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Failure mode and effects analysis

An integrated approach for product design and process control

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Introduction

Quality and reliability of products and manufacturing processes are absolutely critical to the manufacturing outcome – the functional performance of the final products. To ensure good product quality, an efficient and comprehensive quality system must be established in the very early stage of product design. All engineers involved in the project should consider process/product quality and reliability while performing their tasks. For example, the product and design engineers must embed quality and reliability into part design, since even a most advanced and reliable manufacturing operation will not be able to improve the product reliability over the designed reliability. The best product reliability is the designed reliability specified in the product design. Therefore, if there is a reliability problem in the product, engineers must examine the following two things. First, the production team must check the adequacy of the product design. The design may not meet the customer's reliability requirements. Second, the production team should examine the possible flaws in manufacturing operations. In this case, system reliability must be evaluated and improved, and quality control has to be performed at a satisfactory level.

In order to meet product reliability requirements, reliability analysis must contain both product design and process operations. Failure mode and effects analysis (FMEA) is a popular tool for reliability and failure-mode analysis. To cover both design and production, FMEA should include the activities at both design and manufacturing stages. It is common and critical to conduct reliability analysis at the earliest stage of the product life cycle. Design and product engineers need to work with a project team that at least includes customers, reliability engineers and manufacturing engineers to identify the potential quality and reliability failures in the design process. Hence, the problems can be eliminated as early as possible to avoid complicated and costly correction processes. Fault tree analysis (FTA) is another popular tool used to analyse product failures. Through known probabilities of each potential failure

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state at the sub-assemblies, the final assembly, and the manufacturing system operations, one can calculate system reliability by using FTA. However, failure modes have to be identified before performing FTA. The design FMEA and process FMEA can supply the potential failure-state information to FTA.

FMEA is a technique that identifies, first, the potential failure modes of a product during its life cycle; second, the effects of these failures; and, third, the criticality of these failure effects in product functionality. FMEA provides basic information to reliability prediction, and product and process design. FMEA helps engineers find potential problems in the product earlier and thus avoids costly changes or reworks at later stages, such as at the manufacturing stage and at the product warranty stage. In the FMEA process, product functions must be carefully evaluated, and the potential failures must be listed. This analysis process provides a thorough analysis at each detailed functional design element. It allows FMEA to be a very useful tool in quality planning and reliability prediction.

Most of the automotive part designs are required to be evaluated by the use of FMEA in the design process. A FMEA report accompanied with the component/part design is a common practice in automotive industry. A good use of the FMEA technique can provide a manufacturing company benefits such as high product reliability, less design modification, better quality planning, continuous improvement in product and process design, and lower manufacturing cost. A company must fully utilize FMEA to improve the reliability of the products and the processes to obtain the benefits mentioned above. If a company's main purpose of developing the FMEA report is to fulfil customers' demand, then the benefits of performing FMEA will be reduced, and the cost for the FMEA process may not be compensated by the benefits of performing the analysis except that it satisfies customers' demand to have the report.

The main reason that people do not fully utilize the FMEA result is that they do not know how and when to link the FMEA information with process control functions. Is there a linkage between the FMEA report and process control? This paper intends to reveal this hidden linkage. This research has developed an approach to integrate FMEA, product design, and process control to one complete closed loop to establish an overall quality control plan. This paper will first discuss the FMEA procedure. Then, the procedure will be separated into two domains – the product design domain and the process control domain. Design FMEA and process FMEA will be demonstrated, and the integration among design, control, and reliability analysis for a product will be illustrated.

The FMEA procedure

The FMEA procedure is well developed and documented in the military handbook[1] and as a military standard[2]. There are two phases in the FMEA process. The first phase is to identify the potential failure modes and their effects. The second phase is to perform criticality analyses to determine the severity of the failure modes. The first phase has to be done concurrently with

the detailed product design. It should also include defining the possible failures of the product's components, sub-assemblies, final assembly, and its manufacturing processes. At the end of the first phase, the detailed design is completed, and the design drawing is developed. At the second phase of FMEA, engineers in the FMEA team evaluate and rank the criticality of each failure, and then revise each design detail and make required modifications. The most serious failure has the highest rank and is considered first in the design revision. The design is revised to ensure that the probability of occurrence of the highest ranked failure is minimized.

Figure 1 reveals the general procedure of the FMEA process. The first phase is from information gathering to the calculation of risk priority numbers (RPN). The actions in the second phase contain the ranking of RPNs, the

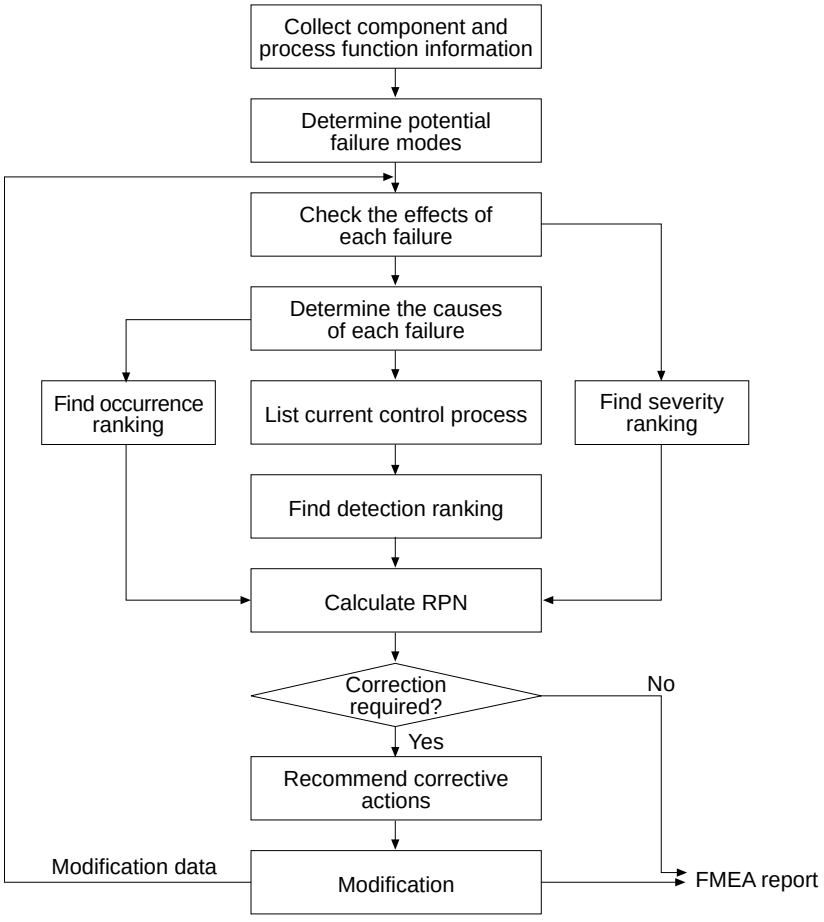

Figure 1.
The FMEA procedure

recommendation of corrective actions, and the modifications of the design. At the end of the procedure, an FMEA report can be obtained, and the required modifications are completed to reduce the number of the potential failure modes to the minimum.

Teamwork is critical to the success of the FMEA process. The team to perform FMEA should include customers, manufacturing engineers, test engineers, quality engineers, reliability engineers, product engineers, and sales engineers. The potential failure modes listed in the FMEA report include the failures at different stages of internal and external customers such as the manufacturing department in the company, the customer – another manufacturing company – and their customers – the end users. The information used in the FMEA process should come from the company's own production lines, the customers, and the field data of similar products. Therefore, the FMEA team has to work with the customers to gather the required information to develop an effective FMEA report.

There are three stages that are very critical in the FMEA process to ensure the success of the analysis. The first stage is to determine the potential failure modes. The second stage is to find the data for occurrence, detection, and severity rankings. The third stage is the modification of the current product/process design and the development of the control process based on the FMEA report.

A total understanding of the product/process functions and careful gathering of the data ensure the correctness of the FMEA report. The usefulness of the FMEA depends on the third stage of the process. To modify the design to eliminate the failure modes, and to develop the process control plan to reduce the occurrence of the failures to a minimum, should be the major goals for the implementation of FMEA.

There are different reasons for companies to invest manpower and efforts in the development of the FMEA report. Dale and Shaw did a survey to investigate the reasons why Ford Motor Company's British suppliers use FMEA[3]. The reasons they found are the mandatory requirement of the customers, product quality and reliability improvement, product and process improvement, production liability and safety concerns, and recalls and warranty claims reduction. The main reason for the majority of these companies to have FMEA procedure is the mandatory requirement of their customers. The same circumstance exists in the US automotive industry.

The current problem in using FMEA

In the current applications of FMEA, many companies terminate their FMEA process whenever their FMEA report is done. As mentioned previously, the purpose of FMEA for some companies is to fulfil their customers' document requirement. If FMEA is just for that purpose, these companies are wasting a great deal of effort, time, and money in the FMEA process. Since the main purposes of performing FMEA are to improve the product/process quality and reliability and to satisfy the customers, FMEA process must go beyond documenting the FMEA report.

Problems associated with FMEA implementation include the timing of the FMEA process at the product/process design stage, the establishment of a well-trained and balanced FMEA team, the co-ordination of individual departments in generating an accurate FMEA report, and agreement on the FMEA report to improve product/process designs by all departments. Similar to the concurrent engineering procedure, the intention of the FMEA application is to shorten the time length for the design of product and process. Reliability concerns must be embedded in the design, and it must be verified that all requirements are met before the completion of the design. Therefore, more effort is required at the design stage. The full co-operation of all departments is required to start the FMEA study. Since concurrent engineering is well received by most companies, the objective then will be to develop an FMEA procedure which runs parallel to the concurrent engineering process. The FMEA report has to supply valuable information for product/process improvement in the concurrent engineering process.

A major problem in FMEA implementation is to utilize the FMEA report in the overall quality system implementation to improve the product and the manufacturing operations. So the problem is not only to generate the FMEA report, but also to use the FMEA information in the overall quality system operation to achieve the goal – to improve the product/process design.

It is very important to define and to specify the interactions between FMEA process and quality control process. In general, the major puzzle in today's FMEA application is how to link FMEA procedure to quality control procedures.

Design FMEA and process FMEA

In the automotive industry, most companies divide FMEA into two FMEA processes – design FMEA and process FMEA[4,5]. Design FMEA is a procedure to identify that the right materials are being used, to conform to customer specifications, and to ensure that government regulations are being met, before finalizing the product design. Product/design engineers are usually the leaders of the design FMEA team. On the other hand, process FMEA deals with the manufacturing and assembly processes. Process FMEA traditionally begins when the design FMEA report is available. It identifies any potential failures that could be caused by manufacturing/assembly processes, machines, fixtures, and production methods. Process/manufacturing engineers usually lead the process FMEA team.

One hidden problem in FMEA processes is that no one considers the manufacturability of the product. It is a grey area in the FMEA process, and no one seems to take charge of this area. Some problems will therefore eventually appear during the normal production period. These problems may include that the production yield being lower than the expected level, and quality problems recurring several times. The "unexpected" problems still happen even if the right materials are being selected, design verifications are being performed and passed, and the production follows every step that the design FMEA team specified. Why do these problems occur? This is because during the design

stages, most of the prototype materials or sub-assemblies are handmade by experienced technicians and/or engineers. No one really thinks about the manufacturing environment in mass production, such as the cycle-time effect, the tool wear effect, and the complexity of the process, until the problem appears.

Product engineers must first clearly define the product functional requirements (FRs) in the design process. They can check all the FRs in the design and develop a list of possible failure modes in design FMEA. Product engineers perform FTA to determine how to modify the design to eliminate the potential failures caused by the design, after the FMEA team have completed design FMEA. As in process FMEA, there is a hidden problem in design FMEA – possible failures of the components. These failures may be from the suppliers or from the material selection process. We suggest a component FMEA process being separated from design FMEA.

Unlike design FMEA, which considers the integration of different components and their interaction effects on the product functions (sub-assembly functions), a component FMEA considers only the selection of materials and the manufacturability of the components. Some inexperienced designers might design some unmanufacturable parts or parts which are very difficult to produce. This type of design will affect the cost, the function, and the assembly process of the product. The component FMEA process might provide information to the related material suppliers for evaluations and suggestions of design changes to eliminate errors and difficulties in producing the parts and to simplify and improve the design. A performance report then can be developed for the continuous monitoring of the supplier's performance.

Process FMEA begins with the development of a process flow chart. This flow chart provides an overview of the complete production processes for the manufacturing of a part. The flow chart should display the sequence of each manufacturing/assembly operation and show how these functions generate the required product characteristics. Process FMEA identifies the potential process failures and determines the possible causes in the manufacturing and assembly operations. The customer effects of the failures are crucial in the rankings of the failure modes. The corrective actions taken for each failure mode in process FMEA eliminate the failure causes in manufacturing/assembly processes, the customer effects, and the occurrence of the failure conditions.

The modification procedure based on the process FMEA report should include the revision of the current control methods and the evolution of the process control plan. The control plan is an important element of the overall quality system. It determines the quality control routines and the inspection methods. The integration of process FMEA and the control plan increases the value of the FMEA report. The report is no longer a document just to accomplish the customer's mandatory requirement. It is the foundation for the development of the process control plan, the living document of the quality system, the reference basis for the next-generation products. The implementation of the control plan can reduce the probability of failure

occurrence at the subsequent manufacturing/assembly processes and increase the probability of failure detection.

The integrated approach

As mentioned previously, developing the FMEA report is not the sole purpose of the FMEA process. Raheja[6] discussed the misuses of the FMEA, which include no teamwork when performing FMEA, no corrective actions taken, and no functional block diagrams used. The integration of the FMEA process into the overall quality system for establishing an effective quality and reliability system for the production of a product is the main reason for performing FMEA, and it can also eliminate the misuses of FMEA listed by Raheja. Therefore, how to utilize FMEA in quality control and quality assurance is the most important task in FMEA implementation.

Lieberman[7] mentioned the use of FMEA in transforming each failure mode into a mathematical model. The model and the available statistical data then can be employed in fault tree analysis to uncover single-point failures in complex system operations. Experts are brought together to improve the design of products and processes in the FMEA process.

Rudy and Wang suggested the use of action threshold value (ATV) and decision threshold value (DTV) for decision making in corrective actions[8]. They reduced the levels of three ranking factors, severity, occurrence, and detection, in FMEA from a fixed scale of 10 to the variable scales based on the decision of the FMEA team. The team uses ATV and DTV to determine the necessity of a corrective action to lower the value of each individual factor and the RPN of a failure mode. The purpose of their research is to increase the effectiveness of the FMEA process.

In this research, we are trying to link various quality control and reliability evaluation tools to the FMEA process. A comprehensive system structure is built to generate required information for process control, reliability prediction, and product/process design. Various reports used in system quality control are connected to the FMEA process. The procedure to link these reports to FMEA will be discussed.

The procedure of process FMEA

The input of process FMEA is a process flow diagram. An example of the diagram is shown in Figure 2. This process flow diagram shows the initial machining operations in a hybrid inflator production process. Figure 3 reveals the configuration of this hybrid inflator which is being manufactured by BAICO, a joint venture of Allied Signal's Safety Restraint Systems and Sequa's Atlantic Research Company. The inflator's process FMEA starts from these machining operations. The first operation group of the production process is set as machining operations. The listing of the sub-groups under the machining operations is based on the process flow diagram. These sub-groups include the processing of the generator, the manifold, the end retainer, and the pressure vessel.

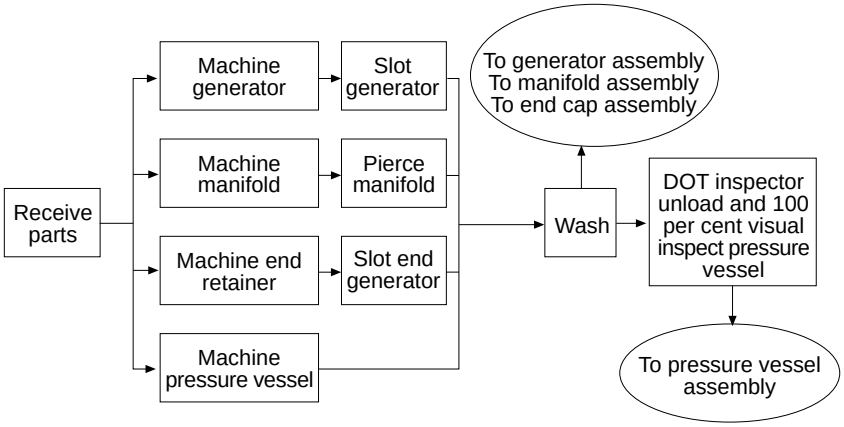

Figure 2.
Process flow diagram for the machining operations in inflator production

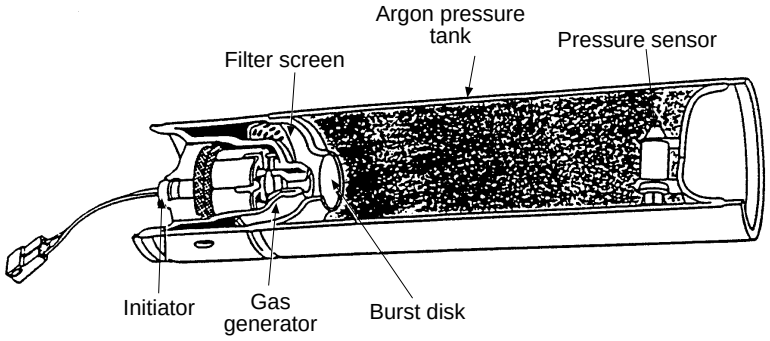

Figure 3.
The configuration of a hybrid inflator

In the generator sub-group, there are three operations – machine, slot and wash. The possible failures in the machining, slotting, and washing of the generators are listed in the process FMEA table as the potential failure modes. All these failure modes are listed in Table I.

The step after determining the failure modes is to find the cause of each failure by utilizing various quality problem-solving techniques like design of experiments, Pareto analysis, and past experiences on similar products. Then the FMEA team should obtain the probability of failure occurrence, the severity with global effects, and the current detection/control method. The probability of failure occurrence is based on engineers' experiences, similar products/processes in the past, Weibull analysis, and other statistical analyses. The severity with global effects comes from various test results, field data, and engineers' experiences. At this stage, the FMEA team lists the possible effects caused by the failures and determines the detection methods to be used in the production process for each failure mode.

Table I.
The process FMEA spreadsheet for generator machining (screen)

	Machining operations generator	Cause of failure	PRB	Sev: severity W/ global effects	Det/ctrl method	Control by	RPN
CFM Machine generator							
	Generator hole i.d. > d1 mm	Improper tooling Generator housing	4	4 Variable ouput	5 IP/sampling	PT:@ Operation	80
*	Generator threads too large	Improper tooling Generator housing	2	10 Eject parts 9 Reduced restraint	5 IP/sampling	PT:@ Operation	100
	Generator threads too small	Generator housing Tool wear	2	4 Internal assm prob	5 IP/sampling	PT:@ Operation	40
	Generator overall length < L1 mm	Improper set up Generator housing	4	4 Internal assm prob	5 IP/sampling	PT:@ Operation	80
*	Generator overall length > L2 mm	Improper set up Generator housing	4	4 Internal assm prob 10 Cause injury	5 IP/sampling	PT:@ Operation	80
	Generator threads too long	Improper set up Generator housing	2	4 Internal assm prob	5 IP/sampling	PT:@ Operation	40
*	Generator threads < *x* full threads	Tool damage Generator housing	2	10 Eject parts 9 Reducing restraint 4 Internal assm prob	5 IP/sampling	PT:@ Operation	100
	Generator o.d. < D1 mm	Tool wear Generator housing	4	4 Internal assm prob	5 IP/sampling	PT:@ Operation	80
	Generator o.d. > D2 mm	Improper set up	4	5 Cust. concern	5 IP/sampling	PT:@ Operation	100
	Generator threads formed wrong (pitch)	Generator housing Tool wear	2	4 Internal assm prob	5 IP/sampling	PT:@ Operation	40
	Generator hole i.d. < d2 mm	Tool wear Generator housing	4	4 Internal assm prob	5 IP/sampling	PT:@ Operation	80

(*Continued*)

Machining operations generator	Cause of failure	PRB	Sev: severity W/ global effects	Det/ctrl method	Control by	RPN
CFM Slot generator						
Generator slot depth > S1 mm	Improper tooling Generator housing	1	4 Internal assm prob	5 IP/sampling	PT:@ Operation	20
Generator slot depth < S2 mm	Improper tooling Generator housing	1	4 Inconsistant performance	5 IP/sampling	PT:@ Operation	20
Generator slot width > W1 mm	Improper tooling Generator housing	1	4 Internal assm prob	5 IP/sampling	PT:@ Operation	10
Generator slot width < W2 mm	Tool wear Generator housing	1	4 Internal assm prob	5 IP/sampling	PT:@ Operation	20
Generator slot omitted	Tool damage Generator housing	2	4 Internal assm prob	4 100% visual	PT:@ Operation	32
Generator tab omitted	Tool damage Generator housing	2	7 Mod. assm problem 5 Squeek/Rattle	4 100% visual	PT:@ Operation	56
Generator slot edges too sharp	Tool damage Generator housing	1	5 Cust. concern 4 Internal assm prob	4 100% visual	PT:@ Operation	20
CFM Wash/protect generator						
Contaminated generators	Improper chemistry Generator housing	1	4 Variable ouput 4 Inconsistant performance	5 IP/sampling	PT:@ Operation	20

Table I.

One thing that members of the team should bear in mind is that no matter how small the probability is for a critical failure mode (with a catastrophic effect), this failure mode should still be in the top list of items to be removed. For example, a leakage is introduced in the compressed air hybrid inflator manufacturing process. If the failure mode is the potential leakage in the inflator, a 100 per cent inspection may be required in the very next process(es), owing to the catastrophic effect of the air leakage. If a costly and timely destructive testing procedure is involved in a non-critical failure mode, sampling a few will be adequate. A very helpful tool – Visual Aids, which can help the operators to identify failures – is another detection method that should be used on the shopfloor.

The ranking of the occurrence, the severity, and the detection method are based on a 1 to 10 scale. The numerical 1 to 10 scale does not have too much meaning to the FMEA team without a meaningful definition of these numbers. A good way is to utilize words to reflect the numerical system. For example, on the severity, 10 represents "catastrophic effect" (non-function or malfunction of the part may cause the death of a user); 9 and 8 mean "critical effect" (cause critical body injury); 7 and 6 denote "major effect"; 4 and 5 indicate "minor effect"; 2 and 3 depict "trivial effect"; and 1 means "no effect". The RPN is calculated by taking the multiplication of these three data. Another piece of information listed in this Table is the detection method which is controlled by the operator, machine, or other means. With the establishment of the process FMEA table, engineers can possess certain required information for process control. If the FMEA table is for documentation only, this information is wasted.

The control plan

A control plan is a plan that ensures the quality of specific parts to satisfy customer requirements and to eliminate any problems in the field of use. It must specify all critical products and process characteristics that require control actions in the production. In a control plan, the failure detection and control method for each control process should be listed, and how to control the production processes is also included in this plan. A control plan also provides information about sampling frequency and gauging information. Hence, the process control plan is the backbone of the statistical process control (SPC) process. The development of the control plan is absolutely critical to the success of the SPC.

A control plan is developed, based on the possible failures of the product functions and the production processes. The production processes are monitored at the particular locations that may cause the potential product failures. So the possible linkage between the FMEA report and the control plan can be established according to the potential failure modes developed in the FMEA report. The control plan is listed similar to the FMEA report. Since the control plan is used to control manufacturing/assembly processes, the linkage is built between process FMEA and the control plan.

The linkage between process FMEA and the control plan

Figure 4 shows the integration of process FMEA and the control plan. The process FMEA report generates the control plan, Visual Aids for inspection, the production process verification check list, and the failure mode, effects and criticality analysis (FMECA) report. The control plan generates the control charts, the gauge study, and the inspection tally sheet. All the control actions developed are based on the failure modes in the FMEA report. The criticality of the failure modes determines the control methods in the control plan.

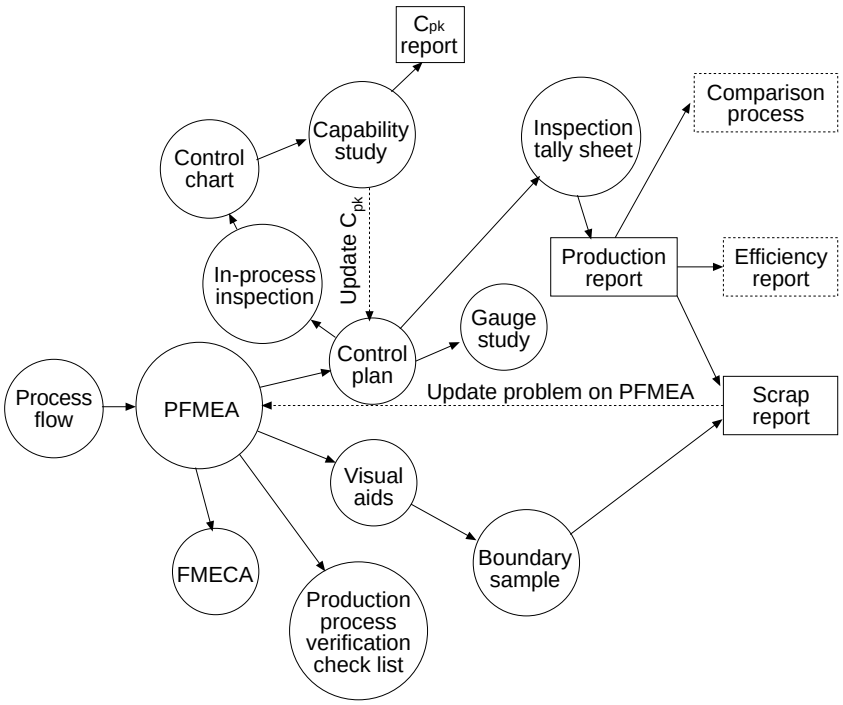

Figure 4.
The integration of process FMEA and the control plan

In FMEA, the failure mode with the highest RPN will be evaluated first to establish the control plan to eliminate or reduce the effect of this failure mode. An RPN list is developed according to the process FMEA report. Critical failure modes (CFMs) are listed in the process FMEA report, based on the severity of each failure mode. A failure mode with a severity scale at 8, 9 or 10 is treated as a critical failure mode. CFMs may not have higher RPN if their probability of occurrence is low.

The procedure for developing the control plan begins at the selection of the failure modes listed in the process FMEA report. Some of the failure modes with very low RPN in the process FMEA report will not be required in the

control plan. The format of the control plan is the same with the process FMEA spreadsheet shown in Table I. In the control plan, the basic information we need to obtain from the process FMEA table includes the list of selected failure modes, the causes of the failures, the detection method and the control mechanism. These pieces of information provide the backbone of the control plan. Table II shows the control plan that is developed according to the FMEA spreadsheet in Table I.

The remaining effort required to develop a complete control plan is to determine the sampling frequency and gauge that will be used in the inspection process. The sampling frequency is based on the need of the operation, the characteristics of the product produced, and the inspection cost. With the determination of the sampling frequency and the type of gauges being used, quality engineers can specify the in-process inspection procedure and develop control charts for each operation that requires control functions. Further capability study may be done to update the capability information listed in the control plan.

The control plan can also be used to create the inspection tally sheet. This sheet will be used as a worklist for all inspection operations. Manufacturing engineers can develop a production report based on the inspection results and may need to update the supplier PPM report if there are supplier-related defects. This production report includes the efficiency report and the scrap report. It is also the basis for process comparisons. The scrap report contains the information of product rejects. This information is then fed back to process FMEA to update the probability data in the FMEA table.

The whole process from the process flow to the scrap report is shown in Figure 4. This integration demonstrates the usefulness of the FMEA process for process control. The development of the process FMEA report results in the evolution of the control plan and, consequently, the overall quality control procedure.

The design FMEA procedure

The information input to design FMEA consists of customer inputs and specifications. Based on customer requirements, the potential failure modes are formed. All the possible functional failures in product design must be caught at the development of the design FMEA report. Component by component evaluations are necessary in design FMEA. A supplementary FMEA table – the component FMEA table – can be established to analyse the potential component failures as a part of the design FMEA process. A well-trained and balanced design FMEA team must be established to initiate the FMEA process and to embed reliability concerns in the product design process. Reliability engineers should provide the potential failure information about the current design concept/prototype to product designers/engineers. Design FMEA is known to be more difficult to handle than process FMEA. Therefore, the selection of personnel in the design FMEA team must be based on the ability to cover all aspects of product functions.

Machining operations generator	Cause of failure	Det/ctrl method	Control by	Sample freque.	Gauge no.	Gauge R&R	CPK
CFM Machine generator							
Generator hole i.d. > d1 mm	Improper tooling Generator housing	5 IP/sampling	PT:@ Operation	5 pcs/hr	P-0046	73.24	
* Generator threads too large	Improper tooling Generator housing	5 IP/sampling	PT:@ Operation	5 pcs/hr	P-0002		
Generator threads too small	Generator housing Tool wear	5 IP/sampling	PT:@ Operation	5 pcs/hr	P-0002		
Generator overall length < L1 mm	Improper set up Generator housing	5 IP/sampling	PT:@ Operation	5 pcs/hr	P-0003	11.51	
* Generator overall length > L2 mm	Improper set up Generator housing	IP/sampling	PT:@ Operation	5 pcs/hr	P-0003	11.51	
Generator threads too long	Improper set up Generator housing	5 IP/sampling	PT:@ Operation	5 pcs/hr			
* Generator threads < *X* full threads	Tool damage Generator housing	5 IP/sampling	PT:@ Operation	5 pcs/hr	P-0003 1st pc/lot	0.00	
Generator o.d. < D1 mm	Tool wear Generator housing	5 IP/sampling	PT:@ Operation	5 pcs/hr	P-0046	37.73	
Generator o.d. > D2 mm	Improper set up	5 IP/sampling	PT:@ Operation	5 pcs/hr	P-0046	37.73	
Generator threads formed wrong (pitch)	Generator housing Tool wear	5 IP/sampling	PT:@ Operation	5 Pcs/Hr	P-0002		
Generator hole i.d. < d2 mm	Tool wear Generator housing	5 IP/sampling	PT:@ Operation	5 Pcs/Hr	P-0046	73.24	

(*Continued*)

Table II.
The control plan for generator machining

Table II.

Machining operations generator	Cause of failure	Det/ctrl method	Control by	Sample freque.	Gauge no.	Gauge R&R	CPK
CFM Slot generator							
Generator slot depth > S1 mm	Improper tooling Generator housing	5 IP/sampling	PT:@ Operation	100%	P-0005		
Generator slot depth < S2 mm	Improper tooling Generator housing	5 IP/sampling	PT:@ Operation	5 pcs/hr	P-0005		
Generator slot width > W1 mm	Improper tooling Generator housing	5 IP/sampling	PT:@ Operation	5 pcs/hr 1st Pc/lot or	P-0005		
Generator slot width < W2 mm	Tool wear Generator housing	5 IP/sampling	PT:@ Operation	5 pcs/hr 1st pc/lot or	P-0005		
Generator slot omitted	Tool damage Generator housing	4 100% visual	PT:@ Operation	100%	P-0007		
Generator tab omitted	Tool damage Generator housing	4 100% visual	PT:@ Operation	100%	P-0007		
Generator slot edges too sharp	Tool damage Generator housing	4 100% visual	PT:@ Operation	100%	P-0007		
CFM Wash/protect generator							
Contaminated generators	Improper chemistry Generator housing	5 IP/sampling	PT:@ Operation	2 Times/shift	P-0006		

The design FMEA team checks the component problems, the functionality problems, the specification problems; and then lists all the possible failures and begins to communicate with customers and suppliers. The members of the team discuss the potential failure modes in design with their customers to make the possible changes in the product specifications to improve its design. They also talk to product engineers to improve the product's manufacturability. They inform suppliers about the potential problems in components or possible improvement required for a better design.

The design FMEA report is used to develop the receiving inspection procedure and the design verification check list. It is also employed to perform fault tree analysis and to predict the reliability of the product. Figure 5 displays the whole procedure. A company can recognize its suppliers' performance through the supplier PPM reports developed here. The probability of occurrence in the design FMEA table can be updated according to the supplier PPM report.

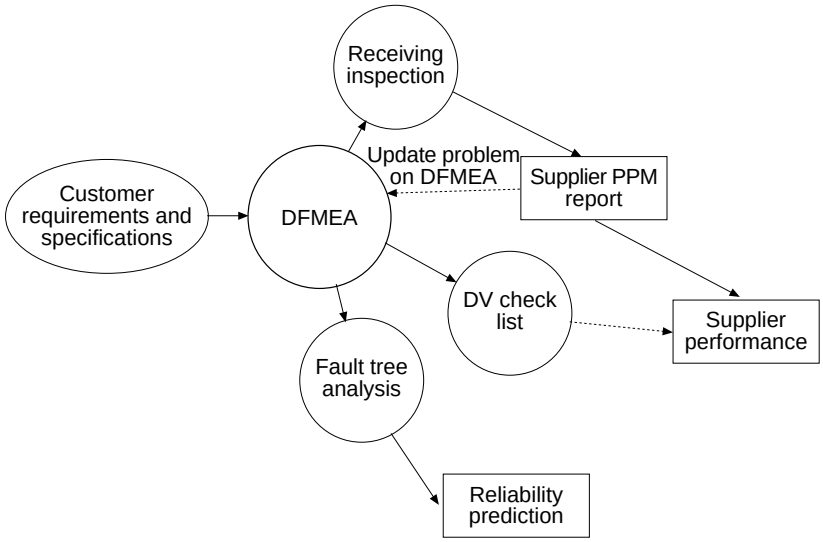

Figure 5.
The design FMEA diagram

Linking design FMEA and process KMEA

Process FMEA provides information to design FMEA for fault tree analysis. The possible process failures in FTA are identified come from the process FMEA report. Meanwhile, the design team uses FTA and other analysis techniques to predict the product's reliability. Certain reliability information can be obtained from the criticality analysis performed in process FMEA and sent to the product reliability prediction process. Another linkage between design FMEA and process FMEA is the supplier PPM report. The inspection tally sheet developed in process control can supply the information on component

rejects. This information, plus the data obtained from receiving inspection, can provide a very accurate supplier PPM report.

Figure 6 shows the overall FMEA process which includes both the design FMEA and the process FMEA. The implementation of the FMEA process is no longer for the FMEA report only. Design FMEA provides the design improvement process and determines the suppliers' performance for supplier control. It also establishes the basis for fault tree analysis and reliability prediction. Process FMEA institutes the control plan and lays the groundwork for SPC.

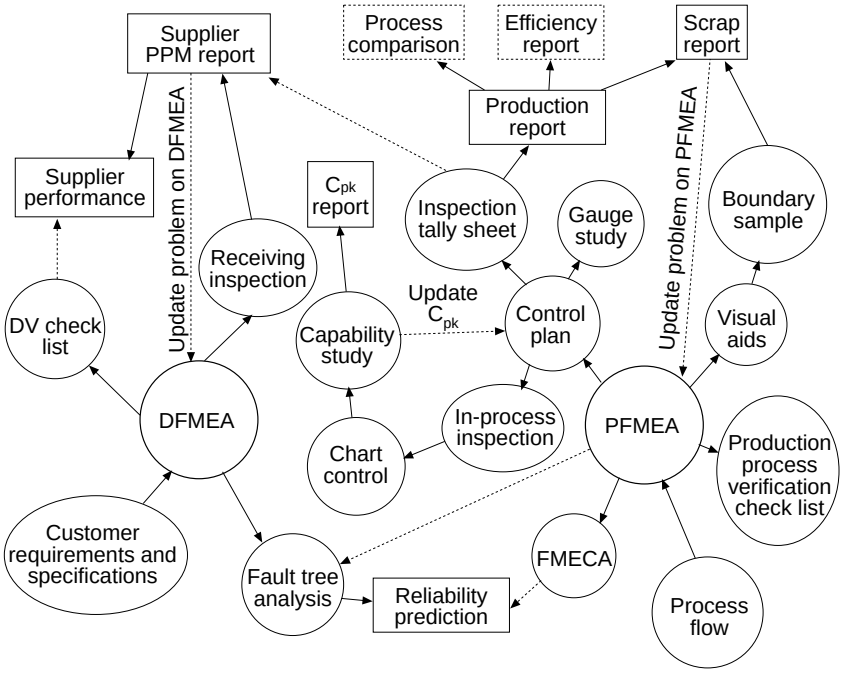

Figure 6.
The integration of design FMEA and process FMEA

The integration of these two FMEA procedures provides an efficient quality planning procedure for a new product or the existing products. The FMEA teams need to update the current FMEA table continuously, to improve product design and the production process. With the execution of this integrated FMEA approach, the effort in preparing a FMEA report will be very beneficial to production system and quality system planning.

The advantages of the integrated FMEA

There are four advantages in integrating FMEA into general quality planning procedure:

(1) Based on the FMEA result, every failure mode is controlled by process control plan under a day-to-day control routine to make sure that no non-conforming products will be shipped to customers.

(2) With the feedback information from the inspection tally sheet and the process C_{pk}/PPM report, the data in the probability column of the FMEA spreadsheet can be accurately estimated and revised. The data in this column will no longer be just numbers of which no one really knows the accuracy. The use of these real probability indexes for the particular failure modes can also help engineers design fixtures and tools for the equipment used. Meanwhile, they are good indexes for future equipment and/or product raw material selection.

(3) Using both design FMEA and process FMEA to institute fault tree analysis can help engineers eliminate the voids (such as some unknown failure modes and high-probability failures) in between these two FMEAs. Design engineers not only design for the product function but also design for manufacturing. For example, some grade of steel may be very suitable for the product's function, but is impossible to process.

(4) The integrated FMEA links quality control tools together and turns data into information, so the FMEA report is no longer a text file only. It is a living document that helps design and process engineers do their jobs better.

FMEA in concurrent engineering

Concurrent engineering is a process which reduces product life cycle cost and speeds up the development of new products and their production/manufacturing systems. Garrett[9] listed eight required steps to achieve concurrent engineering goals which are also very useful for the establishment of the FMEA team. Stoll[10] discussed ten techniques that are being used in concurrent engineering procedure. FMEA is one of these ten techniques. He pointed out that FMEA is an important design and manufacturing engineering tool in concurrent engineering. Boothroyd and Dewhurst[11,12] discussed more details of design for assembly (DFA) in their work.

As shown in Figure 6, the interfaces between design FMEA and process FMEA are reliability prediction and fault tree analysis. In this inflator design example, potential design improvement can be evaluated by checking critical failure modes in the FMEA reports. Design for manufacture and assembly process can be combined with FMEA and fault tree analysis processes to make design changes. Teng and Ho demonstrated this procedure in their research to determine the feasibility of eliminating the low pressure sensor from the inflator design[13]. The analysis is based on the critical failure modes, the fault tree analyses of inadequate inflator system output and gas leakage from the inflator's pressure vessel, and the DFA concerns. This study shows that the removal of the low pressure sensor from the current inflator design does not affect the performance of the inflator. It reduces the number of failure modes and the number of components and assembly steps. Therefore, FMEA process

helps the design team reach the major goal of DFA – reducing the number of components and assembly steps, especially the difficult assembly steps. In our case, assembling (welding) the sensor on to the inflator's end cap is a difficult process because of the requirement of glass seals. Eliminating this process gives manufacturing engineers a big relief in the production process.

Conclusion

The FMEA report is a document that is required by automotive manufacturers to go with the automotive components sent by their suppliers. Because of this requirement, some suppliers establish a procedure in their companies to develop this document. The development of the FMEA report needs time, manpower, and a lot of effort. If all these resources are wrongly spent on a single purpose – just the development of the report – then the implementation of FMEA is very questionable. The aims in performing FMEA should be to develop an effective quality control system, to improve the current production processes, and to ensure high quality and reliability of the products. Hence, the integration of the FMEA process to product design and process control is absolutely critical to the success of FMEA.

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