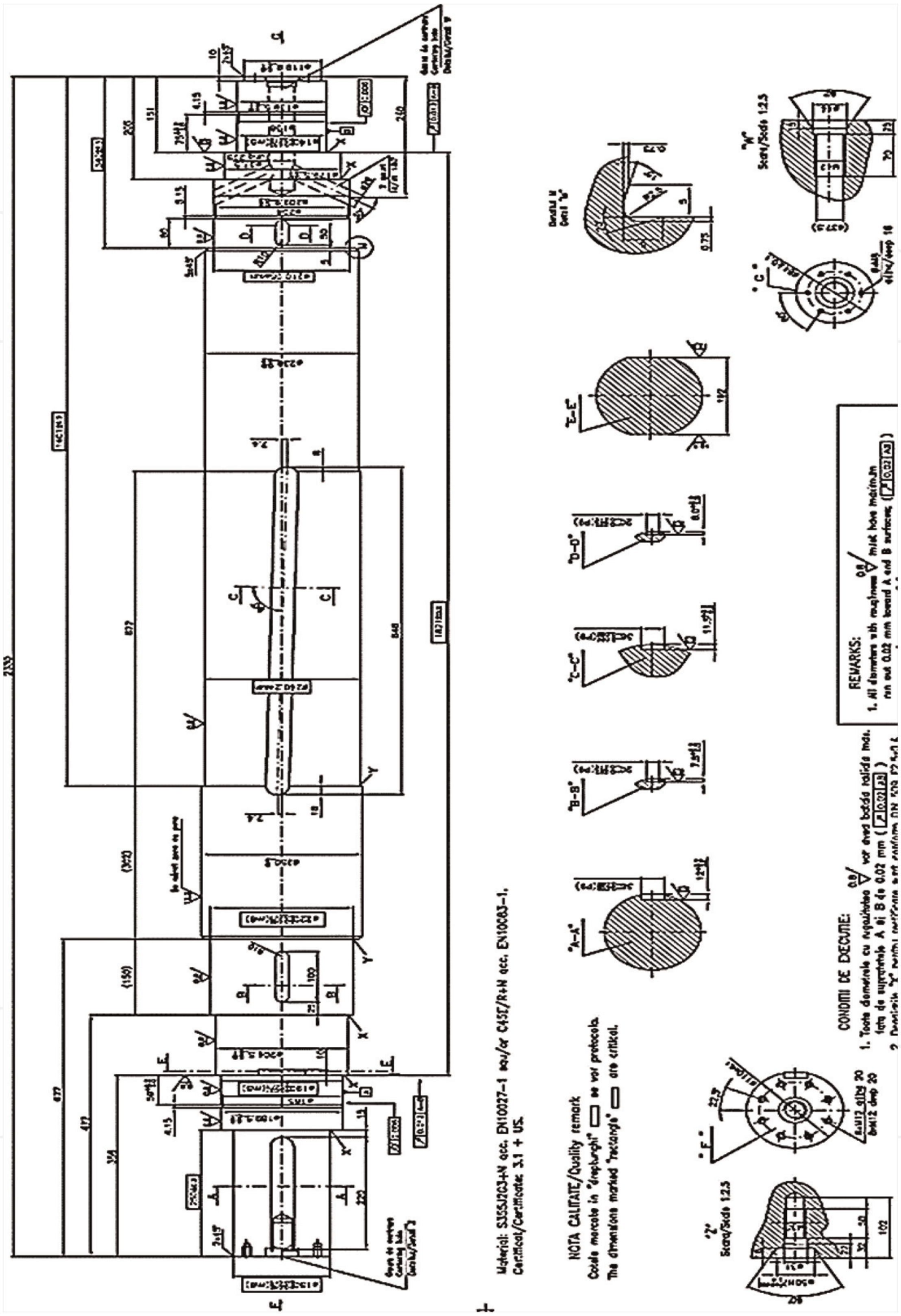


Figure 27.
Execution drawing of the packing shaft.

- for cutting-off operation, when the semi-finished product shows arrow curvature due to deviation from coaxiality because of large successive temperature variations (Severity – score 5, Appearance – score 3, Detection – score 10), so RPN is 150, it is recommended to have material certification from the supplier.

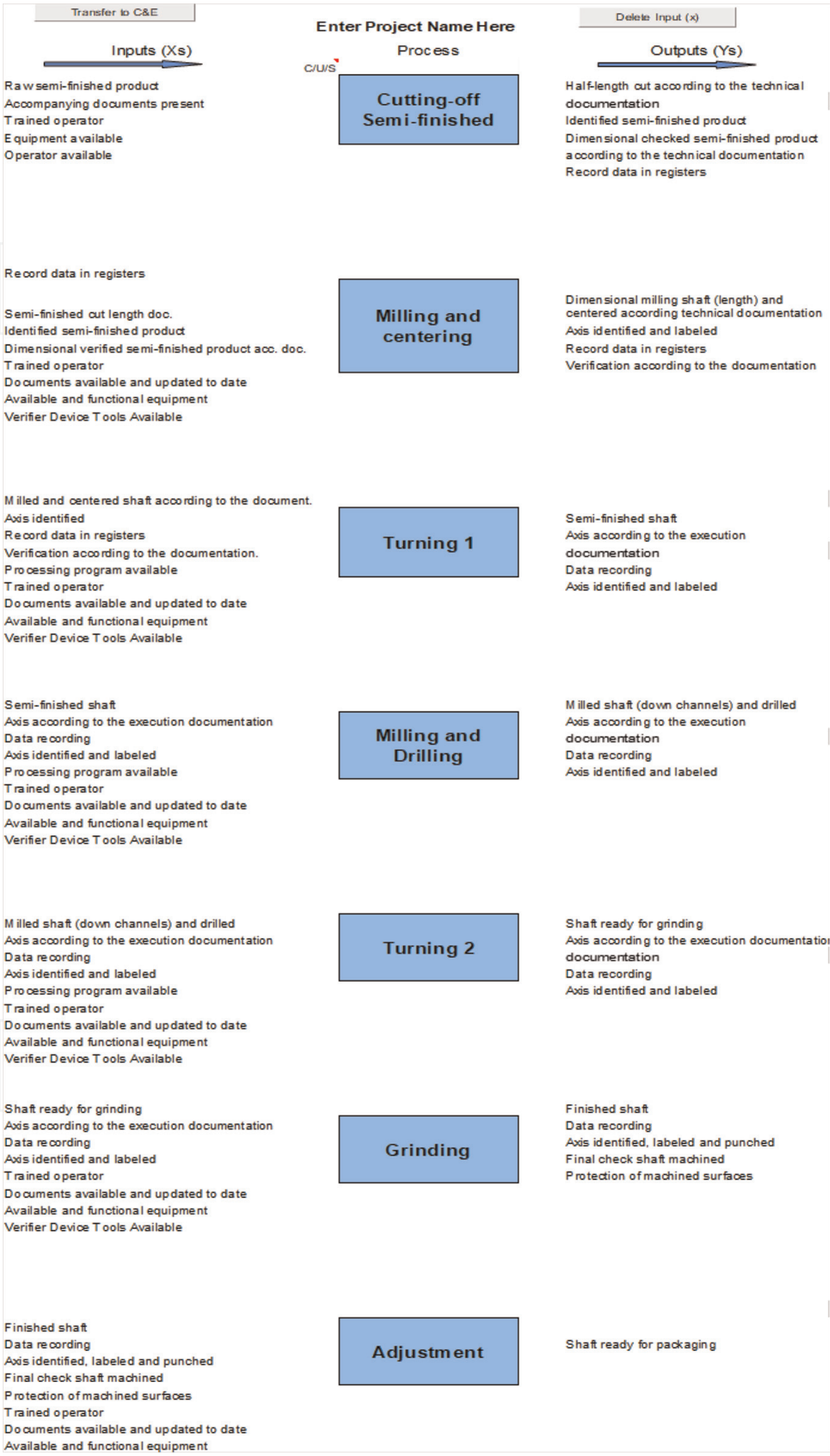


Figure 28.
Process flow of packing shaft subjected to FMEA analysis.

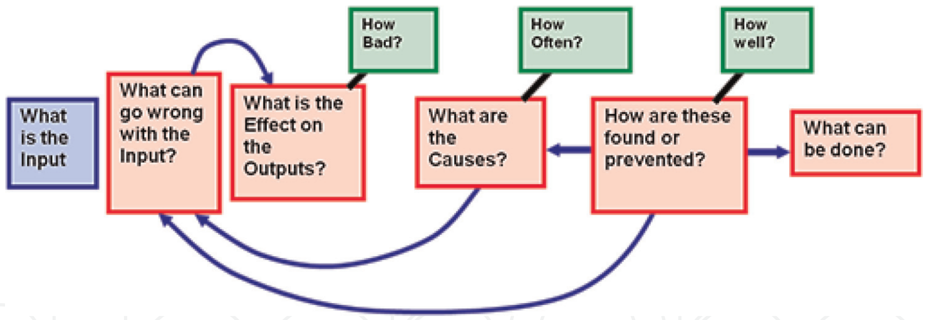


Figure 29.
Method for establishing the influences that occur during technological process [20].

- for cutting-off operation, when the documents are incorrectly completed or incomplete, having the effect of mounting the shaft made of other material than the one mentioned in the specification because of the incorrect filling of the form by the material suppliers (Severity – score 9, Appearance – score 4, Detection – score 3), so RPN is 108, it is recommended to have material certification and control from the supplier;

- for cutting-off operation, when the cut semi-finished product is longer than necessary, which may affect other equipment due to non-compliance with the working instructions (Severity – score 10, Appearance – score 4, Detection – score 3), so RPN is 120, training, regular retraining and self-monitoring on the flow are recommended.

- for turning operation no 1, when the milled and drilled shaft is not in accordance with the documentation and may cause the shaft to be rejected or reclassified due to human error, respectively the operator is trained but does not comply with the manufacturing process (Severity – score 10, Appearance – score 5, Detection – point 4), so RPN is 200 and standard working instructions describing the process steps are recommended.

- for turning operation no 1, when the overhaul is outdated and the shaft may be reshaped, reclassified or rejected due to delayed launch by the design department, respectively the operator is trained but does not comply with the manufacturing process (Severity – score 10, Appearance – score 3, Detection – score 4), so RPN is 120, it is recommended to modify the file later and audit.

It is specified that the abbreviation OTD, which appears in **Table 6** means "on time delivery."

The highest density of risks of occurrence of defects with major result on the product are signaled in the parting-off phases of the semi-finished product, but the highest value of RPN = 250 is recorded in the turning operation, when the milled and drilled shaft does not comply with the documentation, the shaft may be rejected or reclassified due to human error, respectively the operator is trained but does not comply with the manufacturing process.

When recommending measures to improve the process, in order to completely reduce the RPN, the following were considered:

- requesting the material certificate from the supplier;

- self-control and/or check on flow;
- periodic training and/or retraining;
- periodic audit and periodic randomly checks;
- modernization of the milling machine or processing of the shaft by milling at another company;
- purchase of a new milling machine or the modernization of the existing one or processing by third parties;
- change plan for machining tools, work holding devices, and measuring instruments;
- internal orders registration form;
- implementation and supply plan for machining tools, work holding, and tool holding devices and measuring instruments;
- purchasing a new numerically controlled lathe, modernizing the existing one or processing to third parties;
- update for the software of the processing program—introduced in the program, with the processing and revision of the drawings;
- purchase of a program for simulating the turning operation, periodic testing of the program in production;
- periodic testing (once a month) by introducing higher quotas – the first shaft in the series is processed in phase-by-phase mode for error detection;
- update for the software of the processing program—introduced in the program, with the processing and revision of drawings, elaboration data, periodic retraining, clear text verification—self-control;
- periodic trainings and annual audits;
- standard working instructions that describe the process steps.

The RPN values in order of their appearance are presented in the diagram in the **Figure 30** [21].

It can be seen from diagram 30 that the operations with major risk, respectively those with an RPN> 100 appear in the first stages of the shaft processing process, respectively at cutting and turning, a fact also found in **Table 6**.

In **Figure 31**, the RPN values in descending order of parts subjected to FMEA analysis are represented.

After taking the necessary measures to implement the recommendations for each operation with a high RPN, it decreased to zero, which led to the obtaining of finished products with “zero defects.”

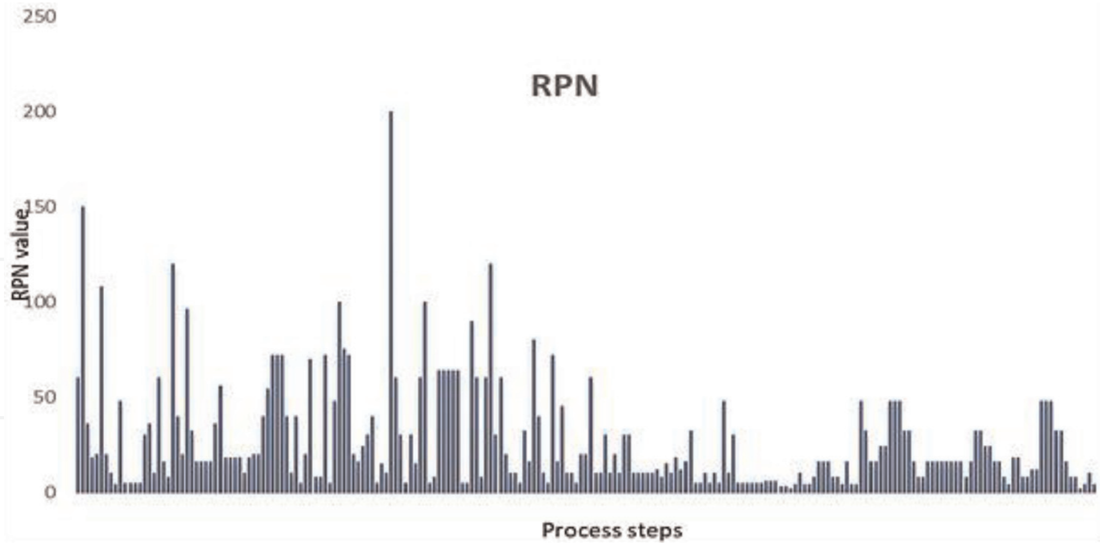


Figure 30.
The RPN values in order of their appearance [20].

The main potential defects analyzed were: deviation from coaxiality due to large successive temperature variations, mounting of the shaft made of a material other than the one mentioned by the specification, milled and drilled shaft is not in accordance with the documentation, shaft reshaping, reclassifying or rejecting, part dimensions damage.

The potential causes of the defects have been determined and improvement measures have been proposed, including:

- implementation and follow-up of preventive maintenance program;
- modernization of the existing milling machine;
- modernization of the numerically controlled lathe on which the turning operations are performed;
- update for the software of the processing program—introduced in the program, with the processing and revision of the drawings;
- purchase of a program for simulating the turning operation, periodic testing of the program in production;
- standard working instructions describing the process steps;
- the operators supervising through noncompliance monitoring actions and operators regular training.

After the application of these measures, a new risk assessment was carried out, finding that the target of having a production with "zero defects" was reached.

Timely use of FMEA-Process analysis can avoid costly changes to the technological process of making the product "packaging tree" by identifying potential defects, avoiding them, and assessing the risks and potential consequences of defects and obtaining "zero defects" as target products [21].

Potential failure mode and effects analysis (process FMEA)

Process step / Function	Potential failure mode	Potential Effect(s) of Failure	Severity "S"	Potential Cause(s)/ Mechanism(s) of Failure	Occurrence "P"	Detection "D"	R.P.N.	Recommended Action(s)
Cutting-off the semi-finished product	Missing identifi-cation	Incorrect material Cutting-off	6	Failure to follow the identification procedure	2	5	60	Self-control Check on flow
	Semi-finished material with deflection	Coaxiality deviation	5	Successive large temperature variations	3	10	150	Certificate of material from the supplier
	Wrongly completed or incomplete documents	Mounting of shaft made of a material other than that specified in the documen-tation	9	Errors in document completion made by the suppliers of the semi-finished material	4	3	108	Certifica-tion and control of material from the supplier
	Unreadable, incom-plete data registra-tion	It affects OTD (On Time Delivery)	5	Non-compliance with the document control procedure	4	3	60	Self-control on flow, training
	Longer cut semi-finished product	It affects OTD	10	Failure to follow work instruction	4	3	120	Training, periodic retraining, self-control on flow
	Longer cut semi-finished product	Increasing internal material losses – reclassification	8	Failure to follow work instruction	4	3	96	Training, periodic retraining
	Wrongly identified semi-finished product	It affects OTD	4	Direct promotion order on flow	7	2	56	
Milling and centering	Semi-finished product cut to size with shorter length	It affects OTD	10	Failure to follow working instructions	4	3	120	Periodic training, versatility
	Semi-finished product cut to size with shorter length	Increasing internal material losses	10	Failure to follow working instructions	4	3	120	Periodic testing (once a week) by entering higher dimensions
	Wrong identified semi-finished product	It affects OTD	5	Direct promotion order on flow	5	8	200	Periodic training, versatility

DOI: http://dx.doi.org/10.5772/intechopen.107401

Potential failure mode and effects analysis (process FMEA)

Process step / Function	Potential failure mode	Potential Effect(s) of Failure	Severity "S"	Potential Cause(s)/ Mechanism(s) of Failure	Occurrence "P"	Detection "D"	R.P.N.	Recommended Action(s)
	Outdated revisions	Material rejection/ reclassifica-tion	9	Wrong technical data sheets	4	2	72	Preventive mainte-nance. Periodic training
	Outdated revisions	Material rejection / reclassifica-tion	9	The archive did not change the drawings	2	4	72	
	Outdated revisions	It affects OTD	9	Material rejection/re-classification	4	2	72	
	Defective machine	It affects OTD	5	Machine wear	7	2	70	Modernization of the milling machine. Periodic retraining
	Defective machine	Deterioration / damage of part dimensions	8	Machine wear	3	3	72	Modernization of the milling machine. Periodic retraining
	Unavai-lable machining tools, work-holding devices and measuring instruments	It affects OTD	5	Poor management of the area	5	4	100	Purchase of a modern milling machine. Calibration of measuring instruments
	Unavailable machining tools, work-holding devices and measuring instruments	It affects OTD	5	They were not supplied on time	5	3	75	Modernization of the milling machine. Periodic retraining
	Damaged machining tools, work-holding devices and measuring instruments	Rejection / reclassifica-tion	8	Advanced wear	3	3	72	

Potential failure mode and effects analysis (process FMEA)								
Process step / Function	**Potential failure mode**	**Potential Effect(s) of Failure**	**Severity "S"**	**Potential Cause(s)/ Mechanism(s) of Failure**	**Occurrence "P"**	**Detection "D"**	**R.P.N.**	**Recommended Action(s)**
Turning 1	The shaft is in accordance with the documenta-tion	It affects OTD	5	Outdated revision of document-tation	4	5	100	Control and up-date of technical documenta-tion
	Unidentified shaft	It affects OTD	5	Non-compliance with the process	5	4	100	In the long run, acquisition of the operation simulation program, periodic testing of the program in production
	Lack of working documenta-tion	Remanu-facture/ reclassify-cation/ waste	10	Work according to another specification	3	3	90	
	Outdated overhaul		10	Launch delayed by Design Department	3	4	120	
	Proces-sing program available, but incorrect		10	Program-ming error	2	4	80	
	Trained operator, but he does not comply with the manufactu-ring process		10	Insertion of wrong corrections in the machine control	5	5	250	Periodic testing (once a week) by entering higher dimensions
	Trained operator, but he does not comply with the manufactu-ring process	It affects OTD	5	Insertion of wrong corrections in the machine control	5	5	125	

Table 6.
Aspects of the FMEA-process analysis performed for the packing axis.

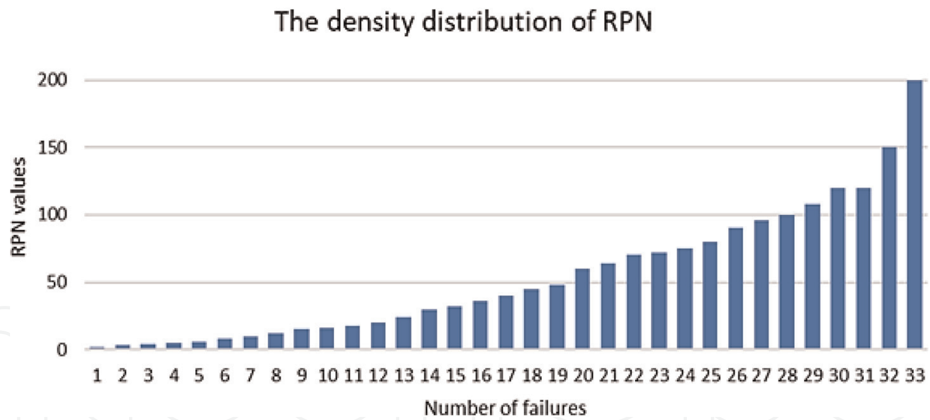


Figure 31.
Diagram of RPN distribution [20].

2.3 Research about the FMEA-Process implementation at First Article Inspection (FAI) for materials composites pieces

Another study focused on some aspects of quality control at the First Inspection Article (FAI) for composite parts used in the railway sector.

An FAI is performed in a planned manner for each first piece or first set of parts made in a project. In many industrial areas, including the railway sector, in the prototyping phase of composite products, this requires strict quality control. The last step in the reproducibility of the validation process is to check that the parts made comply with the technical drawings and specifications of the requirements [22]. Quality control for a prototype, FAI is performed in a planned manner for each first part or first set of parts made in a project. Process performance must be measured by a performance indicator [23].

The FAI will include all details and subassemblies that make up the final product manufactured or ordered. All requirements must be verified by documentation and also all characteristics will be inspected and verified [24]. Approval in the first article is done to demonstrate that the manufacturing process and quality control methods of the products used are appropriate to make a product that meets customer requirements [25].

One of the most important steps in the application of product design FAI is the implementation of the method of efficient process error analysis (PFMEA) for product and process validation [26]. The method of organization and performance is the responsibility of the production department [27]. **Figure 32** shows a detail of the technical drawing of the composite part under study for FAI.

The materials used to obtain the product were [28]:

- low-viscosity polyester resins Giralithe® Ditra GL 2109-10 XP manufactured by Mäder AG Composites, Germany;
- white polyester gelcoat system, based on a NUVOPOL® Gelcoat 37-03 TGP unsaturated polyester unsaturated polyester resin produced by Mäder AG Composites, Germany;
- 3M Scotch-WeldTM 7260 B/A two-component epoxy adhesive manufactured by 3M Deutschland GmbH Industrie-Klebebänder.

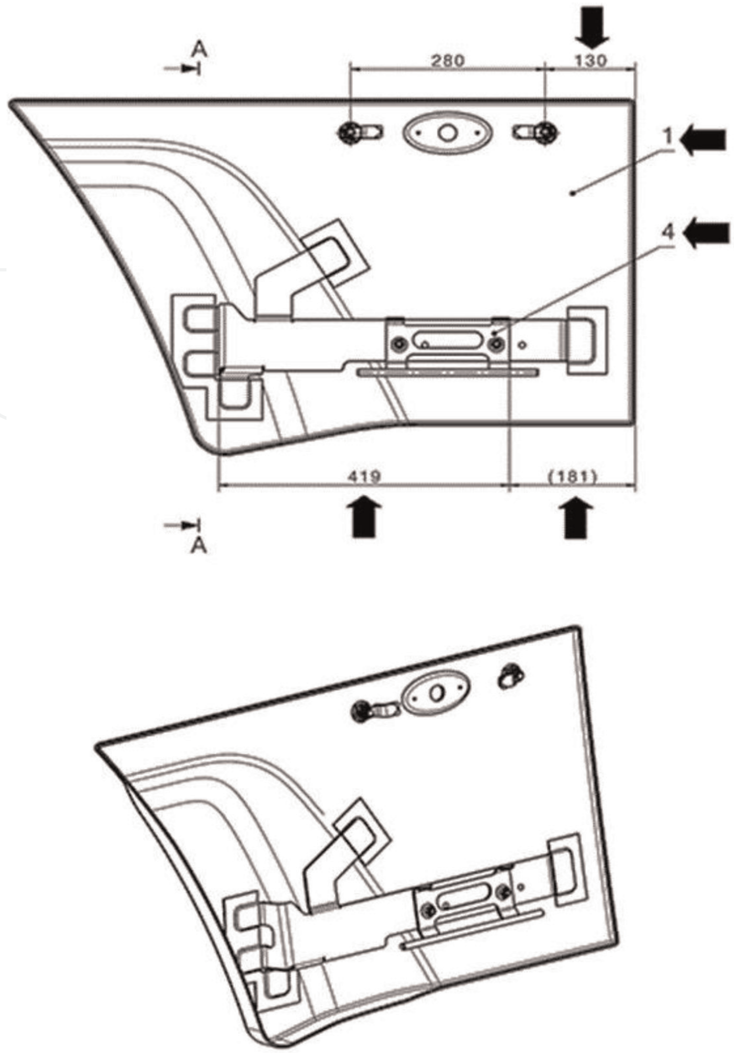


Figure 32.
Details from the technical drawing of the composite piece subjected to FAI study.

Giralithe® Ditra GL 2109-10 XP is a self-extinguishing, self-extinguishing resin made of low-viscosity, low-viscosity polyester resins. It has been specially obtained for applications in public transport engines and vehicles.

NUVOPOL® Gelcoat 37-03 TGP is a specially designed, intumescent, white gelcoat polyester system, based on an isophthalic unsaturated polyester resin.

3M Scotch-WeldTM 7260 B/A Series is a two-component adhesive product that is used at room temperature. These adhesives are designed for bonding hard durable surfaces, elastic hard steel materials, aluminum or composite fibers, and other materials.

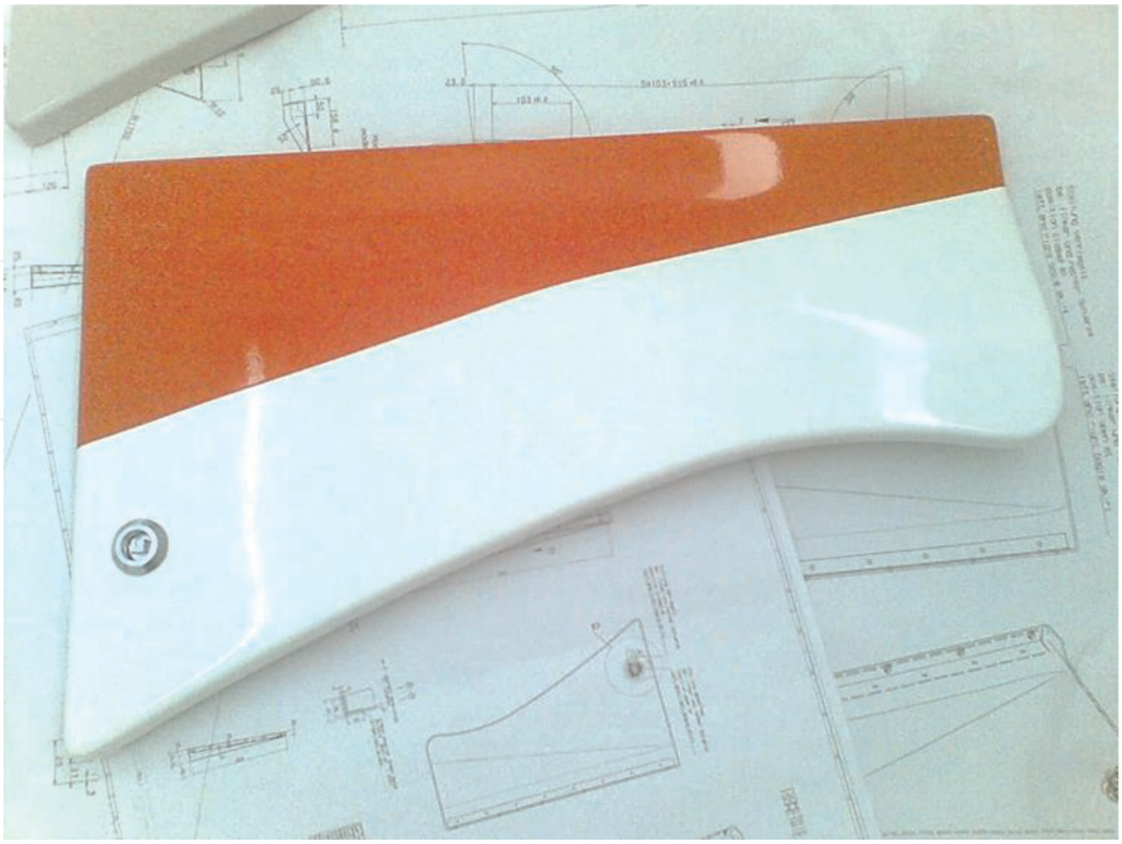
Figure 33a and **b** show the appearance of the final composite part used in the outer front area of the locomotive.

The analysis of product requirements in order to implement FAI for the final composite product is described in the diagram in **Figure 34** [28].

Next, **Figure 35** shows the process diagram for making the composite product.

In order to eliminate the risks of errors and defects during the development of the technological process for the obtaining of the composite part for the railway industry, it was considered absolutely necessary to apply the PFMEA-Process method.

The steps required to develop the PFMEA method were performed according to [29].



(a)

(b)

Figure 33.
The final piece obtained by composite materials.

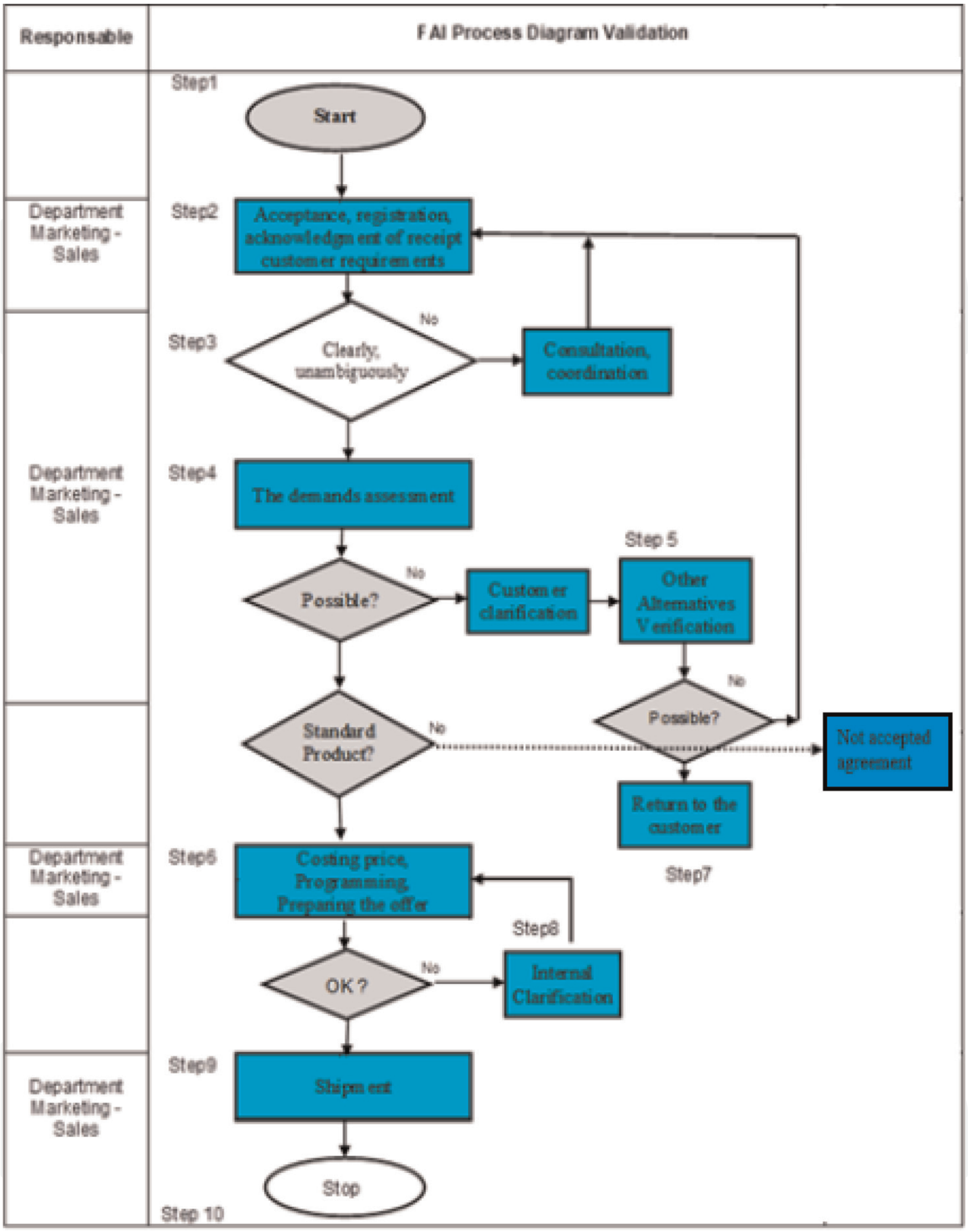


Figure 34.
Logical diagram of the analysis of product requirements [27].

Table 7 shows the important aspects of the PFMEA analysis when making the part, respectively the operations in which the RPN value was higher than 70.

Table 7 shows that, for each operation in which the value of the RPN index was higher than 70 (yellow and red areas), measures were proposed to improve the value of the RPN, finding that, after their application, the value of the criticality index has been greatly diminished.

In **Figure 36**, the distribution of the RPN index for each phase of the technological process is presented [28].

Figure 35.
Diagram of the technological process for the obtaining of the composite product.

Potential failure mode and effects analysis (process FMEA)								
Process step / Function	**Potential failure mode**	**Potential Effect(s) of Failure**	**Severity "S"**	**Potential Cause(s)/ Mechanism(s) of Failure**	**Occurrence "P"**	**Detection "D"**	**R.P.N.**	**Recommended Action(s)**
Material storage	Materials damaged by storage conditions	The part may have manufacturing defects	7	Improper storage conditions	4	4	112	Periodic check of storage conditions
Mold heat treatment	Inadequate treatment of the active surface	The part remains attached to the surface of the mold	8	Operator error	5	4	160	Check in the register of mold records; the last treatment
Materials preparation	The materials are not in validity term	Part does not meet the standards	8	Improper stock turnover	4	4	128	Operator training for stock monitoring and stock monitoring
	The materials are not valid	Part does not meet the standards	8		3	3	72	Operator training and storage conditions check
Gelcoat application	Gelcoat application without catalyst	Part does not meet the standards (not hardening)	7	Broken installation	4	4	112	Application of preventive mainte-nance to the installation
Rolling	Properly unhomoge-nized resin	Part does not meet the standards	8	Broken mixing installation	4	4	128	Traceability sheet
Rolling	Improper manufactu-ring recipe	Part with variable thickness (part does not meet the standards)	8	Operator error	3	3	72	Operator training and checking, tracking
Finishing	Part does not meet the standards	Affecting dimensions when deburring	5	Operator error	4	4	80	Operator training and tracking
Final check	Part does not meet the standards	Shape and dimensional deviations	8	Operator training and tracking	4	4	128	Application of acceptance and verification criteria

Table 7.
Aspects of the FMEA-process analysis performed for the FAI.

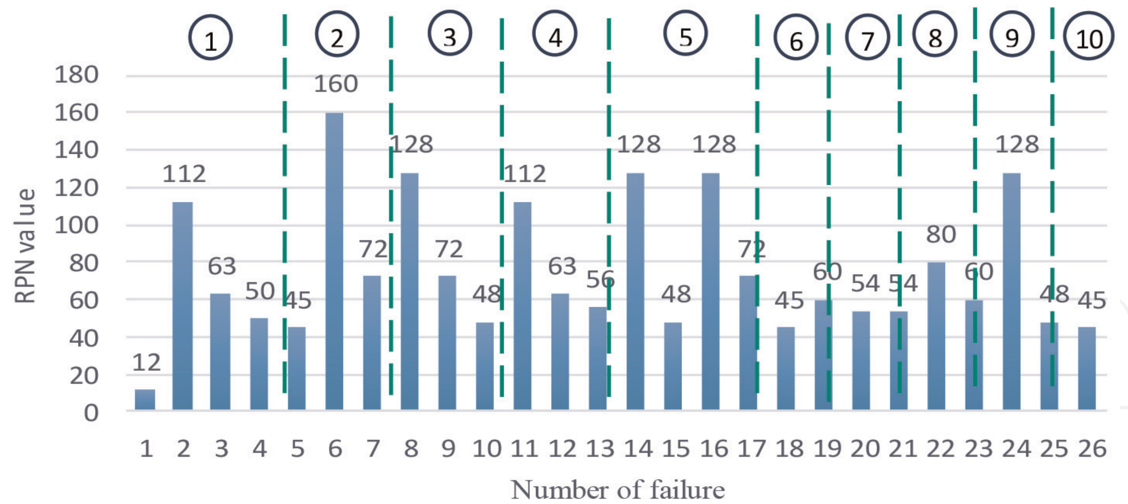


Figure 36.
The RPN index distribution for each phase of the echnological process [28].

In **Figure 36**, the numbers in the circles represent the steps of the technological process: 1 is for the material preparation; 2 is for mold preparation; 3 is the mold treatment; 4 is materials preparation; 5 is the gel-coat applying; 6 is for rolling; 7 is labeling; 8 is for drying; 9 is the finishing; and 10 is the final inspection.

After applying the PFMEA method, the value of the RPN index was reduced below 20 due to the application of the recommended measures. Some of them are presented in **Table** 7.

In conclusion, by applying the FAI, both the product quality and the process were monitored according to customer requirements. Also, during the implementation of the FAI procedures, the risks of errors and defects occurrence were analyzed by applying the PFMEA method and technical and control procedures were developed: Process Diagram, Control Plan, Execution and Control Technology.

The quality of the product is certified by a protocol resulting from the First Article Inspection (FAI) signed between the parties

3. Conclusions

Modern methods of systemic quality design are answers to new quality requirements, they must allow the analysis and elimination of potential defects from the design and implementation stage [7], so that more and more often the notion of "quality design" is encountered.

One of these methods that has become increasingly used in recent decades is the FMEA. Failure modes, effects and analysis (FMEA) is a systematic method of determining and preventing errors, defects, and risks that may occur, applicable to a process, product, or machine used in the process [30].

This method consists of detecting possible defects, inventorying the causes that could cause these failures, demerits effects on users in order to plan the necessary measures to prevent their occurrence. FMEA method is regarded as a basic instrument in project management, the maintenance, and the total quality and could be considered mainly a qualitative analysis.

FMEA is a systematic technique that identifies and prevents product process and system problems (defects) before they occur. It is a method that focuses on preventing problems, therefore increasing safety for improving customer satisfaction.

FMEA can be used in the following situations [31]:

- development of products or processes;
- amendments to existing products processes or system;
- assess the probability of failures, in case of important components in terms of overall safety;
- adapt products to new conditions;
- reduce costs by identifying system, product, process and system improvements early in the development cycle.
- evaluate the design and processes from a new advantageous point.

By applying this method, the risk of failures in the design and manufacturing of products is reduced

On this basis, it ensures reduced costs in all stages of quality spiral: the design through a better reflection of customer requirements in quality design, supply, to avoid problems caused by improper selection of suppliers, production by preventing critical points in the service door, reducing customer complaints, etc.

The method is applied in two main variants [32]: in the product design or process development stage product and process.

FMEA design product to the design of products (components) or their redesign to prevent errors in design and implementation of future product failures is applied. Responsibility for FMEA design product implementation is the responsibility of design department.

After presenting the methodology of FMEA, the application and implementation of some proper research in this area were presented.

The studies developed on the implementation of quality methods in manufacturing processes in automotive engineering focused on the following directions:

- application of the FMEA-Process method;
- quality control on inspection of the first article (FAI);

For the FMEA-Process analysis (PFMEA), it was considered of interest to approach several studies on the application of the method for:

- a packing shaft
- a “stator housing” assembly
- parts made of composite materials used in the railway sector.

After applying the FMEA method, it was found that for both elements studied, after applying the necessary measures, considered after the analysis, in order to execute the recommendations for each operation with a high RPN, it decreased to zero, which led to some finished products with "zero defects."

Another research carried out was the study of aspects on quality control at the inspection of the first article (FAI) for parts obtained from composite materials used in the railway sector. By applying FAI, both product quality and process were monitored in accordance with customer requirements.

Also, during the implementation of the FAI procedures, the risks of errors and defects were analyzed by applying the FMEA process method, and technical and control techniques were developed: Process diagram, control plan, execution, and control technology.

After applying the PFMEA method, the value of the RPN index was reduced below 20 due to the application of the recommended measures, and the product quality was confirmed by the elaboration and signing by the parties (manufacturer and beneficiary) of the protocol resulting from the inspection of the first article.

Acknowledgements

The authors are grateful to the University of Craiova, Faculty of Mechanics, for advice and support. This research was funded by University of Craiova, Faculty of Mechanics, 13 A.I. Cuza Street, RO-200585, Craiova.

Author details

Cristina-Ileana Pascu*, Raluca Malciu and Ilie Dumitru
Faculty of Mechanics, University of Craiova, Craiova, Romania

*Address all correspondence to: ileana.pascu@edu.ucv.ro

References

[1] Swamidass PM. Encyclopedia of Production and Manufacturing Management. Boston: Springer; 2000

[2] Montgomery D. Statistical Quality Control. 7th ed. New York: John Wiley& Sons; 2013. p. 768

[3] Lixandru CG. Supplier quality management for component introduction in the automotive industry. Procedia –\ Social and Behavioral Sciences. 2016;**221**:423-432

[4] Pekuri A, Haapasalo H, Herrala M. Productivity and performance management – Managerial practices in the construction industry. International Journal of Performance Measurement. 2011;**1**:39-58

[5] Ott ER, Schilling EG, Neubauer DV. Process Quality Control: Troubleshooting and Interpretation of Data. 4th ed. Milwaukee: ASQ Quality Press; 2005. p. 628

[6] Ashley RR. Total Quality Management (TQM). Bloomington: AuthorHouse; 2008. p. 324

[7] Mhetre RS, Dhake RJ. Using failure mode effect analysis in a precision sheet metal parts manufacturing company. International Journal of Applied Sciences and Engineering Research. 2012;**1**(2): 302-311

[8] Segismundo P, Cauchick M. Failure mode and effects analysis (FMEA) in the context of risk management in new product development: A case study in an automotive company. International Journal of Quality & Reliability Management. 2008;**25**:899-912

[9] Carlson CS. Understanding and applying the fundamentals of FMEAs. In: Annual Reliability and Maintainability Symposium (RAMS); 27-30 January 2014. USA: Colorado Springs; 2014. p. 32

[10] Marvin RM, Hoylan A. System Reliability Theory: Models, Statistical Methods, and Applications. 2nd ed. New York: Wiley Series; 2004. p. 672

[11] VDA 4-Chapter FMEA: Product and Process FMEA, 2nd ed. 2019

[12] Bouti A, Aitkadi D. A state-of-the-art review of FMEA/FMECA. International Journal of Reliability, Quality and Safety Engineering. 1994;**1**(4):515-529

[13] Pugna AP, Potra S. Controlul și Asigurarea Calității. Ghid de redactare a Documentelor Calității. Timişoara: Editura Solness; 2015. p. 165

[14] Ford Design Institute. Failure Mode 60 and Effects Analysis. FMEA Handbook Version 4.1. Copyright © 2004. Dearborn, MI: Ford Motor Company. p. 290

[15] Guide-Methodologique-Audit-Processus-Renault. 1st ed. 2002

[16] Oprean C, Kifor CV. Quality Management. Germany: Callidus Publishing House; 2008

[17] Zheng LY, Liu Q, McMahon CA. Integration of process FMEA with product and process design based on key characteristics. In: Proceedings of the 6th CIRP-Sponsored International Conference on Digital Enterprise Technology, Advances in Intelligent and Soft Computing (DET 2009); 14-16 December 2009. Hong Kong. pp. 1673-1686

[18] AIAG. Statistical Process Control (SPC), Reference Manual. 2nd ed. 2005.

DaimlerChrysler Corporation, Ford Motor Company, and General Motors Corporation. p. 232

[19] AES Standards. Available from: http://quality.aes-standards.com/fmea.htm [Accessed: April 28, 2022]

[20] Pascu CI, Paraschiv D. Study about Improving the Quality Process Performance for a Steel Structures Components Assembly using FMEA Method. In: Proceedings of International Congress Automotive, Safety and Environment (SMAT), 23-25 October 2014. Craiova, Romania. pp. 103-109

[21] Pascu CI, Paraschiv D. Research about using the Failure Mode and Effects Analysis method for the quality process performance. IOP Conference Series: Material Science and Engineering. 2020; **898**:235-240

[22] Guidelines for the Development of Process Specifications, Instructions, and Controls for the Fabrication of Fiber-Reinforced Polymer Composites. 2003. Available from: http://www.tc.faa.gov/its/worldpac/techrpt/ar02-110.pdf. [Accessed: April 28, 2022]

[23] Morris R, Enhance R. First Article Inspection. New York: E-Publishing Inc; 2007

[24] Pennella CR. Managing Contract Quality Requirements. Wisconsin, USA: Quality Press Publishing; 2006. p. 233

[25] Chrysler Corporation, Ford Motor Company, General Motors Corporation. Advanced Product Quality Planning (APQP) and Control Planning. Reference Manual. 2nd ed. New York: Chrysler LLC, Ford and General Motors; 2008. p. 117

[26] Stamatis DH. FMEA: A General Overview, Failure Mode and Effect Analysis: FMEA from Theory to Execution. 2nd ed. Milwaukee, WI, USA: ASQ Quality Press; 2003. p. 488

[27] Nannikar AA, Raut DN, Chanmanwar RM, Kamble SB. FMEA for manufacturing and assembly process. In: Proceedings of International Conference on Technology and Business Management (ICTBM-13), March 18-20. Dubai; 2012. pp. 501-509

[28] Pascu CI, Gheorghe S, Popa D. Aspects about the quality control at first article inspection (FAI) for parts obtained by materials composites used in the railway sector. In: Advanced Engineering Forum. Switzerland: TransTech Publication; 2018. pp. 262-267

[29] Chrysler Corporation, Ford Motor Company, General Motors Corporation. Potential Failure Mode and Effects Analysis (FMEA). Reference Manual. 2nd ed. Detroit, Michigan, USA: Chrysler LLC, Ford and General Motors; 1995. p. 64

[30] Paciarotti C, Mazzuto G, D'Ettorre D. A revised FMEA application to the quality control management. International Journal of Quality & Reliability Management. 2014;**31**(7): 788-810

[31] Jain K. Use of failure mode effect analysis (FMEA) to improve medication management process. International Journal of Health Care Quality Assurance. 2017;**30**(2):175-186

[32] Lakhmi CJ, Lim CP. Handbook on Decision Making. Vol 1: Techniques and Applications. Springer-Verlag Berlin Heidelberg; 2010. p. 545