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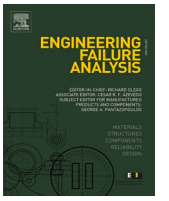

Short communication

Overcoming FMEA shortcomings: Proposal of an adapted risk analysis matrix

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ABSTRACT

Development of a FMEA method to reduce ambiguity in criteria and provide a more time-effective way of applying it, without creating complicated and complex additional criteria or bureaucracy. Using Design Science for the proposal and testing of a new FMEA tool in a specific industrial process context. The proposed method minimized time needed for the analysis, simplified documentation, and minimized ambiguities in risk criteria. The proposed tool has been evaluated in only one company and no structured feedback from users has been taken. The proposed method can be applied to make FMEA analysis more effective and less time-consuming. The proposed method has been created during the research process and addresses some of the FMEA's shortcomings that are frequently remarked by literature in an innovative way.

1. Introduction

Failure Mode Effect Analysis (FMEA) studies exist and have been applied as early as the space race during the cold war [5]. At that time, it was a military standard. Later, it has spread on a variety of applications, and is currently applied in a wide range of areas from maintenance planning to the development of new products. In the automotive manufacturing context FMEA use is required by several automakers [24]. In health care FMEA has already been a requirement for accreditation as part of patient safety measures [25]. And remains one of the recommended tools, for example by The Joint Commission [17] in the United States and even renewable energy applications [26]. As example a simplified descripton of the FMEA table is presented on Table 1.

Still, this method for risk management went through minor changes for a long period of time. several researchers found that this tool is complex and that the ambiguity of application and selecting the scores are a major setback on any study [1]. The concept of what is a root cause or how does it should relate to a failure mode is weakly defined on the standard [21].

Spreafico, Russo and Rizzi [22] listed FMEA general shortcomings from the literature and identified issues regarding: Applicability of the tool, cause and effect analysis inconsistencies, risk analysis and problem-solving failures. Some examples of the causes of these shortcomings are subjectivity of the criteria, time consumption, management of complex systems, cost, level of details required and results evaluation.

Therefore, the two main topical questions regarding the FMEA methodology could be described as establish rules that reduce the ambiguity of the scales used to calculate the risk index that is used to sort and stablish the minimum risk acceptable and obligation to action to mitigate risk. The second question to address would be the complexity to comprehend the tool and how to conduct the study,

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Table 1
Simplified description of a FMEA table (Author).

Process	Failure Mode	Effect on Customer	Severity	Potential causes	Occurrence	Control	Detection	RPN	Actions taken	Severity	Occurrence	Detection	Future RPN
1													
2													
3													

being the discussion on how to simplify the method the objective on this study.

New methods have been used to reduce ambiguity on the process of criteria including the adoption of genetic algorithms [9,11], neural networks [4,13,16], ERP integration [22],but always discussing only the fragility on the decision process on how to decide the scores or how to evaluate the scores for priority on corrective actions.

Discussing the application methodology the AIAG [19] released a handbook with best practices aligning the AIAG and VDA standards with discussion on how to gather information for the study and a strategy to evaluate the priority of corrective actions after the newer version of the FMEA standard [2] A study that also address the complexity of the method and proposes an matrix approach such as this paper has already been made, but with significant cutbacks on the information gathered only discussing which are the failures, the costs of the failure, corrective actions and cost of the corrective action, without discussing the causes nor the methods of control for the failures [21].

This paper aims at describing a FMEA methodology to reduce ambiguity in criteria and provide a more time-effective way of applying it, without creating complicated and complex additional criteria or bureaucracy.

2. Materials & methods

2.1. The FMEA method development and current state

FMEA started as a military standard for risk assessment. It was developed by the North American Department of Defense [5] and it has been applied in multiple projects including the Apollo missions. The first versions of the tool were mainly qualitative, [6].

Looking back on its origins the tool had complex methods to evaluate the criticality number Cr as presented on Eq. (1) [5].

$$C_r = \beta\alpha\lambda_P t \tag{1}$$

On this equation the information to calculate Criticality is the probability of mission loss given the failure to occur (β) times the failure mode ratio (α), the part failure rate (λ_P) and the time (t) of the given scenario [5].

Eventually the criticality evaluation has been abandoned and the variable has been excluded. Three other variables that are less complex were added, namely severity, frequency and detection ratios that are combined to produce the Risk Priority Number or RPN [23].

[23] describes the usual steps to perform FMEA analyses:

a) Define system boundaries – can be a product, a component or a process step or a complex process.
b) Define key system functions – what are the product's or process's deliverables, functions?
c) For each function, what are the potential failure modes?
d) For each fail mode, what are the potential causes?
e) For each cause, what are the preventive measures the organization must avoid them?
f) For each fail mode / cause set, what are the resources the organization must detect the problem early enough to correct it?
g) For each fail mode / cause set, establish scores for severity of damage, expected frequency of fail (based upon preventive measures and/or previous experience), and detection capacity, which is an inverted scale because a higher number means a lower detection capacity that would lead to a higher risk.
h) Calculate priority risk number, usually by multiplying severity score, frequency score and detection score.
i) Select a set of problems with a high priority number and define additional preventive actions to reduce the risk.
j) After enough time to implement preventive actions, take the action results as feedback to update scoring and risk priority numbers and repeat the cycle.

It is usually recommended that FMEA is not suitable as an individual technical work. Because scoring is always subject to imprecisions and personal risk view, it is important that a multidisciplinary or multi-department team is responsible for the entire process. This is believed to reduce bias in the risk assessment [23,24].

Since its earliest applications, the tool has shown itself as a valuable resource to reduce redundancies in new developments [20]. However, FMEA has become increasingly complex and difficult to manage. Typical complaints on the literature are the excess of repetition of information, extensive team meetings and the scoring being subject to arbitrability and subjectivity [22].

Currently most studies on this methodology are focused on algorithms for the RPN automation or refinement [4,7–9,11–16,18,25].

2.2. The design proposal

2.2.1. Artifacts in design Science

According to Hevner et al. [10], the definition of an artifact is broad because it doesn't limit to IT artifacts such as a software, it could be considered as well as a construct, model or applied method. It should not be considered part of the artifact: people, organizations, or future developments. Hence artifacts developed by this method are usually models that aren't fully mature or diffused. These artifacts are innovations that define ideas, new practices, technical capacities, and products with focus on efficiency.

The artifact development was conducted by testing a simpler method to visualize large data sets in a more intuitive way and the data collection strategy. An objective in the development was to still be able to transport the data on the Risk Analysis Matrix to the

classical FMEA model being equivalent in what data is gathered.

The matrix layout such as a pivot table is a common solution to work with large data sets that have common information with different results. The cross section between one line and one column is the result of one iteration of these variables, therefore the cross section of a root cause and multiple failure modes has the same behavior.

Considering that the FMEA method needs the participation of a multidisciplinary team and gathers large volumes of information, the first step was to create a strategy on how to organize brainstorming processes to keep the possibility of new insights to be shown without creating rupture in the logical processes being discussed at any given time.

Therefore, the discussion was divided in topics, and it is planned to not go back and forth until each topic has been fully discussed, namely:

1. Effects and failure modes
2. Root causes
3. Existing controls for occurrence
4. Frequency of occurrence
5. Existing controls for detection
6. Probability of detection
7. Proposed actions

The second main difference in the methodology is the set of time limits for each topic to be discussed, to not let discussion on a single topic strain the participants and if needed any component, or process step could be discussed in multiple meetings.

The third main modification to the methodology is the organization, that using the logic of a pivot table should be easier to understand and still have the same information as the original method.

The original categories design of the data collection table on FMEA is as follows:

Using the idea of an pivot table and that the FMEA is commonly used in a excel spreadsheet, the same logic was used to list the effects, failures and severity as columns and the causes of these failures as lines on a table, enabling to discuss a single cause across multiple failures at once that was not possible with the original method and is similar on the idea that the neural generative fault tree from [4] has proposed. The Model is illustrated in a straightforward way as shown on Table 2.

After the development of first version of prototype procedure and form, the decision was taken to conduct the study using the method under test and to migrate the data to the report model of the 5th Edition of the FMEA Manual [2].

2.3. Model testing protocol

The evaluation of this artifact was conducted analyzing the production process for a new model of bearing that belongs to a family of products that has been produced for over 10 years. These products have already gone thru FMEA studies several times, and this process took roughly 3 months of development with bi-weekly meetings lasting up to 5 h or more. The overall quality of information and the time spent on the new product study will be used as reference for the evaluation of the success on the methodology changes.

2.3.1. Description of the study sessions

The new methodology works with meetings that lasts 1 h, all meetings were conducted by the research author with usually 5 other coworkers, being at least one of the machine operators that would perform that specific process, one quality inspector, one member from the maintenance team, the engineer responsible for that process development and one quality analyst; This setup of a multidisciplinary team is common ground between all literature, from books to recent works that uses even AHP techniques.

Every meeting would take place on the last hour of the workday, or during the first hour after lunch break. The 10 first minutes a blank matrix would be presented, and the strategy to conduct the meeting was presented for the participants that follow this structure:

15 min- Discussion of all possible failure modes plausible on the target process

15 min – Discussion of every possible root cause for each one of these failure modes, including the dependence of multiple failure modes on one root cause.

Table 2
Simplified model of FMEA (Author).

Effect	Effect 1	Effect 2	What are the processes to avoid the occurrence of the cause	What is the occurrence of the root cause	How do we identify the cause (or effects)	What is the frequency of detection of the cause
Failure mode	Failure 1	Failure 2				
Cause/ Severity	Severity of Failure 1	Severity of Failure 2				
Root cause 1	X					
Root cause 2	X	X				

10 min – For each root cause the discussion of preventive actions in place and control methods for that specific root cause.
10 min – the last topic to be discussed is the scoring of Severity, Frequency of the root cause and control methods.

3. Results and discussion

Each process on the project lasted between 2 and 3 days, traversing the steps of roughing, tempering, drilling, gear milling, finishing, assembly, surface treatment and final packaging. All meetings were aimed at 1-hour evaluation and the following day a review and inclusion of new cases if needed. The complete analysis lasted a total of 15 workdays with 1-hour meetings of the team totaling 15 h of analysis.

At the end of each meeting the team would give general feedback of the results, the main arguments presented were the celerity on the analysis that became both deeper and broader. Hence the team focus would be entirely on each step of the development and the analysis started to appear as one linear set of activities. Many comparisons were also made that the former method causes confusion specially for the less instructed workers that found the original methodology to be too much abstract where everyone could collaborate with any given part of information at any time on a brainstorming approach.

3.1. Results of the FMEA study

Following on Table 3 is the presentation of one excerpt of the analysis that took place, it is possible to understand that the matrix form factor helps to understand the link between multiple failure modes and one single root cause or an effect that has many uncontrolled root causes, being the cross section on the table the result of the RPN of each cause x failure mode.

Any FMEA study will have an index to evaluate the risk priority number and according to it evaluate which are the priorities on preventive or corrective actions to reduce the overall risk on the process to a set objective.

A similar technique to what is proposed on the former methodology was used to summarize the results of the study and serve as indicator to evaluate the need of corrective actions. The Table 4 has 3 sections that presents the total of cases studied, the highest risk listed and the second and third sections divide the failure modes in categories that are used to evaluate the priority, being priority the risks with RPN above 200 and with severity of 9 and above that presents an RPN above 50 or severity of 6 and above with RPN above 100.

It also presents the distribution of the failure modes that should be achieved after improvements of preventive and corrective actions.

According to the corporation headquarters orientations this exact same data was rearranged on a traditional FMEA form as afore

Table 3
Excerpt of a Risk Analysis Matrix (Author).

Effect / Failure mode / Cause/ Severity	Material loss or rework / Maximum radial roundness 0,3mm / 6	Material loss or rework / Diameter larger/shorter or conical / 8	What are the processes to avoid the occurrence of the cause	What is the occurrence of the root cause	How do we identify the cause (or effects)	What is the frequency of detection of the cause
High internal tension on material	36		Stress relief on the material	3	Measured at the next workplace	2
Dull fixtures	90		Visual inspection prior to machining	3	visual	5
Fixtures pressure	90		Training	3	Visual	5
Error during setup		192	Training	6	Geometry check after the first lap on machining	4
Mismeasurement		128	Training	8	Measured at the next workplace	2
CNC program errors		32	Double check by a second engineer	2	First product produced is machined block by block with double check on measurements	2
Misinterpretation of drawings		32	Production supervisor does a follow up on the initial production	2	Measured at the next workplace	2
Misinterpretation of processes		32	Production supervisor does a follow up on the initial production	2	Measured at the next workplace	2
Broken tooling		16	Visual inspection prior to machining	2	Visual control	1
Machinery axis stabilization	24	32	Predictive Maintenance on machine axis gaps.	2	Measured at the next workplace	2

Table 4
Preliminary study results FMEA (Author).

General	**Failure Modes**			303	
	Highest RPN			400	
				Actual	**Impr.**
Risk Priority Number	**RPN<50**			219	222
	50 ≤ RPN<100			52	54
	100 ≤ RPN<200			24	24
	RPN≥200			9	4
Critical and Significant Caracteristics	**Severity**		<	**X**	≥
	CC	**S≥9**	5	**50**	9
	SC	**S≥6**	156	**100**	28
	–	**S<6**	105	**150**	0

mentioned on topic 2.2.2 on the test case definition, this is due the fact that every other company on the group uses the same FMEA template.

The direct comparison leads to understand that the same information is presented on both tables, still the form factor on the original FMEA model is the replication of the lines from each root cause with each link found on that matrix to a failure mode, as seen on Table 3. This replication is the main cause of ambiguity since the root cause on the traditional FMEA is mainly discussed regarding its frequency and detection alongside one of the possible failure modes. Ambiguity is common on a FMEA study since the same root cause or even effect is presented multiple times on equivalent conditions with two or even more variations on the consensus of the scores of severities, frequency, and detection.

By standardizing the severity on the effect and not in the interaction with the given root cause and failure mode; the analysis of severity is prone to a better understanding and easier interpretation as it is not related with the cause frequency of occurrence.

Ex: roundness out of specification due to setup error could be presented as 8 in severity and minutes later with the same team be presented as 6 with the same consequences because it is now linked to misinterpretation of a drawing.

The effect is the same independently of the root cause, but there is a bias to increase or reduce the scoring whether it is not clear the orientation of the study. The same effect is also present relating the frequency on a same root cause with the given failure mode instead of only the frequency of that given phenomena.

The result is a list of similar or equal root causes on numerous lines of FMEA that even contradicts themselves. This confusion on the same root cause having multiple detections and controls doesn't help the pace of discussion during the development of the study.

Therefore, looking the causes and failure modes independently, even if there is connection between them, has simplified the understanding of the team on the problem. Instead of spending hours discussing why the same root cause should be considered with different frequencies and detection capacity on similar conditions on the same workplace, the discussion shifted to how broad the given root cause's effect are and the possibilities for mitigation.

Table 5 represents the results of the first review of the study after conducting the preventive and corrective actions on the preliminary study.

Former studies lasted 96 h on equivalent process, with the aid from the risk analysis matrix to the time to conclusion was reduced to 15 h (over 84 % reduction). This reduction in required time shows that the adapted tool has the potential to solve one of the main FMEA shortcomings, the ambiguity of the methodology and the time spent on a study.

Table 5
Revised study results after corrective actions (Author).

General	**Failure Modes**			304	
	Highest RPN			128	
				Actual	**Impr.**
Risk Priority Number	**RPN<50**			231	233
	50 ≤ RPN<100			66	65
	100 ≤ RPN<200			7	6
	RPN≥200			0	0
Critical and Significant Caracteristics	**Severity**		<	**X**	≥
	CC	**S≥9**	5	**50**	9
	SC	**S≥6**	180	**100**	3
	–	**S<6**	107	**150**	0

4. Conclusions

The objective of proposing a change in methodology to reduce ambiguity and adapt the study of a process on a more intuitive and streamlined process is considered successful, as the study was concluded in less time, with less human resources constrained for several hours and with more focused preventive actions that had broader impact possibilities across multiple stages of the process.

Further studies could benefit of planning a method to collect feedback of participants to further discuss the differences between methods, given that many current studies discuss algorithms to better evaluate the indexes for the RPN calculation could also be directed applied to the Risk Analysis Matrix as further development of this method.

Novelty statement

This paper discuss on a industry standard that is FMEA to propose a new workflow that has permitted a better analysis of processes discussing the effects of multiple root causes and effects on a matrix and enabling the analysis team to evaluate cross relevance of root causes and a better overall proposition of corrective and preventive actions for new failures while still being 84% faster to accomplish as an normal workflow FMEA study.

CRediT authorship contribution statement

Luis Alberto Ccopa Ibarra: Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Elita Fontenele Urano de Carvalho:** Writing – review & editing, Supervision. **Michelangelo Durazzo:** Writing – review & editing, Supervision.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: [Luis Alberto Ccopa Ibarra reports financial support was provided by Coordination of Higher Education Personnel Improvement. Author previously employed by thyssenkrupp Brazil Bearings division, where the study was conducted. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper].

Data availability

The authors do not have permission to share data.

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Further reading

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