Understanding and Applying the Fundamentals of FMEAs

Carl S. Carlson

Carl S. Carlson
ReliaSoft Corporation
1450 S. Eastside Loop
Tucson, Arizona 85710 USA
e-mail: Carl.Carlson@ReliaSoft.com
SUMMARY & PURPOSE

Across the globe, development times are becoming shorter, cost concerns more acute, and customers are demanding and expecting absolute safety and high reliability. While it may have been sufficient in the past to focus on testing and analysis as the primary methods for ensuring high reliability, this is no longer sufficient. The focus needs to be on problem prevention, anticipating the factors that lead to failure and ensuring designs are robust. Failure Mode and Effects Analysis (FMEA) can anticipate and prevent problems, reduce costs, shorten product development times, and achieve safe and highly reliable products and processes. The plain truth is FMEA has the potential to be a very powerful tool to achieve high reliability in products and processes; and when done well, it is remarkably effective. Yet in practice, FMEA does not always achieve the expected results. It has to be done correctly: performed on the correct parts, by the correct team, during the correct timeframe, with the correct procedure. The purpose of this tutorial is to share the fundamental concepts and procedures for effective FMEAs and highlight the FMEA success factors.

Carl S. Carlson

Carl S. Carlson is a consultant and instructor in the areas of FMEA, reliability program planning and other reliability engineering disciplines. He has 30 years of experience in reliability testing, engineering, and management positions, and is currently supporting clients of ReliaSoft Corporation with reliability and FMEA training and consulting. Previous to ReliaSoft, he worked at General Motors, most recently as senior manager for the Advanced Reliability Group. His responsibilities included FMEAs for North American operations, developing and implementing advanced reliability methods, and managing teams of reliability engineers. Previous to General Motors, he worked as a Research and Development Engineer for Litton Systems, Inertial Navigation Division.

Mr. Carlson co-chaired the cross-industry team that developed the commercial FMEA standard (SAE J1739, 2002 version), participated in the development of SAE JA 1000/1 Reliability Program Standard Implementation Guide, served for five years as Vice Chair for the SAE's G-11 Reliability Division, and was a four-year member of the Reliability and Maintainability Symposium (RAMS) Advisory Board. He holds a B.S. in Mechanical Engineering from the University of Michigan and completed the 2-course Reliability Engineering sequence from the University of Maryland's Masters in Reliability Engineering program. In 2007, he received the Alan O. Plait Award for Tutorial Excellence. He is a Senior Member of ASQ and a Certified Reliability Engineer. His book, Effective FMEAs, was published in 2012 by John Wiley & Sons.

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1. INTRODUCTION

1.1 Brief history of FMEA

FMEA was formalized in 1949 by the US Armed Forces by the introduction of Mil-P 1629 Procedure for performing a failure mode effect and criticality analysis. The objective was to classify failures “according to their impact on mission success and personnel/equipment safety.” It was later adopted in the Apollo space program to mitigate risk due to small sample sizes. The use of FMEA gained momentum during the 1960s, with the push to put a man on the moon and return him safely to earth. In the late 1970s the Ford Motor Company introduced FMEA to the automotive industry for safety and regulatory consideration after the Pinto affair. They also used it to improve production and design. In the 1980s, the automotive industry began implementing FMEA by standardizing the structure and methods through the Automotive Industry Action Group. Although developed by the military, the FMEA method is now extensively used in a variety of industries including semiconductor processing, foodservice, plastics, software, aeronautics, automotive, and healthcare, to name a few.

1.2 FMEA Standards

There are many standards and guidelines published that cover the scope and general procedure for doing FMEAs or FMECAs. Some of the more common and relevant are:

- SAE J1739, Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA) [2009]
- MIL-STD-1629A, Procedures for Performing a Failure Mode Effects and Criticality Analysis (Cited for cancelation in 1994, but still used in some military and other applications)
- SAE ARP5580, Recommended Failure Modes and Effects Analysis (FMEA) Practices for Non-Automobile Applications [2001]
- IEC 60812, Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA) [2006]

1.3 Why do FMEAs?

There are a number of business reasons to implement an effective FMEA Process. When done well, FMEA is a proven tool to reduce life cycle warranty costs. When done well, FMEAs will reduce the number of “oops” during product development. It is far less expensive to prevent problems early in product development than fix problems after launch. FMEAs can identify and address safety issues before a potential catastrophe.

1.4 Definition and purpose of FMEA

Failure Mode and Effects Analysis is a method designed to:

- Identify and fully understand potential failure modes and their causes, and the effects of failure on the system or end users, for a given product or process.
- Assess the risk associated with the identified failure modes, effects and causes, and prioritize issues for corrective action.
- Identify and carry out corrective actions to address the most serious concerns.

An FMEA is an engineering analysis done by a cross-functional team of subject matter experts that thoroughly analyzes product designs or manufacturing processes, early in the product development process. Its objective is finding and correcting weaknesses before the product gets into the hands of the customer.

An FMEA should be the guide to the development of a complete set of actions that will reduce risk associated with the system, subsystem, and component or manufacturing/assembly process to an acceptable level. Performing an FMEA just to fill a checkbox in the Product Development Process and then filing it away, never to be seen again, is a waste of time and adds no value. If not for use as guidance through the development process, why waste the time and resources to do it in the first place? If effectively used throughout the product life cycle, it will result in significant improvements to reliability, safety, quality, delivery, and cost.

The primary objective of an FMEA is to improve the design. For System FMEAs, the objective is to improve the design of the system. For Design FMEAs, the objective is to improve the design of the subsystem or component. For Process FMEAs, the objective is to improve the design of the manufacturing process.

There are many other objectives for doing FMEAs, such as:

- identify and prevent safety hazards
- minimize loss of product performance or performance degradation
- improve test and verification plans (in the case of System or Design FMEAs)
- improve Process Control Plans (in the case of Process FMEAs)
- consider changes to the product design or manufacturing process
- identify significant product or process characteristics
- develop Preventive Maintenance plans for in-service machinery and equipment
- develop online diagnostic techniques

1.5 Types of FMEAs

The most common types of FMEAs are System FMEA, Design FMEA and Process FMEA.

System FMEA is the highest-level analysis of an entire system, made up of various subsystems. The focus is on system-related deficiencies, including system safety, system integration, interfaces or interactions between subsystems or
with other systems, interactions with the surrounding environment, human interaction, service, and other issues that could cause the overall system not to work as intended. In System FMEAs, the focus is on functions and relationships that are unique to the system as a whole (i.e., do not exist at lower levels). Included are failure modes associated with interfaces and interactions, in addition to considering single-point failures (where a single component failure canresult in complete failure of the entire system). Some practitioners separate out human interaction and service into their own respective FMEAs.

**Design FMEA** focuses on product design, typically at the subsystem or component level. The focus is on design-related deficiencies, with emphasis on improving the design and ensuring product operation is safe and reliable during the useful life of the equipment. The scope of the Design FMEA includes the subsystem or component itself, as well as the interfaces between adjacent components. Design FMEA usually assumes the product will be manufactured according to specifications.

**Process FMEA** focuses on the manufacturing or assembly process, emphasizing how the manufacturing process can be improved to ensure that a product is built to design requirements in a safe manner, with minimal downtime, scrap and rework. The scope of a Process FMEA can include manufacturing and assembly operations, shipping, incoming parts, transporting of materials, storage, conveyors, tool maintenance, and labeling. Process FMEAs most often assume the design is sound.

Failure Mode Effects and Criticality Analysis (FMECA) is similar to FMEA, with the added step of a more formal Criticality Analysis. This added step commonly requires objective data to support the criticality calculation. It is recommended for practitioners who are required to perform a FMECA analysis to understand the basics of FMEA first, and then to learn the FMECA procedure.

Some other types of FMEAs include Concept FMEA, a short version of FMEA to aid in selecting optimum concept alternatives or to determine changes to system design specifications; Maintenance FMEA, in support of Reliability Centered Maintenance projects; Hazard Analysis, which focuses on identifying and addressing potential hazards associated with the use of a product; and Software FMEA, which identifies system weaknesses, and evaluates the effectiveness of the software architecture and software specifications.

### 1.6 Success Factors

There are six broad success factors that are critical to uniformity of success in the application of FMEA in any company. The six success factors are listed here, and will be elaborated on later in this tutorial.

1. Understanding the fundamentals and procedures of FMEAs, including the concepts and definitions.
2. Selecting the right FMEA projects
3. Preparation steps for each FMEA project
4. Applying lessons learned and quality objectives
5. Providing excellent facilitation
6. Implementing an effective company-wide FMEA process.

Implementing these FMEA success factors will help ensure FMEAs achieve safe, reliable and economical products and processes.

## 2. UNDERSTANDING THE FUNDAMENTALS AND PROCEDURES OF FMEAS

It is important to begin with an understanding of the basic definitions of FMEAs. Time spent toward understanding the fundamental concepts and definitions of FMEAs will shorten the time in meetings and help ensure high quality results. There is no substitute for having a thorough knowledge and understanding of the FMEA definitions and concepts.

Figure 1 is an example of a Generic FMEA Worksheet, truncated after the “Recommended Actions” column. The numbers in the illustration correspond to the subsections in this paper. The definitions are presented in the sequence they are normally developed in an FMEA project.

![Figure 1. Generic FMEA Worksheet, up through “Recommended Actions”](image)

### 2.1 Item

An “item” (1) is the focus of the FMEA project. For a System FMEA this is the system itself. For a Design FMEA, this is the subsystem or component under analysis. For a Process FMEA, this is usually one of the specific steps of the manufacturing or assembly process under analysis, as represented by an operation description. Figure 2 is an example of an “Item” for a Design FMEA. Figure 3 is an example of an “Item” for a Process FMEA.

![Figure 2. Example of an “Item” for Design FMEA](image)
2.2 Function

A “function” (2) is what the item or process is intended to do, usually to a given standard of performance or requirement. For Design FMEAs, this is the primary purpose or design intent of the item. For Process FMEAs, this is the primary purpose of the manufacturing or assembly operation. Functions are typically described in a verb-noun format. It is essential to include the standard of performance as part of the function statement in order to help describe the failure mode. There can be many functions for each item or operation. Figure 4 is an example of a “Function” for a Design FMEA [3]. Figure 5 is an example of a “Function” for a Process FMEA. Note, in the case of Process FMEAs, the “function” can be similar to the “item”, as described in the operation description for the manufacturing or assembly process.

2.3 Failure Mode

A “failure mode” (3) is the manner in which the item or operation potentially fails to meet or deliver the intended function and associated requirements. It may include failure to perform a function within defined limits, inadequate or poor performance of the function, intermittent performance of a function, and/or performing an unintended or undesired function. The term “failure mode” combines two words that both have unique meanings. The Concise Oxford English Dictionary defines the word “failure” as the act of ceasing to function or the state of not functioning. “Mode” is defined as a way in which something occurs. Figure 6 is an example of a “Failure Mode” for a Design FMEA. Figure 7 is an example of a “Failure Mode” for a Process FMEA.
can be more than one effect for each failure mode. However, typically the FMEA team will use the most serious of the end effects for the analysis. Figure 8 is an example of an “Effect” for a Design FMEA. Figure 9 is an example of an “Effect” for a Process FMEA.

2.5 Severity

“Severity” (5) is a ranking number associated with the most serious effect for a given failure mode, based on the criteria from a severity scale. It is a relative ranking within the scope of the specific FMEA determined without regard to the likelihood of occurrence or detection. Figure 10 is an example of a Severity scale for Design FMEAs. Figure 11 is an example of a Severity scale for Process FMEAs. Note, when applying the severity scale for Process FMEAs, the team assesses the severity of the effect on both product and process and uses the worst case.

2.6 Cause

A “cause” (6) is the specific reason for the failure, preferably found by asking “why” until the root cause is determined. For Design FMEAs, the cause is the design deficiency that results in the failure mode. For Process FMEAs, the cause is the manufacturing or assembly deficiency that results in the failure mode. At the component level, cause should be taken to the level of failure mechanism. If a cause occurs, the corresponding failure mode occurs. There can be many causes for each failure mode. Figure 12 is an example of a “Cause” for a Design FMEA. Figure 13 is an example of a “Cause” for a Process FMEA.
2.7 Occurrence

“Occurrence” (7) is a ranking number associated with the likelihood that the failure mode and its associated cause will be present in the item being analyzed. For System and Design FMEAs, consider the likelihood of occurrence during the design life of the product. For Process FMEAs consider the likelihood of occurrence during production. It is based on the criteria from the corresponding occurrence scale, and has a relative meaning rather than absolute value, determined without regard to the severity or likelihood of detection. Figure 14 is an example of an Occurrence scale for Design FMEAs. Figure 15 is an example of an Occurrence scale for Process FMEAs.

For System or Design FMEAs, prevention-type design controls describe how a cause, failure mode, or effect in the product design is prevented based on current or planned actions. They are intended to reduce the likelihood that the problem will occur, and are used as input to the occurrence ranking. Only those prevention-type controls that are currently planned, or are already in place, should be entered onto the FMEA worksheet. Detection-type design controls describe how a failure mode or cause in the product design is detected, based on current or planned actions before the product design is released to production, and are used as input to the detection ranking. They are intended to increase the likelihood that the problem will be detected before it reaches the end user. Only those detection-type controls that are currently planned, or are already in place, should be entered onto the FMEA worksheet. [3]

Figure 16 is an example of “Design Controls” for a Design FMEA.

For Process FMEAs, prevention-type process controls describe how a cause, failure mode or effect in the manufacturing or assembly process is prevented, based on current or planned actions. Detection-type process controls describe how a failure mode or cause in the manufacturing or assembly process is detected, based on current or planned action, before the item is shipped from the manufacturing or
assembly plant, and are used as an input to the detection ranking. [3]

Figure 17 is an example of “Process Controls” for a Process FMEA.

<table>
<thead>
<tr>
<th>Potential Cause(s) of Failure</th>
<th>Current Design Controls (Prevention)</th>
<th>Current Design Controls (Detection)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cable binds due to inadequate lubrication or poor routing</td>
<td>Hand Brake Design Guide #123</td>
<td>Bicycle system durability test #789</td>
</tr>
<tr>
<td>External foreign material reduces friction</td>
<td>Cable material selection based on ANSI #ABC</td>
<td>Bicycle system durability test #789</td>
</tr>
</tbody>
</table>

Figure 16. Example of “Design Controls” for a Design FMEA.[3]

2.9 Detection

“Detection” (9) is a ranking number associated with the best control from the list of detection-type controls, based on the criteria from the detection scale. It considers the likelihood of detection of the failure mode/cause, according to defined criteria. It is a relative ranking within the scope of the specific FMEA, and is determined without regard to the severity or likelihood of occurrence. Figure 18 is an example of a Detection scale for Design FMEAs. Figure 19 is an example of a Detection scale for Process FMEAs.

Caution is advised when using a Detection scale. The examples in figures 18 and 19 attempt to integrate three types of detection risk into one scale: risk due to the likelihood that the detection-type controls will detect the cause of the failure, risk due to the timing of the detection-type controls, and risk due to the type of detection controls. Practitioners need to be aware of the criteria inherent in detection scales and ensure they are properly used.

2.10 Risk Priority Number (RPN)

“RPN” (10) is a numerical ranking of the risk of each potential failure mode/cause, made up of the arithmetic product of the three elements: severity of the effect, likelihood of occurrence of the cause, and likelihood of detection of the cause.

2.10.1 RPN Limitations

RPN has a number of limitations and is not a perfect representation of the risk associated with a failure mode and associated cause. Practitioners who use RPN should be aware of the inherent limitations and take measures to be sure product and process risks are properly characterized and addressed. Examples of limitations to RPN include:

Example: If the effect of a failure mode has a severity ranking of 10, and the cause of the failure mode has an occurrence ranking of 6 and detection ranking of 4, then the RPN will be 240 (severity 10 x occurrence 6 x detection 4)
1. It is subjective, not objective
2. The potential values of RPN are not continuous
3. The Detection scale has its own limitations
4. There are many duplicate RPN values, representing different combinations of severity, occurrence and detection rankings
5. The practice of using RPN thresholds is not advised. When RPN is used, high severity must be considered regardless of RPN value.

Many companies use alternatives to RPN, such as severity and occurrence. For example, FMECA (FMEA, with the added step of Criticality Analysis) uses severity and occurrence risk rankings as input to the criticality risk, without the use of a detection risk ranking.

When severity and occurrence risk rankings are used by themselves, care must be taken to understand potential risk due to inability to detect failure modes and their causes, and properly characterize and address this risk.

2.10.2 Use of Risk-Ranking Scales

If the risk-ranking scales are not mandated and the team has the flexibility to establish their own scales, the risk-ranking criteria can be tailored, along with the worksheet columns, to satisfy company-specific applications. Regarding the number of scale ranking levels, there is a simple rule to follow: use the minimum number of ranking levels for each scale that adequately differentiates the risk criteria. In other words, if the team can manage with five ranking levels and the needed differentiation of risk for a given application is adequately defined, then use ranking scales with five levels. If ten ranking levels are needed to adequately differentiate and define the risk, use scales that have ten ranking levels.

2.11 Recommended Actions

“Recommended actions” (11) are the tasks recommended by the FMEA team to reduce or eliminate the risk associated with potential causes of failure. They should consider existing controls, relative importance (prioritization) of the issue, and the cost and effectiveness of the corrective action. There can be many recommended actions for each cause. In practice, it usually takes more than one, and sometimes many actions to address high risk issues.

The FMEA team must adequately address all high-severity as well as high-RPN issues. Every task the FMEA team recommends (that is different from what is already planned or in place) shows up in the Recommended Actions column. Figure 20 is an example of “Recommended Actions” for a Design FMEA. Figure 21 is an example of “Recommended Actions” for a Process FMEA.

Completing the FMEA worksheet, “Actions Taken” is the specific action that is implemented to reduce risk to an acceptable level. It should correlate to the specific recommended action, and be assessed as to effectiveness by a revised severity, occurrence, detection ranking, and corresponding revised RPN.

Figure 22 shows the logical relationship between the various elements of FMEAs.

3. SELECTING THE RIGHT FMEA PROJECTS

FMEAs take time and cost money. They should be done when a certain level of risk can be effectively addressed by the FMEA procedure. New product designs can include hundreds or even thousands of subsystems and components. Few companies have the resources to properly do FMEAs on everything. New or modified designs usually require a System FMEA. Lower level FMEA projects can be identified based on well-defined selection criteria.
Companies can identify important criteria for selecting FMEA projects. Selection criteria may include:

- New technology
- New designs where risk is a concern
- New applications of existing technology
- Potential for safety issues
- History of significant field problems
- Potential for important regulation issues
- Mission Critical applications
- Supplier Capability

The risk criteria can each be assessed on a variable scale for the items being considered for FMEAs. Preliminary Risk Assessment criteria can be tailored to the unique needs of any company.

Figure 23 shows an example of preliminary risk assessment done on a bicycle system. This example only shows the bicycle subsystems. The same process can be applied to all of the bicycle components to select FMEA projects.

### 3.1 Timing criteria for FMEAs

In general, FMEAs should be done early in the product development process, where design and process changes can be most easily implemented. Concept FMEAs should be performed during the time when concept alternatives are being considered and before design or process concepts have been selected. System FMEA should be started as soon as the system configuration is determined and completed before the system configuration freeze-date. Design FMEAs should be started as soon as the design concept is determined and completed before the design freeze date. Process FMEAs should be started as soon as the manufacturing or assembly process is determined at the concept level, and completed before the manufacturing or assembly process freeze date.

The high level timing for FMEAs is shown in Figure 24.

### 4. PREPARING FOR FMEA PROJECTS

The importance of good preparation for FMEA projects cannot be emphasized enough. All of the preparation steps are essential for the FMEA project to be successful and completed in a timely manner. Some tasks, such as selecting FMEA software, selecting or modifying FMEA standards and scales, FMEA team training, meeting logistics, and defining the system hierarchy, need doing only once, for all of the FMEA projects. Other tasks may be unique for each project.

Each selected FMEA project requires thorough preparation. The following are the high level preparation tasks. Each of these tasks must be done thoroughly. Short cutting FMEA preparation time will significantly increase the amount of time to do FMEAs and jeopardize quality of results.

- Determine the scope of the FMEA project
- Make the scope visible and get consensus on boundaries (such as FMEA Block Diagram or Process Flow diagram)
- Assemble the right FMEA team (not done by one or two people)
- Establish ground rules and assumptions
- Gather information
- Prepare for the FMEA meetings

An example of an FMEA Block Diagram is shown in Figure 25. It is a System FMEA Block Diagram for a bicycle system, showing only the major subsystems and interfaces. For self-study, you may be able to identify a few interface elements that were intentionally omitted from the diagram.
for a Design FMEA includes representation from systems engineering, design engineering, manufacturing engineering, test engineering, field service, and quality or reliability. An example core team for a Process FMEA includes representation from: manufacturing engineering, plant assembly, product engineering, supplier quality, end-of-line test, maintenance, and quality or reliability. Recommend between 4 and 8 team members.

Examples and checklists for ground rules and assumptions, gather information, and FMEA meeting readiness are available on www.effectivefmeas.com.

5. APPLYING LESSONS LEARNED AND QUALITY OBJECTIVES

Much is learned by observing the mistakes companies have made in doing FMEAs. Based on the experience of over two thousand FMEAs and working with hundreds of companies in a wide variety of applications, certain common mistakes show up repeatedly. What are the primary ways that FMEAs can be done wrongly (mistakes made)? What are the leading factors that make for effective FMEAs (quality objectives)?

Figure 26 shows common FMEA mistakes converted into Quality Objectives.

![Figure 26. FMEA Quality Objectives](image)

Make these FMEA Quality Objectives part of FMEA team training. Review them at each FMEA meeting. Conduct FMEA Quality audits based on these quality objectives. Keep FMEAs open until Quality Objectives are met.

6. PROVIDING EXCELLENT FMEA FACILITATION

FMEA facilitation is a different subject than FMEA methodology. Poorly led FMEA teams will not achieve excellent results. To be successful, FMEA leaders need to develop expert facilitation skills, including brainstorming, encouraging participation, active listening, controlling discussion, making decisions, conflict management, managing level of detail, managing time, and unleashing team creativity.

Facilitators must be well trained in effective meeting facilitation techniques, know the FMEA procedure, and know how to effectively use FMEA software. FMEA team members need to be trained in an overview of FMEA procedure. Good facilitation is essential to prevention of high-risk problems without wasting time.

Figure 27 shows the FMEA Roadmap, which outlines at a high-level the steps for performing effective FMEAs.

![Figure 27. FMEA Roadmap – High Level](image)

7. IMPLEMENTING AN EFFECTIVE FMEA PROCESS

A company-wide FMEA process is the entire set of systems and tasks essential to support development of high-reliability products and processes through timely accomplishment of well-done FMEAs. Key elements of this process include management support for strategy and resources, well-defined roles and responsibilities, management review of high risk issues on an ongoing basis, FMEA quality audits, execution of FMEA recommended actions, and a feedback loop to incorporate lessons learned. Figure 28 shows an effective FMEA process.

The importance of broad support from management in implementing an effective FMEA process cannot be overstated. Management provides agreement on strategy and supports needed resources, assists in integrating FMEA with other business processes, provides effective reviews of high risk failure modes and recommended actions, and mandates attendance of expert FMEA team members.
Figure 28. An Effective FMEA Process

7.1 FMEA Linkages

FMEAs can provide important input for other processes. System/Design FMEAs input to Design Verification Plans, Process FMEAs input to Process Control Plans, and Design FMEAs input to Process FMEAs. In addition, FMEA must be fully integrated with the Product Development Process. Although FMEA can be implemented as a stand-alone process and make significant design or process improvements, properly linking FMEAs to other processes results in efficiencies, and can greatly enhance the effectiveness of individual FMEAs.

8. CONCLUSIONS

Everyone wants to support the accomplishment of safe and trouble-free products and processes while generating satisfied and loyal customers. When done correctly, FMEA can anticipate and prevent problems, reduce costs, shorten product development times, and achieve safe and highly reliable products and processes. Using the FMEA success factors will help ensure the success of FMEA projects.

REFERENCES

1. United States Military, 1949, Mil-P 1629 “Procedure for performing a failure mode effect and criticality analysis”
4. AIAG, Potential Failure Mode and Effects Analysis (FMEA) Reference Manual Fourth Edition [2008]; note, the scales in this tutorial have been re-formatted, abbreviated and/or shortened for readability

APPENDIX - PROBLEMS AND SOLUTIONS

The following FMEA problems and solutions are excerpted from the book Effective FMEAs. The book, along with the companion Solutions Manual, has over 100 problems and solutions, ranging from fundamentals of FMEAs to all aspects of FMEA applications, including case studies, quality audits, FMEA facilitation, FMECA, Design Review Based on Failure Mode (DRBFM), Fault Tree Analysis (FTA), Reliability Centered Maintenance (RCM), Hazard Analysis, and Software FMEA. A few have been selected to introduce FMEA practitioners to this form of self-study. Answers to problems 1 to 5 are at the end of the paper. Problems 6 and 7, along with their respective solutions can be found on the website www.effectivefmeas.com.

Problem 1

Which of the following are true statements about FMEA? (Select all that apply)
1. An FMEA is an engineering analysis done by the most knowledgeable person on the engineering team.
2. Part of the FMEA is to identify and carry out corrective actions to address the most serious concerns.
3. The primary objective of an FMEA is to understand the design.
4. Risk assessment is not part of the FMEA procedure.

Problem 2

Indicate whether each statement about the application of FMEA is true or false.
1. One of the uses of FMEA is to improve the reliability of the product.
2. One of the uses of FMEA is to improve the safety of the product.
3. FMEAs can be used to improve the quality of the manufacturing process.
4. One of the primary applications of FMEA is to fix field problems.

Problem 3

In an FMEA, which of the following is true about a “function”? (Select all that apply)
1. A “function” is what the item is intended to do, without respect to any standard of performance.
2. A “function” is what the item is intended to do, usually to a given standard of performance.
3. There is one function for each item in an FMEA.
4. The function description in an FMEA must include the consequence or impact on the end user.

Problem 4
In an FMEA, which of the following is true about a “failure mode”? (Select all that apply)
1. A “failure mode” is the specific reason for the failure.
2. A “failure mode” is the manner in which the item or assembly could fail to meet the intended function and its requirements.
3. In an FMEA, there is one failure mode for each function.
4. The failure mode description in an FMEA must include the consequence or impact on the end user.

Problem 5
In an FMEA, which of the following is true about a “control”? (Select all that apply)
1. A “control” is the specific recommendation by the FMEA team to control the risk associated with the cause of failure.
2. A “control” needs to be taken to the level of root cause of the failure.
3. There are often two types of controls identified in an FMEA: prevention-type controls and detection-type controls.
4. “Controls” are the methods or actions that are not currently planned, but need to be done to reduce or eliminate the design-related risk associated with the cause of failure.
5. “Controls” are the methods or actions that are planned or currently in place to reduce or eliminate the design-related risk associated with the cause of failure.

Problem 6
- Study the “Pencil Problem” on the website www.effectivefmeas.com (click on link “FMEA Links and Articles”, click on “Pencil Problem”)
- Perform problems 1 through 9. Compare answers to Solutions at the end of the Pencil Problem.

Problem 7
- Study the “Projector Lamp Problem” on the website www.effectivefmeas.com (click on link “FMEA Links and Articles”, click on “Projector Lamp Problem”)
- Perform problems 1 through 9. Compare answers to Solutions at the end of the Projector Lamp Problem.

Solutions to Self-study Problems
Solution 1
Which of the following are true statements about FMEA? (Select all that apply.)
1. An FMEA is an engineering analysis done by the most knowledgeable person on the engineering team. (False. An FMEA is an engineering analysis done by a cross-functional team of subject-matter experts.)
2. Part of the FMEA is to identify and carry out corrective actions to address the most serious concerns. (True)
3. The primary objective of an FMEA is to understand the design. (False. The primary objective of an FMEA is to improve the design.)
4. Risk assessment is not part of the FMEA procedure. (False. Risk assessment is an integral part of the FMEA procedure.)

Solution 2
Indicate whether each statement about the application of FMEA is true or false.
1. One of the uses of FMEA is to improve the reliability of the product. (True)
2. One of the uses of FMEA is to improve the safety of the product. (True)
3. FMEAs can be used to improve the quality of the manufacturing process. (True)
4. One of the primary applications of FMEA is to fix field problems. (False)

Solution 3
In an FMEA, which of the following is true about a “function”? (Select all that apply)
1. A “function” is the specific reason for the failure. (False. A function description needs to include the standard of performance.)
2. A “function” is what the item is intended to do, usually to a given standard of performance. (True)
3. There is one function for each item in an FMEA. (False. There can be many functions for an item.)
4. The function description in an FMEA must include the consequence or impact on the end user. (False. An effect must include the consequence or impact on the end user, not a function.)

Solution 4
In an FMEA, which of the following is true about a “failure mode”? (Select all that apply)
1. A “failure mode” is the specific reason for the failure. (False. A “failure mode” is the manner in which the item or assembly could fail to meet the intended function and its requirements.)
2. A “failure mode” is the manner in which the item or assembly could fail to meet the intended function and its requirements. (True)

3. In an FMEA, there is one failure mode for each function. (False. There can be many failure modes for each function.)

4. The failure mode description in an FMEA must include the consequence or impact on the end user. (False. An effect must include the consequence or impact on the end user, not a failure mode.)

Solution 5

In an FMEA, which of the following is true about a “control”? (Select all that apply)

1. A “control” is the specific recommendation by the FMEA team to control the risk associated with the cause of failure. (False. Controls are the methods or actions that are planned or currently in place to reduce or eliminate the design-related risk associated with the cause of failure. Recommendations need to be in the Recommended Actions column of the FMEA.)

2. A “control” needs to be taken to the level of root cause of the failure. (False. Causes in the FMEA need to be taken to the level of root cause, not controls.)

3. There are often two types of controls identified in an FMEA: prevention-type controls and detection-type controls. (True)

4. “Controls” are the methods or actions that are not currently planned, but need to be done to reduce or eliminate the design-related risk associated with the cause of failure. (False. Controls are methods or actions that are planned or currently in place.)

5. “Controls” are the methods or actions that are planned or currently in place to reduce or eliminate the design-related risk associated with the cause of failure. (True)

Solution 6

The solution to the “Pencil Problem” can be found on the website www.effectivefmeas.com (click on link “FMEA Links and Articles”, click on “Pencil Problem”)

Solution 7

The solution to the “Projector Lamp Problem” can be found on the website www.effectivefmeas.com (click on link “FMEA Links and Articles”, click “Projector Lamp Problem”)
Understanding and Applying the Fundamentals of FMEAs

Carl S. Carlson
ReliaSoft Corporation

Purpose
The purpose of this tutorial is to share the fundamental concepts and procedures for effective FMEAs and highlight the six FMEA success factors.

Failure Mode and Effects Analysis
• You either love it ... 
• ... or hate it.

Everyone has an opinion!

Heard at the “Virtual” Water Cooler
• “Waste of time,” “lack of support,” “don’t want anything to do with it”
• “Powerful tool,” “effective way to prevent problems” and “needs to be done across the board”

So, What’s the Truth About FMEA?
• Is it a giant waste of time and resources?
• Or is it a powerful tool that is essential to the goal of designing in reliability?

Drum Roll!
And the answer is...
It depends!

OK. So what does the success of this potentially powerful tool depend on?

FMEA Success Factors

Six broad success factors are critical to uniformity of success in the application of FMEA in any company:
1. Understanding the fundamentals and procedures of FMEAs, including the concepts and definitions
2. Selecting the right FMEA projects
3. Preparing for FMEA projects
4. Applying lessons learned and quality objectives
5. Providing excellent facilitation
6. Implementing an effective company-wide FMEA process

Implementing FMEA success factors will uniformly ensure FMEAs achieve safe, reliable and economical products and processes.

History of FMEA

- FMEA was formalized in 1949 by the US Armed Forces in the publication Mil-P-1629 Procedure for performing a failure mode effect and criticality analysis. The objective was to classify failures according to their impact on mission success and personnel/equipment safety.
- It was later adopted in the Apollo space program to mitigate risk due to small sample sizes.
- The use of FMEA gained momentum during the 1960s with the push to put a man on the moon and return him safely to earth.

History of FMEA (continued)

- Ford Motor Company introduced FMEA to the automotive industry in the late 1970s for safety and regulatory consideration after the Pinto affair.
- In the 1980s, the automotive industry began implementing FMEA by standardizing the structure and procedures through the Automotive Industry Action Group.
- FMEA is now extensively used in a variety of industries including semiconductor processing, foodservice, plastics, software, automotive, aerospace and healthcare.

Why Perform FMEAs?

- There are a number of business reasons to implement an effective FMEA Process
  - When done well, FMEA is a proven tool to reduce life cycle warranty costs, and reduce the number of “oops” during product development
  - It is far less expensive to prevent problems early in product development than fix problems after launch
  - FMEAs can identify and address safety issues before a potential catastrophe
1st FMEA Success Factor

Understanding the fundamentals and procedures of FMEAs, including concepts and definitions

Definition of FMEA

Failure Mode and Effects Analysis (FMEA) is a method designed to:
- Identify and fully understand potential failure modes and their causes, and the effects of failure on the system or end users, for a given product or process.
- Assess the risk associated with the identified failure modes, effects and causes, and prioritize issues for corrective action.
- Identify and carry out corrective actions to address the most serious concerns.

What is FMEA?

An FMEA is an engineering analysis
- done by a cross-functional team of subject matter experts
- that thoroughly analyzes product designs or manufacturing processes
- early in the product development process.
- Finds and corrects weaknesses before the product gets into the hands of the customer.

Primary Objective of FMEA

The primary objective of an FMEA is to improve the design.
- For System FMEAs, the objective is to improve the design of the system.
- For Design FMEAs, the objective is to improve the design of the subsystem or component.
- For Process FMEAs, the objective is to improve the design of the manufacturing process.

Primary Objective of FMEA

There are many other objectives for doing FMEAs, such as:
- prevent safety hazards
- improve Design Verification Plans (in the case of System or Design FMEAs)
- improve Process Control Plans (in the case of Process FMEAs)
- consider changes to the product design or manufacturing process
- develop Preventive Maintenance plans for in-service machinery and equipment

Types of FMEAs

The three most common types of FMEAs are:
- System FMEA
- Design FMEA
- Process FMEA
System FMEA

Highest-level analysis of entire system, made up of various subsystems; focus on system-related deficiencies:
- system safety, system integration
- interfaces between subsystems, adjacent systems, or surrounding environment
- single-point failures
- functions and relationships unique to system
- human interactions,
- service

Design FMEA

Analysis is at the subsystem or component level; focus on product design-related deficiencies:
- improving the design
- ensuring product operation is safe and reliable
- interfaces between adjacent components.
Design FMEA usually assumes the product will be manufactured according to specifications.

Process FMEA

Analysis at manufacturing/assembly process level; focus on manufacturing related deficiencies:
- improving the manufacturing process
- ensuring the product is built to design requirements in a safe manner, with minimal downtime, scrap and rework.
- manufacturing and assembly operations, shipping, incoming parts, transporting of materials, storage, conveyors, tool maintenance, and labeling.

Process FMEAs most often assume design is sound

Other Types of FMEAs

- Failure Mode Effects and Criticality Analysis (FMECA)
- Concept FMEA
- Maintenance FMEA
- Hazard Analysis
- Software FMEA

The fundamentals of FMEA apply to all types of FMEAs

FMEA Definitions and Examples

<table>
<thead>
<tr>
<th>Item</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity</th>
<th>Potential Cause(s) of Failure</th>
<th>Occurrence</th>
<th>Current Design Controls (Prevention)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
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<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Item Identification – Bicycle Example**

1.0 All-Terrain Bicycle System
   - 1.1 Frame Subsystem
   - 1.2 Front Wheel Subsystem
   - 1.3 Rear Wheel Subsystem
   - 1.4 Pedal-Pedal Subsystem
   - 1.5 Chain-Carder Subsystem
   - 1.6 Seat Subsystem
   - 1.7 Handle Bar Subsystem
   - 1.8 Hand Brake Subsystem
      - 1.8.1 Brake Cable
      - 1.8.2 Brake Pads
      - 1.8.3 Brake Calliper
   - 1.9 Suspension Subsystem

**Item Identification for Process FMEA**

1.0 All-Terrain Bicycle Assembly
   - 1.1 Frame Subassembly
   - 1.2 Front Wheel Subassembly
   - 1.2.1 Get wheel hub from parts presentation device
   - 1.2.2 Orient and place wheel hub in wheel assembly fixture
   - 1.2.3 Get wheel rim from parts presentation device
   - 1.2.4 Orient and place wheel rim in wheel assembly fixture
   - 1.2.5 Get set of wheel spokes from parts presentation device
   - 1.2.6 Orient and place wheel spokes in wheel assembly fixture
   - 1.2.7 Attach and tighten spokes to wheel rim and wheel hub
   - 1.2.8 Adjust spoke tightness to ensure wheel rim is round to specs
   - 1.2.9 Get tire liner from parts presentation device
   - 1.2.10 Orient and install tire liner around wheel rim

**Sample Item Description: DFMEA Example**

Item: Power steering pump

**Poorlyworded example of an Item:**

**System**

**Sample Item Description: PFMEA Example**

Process Step: Induction harden vehicle axle shafts using induction-hardening machine

**Poorlyworded example of a Process Step:**

Install part A

**Item [1]**

An “item” is the focus of the FMEA project.

- For a System FMEA, this is the system itself.
- For a Design FMEA, this is the subsystem or component under analysis.
- For a Process FMEA, this is usually one of the specific steps of the manufacturing or assembly process under analysis, as represented by an operation description.
Function [2]

A “function” is what the item or process is intended to do, usually to a given standard of performance or requirement.
- For Design FMEAs, this is the primary purpose or design intent of the item.
- For Process FMEAs, this is the primary purpose of the manufacturing or assembly operation.
- Functions are typically described in a verb-noun format.
- There can be many functions for each item or operation.

Sample Function Description: DFMEA Example

Item: Power steering pump

Function: Delivers hydraulic power for steering by transforming oil pressure at inlet \([xx]\) psi into higher oil pressure at outlet \([yy]\) psi during engine idle speed

Poorly worded example of a Function: Provides hydraulic power

Sample Function Description: PFMEA Example

Process Step: Induction harden vehicle axle shafts using induction-hardening machine

Function: Induction harden shafts using induction-hardening machine ABC, with minimum hardness Brinell Hardness Number (BHN) “X”, according to specification #123.

Poorly worded example of a Function: Induction harden the shafts

Failure Mode [3]

The term “failure mode” combines two words that both have unique meanings.
- The Concise Oxford English Dictionary defines the word “failure” as the act of ceasing to function or the state of not functioning.
- “Mode” is defined as a way in which something occurs.
**Failure Mode**

A “failure mode” is the manner in which the item or operation potentially fails to meet or deliver the intended function and associated requirements.
- may include failure to perform a function within defined limits
- inadequate or poor performance of the function
- intermittent performance of a function
- and/or performing an unintended or undesired function

**Sample Failure Mode Description: DFMEA Example**

Item: Power steering pump

Function: Delivers hydraulic power for steering by transforming oil pressure at inlet \((x)\) psi into higher oil pressure at outlet \((y)\) psi during engine idle speed

*Failure Mode:* Inadequate outlet pressure (less than \([y]\) psi)

*Poorly worded example of a Failure Mode:* Power steering pump fails

**Sample Failure Mode Description: PFMEA Example**

Process Step: Induction harden vehicle axle shafts using induction-hardening machine

Function: Induction harden shafts using induction-hardening machine ABC, with minimum hardness Brinell Hardness Number (BHN) ‘X’, according to specification #123.

*Failure Mode:* Shaft hardness less than BHN “X”

*Poorly worded example of a Failure Mode:* Shaft fails

**Effect [4]**

An “effect” is the consequence of the failure on the system or end user.
- This can be single description of the effect on top-level system and/or end user, or three levels of effects (local, next-higher level, and end effect)
- For Process FMEAs, consider the effect at the manufacture or assembly level, as well as at the system or end user.
- There can be more than one effect for each failure mode. However, typically the FMEA team will use the most serious of the end effects for the analysis.
Sample Effect Description:
DFMEA Example
Item: Power steering pump

Effect (Local Pump): Low pressure fluid goes to steering gear
Effect (Next level: Steering Subsystem): Increased friction at steering gear
Effect (End user): Increased steering effort with potential accident during steering maneuvers

Poorly worded example of an Effect: Unsafe

Sample Effect Description:
PFEA Example
Process Step: Induction harden vehicle axle shafts using induction-hardening machine

Effect (In plant): 100% scrap
Effect (Assembly): Not noticeable during assembly
Effect (End user): Shaft fractures with complete loss of performance, and increased potential for loss of vehicle control

Poorly worded example of an Effect: Customer unhappy

Severity [5]

"Severity" is a ranking number associated with the most serious effect for a given failure mode. Based on the criteria from a severity scale, a relative ranking within the scope of the specific FMEA, determined without regard to the likelihood of occurrence or detection.

Example Severity Scale

<table>
<thead>
<tr>
<th>Effect</th>
<th>Criteria: Severity of Effect on Product</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to Meet Safety or Regulatory Requirements</td>
<td>Potential failure mode affects safe operation or regulatory requirements w/o warning</td>
<td>10</td>
</tr>
<tr>
<td>Loss or Degradation of Primary Function</td>
<td>Degradation of primary function</td>
<td>7</td>
</tr>
<tr>
<td>Loss or Degradation of Secondary Function</td>
<td>Degradation of secondary function</td>
<td>5</td>
</tr>
<tr>
<td>Potential failure mode affects safe operation or regulatory requirements with warning</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Loss or Degradation of Primary Function</td>
<td>Loss of primary function</td>
<td>8</td>
</tr>
<tr>
<td>Loss or Degradation of Secondary Function</td>
<td>Loss of secondary function</td>
<td>6</td>
</tr>
</tbody>
</table>

TRUNCATED
Cause [6]

A “cause” is the specific reason for the failure, preferably found by asking “why” until the root cause is determined.
- For Design FMEAs, the design deficiency that results in the failure mode.
- For Process FMEAs, the manufacturing or assembly deficiency that results in the failure mode.
- At the component level, cause should be taken to the level of failure mechanism.
- If a cause occurs, corresponding failure mode occurs.
- There can be many causes for each failure mode.

Sample Cause Description: DFMEA Example

Item: Power steering pump

- Failure Mode: Inadequate outlet pressure (less than [yy] psi)

  Cause: Fluid incorrectly specified (viscosity too low)

  Poorly worded example of a Cause: Outlet pressure too low

Sample Cause Description: PFMEA Example

Process Step: Induction harden vehicle axle shafts using induction-hardening machine

- Failure Mode: Shaft hardness less than BHN "X"

  Cause: Induction machine electrical voltage/current settings incorrect for part number

  Poorly worded example of a Cause: Operator error

Occurrence [7]

“Occurrence” is a ranking number associated with the likelihood that the failure mode and its associated cause will be present in the item being analyzed.
- For System and Design FMEAs, consider the likelihood of occurrence during the design life of the product.
- For Process FMEAs, consider the likelihood of occurrence during production.
- Based on the criteria from the corresponding occurrence scale.
- Relative meaning rather than absolute value, determined without regard to severity or likelihood of detection.
Example Occurrence Scale

<table>
<thead>
<tr>
<th>Likelihood of Cause</th>
<th>Criteria: Occurrence of Cause</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High</td>
<td>≥ 100 per thousand</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>≥ 1 in 10</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>50 per thousand</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>1 in 20</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20 per thousand</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>1 in 50</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 per thousand</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>1 in 100</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>2 per thousand</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>1 in 500</td>
<td></td>
</tr>
</tbody>
</table>

Controls [8]

“Controls” are the methods or actions currently planned, or are already in place, to reduce or eliminate the risk associated with each potential cause.

- Controls can be the methods to prevent or detect the cause during product development, or actions to detect a problem during service before it becomes catastrophic.
- There can be many controls for each cause.

Prevention-type Controls

- For Design FMEAs: how a cause, failure mode, or effect in the product design is prevented based on current or planned actions.
- For Process FMEAs: how a cause, failure mode, or effect in manufacturing or assembly is prevented based on current or planned actions.
- They are intended to reduce the likelihood that the problem will occur, and are used as input to the occurrence ranking.

Detection-type Controls

- For Design FMEAs: how a failure mode or cause in the product design is detected based on current or planned actions.
- For Process FMEAs: how a failure mode or cause in manufacturing or assembly is detected based on current or planned actions.
- They are intended to increase the likelihood that the problem will be detected before it reaches the end user.

Sample Control Description: DFMEA Example

**Item:** Power steering pump

**Failure Mode:** Inadequate outlet pressure (less than [x] psi)

**Cause:** Fluid incorrectly specified (viscosity too low)

**Prevention Control:** Design guideline #ABC for hydraulic fluid selection

**Detection Control:** Vehicle durability testing #123

**Poorly worded example of a Prevention Control:** Design Guide

**Poorly worded example of a Detection Control:** Vehicle Durability Test
Detection [9]

“Detection” is a ranking number associated with the best control from the list of detection-type controls, based on the criteria from the detection scale. 
- considers the likelihood of detection of the failure mode/cause, according to defined criteria. 
- a relative ranking within the scope of the specific FMEA. 
- determined without regard to the severity or likelihood of occurrence.

Example of Detection Scale

<table>
<thead>
<tr>
<th>Likelihood of Detection</th>
<th>Criteria: Likelihood of Detection by Design Control</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute Uncertainty</td>
<td>No current design control or cannot be detected</td>
<td>10</td>
</tr>
<tr>
<td>Very Remote</td>
<td>Design analysis/detection controls have a weak detection capability</td>
<td>9</td>
</tr>
<tr>
<td>Remote</td>
<td>Product verification after design freeze and prior to launch with pass/fail testing</td>
<td>8</td>
</tr>
<tr>
<td>Very Low</td>
<td>Product verification after design freeze and prior to launch with test to failure testing</td>
<td>7</td>
</tr>
<tr>
<td>Low</td>
<td>Product verification after design freeze and prior to launch with degradation testing</td>
<td>6</td>
</tr>
</tbody>
</table>

Risk Priority Number (RPN) [10]

“RPN” is a numerical ranking of the risk of each potential failure mode/cause, made up of the arithmetic product of the three elements:
- severity of the effect
- likelihood of occurrence of the cause
- likelihood of detection of the cause.

Example: 240 (10 x 6 x 4)

Limitations of RPN

RPN is not a perfect representation of the risk associated with a failure mode and associated cause.
- Subjective
- Not continuous
- Detection scale limitations
- Duplicate RPNs
- RPN Thresholds (not advised)

High severity must be considered regardless of RPN value
Recommended Actions [11]

“Recommended Actions” are the tasks recommended by the FMEA team to reduce or eliminate risk associated with potential causes of failure.

- They should consider existing controls, relative importance (prioritization) of the issue, and cost-effectiveness of the corrective action.
- There are many recommended actions for each cause.
- FMEA team must adequately address all high-severity as well as high-RPN issues.
- Every task the FMEA team recommends (that is different from what is already planned or in place) shows up in the Recommended Actions column.

Sample Action Description: DFMEA Example

Item: Power steering pump

Potential Cause(s) of Failure: Inadequate outlet pressure (less than [xy] psi)

- Failure Mode: Inadequate outlet pressure (less than [xy] psi)
- Cause: Fluid incorrectly specified (viscosity too low)
- Prevention Control: Design guideline #ABC for hydraulic fluid selection
- Detection Control: Vehicle durability testing #123

**Recommended Action:** Increase fluid viscosity to standard #xyz

Sample Action Description: PFMEA Example

Process Step: Induction harden axle shafts using induction-hardening machine

Potential Cause(s) of Failure: Shaft hardness less than BHN “X”

- Failure Mode: Shaft hardness less than BHN “X”
- Cause: Induction machine electrical volt/current settings incorrect

**Recommended Action:** Install machine alert light (red) to let operator know when voltage/current is set too high

**Recommended Action:** Implement SPC charts on machine voltage and current

Actions Taken

“Actions Taken” is the specific action that is implemented to reduce risk to an acceptable level.

- It should correlate to the specific recommended action.
- It is assessed as to effectiveness by a revised severity, occurrence, detection ranking, and corresponding revised RPN.
Is that all there is to FMEA?

- If FMEA were only an exercise in “filling out a form” then the definitions would be all you need to know.
- There is much more to learn about FMEAs!

2nd FMEA Success Factor

Selecting the right FMEA projects

Criteria for selecting FMEA projects

- Companies can identify important criteria for selecting FMEA projects, such as:
  - New technology
  - New designs where risk is a concern
  - New applications of existing technology
  - Potential for safety issues
  - History of significant field problems
  - Potential for important regulation issues
  - Mission Critical applications
  - Supplier Capability
- Preliminary Risk Assessment criteria can be tailored to unique needs of company.

“The art of being wise is the art of knowing what to overlook.”

--William James, American Philosopher
Preliminary Risk Assessment for New Trail Bike

<table>
<thead>
<tr>
<th>Bicycle Subsystems</th>
<th>Safety</th>
<th>Reliability</th>
<th>Maintainability</th>
<th>New Applications</th>
<th>Field Evaluations</th>
<th>Regulatory</th>
<th>Other</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frame S/S</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>Front Wheel S/S</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
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<tr>
<td>Rear Wheel S/S</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Sprocket S/S</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Chain S/S</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Seat S/S</td>
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<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Handle Bar S/S</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Hand Brake S/S</td>
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<td>2</td>
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<td>1</td>
<td>1</td>
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Timing Criteria for FMEAs

- Concept FMEAs should start when concept alternatives are being considered and complete before concept selection.
- System FMEAs should start when system configuration is determined and complete before system freeze date.
- Design FMEAs should start when design concept is determined and complete before design freeze date.
- Process FMEAs should start when manufacturing or assembly process is determined and complete before manufacturing or assembly process freeze date.

3rd FMEA Success Factor

Preparing for FMEA projects

Preparation Steps for Each FMEA Project

- Each selected FMEA project requires important preparation steps:
  - Determine the scope of the FMEA project
  - Make the scope visible
  - Assemble the right FMEA team
  - Establish ground rules and assumptions
  - Gather information
  - Prepare for FMEA meetings

Preparing for FMEA Projects

- Good preparation is essential!
- Some tasks need doing once, for all FMEA projects, such as:
  - selecting FMEA software
  - selecting or modifying FMEA standards and scales
  - FMEA team training
  - meeting logistics
  - defining the system hierarchy
Determine the scope of the FMEA project

- Refer back to earlier slide on Types of FMEAs, which shows what is included in System, design and process FMEAs.
- Agree on the exact scope of the project and do not allow “scope creep.”

Make the scope visible

- For System/Design FMEAs, an FMEA Block Diagram is a visual depiction of the entire system or design.
- Other optional visual depictions include:
  - FMEA interface matrix
  - The Parameter Diagram (P-Diagram)
  - Functional Block Diagram

Assemble the right FMEA team

- Selecting the right expert team is essential!
- FMEA is a cross-functional team activity
- Performing FMEAs with 1 or 2 people is unacceptable
- Example core team for System/Design FMEA: systems engineering, design engineering, manufacturing engineering, test engineering, field service, and quality or reliability.
- Example core team for Process FMEA: manufacturing engineering, plant assembly, product engineering, supplier quality, end-of-line test, maintenance, and quality or reliability.
- Recommend between 4 and 8 team members

Establish ground rules and assumptions

- Agree on underlying assumptions for analysis, and ground rules for how it will be performed.
- Design FMEAs usually assume the product will be manufactured within engineering specifications.
- Process FMEAs typically assume incoming parts and materials to an operation meet design intent.
- Other assumptions such as environment, operating profiles, meeting norms need to be agreed upon.
Gather information

- Gather all relevant documents and information, including:
  - system configuration
  - drawings
  - past FMEAs
  - technical requirements
  - field history
  - test plans
  - etc.

Prepare for the FMEA meetings

- The time of subject-matter experts is very important and must not be wasted.
- Proper preparation helps ensure time is well spent to the desired result.
- Meeting preparation includes ensuring all of the preparation steps have been properly completed.
- "Ready-for-First-Meeting checklists" are available at www.effectivefmeas.com.

4th FMEA Success Factor

Applying lessons learned and quality objectives

Applying Lessons Learned & Quality Objectives

Much is learned by observing mistakes companies make in doing FMEAs. Certain common mistakes show up repeatedly.

- What are the primary ways that FMEAs can be done wrongly (mistakes made)?
- What are the leading factors that make for effective FMEAs (quality objectives)?

FMEA Quality Objectives

1. DESIGN IMPROVEMENTS The FMEA drives product design or process improvements as the primary objective
2. HIGH RISK FAILURE MODES The FMEA addresses all high-risk failure modes with effective and executable action plans
3. DVP/CONTROL PLAN The Design Verification Plan (DVP) or the Process Control Plan (PCP) considers the failure modes from the FMEA
4. INTERFACES The FMEA scope includes integration and interface failure modes in both block diagram and analysis
5. LESSONS LEARNED The FMEA considers all major "lessons learned" (such as high warranty, campaigns, etc.) as input to failure mode identification

FMEA Quality Objectives

6. LEVEL OF DETAIL The FMEA provides the correct level of detail in order to get to root causes and effective actions
7. TIMING The FMEA is completed during the "window of opportunity" whence it can most effectively influence the product or process design
8. TEAM The right people are adequately trained in the procedure and participate on the FMEA team throughout the analysis
9. DOCUMENTATION The FMEA document is completely filled out "by the book," including "Action Taken" and final risk assessment
10. TIME USAGE Time spent by the FMEA team is an effective and efficient use of time with a value added result
Meeting FMEA Quality Objectives

- Make FMEA Quality Objectives part of FMEA training
- Review them at each meeting
- Participate in FMEA Quality audits
- Keep FMEA open until Quality Objectives are met

5th FMEA Success Factor

Providing excellent facilitation

What are Characteristics of Successful FMEA Facilitation?

- FMEA facilitators must be well trained:
  - effective meeting facilitation techniques
  - FMEA procedure
  - proper use of software
- FMEA team members need to be trained:
  - FMEA concepts and definitions
  - overview of FMEA procedure
- Good facilitation is key to prevention of high-risk problems without wasting time.

Providing Excellent Facilitation

- FMEA facilitation is a different subject than FMEA methodology.
- Poorly led FMEA teams will not achieve excellent results.
- To be successful, FMEA leaders need to develop expert facilitation skills.

Primary FMEA Facilitation Skills

1. Brainstorming
2. Encouraging Participation
3. Active Listening
4. Controlling Discussion
5. Making Decisions
6. Conflict Management
7. Managing Level of Detail
8. Managing Time
9. Unleashing Team Creativity

FMEA Facilitation Roles and Responsibilities (high-level)

1. Ensure the scope and timing of FMEA projects are well defined.
2. Establish and train the FMEA team.
3. Ensure all pre-work is done before first meeting (such as ground rules & assumptions, gather information, etc.).
4. Perform FMEA up through “Recommended Actions.”
5. Review risk and “Recommended Actions” with management.
FMEA Facilitation Roles and Responsibilities (continued)

6. Ensure all “Recommended Actions” are executed.
7. Provide linkage of FMEA with other processes.
8. Verify FMEA Quality Objectives are met.
9. Review and approve critical Supplier FMEAs.
10. Verify risk is reduced to an acceptable level.

6th FMEA Success Factor

Implementing an effective company-wide FMEA process

What is a “Company-wide FMEA Process”?

A company-wide FMEA process is the entire set of systems and tasks essential to support development of high-reliability products and processes through timely accomplishment of well-done FMEAs.

Some Notes on FMEA “Management Support”

The importance of broad support from management in implementing an effective FMEA process cannot be overstated.

- Provides agreement on strategy and supports needed resources
- Assists in integrating FMEA with other business processes
- Provides effective reviews of high risk failure modes and recommended actions
- Mandates attendance of expert FMEA team members
FMEA Linkages

- FMEAs provide important input for other processes:
  - System/Design FMEAs input to Design Verification Plans
  - Process FMEAs input to Process Control Plans
  - Design FMEAs input to Process FMEAs
- FMEA must fully integrate with Product Development Process.
- FMEA can be implemented as a stand-alone process and make significant design or process improvements.
- Linking to other processes increases the effectiveness of FMEAs.

Summarizing the FMEA Success Factors

Implementing FMEA success factors will uniformly ensure FMEAs achieve safe, reliable and economical products and processes:
1. Understanding the fundamentals and procedure of FMEAs, including the concepts and definitions
2. Selecting the right FMEA projects
3. Preparing for each FMEA project
4. Applying lessons learned and quality objectives
5. Providing excellent facilitation
6. Implementing an effective company-wide FMEA process

FMEA Training

- This tutorial is an introduction to the fundamentals of FMEA.
- Learning the fundamentals should be expanded with comprehensive FMEA training.
- One way to become more proficient in FMEA is to study FMEA problems and solutions.
- A few self-study problems and solutions are included at the end of the tutorial manuscript.

In Summary . . .

- Everyone wants to support the accomplishment of safe and trouble-free products and processes while generating happy and loyal customers.
- When done correctly, FMEA can anticipate and prevent problems, reduce costs, shorten product development times, and achieve safe and highly reliable products and processes.

FMEA Resources

- This tutorial is based on the book Effective FMEAs, by Carl S. Carlson, published by John Wiley & Sons, © 2012
- Information about the book and links to useful FMEA articles and aids can be found on www.effectivefmeas.com.
- If you have questions or comments about this tutorial, the subject of FMEAs, or the book Effective FMEAs, please contact the author at Carl.Carlson@EffectiveFMEAs.com.

FMEA Standards

There are many published standards and guidelines that cover the scope and general procedure for doing FMEAs or FMECs. Some of the more common and relevant are:
- SAE J1739, Potential Failure Mode and Effects Analysis in Design (Process FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA) [2009]
FMEA Standards (continued)

- MIL-STD-1629A, Procedures for Performing a Failure Mode Effects and Criticality Analysis (Cited for cancelation in 1994, but still used in some military and other applications)
- SAE ARP5580, Recommended Failure Modes and Effects Analysis (FMEA) Practices for Non-Automobile Applications [2001]
- IEC 60812, Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA) [2006]

Biography

- Carl S. Carlson is a consultant and instructor in the areas of FMEA, reliability program planning and other reliability engineering disciplines, currently supporting clients of RelaSoft Corporation.
- He has over 30 years experience in reliability testing, engineering, and management positions, including manager of product reliability at General Motors.
- Mr. Carlson co-chaired the cross-industry team that developed the commercial FMEA standard (SAE J1739, 2002 version) and was a past member of the RAMS Advisory Board.
- He holds a B.S. in Mechanical Engineering from the University of Michigan, is a senior member of ASQ and a Certified Reliability Engineer. In 2007, he received the Alan O. Platt Award for Tutorial Excellence.
- He can be reached at Carlson@EffectiveFMEAs.com