The Development of a FMEA Process for Design and Maintenance

Tearesa Lynn Wegscheid

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THE DEVELOPMENT OF A FMEA PROCESS
FOR DESIGN AND MAINTENANCE

by

Tearesa Lynn Wegscheid

A Thesis
Submitted to the
Faculty of The Graduate College
in partial fulfillment of the
requirements for the
Degree of Master of Science in Engineering
Department of Industrial and Manufacturing Engineering

Western Michigan University
Kalamazoo, Michigan
June 2000
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Teresa Lynn Wegscheid
2000
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Teeresa Lynn Wegscheid
Failure Modes and Effects Analysis (FMEA) is a systematic way to identify and evaluate potential product and process related failure modes, the associated causes of failures, and the necessary actions to eliminate or reduce the chance of the failure. There are a number of published manuals and books on FMEA. The materials provide a definition of the FMEA form and examples of the Design and Process FMEA. However, there are many inconsistencies throughout the literature. As a result, FMEA is not always value-added.

The thesis is twofold. First, it documents a case study that uses Design FMEA extensively. The case study illustrates the differences between the various types of FMEA, the role of FMEA and Quality Function Deployment (QFD), and the role of management in the successful implementation of an FMEA procedure. Second, the thesis applies FMEA to manufacturing equipment. Design and Maintenance FMEA are defined as a way to decrease total downtime of capital intensive manufacturing equipment. The results show the importance of a well-defined form, the need to integrate the FMEA process into the organization's system, and the importance of the organizational culture or environment in the support of FMEA.
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CHAPTER I

INTRODUCTION

Failure Mode and Effects Analysis (FMEA) is a systematic method to define, identify, and eliminate potential failures or problems from product designs and manufacturing processes before the failures reach the customer. The purpose of FMEA is to avoid costly changes by identifying latent design and process failures early in design and testing phases. FMEA has been used for more than thirty-five years in the aerospace industry. NASA has historically used FMEA for the unmanned and manned space missions. In the early 1970s, FMEA was adapted by the automobile industry. Other industries, including the nuclear, chemical, and electronic, use FMEA to identify potential failures of products and processes. FMEA identifies potential failure modes and the effects of the failure modes, the associated causes of the failure modes, and actions taken to reduce the chance or the effect of the failures. The value of FMEA is reflected in the reduction of failures in products reaching a customer, savings in prototype design and development, improved test planning, and decreases in warranty cost.

Up to the 1990s, FMEA procedure was not well documented. MIL-STD 1629A-Procedures for Performing a Failure Mode, Effects, and Criticality Analysis (FMECA) was initially published in 1974 and Ford Motor Company published a manual on Process FMEA in 1972. Both references described the mechanics involved
publications of ISO–9000 and QS–9000 that required the use of Design and Process FMEA. Since 1990, numerous papers have appeared in the literature. The articles define FMEA, show the use of FMEA in design and process development, list the advantages of FMEA, provide examples of completed FMEA, describe the relationship between the FMEA and other quality techniques, and explore the concept of automated FMEA. Even though there is a wealth of information about FMEA, FMEA are not effectively used. The applications of FMEA tend to be confusing, time consuming, and simply exercises in completing a form. Manuals and training materials provide definitions of each column and the process for completing the form. However, there are inconsistencies in the materials with respect to the definitions of the various column, the scope, and purpose of the FMEA. In addition, the material does not address the organizational environment needed to support the successful implementation of FMEA.

This study is twofold. A case study is presented that uses an improved method of implementing FMEA. The method differentiates the analysis portion of FMEA, initiated by a team of engineers, and the planning portion of the FMEA, following up with design improvements. It defines the scope of Design FMEA and integrates Quality Function Deployment (QFD) and FMEA. The method integrates the supplier FMEA and Design FMEA, the Process FMEA and Design FMEA. The case study suggests a way to update the FMEA form to reflect changes in the design and process. The study documents the application of the new FMEA method in the design process of a new product.
The second part of the study applies the FMEA process to capital intensive manufacturing equipment. It reviews the basic steps in the use of a modified Design FMEA and introduces the use of a Maintenance Failure Mode and Effect Analysis (MFMEA). It presents a formal procedure to document the crucial modes of failure to maintain a machine, the root causes of failure to maintain, and the effect of those failures on the performance of the machine. A ranking system is offered that combines the severity of the failure mode, the occurrence of the cause of the failure, and the detection of the cause of failure criteria to rank those modes of failure, and select the most prominent ones for further study to reduce the impact of those failures.
CHAPTER II

LITERATURE REVIEW

Failure Mode and Effects Analysis (FMEA) is a systematic method of defining, identifying, and eliminating potential failures or problems caused by product designs and manufacturing processes before they reach the customer. Since FMEA is a defect prevention methodology, it is an important element in a reliability program (Ireson and Coombs, 1988; Kececioglu, 1994). Even though the purpose of FMEA is clear, some of the literature (Arnzen, 1966; Greene and Cunningham, 1968; Rahija, 1981; Lieberman, 1990; Healey, 1994) refers to FMEA as an analytical tool for system design, evaluation, and reliability improvement. Others (Dale and Shaw, 1990; Gevirts, 1991; Hatty and Owens, 1994) refer to FMEA as a quality-planning tool for identifying, at the design or manufacturing stage, failures that may occur during customer use. Failure Mode and Effects Analysis can be used as both an analytical tool and a quality-planning tool. The analytical portion of FMEA consists of the functions of a system, subsystem, or component; the failure modes associated with each function; the effects of each failure mode; the potential causes for each failure mode; and the current design controls for each cause. The recommended action, target dates, person responsible, and revised Risk Priority Number define the planning portion of FMEA. The greatest benefits are obtained when the recommended actions are completed and changes are made to the design and process
to eliminate failures or reduce the occurrence of the failures. Thus, a completed FMEA should include the analytical portion and the planning portion.

History

FMEA were first utilized at Grumman in the early 1950s by the reliability sector (Arnzen, 1966). They were used in the military and by NASA in the 1960s (Perkins, 1995). Military and automotive industries started publishing FMEA manuals in the early 1970s. MIL-STD 1629A-Procedures for Performing a Failure Mode, Effects, and Criticality Analysis (FMECA) was first released in 1974 and revised in 1980. The objective of the FMECA was to identify all modes of failure within a system design. More specifically, the purpose was early identification of catastrophic and critical failures so failures could be eliminated or minimized through design correction at the earliest possible time. The standard applied to the acquisition of all designated Department of Defense (DoD) systems and equipment. It primarily applied to the program activity phases of demonstration and validation for full-scale engineering development, design, research and development, and test and evaluation.

In the late 1980s, the Purchasing and Supply Vice Presidents of Ford, General Motors, and Chrysler chartered a Task Force to standardize reference manuals. The Task Force worked together to develop a common quality system for their supplier base. The task force developed QS-9000. QS-9000 was first released in August of 1994. The QS-9000 standard mandated the use of the reference manual for Design and Process FMEA. All the suppliers to Ford, Chrysler, and GM are required to do FMEA.

In 1987, ISO-9000 series was released. The ISO-9000 became the accepted basis for quality system requirements. ISO-9001- Quality System – Model for Quality Assurance in Design, Development, Production, Installation and Servicing required the use of Design and Process FMEA to evaluate new product designs and new manufacturing processes. ISO-9002 – Quality System – Model for Quality Assurance in Production, Installation and Serving required the use of Process FMEA to evaluate new and existing manufacturing processes. As a result of ISO-9000 under 9001 & 9002, companies seeking ISO certification were required to use Design and Process FMEA.

The FMEA Process

There are many different ways to use FMEA. QS-9000–Potential Failure Mode and Effects Analysis distinguishes between Design and Process FMEA. MIL-STD 1629A-Procedures for Performing a Failure Mode, Effects, and Criticality Analysis does not specifically define Design and Process FMEA. However, it
describes a Design FMECA, a FMECA for maintainability information, and a
damage mode and effects analysis. Most of the existing literature (Raheja, 1989;
Aldridge, Taylor, and Dale, 1991; Healey, 1994; Hatty and Owens, 1995) describes
two types of FMEA, Design and Process. Design FMEA assesses potential failure
modes of the product with respect to possible weaknesses in the design. Process
FMEA focuses on potential failures during manufacturing as a consequence of non-
compliance to specification or design intent. The Design FMEA provides input to the
Process FMEA and helps retain design intent during manufacturing. Stamatis (1994b)
describes four types of FMEA that include System, Design, Process, and Service
FMEA. A System FMEA is used to analyze systems and subsystems in the early
concept and design stage. A Design FMEA is used to analyze products before they
are released to manufacturing and focuses on failure modes caused by design
deficiencies. A Process FMEA is used to analyze manufacturing and assembly
processes and focuses on failure modes caused by process or assembly deficiencies.
A Service FMEA is used to analyze a service before it reaches the customer. It
focuses on failure modes caused by system or process deficiencies. The four types of
FMEA described by Stamatis are used at different phase of the product development
cycle.

Onodera (1997) reviewed 100 FMEAs conducted at various industries in
Japan. He determined that FMEA were used at the design and development stage, the
manufacturing and inspection stage, the assembly stage, and the operation and
maintenance stage. FMEA were used throughout the entire product cycle.
For the purpose of this paper, Design and Process FMEA will be discussed in some detail and manufacturing equipment and product maintenance FMEA will be introduced. The following is a description of a Design and a Process FMEA.

The Form

There is not a consensus on a standard FMEA/FMECA method (Ashley, 1993). Each company has its own form that reflects the needs of the organization and the concerns of their customers. However, two methods dominate the literature, MIL-STD 1629A and the Society of Automotive Engineers, QS-9000. Both methods have an analytical portion that includes the system function, the potential failure modes, the effects, and the causes of the failure modes.

The Function defines the function of the system, subsystem, or component. It is defined from the system definition, mission function and operational modes, environmental profiles, mission time, block diagrams, functional diagrams, and reliability diagrams. Function includes the inherent function of the component and its relationship to interfacing systems, subsystems, or components (MIL-STD 1629A, 1980). The system, subsystem, or component may have many functions. The Function for a Process FMEA is defined as a description of the process or operation being analyzed.

Potential Failure Mode describes all the possible ways the system, subsystem, or component can fail to satisfy the design intent described in the Function. It considers how the component can fail and what can go wrong with the component.
Potential Failure Mode considers potential failures at the different life cycle phases of the product. Potential Failure Mode is identified from past test data, field test data, service records, function block diagrams, and customer complaints. For a Process FMEA, Potential Failure Mode defines the way a process can fail to meet the process requirements or design intent. It can be a failure mode for a subsequent operation or an effect associated with a failure in a previous operation.

The Potential Effect of Failure is the consequence of the failure on the next higher level system, product, customer, or government regulation (Stamatis, 1994b). A failure mode may have more than one effect, and an effect may be the result of more than one failure mode. MIL-STD 1629A differentiates between local, next level, and end effects. In a Process FMEA, Potential Effect of Failure is the effect of the failure mode on the customer(s). The customer(s) is defined at the next operation, any subsequent operations, or the customer or consumer.

Potential Causes of Failure provides a list of every possible cause of the failure mode. In a Design FMEA, the Potential Causes of Failure address design weaknesses. For a Process FMEA, the Potential Causes of Failure address process weaknesses. The Potential Causes of Failure must address the root cause of the failure, not the symptom. The Process FMEA defines the Potential Causes of Failure as the way the failure could occur, described as something that can be corrected or controlled.

The Current Design Control (Design Verification, Failure Detection Method) is defined differently for different industrial standards and, as a result, introduces
confusion about the meaning of the column. MIL-STD 1629A defines Failure Detection method as the method by which an operator can detect the occurrence of the failure mode. QS-9000 defines Current Design Control as a list of design validation or verification tests or other activities that will assure the design adequacy for the failure mode. Healey (1994) describes Design Verification as current activities used to verify the aspect of design under consideration. For the Process FMEA, the column header is “Current Process Control.” It defines the controls that are currently in place that either prevents the failure mode from occurring or detects the failure mode if it occurs.

Once the Potential Failure Modes, Potential Effects of Failure, Potential Causes of Failure Mode, and Current Design Controls are identified for each function, an assessment of the importance of each potential cause is conducted. The assessment is done in one of two ways. MIL-STD 1629A describes a criticality analysis. The purpose of the criticality analysis is to rank each potential failure mode identified. The criticality of the failure is ranked by the probability of occurrence of the failure and the severity of the failure. The probability of occurrence can be qualitatively assessed (frequent, reasonably probable, occasional, remote, or extremely unlikely) or quantitatively assessed. The quantitative analysis calculates the probability of failure from the probability of the effect of the failure, failure mode ratio, part failure rate, and the operating time. A severity classification is assigned to each failure mode according to the failure effect. Severity classifications include catastrophic, critical, marginal, and minor. A criticality matrix is constructed from the severity
classification and the probability of occurrence level. There is a more urgent need to implement corrective action for items with a greater criticality.

QS-9000 uses a Risk Priority Number (RPN) to assess the critical of the Potential Cause of Failure Mode. RPN is a ranking for the Potential Cause of Failure Mode based on the severity of the effect, the probability of occurrence of the failure, and the ability of the Current Design Control to detect the failure. Table 1 illustrated the

Table 1
Severity Evaluation Criteria for Product and Process FMEA

<table>
<thead>
<tr>
<th>Rank</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Minor</td>
<td>It is unreasonable to expect that the minor nature of this failure would cause any real effect on the product performance. The customer will not notice the failure.</td>
</tr>
<tr>
<td>2, 3</td>
<td>Low</td>
<td>The nature of the failure causes only slight customer annoyance. The customer will notice a slight deterioration in performance.</td>
</tr>
<tr>
<td>4, 5, 6</td>
<td>Moderate</td>
<td>The failure causes some customer dissatisfaction. The customer is uncomfortable or is annoyed by the failure. The customer will notice some performance deterioration.</td>
</tr>
<tr>
<td>7, 8</td>
<td>High</td>
<td>There is a high degree of customer dissatisfaction due to the nature of the failure, such as an inoperable product or subsystem. The customer will notice severe performance deterioration.</td>
</tr>
<tr>
<td>9, 10</td>
<td>Very High</td>
<td>The potential failure mode affects safety and/or non-conformance with government regulations.</td>
</tr>
</tbody>
</table>

Severity ranking number and associated evaluation. The Severity ranking is a number
ranging from 1 to 10, with 1 meaning no effect and 10 meaning hazardous-without warning.

The Occurrence ranking is defined in two ways. Stamatis (1994b) defines occurrence with respect to the failure mode. Others define Occurrence with respect to the individual causes of the failure mode. In either case, it is a number ranging from 1 to 10, with 1 being remote and 10 being very high. Table 2 describes the ranking and

Table 2
Occurrence Evaluation Criteria for Product and Process FMEA

<table>
<thead>
<tr>
<th>Rank</th>
<th>Design Life Possible Failure Rate</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&lt; 1 PPM</td>
<td>Remote</td>
<td>Failure is unlikely</td>
</tr>
<tr>
<td>2</td>
<td>1-50 PPM</td>
<td>Low</td>
<td>Relatively few failures</td>
</tr>
<tr>
<td>3</td>
<td>50-250 PPM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>250 PPM - .1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>.1% - .25%</td>
<td>Moderate</td>
<td>Occasional failures</td>
</tr>
<tr>
<td>6</td>
<td>.25% - 1.25%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>1.25% - 2.50%</td>
<td>High</td>
<td>Repeated failures</td>
</tr>
<tr>
<td>8</td>
<td>2.50% - 5.00%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>5.00% - 12.5%</td>
<td>Very High</td>
<td>Failure is almost certain</td>
</tr>
<tr>
<td>10</td>
<td>12.5% - 100%</td>
<td></td>
<td>Failure is certain</td>
</tr>
</tbody>
</table>
the associated descriptions for Occurrence rankings. Internal and external failures can be used to estimate occurrence.

The Detection ranking is defined differently in MIL-STD 1629A and in QS-9000. MIL-STD 1629A defines detection as the ability of the customer to detect the failure before it occurs. Table 3 shows the ranking for Detection with a description

Table 3

Detection Criteria for Product FMEA

<table>
<thead>
<tr>
<th>Rank</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 2</td>
<td>Very High</td>
<td>The failure will be detected prior to releasing for production.</td>
</tr>
<tr>
<td>3, 4</td>
<td>High</td>
<td>The failure is very likely to be detected prior to final release. It will be detectable after release but before mass production.</td>
</tr>
<tr>
<td>5, 6</td>
<td>Moderate</td>
<td>The failure may detect prior to final release. It will be detected prior to shipment of the finished product.</td>
</tr>
<tr>
<td>7, 8</td>
<td>Low</td>
<td>The control may not detect a potential design problem, however, the failure mode will be detected prior to occurring in the field.</td>
</tr>
<tr>
<td>9, 10</td>
<td>Very Low</td>
<td>The failure is undetectable until failure occurs in the field.</td>
</tr>
</tbody>
</table>

for each value QS-9000 defines the Detection ranking as the ability to detect the failure before it reaches the customer. It is a number ranging from 1 to 10, with 1
indicating that the cause is most certainly detected and 10 indicating that the cause is not detected.

The Severity and the Occurrence rankings are defined similar for the Process FMEA. The Detection ranking is different for the Process FMEA. Table 4 shows the

Table 4
Detection Criteria for Process FMEA

<table>
<thead>
<tr>
<th>Rank</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 2</td>
<td>Very High</td>
<td>There is a remote chance the product is shipped containing the defect.</td>
</tr>
<tr>
<td>3, 4</td>
<td>High</td>
<td>There is a low chance the product is shipped containing the defect.</td>
</tr>
<tr>
<td>5, 6</td>
<td>Moderate</td>
<td>There is a moderate chance that the product is shipped containing the defect.</td>
</tr>
<tr>
<td>7, 8</td>
<td>Low</td>
<td>There is a high chance that the product is shipped containing the defect.</td>
</tr>
<tr>
<td>9, 10</td>
<td>Very Low</td>
<td>There is a very high chance that the product is shipped containing the defect.</td>
</tr>
</tbody>
</table>

Detection ranking for the Process FMEA. The detection number for both the Design FMEA and Process FMEA focuses on the chance of finding the failure before the product reaches the customer. However, the Design FMEA addressed the detection of a design weakness in the product development cycle and the Process FMEA addressed the weakness in the manufacturing process.
The Risk Priority Number (RPN) is simply the multiplication of the three rankings. It shows a relative likelihood of a Potential Cause of Failure Mode within the FMEA (Healey, 1994). Table 5 shows the ranking for the RPN. The RPN is a number used as an aid to indicate the priority of actions (Webber, 1990). It shows the relative likelihood of a Potential Cause of Failure Mode (Healey, 1994). Higher RPN indicate an urgent need for corrective action. The maximum value is 1000, however, RPN are generally below 450. Onodera (1997) states that the significant failure modes are those with a RPN in the upper 10 percent of all failure modes analyzed when considering improvements in reliability. RPN does not provide a measure to compare companies, manufacturing routes, or even other FMEA (Webber, 1990).

The quality-planning portion of FMEA includes Recommended Action(s), Target Date & Responsibility, Action Taken, and the Revised RPN. Each of the columns has the same definition for both the Design and Process FMEA. Recommended Action(s) is defined as an action to reduce any one or all of the

<table>
<thead>
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<th>RPN Range</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>450-100</td>
<td>Very Critical</td>
</tr>
<tr>
<td>100-60</td>
<td>Less Critical</td>
</tr>
<tr>
<td>60- below</td>
<td>Not critical</td>
</tr>
</tbody>
</table>
rankings. It can be a specific action, further study, or no action required. Target Date & Responsibility identifies the person(s) responsible for completing the Recommended Action(s) and the estimated date for the completion of the Recommended Action(s). The Action Taken is a brief description of the actual action taken and the date it was taken. Action Taken is the follow-up to the Recommended Action(s). After the action has been completed, the RPN is recalculated to account for the changes. All revised RPN are reviewed and if further action is considered necessary, then the Recommended Action(s) and Action Taken are revised. FMEA is an iterative process. MIL-STD 1629A does not specify a planning portion for the FMECA. The standard requires action to be taken on critical failure modes, but it does not provide for the documentation of the actions in the form itself.

The Process

Completing the form is only part of the FMEA process. There are several organizational factors that determine the effectiveness of FMEA. One of the factors is the timing of the FMEA. FMEA is meant to be a “before-the-event” activity, not an “after-the-fact” exercise. MIL-STD 1629A specified that FMECA should be initiated as soon as preliminary design information is available at the higher system levels. Raheja (1989) states that to make FMEA effective, Design FMEA needs to be done after specifications are written, but before the prototype units are built. QS-9000 states that the Design FMEA should be initiated before or at the design concept finalization. Process FMEA should be initialized before or at the feasibility stage,
prior to tooling for production, and take into account all manufacturing operations
(Stamatis, 1994a).

The level of detail is another important consideration. QS-9000 states that a
Design FMEA should be completed for every end item, along with every related
system, subassembly and component for all new parts; changed parts, and carryover
parts in new applications or environments. MIL-STD 1629A states that the contractor
should establish the lowest indenture level of analysis so that items are assigned a
catastrophic or critical severity classification and the specified or intended
maintenance and repair level for items are assigned a marginal or minor severity
classification. Greene and Cunningham (1968) defines three levels of detail – part
level, circuit level, and box level. They state that the level of detail should be
determined by considering the reliability requirements of the system, the reliability
history of the subsystem, and the cost and schedule constraints of the program. The
level of detail increases as the design continues to progress through the design cycle.
Most literature states that FMEA is done at the component level (Raheja, 1989;
Healey, 1994; Perkins, 1996). However, Raheja (1989) notes that there is confusion
about the level of detail required for FMEA.

It is universally agreed that FMEA should be conducted as a team (Raheja,
1989; Aldridge, Taylor, and Dale, 1991; Healey, 1994; Hatty and Owens, 1995; and
Stamatis, 1994). Even though responsibility for the preparation of the FMEA must be
assigned to an individual, FMEA input is a team effort. The product engineer should
complete the analytical portion of the FMEA, as a draft, at the concept phase. The
Design FMEA team reviews the draft and discusses and prepares the formal FMEA (Aldridge, Taylor, and Dale, 1991). For a Design FMEA, the team members include design/product engineers, manufacturing engineers, assembly engineers, quality engineers, lab testing engineers, process engineers, reliability engineers, and sales engineers. For a Process FMEA, the team members include design engineers, product engineers, manufacturing engineers, assembly engineers, quality engineers, process engineers, reliability engineers, maintenance people, and operations staff.

The final factor is the use of FMEA. QS-9000 refers to the FMEA as a “living” document (Ashely, 1993; and Stamatis, 1995). It should be changed and updated to reflect design changes and knowledge gained through testing. It is fundamentally completed before the production drawings and final release for tooling.

**Benefits**

There are a number of advantages of using FMEA. It provides a method to categorize risks to assure that all previous problems are addressed. It provides a means of assessing risk of a failure based on the severity of the failure, frequency of occurrence, and detection of the failure. FMEA provides a method of reducing risk of a failure by aiding in the planning of thorough and efficient design tests and development programs. It provides an open format for recommending and tracking risk-reducing actions. FMEA supplements and refines other reliability tasks. It provides documentation of design and process issues for the next generation of
engineering. It assures the use of a multidiscipline design and process team. Finally, if effectively used, it can reduce internal costs due to rework, reduce customer complaints and warranty costs, and lead to improve customer satisfaction.

**Drawbacks**

There are only two drawbacks to FMEA, the time and resources required in completing the analysis. Even though FMEA may take 30 minutes to 6 months to complete, (Stamatis, 1994b) the cost benefits are worth the time investment. Hatty and Owens (1995) explains the cost benefits by a ratio of money spent to money saved. A 1:100 ratio is gained if a failure is eliminated in the product design phase, a 1:10 ratio is gained if a failure is eliminated in the manufacturing process, and a 1:1 ratio is gained if the failure is detected before it leaves the manufacturing plant. Prasad (1991) provides a cost saving example of an IC package. As a result of the analysis, a higher hardness of copper alloy was used in the initial design. The design change resulted in reducing failures in the field and eliminating costly product redesign. One issue with using FMEA is the inability to identify cost benefits. It is easier to track man-hours than track cost avoidance. As a result, there is an emphasis on minimizing the amount of time required to complete the FMEA, resulting in a superficial analysis.
Applications

Early FMEA work was primarily driven by the military, NASA, and the nuclear power industry (Perkins, 1996). Arnzen (1966) stated that FMEA could be used in airline and military ground support systems, automotive vehicle design, commercial and navy vessel systems development, commercial and military communications network systems, electrical power generating and supply systems, and railroad systems. The following are published applications of FMEA.

Aerospace

In 1966, Arnzen presented a paper to the Reliability and Maintainability Conference. The paper illustrated the application of the FMEA in a longitudinal flight control system and an attitude control system for manned spacecraft. Tiernan (1993) described the quality process used at Loral Aeronutronic to move their division from contract compliance to self-directed work teams. A Process FMEA was used to help identify process controls. Littlefield (1996) illustrated the use of FMEA and CIL (Critical Item List) in the design of a new turbopump for the space shuttle. Zinkgraf (1998) described an overview of operational excellence and six-sigma at AlliedSignal. FMEA was used as an analytical technique to reduce the number of failures in the product before production.
Electronics

Prasad (1991) demonstrated improvements in manufacturing reliability for an IC package assembly by using FMEA. Craig (1993) used FMEA in DuPont Connector Systems' six-sigma quality approach. A Design FMEA was used to help define the control parameters. A Process FMEA was used to "fool proof" the process and identify major control parameters and the degree of control required. Hatty and Owens (1995) illustrated a FMEA procedure with an example of semiconductor wafer processing.

Automotive

Aldridge, Taylor, and Dale (1991) illustrated the use of a FMEA procedure at Garrett Automotive Ltd. in Lancashire, England. Duffin (1994) showed the benefits of FMEA in the comparison of two braking systems. The goal of the study was to predict the effect of reliability on vehicle safety. He used the number of failures and causes and the number of RPN over 150 to compare the two braking designs.

Commercial

Clausing (1996) developed an effective system-engineering model at Xerox which incorporated Quality Function Deployment (QFD), Design of Experiments (DOE), Signal/Noise ratio, FMEA, and Fault Tree Analysis (FTA). FMEA and FTA
were used to identify the critical functional parameters of the product for parameter design.

**Nuclear**

McBride (1985) described the use of FMEA in the ICS/NNI electric power distribution circuitry at the Oconee 1 Nuclear Plant. Maskuniitty and Pulkkinen (1995) illustrated the use of Fault Tree Analysis and FMEA in the analysis of digital safety functions for a nuclear power plant in Finland.

**Medical**

Cohen, Sender, and Davis (1994) used FMEA to identify potential human errors in a hospital setting. As part of the continuous quality improvement program, FMEA was used to analyze system failures and ways were designed to eliminate the failures or reduce the effects of the failures. Fletcher (1997) also applied FMEA to reduce the number of failures in the hospital procedures.

**Safety, Health, and Environmental Hazard Analysis**

Goyal (1993) discussed the use of FMEA as an alternative method to Process Hazard Analysis. Goyal compared FMEA to the more traditional hazard analysis tools and illustrated the use with two examples. Goetsch (1996) listed FMEA as a method for performing safety analysis. All potential failures were identified for each individual component of the system, the effect of each failure was listed, and each
potential failure was rated according to the degree of hazard posed. Vandenbrande (1998) suggested the adaptation of FMEA to the environmental management system, ISO 14001. The scoring for the severity of the failure was specifically designed to assess the environmental impact.

Issues

As mentioned earlier, there is more to the FMEA process than completing the form. Correct timing, proper level of detail, teamwork, and updating the FMEA are all factors that determine the effectiveness of FMEA. As early as 1981, Raheja documented several issues that reduced the effectiveness of FMEA. Raheja (1981) discussed the uses and misuses of FMEA as defined in MID-STD 1629A. Along with the timeliness of FMEA, teamwork, the level of detail, and updating FMEA, Raheja listed four additional factors. The factors included the cost of completing the FMEA and supporting documentation; not having a person responsible for implementing changes to the design; rationalizing failures as not having a critical effect; and not using a functional block diagram/flow chart with FMEA. Eight years later, Raheja (1989) repeated many of his earlier concerns. He noted that companies invested substantial amounts of time completing FMECA, but they failed to take corrective action and improve the product design. He pointed out the misuse of the Recommended Action(s) column. Recommended Action(s) included inspection and testing rather than recommendations to eliminate the failure by design changes. In
summary, Raheja noted that FMEA was done, but the design was not changed and potential failures were not designed out of the product.

In 1990, Dale and Shaw published the results of a survey that looked at the use of FMEA within the Ford Motor Company supplier base in the United Kingdom. The results showed that FMEA was conducted in teams and FMEA was prepared as part of the initial design and development phase. Some difficulties encountered in using FMEA included time constraints, lack of understanding of the purpose of FMEA, lack of training, and the lack of management commitment. Much of the training was conducted ad hoc and was conducted only for quality engineering, production engineering, and middle management. Only a quarter of the organization provided FMEA training for design personnel and quality of the training was rated below average.

Issues identified in 1981, and 1990 were similar. With the increased use of FMEA in the 1990s, many papers addressed some of the issues. Research has been done in the automation of FMEA, to reduce the time needed to complete one. New schemes for calculating RPN were developed to provide a better measure of importance, and FMEA were integrated into the quality system to make it more effective. The following is a review of literature in these areas.

Automation

The Department of Computer Science at the University College of Wales has published a number of papers on the automation of FMEA. Price, Hunt, and Ormsby
(1992) developed a model-based approach to automate the analysis portion of the FMEA process for electrical circuits in the automobile. The system integrated a functional modeling system with a qualitative circuit simulator. Input to the system included a system breakdown, electrical circuit definition, the input device description, and the functional description. The output from the system was the system name and function, potential failure mode, and potential effect of failure mode. Hunt, Pugh, and Price (1995) integrated the functional modeling system and the qualitative circuit simulator. The failure modes were described in terms of the structural changes to the circuit and the effects were determined at the functional level. In addition, the RPN were generated as part of the output. Pugh and Snooke (1996) generated FMEA for larger, more complex circuits, by modifying the qualitative analysis technique. Price and Neil (1998) extended the model to examine all possible combinations of failures, rather than a single failure. A pruning technique, based on the likelihood of occurrence, was used to reduce the number of feasible failure modes. Montgomery and Marko (1997) developed a system that used a quantitative rather than a qualitative simulator. The results were more accurate and useful FMEA for test and diagnostic engineers. Bluvband and Zilberberg (1998) developed a knowledge-based system that integrated FMEA component failure modes and failure causes. The system required six separate libraries: component, corrective action, end effect and severity, test methods, detectability, and current controls. The output was a completed FMEA form with Risk Priority Numbers.
Risk Priority Number

RPN is a number that ranks the importance of the Potential Causes of Failure Mode. It is calculated by multiplying the Severity, Occurrence, and Detection rankings. Severity, Occurrence, and Detection are ranked based on engineering judgement and historical data. Gilchrist (1993) developed a more rigorous approach to calculating a RPN. An expected cost model (EC) considered the cost per failure (C), the number of items produced (n), the probability of failure (prf), and the probability of detecting the failure before it reached the customer (pct).

\[ EC = Cnpfrpd \]

The expected cost (EC) was expressed in actual dollars. The number of failures expected to reach the customer was represented by npfrpd and C was the cost for each failure. There was not a maximum value for EC, since it was dependent on the number produced and the cost of the failure. The advantage of the expected cost model was it forced management to view failures in terms of actual dollars. In addition, the model could easily be extended to cover several possible costs to the customer and different costs for different failures.

Rudy and Wang (1995) suggested another approach to defining RPN. They proposed that each team developed their own ranking scale for Severity, Occurrence, and Detection rankings. The ranking scale was either a 1-10 scale or a 1-5 scale or a combination of both. Each team included the definition of each value used in the scale. The team developed an Action Threshold Value (ATV) and a Decision
Threshold Value (DTV). An ATV defined the minimum value that required corrective action. DTV was the maximum value for “no action taken at current time.” The rankings, ATV and DTV were defined prior to the start of the FMEA and were published with each FMEA.

Ben-Daya and Raouf (1996) revisited Gilchrist’s work and suggested another scheme to determine the risk of a failure. They gave the Occurrence ranking more importance since it affected the likelihood of a failure reaching a customer. Rather than using the scale 1 to 10, they suggested using 2 to the power of the ranking for the occurrence, i.e. \(2^0, 2^1, 2^2, 2^3\), etc. The RPN was equal to Occurrence, Severity, and Detection multiplied together. According to the authors, the new RPN was a better measurement tool.

Quality Improvement Programs

Several articles appeared from 1991 to 1998 that included FMEA as part of a total quality system. Gevirtz (1991) discussed the fundamentals of advanced quality planning. A quality-planning checklist was developed which included the use of Design and Process FMEA. Snee (1993) compared robust design, FMEA, and Fault Tree Analysis (FTA). He suggested using the three to prevent problems through proper design and process planning. McLinn (1994) identified Quality Function Deployment (QFD), FMEA, and Process Analysis as three important tools in new product development. QFD provided a good description of the product and specify the measurable goals. FMEA identified potential failures of the design early in the
development process and provided inputs for qualification test plans and in-process controls. Process Analysis identified the shortest, most efficient process path as well as the impact of key process steps. Nuemann (1995) described a quality information system that facilitated the use of design improvement and problem solving techniques. The model suggested the use of FMEA, Fault Tree Analysis, and Design of Experiments to analyze the design. Teng and Ho (1996) described an integrated approach for product design and process control. Their model showed that the Design FMEA received input from the customer requirements and provided output to receiving inspection, fault tree analysis, reliability prediction, and a Design Verification check list. The input to the Process FMEA was the process flow diagram and the Process FMEA provided information to FMECA, production process verification check list, visual aids for inspection, and control plans. Somerton and Mlinar (1996) identified QFD, FMEA, and Interrelationship Digraph (ID) as tools for prioritization of key characteristics that were important to the customer. QFD was used to identify the most important customer requirements. Interrelationship Digraph was used to determine the interrelationship and interdependencies of the key characteristics. FMEA was used to analyze process parameters.

**Mandated Use of FMEA**

As the result of ISO-9000, smaller organizations were required to use FMEA. QS-9000 drove first and second tier automotive suppliers to use FMEA. In some cases, FMEA was done to complete the supplier requirements. FMEA was not viewed
as an analytical method to identify and eliminate failures, rather it was viewed as a paper work exercise. As a result of mandating the use of FMEA, it was too easy to simply complete the task without taking full advantage of the analysis and realizing the benefits of the planning portion.

Conclusion

FMEA has been used for more than 40 years, but there are still issues surrounding its effectiveness. For instance, mandating the use of FMEA only focused on the completion of the form and did not assure that the process of completing the FMEA was useful. Dale and Shaw (1990) pointed out the difficulties companies encounter when using FMEA. The lack of understanding of the purpose of FMEA and the lack of management commitment contributed to the improper use of the FMEA. Confusion in the definitions of various columns added to the misapplication. The requirement for a component level FMEA that contributed to the amount of time spent completing the FMEA.

This paper describes the process used to implement FMEA on a new product. To begin the process, the scope of the FMEA and the level of detail of the FMEA were defined. Since FMEA was used with Quality Function Deployment (QFD), the scope of the FMEA was restricted to the functionality of the product over time. QFD was used to track the development and the correctness of the product specification. The level of the FMEA was limited to the subassembly level rather than the
component level. The subassembly level allowed for the identification of component design weakness and led nicely to Designs of Experiment.

The FMEA was completed for each subassembly team during separate meetings. The Function, Potential Failure Mode, Potential Effect of Failure, Potential Causes of Failure and RPN was part of the analysis of the subassembly. The analytical portion of the FMEA was facilitated by one of two facilitators. The facilitators worked together to keep the column definitions consistent between the FMEAs.

After the analytical part of the FMEA was completed, each engineer worked with their manager to determine the required Recommended Action(s) and Target Dates & Responsibility. The FMEA form was updated by the engineer and reviewed periodically with their manager. After the target date, the Action Taken was documented and a new RPN was calculated. The FMEA was updated to reflect the effect of Action Taken and the results of testing as specified in the Current Design Control. Additional work was planned based on the revised RPN. The facilitators worked with the managers to help them use the FMEA as a planning tool.

The subsystem FMEA served as the input to both supplier and Process FMEA. Product engineering was encouraged to work with suppliers to define failure modes and effects for each major component, then the suppliers were asked to define the causes of failure and use the FMEA as a planning tool to reduce the Potential Cause of Failure Mode with high RPN. In addition, product engineering worked with
manufacturing on the development of Process FMEA to insure the maintenance of design intent in manufacturing.

This paper described the use of FMEA for the design of assembly and manufacturing equipment. The purpose, the advantages, and the columns for the equipment FMEA were defined and discussed. A fourth type of FMEA was introduced: Maintenance FMEA. The purpose, the advantages, and the columns for the Maintenance FMEA were defined and discussed.
CHAPTER III

CASE STUDY

The study was conducted at a Fortune 500 firm in the mid-west. The firm started using FMEA in 1974 as a method to control manufacturing defects in the product. The purpose was to establish a procedure for highlighting potential safety hazards and field problems in a design during the manufacturing process and establish adequate precautionary measures. The FMEA provided a disciplined approach to identify failure modes, effects, controls, and risks for components or assemblies. It provided an opportunity for the individuals involved in the design and production of the component to discuss and agree on the criticality of the failure modes identified. The FMEA documented the individuals responsible for the necessary controls and it served as documentation for the various failure modes and effects.

In 1976, a corporate FMEA procedure was issued for the manufacturing and engineering functions. The procedure stated that FMEA would be used for new designs or components with critical or major failure modes, and current projects that did not meet the in-warranty failure rate goals. FMEA was initiated by design engineering as early in the design process as possible. The assessment team consisted of design engineering, manufacturing engineering, quality control, and customer assurance. Copies of the FMEA were stored with design engineering and
subsystem interactions diagrams were intended to serve as input for the FMEA procedure.

Figure 1. Subsystem Interactions.

The nine subsystems were further divided into subassemblies. A block diagram was developed to show the inputs and outputs of each subsystem and many of the subassemblies. The diagrams were used to illustrate the functional relationships between subsystems, subassemblies, and components. Figure 2 shows a block
diagram for a cabinet subassembly. The cabinet served as a support for the top, bottom, and suspension. In addition, the cabinet relied on the rear leveling system, front feet, and rear feet for support. Based on subsystem interactions, block diagrams, service reports, and the application of new technologies, 37 subassemblies were identified for the Design FMEA process. For example, the "structure" subsystem was broken down into six subassemblies, including the cabinet. An FMEA was required for a subassembly if new technology was involved in the subassembly, past field failure data showed high failure rates for the subassembly, or the subassembly was a new design.

Figure 2. Sample Block Diagram.
A numbering scheme was developed to identify FMEA with the appropriate subassembly. The lead engineer of each subassembly was responsible for the development and completion of the FMEA. FMEA were required at each of the design reviews.

**FMEA Scope**

Quality Function Deployment (QFD) was used extensively on the project. QFD is a methodology to translate customer requirements into design requirements for products and services. The methodology was extended to the design of systems, parts, processes, and control mechanisms. Figure 3 shows the iterative method of translating the customer requirements into product design, process design and operations planning.

![Figure 3. QFD Process.](image-url)
As the result of marketing surveys and customer input, seven critical consumer requirements were identified in House I. Critical product performance specifications were identified for each of the seven critical consumer requirements. Houses II and IIb related the performance requirements to subsystem and part characteristics. House II defined subsystem specifications for the performance requirements based on qualitative and quantitative methods. House IIb defined part characteristics for the critical subsystem requirements through engineering experience, design of experiments, Finite Element Analysis (FEA), tolerance stack-ups, and simulation. Figure 4 shows the deployment of the performance requirements through each subassembly, resulting in part characteristics. The optimal values for each part characteristic was established based on product performance requirements.

<table>
<thead>
<tr>
<th>House 2</th>
<th>Subsystem 1</th>
<th>Subsystem 2</th>
<th>......</th>
<th>Subsystem n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y's</td>
<td>X's</td>
<td>X1</td>
<td>X2</td>
<td>X3</td>
</tr>
<tr>
<td>&quot;CLEAN&quot;</td>
<td>Y1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Y2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Y3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&quot;QUIET&quot;</td>
<td>Y4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Y5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Y6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Part characteristics or subsystem performances

Figure 4. House IIb QFD.

QFD focused on the subsystems and part characteristics that impacted product performance, assuming proper functionality. For example: a critical performance
parameter was sound level. QFD addressed the specification for the sound level through experimentation (DOE). The "correctness" of specifications was tracked through the QFD process.

QFD did not address part characteristics that impacted product functionality. Functionality was defined as any potential part failure that would affect the critical consumer requirement. FMEA addressed the part characteristics that would change over time and resulted in functional failures or a degradation of the critical performance requirements. FMEA assumed that the initial material and performance specifications were correct. For example, a correct failure mode was "sound level too high", and an incorrect failure mode was "improper sound level specified." The subsystems were consistent between the FMEA and the QFD.

Consumer safety issues were handled through a Safety Issues Procedure. The procedure was established by the Corporate Safety Department to address the resolution and documentation of consumer safety issues. The Design FMEA was used as a key source of input to the safety issues, along with consumer usage surveys, field tests, and lab tests.

Level of Detail

There is often confusion between a potential failure mode, potential effect of the failure mode, and the potential cause(s) of the failure mode. Table 6 shows a list of potential failure modes, a list of potential effects of failure mode, and a list of
potential causes of failure. Lists like these are commonly used in training manuals. However, the lists can be misleading. As seen in Table 6, the same word, “deforms,” appears as a potential failure mode, potential effect(s) of failure mode, and a potential cause of a failure. To determine if “deforms” is a Failure Mode, a Potential Effect of Failure Mode, or a Potential Cause of Failure depends on the level of the FMEA. A Design FMEA can be done at the system, subsystem, and component level.

Table 6
Common Potential Failure Modes, Effects, And Causes

<table>
<thead>
<tr>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure Mode</th>
<th>Potential Cause(s) of Failures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short/open</td>
<td>Loss of function</td>
<td>Corrosion</td>
</tr>
<tr>
<td>Broken/severed wire</td>
<td>Emits odor</td>
<td>Insufficient strength</td>
</tr>
<tr>
<td>Excess wear</td>
<td>Poor appearance</td>
<td>Cold solder joints</td>
</tr>
<tr>
<td>Terminal clip not fully engaged</td>
<td>Excess force required</td>
<td>Excess force</td>
</tr>
<tr>
<td>Fracture</td>
<td>Noisy</td>
<td>Binds</td>
</tr>
<tr>
<td>Jammed</td>
<td>No output</td>
<td>Leaks</td>
</tr>
<tr>
<td>Short to ground</td>
<td>Loss of fluid</td>
<td>Deforms</td>
</tr>
<tr>
<td>Binds</td>
<td>Deforms</td>
<td>Broken wires</td>
</tr>
<tr>
<td><strong>Deforms</strong></td>
<td>Water spills to floor</td>
<td>Environmental extreme</td>
</tr>
</tbody>
</table>
"Deforms" is a Potential Effect of Failure for a component level FMEA, a Potential Failure Mode for a subsystem FMEA, and a Potential Cause(s) of Failure for a system FMEA. Figure 5 illustrates how "Deforms" is a Potential Failure Mode, a Potential Effect of Failure, or a Potential Cause(s) of Failure, depending on the level of the FMEA. As a result, to help reduce the confusion between the three columns, the level of the FMEA should be determined before the development of any FMEA.

For the case study, the level of analysis needed to be specified. As defined by Stamatis (1994b), the purpose of a system FMEA is to determine the preliminary

<table>
<thead>
<tr>
<th>'System' FMEA: Washing Machine (Function: Good sound performance)</th>
<th>Potential Failure Mode</th>
<th>Potential Effect of Failure Mode</th>
<th>Potential Cause(s). (mechanism of Failure)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit too Loud</td>
<td>Consumer dissatisfied</td>
<td>Damping Material Deforms</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>'Subsystem' FMEA: Damping Material (Function: Deadens Sound)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Damping Material Deforms</td>
<td>Unit too Loud</td>
<td>Material not designed to hold shape over time</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>'Component' FMEA: Side Damping (Function: Hold Shape)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Material slides down surface</td>
<td>Damping Material Deforms</td>
<td>Improper material specification</td>
</tr>
</tbody>
</table>

Figure 5. Relationship Between FMEA Levels and Definitions.
design and functional specifications. Since the design concept was established and the subsystems were determined, functional diagrams were developed; a System FMEA was not conducted.

Most of the literature recommends the use of component FMEA. However, as seen in Figure 6, a component FMEA leads to part characteristics for Potential Cause(s) of Failure. Since QFD House IIb already addressed part characteristics, it was not necessary for the FMEA to address them again. In addition, component level FMEA addressed improvements to the specific part characteristic, leading to the potential of sub-optimization of the subsystem.

Potential Causes of Failure for a subsystem FMEA addressed the failure modes of the parts or components, leading to the identification of design weaknesses of the part. A subsystem FMEA resulted in improvement of failure modes for a part or component. The component was optimized or improved to eliminate the failure
mode or reduce the severity of the effect. A subsystem FMEA tended to result in a
design of experiments to identify the critical part characteristic(s) that produced a
failure of the part. Finally, the subsystem FMEA was shorter and less time
consuming. Therefore, subassembly FMEAs were done for the project.

Form Used

The FMEA form was updated for the project. Figure 7 shows the old form
used for past projects. The old form did not have a place for Recommended Action(s)
or an area for the revised Risk Priority Number (RPN). The form was revised to
include Recommended Action(s), Responsibility & Target Completion Data, Action

<table>
<thead>
<tr>
<th>Component/ System</th>
<th>Failure Mode</th>
<th>Effects of Failure</th>
<th>Cause of Failure</th>
<th>Occ</th>
<th>Verification</th>
<th>Det</th>
<th>RPN</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Figure 7. Old FMEA Form.

Taken, and Revised RPN. By adding the columns, the FMEA became as a planning
tool for improvement activities. Figure 8 shows the form that was used for the project.
The template was developed in Microsoft Word and could be transported corporate wide through the electronic mail system. The updated form was very similar to the Ford software, FMEAPLUS for Windows. The FMEAPLUS was also available for the project. The Ford software offered many features such as the automatically calculating the RPN and sorting on various ranking numbers. Engineers were allowed to use either the updated form in Microsoft Word or FMEAPLUS.

![Figure 8. New FMEA Template.](image)

Column Definitions

Engineers tended to link the Potential Cause(s) of Failure with the Potential Effects of Failure, rather than the Potential Failure Mode. Figure 9 was used to illustrate the relationship between the columns of the FMEA form. FMEA focused on the Potential Failure Mode resulting in the Potential Effect(s) of Failure and Potential Cause(s) of Failure resulting in the Failure Mode. In addition, the model illustrates the relationship between the different columns and the rankings. It shows that
the relationship between the different columns and the rankings. It shows that Severity is associated with the Potential Effect of Failure, Occurrence is related to the Potential Cause(s) of Failure, and Detection is related to the detection of the Potential Cause(s) of Failure by the Current Design Control. Facilitators referred to the model during the brainstorming session, as the form was being completed.

Figure 9. Column Relationships.

The Function was a statement about the design intent of the subsystem under investigation. The Function was the actual function of the subassembly and all interactions between the subassembly and other mating subassemblies. The Function included any support functions of the subsystem. The documentation used in the development of the list of functions included interaction diagrams, block diagrams, QFD requirements, and consumer usage reports. For example, the cabinet had two functions (1) protect the components from contamination, and (2) serve as a noise barrier. In addition, the cabinet had two supporting functions (1) serve as a mounting
base for the top, and (2) serve as an attachment mechanism for the suspension subsystem.

The Potential Failure Mode defined the manner in which a subsystem could potentially fail to meet the design intent specified by the Function. The Function served as an input to the Potential Failure Mode, as shown in Figure 9. When defining the Potential Failure Mode, engineers listed all the ways that the subassembly could fail to meet the intended function. Figure 10 shows a number of Potential Failure Modes for the Function “serve as a barrier for sound.” There could be more than one Potential Failure Mode per Function. If the functions of the subassembly were clearly defined and exhaustive, then the list of Potential Failure Modes was more complete.

The Potential Effect of Failures was the result of the occurrence of the failure mode. The Potential Effect of Failures was considered for each Potential Failure Mode. In most literature, the Potential Effect of Failures is defined as the effect of the failure on the consumer. However, since FMEA was done at the subassembly level, the Potential Effect of Failures described the effect of the failure mode on the system. Figure 10 shows the Potential Effect of Failures for each Potential Failure Mode. For some Potential Failure Modes, there was more than one Potential Effect of Failure. All Potential Effects of Failures were listed and the most severe effect was considered when ranking the severity.
<table>
<thead>
<tr>
<th>Component System</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Failure Effects of Failure</th>
<th>Potential Cause(s) / Mechanism(s) of Failure</th>
<th>Current Design Controls</th>
<th>Recommended Action(s)</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cabinet</td>
<td>Pliable the components from contamination</td>
<td>Damaged grille into the cabinet from bottom</td>
<td>Damaged grille results in poor performance</td>
<td>8 Gap develops between cabinet and bottom</td>
<td>Tolerance stack-ups, Life test, shear test</td>
<td>None at this time</td>
<td>J. Doe J. Smith Critical dimensions were identified in the DOE and the design was</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sound comes out around the top and cabinet</td>
<td>Sound is too loud for the consumer</td>
<td>5 The top and cabinet begin to rub and start to rattling</td>
<td>Life test, FEA</td>
<td>3 30</td>
<td>2/15/2000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sound barrier material becomes brittle and failures to absorb sound</td>
<td>Sound is too loud for the consumer</td>
<td>5 The material may be too heavy, the adhesive may lose strength</td>
<td>Life test</td>
<td>5 200</td>
<td>J. Doe J. Smith</td>
<td>Test to determine the critical factors of the damping material</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Damping material too dense</td>
<td>Excessive wear of the sound barrier</td>
<td>4 The gap between the top and cabinet increases</td>
<td>Tolerance stack-ups, Life test</td>
<td>None at this time</td>
<td>J. Doe J. Smith</td>
<td>Put samples on accelerated test and measure the critical dimensions at 100, 300, 500, 700, 1000, 1500, 2000, and 3000 cycles of life. Use information to develop model for dimension drift.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sound is transmitted through the sides</td>
<td>Sound is too loud for the consumer, Consumer uses the set vibrating, may call for service</td>
<td>7 Sound barrier material becomes brittle and failures to absorb sound</td>
<td>Material testing, Test spec CD3AX, Life test</td>
<td>None at this time</td>
<td>J. Doe J. Jones FEA model showed that the grill would not increase enough to result in significantly higher sound levels</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sound is transmitted through the cabinet to the back panel</td>
<td>Sound is too loud for the consumer, Wear on hoses and water values</td>
<td>9 Fracture between back panel and cabinet loosen over time</td>
<td>Life test, Shaker test</td>
<td>None at this time</td>
<td>J. Doe J. Jones</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sound is transmitted through the cabinet to the bottom panel</td>
<td>Sound is too loud for the consumer</td>
<td>5 Sound barrier material becomes brittle and failures to absorb sound</td>
<td>Material testing, Test spec CD3AX, Life test</td>
<td>None at this time</td>
<td>J. Doe J. Jones</td>
<td></td>
</tr>
</tbody>
</table>

Figure 10. Example of Design FMEA.
Severity was a subjective measure of the seriousness of the Potential Effect of Failure of a Potential Failure Mode. Table 7 provided a guideline for Severity. For

Table 7
Severity Evaluation Criteria

<table>
<thead>
<tr>
<th>Rank</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Minor</td>
<td>It is unreasonable to expect that the minor nature of this failure would cause any real effect on the product performance. The customer will not notice the failure.</td>
</tr>
<tr>
<td>2, 3</td>
<td>Low</td>
<td>The nature of the failure causes only slight customer annoyance. The customers will notice a slight deterioration in performance.</td>
</tr>
<tr>
<td>4, 5, 6</td>
<td>Moderate</td>
<td>The failure causes some customer dissatisfaction. The customer is made uncomfortable or is annoyed by the failure. The customer will notice some performance deterioration.</td>
</tr>
<tr>
<td>7, 8</td>
<td>High</td>
<td>There is a high degree of customer dissatisfaction due to the nature of the failure, such as an inoperable product or subsystem. The failure does not involve safety or non-compliance with government regulations.</td>
</tr>
<tr>
<td>9, 10</td>
<td>Very High</td>
<td>The potential failure mode affects safety and/or non-conformance with government regulations.</td>
</tr>
</tbody>
</table>

instances, if damage occurred, injury occurred, or there was a failure to meet government regulations, then a 9 or 10 was assigned. If the machine stopped operating or a major service call was needed, a 7 or 8 was assigned. If the failure caused some customer dissatisfaction, performance deterioration, or a minor service call, then a 4, 5, or 6 was assigned. Figure 10 illustrates the difference in the Severity ranking based on the critical effect.
call, then a 4, 5, or 6 was assigned. Figure 10 illustrates the difference in the Severity ranking based on the critical effect.

The Potential Cause(s)/Mechanism of Failure was defined as a design weakness, resulting in the Failure Mode. The Potential Cause(s)/Mechanism of Failure focused on time related causes, such as wear, deterioration, design life too short, breakdown of lubricants, or loss of a specific property. For the Design FMEA, two assumptions were made, (1) the product was manufactured and assembled correctly, and (2) the mating subassemblies functioned properly. Figure 10 shows the use of the Potential Cause(s) of Failure. Some examples of Potential Cause(s) of Failure that were not considered included “assembled incorrectly”, “wrong material specified for the sound barrier”, “gap between the top and the cabinet too big”, and “barrier assembled incorrectly.” These failures were tracked through QFD. Even though assembly defects were not considered, changes to reduce misassembly or to ease assembly were noted at the end of the FMEA.

The Occurrence ranking was a subjective rating of the likelihood that the design would result in the failure mode produced by the Potential Cause(s) of Failure (the probability that the cause happened and it then led to the failure mode). Table 8 shows the scale used to specify the Occurrence ranking. In some cases, Parts Per Million (PPM) was used to predict the likelihood of the cause leading to the potential failure mode. For example, the number of machines that demonstrated the wear of the sound barrier material had a PPM between 1 and 50. In general, the engineers were more comfortable rating the Occurrence as “remote, low, moderate, high, and very
Table 8
Occurrence Evaluation Criteria

<table>
<thead>
<tr>
<th>Rank</th>
<th>Design Life Possible Failure Rate</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&lt; 1 PPM</td>
<td>Remote</td>
<td>Failure is unlikely</td>
</tr>
<tr>
<td>2</td>
<td>1-50 PPM</td>
<td>Low</td>
<td>Relatively few failures</td>
</tr>
<tr>
<td>3</td>
<td>50-250 PPM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>250 PPM - .1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>.1% - .25%</td>
<td>Moderate</td>
<td>Occasional failures</td>
</tr>
<tr>
<td>6</td>
<td>.25% - 1.25%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>1.25% - 2.50%</td>
<td>High</td>
<td>Repeated failures</td>
</tr>
<tr>
<td>8</td>
<td>2.50% - 5.00%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>5.00% - 12.5%</td>
<td>Very High</td>
<td>Failure is almost certain</td>
</tr>
<tr>
<td>10</td>
<td>12.5% or more</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

high.” The Occurrence ranking expressed the amount of confidence the engineer had in the design. Historical data from the field and lab were used to better estimate Occurrence ranking. Figure 10 shows the Occurrence ranking of the Potential Cause(s) of Failure. An Occurrence ranking was assigned to each Potential Cause(s) of Failure.
Current Design Control was a design validation, or verification test conducted to determine if the Potential Failure Mode or the Potential Cause(s) of Failure existed. It could be a pass or fail type of test, a performance test, or Finite Element Analysis (FEA), but the emphasis was on current testing and analysis of the design. Current Design Control addressed either the Potential Failure Mode or the Potential Cause(s) of Failure. There may be more than one Current Design Control for a Potential Cause(s) of Failure but every Potential Cause(s) of Failure had at least one Current Design Control. Figure 10 shows a number of Current Design Controls for each of the Potential Cause(s) of Failure. The Current Design Control served as input to the test.

The Detection ranking was used differently than specified in MIL-STD 1629A. In MIL-STD 1629A, Detection ranked the ability of the user to detect the failure before the failure occurs. For the project, the objective of Detection ranking was to assess the ability of the Current Design Control to detect the Potential Cause(s) of Failure prior to the release of the product for production. The Detection ranking used an inverse scale, very high detection was 1 and very low detection was 10. Table 9 shows the ranking scheme used. If the Current Design Control detected the failure or cause in prototype designs, then the Detection ranking is a 1 or 2. If the Current Design Control could not detect the failure or cause before the product was in the field, then the Detection ranking is a 9 or 10. Figure 10 shows Detection ranking for each of the Current Design Controls. In the case of multiple design controls, detection was based on the complete set of controls.
The RPN was a subjective ranking based on the product of Severity, Occurrence, and Detection rankings. RPN was considered a ranking rather than an absolute number. It was used to rank the Potential Failure Mode and Potential Cause(s) of Failure combinations within an FMEA. Figure 10 shows an example of the RPN. Higher Risk Priority Numbers indicated the need for further action. For the project, the highest 10-15% of the RPNs were considered important, as were issues with high Severity and Occurrence rankings. RPN were compared within a FMEA but not between different FMEA because of the subjective nature of the values. Once the RPN was calculated, the analysis portion of the FMEA was completed.

Table 9
Detection Evaluation Criteria

<table>
<thead>
<tr>
<th>Rank</th>
<th>Name</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>1, 2</td>
<td>Very High</td>
<td>The failure will be detected prior to releasing for production.</td>
</tr>
<tr>
<td>3, 4</td>
<td>High</td>
<td>The failure is very likely can be detected prior to final release. It will be detectable after release but before mass production.</td>
</tr>
<tr>
<td>5, 6</td>
<td>Moderate</td>
<td>The failure may be detect prior to final release. It will be detected prior to shipment of the finished product.</td>
</tr>
<tr>
<td>7, 8</td>
<td>Low</td>
<td>The control may not detect a potential design problem, however, the failure mode will be detected prior to occurring in the field.</td>
</tr>
<tr>
<td>9, 10</td>
<td>Very Low</td>
<td>The failure is undetectable until failure occurs in the field.</td>
</tr>
</tbody>
</table>
Recommended Action(s) started the planning portion of the FMEA. It was
defined as a proactive design activity intended to investigate back-up solutions in case
the Potential Cause(s) of Failure actually occurred during the Current Design Control.
For example, Recommended Action(s) included investigating different types of
grease, running a material lab evaluation, or conducting a DOE to determine critical
design parameters. The Recommended Action(s) was not a design change, design
changes were documented in Action Taken. Recommended Action(s) were not
current tests, Current Design Controls documented testing that was currently being
done. Recommended Action(s) produced additional research into identifying the
design weakness. Figure 10 illustrates the use of Recommended Action(s) for the
Potential Cause(s) of Failure with high RPN.

Responsibility documented the person(s) responsible for completing the
Recommended Action(s). It included the engineer responsible for the subassembly,
and other test, manufacturing, and lab personal. Target Completion Date specified the
completion of the recommended action. Responsibility & Target Completion Date
was the way to assign responsibility and a completion date for actions taken to
improve the RPN. For the project, Responsibility & Target Completion Dates were
reviewed with each manager as a way to plan for required resources and establish
priority for engineers dealing with more than one subassembly.

As the result of the Recommended Action(s), or further testing of the design,
design changes were made to the subassembly that reduced the chance of failure or
improved the detection of the failure. Action Taken documented the design change or
the new Current Design Control. Figure 10 illustrates the documentation of the design changes. Reducing the occurrence of the Potential Cause(s) of Failure, reducing the severity of the failure, or improving the detection of the Potential Cause(s) of Failure during testing reduced the RPN.

![Diagram of Revised RPN]

Figure 11. Revised RPN.

As shown in Figure 11, the Revised RPN reflected changes in the Occurrence, Severity, or the Detection ranking. A change to the design resulted in a decrease in either the Severity or the Occurrence ranking. For example, the Severity was reduced if a circuit was redesigned to fail open rather than fail closed, thus reducing the risk of electrical shock. The Occurrence ranking was reduced if a subassembly was redesigned with a heavier gauge steal, thus reducing the chance of the Potential Cause(s) of Failure. The Detection ranking was improved if a new test was developed
to improve the detection of the Potential Cause(s) of Failure. However, emphasis was placed on the improvement of the design rather than the improvement of the test procedures. The RPN was also reduced or increased as the result of completing testing documented in the Current Design Controls. If the testing did not result in the potential failures, the Occurrence ranking was reduced. If the testing resulted in failures, the Occurrence ranking was increased. Once the RPN was revised, they were prioritized again for further Recommended Action(s).

Design FMEA Process

Analytical Portion

Two engineers with working knowledge of FMEA and the product served as FMEA facilitators for the project. The facilitators had two goals, (1) maintain consistency between the 37 subassembly FMEA, and (2) use the FMEA for planning reliability focused design activities. Before starting, the facilitators worked together to define each column, the process used to construct FMEA, and the process used to plan additional design activities. The facilitators divided the responsibilities of the FMEA between themselves based on product knowledge.

For each FMEA, the facilitators arranged for the FMEA meeting, established the agenda, led the FMEA session, and served as a scribe during the session. In addition, the facilitators worked to coordinate issues between the various
subassemblies. The subassembly engineer was responsible for setting the meeting date, determining the attendance, and providing the subassembly information.

The initial FMEA session was conducted in teams of 6-10 people. The team consisted of the engineer responsible for the subassembly, product engineers of mating subsystems, manufacturing engineering, process engineering, quality engineer, designer, suppliers, and a test engineer. The FMEA session lasted between 2-4 hours, with three hours working the best. Through experience, it was found that two hours was too short because not enough information was completed by the end of two hours, and four hours was too long because the team got very tired. During the session, the information generated was recorded directly onto the form. The form was projected by computer onto the screen and was visible to all the team members. The goal for each session was to complete the Function, Potential Failure Mode, Potential Effects of Failure, and Potential Cause(s) of Failure. For several subassemblies, more than one session was required.

At the beginning of the session, the engineer reviewed the subassembly requirements, the block diagram, and any available hardware with the group. They answered any questions from the team. The facilitator reviewed the FMEA form, the definition of each column and provided a handout with the definitions for the team. The assumptions for a Design FMEA were reviewed. During the initial session(s), Severity, Occurrence, and Detection rankings were not discussed.

After the initial analysis was conducted, the lead engineer met with the facilitator to complete the analytical portion of the FMEA. The session lasted
between 1 to 3 hours. During the meeting the Current Design Controls were specified for each Potential Cause(s) of Failure. The Severity of the effect was assessed, based on the scale shown in Table 7. The Occurrence of the Potential Cause(s) of Failure leading to the failure was estimated based on the scale shown in Table 8. The Detection ranking for the Current Design Control was assessed based on the scale shown in Table 9. The Risk Priority Number was calculated and the Potential Cause(s) of Failure with the highest RPN were discussed with the engineer. The engineer was instructed to review the RPN with their manager and develop Recommended Action(s) for the top 10-15% high ranking RPN. Finally, the Current Design Controls specified in the FMEA served as input to the test plan developed by each engineer. All the work done during this session was recorded on the FMEA form as the information was generated.

Planning Portion

In the past, the analytical portion of the FMEA was completed and the FMEA was filed away. The box on the Design Review form was checked for the completion of the FMEA. Since one of the goals of the FMEA was to use it to plan further design activity, the FMEA needed to be a visible, working document. Therefore, a series of meetings were held to discuss the use of the FMEA with the managers.

At a staff meeting, the facilitators prepared a 45-minute presentation to review the FMEA form and the definition for each column. The facilitators discussed the use
of the Current Design Controls in the development of the test plans. Emphasis was placed on the discussion of the Recommended Action(s).

Once the form was reviewed, the FMEA process was reviewed with the managers. Figure 12 illustrates the process. The managers were asked to review the FMEA with the engineer responsible for the subassembly. For each issue with a high RPN, the manager and engineer developed a Recommended Action(s) to address the

![Diagram of FMEA Planning Process]

Figure 12. FMEA Planning Process.
issue. The engineer documented the Recommended Action(s), the person responsible, and a target date in the FMEA. Figure 12 emphasizes the passage of time between the Recommended Action(s) and the completion of the Action Taken. Based on the results of the Current Design Controls, the Recommended Action(s), and the Action Taken, the RPN was updated and the planning process repeated. The time between iterations was based on the time between prototype builds. There were four prototypes, so the FMEA should have been updated four times.

After the initial meeting with the managers, the facilitators met with each manager and engineer to discuss specific FMEA. The iterative FMEA process was explained to both the manager and engineer. The goal of the meetings was to encourage the managers and engineers to work together to develop a clear and practical understanding of Recommended Action(s), Responsibility & Target Completion Date and Action Taken. At the end of the thirty-minute meeting, the facilitators recommended a two-hour meeting between the manager and engineer to complete the Recommended Action(s) and Responsibility & Target Completion Date.

Updating FMEA

For the FMEA to be a "living document," it needs to be updated throughout the project. The literature states that the FMEA is a "living document," but it does not state "how" to make it so. The document needs to be updated as new insights are gained from the development work and lab testing. Some of the reasons for updating the FMEA include supporting the prioritization of reliability issues, brainstorming
new Potential Cause(s) of Failure, continued planning for next steps, creating a communication document, and creating a reference document for the future use.

The case study identified four different types of updates. The first FMEA update was the result of the completions of the Recommended Action(s). Figure 10 Letter A reflects the update made to the Action Taken column and the revision of the RPN as the result of the Action Taken.

The FMEA was updated to reflect new types of failure modes that occurred as the result of the Current Design Control. Figure 10 Letter B shows the addition of a new Potential Failure Mode for the subassembly. The Potential Effects of Failure, Potential Cause(s) of Failure, Severity, Occurrence, Current Design Control, and Detection were completed for the new failure mode. An RPN was calculated and, based on the RPN, a Recommended Action(s) and Responsibility & Completion Date were assigned.

In addition to the discovery of new failure modes during the completion of the Current Design Control, the Current Design Control could demonstrate an increase or decrease in the occurrence of the Potential Cause(s) of Failure. The Revised RPN needed to reflect the results of the testing. Figure 10 Letter C shows a change in the Occurrence ranking in the Revised RPN to reflect the results of the testing. The Occurrence ranking was updated for all Potential Cause(s) of Failure if the test results showed a change in the occurrence of the Potential Cause(s) of Failure.

Finally, an update occurred when the Action Taken for one Potential Cause(s) of Failure introduced a Potential Cause(s) of Failure or a Failure Mode for another
function. Figure 10 Letter D shows a new Potential Cause(s) of Failure was identified, overheating, as the result of the new damping material. The updated FMEA reflecting the change in the design was reviewed by the manager and the engineer before the development of the test plans for the next prototype build.

Supplied Parts

Twelve major components were purchased. The components included the motor, bearings, pump, and electronics. For the purchase of major components, procurement quality required a Design FMEA and a Process FMEA from the supplier. From past experience, supplier Design FMEA tended to be lengthy and had too much detail to be useful. To make the supplier Design FMEA useful, the facilitators suggested working with the engineer and the supplier to develop the FMEA. The Function, Potential Failure Mode, Potential Effects of Failure, Severity, and Occurrence ranking for the failure mode were discussed as a team. The team included the design engineer, manufacturing, quality control, and the supplier. After completing the Function, Potential Failure Modes, Effects of Failure Mode, and Potential Cause(s) of Failure, the supplier completed the Current Design Control, Detection, and RPN. The engineer and the supplier reviewed the FMEA and agreed on the Recommended Action(s). This process allowed agreement between design engineers and component suppliers on critical issues and needed actions.

An example of the process is illustrated using a motor. Product engineering defines the motor specification, which included peak torque, efficiency, torque,
geometry, etc. The Failure Mode of the motor stated "how" the motor could potentially fail to fulfill the functions. The group discussed the Occurrence ranking for the failure mode based on field failures, lab testing, changes to the design, and new stresses on the motor. The Potential Effect of the Failure Mode included local effect on the functionality of the product and end effect on the level of the performance. The Severity ranking was discussed with the group. The Potential Cause(s) of Failure, Current Design Control, Detection, and RPN was completed by the motor supplier and reviewed with the group. Then, the group developed the Recommendation Action(s).

**Process FMEA**

The product was manufactured at a plant currently in operation. Several component assembly lines were used with little or no modification. However, three new lines were added and the final assembly line was redesigned.

The manufacturing division developed a Process FMEA procedure for the new product. The purpose of the Process FMEA was to review and analyze new processes during the planning phase and to anticipate and resolve potential process issues. The director or manufacturing manager assigned the process project to a manufacturing or process engineer. The manager and the engineer determined if a Process FMEA was needed. If a Process FMEA was required, the engineer led the development of the FMEA. The engineer included other manufacturing or process engineers, quality engineers, design engineers, and facilitators as needed. The
manager made sure the engineer had the required resources for the completion of the FMEA.

A process flow chart was developed identifying each process function, the product characteristics produced at each operation of the process, and the significant process characteristics to be controlled. The process flow chart was used as input for the Process FMEA. Figure 13 shows the form that was used for the Process FMEA.

<table>
<thead>
<tr>
<th>Operation</th>
<th>Function</th>
<th>Failure Mode</th>
<th>Effects of Failure</th>
<th>Sev</th>
<th>Cause of Failure</th>
<th>Occ</th>
<th>Controls</th>
<th>Det</th>
<th>RPN</th>
<th>Corrective Action</th>
</tr>
</thead>
</table>

Figure 13. Process FMEA.

Operation specified the name of the process or operation. Function provided a description of the process operation. Failure Mode provided a list of each potential failure mode for the operation. Failure Mode was defined as the way that the part or assembly could fail to conform to specifications, process requirements, or customer requirements. Effects of Failure described the results of the failure mode identified. Severity assessed the seriousness of the effect of the failure mode to the customer, either internal or external. Cause of Failure identified all potential causes for each failure mode. Causes of Failure were process variables that resulted in the failure mode. Occurrence assessed the frequency of the failure mode as the result of the
cause. Controls were the current process control in place to prevent the failure from occurring or to detect the failure mode. Controls included process controls such as inspection/testing and SPC. Detection assessed the probability that the process controls detected the failure mode before the product left the manufacturing location. The RPN was the product of Severity, Occurrence, and Detection. It was used to prioritize process improvement activities. Recommended Improvement Actions were either design or process changes that reduced the RPN. All Process FMEA developed for the product were retained for the life of the process.
In recent years, work has been done to adapt FMEA to the design and maintenance of capital intensive industrial machinery (Lamberson and Faricy, 1995 and Sroka and Givens, 1996). Samatis suggests the use of Service FMEA in the assessment of maintenance service. Sroka and Givens (1996) recommend the use of Maintenance FMEA to evaluate equipment, machinery, and tooling during the design phase to improve operator safety and the reliability of the machinery. Manufacturing organizations are interested in the availability of the machinery, not just the reliability of it. The availability of the machinery is not only dependent on the reliability of the machinery, but also the maintainability of the machinery. Figure 14, developed by Lamberson (1996), illustrates the need to consider both reliability and maintainability for product availability. Maintainability consists of the serviceability of the equipment, the availability of the spare parts, and the policies surrounding maintenance. The machinery is available if the reliability is high and maintenance time is low. A Machinery and Equipment FMEA process was developed to consider both inherent reliability and maintainability of the equipment.

This paper recommends the use of two types of FMEA for capital intensive equipment, a traditional Design FMEA (DFMEA) and a Maintenance FMEA (MFMEA). The goal of the DFMEA is to achieve inherent reliability by designing
equipment that is highly reliable, increasing the Mean Time Between Failures (MTBF). The goal of the MFMEA is to reduce Mean Time To Repair (MTTR) by addressing maintainability, spare part availability, and administrative policies.

Figure 14. Customer Satisfaction Model.

Design FMEA

The traditional Design FMEA is adapted to manufacturing equipment with minor changes. As with all Design FMEA, preliminary work must be done to define the system, the operating environment, and the development of a block diagram. The level of detail (system, subsystem, or component FMEA) is determined prior to the start of the FMEA. The degree of detail is determined by the amount of time available, the complexity of the system, the number of participants in the team, and
the customer requirements. The timing of the Design FMEA is important; the earlier in the design phase the better because it is easier to make design changes. DFMEA is done in a team that consists of the engineer, designer, user, supplier, and design management. Figure 15 shows the form used for the DFMEA. The DFMEA for machinery uses the same form as the traditional Design FMEA. The difference is the context of the columns.

![Figure 15. Equipment Design FMEA Template.](image)

The header block identifies the principal engineer(s), manager, FMEA team, date prepared, prepared by whom, date revised and department. The header block can be modified to include additional information such as the component identification number, revision number, FMEA number, and release data. It must be completed in order to identify the subsystem or component, FMEA, and principal team members.

Component/Subsystem is a brief description of the system or subsystem under analysis. It establishes the level of the FMEA along with the description of the
component or system. The description should be complete, accurate, and brief. The
description reflects the subsystem or component identified by the block diagram or
blueprint. Component/Subsystem may include the latest engineering drawing number.

The Function of the system or subsystem identifies the wants and needs as
specified by the customer. The Function lists the design intent for the system or
subsystem. The Function covers safety issues, user interface issues, design intended
functions, and any upstream or downstream support functions. Functions are
identified through the block diagram, functional analysis, and user requirements. A
well-defined function list is critical to a complete FMEA since the Function serves as
input to the rest of the FMEA.

The Potential Failure Mode lists the way the subsystem or component can fail
to meet the function, design intent, performance requirement, or customer
expectation. It is a potential failure, it may or may not occur. The operating
conditions, environmental conditions, and usage conditions are considered when
determining Potential Failure Modes. A Potential Failure Mode may cause a failure at
a higher level within the system or it may be caused by a failure at a lower level
within the subsystem. The Potential Failure Modes are listed for each of the
functions. There are many Potential Failure Modes for each function. Figure 16
illustrates several different Functions and Potential Failure Modes for a subsystem.

The Potential Effect of the Failure describes the consequence of the failure
with respect to the user, either internal or external to the process. Potential Effect of
<table>
<thead>
<tr>
<th>Component</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>S e v</th>
<th>Potential Cause(s)/Mechanism(s) of Failure</th>
<th>O c c</th>
<th>Current Design Controls</th>
<th>Responsible Action(s) &amp; Target Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progressive Press with Die</td>
<td>Feed material into die</td>
<td>Improper location of feeding edge of stress</td>
<td>Die Damage</td>
<td>Partial cutting</td>
<td>Shaving of punch</td>
<td>6</td>
<td>Leads on lead-in gauge too small</td>
<td>Prototype testing</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No ledge on lead-in gauge</td>
<td>3</td>
<td>Prototype testing</td>
<td>96</td>
<td>No action at this time</td>
<td>R. Hall 3/0/00</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Gauge not adjustable to different strip widths</td>
<td>5</td>
<td>Product testing with different strip widths</td>
<td>120</td>
<td>Investigate factors that are robust to material size</td>
<td>R. Hall 3/0/00</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Shift in upper die in relation to the lower die</td>
<td>3</td>
<td>FEA</td>
<td>168</td>
<td>Investigate alternative methods to determine shift</td>
<td>S. Jones D. Doe 9/30/99</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No point to locate material</td>
<td>3</td>
<td>Test for at customer plant</td>
<td>168</td>
<td>Investigate physical location methods</td>
<td>S. Jones R. Hall 10/1/99</td>
<td>8</td>
</tr>
<tr>
<td>Part Lifters - lift strip from station to station</td>
<td>Lift strips higher than specified</td>
<td>Strip is not aligned for next station</td>
<td>Strip is jammed</td>
<td>Spring pins do not adjust to material weight</td>
<td>6</td>
<td>20 hour test</td>
<td>60</td>
<td>Investigate better testing methods</td>
<td>S. Jones 11/30/99</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Straps not lifted enough</td>
<td>6</td>
<td>Spring pins insufficient</td>
<td>96</td>
<td>Investigate better testing methods</td>
<td>S. Jones 11/30/99</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lifters raise at different heights</td>
<td>Strip sag during spring pins</td>
<td>6</td>
<td>20 hour test</td>
<td>72</td>
<td>Investigate better testing methods</td>
<td>S. Jones 11/30/99</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Strip not balanced on lifter</td>
<td>Strip falls to one side during feed, jam</td>
<td>7</td>
<td>Wear on spring pins</td>
<td>112</td>
<td>Investigate better testing methods</td>
<td>S. Jones 11/30/99</td>
</tr>
</tbody>
</table>

Figure 16. Design Maintenance FMEA Example.
the Failure considers the effect of the failure on the design itself, other systems, the
equipment, and the user. The effect of the potential failure mode may result in safety
or regulatory issues, loss of operation, degradations of performance, or failures
upstream. Figure 16 shows several examples of the Potential Effects of Failure for
each Potential Failure Mode.

The Severity ranking is an assessment of the seriousness of the effect if the
failure occurs. Severity only applies to the Potential Effects of Failure. The objective
of the Severity ranking is to identify the failure modes that may result in injury or
excessive downtime. The Severity of the effect is ranked on a scale of 1 to 10. The
same ranking criteria is used for the DFMEA as in the traditional DFMEA, as shown
in Table 10. Figure 16 shows the use of the Severity ranking to assess the effects of
each of the failure modes. If there is more than one effect listed, then the Severity
ranking applies to the most severe effect or the severity of all the effects combined.

The Potential Cause(s) of Failure list all the possible reasons for the specific
failure mode. The Potential Cause(s) of Failure focus on design related causes of the
failure, i.e., what in the design caused the failure and how can the design be improved
to eliminate the cause. The Potential Cause(s) of Failure includes inadequate design
of the parts to withstand foreseen stresses, the design of the part that is not robust to
environmental and material factors, unacceptable variation in the manufacturing
process, and oversights of the design engineers. The failure mode may result from
manufacturing or assembly misbuild, but the misbuild is the result of a design failure.
It is important to note that the Potential Cause(s) of Failure is related to the failure
mode rather than related to the effect. Figure 16 illustrates several potential causes for a single failure mode.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Minor</td>
<td>Unreasonable to expect that the minor nature of this failure would cause any real effect on the product performance. The operator will never notice the failure.</td>
</tr>
<tr>
<td>2, 3</td>
<td>Low</td>
<td>The operator will notice a slight deterioration in performance. Failure can be prevented with normal preventative maintenance. Failure is expected and accepted.</td>
</tr>
<tr>
<td>4, 5, 6</td>
<td>Moderate</td>
<td>The operator will notice some performance deterioration. Defective parts may result. The failure can be prevented with major preventative maintenance. Failure may or may not be planned. Failure may require minor unscheduled down time. Repair parts may be kept on location.</td>
</tr>
<tr>
<td>7, 8</td>
<td>High</td>
<td>High degree of dissatisfaction due to the nature of the failure, such as an inoperable product or subsystem. Major unscheduled maintenance is required. Special personnel are required to fix failure. Parts may need to be ordered.</td>
</tr>
<tr>
<td>9, 10</td>
<td>Very High</td>
<td>Potential failure mode affects safety and/or non-conformance with government regulations. User may be injured as a result of the failure.</td>
</tr>
</tbody>
</table>

The Occurrence ranking evaluates the chance of a Potential Cause(s) of Failure occurs which results in the failure mode. Table 11 shows that a design life failure rate can be used to determine the ranking. The design life is the target
reliability goal. Occurrence can be based on the reliability data of like or very similar components, estimated from data, or a subjective evaluation of new components. The estimate of the likelihood of occurrence is based on a scale from 1 to 10. It is important to remember that the rank number has a meaning rather than a value. Figure 16 shows the use of a subjective ranking when previous data is not available to estimate the occurrence of the Potential Cause(s) of Failure.

Table 11

DFMEA: Occurrence Evaluation Criteria

<table>
<thead>
<tr>
<th>Rank</th>
<th>Design Life Possible</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&lt; 1.0x10^-6</td>
<td>Remote</td>
<td>Failure is unlikely</td>
</tr>
<tr>
<td>2</td>
<td>1.0x10^-6 - 5x10^-5</td>
<td>Low</td>
<td>Relatively few failures</td>
</tr>
<tr>
<td>3</td>
<td>5x10^-5 - 2.5x10^-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>2.5x10^-4 - 1.0x10^-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>1.0x10^-3 - 2.5x10^-3</td>
<td>Moderate</td>
<td>Occasional failures</td>
</tr>
<tr>
<td>6</td>
<td>2.5x10^-3 - 1.25x10^-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>1.25x10^-2 - 2.5x10^-2</td>
<td>High</td>
<td>Repeated failures</td>
</tr>
<tr>
<td>8</td>
<td>2.5x10^-2 - 5x10^-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>5x10^-2 - 1.25x10^-1</td>
<td>Very High</td>
<td>Failure is almost certain</td>
</tr>
<tr>
<td>10</td>
<td>&gt;1.25x10^-1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Current Design Control describes the verification or validation methods used to determine if the cause of the failure mode exists. The Current Design Control is any test or verification used prior to an actual production runs on-site. Current Design Controls are tests, controls, or systems currently in place within the design organization. Current Design Controls include design analysis, product testing, design reviews, mathematical studies, lab testing, feasibility reviews, and prototype testing. They can detect a first level cause of a potential failure mode or the failure mode itself. Figure 16 lists some tests that are used to detect each of the Potential Cause(s) of Failure.

Detection ranking is the ability of the Current Design Control to determine if the Potential Cause(s) of Failure exists. The ranking of the Current Design Control is the same as for a traditional Design FMEA. Table 12 illustrates the use of the ranking

<table>
<thead>
<tr>
<th>Rank</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 2</td>
<td>Very High</td>
<td>Will be detected during the design of the product</td>
</tr>
<tr>
<td>3, 4</td>
<td>High</td>
<td>Will be detected prior to final design</td>
</tr>
<tr>
<td>5, 6</td>
<td>Moderate</td>
<td>Will be detected during installation</td>
</tr>
<tr>
<td>7, 8</td>
<td>Low</td>
<td>Will be detected during the debugging phase</td>
</tr>
<tr>
<td>9, 10</td>
<td>Very Low</td>
<td>Undetectable until failure occurs during operation.</td>
</tr>
</tbody>
</table>
to predict the occurrence of the Potential Cause(s) of Failure, given the Current Design Control. When a Current Design Control is not developed, then the Detection ranking is ten. The Detection ranking can be improved with verification methods that detects the Potential Cause(s) of Failure prior to the actual use of the equipment in a production application. Figure 16 shows the application of the various levels of detection of the Current Design Control.

The Risk Priority Number (RPN) is the product of Severity, Occurrence, and Detection rankings. It ranks the Potential Cause(s) of Failure on a scale of 1 to 1000. RPN should only be used to rank the potential design weaknesses for consideration of possible design actions to reduce Severity, reduce Occurrence, or develop early detection. It is used to prioritize design activities by focusing the activities on the Potential Cause(s) of Failure with the higher RPN. In addition to using the RPN to generate improvement activities, activities need to be planned for failure modes with a Severity ranking of 9-10 or a Potential Cause(s) of Failure with a high Severity ranking and a high Occurrence ranking. The RPN does not have a value in itself. It is simply a ranking. Figure 16 illustrates the use of RPN to prioritize the various Potential Cause(s) of Failure. The Potential Cause(s) of Failure that are most critical will have higher RPN.

Recommended Action(s) is a planned activity to investigate design weaknesses identified in the DFMEA. The actions should be developed for the Potential Cause(s) of Failure with high RPN. It is a proactive design activity intended to investigate design alternatives that will reduce the RPN. For example,
Recommended Action(s) includes Design of Experiments, revised test plans, exploratory testing, analytical modeling, and additional material testing.

Recommended Action(s) list the activities required to better determine the causes of the failure mode. Figure 16 shows the investigative nature of the Recommended Action. They are design activities that will further explain the failure mode or further define the causes of the failure.

Responsibility & Target Completion Date is used the same as it is used in a traditional DFMEA. Responsibility documents the person(s) responsible for completing the Recommended Action(s). Target Completion Date specifies the completion of the Recommended Action(s). Responsibility & Target Completion Date are reviewed with each manager as a way to plan for required resources and establish priority for an engineer involved with more than one subassembly.

The result of the DFMEA for manufacturing equipment is a list of design activities to improve the reliability of the product by eliminating or decreasing the occurrence of design weaknesses that results a failure. Action Taken documents the design change or new current design control. As the result of the Recommended Action(s) or further testing of the design, design changes are made to the subassembly. Design changes can reduce the severity of the failure by eliminating the failure mode, reducing the occurrence of the failure by improving the reliability of the component, or improving the detection of the failure. If no actions are taken, then “No action at this time” is entered. Figure 16 shows the documentation process. It should be noted that Target Completion Date is some time in the future. Action Taken
is completed when design activities have taken place and changes are made to the design.

The Revised RPN reflects a change in the Occurrence, Severity, or Detection ranking. A change to the design may result in a decrease in either the Severity or Occurrence ranking. For example, the Severity may be reduced when the device is made foolproof. The Occurrence ranking is reduced when changing to a stronger material decreases the likelihood of failure. Once the RPN is revised, it should be prioritized again for further Recommended Action(s). Figure 16 illustrates the completion of the DFMEA. Even though the FMEA is completed, it is still a living document and must be updated as the design changes.

Maintenance FMEA

The use of the Maintenance FMEA is recommended to address maintainability issues during the design, development, and debugging of the equipment. The goal of the Maintenance FMEA is to improve the ability to maintain the equipment during the design phase by reducing the Mean-Time-To-Repair (MTTR) through design changes and early planning. By identifying MTTR, Mean-Time-Between-Failure (MTBF) for the cause, and the detection of the failure mode, changes can be made to the design to improve the maintainability of the equipment. The Maintenance FMEA uses the same form as other FMEA, but the context is different. Figure 17 shows the MFMEA form.
Figure 17. Maintenance FMEA Template.

The header block contains the same information: who is the manager, who participated on the team, what is the FMEA on, when is it done, when is it revised, and where is it done.

The MFMEA may be done at different levels, for example, machine level, system level, or subsystem level. The amount of time available, the cost, and the complexity of the machine determine the level of detail. The level of detail should be identified prior to the start of the FMEA activity. To maintain continuity between the DFMEA and the MFMEA for equipment, the Component/System should include the same systems or subsystems as the DFMEA. In that case, the Functions for each system or subsystem may be the same for the MFMEA and DFMEA.

The Potential Failure Mode defines the manner in which the equipment fails to be available to produce parts to the required specifications. For every failure mode,
an action is required to bring the machine back to its intended production capability. Failures include hardware failures, degradation of performance, or performance that results in quality defects. Historical documents such as field reports may be used to help identify failure mode. Figure 18 shows the different types of failure modes that potentially result in downtime.

The Potential Effects of Failure describes the consequence of the failure on the system with respect to the MTTR for the machinery. The effect of the failure considers failure as the equipment is running during normal production. It identifies the breakdown, reduced cycle time, setup and adjustments, start-up losses, tooling, stoppages, and defective parts. A failure mode can have more than one effect and all the effects should be listed. Figure 18 illustrates the Potential Effects of Failure, given that the failure occurred.

Severity is a subjective measure of the seriousness of the Potential Effect(s) of Failure. The seriousness of the effect is assessed on the basis of the total cost of the repair, including the total downtime and total cost of missed production. Total downtime includes amount of time required for the repair, availability of the maintenance personnel, and availability of spare parts. Table 13 provides a guideline for the rating of the Severity. Figure 18 shows that the severity is associated with each Potential Effects of Failure. If two or more effects are listed, then the most severe effect is ranked.

The Potential Cause(s)/Mechanism(s) of Failure identifies the cause of machine downtime. It focuses on the needed repairs, in order to return it to operating
<table>
<thead>
<tr>
<th>Component System</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Potential Cause(s)/Mechanism(s) of Failure</th>
<th>O</th>
<th>C</th>
<th>Current Design Controls</th>
<th>D</th>
<th>e</th>
<th>t</th>
<th>R</th>
<th>P</th>
<th>N</th>
<th>Recommended Action(s)</th>
<th>Responsibility</th>
<th>Action Results</th>
<th>S</th>
<th>e</th>
<th>c</th>
<th>t</th>
<th>R</th>
<th>P</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lift and clamp assembly</td>
<td>Motor Failure</td>
<td>No lift - motor tear down</td>
<td>7</td>
<td>Defective motor</td>
<td>3</td>
<td>Operator loses for changes in sound of motor. Operator notices incorrect lift.</td>
<td>8</td>
<td>18</td>
<td>8</td>
<td>Investigate use of indicator lights on motor to energy consumption and temperature</td>
<td>J. Smith 1/3/99</td>
<td>Indicator dial added for temperature and energy</td>
<td>7</td>
<td>3</td>
<td>2</td>
<td>42</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actuator failure</td>
<td>Replace actuator cylinder</td>
<td>4</td>
<td>Defective actuator cylinder</td>
<td>2</td>
<td>Strain sound of the motor.</td>
<td>9</td>
<td>14</td>
<td>4</td>
<td>Investigate system for indicating low air pressure</td>
<td>J. Smith G. Hall 12/30/99</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coupling failure</td>
<td>No lift - twisted components</td>
<td>5</td>
<td>Defective coupling</td>
<td>5</td>
<td>Be checked during preventive maintenance</td>
<td>3</td>
<td>75</td>
<td></td>
<td>No action at this time</td>
<td>J. Smith G. Hall 12/30/99</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gearbox failure</td>
<td>Replace gearbox subassembly</td>
<td>7</td>
<td>Defective gearbox</td>
<td>3</td>
<td>Be checked during preventive maintenance</td>
<td>3</td>
<td>63</td>
<td></td>
<td>No Action at this time</td>
<td>J. Smith G. Hall 12/30/99</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gearbox failure</td>
<td>Replace gearbox subassembly</td>
<td>7</td>
<td>Defective gear</td>
<td>3</td>
<td>Be checked during preventive maintenance</td>
<td>3</td>
<td>63</td>
<td></td>
<td>No Action at this time</td>
<td>J. Smith G. Hall 12/30/99</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LEA fails to provide position data</td>
<td>Press stops - determine error in LEA system</td>
<td>8</td>
<td>Defective LEA</td>
<td>8</td>
<td>Use of built in diagnostic</td>
<td>1</td>
<td>48</td>
<td></td>
<td>No action at this time</td>
<td>J. Smith G. Hall 12/30/99</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Failure of track bearing</td>
<td>Replace bearings</td>
<td>7</td>
<td>Bearings wear</td>
<td>7</td>
<td>Be checked during preventive maintenance</td>
<td>3</td>
<td>14</td>
<td>7</td>
<td>Design bearing for easier access</td>
<td>B. Greene 2/15/00</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>To move rails in and out</td>
<td>Motor Failure</td>
<td>No dapping - motor tear down</td>
<td>7</td>
<td>Defective motor</td>
<td>3</td>
<td>Operator loses for changes in sound of motor. Operator notices incorrect lift.</td>
<td>8</td>
<td>18</td>
<td>8</td>
<td>Investigate use of indicator lights on motor to energy consumption and temperature</td>
<td>J. Smith 9/9/99</td>
<td>Indicator dial added for temperature and energy</td>
<td>7</td>
<td>3</td>
<td>2</td>
<td>42</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rack and pinion failure</td>
<td>Replace dapping</td>
<td>5</td>
<td>Defective rack and pinion subassembly</td>
<td>4</td>
<td>Observation of operation</td>
<td>9</td>
<td>18</td>
<td>0</td>
<td>Investigate system for failure in the rack and pinion subassembly</td>
<td>J. Smith G. Hall 3/100</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 18. Equipment Maintenance FMEA Example.
conditions. Potential Cause(s)/Mechanism(s) of Failure focuses on process variation

Table 13

MFMEA: Severity Evaluation criteria

<table>
<thead>
<tr>
<th>Rank</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Very Minor Repair</td>
<td>Maintenance personnel can do repairs and/or adjustments during normal scheduled maintenance times. The process does not produce defective parts. No repair parts needed.</td>
</tr>
<tr>
<td>2, 3</td>
<td>Minor Repair</td>
<td>Repairs and/or adjustments need to be done during production, but downtime is not required. The operator is capable of making adjustments. The process does not produce defective parts. No repair parts needed. MTTR is less than 30 minutes.</td>
</tr>
<tr>
<td>4</td>
<td>Low</td>
<td>Repairs and/or adjustments need to be done during production, some downtime is required (&lt; 30 min). The operator is capable of making required adjustments. The process does not produce defective parts. No repair parts needed. MTTR is between 30 and 120 minutes.</td>
</tr>
<tr>
<td>5,6</td>
<td>Moderate</td>
<td>Between 30 min to 2 hour of down time is required. A maintenance personnel is required to make repairs. The process may produce defective parts. In-house repair parts are needed. Repair part cost does not exceed $100. MTTR is between 120 minutes to 4 hours.</td>
</tr>
<tr>
<td>7, 8</td>
<td>Major</td>
<td>Between 2 min to 4 hour of down time is required. Maintenance personnel are required to make repairs. The process may produce defective parts. In-house repair parts are needed. Repair part cost does not exceed $500. MTTR is between 4 to 8 hours.</td>
</tr>
<tr>
<td>9, 10</td>
<td>Very Major</td>
<td>More than 4 hours of down time is required. Special maintenance personnel are required to make repairs. Repair parts must be special ordered. Repair part cost exceeds $500. MTTR is greater than 8 hours.</td>
</tr>
</tbody>
</table>

that can be described in terms of a cause that can be corrected or controlled. The
Potential Cause(s) of Failure may be a hardware failure of the machine or a Potential Cause(s) of Failure may result in excessive process variation. Figure 18 shows several Potential Cause(s) of Failure for a single failure mode. An effective FMEA will have several Potential Causes of Failure for each failure mode.

The Occurrence ranking is the MTBF of the component identified as the cause of the potential failure. Table 14 shows the scale used to specify the Occurrence

Table 14
MFMEA: Occurrence Evaluation Criteria

<table>
<thead>
<tr>
<th>Rank</th>
<th>Design Life Possible Failure Rate</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MTBF &gt;10,000 hours</td>
<td>Remote</td>
<td>Failure is unlikely</td>
</tr>
<tr>
<td>2, 3</td>
<td>MTBF between 10,000 and 5,000 hours</td>
<td>Low</td>
<td>Failure has rarely occurred</td>
</tr>
<tr>
<td>4, 5, 6</td>
<td>MTBF between 5001 and 1000 hours</td>
<td>Moderate</td>
<td>Failure has occasionally occurred</td>
</tr>
<tr>
<td>7, 8</td>
<td>MTBF between 999 and 100 hours</td>
<td>High</td>
<td>Failure has occurred repeatedly</td>
</tr>
<tr>
<td>9, 10</td>
<td>MTBF between 99 and 1 hour</td>
<td>Very High</td>
<td>Failure is almost certain</td>
</tr>
</tbody>
</table>

Ranking. If the MTBF is not known, the Occurrence ranking can be estimated from data available on similar or like parts in similar applications. If information is not available, Occurrence ranking is a subjective rating of the likelihood of the Potential Cause(s) of Failure. Factors to consider when assessing the Occurrence ranking
includes historical field service data for similar products, the complexity of the component, repairs made during debugging, and the occurrence of the causes during installation. An Occurrence ranking is assigned for each cause. Figure 18 shows the Occurrence ranking for each of the causes listed.

Current Design Controls describes the current methods in place to detect the failure for a given cause. Current Design Controls are specific methods, techniques, or devices in place to detect the failure. Examples include the use of sensors, lights, indicators, preventive maintenance, or Statistical Process Control (SPC). Current Design Controls are good if failures are detected prior to the occurrence of the failure, such as the use of oil level indicators for detecting low levels. Current Design Controls do not exist if the failure is not detected until additional damage occurs as the result of the failure. There may be more than one current design control per Potential Cause of Failure. All Current Design Controls should be listed within a single block. Figure 18 lists Current Design Controls for each of the Potential Causes of Failure.

Table 15 shows the Detection ranking scheme used in the Current Design Controls for an MFMEA. See Figure 18 for an example. If more than one Current Design Control is listed, then the detection number ranks the effectiveness of the combination of controls.

The Risk Priority Number (RPN) is the product of Severity, Occurrence, and Detection ranking. RPN ranks each Potential Cause(s) of Failure on a scale of 1 to 1000. It is used to prioritize activities by focusing activities on the Potential Cause(s)
of Failure with the higher RPN. In addition to using the RPN to generate improvement activities, activities should be planned for failure modes with a Severity ranking of 9-10 and high Severity and Occurrence rankings. RPN is used only to rank the potential design weaknesses for consideration. Figure 18 shows the RPN for each of the potential causes of failure. The RPN represents the cost of downtime, the chance of downtime, and the ability to detect the failure. For high RPN, action should be taken to improve any combination of Severity, Occurrence, or Detection.

Table 15

MFMEA: Detection Evaluation Criteria

<table>
<thead>
<tr>
<th>Rank</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 2</td>
<td>Very good</td>
<td>The failure is detected prior to the need for unscheduled downtime.</td>
</tr>
<tr>
<td>3, 4</td>
<td>Good</td>
<td>The failure is detected early enough to make repairs at the end of a shift.</td>
</tr>
<tr>
<td>5, 6</td>
<td>Fair</td>
<td>The failure is detected prior to the manufacture of defective parts. Unscheduled down time is required.</td>
</tr>
<tr>
<td>7, 8</td>
<td>Poor</td>
<td>The failure is not detected until defective parts are produced. Unscheduled down time is required.</td>
</tr>
<tr>
<td>9, 10</td>
<td>Very Poor</td>
<td>The failure is not detected. Operations continue and additional damage to the equipment occurs before the failure is discovered.</td>
</tr>
</tbody>
</table>
Recommended Action(s) provides the opportunity to plan and document the improvement activities that will reduce the RPN. Recommended Action(s) is developed for the Potential Cause(s) of Failure with high RPN. It is a planned activity to investigate design changes, maintenance policies, information needed in the repair manual, or spare parts inventory issues identified through the MFMEA. It is a proactive design activity intended to investigation design alternatives that will reduce the RPN. For example, Recommended Action(s) includes the investigation of use of better materials to increase MTBF, changes in the design to improve accessibility, improved maintenance instructions, and design changes to reduce MTTR or design changes to increase the detection of a failure. Figure 18 illustrates Recommended Action(s) for only the Potential Cause(s) of Failure with a high RPN.

Responsibility & Target Completion Date is used the same as it is used in Design FMEA. Responsibility documented the person(s) responsible for completing the Recommended Action(s). Target Completion Date specifies the completion of the Recommended Action(s). Responsibility & Target Completion dates should be reviewed with each manager as a way to plan for required resources and establish priority for an engineer who deals with more than one subassembly.

The result of the MFMEA for manufacturing equipment is a list of design activities to improve the maintainability of the product by reducing the overall MTTR of design. Action Taken documents any design or procedure change. As the result of the Recommended Action(s), design changes, policy changes, or maintenance schedules are documented. Design changes reduce the Severity of the failure by
the Recommended Action(s), design changes, policy changes, or maintenance schedules are documented. Design changes reduce the Severity of the failure by reducing MTTR, increasing the MTBF, or improve the Detection of the failure. If no actions are taken, then “No action at this time” is enter. Figure 18 illustrates the use of Action Taken. Changes to the design that effect the RPN of other Potential Cause(s) of Failure are also documented in Action Taken.

The Revised RPN reflected a change in the Occurrence, Severity, or Detection rankings. A change to the design may result in a decrease in either the Severity or Occurrence ranking. Once the RPN is revised, it should be prioritized again for further Recommended Action(s). Figure 18 shows a completed MFMEA.

Process

As mentioned early in the paper, the implementation process for a FMEA is as important as the description of the form. The use of FMEA for capital equipment and tooling follows a similar process as the Design FMEA, perhaps with fewer iterations. A facilitator or a team of facilitators is used to coordinate the Machine Design and Maintenance FMEA. It is useful to have the same facilitators lead both the Design and Maintenance FMEA, since the Design FMEA serves as input to the Maintenance FMEA. The facilitator’s responsibilities include setting up the meetings, leading the meetings, and making notes during the meetings. The facilitators coordinating the various Design and Maintenance FMEA can assure consistency within each type of FMEA and a distinguishing between the two types of FMEA.
Teams should be used in the development of the both types of FMEA. Potential team members for the DFMEA include design engineers, engineering management, process engineers from the customer, and engineering management from the customer. The team involved with the development of the Product Maintenance FMEA should have 6-8 members and include the design engineer, service personnel, quality engineer, and customer assurance. Other members could include marketing/sales, design technicians, and manufacturing. The design engineer should initiate the meeting, specify the members, and determine the time to start the Product Maintenance FMEA, with respect to the product development schedule.

The Maintenance FMEA is done after the initial work on the Design FMEA and before the completion of the project. Team meetings should be between 2-4 hours, with three hours being optimal. If meetings are scheduled for a day, then a two-hour break in the middle can help the effectiveness of the long meeting time. During the DFMEA meeting, the lead engineer reviews the subsystem with the team, describes the mating system/subsystem, the assembly of the subsystem, the design intent and the past history of failures for similar subsystems. A similar process is used at the start of the MFMEA, the lead engineer reviews the subsystem with the team, the assembly of the subsystem, the required tools to change parts, historical data on MTTR for similar subsystems, and the Design FMEA for the subsystem or component.

FMEA is an iterative process, as specified earlier. The FMEA is updated to reflect the information obtained during each phase of the development of the tool. As
customer requirements are better understood, Potential Failure Modes and the Potential Effect of Failure are better identified. Through testing, the MTBF and MTTR can be more accurately measured. Testing can identify new failure modes and better estimate the occurrence of the causes leading to the failure mode. Changes to the design need to be documented and the design should be reevaluated to assure that new failure modes were not introduced. By working closely with the customer, a better understanding of the operational environment is obtained, the information may impact the type of failure modes and the frequency of the failure modes. The FMEA can be used to document the information as it is obtained.

As the FMEA is updated, it should be reviewed with the team prior to each major project milestone. The purpose of the review is to update the team with respect to the changes made to the design, assumptions about preventative maintenance and maintenance policy assumptions, and modification of the project specification. The reviews serve as a forum to share and discuss relevant design information with the different customers of the tool.
CHAPTER V

DISCUSSION

The effectiveness of the FMEA is determined by three factors: (1) the usefulness of the form, (2) the degree of integration, and (3) the management support. The logical flow of the form determines the success of the process. Is the form useful? Is the form clear? Does the form fulfill the intended function? Once the form has satisfied the basic need of being usable, then the scope of the form needs to be defined. How much detail is needed? What are the risks at the different levels of detail? What are the limits of the form? Is the form expected to handle all types of failure? Once the scope is defined, the integration of the form in the product development system needs to be evaluated. Is the form simply left on its own, with no connection to the current processes? Are the inputs and outputs for the FMEA defined? Is the form integrated into the system? Finally, the new form is effective if the organizational structure supports it. Are rewards and consequences established with respect to the use of the form? Does the management establish the proper expectations for the FMEA? Does the organizational environment support the behavior required for an effective FMEA procedure? The results/conclusion is discussed in terms of the Form, Process, and Environment.
The Form

Three modifications were made to the old form that affected the flow, intention, and structure of the FMEA. The first change was a clarification of the Occurrence ranking. Occurrence ranking was assigned to the occurrence to the Potential Cause(s) of Failure Mode. In the past, it was not clear if the Occurrence ranking was associated with the Potential Failure Mode or the Potential Cause(s) of Failure. To confuse the issue, it was assumed that failure data could be used to rigorously assign an Occurrence ranking. Since the failure data was determined from the failure mode, the Occurrence ranking was frequently associated with the Potential Failure Mode rather than Potential Cause(s) of Failure. However, it was desirable to assess the occurrence of each Potential Cause(s) of Failure rather than the occurrence of the failure mode. In the case study, every Potential Cause(s) of Failure had an Occurrence ranking that reflected the chance of the Potential Cause(s) of Failure occurring that resulted in the Potential Failure Mode. By associating the Occurrence ranking with the Potential Cause(s) of Failure, the Occurrence ranking was more subjective. For example, when evaluating the occurrence of the Potential Cause(s) of Failure leading to the failure mode, engineers were asked to estimate the likelihood of the Potential Cause(s) of Failure. For the Occurrence ranking to be quantitative, more accurate failure data was needed. Failure data needed to include the failure mode and an assessment of the cause of the failure mode. Without the detailed data, the Occurrence ranking was a subjective estimate.
The second clarification was the definition of the Detection ranking. In the past, it was not clear if the Detection ranking was the ability of the customer to detect the failure before it occurred or the ability of the Current Design Control to detect the Potential Cause(s) of Failure prior to final release of the product for production. In the case study, the Detection ranking was defined as the ability of the Current Design Control to detect the Potential Cause(s) of the Failure Mode prior to final release of the design for production. Detection ranking evaluated the effectiveness and the adequacy of the current testing practices. The Detection ranking was high if the test was not able to detect the Potential Cause(s) of Failure or if the test detected the Potential Cause(s) of Failure after the design was released. Detection ranking evaluated the effectiveness and the timeliness of the test as specified in the Current Design Control.

The third change was the addition of the Recommended Action(s), Responsibility & Target Completion Date, Action Taken, and Revised RPN to stress the importance of design changes. In the past, Action Taken was the only follow-up requirement. The introduction of the new columns required additional clarification between Action Taken and Recommended Action(s). QS-9000 and the Ford Training Manual (1994) describe the Recommended Action(s) and related the Recommended Action(s) back to a change in the design to reduce the RPN, but there was not a clear definition of Recommended Action(s). As a result, the Recommended Action(s) tended to state a change to the design that reduced the RPN, and Action Taken was simply the verification of the action described in the Recommended Action(s).
If the additional columns were added to reinforce the proactive approach for eliminating the failure mode, then the Recommended Action(s) needed to reflect the investigation required in determining the actual Potential Cause(s) of Failure. The Action Taken documented the actual design change or change to the Current Design Control. The Recommended Action(s) specified the investigation needed to determine the actual cause of the failure mode or the work needed to design a new Current Design Control to detect the failure mode. The Responsibility & Target Completion Date specified the resources needed to complete the Recommended Action(s). Time specified by the Target Date implied the passage of time to carry out the investigation and make design changes. The design changes were documented in the Action Taken. Then the Action Taken was used to revise the RPN.

The results from clarifying the form showed an increase in the consistency of the 37 FMEA. The form was completed with a greater degree of consistency and accuracy. Potential Failure Modes were failure modes of the subsystem, not simply the negation of the function. The Potential Cause(s) of Failure addressed the Potential Failure Mode rather than the Potential Effect of Failure. The Current Design Control and Detection ranking addressed the testing procedures and the ability of the test to detect the failure mode. In some cases, the established tests were not effective in detecting the Potential Cause(s) of Failure and new tests were developed. The Occurrence ranking assessed the occurrence of the Potential Cause of Failure leading to the Potential Failure Mode. As a result, engineers had a better understanding of the FMEA form and, more importantly, a better failure analysis of their subsystem.
Once the form was clarified, the level of the FMEA was addressed. The case study conducted all the FMEA at a subassembly level. As shown earlier, the Potential Failure Mode, Potential Effect of Failure, and Potential Cause(s) of Failure changed, dependent on the level of the FMEA. If the FMEA was done at the component level, then the Potential Cause(s) of Failures specified part characteristics, i.e. improper specifications, wrong diameters, incorrect materials. Recommended Action(s) for the Potential Cause(s) of the Failure Mode lead to the investigation of the specific component characteristics. For a subsystem FMEA, the Potential Cause(s) of Failure became weaknesses of the components and the Recommended Action(s) investigated part weaknesses rather than part characteristics. The Recommended Action(s) unintentionally changed the emphasis of the component FMEA to the redesign of part characteristics and the subsystem FMEA to the redesign of the component. As a result, the Recommended Action(s) focused on the evaluation of the component rather than the specific part characteristics.

The use of the QFD and FMEA in the same project impacted the FMEA. In the past, the FMEA frequently addressed performance specification. The case study distinguished between performance requirements and functional requirements. QFD focused on the part characteristics that impacted product performance, assuming proper function. FMEA addressed the part weaknesses that changed over time and result in a functional failure or degradation of performance. By using QFD with the FMEA, the FMEA was more focused on reliability and it analyzed the subsystem with respect to failures over time.
The subsystem FMEA resulted in FMEA that were shorter and easier to manage than component FMEA in the past. However, some of the subsystem FMEA lacked the needed details. Restricting the scope of the FMEA to the functional failures enables more descriptive Potential Cause(s) of Failure. The Potential Cause(s) of Failures were no longer "improper specification." Potential Cause(s) of Failure described the cause of the failure of the subsystem.

With the addition of the new columns, Recommended Action(s), Responsibility & Target Completion Date, Action Taken, and Revised RPN, the FMEA took on another role. The case study addressed the issue of planning by developing a procedure that considered the passage of time between the Recommended Action(s) and Action Taken. In addition, the case study recommended an update procedure that kept all the information on the original FMEA form and requested the update of the FMEA prior to the release of prints for the next prototype. The facilitators reviewed the process with each of the managers and explained the role that the managers needed to play. The managers reviewed the updated FMEA with the engineers and determine the required resources to complete the Recommended Action(s) by the target date. The managers did not question the process and they agreed to follow the process. However, FMEA were not updated as requested. When the FMEA was required by the lab manager to develop the test plan for each prototype, the engineers started to update the FMEA. When the Safety Department requested the use of the FMEA to identify critical safety issues, the
engineers started to use the FMEA. The FMEA needs to be part of the system in order to be a visible, useful tool.

The Process

Published literature provided examples of individual FMEA (Duffin, 1994, Prasad, 1991, and Marchant & Stangle, 1995), but it did not discuss a process for the use of multiple FMEA or a systematic approach to FMEA. This paper suggested a process that included the timeliness of the FMEA, a team focus, the passage of time between the Recommended Action(s) and Action Taken, and the use of revised RPN to further prioritize design issues. The paper also discussed the different updates that occurred during the development phase, to keep the FMEA “a living document.” The procedure illustrated the use of facilitators to coordinate efforts and lead group discussion. The issue of timeliness was addressed by scheduling the brainstorming meeting during the concept stage of the design, leaving time to update the FMEA as the design changes were made.

Along with the process used, the integration of the FMEA into other functions was needed. Teng and Ho (1996) discuss the integration of the Design and Process FMEA into the design and manufacturing function, respectively. In the case study, the FMEA was reviewed as part of the design review procedure and it was used to develop the test plans for each prototype build. Lab management required engineers to explain and show the direct link between the FMEA and proposed test plans. The Safety Department required the FMEA as part of the input to address safety issues.
Severity rankings of 9 or higher were reviewed with Safety Department. The FMEA was integrated to the development process by serving as input to other product development requirements.

As a result of the process established for the FMEA, the FMEA form was updated more frequently than past projects. Engineers were asked to update the FMEA four times during the design process, once for each prototype. The design review team asked to see the FMEA at each review. By the end of the project, the design review team asked to see the updated FMEA. FMEA was no longer a box on a design review check sheet. The FMEA was more visible and it was used as input for other procedures. As Teng and Ho (1996) pointed out, the more integrated the FMEA with other design activities, the more effective it will be. FMEA was more effective in the case study because other functions integrated the results of the FMEA in other activities.

The Environment

The organizational environment was a critical component to the effectiveness of the FMEA process. Management reinforced or discouraged the use of the FMEA process by providing positive or negative consequence. Tosi, Rizzo, and Carroll (1994) discuss a motivational model that involves the establishment of expectations. Expectations need to be established between the amount of effort required by a task and individual’s performance of the task. Expectations need to be established between the individual’s performance and consequence of the performance. The model was
applied to the FMEA procedure. The expectations were established between performance and outcome. The engineers were required to have the FMEA in order to review the test plans, define safety issues, and pass the design reviews. To meet those expectations, engineers completed the FMEA a day or two before the initial design review and updated the FMEA a day or two prior to other design reviews. Unfortunately, the FMEA was not done at the best possible time, when proactive actions could be planned and implemented. Rather the FMEA was done to meet the requirements of the design review or the discussion of the test plan. Management needed to clarify the expectations of the FMEA and emphasize the use of the FMEA in a proactive approach rather than simply updating and completing the FMEA before the required due date.

In addition, management needed to establish the expectations between effort and performance with respect to the FMEA. The individual engineer determined the amount of effort invested in the FMEA. Some FMEA were very detailed, while others lacked the detailed to be useful. The quality varied within each of the manager’s groups because the expectations for quality of the FMEA were not established. In addition to the lack of established expectations for the FMEA, management set competing expectation in other areas, using other checklists such as design issues, safety issues, and prototype build lists. The other lists and procedures duplicated some FMEA information and competed with the time the engineers needed to devote to the FMEA. The amount of influence management had over the engineer’s behavior was powerful, and it was often unrecognized by management.
The second part of the paper introduced the application of FMEA to equipment manufacturers. This paper recommended the applications of a Design and Maintenance FMEA to manufacturing equipment to improve equipment availability. The use of FMEA early in the design phase could reduce the project time and cost by identifying potential failure modes and recommending actions early in the design phase. FMEA provided a process to prioritize design activities based on the assessment of the risk for each identified failure mode. FMEA provided documentation for potential failure modes and the follow-up actions. It was used as a planning tool for design testing, additional investigative design work, maintenance requirements, and diagnostic procedures. It provided a forum for a team evaluation of the design with respect to failure modes and allowed the team an opportunity to develop improvement activities. FMEA helped to insure that product specifications, environmental conditions, and customer requirements were defined early in the program. It provided an opportunity to determine the actual occurrences of failure modes and document them. It provided a historical document to be referenced by future project team. The completion of a FMEA and follow-up on the Recommended Action(s) resulted in a more reliable product by reducing MTTR and increasing the MTBF through design changes.

There were some disadvantages to the use of FMEA. It was a time consuming process. An earnest effort in the development of an FMEA took time. The facilitator
and team needed good training in using the FMEA and the philosophy behind the FMEA program. The team was required to meet several times for 2-6 hours at a time. It took a conscious effort to keep the FMEA updated to reflect design changes. It took effort to understand the form and use it consistently. It took discipline to discuss the details of the design and list the Potential Cause(s) of Failure, assess the impact of them, and follow-up with corrective action. It took management support and a knowledgeable management team to evaluate the effectiveness of the FMEA. FMEA was a valuable tool, but it could lead to a sense of false security if not completed with the goal of design improvement. If the FMEA was completed as a paper-work exercise, the benefits would not be recognized.

Several authors (Lamberson and Faricy (1995), Stamatis (1995), and Sroka and Givens (1996)) suggested the use of MFMEA for machinery and equipment. They recommended a procedure that combined the design and maintenance together into a single FMEA. The current paper suggested a procedure to construct two FMEA, Design and Maintenance FMEA. The advantage of DFMEA and MFMEA was the ability to separate failure modes that were related to inherent unreliability and repair issues. The DFMEA addressed the reliability of the machinery or equipment by identifying and assessing the risks of design failures. MFMEA addressed the maintainability of the machinery and equipment by identifying failure modes that result in downtime and assessing the risk of the repair. The use of DFMEA and MFMEA separated the two types of failure mode rather than treating the different failure modes in the same way. DFMEA assessed the effect of the failure with respect
to the manufacturing process. It provided the opportunity to investigate design weaknesses as causes for the failure, and it assessed the ability of product testing to detect the failure prior to use. The results of DFMEA were Recommended Action(s) that improved the reliability of the equipment through design changes. A MFMEA assessed the effect of a failure mode on the ability to repair the machinery. It provided the opportunity to investigate causes of the failure modes that were resolved through the maintenance of the equipment. MFMEA assessed the ability to detect the failure prior to the occurrence of the failure. The results of MFMEA were Recommended Action(s) that reduced the repair time through design changes, improved maintenance policies, and changes to the administrative policies. Another advantage was the reduced length of the FMEA. Since design weakness and maintainability issues were separated, each FMEA was shorter. By using the two forms, the subsystem/component was evaluated twice, which increases the chance of identifying critical failure modes. Finally, both types of FMEA used the standard FMEA form, so current software was used.

A disadvantage of the proposed process was the additional time required completing two FMEA rather than one FMEA. It was difficult for a design team complete a FMEA in the first place. The procedure suggests two FMEA, which took more time and effort. The proposed procedure required additional training for the project teams in order to distinguish between the two FMEA forms. The use of the two FMEA was confusing since the same subsystem were analyzed twice. The organization’s management team needed to be committed to the procedure and
understand the benefits of the additional time and cost in order for the organization to benefit from the process. There was a need for additional discipline and dedication to the FMEA process to make the DMFEA and MFMEA process more effective than the use of a single FMEA for machinery and equipment.
CHAPTER VI

CONCLUSION

The definition and understanding of the form is critical to the effectiveness of the FMEA. The form must be easy to use, meaningful, without redundancy, and have a logical flow. A team of experts experienced with the FMEA can define the form. The facilitators in this case study defined the Design FMEA form by reviewing the literature and talking with experts. Through FMEA brainstorming sessions, the facilitators were able to clarify the parts of the form that were misunderstood, and reinforce the definitions for the columns that were understood. The facilitators were able to keep the group focused on the task and clarify the FMEA process. At the end of each session, the team felt a sense of accomplishment when the design engineer left with a completed FMEA.

Most of the literature involving FMEA focuses on definitions and examples of Process and Design FMEA. This includes descriptions of Process and Design FMEA for both FMECA and FMEA, discussion on the assessment of the Risk Priority Number (RPN), and the automation of the FMEA. Training seminars focus on defining the form, providing examples, and practice in completing the form. The definition of the form and the completion of the FMEA forms are concrete, bounded activities. With help from an experienced assistant, a team can complete the FMEA
analysis. The basic construction of the FMEA is independent of the organization and the culture of the organization.

The paper demonstrates the understanding of the form by applying the FMEA form to manufacturing equipment. The paper recommends a separate Equipment Design FMEA and Equipment Maintenance FMEA to emphasize the inherent design reliability and the inherent maintainability of the equipment. By separating the Equipment FMEA into a Design FMEA and Maintenance FMEA the confusion between the Severity, Occurrence, Current Design Control, and Detection ranking is reduced. The form becomes easy to understand, more meaningful, and it produces beneficial results. Once the form is defined, training material can be constructed and teams can start to use the forms.

The scope and the level of the FMEA is harder to define. The issue of the FMEA scope and the relationship between FMEA and QFD needs to be discussed before the FMEA form is started. In the case study, the scope is defined by distinguishing between performance and functional parameters. The level of the FMEA is based on the time available for the project and the understanding of the FMEA form. The time constraints, the available resources, and the risk of the design were weighted in the decision. However, the organizational leaders need to understand the risks involved with subsystem FMEA. The failure to discuss the risks may result in the lack of management understanding support.

The literature can address the pros and cons of the various levels of FMEA and training sessions can discuss the advantages and disadvantage, but the ultimate
decision must be made within the organization. In addition, the level of the FMEA may vary from project to project, depending on the available time, resources, and risk factors.

The literature describes different ways of making the FMEA part of the quality system. The FMEA must be integrated into the organization's product delivery system in order to be effective. Papers have described various schemes used by an organization to incorporate the FMEA into the organization. Clausing (1995) discusses a method to integrate QFD, FMEA, and Design of Experiments at various stages of product development. Clausing's work provides examples for system, subsystem, and component FMEA for the development of a copy machine. However, the method used must be part of the organization, not simply a duplication of another organization's system. The system must match the culture and structure of the specific organization. Fitting a process such as FMEA into an organization can not be taught in a training seminar. It must be discussion and assimilated into the system. There is an opportunity for further research into the product delivery and the integration of the many quality techniques into a total system.

The way the FMEA fits into the organization is critical to the successful implementation. Repeatedly, the literature states that the FMEA is simply done as a paperwork exercise, to meet the requirement of a design review. Management drives employee behavior by the measurements used to assess the individual's performance. If management, or more specifically, directors and vice-presidents, emphasize competing activities, then the focus will be on the competing activities. FMEA will
be a paperwork activity if there are not positive consequences for effective FMEA. The FMEA process was successful in the space program in the 1960's because the “organizational culture” supported the resources required to produce an effective FMEA. FMEA is successful in some organizations, but not others, because of the support of the culture. Further research can be done to identify the mechanisms in place within an organization that drive behavior and to develop measures consistent with the use of a given process. As long as FMEA remains a check box for a design review, it will continue to be a paperwork activity.

In conclusion, the literature has focused on the definition of the form. The various columns of the FMEA have been defined and examples have been developed. The usability of the form is critical, but it is only the first step in the integration of a quality method into a system. The integration of the FMEA into the delivery system is key to the application of the FMEA. The literature has only started to investigate the integration of the FMEA. The final element in the successful application of any new process is the performance measure system implemented by management. The organization’s culture must be consistent with the goals and purpose of any new process.
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