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CRITERIA FOR THE ASSESSMENT OF FMEAS

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A B S T R A C T

Quality failures can be costly to an organization. To avoid failures, organizations perform a Failure Modes and Effects Analysis for both the design of a product, and the manufacturing and assembly processes that create the product. However, there is a lack of assessment criteria for Failure Modes and Effects Analysis. The approach used is design methods, which consist of exploration of a problem, solution creation, solution evaluation, and communication of the solution. Literature was explored to understand what is required for performing a Failure Modes and Effects Analysis and assessment criteria were developed. The assessment criteria were then evaluated using a case study consisting of applying the criteria to an organization's Failure Modes and Effects Analysis. An assessment of the Failure Modes and Effects Analysis for the development of a product and a process identified shortcomings, which presented opportunities for improvements. The assessment criteria were found to be suitable for manufactured products, with minor improvements. This paper provides concrete criteria for the assessment of Failure Modes and Effects Analysis, which is lacking in the literature. The criteria identified provide organizations with an opportunity to assess and improve their Failure Modes and Effects Analysis.

1. INTRODUCTION

The costs of quality failures can be high, with one automotive organization billed almost three-quarters of a million Euros per year in warranty costs from only one dealer (Cunha & Dominguez, 2015) and failures may result in injury to the user of products or a costly recall of products (Ghadge et al., 2017).
A commonly used (He et al., 2021) systematic method for identifying and mitigating risks associated with the design and production of a product is an FMEA (Failure Modes and Effects Analysis) (Paciarotti et al., 2014). The use of FMEAs can lead to reduced costs, fewer failures, shortened development time, increased customer satisfaction (Liu et al, 2019), and increased reliability (Cavique et al., 2019).
The use of FMEAs in the automotive industry is a requirement of the standard IATF 16949 and specific guidance is given by national organizations such as AIAG in America and VDA in Germany (Chiarini & Vagnoni, 2018). Although mandatory for the automotive industry, FMEAs are also used across a wide range of industries (Liu et al, 2019). An FMEA may be performed as a stand-alone quality method, as part of a Six Sigma project (Prashar, 2018; Pugna et al., 2016), or a Design for Six Sigma project (Gijo et al., 2021).
Not all FMEAs provide value to an organization due to flaws in the execution of the FMEA. Estorillo and Posso (2010) investigated 70 FMEAs across organizations and found frequent problems, such as inconsistent function and failure description, lack of a table of standard effects, failure effects that did not consider effects outside of the organization, inconsistent detection ratings, doubts about all listed team members attending meetings, and lack of team member training. Lorenzi and Ferreira (2018) identified FMEAs starting too late, such as a DFMEA

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late in the design process, as a problem with FMEAs. Additional problems with FMEAs include not having a moderator or facilitator, untrained or inexperienced moderators, lack of management support, only one person working on the FMEA, and attempting to complete an FMEA in only one session (Silverman and Johnson, 2013).

An inadequate FMEA can lead to the waste of an organization's resources. Conducting an FMEA requires the participation of many employees (Lorenzi and Ferreira, 2018), may consume a large amount of time and resources, and there may be much variation in the quality of FMEAs (Onofrio et al., 2015). Furthermore, inadequate execution of FMEAs has contributed to the poor reputation of FMEAs (Davison & Fairbaum, 2016). Therefore, this paper aims to establish criteria for assessing FMEAs consistently across an organization's FMEAs.

2. LITERATURE REVIEW

An FMEA may be a DFMEA (Design Failure Modes and Effects Analysis) for the development of a product, or a PFMEA (Process Failure Modes and Effects Analysis) for a process (Manos and Vincent, 2012). There are also variations on the FMEA for systems and services (Doshi and Desai, 2017). Both DFMEAs and PFMEAs use cross-functional teams with members from departments across the organization (Singh et al. 2020), such as engineering, quality, testing, manufacturing, design, safety, and maintenance (Maisano et al, 2020).

The preparation for a DFMEA and a PFMEA also differs. Preparation for a DFMEA includes the use of a p-diagram (parameter diagram) and boundary or block diagrams (Anleitner, 2011). A boundary diagram depicts the components within a system (Hensley and Utley, 2011) and helps to both identify the scope of the FMEA and the interfaces between components and assemblies.

The p-diagram includes inputs into the system, the intended function of the system, error states, control factors, and noise factors. The noise factors are typically classified as variation between parts, interactions with other systems, environmental influences, wear, and usage by the customer (Huffman et al., 2013). Examples of noise factors include untrained users and the deterioration of seals (Silverman and Johnson, 2013). The noise factors are potential causes of failure (Jayatilleka, 2020). An output of the DFMEA is input for a DVP (Design Validation Plan), which lists tests and evaluations to perform (Haughey, 2019) during product development.

Preparation for a PFMEA includes the creation of flow charts (Stirbu et al., 2011) known as PFDs (Process flow Diagrams) to provide a visualization of the flow of material through the manufacturing and assembly processes (Haughey, 2019). The PFMEA is a critical input for the control plan, which lists checks and evaluations to perform (Jumbad and Chel, 2018) during manufacturing and assembly.

An FMEA requires an identification of functions, which are a description of what must be done by a process or product (Fabis-Domagala and Domagala, 2020). A function in a DFMEA could be "Provide the correct level of friction between brake pad assembly and heel rim to safely stop bicycle in the required distance, under all operating conditions" and a PFMEA function could be "Securely clamp upper tube in weld fixture, without damaging part and without looseness or movement of part in fixture" (Carlson, 2012).

Failures are assigned to the functions and may be failure effects, failure modes, or failure causes (AIAG/VDA, 2022). Failure effects may consist of "Gas cylinder PGS explodes" and "Deformation of rotary Kiln" (Indrawati and Ridwansyah, 2015). Examples of failure modes include "too much gap" and "position deviation" (Liu et al., 2023). Each failure mode may have multiple possible failure causes (Ramaschandran et al., 2020), and a failure cause could be an "Incorrect electrode angle" or "Incorrect welding current setting" (Anderson and Kovach, 2014).

Failure causes are the reason the failure mode happens, and the failure causes in a PFMEA are the result of problems in the process and the DFMEA failure causes are design-related and should not be the result of a process failure. For example, an incorrectly bored hole should not be a failure cause in a DFMEA because the incorrectly bored hole is a process failure (Anleitner, 2011).

Especially critical characteristics in the DFMEA may be assigned a special characteristic symbol. The special characteristic symbol is carried over to the drawing. The PFMEA team then needs to determine if there is a high risk of the problem occurring in the process, and if so, the special characteristics are transferred to the PFMEA (Harpster, 2016).

Controls for the prevention and detection of failures are identified in the FMEA. These controls are ones that are currently planned and will be performed (Carlson, 2012). Prevention controls are to ensure the failure cause does not occur and detection controls are to detect the failure cause or the failure mode, if they occur (AIAG/VDA, 2022).

Ratings are assigned for severity, occurrence, and detection. The severity rates how bad the consequences are, if the failure occurs. The occurrence rates the chance of the failure occurring and detection rates how well the failure can be detected if it occurs (Balaraju et al., 2020). Tables with values ranging from one to ten are used for severity, occurrence, and detection, with higher values being worse (Luo and Lee, 2015). If both the DFMEA and the PFMEA for a product have the same failure effect, the failure effect must have the same severity rating (Fasolo and Elgh, 2022).

The severity, occurrence, and detection ratings are multiplied to derive RPN (Risk Priority Number), which is a number ranging from one to 1,000 (Kocabaş and Savaş, 2021) that is used to prioritize improvements (Bilgen and Şen, 2012) to reduce the RPN (Kardos et al., 2021). One method used for assessing RPNs for prioritization is the Pareto chart (Rahmania et al., 2020), which displays RPNs in order from highest to lowest.

An FMEA must be updated when new risks are discovered (Bozola, et al., 2023), such as after problem-solving activities (Yadav et al., 2022). The use of FMEAs can be streamlined through the use of templates stored in a template library, with generic details already included in the template (Anleitner, 2011).

Previously, FMEAs in the automotive industry were governed by AIAG's (Automotive Industry Action Group) *Potential Failure Modes and Effects Analysis (FMEA): Reference Manual* (Chrysler LLC et al., 2008) and VDA's (German Association of the Automotive Industry) *Quality in the Automotive Industry Volume 4: Quality Assurance in the Process Landscape – General, Risk Analyses, Methods, Procedure Models, Product-and Process FMEA* (VDA, 2012). The AIAG approach used PFDs for PFMEAs and boundary diagrams and p-diagrams for DFMEAs (Chrysler LLC et al., 2008). In contrast, the VDA approach to FMEAs had five steps consisting of "structure analysis, function analysis, failure analysis, measure analysis and optimization (Haefner et al., 2014). The AIAG approach used Excel sheets and the VDA approach was heavily software-driven (Harpster, 2022).

The two guides for FMEAs resulted in organizations needing separate FMEAs, such as an FMEA per AIAG for Ford and a separate VDA-style FMEA for VW (Plinta et al., 2021). Therefore, the AIAG and VDA approaches to FMEAs were combined in the *AIAG/VDA FMEA Handbook* in 2019 (AIAG/VDA, 2019). The handbook underwent minor updates in 2022 (AIAG/VDA, 2022).

The new guide has a seven-step approach consisting of planning and preparation, structure analysis, function analysis, failure analysis, risk analysis, optimization, and results and documentation (Nök and Yildiz, 2023). The structure analysis for a DFMEA identifies the subassemblies that come together to form a system, as well as the components that form the subassemblies and process steps for a PFMEA. During the function analysis, functions are identified for each level of a system with lower-level functions describing what must be done to fulfill higher-level functions (Walker, 2017).

Although software is not mandatory for an FMEA per *AIAG/VDA FMEA Handbook*, software is helpful (Kluse, 2020). Guidance varies based on whether software is used or if only an FMEA form sheet is used. A DFMEA using only a form sheet must use a boundary diagram and p-diagram. If a DFMEA is created using software, a structure tree and function tree are used as an alternative to boundary diagrams and p-diagrams. A PFMEA using only a form sheet must have a PFD and an Ishikawa diagram listing potential failure causes. If software is used, a PFMEA needs a structure tree and a failure network (AIAG/VDA, 2022). The *AIAG/VDA FMEA Handbook* requires PFMEA failure effects to consider the impact in the organization, at the customer, and at the end user of the product (Ramly and Atan, 2020). The *AIAG/VDA FMEA Handbook* also requires a status for improvement actions, as well as deadlines and completion dates (Gueorguiev et al., 2020).

A weakness of FMEAs is the use of RPN with severity, occurrence, and detection having equal importance with different combinations of severity, occurrence, and detection all having the same RPN value (Shaker et al., 2019; Jakkula et al., 2020). This weakness has long been known as far back as the 1990s and the use of only severity and occurrence was recommended as compensation for the shortcoming of RPN (Sanhueza & Nikulin, 2019). The *AIAG/VDA FMEA Handbook* addressed this weakness by introducing AP (Action Priority) in place of RPN, with AP derived using a table with the most emphasis on severity and the least emphasis on detection. The possibilities for AP are high, medium, and low (Fabis-Domagala & Domagala, 2020)

Researchers are interested in FMEAs, which are a major topic in academia with 75 journal papers published between 1992 and 2012, and with an increase in the number of publications per year from 2013 to 2018 Wu et al. (2021). Literature often describes the application of variations on the FMEA, such as fuzzy FMEAs (Yeh & Hsieh, 2007; Wessiani & Sarwoko, 2015; Ghadge et al. 2017; Singh et al. 2020; Balaraju et al., 2020; Zhou et al., 2021). Other variations on approaches to the FMEA include TOPSIS and VOKPOR (Das et al., 2022) and MCDM (Liu et al, 2019).

There are also many case studies illustrating the use of FMEAs (dos Santos et al., 2012; Pugna, et al., 2016; Doshi, and Desai, 2017; Prashar, 2018; Kocabaş and Savaş, 2021; Liu et al., 2023). Research into FMEAs has long been performed and includes determining awareness of FMEAs (Tarí and Sabater, 2004) and usage of FMEAs (Starzyńska, 2014). However, research into assessment criteria for FMEAs is lacking, with only one paper by Feng and Jing (2023) offering criteria directly from the *AIAG/VDA FMEA Handbook*.

3. METHODOLOGY

Design methods were used to develop an FMEA assessment tool. Design methods have four phases consisting of exploring the problem, generating solutions, evaluating the solutions, and then communicating the solution (Sanhueza and Mikulin, 2019). Design methods were selected due to a methodology that provides guidance, but with flexibility permitting adaptation for unique situations (Eisenmann et al., 2021).

The literature was consulted to explore the problem and gain a better understanding of the problems with FMEAs. (Onofrio et al., 2015; Davison & Fairbaum, 2016; Lorenzi and Ferreira, 2018). The literature was also consulted to identify criteria to use as requirements for an FMEA in an FMEA assessment tool.

To develop a framework for the assessment of FMEAs, the approach used by VDA (2018) for the assessment of 8D reports was used. The assessment for 8D reports provides criteria to achieve both a basic and an excellence rating with results indicating fulfilled or not fulfilled. Answers of OK and NOK (not OK) were used for basic criteria and 1 for fulfilled and 0 for not fulfilled for excellence criteria. Table 1 shows the assessment questions together with sources and the basic and excellence classifications.

Table 1. FMEA assessment questions and sources

Requirement	Source	Basic	Excellence
The scope of the FMEA is defined	AIAG/VDA (2022)	■	
Moderator trained in FMEAs	Estorillo and Posso (2010)		■
Team members trained in FMEAs	Estorillo and Posso (2010)	■	
FMEA moderator is a professional FMEA moderator or FMEA moderation specialist	Kubiak (2014)	■	
Start early in development of product or process	Lorenzi and Ferreira (2018		■
Start point for FMEA defined by policy, procedure, instruction, etc.	Ford (2012)	■	
FMEA team members attend FMEA sessions	Estorillo and Posso (2010)		■
Moderator, responsible person, and team members listed in form sheet	AIAG/VDA (2022)		■
DFMEA team is cross-functional and includes designers, test engineers, reliability engineers, and quality engineers	Stamatis (2019)		■
PFMEA team is cross-functional and includes manufacturing engineers, maintenance technicians, operators and quality engineers	Stamatis (2019)		■
Form sheet has a unique identification number	Ford Motor Company (2012)	■	
An identifiable standard is used	Borror (2009)	■	
FMEA templates are used, unless product or process is new	Anleitner (2011)		■
Updates are in FMEA template, if used	SAE (2022)		■
FMEA (PFMEA, DFMEA, System FMEA) type is listed in FMEA	Chrysler et al. (2008)		■
DFMEA: p-diagram available (if working in form sheet)	AIAG/VDA (2022)		■
DFMEA: p-diagram includes noise factors consisting of environment, changes over time, customer usage, interactions with other systems, and variation (if used)	Anleitner (2011)		■
DFMEA: p-diagram includes controls for prevention and detection (if used)	Tague (2023)	■	
DFMEA: p-diagram created with a cross-functional team (if used)	Tague (2023)	■	
DFMEA: Noise factors listed in DFMEA as failure causes (if used)	AIAG/VDA (2022)	■	
DFMEA: Boundary diagram available with contact depicted (if working in form sheet)	Ford Motor Company (2012)		■
DFMEA: Boundary diagram depicts system limits (if used)	Ford Motor Company (2012)		■
DFMEA: Boundary diagram depicts interactions including, physical touching transfer of energy, transfer of information, and exchange of material (if used)	SAE (2022)	■	
DFMEA: Boundary diagram created with a cross-functional team (if used)	Tague (2023)	■	
DFMEA: Customer requirements and specifications reviewed	Laman, (2022)		■
Bill of material and drawings reviewed for FMEA preparation	Barsalou (2016)		■
Warranty claims, scrap data, and rework data reviewed as part of preparation	Laman (2022)		■
PFMEA: PFD available (if working in form sheet)	AIAG/VDA (2022)		■
PFMEA: Process steps in PFD numbered (if used)	SAE (2022)	■	
DFMEA: Structure tree with system elements linked (if working ins software)	AIAG/VDA (2022)		■
DFMEA: Function tree available with functions linked (if working in software)	AIAG/VDA (2022)		■
Functions assigned to each system element	AIAG/VDA (2022)		■
Functions include a noun and a verb	Tague (2023)		■
Functions are in the present tense	Tague (2023)		■
Functions include a measurable characteristic	Ford (2012)	■	
DFMEA: Customer requirements represented in functions	Ford Motor Company (2012)		■
DFMEA failure causes are related to the design or noise factors during operation	Yang and El-Haik (2009)		■
PFMEA: Function or characteristic for the failure mode can be evaluated on the product	AIAG/VDA (2022)		■

PFMEA: Function or characteristic for the failure cause can be evaluated at the process	AIAG/VDA (2022)		
PFMEA: Failure causes are related to the process or noise factors during manufacturing or production	Yang and El-Haik (2009		
Special characteristics listed in FMEA	Ford Motor Company (2012)		
Failure cause logically happens before failure mode	Barsalou (2022)		
Failures described and not simply listed as “failed”	Pyzdek (1993)		
The failure cause listed is the underlying root cause	Barsalou (2022)		
Failure mode logically happens before failure effect	Sharma and Sharma (2010)		
Failure descriptions are consistently worded	Estorillo and Posso (2010)		
Failure cause plausibly leads to failure mode, which plausibly leads to failure effect	Estorilio and Posso (2010		
Prevention controls can prevent occurrence of failure cause	Sharma and Sharma (2010)		
Detection controls can detect failure cause, failure mode, or failure effect	Sharma and Sharma (2010)		
Detection controls can detect failure cause or failure mode	Sharma and Sharma (2010)		
Standard tables used for ratings	Estorillo and Posso (2010		
Assigned ratings correctly conform to the criteria given in the tables used	SAE (2021)		
Documents listed as prevention controls include identification number or unique name	Chrysler LLC et al. (2008)		
Tests listed as detection controls include identification number or unique name	Chrysler LLC et al. (2008		
List “none” or equivalent when no improvement actions are planned	Stamatis (2015)		
DFMEA: Detection controls are transferred to the DVP	Haughey, 2019		
PFMEA: Prevention and detection controls are transferred to a control plan	Ford Motor Company (2012)		
Improvement actions assigned to high APs	AIAG/VDA (2022)		
Improvement actions assigned to medium APs	AIAG/VDA (2022)		
Improvement actions have a person responsible, deadline, and status	AIAG/VDA (2022)		
Improvement actions are not overdue	Ford (2012)		
Implemented improvement actions are documented	AIAG/VDA (2022)		
Verifications of implemented improvement actions are supported by evidence	AIAG/VDA (2022)		
New ratings for improvement actions are not given until actions are implemented and evaluated	Stamatis (2019)		
Common failure effects from DFMEA and PFMEA with the same severity rating	Stamatis (2019)		
DFMEA started by Improve phase of DMAIC when used for Six Sigma or started by Design phase of DMADV when used for Design for Six Sigma	Pyzdek (2003)		
Revision/change history exists and demonstrates regular updates	AIAG/VDA (2022)		

Design methods require a validation, which often consists of a case study (Eisenmann et al., 2021). Therefore, the developed FMEA assessment tool was evaluated with a case study, consisting of assessing both a PFMEA and a DFMEA created according to AIAG/VDA FMEA Handbook using FMEA software. Both FMEAs are from the same manufactured product that was designed and produced by a large multinational organization.

There were many basic and excellence requirements that were not applicable for the DFMEA because the requirements only applied if the DFMEA was created in a form sheet and the DFMEA was created in an FMEA software program. The DFMEA fulfilled a lower percentage of basic and excellence requirements than the PFMEA. The main contributors to the difference in basic percentages were the DFMEA using vaguely described failure causes that were not the underlying root cause, and overdue improvement actions. The main difference in excellence percentages were the DFMEA failing to include the scope and not listing specific document names or numbers for both prevention and detection controls.

4. RESULTS

The DFMEA fulfilled 82.3% of basic requirements and 61.5% of excellence requirements. In contrast, the PFMEA fulfilled 90.6% of requirements and 86.7% of excellence requirements. There were also three DFMEA excellence requirements that were not fulfilled. The results of the assessment are displayed in Table 2.

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percentages were the DFMEA using vaguely described failure causes that were not the underlying root cause, and overdue improvement actions.

Table 2. Summary of assessment results

	DFMEA	PFMEA
Basic: Maximum possible	33	32
Basic: Count	28	29
Basic: Percent	82.3%	90.6%
Basic: Count of no applicable	7	2
Excellence: Maximum possible	13	15
Excellence: Count	8	13
Excellence: Percent	61.5%	86.7%
Excellence: Count of not applicable	3	0

The main difference in excellence percentages were the DFMEA failing to include the scope and not listing specific document names or numbers for both prevention and detection controls.

5. DISCUSSION

Although a conclusion may review the main points of the Several requirements were found to need modification. The requirement form listed "Warranty claims, scrap data, and rework data reviewed as part of preparation" as specific to PFMEAs; however, design failures can lead to warranty claims. Therefore, the requirement needs to be changed to apply to both DFMEAs and PFMEAs. The requirement "Functions include a measurable characteristic" also requires changing for situations such as checks of packaging that result in attribute data. Therefore, the requirement needs to be changed to "Functions include an assessable characteristic."

The requirements "Failure cause logically happens before failure mode" and "Failure mode logically happens before failure effect" were found to be included in the requirement "failure case plausibly leads to failure mode, which plausibly leads to failure effect," so the first two need to be removed from the assessment as they are covered by the last requirement.

Additional optimization opportunities were also identified. The requirement "Standard tables used for ratings" specifies the need to use standard tables, but does not consider that the customer or organization may require specific tables (Tague, 2023) and the requirement should be changed to "Correct standard tables used." There were also several requirements that included the words "if used," such as for the use of p-diagrams, which are not required when creating DFMEAs in software with a structure tree, or the use of PFDs when creating PFMEAs in software with a structure tree (AIAG/VDA, 2019). Therefore, there is a need to rate some requirements as N/A (Not Applicable).

This paper assessed FMEAs in a manufacturing context, which is a limitation. An opportunity for future research would be to apply the assessment criterial to the development and operation of a process. An additional opportunity for further research would be to investigate the adaption of the requirements for use with FMEAs that must conform to other industry-specific requirements.

There are also implications for managers. Managers should require both DFMEAs and PFMEAs to be assessed according to the requirements in this paper. In addition, managers should require a plan to correct any identified deficiencies. Once deficiencies are corrected, managers should require a reassessment of any requirements that were not met during the first assessment.

6. CONCLUSION

Although a conclusion may review the main points of the Criteria for an FMEA assessment are available; however, the criteria consist of only 21 points copied from the *AIAG/VDA FMEA Handbook* (Feng and Jing, 2023). An FMEA may fail to identify and mitigate risks if the FMEA was not correctly created and there is little clear criteria for assessing the quality of FMEAs. This can lead to potential harm to users of the product, costly recalls, and a reduction in employee motivation when significant time is invested in an ineffective FMEA and an assessment is not performed to identify inadequacies.

This paper provides clear requirements for the assessment of DFMEAs and PFMEAs based on the literature. The assessment criteria can be applied in organizations to help ensure FMEAs are preventing failure causes and detection failure causes or failure modes, if the failure cause does occur despite actions organizations have taken to ensure the failure cause was prevented.

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