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QUALITY PAPER

An ISO 9001 based approach for the implementation of process FMEA in the Brazilian automotive industry

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Abstract

Purpose – The purpose of this paper is to present a structured way for the definitions of the Process Failure Mode and Effect Analysis (FMEA) attributes, such as potential failure mode, potential cause and potential effect, in order to make it simpler to define the controls and scores.

Design/methodology/approach – This study performs, through a case study in incoming inspection of raw material, the comparison of a conventional application of the Process FMEA with a proposal based on the concepts of process approach defined by ISO 9001.

Findings – Even written in a form similar to a script, the application of Process FMEA is a very complex activity and, like most quality tools, before being applied, FMEA should be clearly understood by the team. One way to facilitate this understanding is considering the sequence of events in the failures analysis to understand their causes and effects, just as are the sequences of inputs and outputs in the definition of the process approach addressed in ISO 9001.

Originality/value – This paper shows a simple way to better structure Process FMEA, facilitating meetings with multidisciplinary teams.

Keywords ISO 9001, Process approach, Process FMEA

Paper type Case study

1. Introduction

In recent years, a large number of organizations have been using the Failure Mode and Effect Analysis (FMEA) to develop their processes. However, the technical specification ISO/TS16949 requires the use of this tool for the whole automotive supply chain, during the development of a new product, which made them look at FMEA more seriously. Unfortunately, despite the published reference manuals and constant training, hardly any organization is able to use all the benefits that FMEA provides.

A search at the ISI Web of Knowledge site shows that in the last ten years in the research area of engineering presented 123 works with the acronym "FMEA" in the title, and only 40 of the total were scientific papers. From these 40 papers, the Year 2013 was presented the largest number of published articles (eight). However, what stands out is that the number of citations to these 40 papers is increasing between 2007 and 2013, starting with less than ten citations and coming to the end of that period to more than 90 citations. Figure 1 presents a summary of this survey.

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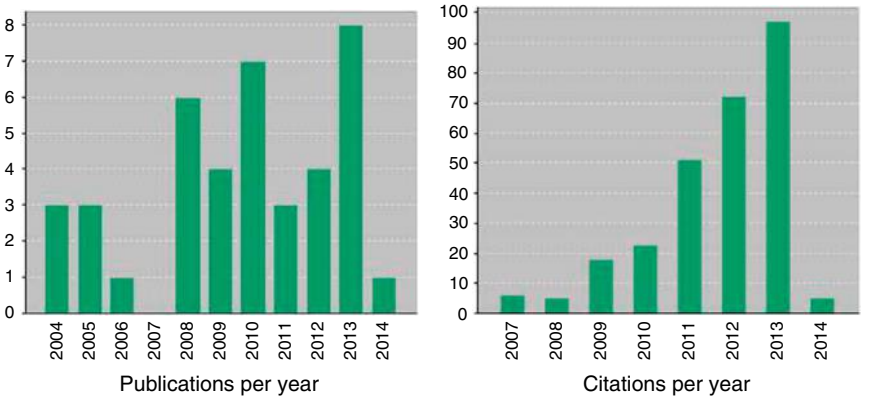

Figure 1.
Published and cited papers about FMEA in engineering area

Through a survey in some companies in the automotive segment, Aguiar *et al.* (2010) conclude that most of people who know and use FMEA do not see it as a powerful tool, but as something that needs to be done in order to satisfy regulatory requirements. One of the main reasons for this approach is that most FMEA are erroneously constructed and used.

FMEA should be applied as a key element of quality planning in companies' processes. Authors such as Stamatis (1995), Palady (1995), Reid (2005) and Teng *et al.* (2006) converge on the idea that organizations which use FMEA correctly save resources and reach high levels of customer satisfaction. FMEA can be a very powerful tool when applied accurately. Like any other quality tool, before being used, it must be understood and, once this understanding is obtained, and added to the commitment of the team involved, it becomes possible to identify the financial benefits which will result from improvements to their products and processes.

Companies that implement a manufacturing process connected to most of the controls defined in the FMEA are able to develop systems that provide accurate data on the impact of the failure, the rate of occurrence, as well as the detectability of failure. Due to this precision, the risk of each failure can be clearly identified and, if required, some changes in the production process can be made. However, it would be necessary to review the Process FMEA and Control Plan, in order to determine the impact of such changes.

To demonstrate the differences between those companies which do and do not use Process FMEA correctly and efficiently, this paper presents an application of this tool based on the concepts of process approach defined in ISO 9001, which is the newness regarding this subject in this paper. In order to demonstrate how significant is this new approach, a comparison with the conventional application is performed in a case study at an automotive company's incoming inspection activity.

2. ISO 9001 and the process approach

The standards of the ISO 9000 series were edited for the first time in 1987 by the International Organization for Standardization and rapidly became a reference for managing quality in companies (Pinto *et al.*, 2008). As written by Rusjan and Alic (2010), the standards have been revised approximately every seven years by developing their requirements and expected effects on business performance. In November 2008 the fourth edition was issued (following editions in 1987, 1994 and 2000), this revision of the

norm, compared to the 2000 version on which this study is based, represents fine tuning, rather than a thorough overhaul.

According to Wahid *et al.* (2011) the new standard does not contain any new requirements. Furthermore, the structure and outline of ISO 9001:2008 is identical to that of ISO 9001:2000. The ISO 9001:2000 contains five main clauses such as quality management system, management responsibility, resource management, product realization, and measurement, analysis and improvement. Pinto *et al.* (2008) complete the setting with other important points such as: process approach structure; emphasis on the continuous improvement of products and services, stronger commitment of the company's management to the quality management system, focus on the measurement and the analysis of the organization results and monitoring of customers' satisfaction.

These guidelines are focussed on procedures, controls and documentation, with standards designed to help companies identify vulnerabilities, streamline operations and ensure a consistent level of quality (Kartha, 2004). With the issue of the ISO 9000:2000 requirements like customer focus, process orientation and continuous improvement are emphasized and hence more benefits are expected (Rusjan and Alic, 2010). The worldwide spread of these standards has boosted the advancement of quality management and its current stage of evolution in organizations allowed to pass their adoption to be recognized in the market as a quality assurance certificate.

The requirements of the latest two editions of the ISO 9000 more strongly emphasize the effective implementation of business processes (Rusjan and Alic, 2010). One of the most striking aspects is related to the process approach, whose basic concept provides a new way to structure and manage the activities by processes in a systematic and integrated way, aligning the expectations of customers to the effectiveness of the entire organization. In designing the most frequent process is any activity or set of activities that takes an input, adds value to it and provides an output to a specific customer as shown in Figure 2, based on concepts from ISO 9001:2000.

3. Process FMEA

The method for FMEA, has its first recorded use concept in 1949 (Marriott *et al.*, 2013), from US military development in order to determine the effect of the occurrence of failure to systems and equipment. The first formal application was made in the 1960s, the USA's aerospace industry, specifically in the Apollo Project of the National Aeronautics and Space Administration (NASA) that, as reported by Sharma *et al.* (2005), developed a method to identify, systematically, potential failures in processes by defining the causes and effects, and from this, define actions to reduce or eliminate the risk associated with these failures. According to the Society of Automotive Engineers (2001), in the late 1960s and early 1970s, several professional groups have begun to publish procedures for performing the FMEA, among these are:

- SAE ARP 926, published in 1967 titled "Fault/Failure Analysis Procedure"; and
- MIL STD 1629, published in 1974 titled "Procedures for Performing a Failure Mode, Effects and Criticality Analysis."

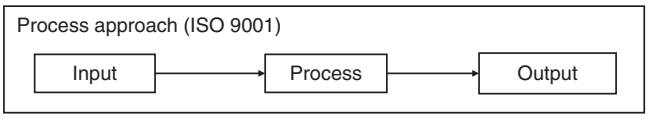

Figure 2.
Process approach

In the 1980s, the FMEA started to become a benchmark for process development, initially in the aerospace industry. In 1988 the Ford Motor Company published a manual "Design and Process FMEA" that applies the methodology for product development and manufacturing process (Society of Automotive Engineers, 2001). The automotive industries have developed standards for their suppliers to assure the quality of their products. In order to harmonize into a single set of quality requirements to be applied in the supply chain, the US automakers General Motors Corporation, Chrysler Corporation and Ford Motor Company created in 1994 the QS-9000 standard. This standard has developed a program called Advanced Product Quality Planning (APQP) where, among other methodologies, has joined FMEA with some changes, primarily in the definitions of the scoring criteria. Currently, the quality systems of Brazilian companies in the automotive sector follow the technical specification ISO/TS 16949 that somehow have inherited FMEA requirement from QS-9000 system.

According to Aguiar *et al.* (2010), FMEA should be used to perform risk assessment of understanding what the impacts on the costumer if the process were to fail. The team must analyze any action to minimize the risks of process and guide improvement activities. FMEA is known as a live document that must be reviewed and updated whenever procedures are changed, requiring its query and modification in cases where the process has any quality problem, in order to ensure all possible actions to avoid a recurrence in the future. Puente *et al.* (2002) emphasize that the FMEA evaluates the severity of each failure on the impact into customers, as well as its possibility of cause occurrence and failure detection before achieving the customers. The use of the FMEA is currently considered a key element in quality process planning, according to Stamatis (1995), Palady (1995), Reid (2005), Teng *et al.* (2006) and Vinodh and Santhosh (2012): the organizations save resources and they have high levels of customer satisfaction when they perform a full application of FMEA. Thus, FMEA is a very powerful method when applied correctly, but, otherwise, does not show its benefits (Devadasan *et al.*, 2003; Xiao *et al.*, 2011).

Chang *et al.* (2013) and Cassanelli *et al.* (2006) state that the FMEA is known to be a procedure for analyzing a given system, used to identify potential failure modes, causes and effects on process performance and its analysis performed preferably in advance, within the cycle development so that the removal or relief of the failure mode is valid and effective preventive way. This analysis can be started once the process is defined. Reid (2005) also highlights that the FMEA provides the ability to quantify the risks of the process so that the highest risks are more easily identified, which is of great importance, since in the field of quality, the actions to be taken should not be defined intuitively. Thus, Process FMEA should be represented as a sequence of three events defined as: causes, failures and effects, as shown in Figure 3.

Process FMEA is applied by the team responsible for manufacturing in order to ensure that an assessment of the failure modes of the process and the consequent definition of control mechanisms. According to Ahsen (2008) and Mandal and Maiti (2014), the objective of FMEA is to prevent unacceptable failures from reaching the customer and to assist management in a more efficient allocation of resources,

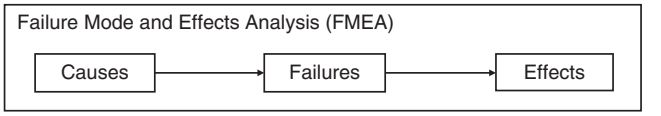

Figure 3.
Events that address Process FMEA

due the identification of potential failure modes of the process, evaluating their causes and their effects.

Chang and Sun (2009) repot that FMEA is a decision-making tool for prioritizing corrective action to enhance product/system performance by eliminating or reducing failure rate. The use of Process FMEA eliminates the weaknesses of process, reducing the risk of failure to acceptable values. When effectively used, Process FMEA, besides being a powerful method in the analysis process, enables continuous improvement and works as a historical record for future studies. The use of FMEA is to identify the process characteristics that are critical for the various failures modes, by questions regarding the consequence of failure, probability of occurrence and probability of detection before they affect the customer (Slack *et al.*, 2007). Thus, the relationship between the severity of the failure mode, the frequency which failure can occur and the probability of detecting a failure, Process FMEA aims to define, demonstrate and improve the engineering solutions in response to the quality, reliability, maintainability, cost and productivity. The use of Process FMEA is recorded in a standard form that combines the potential failure modes associated with the causes, effects, recommended actions, among others as shown in Table I.

FMEA begins with the formation of a group of people to identify the process to be analyzed, its functions, the types of failures that can occur, the effects and possible causes of such failures. Then the group evaluates the risks of each cause of failure.

FMEA is a decision-making tool for prioritizing improving action to enhance process performance by eliminating or reducing failure rate, and, in FMEA, there are three factors that determine failure risk priority (Chang and Sun, 2009). The first factor is severity (S), which is the seriousness of effect of the failure. The second factor is

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS
(PROCESS FMEA)

Key Date: FMEA Number:
Project: Page ____ of ____
Item: Prepared By:
Core Team: FMEA Date (Orig.): _____ (Rev.) _____

													Action Results				
Process Function / Requirements	Potential Failure Mode	Potential Effect (s) of Failure	Sev	Class	Potential Cause (s) / Mechanism (s) of Failure	Occur	Current Process Controls prevention	Current Process Controls Detection	Detec	RPN	Recommended Action (s)	Responsibility and Target Completion Date	Actions Taken	Sev	Occur	Detec	RPN

Table I.
FMEA form

occurrence (O), which is the probability for each potential cause becomes a failure. The third factor is detection (D), which refers to the ability to detect potential failures before the impact of the effect is realized. As stated by Estorilio and Posso (2010), the RPN is the product of the severity, occurrence and detection rates and its purpose is to indicate the priorities for recommended actions.

Sant'Anna (2012) pointed out that the team examines all actions that can be taken to reduce risks. These measures are analyzed for viability, and then those that can be deployed are determined. One way to control the outcome of these measures is by the FMEA form, through columns where are recorded the measures recommended by the group, name of responsible and duration. A record of the measures actually taken must be produced before undertaking any new risk assessment.

Within the process approach defined by the ISO 9001, Process FMEA fits as shown in Figure 4, where the failures and the causes to be analyzed are within the current process and its effects are treated as outputs. Eventual causes or failures previous processes should be analyzed in these earlier Process FMEAs, considering the effect of impact analysis in this current process.

4. Research method

Yin (1994) defines case study as an empirical inquiry that investigates a contemporary phenomenon within its real life context, especially when the boundaries between phenomenon and context are not clearly defined. The case study developed in this study has some descriptive characteristics, as aims to signal to the reader a reality he does not know. Not seeking to establish relations of cause and effect, but just showing reality as it is, although results may be used later in hypotheses formulation of cause and effect.

Due to confidentiality issues, the company selected for performing this case study was called "ABC Company." The reason for selecting this company is based in attendance in some pre-determined criteria. Table II presents the criteria used and how they were met.

As techniques of data collection, semi-structured interviews with the coordinator of FMEA in "ABC Company" and direct observation of the FMEA forms already developed and implemented were performed. For purposes of this study, was used as the unit of analysis, the Process FMEA incoming inspection of "ABC Company."

5. Results and discussion

According to Eisenhardt (1989) the case should be chosen by reason of having certain desirable characteristics. In a research conducted in automotive companies, Aguiar and Salomon (2007) identified some specific aspects in the Process FMEA implementation that, according to the cited references, were classified as irregularities that are detrimental to quality management throughout the stages of the process manufacturing automotive parts. Among these steps, there is the activity of incoming inspection, where the characteristics of the products purchased are checked in order to assess their

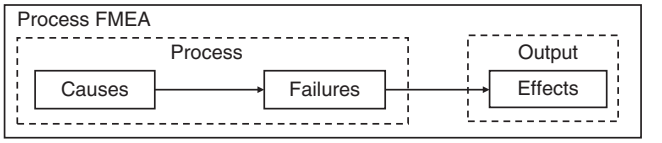

Figure 4.
Process FMEA within the process approach

Selection criteria	Criteria acceptance
Company from automotive sector whose application of FMEA is a mandatory requirement	The object of study's company is from automotive sector, with ISO/TS16949 certification for quality management system
FMEA application based on the concepts of process approach	The company applied in the process of incoming inspection the two techniques in an integrated way
Absence of a formal systematic process to identify reference as a way to obtain a greater effectiveness in management	Before performing integration and achieving their results, the company had no formal system for the integration of different techniques
Development of management projects that may be interesting to other companies	The developed method is great potential for extending the supply chain of "ABC Company"
Willingness to provide access to information, data and time available for interviews	The "ABC Company" belongs to the group of companies that have partnered with the educational institution in which the authors of this paper belong

Table II.
Selection criteria and how they were met

conformity to specification requirements described in the purchase orders. As this is not a stage where changes occur in the product, many companies do not devote enough attention to this activity, but any failure can cause very serious effects, including production of parts with the material different from specified.

Adopting multiple cases, a higher degree of generalization is achieved (Yin, 1994), therefore aiming at a deeper evaluation, a single case is adopted. This situation is presented in Table III, which depicts a typical condition of Process FMEA application in sheets receiving in a metallurgical company that belongs to the Tier 2 automotive supply chain.

In this example it is possible to point out some irregularities in the application of FMEA which reflect a condition of less value added regarding quality management. Initially, it is clearly possible to identify that the definition of failure mode does not consider the function of the process in analysis. Besides being set in a generic way, without specifying the actual failure mode, these are failures that belong to earlier processes and should be analyzed in the corresponding Process FMEA, where there is the possibility of such damages. It is important to make clear that in FMEA failure and defect is not the same thing.

Failure occurs when a component or system fails to perform its function, and the defect occurs when a component or system does not meet a technical specification measurable, more applicable in Design FMEA. Thus, whether material is out of specification should be seen as an effect of the failure whose function would be something related to the production of material, but not inspection. For the incoming inspection procedure, the material is one of the inputs, and if it is in accordance with the specification or not, it is considered to be the output of the previous process as shown in Figure 5.

In order to avoid defining the failure mode referring to a process input, Palady (1995) recommends that it should be written as a negative expression of function of the process. Since the function of the inspection process is related to ensure product conformity, the failures of this process can be summed up in "approving material not conforming" or "rejecting material conforming," however, for greater consistency in the scores, it is necessary to specify the characteristics of the material according to the causes and potential effects.

Process Function / Requirements	Potential Failure Mode	Potential Effect (s) of Failure	SEV.	CLASS.	Potential Cause (s) / Mechanism (s) of Failure	OCCOR.	Current Process Controls prevention	Current Process Controls Detection	DET.	RPN	Recommended Action (s)	Responsibility and Target Completion Date	Action Results				
													Actions Taken	SEV.	OCC.	DET.	RPN
Receiving	Material outside the specified	It may cause lack of material in the part	5		Suppliers' fault	1	Certificate of quality before shipping the material	Measuring tape	4	20							
	Material outside the specified	It causes lack of material	4		Fault in the purchase order specification	1	Certificate of quality before shipping the material	Measuring tape	4	16							
	Material outside the specified (chemical and mechanical)	Does not allow continuation of the process	8		Fault in the purchase order specification	1	Certificate of quality before shipping the material	Certificate of quality	4	32							
	Wrongly material identification	Inability the correct process of the part	4		Material misidentification	2	-	Visual + supplier's quality certificate	5	40							
	Wrongly material identification	It may damage the material	4		Material misidentification	2	-	Visual + supplier's quality certificate	5	40							

Table III.
Usual Process FMEA form in incoming inspection operation

To define the effect, the word "may" contained in the definition "it may cause lack of material in the part" (see Table III) is redundant, since the effect is already considered as a possibility by its definition: potential effects of failure. The same occurs when the effect is defined by the term "may damage the material" (see Table III). Defining the effect, it is also possible to identify generic definitions such as "does not allow continuation of the process" and "prevents the correct process of the part" (see Table III) that do not specify what the real potential impact to be generated in process sequence, it is not possible to assure the definition of a consistent value for the severity score.

Besides this situation, it is possible to see another kind of inconsistency in the severity score: assigning two different scores to the same effect, or severity with value 5 to the effect "it may cause lack of material" and severity value 4 for "it causes lack of material" (see Table III).

In the case of identification of potential causes of failures, since the FMEA of Table III has not identified a failure mode related to the incoming inspection operation, neither causes defined refer to the process in analysis. It is valid to comment that, if it were a FMEA from manufacturing process of sheets, the causes defined would be actually failures. For a proper adjustment of the terms "suppliers' fault" and "Fault in the purchase order specification" (see Table III) as a cause, we must find situations in which these types of failure could occur, and in the first case the fault is described in a very generic way, that is unable to identify which of the many "functions of the supplier" could fail. As the score of occurrence is an attribute directly related to the definition of the causes, and these are not related to the process of incoming inspection, we can state that the occurrence values in this FMEA are not in accordance with the failures that should be being analyzed.

The definition of causes unrelated to the process in analysis might impossibility the correct definition of preventive controls, linking them to factors that are not control, such as "quality certificate before sending the material" (see Table III), or simply not putting any definition. This definition of failure which does not consider the function of the process results in problems for the correct definition of detection controls as well. The terms "measuring tape" and "certificate of quality" (see Table III) are actually input to this process as shown in Figure 5, and no controls for detection, whose purpose is to detect the failure before it becomes an effect, avoiding possible negative impacts on the process sequence or even the end customer.

As detection score is performed in accordance with the detection power of the controls and the controls defined in the FMEA are not relevant to the process of incoming inspection, it is easy to say that, like the occurrence score, the values of the detection score are not according to the failures that should have being analyzed in this process.

From the incorrect setting of the values of scores of occurrence and detection, and identification of the inconsistency in the severity score, it can be stated that the FMEA form shown in Table III has not being properly applied, once the NPR scores are not

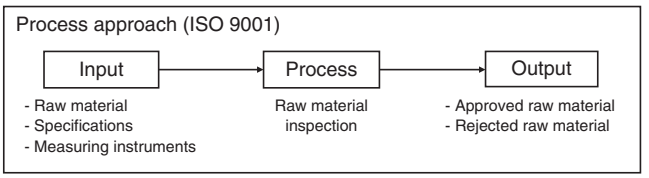

Figure 5.
Process FMEA interpretation for incoming inspection operation

able to measure the risks of the process. This incorrect identification starts from the eight types of deficiencies identified in this FMEA application. Table IV shows the synthesized form, such irregularities in accordance with the number of times that each of them occur within the five possible occurrence of this application Process FMEA.

Combining the concepts of Approach Procedures in accordance with the premises of ISO 9001 with the concepts of Process FMEA discussed in Section 3 of this paper, it is possible to propose an application of FMEA in the process of incoming inspection form implemented as shown in Table V.

This proposal shown in Table V is specific to the receiving sheet for the laser cutting process, thereby making easier to drive the potential effects in accordance with the following operations in the production process. Unlike FMEA shown in Table III, at this proposal the material identification is not considered as a function of process of the, since the traceable and inventory management issues are guaranteed by the label of the steal sheet supplier.

With consistent scoring criteria based on failures, causes and controls actually related to the function of the activity of incoming inspection, the FMEA presented in Table V allows the quantification of risks more adequately. It is possible to identify the values of NPR that link the weaknesses of this process and, from these values, an action may recommended in order to minimize the risk of failure as shown in Table VI.

The recommended action "Receiving during business hours" (Table VI) has a preventive character, acting to prevent the occurrence of the cause "Material received after working hours" (see Tables V and VI) reducing the occurrence scores from 7 to 2. As this is a control, this formalization should be set in the Control Plan of this process, whether a situation of receiving outside the hours set occurs, a reaction plan should be started in order to provide the containment of this issue, avoiding that potential failure. Within the quality management systems, the response plans are formal documents previously defined by the quality team and in this case it could be detailed in a specific procedure for the receipt of materials in an emergency way.

6. Conclusion

This study allowed making a comparison between a conventional application of the Process FMEA without proper implementation of their concepts with a updated proposal based on ISO 9001 concepts, specifically the case of the process approach definitions. In this comparison, made in the activity of incoming inspection of raw materials, it was possible to identify the differences between the FMEA improved by ISO 9001 concepts application in contrast to an example where the usual FMEA is performed only for caring regulatory requirements.

Table IV. Occurrence of irregularities in the Table III FMEA

Irregularities	Occurrence/application
Failure Mode unrelated to the function of the process	5/5
Generic description of the effect	2/5
Inconsistency in severity scoring	2/5
Causes unrelated to the process	5/5
Occurrence scoring unrelated to causes of process failure	5/5
Preventive control does not act in cause	5/5
Detection control unrelated to failure mode	5/5
Detection scoring unrelated to detection control	5/5

Process Function / Requirements	Potential Failure Mode	Potential Effect (s) of Failure	SEVER.	CLASS.	Potential Cause (s) / Mechanism (s) of Failure	OCCOR.	Current Process Controls prevention	Current Process Controls Detection	DETC.	RPN	Recommended Action (s)	Responsibility and Target Completion Date	Action Results				
													Actions Taken	SEVER.	OCCOR.	DETC.	RPN
Incoming inspection of raw material	Approving plate with smaller length	Lack of material in the last part	5		Material received after working hours	7	-	Periodic audit of incoming inspection	4	140							
					Use of inappropriate instrument	1	Provide only tape measurement and caliper in place	Periodic audit of incoming inspection	4	20							
	Approving plate with smaller thickness	Production of parts with smaller thickness	8		Material received after working hours	7	-	Periodic audit of incoming inspection	4	224							
					Use of inappropriate instrument	1	Provide only tape measurement and caliper in place	Periodic audit of incoming inspection	4	32							
	Approving warped plate	Impossibility of laser cutting	4		Material received after working hours	7	-	Periodic audit of incoming inspection	4	112							
	Approving rusty plate	Presence of burrs in the cut laser	4		Receiving location in poor visibility	4	Adequate lighting for visual inspection	Periodic audit of incoming inspection	4	64							

Table V.
Updated Process FMEA form (partially completed)

Process Function / Requirements	Potential Failure Mode	Potential Effect (s) of Failure	SEV.	CLASS.	Potential Cause (s) / Mechanism (s) of Failure	OCCOR.	Current Process Controls prevention	Current Process Controls Detection	DET.	RPN	Recommended Action (s)	Responsibility and Target Completion Data	Action Results				
													Actions Taken	SEV.	OCCOR.	DET.	RPN
Incoming inspection of raw material	Approving plate with smaller length	Lack of material in the last part	5		Material received after working hours	7	-	Periodic audit of incoming inspection	4	**140**	Receiving during business hours	Antônio 25/04	Receiving from 8:00 am to 6:00 pm	5	2	4	**40**
					Use of inappropriate instrument	1	Provide only tape measurement and caliper in place	Periodic audit of incoming inspection	4	**20**							
	Approving plate with smaller thickness	Production of parts with smaller thickness	8		Material received after working hours	7	-	Periodic audit of incoming inspection	4	**224**	Receiving during business hours	Antônio 25/04	Receiving from 8:00 am to 6:00 pm	8	2	4	**64**
					Use of inappropriate instrument	1	Provide only tape measurement and caliper in place	Periodic audit of incoming inspection	4	**32**							
	Approving warped plate	Impossibility of laser cutting	4		Material received after working hours	7	-	Periodic audit of incoming inspection	4	**112**	Receiving during business hours	Antônio 25/04	Receiving from 8:00 am to 6:00 pm	4	2	4	**32**
	Approving rusty plate	Presence of burrs in the cut laser	4		Receiving location in poor visibility	4	Adequate lighting for visual inspection	Periodic audit of incoming inspection	4	**64**							

Table VI.
Updated Process FMEA form (fully completed)

Even written in a form similar to a script, the application of Process FMEA is a very complex activity and, like most quality tools, before being applied, FMEA should be clearly understood by the team. One way to facilitate this understanding is considering the sequence of events in the failures analysis to understand their causes and effects, just as are the sequences of inputs and outputs in the definition of the process approach addressed in ISO 9001, aspect that exposes the originality of this paper.

It was concluded that the practical implication of this research can be seen by comparing Tables III and VI. In Table III we have a conventional application of Process FMEA, which scores are performed in a scenario of great uncertainty, resulting in inaccuracy of the RPN score and not presenting the weaknesses of the process under analysis. On the other hand, Table VI shows a process with the weaknesses identified and corrected, which is possible due to the more complete definition of the factors to be scored and consequently more consistent score. FMEA within the process approach (Figure 4) can be clearly seen as a bridge in the gap between theory and practice, which can be widely applied in training, so it can be possible to extract the maximum benefits that FMEA makes available to users.

A proposal for future study could be measurement of the impact of occurrence of each irregularity and obtain a classification within a hierarchical scale. This measurement should address the shortcomings that the weaknesses of the process are identified resulting in the false impression that the risk of failure is reduced to acceptable values.

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