

Case Study on Development of Process Failure Mode Effect Analysis (PFMEA) – Issues and Recommendation

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Abstract

The Automotive Quality Management System of IATF16949:20016 required the organization to establish and maintain the PFMEA to support the implementation a risk based thinking for achieving effective quality management system and defect prevention. Even there are several guidelines to develop the PFMEA, there are inconsistency in development of FMEA and determining the elements in PFMEA. Hence PFMEA fail to deliver the intended results to prevent product defect origins from manufacturing process. This paper explores the common issues in FMEA through case study and proposed the countermeasure to develop an effective PFMEA through series of workshops. The output of this paper is guideline to develop effective PFMEA.

Keywords: Quality Management System, FMEA, Risk Management, Risk Assessment, Risk Analysis, Decision support tools.

1. Introduction

The latest updates to the IATF16949: 2016 Automotive Quality management system standard required product risk assessment. Although the standard does not explicitly indicated the used of FMEA for product or process risk assessment, the standard recommended the used of FMEA and previous standard of ISO/TS16949:2009 (ISO 2009) does indicated the need of FMEA. Potential Failure Modes and Effects Analysis in Manufacturing and Assembly Processes (PFMEA) is an important preventive method for quality assurance, and through it the decisions based on the severity levels and probabilities of occurrences and detection of the failure modes can be planned and prioritized, seeking to improve the quality of the manufactured products (Mikos et al, 2011). FMEA is one potential tool with extended use in reliability engineering for the electrical and electronic components production field as well as in complicated assemblies (aerospace and automotive industries). The FMEA technique can be applied in the design stage of a system or product (DFMEA) as well as in the manufacturing process (PFMEA) (Pantazopoulos and Tsinopoulos 2005). The Potential Failure Modes and Effects Analysis in Manufacturing and Assembly Processes (PFMEA) represents an important preventive method for quality assurance, including method in the investigation of all the causes and effects (Mikosa & Ferreira, 2007; Dunkle, 2005; Ştirbu et al, 2011; Neshkov et al, 2012).

Johnson & Khan (2003) indicated that the concerns of as a problem prevention technique. The sharing and reuse of this knowledge is a challenge and depends on the understanding of the specialists involved (Mikos et al, 2011). ISO 31000 standards is intended to assist the organization to develop the framework to manage the risk (ISO Technical Management Board Working Group 2009). Although the ISO 31000 standard has effectively integrated the

principles and practices considered most effective by many experts and researchers in the field, the experience and feedback in integration of ISO31000 framework with FMEA is lacking. This paper shares the development of PFMEA and use of this technique effectively integrated with ISO31000 framework.

2. Methodology

Dane (1990) asserts that it is through the action research that researchers are able to test the application against other research results. This way, researchers will be able to assist managers in deepening their understanding of the issue(s) in hands so that they can resolve the problem(s) confronting them. The major strategy for this research is action based case study, in order to develop the effective PFMEA. The steps in implementation of action research are depicted in figure 1. The case study protocol was developed to ensure consistency and reliability of the data collection process.

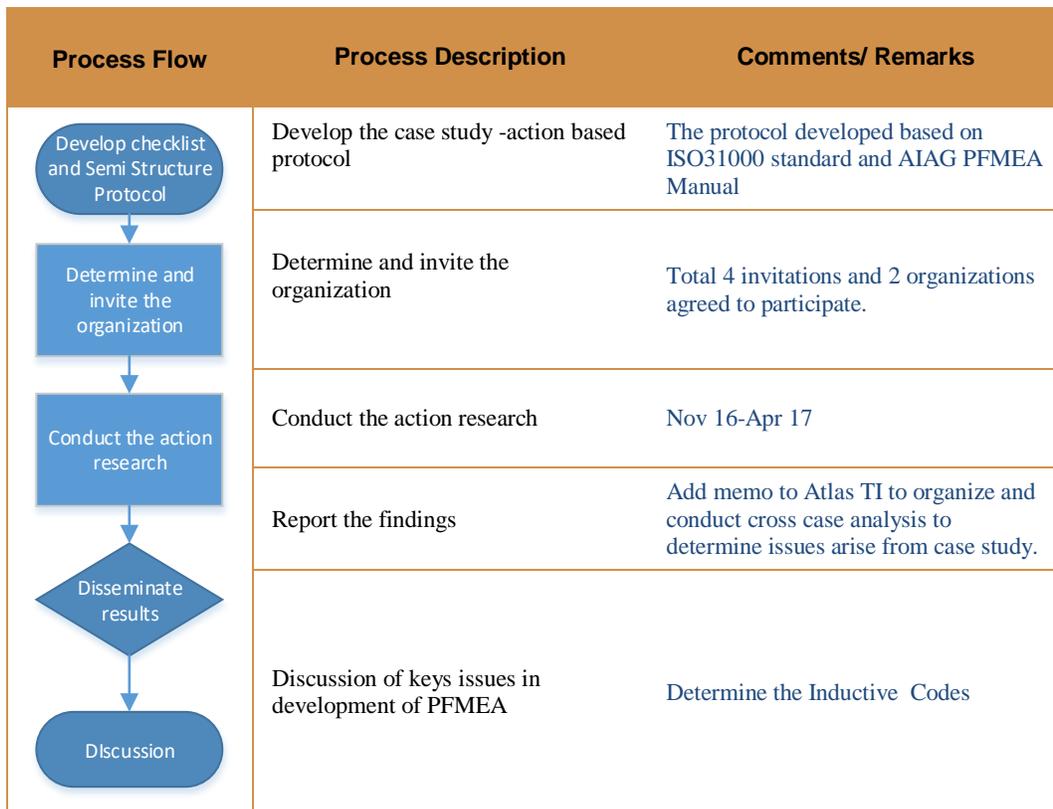


Figure 1 : Process flow for the action based case study

The case study protocol is developed through the standard of ISO 31000:2009 (As shown in figure 2) and Automotive Industry Action Group (AIAG) FMEA reference manual fourth edition 2008. Sample of PFMEA form as shown in figure 3. The first phase of case study is to determine the organization main product from the operation and work process to produce the product. The second phase is to determine the product risk, the effect and cause of the risk.

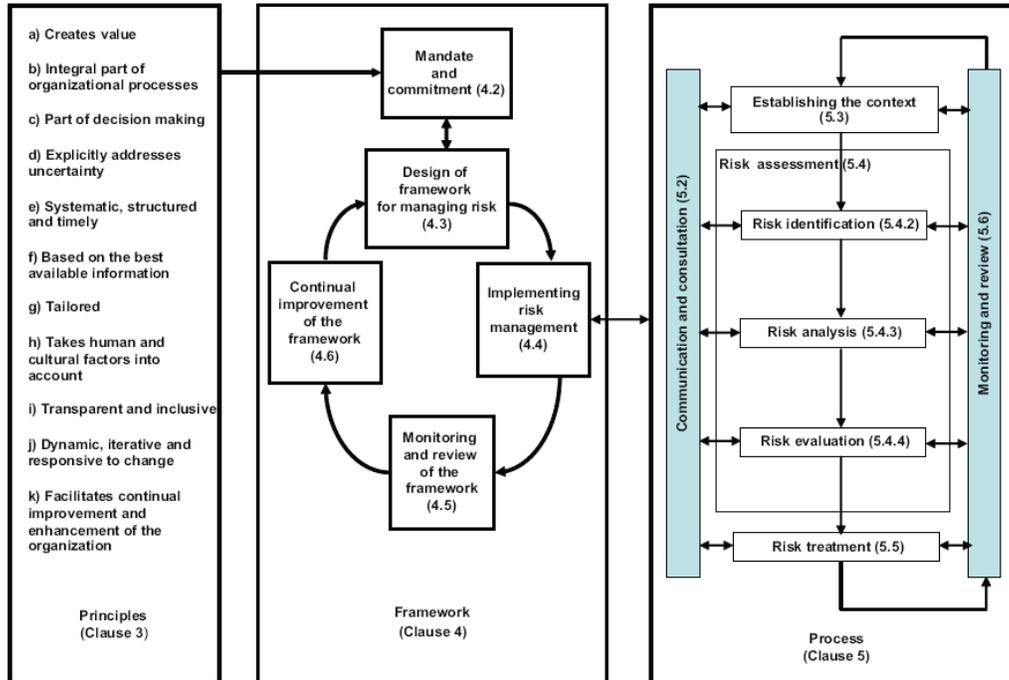


Figure 2: Relationships between the risk management principles, framework and process (ISO Technical Management Board Working Group 2009)

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA)

FMEA Number _____
Page _____ of _____

Item _____ Process Responsibility _____ Prepared By _____
Model Year(s)/Vehicle(s) _____ Key Date _____ FMEA Date (Orig.) _____ (Rev) _____
Core Team _____

Stage 1

Process	Potential Failure Mode	Potential Effect(s) of Failure	Cause(s)/Mechanism(s) Of Failure	Current Process Controls Prevention	Current Process Controls Detection	Recommended Action(s)	Responsibility & Target Completion Date	Actions Taken	Success	Open	Delayed	Rejected
Requirements												
STAGE 2												
STAGE 3												
STAGE 4												
STAGE 5												
STAGE 6												

Figure 3: Sample of AIAG PFMEA form

3.0 Results and Discussion

3.1 Product or Process

Most of FMEA is much focus on either DFMEA or PFMEA. Both DFMEA and PFMEA are equally important. This is where element 4.3 and 5.3 of ISO31000 applied. Element 4.3 described the design of the framework and element 5.3 determined the need to establish context of organization. In both of case study, the context of organization focus in risk management circles revolved around product risk and failure. However, both of DFMEA and PFMEA cover product risk. The only different of DFMEA and PFMEA is the analysis either through components or subsystem or for DFMEA or Manufacturing process for PFMEA. Since the case organization is more interested to determine the type of product failure during manufacturing process, the PFMEA framework is more suitable based on context of organization.

3.2 Defect Prevention

For FMEA, mandate and commitment as required by ISO31000 should be “Defect Prevention”. During the discussion with the case organizations, several suggestions recorded such as that the mandate can be added such as process control, quality first, and customer focus. However, after going through the development of PFMEA, all the team agree that the mandate and goal should be focus on defect prevent. This is due to each steps of PFMEA is focusing towards defect prevention.

In stage 2 of PFMEA (refer to figure 3), there are column on “Requirement”. Requirements can be refer to specification or characteristic of the product such as dimension, color, functionality and appearance. The requirements column is recommended since it can help the team to determine the potential failure mode in term of defects or opposite to the requirements such as Bent, Burred, Hole off-location, Cracked, Hole too shallow, Hole missing, Dirty, Surface too rough, Deformed, Open circuited, Short circuited and Mis-labeled.

3.3 Process Flow

There are argument from the team on “should the PFMEA include all the process such as inspection, each of movement, each of storage and work in progress?” After several round of discussion, the team agree that the PFMEA shall include all the value added process that change the physical of the product. The team also agreed that the inspection process should be excluded from the PFMEA due to: 1) The PFMEA is the tools to determine the inspection/ control needed; 2) The potential failure of inspection process (such as wrong decision) is control through calibration and Gage Repeatability and Reproducibility (GRR) study; 3) The risk of producing another defect during inspection should be highlighted in inspection standard or procedure. As for the move (Transfer between station) and wait process (Raw material storage, Work in progress and Finish good storage), the team decided whether to include in the analysis based on probability of defect occurred during the process. If there are minimum defect can occurred, the process can be omitted from the PFMEA.

3.3 Effects to determine severity score

The AIAG FMEA reference manual have provide clear guideline to determine the severity score for the defects based on the effect to customer or next process. The effects can be categorized to Safety and Regulation related, Functionality including fitment related, and Appearance related. So far, the team does not face any issues in determine the effect of defect in terms of what the customer might notice or experience, remembering that the customer may be an internal customer as well as the ultimate end user.

3.4 Top three causes

Potential cause of failure is defined as how the failure could occur, described in terms of something that can be corrected or can be controlled. The team is required to list, to the extent possible, every cause assignable to each od potential defect (potential failure mode). If a cause is exclusive to the failure mode, i.e., if correcting the cause has a

direct impact on the failure mode, then this portion of the FMEA thought process is completed. Many causes, however, are not mutually exclusive, and to correct or control the cause, a design of experiments, for example, may be considered to determine which root causes are the major contributors and which can be most easily controlled. The causes should be described so that remedial efforts can be aimed at those causes which are pertinent.

The FMEA development team attempted to determine the potential cause through cause and effect (defect) diagram (fishbone diagram). The team also attempt to utilize the five why. However, the teams were unable to document all the causes due to limited space (column and row) in the AIAG PFMEA sheet. The team decided to document only top three causes in the sheet through team consensus. The copy of each cause and effect (defect) diagram is recommended to be documented for future reference.

3.5 Determining occurrence score

Occurrence is the likelihood that a specific cause/mechanism of defect will occur. The likelihood of occurrence ranking number has a relative meaning rather than an absolute value. Preventing or controlling the causes/mechanisms of failure through a design or process change is the only way a reduction in the occurrence ranking can be effected. A consistent occurrence ranking system should be used to ensure continuity. The occurrence ranking number is a relative rating within the scope of the FMEA and may not reflect the actual likelihood of occurrence. AIAG recommend the use of “incident per items/vehicles” to used to indicate the number of defect (failures) that are anticipated during the process occurring. If statistical data are available from similar process, the data should be used to determine the occurrence ranking. In all other cases, a subjective assessment can be made by using the word descriptions in the left column of the table. The team should agree on an evaluation criteria and ranking system that is consistent, even if modified for individual process analysis. (See the following table). Occurrence should be estimated using a 1 to 10 scale. The AIAG fourth edition recommend the design or process controls “prevention” to the left of the Occurrence Ranking. The team indicated that it is very good format as prevention affects the occurrence ranking which had previously been the left of the column. The initial occurrence rankings will be affected by the prevention controls provided they are integrated as part of the process

However the team have difficulties in deciding whether the occurrence should be reflected on the “defect” or the occurrence of “cause”. For the first organization, the team selected to use the “defect” as indicator for occurrence score. While the second organization, develop the occurrence score rating which are “defect score rating” and cause occurrence score rating”.

3.6 Determine control

Current Process Controls are descriptions of the controls that either prevent to the extent possible the failure mode or cause/mechanism of failure from occurring, or detect the failure mode or cause/mechanism of failure should it occur. Two types of Process Controls to consider: 1) Prevention: Eliminate (prevent) the cause of the failure or the failure mode from occurring, or reduce their rate of occurrence, 2) Detection: Identify (detect) the cause of failure or the failure mode, leading to the development of associated corrective action (s) or counter measures. The preferred approach is to first use prevention controls, if possible. The initial occurrence rankings will be affected by the prevention controls provided they are integrated as part of the process. The initial rankings for detection will be based on process controls that either detect the cause/mechanism of failure, or detect the failure mode.

The team decide the prevention control only cover: 1) Error Proofing to the cause of defects; 2) Set-up verification. The detection controls cover the inspection process either during incoming, in-process or outgoing inspection. Each of this control have to be transfer to control plan to detail up the inspection process.

3.7 Continual Improvement Prioritization

The improvement prioritization normally prioritizes through risk priority number (RPN) threshold. The team decided the all defects that are more than 125 of RPN required improvement action. To reduce the RPN, the team have difficulty to reduce the severity due to nature of the product. If the nature of product is safety feature product, the severity score cannot be change. Even the AIAG FMEA manual required to prioritized based on highest severity

first, the occurrence Second and the detection third, the action cannot be take if the severity score is 10, while occurrence is 2 and detection is 2. It is because the occurrence and detection are already considered as low as practicable.

4.0 CONCLUSION

PFMEA is proven risk assessment methodology to prevent defects. However there are seven issues that face by the organization and the team that develop the PFMEA for their manufacturing process. The issues include determining whether to develop the design FMEA or process FMEA, setting up the objectives of PFMEA, determining the processes, determining the severity score, listing the causes, determining occurrence score, determining control and prioritizing the improvement. Each of the issue have the solution as discussed in this paper. The future research should focus on linking the PFMEA and other quality improvement tools such as cause and effect diagram, control plan and application of PFMEA in quality improvement initiatives such as six sigma and lean manufacturing.

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Biography

Edly F. Ramly is Certification Director for EFR Certification. He is renowned coach, auditor, consultant and trainer. With his excellent technical expert and interpersonal skills, he has conducted various high impact trainings and workshop in the area of operation management, industrial engineering, management system including quality, environment and occupational health and safety, workplace improvement, variation and waste reduction, and practical problem solving techniques including statistical tools. Apart from being trained as Lead Auditor in various management system, he is also qualified auditor for Automotive Industry ISO/TS 16949. During his service with Pera Neville Clarke, he is also tutor for QMS lead auditor course. His industrial experience was in the automotive industry. During his stayed with the TRW Automotive, he was tasked with the responsibility of promoting and implementing Lean and Six-Sigma within the Organization. Due to his extensive exposure in Lean and Six-Sigma Management System, he was invited by Malaysia Productivity Corporation (MPC) and Asia Productivity Organization (APO) to conduct public training in the area of Six-Sigma implementation and Lean Implementation. In 2014, he been awarded as one of Malaysia Productivity Specialist by Malaysia Ministry of International Trade and Industry.

Hood Atan is a full time project consultant and qualified auditor in the fields of Quality, Health & Safety and Environmental Management system. Mr. Hood Atan holds a Bachelor of Engineering in Mechanical (Industrial) degree and a Master in Engineering (Industrial Engineering) degree from Universiti Teknologi Malaysia. Having worked as a Quality Engineer, Quality Manager, Quality and Environmental Management Representative for numerous years from bottom, middle and to top management. His industrial experience was in the manufacturing industry. During his stayed with the TRW Automotive, he was tasked with the responsibility of promoting and implementing VDA 6.3, QS-9000, ISO TS 16949, ISO14001, ISO 13485, ISO50001, OSHAS 18001 management system and Lean Six Sigma initiatives within the organization. Besides, he also responsible for supplier audit either local or oversea such as Thailand, Singapore, Vietnam, Indonesia, China and India. With his more than 16 years of working experience in the management system standard, he has conducted various trainings and workshop in the area of workplace improvement, QS-9000, ISO/TS 16949 standard, variation and waste reduction, and practical problem solving techniques including statistical tools.