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Effective FMEAs: Achieving Safe, Reliable, and Economical Products and  
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# Effective FMEAs

## Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis

**Carl S. Carlson**



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*In memory of my parents, for their unwavering support and guidance,  
which continues to inspire my life.*

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# *Series Editor's Foreword*

by Dr. Andre Kleyner  
*Editor of the Wiley Series  
in Quality & Reliability Engineering*

The importance of quality and reliability to a system can hardly be disputed. Product failures in the field inevitably lead to losses in the form of repair cost, warranty claims, customer dissatisfaction, product recalls, loss of sale, and, in extreme cases, loss of life. Thus quality and reliability plays a critical role in the modern science and engineering and as such sees various opportunities and faces a number of challenges.

As quality and reliability science evolves, it reflects the trends and transformations of the technologies it supports. A device utilizing a new technology, whether it be a solar power panel, a stealth aircraft, or a state-of-the-art medical device, needs to function properly and without failure throughout its mission life. New technologies bring about new failure mechanisms (chemical, electrical, physical, mechanical, structural, etc.), new failure sites, and new failure modes. Therefore, continuous advancement of the physics of failure combined with a multidisciplinary approach is essential to our ability to address those challenges in the future.

In addition to the transformations associated with changes in technology, the field of quality and reliability engineering has been going through its own evolution, developing new techniques and methodologies aimed at process improvement and reduction of the number of design- and manufacturing-related failures.

The concepts of Design for Reliability (DfR) have been gaining popularity in recent years, and their development is expected to continue for years to come. DfR methods shift the focus from reliability demonstration and the outdated “Test-Analyze-Fix” philosophy to designing reliability into products and processes using the best available science-based methods. The important part of the DfR process is Failure Mode and Effects Analysis (FMEA).

FMEA helps to transform past design experience into the ability to foresee future problems and to avoid or mitigate them at the early stages of the design, thus effectively translating the old expression “Forewarned is forearmed” into a powerful engineering practice. Properly done, FMEA can anticipate and prevent problems,

reduce costs, shorten product development times, and achieve safe and highly reliable products and processes.

The book you are about to read presents the foundation and a step-by-step procedure for an efficient and cost-effective FMEA. It offers an excellent mix of theory, practice, applications, and common-sense engineering. This book also demonstrates the extensions of FMEA concepts, such as Failure Mode, Effects, and Criticality Analysis (FMECA), Fault Tree Analysis (FTA), Design Review Based on Failure Modes (DRBFM), and their applications to various engineering fields.

As a process, DfR often transforms the role of the reliability engineer from being primarily focused on product test and analysis to being a mentor to the design team, who is responsible for finding and applying the best design methods to achieve reliability. Properly applied DfR process along with FMEA ensures that pursuit of reliability is an enterprise-wide activity.

Several other emerging and continuing trends in quality and reliability engineering are also worth mentioning here. For an increasing number of applications, risk assessment will enhance reliability analysis, addressing not only the probability of failure, but also the quantitative consequences of that failure. Life-cycle engineering concepts are expected to find wider applications to reduce life-cycle risks and minimize the combined cost of design, manufacturing, quality, warranty, and service.

Additionally, continuous globalization and outsourcing affect most industries and complicate the work of quality and reliability professionals. Having various engineering functions distributed around the globe adds a layer of complexity to design coordination and logistics. Also moving design and production into regions with little knowledge depth regarding design and manufacturing processes, with a less robust quality system in place, and where low cost is often the primary driver of product development, affects a company's ability to produce reliable and defect-free parts.

Despite its obvious importance, quality and reliability education is paradoxically missing in today's engineering curriculum. Few engineering schools offer degree programs or even a sufficient variety of courses in quality or reliability methods. Therefore, a majority of the quality and reliability practitioners receive their professional training from colleagues, professional seminars, publications, and technical books. The lack of formal education opportunities in this field greatly emphasizes the importance of technical publications for professional development.

The main objective of the Wiley Series in Quality & Reliability Engineering is to provide a solid educational foundation for both practitioners and researchers in quality and reliability and to expand the reader's knowledge base to include the latest developments in this field. This series continues Wiley's tradition of excellence in technical publishing and provides a lasting and positive contribution to the teaching and practice of engineering.

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Finally, my parents taught me the values of education, perseverance, diligence, humility, respect for a diversity of ideas, and that no one person has all the answers to any subject. Those values have been an immense help in writing this book, for which I am exceedingly grateful.

# *Introduction*

Anything that can possibly go wrong, does.

—Ancient mountaineering adage

Some call it the fourth law of thermodynamics. Some call it an ancient mountaineering adage. The most common ascription is Murphy's Law: "If anything can go wrong, it will." Whatever the source, it pays to anticipate problems and solve them before they entangle customers, or worse, become catastrophic.

Across the globe, development times are becoming shorter, cost concerns more acute, and customers are demanding and expecting absolute safety and high reliability. Companies need to rethink how they achieve these objectives. While it may have been sufficient in the past to focus on testing and analysis as the primary methods of ensuring high reliability, this is no longer sufficient because test-and-fix can take too long and is too costly. It is essential to ensure high design quality and reliability during the early development stages in order to shorten development times and stay within budgets. To do this, it is necessary to focus first on problem *prevention*, rather than merely problem solving, anticipating the factors that can lead to failure and ensuring designs are robust. Failure Mode and Effects Analysis (FMEA) can anticipate and prevent problems and help companies achieve high reliability in products and processes within considerably shorter development times, and within budget.

During my 30-year career in reliability engineering and management, I have had the pleasure of working with thousands of engineers and managers and hundreds of companies. I have never met a single person who does not want to contribute to a successful team effort to develop trouble-free products or processes. Whether part of a design team, manufacturing, management, or a support activity, we all want to see our efforts make a difference in the quality and reliability of the products or services we support. There is a natural passion and energy of employees to achieve trouble-free products. Failure Mode and Effects Analysis is a key tool for accomplishing this objective.

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, and can lose effectiveness.

While working in the fields of aerospace, vehicle engineering, and reliability consulting, I have supervised or performed over 2,000 FMEAs. During this time, I have seen just about every possible way to do FMEAs incorrectly, and discovered simple strategies to learn from these mistakes and turn them into quality objectives. The purpose of this book is to share these best practices for doing FMEAs effectively.

One of the objectives of the book is to teach by example. Many case studies are discussed and examined, including industry-specific applications, two well-known catastrophes (the space shuttle *Challenger* and the McDonnell Douglas DC-10 cargo door blowout), and an FMEA case study on an all-terrain bicycle. Other case studies and stories about FMEA application are interspersed throughout the book. At the end of each chapter is a set of problems that can be useful in learning the fundamentals of FMEA and how FMEA can be applied to many different activities and industries.

To get good results from FMEAs, it is necessary to learn and apply the correct procedures. To get uniformly outstanding results with each and every FMEA, it is essential to learn and apply a set of simple strategies. This book teaches these strategies.

FMEA has been around for many decades and has a long history as a method to support product designs, manufacturing processes, service, and maintenance. There is a wide range of applications and types of FMEAs. This book is for anyone who wants to learn about FMEAs and how to do them effectively and efficiently regardless of job discipline or prior FMEA experience.

Whether you are involved in product designs, manufacturing, service, maintenance, management, quality, or any other discipline that supports product development and operations, FMEA can be a valuable tool to dramatically increase reliability and ensure safety of equipment, personnel, processes, or services. What is important is to learn from mistakes, follow the simple strategies covered in this book, and do the procedure correctly.

## MY PERSONAL PHILOSOPHY REGARDING FMEAS

Through the synergy engendered by the right team of experts, and by implementing correct and proven methods and procedures, problems can be anticipated and prevented, resulting in safe and trouble-free products and processes, with the inherent risk in any system or process reduced to a very low level.

## END OF CHAPTER PROBLEMS

Beginning with Chapter 2, there is a Problems section at the end of the each chapter to support the learning process of the chapter content. The Problems range from relatively easy to more challenging, including evaluation of actual

FMEA case studies. The solutions to the Problems can be found in the Solutions Manual, which will be available to instructors and industry professionals, at no additional charge. The ordering information can be found at the following web site: <http://www.wiley.com/go/effectivefmeas>.

This web site will also have additional resources, as they become available, including more examples of FMEA definitions, case studies, related FMEA material, illustrations, and useful links.

## **MY PLEDGE TO READERS**

Humility, that low, sweet root, from which all heavenly virtues shoot.

—Thomas More

FMEA is a broad subject, with a wide variety of standards, procedures, and applications. There is no shortage of opinions and ideas from practitioners, both new and experienced. It is impossible to fully satisfy everyone, from every level of experience and every industry and application. However, I encourage feedback, and I will carefully listen to all comments, concerns, criticisms, and suggestions. I will stay engaged and find ways to share comments, suggestions, and knowledge about the subject of FMEA with students, readers, and industry practitioners. In the words of a great teacher, “learning is not a spectator sport.” No one person has all of the answers, and by sharing our experience and knowledge, we can learn from each other.

I sincerely wish you the best in your quest to support safe and trouble-free products and processes.

CARL S. CARLSON

# *Chapter* 1

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## *The Case for Failure Mode and Effects Analysis*

I haven't failed; I've found ten thousand ways that don't work.

—Thomas Edison

### **IN THIS CHAPTER**

Companies and industries across the globe are cutting costs and shortening development times. Yet high reliability and impeccable safety are essential to customer satisfaction and financial viability. This chapter introduces Failure Mode and Effects Analysis (FMEA), highlights FMEA successes, and illustrates how FMEA improves reliability and safety while reducing warranty costs in a variety of industries. This chapter makes the case for FMEA.

#### **1.1 THE NEED FOR EFFECTIVE FMEAs**

One only has to look at past news headlines to see the huge cost of product failures for businesses.

Headline in CNET News:

##### **Microsoft to Extend Xbox 360 Warranty, Take \$1 Billion Hit**

Microsoft said . . . it will take a \$1 billion charge as it extends the warranty on the Xbox 360, after an investigation showed the game console can be prone to hardware failures.<sup>[1]</sup>

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*Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis*, First Edition. Carl S. Carlson.

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U.S. Consumer Product Safety Commission:

**PC Notebook Computer Batteries Recalled Due to Fire and Burn Hazard**

Name of Product: Lithium-Ion Batteries used in Hewlett-Packard, Toshiba and Dell Notebook Computers. Hazard: These lithium-ion batteries can overheat, posing a fire and burn hazard to consumers.<sup>[2]</sup>

Headline in CNN Money:

**Firestone Tires Recalled**

Bridgestone Corp. . . . recalled 6.5 million of its Firestone-brand tires—the second largest tire recall in U.S. history—in response to complaints the tires may be linked to fatal crashes involving sport utility vehicles.<sup>[3]</sup>

U.S. Consumer Product Safety Commission:

**Yamaha Recalls Snowmobiles Due to Loss of Steering Control**

Name of Product: 2009 Model Year FX10 Snowmobiles. Hazard: A bolt in the right front A arm can loosen in the suspension/steering system, resulting in the sudden loss of steering control. This poses a risk of injury or death to riders.<sup>[4]</sup>

Product recalls, in-service warranty problems, and safety issues can ruin the reputation of companies and put them out of business, in addition to the potential harm or loss to consumers. At minimum, they place a huge financial burden on the bottom line. Can FMEA prevent product failures such as these? The answer is “Yes.” FMEAs, when properly performed on the *correct parts* with the *correct procedure* during the *correct time frame* with the *correct team*, can prevent costly failures before products enter the marketplace. It is far less costly to prevent problems through the proper use of FMEA than to pay for expensive field problems or expensive litigation, and suffer from loss of reputation. Once lost, reputation is very difficult to earn back.

Today, companies face unprecedented worldwide competition through three ever-present challenges: the mandate to reduce costs, faster development times, and high customer expectations for the reliability of products and processes. One of the most powerful tools to meet all three of these challenges is FMEA. Properly done, FMEA will reduce costs by making products more reliable, thus lowering warranty costs and the costs associated with product failures. FMEA will shorten product development times by addressing problems early in the process thus reducing the costly, and time-consuming, test-and-fix treadmill. FMEA will help companies meet customer high expectations for reliability by eliminating or mitigating failures before users or consumers discover them.

Companies already using FMEAs know their value and understand the necessity of doing them. The question is, are the FMEAs being done correctly, with the highest possible quality, and are the powerful results of which they are capable being achieved? Are product designs and manufacturing processes uniformly improving through use of FMEAs? Is field warranty going down? Is rock solid safety being achieved? In business terms, what is the return on investment? This book will enhance the *effectiveness* of FMEAs where currently in use, and reinforce correct application.

Companies not yet doing FMEAs or that are having questionable results from FMEA programs should take a hard look at the cost of quality and reliability failures. Both should seriously consider implementing effective FMEAs as part of their product development process or quality improvement systems. Those having questionable results need to modify their approach and conduct their FMEAs more effectively, which this book is meant to facilitate.

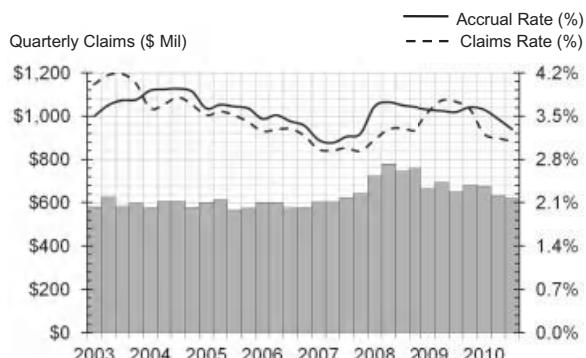
Most corporate and military applications require some form of FMEA, yet questions persist about the overall effectiveness of FMEA as applied in many companies and organizations today. Today, with good reason, results in FMEA applications are mixed. Few reliability tools elicit stronger responses from quality and reliability professionals than FMEA. As for reactions to FMEA around the virtual water cooler, one may hear comments like “waste of time,” “lack of support,” and “don’t want anything to do with it,” at one end, to “powerful tool,” “effective way to prevent problems,” and “needs to be done across the board,” at the other end. So why is there so much variation in the application of a tool that has been around for many decades? How can results be achieved more uniformly and successfully?

The purpose of this book is to teach clearly and simply the entire subject of FMEAs, including the best practice procedures for doing FMEA projects, the pitfalls, the lessons learned to make FMEAs more effective, and how to implement an effective FMEA process in any company or industry.

Take the analysis Figure 1.1, which shows the cost of warranty servicing at Hewlett-Packard from 2003 to 2010. The chart is based on actual warranty expenses, which is lost revenue and demonstrates one of the costs of product failures and customer dissatisfaction. As can be seen from the chart, billions of dollars per year were spent servicing warranty claims, averaging over 3% of total sales.<sup>[5]</sup>

Figure 1.2 shows the warranty costs at the top 20 U.S.-based companies.<sup>[6]</sup>

It is easily seen that many companies are spending huge amounts of money servicing warranty claims, money that could be much better spent designing higher quality products that result in higher customer satisfaction. FMEA used properly is a highly effective tool for accomplishing this objective. The potential cost savings is enormous.



**FIGURE 1.1** Hewlett-Packard warranty claims and accruals 2003–2010.

(Source: Warranty Week from SEC data.)

		Accruals made in 2010	Accrual rate on 12/31/2010
1	General Motors Co.	\$3,204	2.40%
2	Hewlett-Packard Co.	\$2,689	3.20%
3	Ford Motor Co.	\$1,522	1.30%
4	Apple Inc.	\$1,151	1.60%
5	Dell Inc.	\$1,146	2.31%
6	Caterpillar Inc.	\$841	2.10%
7	General Electric Co.	\$583	0.80%
8	Deere & Co.	\$568	2.40%
9	Cisco Systems Inc.	\$471	1.30%
10	United Technologies	\$440	1.14%
11	IBM Corp.	\$407	2.26%
12	Cummins Inc.	\$401	3.00%
13	Motorola Solutions	\$372	1.90%
14	Whirlpool Corp.	\$349	2.50%
15	Motorola Mobility Holdings	\$323	2.80%
16	Navistar International	\$269	2.30%
17	Johnson Controls Inc.	\$250	0.70%
18	Ingersoll-Rand	\$245	1.90%
19	Emerson Electric Co.	\$243	1.00%
20	Honeywell International	\$214	0.81%
<b>TOTAL</b>		<b>\$15,688</b>	

**FIGURE 1.2** Top 20 U.S.-based warranty providers: 2010 annual warranty costs and accrual rates (in \$ millions and as a percent of sales).

(Source: Warranty Week from SEC data.)

Well-done FMEAs improve reliability, ensure safety, and reduce risk to organizations. They are an essential part of doing business.

## 1.2 FMEA APPLICATION BY INDUSTRY

FMEA is a vital task supporting reliability programs in nearly every industry worldwide. Based on a survey of approximately 500 reliability professionals across the globe, FMEA is the most important task in their reliability programs.<sup>[7]</sup>

The American Society of Quality (ASQ) certifies Six Sigma Black Belt candidates. One of the primary topics in ASQ's published Six Sigma Certification Body of Knowledge is FMEA.<sup>[8]</sup>

The automotive industry uses the International Organization for Standardization Technical Specification (ISO/TS 16949:2009) as the quality standard for its suppliers. This standard specifies the precise quality system requirements for suppliers in the automotive sector. FMEA plays a central role in the implementation of this standard.<sup>[9]</sup>

Advanced Product Quality Planning (APQP) is a framework of procedures and techniques used to develop products in industry, particularly the automotive industry. According to the Automotive Industry Action Group (AIAG), the purpose of APQP is "to produce a product quality plan which will support development of a product or service that will satisfy the customer." FMEA is a key requirement of APQP.<sup>[10]</sup>

The Joint Commission Resources (JCR) is a not-for-profit affiliate of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and has as

its mission “to continuously improve the safety and quality of care in the United States and in the international community through the provision of education and consultation services and international services.” The Joint Commission and JCR were named as the first World Health Organization Collaborating Centre for Patient Safety Solutions. In the JCR publication titled *Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction*, it says “FMEA can improve the safety for individuals receiving care by helping to identify failures and near misses and by protecting individuals from harm when, despite an organization’s best efforts, failures do occur.” The publication goes on to say, “It can narrow or eliminate gaps in quality and performance and yield improved outcomes. It is easy to learn and enhances organization-wide collaboration and understanding. Simply stated, its use is good business practice.”<sup>[11]</sup>

A type of FMEA called *Hazard Analysis* plays a central role in the risk assessment approach required in ISO 14971:2007 for medical devices.<sup>[12]</sup>

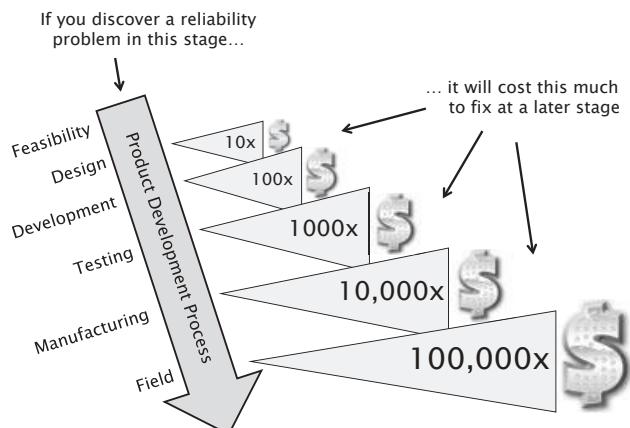
Reliability-Centered Maintenance (RCM) is the analytical process used by most companies to determine preventive maintenance (PM) requirements and ensure safe and cost-effective operations of any system. The core of an RCM project is an FMEA on selected manufacturing or operational equipment.

All branches of the military require FMEAs for joint programs and supplied parts. The type of FMEA often required by the military is Failure Mode Effects and Criticality Analysis (FMECA), which is covered in Chapter 12 of this book.<sup>[13, 14]</sup>

Regardless of what industry one is involved in— aerospace, medical, appliances, electronics, automotive, chemical, energy, services, information, and so on—FMEA is a key tool that supports high reliability, ensures safety, and achieves customer satisfaction.

### 1.3 THE FACTOR OF 10 RULE

Figure 1.3 describes the increasing costs of finding and fixing problems depending on when the problems are discovered. The later problems are found in the product development process, the more it costs to fix them, symbolized by factors of 10.<sup>[15]</sup>



**FIGURE 1.3** Factor of 10 rule.

What can be learned from the “Factor of 10 Rule” about how FMEA supports product improvement?

- FMEAs can assess which designs are best from a feasibility standpoint.
- FMEAs can ensure designs are safe, robust, and have inherently high reliability.
- FMEAs can support streamlined development of products and anticipate problems before being discovered in testing.
- FMEAs can improve the effectiveness of testing to ensure no problems are conveyed to the customer.
- FMEAs can ensure the manufacturing process is stable and in control.
- FMEAs can ensure operation of equipment is safe and cost-effective.

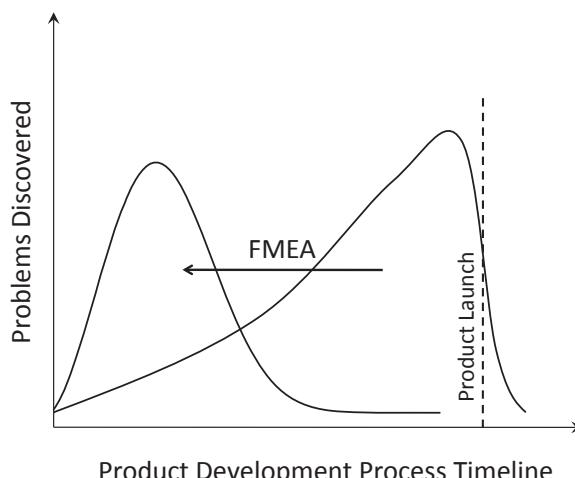
If a company budget cannot support reliability improvement during product development, how can the company expect to budget for the costs of warranty, recalls, and other expensive corrective actions?

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

Figure 1.4 illustrates how FMEA shifts problem discovery to much earlier in the Product Development Process timeline.

#### 1.4 FMEA SUCCESSES

Many companies have had great benefits from the use of FMEAs. The following are brief synopses of five company successes, minus specific details in order to protect



**FIGURE 1.4** FMEA shifts problem discovery earlier in the product development process.

confidentiality. Chapter 8 gives detailed case studies and other case studies are interspersed throughout the book.

### **FMEA Case Study 1**

Cooling systems are an important part of vehicles and residential and commercial buildings. In this example, an FMEA was done on the cooling system of a complex vehicle system. The FMEA team discovered 24 safety-related failure modes with the potential for high frequency in service. If these failure modes were not properly addressed, they could have been dangerous to the customer and catastrophic to the company. All of the safety-related failure modes were addressed with actions recommended by the FMEA team. One example of a failure mode discovered by this FMEA team was a radiator leak caused by corrosion, which was almost certain to occur. The cause of the problem was resolved when the FMEA team recommended changing the design of the radiator using a new corrosion-resistant material.

### **FMEA Case Study 2**

An exercise company was developing a new product with considerable innovation and new technology. The company wanted to ensure their equipment was both safe and reliable. In this example, a System FMEA was conducted on the new exercise equipment. The FMEA team discovered nine failure modes with potential to cause injury to the user. All of these potential failure modes were addressed with specific corrective actions. One of the failure modes had the potential to cause injury to the user due to improper stride length limits. This was resolved by redesigning the stride length feature, making it safe for all users.

### **FMEA Case Study 3**

A company performed a System FMEA on new equipment that uses food products. Particular attention was paid to ensure there were no safety problems due to contamination. The FMEA team uncovered 20 failure modes with potential for bacterial harm to customers. All of them were addressed with adequate action plans. An example was a potential failure mode of a valve leaking due to high pressure in the system. A valve redesign resolved the problem.

### **FMEA Case Study 4**

A company that makes small electronic devices was developing a new product that utilized a tiny speaker. A Design FMEA was done on the speaker subsystem. In this example, seven failure modes were discovered that could potentially result in complete loss of performance, and the FMEA team believed they were very likely to occur. All of these potential failure modes were addressed with specific actions. One example was a diaphragm that was too stiff due to a narrow racetrack. The racetrack was redesigned with better stiffness parameters, resolving this problem.

### **FMEA Case Study 5**

A Process FMEA was done on a vehicle door hanging operation, where the door assembly is bolted onto the vehicle in the assembly plant. At the time of this FMEA,

door fit was not possible within specifications without using an unusual and expensive adjustment procedure. The FMEA team raised this issue to management for review and correction, resulting in a new robust door opening design that no longer required the expensive in-plant adjustment.

In the first four of these case studies, actions were taken to eliminate or mitigate the failures before testing was begun, ensuring the products were safe and reliable, and generating considerable cost savings. When FMEAs are done this way, testing can be done with the objective of confirmation rather than initial discovery. In the fifth case study, an expensive plant operation was eliminated.

## 1.5 BRIEF HISTORY OF FMEA

FMEA was formalized in 1949 by the U.S. Armed Forces by the introduction of Military Procedures document (MIL-P)-1629, “Procedures 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.”<sup>[16]</sup> 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, automotive, and healthcare to name a few.”<sup>[17]</sup>

## 1.6 FMEA STANDARDS AND GUIDELINES

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 guidelines are:

- Society of Automotive Engineers (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]
- AIAG, *Potential Failure Mode and Effects Analysis (FMEA) Reference Manual Fourth Edition* [2008]
- Military Standard (MIL-STD)-1629A, *Procedures for Performing a Failure Mode Effects and Criticality Analysis* (cited for cancellation in 1994, but still used in some military and other applications)

\* Throughout this book, there will be many references to the acronyms FMEA and FMECA. The grammatical convention used will be to refer to *an* FMEA, and *a* FMECA. The reason for this is most practitioners say “ef-em-ee-ae” when referring to FMEA; however, most practitioners say “fah-mee-kah” when referring to FMECA. Therefore, the convention will be to refer to an FMEA and a FMECA.

- SAE ARP5580, *Recommended Failure Modes and Effects Analysis (FMEA) Practices for Non-Automobile Applications* [2001]
- International Electrotechnical Commission (IEC) 60812, *Analysis techniques for system reliability—Procedure for failure mode and effects analysis (FMEA)* [2006]

Many other standards and guidelines promote or mandate the use of FMEA. These will be referenced when relevant to the topics covered in this book.

## 1.7 HOW TO USE THIS BOOK

Most people will benefit from reading the entire book in sequence, chapter by chapter. However, understanding the limited availability of time in people's lives, here are a few suggestions to accommodate those whose scope of application is limited.

Chapter numbers and titles are recapped here for ease in reviewing the section below.

- Chapter 1: The Case for Failure Modes and Effects Analysis
- Chapter 2: The Philosophy and Guiding Principles for Effective FMEAs
- Chapter 3: Understanding the Fundamental Definitions and Concepts of FMEAs
- Chapter 4: Selection and Timing of FMEA Projects
- Chapter 5: How to Perform an FMEA Project: Preparation
- Chapter 6: How to Perform an FMEA Project: Procedure
- Chapter 7: How to Develop and Execute Effective Risk Reduction Actions
- Chapter 8: Case Studies
- Chapter 9: Lessons Learned for Effective FMEAs
- Chapter 10: How to Facilitate Successful FMEA Projects
- Chapter 11: Implementing an Effective Company-Wide FMEA Process
- Chapter 12: Failure Mode Effects and Criticality Analysis (FMECA)
- Chapter 13: Introduction to Design Review Based on Failure Modes (DRBFM)
- Chapter 14: Introduction to Fault Tree Analysis (FTA)
- Chapter 15: Other FMEA Applications
  - Reliability-Centered Maintenance (RCM)
  - Hazard Analysis
  - Concept FMEA
  - Software FMEA
  - Failure Modes, Mechanisms, and Effects Analysis
  - Failure Modes, Effects, and Diagnostic Analysis
- Chapter 16: Selecting the Right FMEA Software

Students who are using the book to learn the fundamentals of FMEA as part of a course of study such as engineering should read at least through Chapter 9 and

further, depending on the individual course of study and its unique objectives. The student should perform the end of chapter problems.

In academia, teachers who would like to integrate FMEA into engineering or other curricula should utilize the material in the book at least through Chapter 9. Instructors may want to add other applications, such as FMEA facilitation, RCM, DRBFM, and so on, as per individual course of study needs. However, it is important to ensure the student understands the basics and applications of FMEA up through Chapter 9, as the unique application chapters build on the foundation established in those chapters.

Industry professionals and practitioners who wish to learn how to perform FMEAs, if new to the subject, or want to improve their results if already experienced with the subject matter, should read at least through Chapter 10. End of chapter problems are optional. Later chapters cover unique applications such as FMECA, FTA, DRBFM, RCM, Hazard Analysis, and so on, and build on the knowledge base of the earlier chapters up through Chapter 10. Therefore, it is important to understand the material from the first 10 chapters, regardless of one's focus on a unique application.

The application of FMEAs to product designs is usually called System or Design FMEAs. The application of FMEAs to manufacturing or assembly processes is called Process FMEAs. These applications share many of the same definitions, concepts, and procedures. Therefore, material relating to both System/Design FMEAs and Process FMEA applications is integrated into each of the chapters in the book. However, wherever there are unique definitions, concepts, or procedures between System/Design FMEAs and Process FMEAs, these are clearly identified.

Managers or executives who will be involved in implementing FMEA processes should read Chapters 2, 4, 9, 10, and 11. Chapters 3 and 5 through 8 are optional, depending on how deeply the manager wishes to learn the fundamentals of FMEA. It is the author's opinion, based on managing engineering and reliability groups for many years, that managers are well served to understand the fundamentals of FMEA as part of implementing a successful FMEA process. However, as mentioned in the beginning of this section, time is limited, and the above chapters are the minimum required for good understanding and application.

## 1.8 WEB COMPANION TO *EFFECTIVE FMEAs*

There is a companion web site to this book. Students and practitioners are encouraged to visit <http://www.wiley.com/go/effectivefmeas>. Additional resources will be posted on this web site as they become available, including more examples of FMEA definitions, case studies, related FMEA material, illustrations, and useful links.

## 1.9 END OF CHAPTER PROBLEMS

Beginning with Chapter 2, end of chapter problems are included to support FMEA application knowledge.

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# *Chapter* 2

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## *The Philosophy and Guiding Principles for Effective FMEAs*

In matters of style, swim with the current; in matters of principle, stand like a rock.  
—Thomas Jefferson

### **IN THIS CHAPTER**

One of the keys to effective Failure Mode and Effects Analyses (FMEAs) is for the entire FMEA process to be driven by the correct philosophy, meaning that the approach is based on the vital few guiding principles that support achieving high reliability in today's competitive environment. This chapter lays out the primary focus areas for doing timely FMEAs effectively. The remaining chapters in this book build on these guiding principles.

#### **2.1 WHAT IS PHILOSOPHY AND WHY DOES IT MATTER TO FMEAs?**

We are boxed in by the boundary conditions of our thinking.

—Albert Einstein

*Philosophy* is a theory or attitude that guides one's behavior. FMEA is a tool that exists in the larger framework of quality and reliability processes. If one's approach to achieving quality and reliability is sound, then it will properly guide the

use of the FMEA tool. Basing one's approach to FMEAs on wrong principles, such as fixing existing problems rather than anticipating and preventing them, or on incorrect objectives, such as "to fill out a form" or "to comply with a mandate," will reap unsatisfactory results.

The guiding principles below originate from the overall philosophy of FMEA as communicated in the Introduction to this book. Again:

Through the synergy engendered by the right team of experts, and by implementing correct and proven methods and procedures, problems can be anticipated and prevented resulting in safe and trouble-free products and processes, with the inherent risk in any system or process reduced to a very low level.

## 2.2 GUIDING PRINCIPLES FOR EFFECTIVE FMEAs

Each of the following is an important guiding principle, applicable to any type of FMEA, which should direct the FMEA process and FMEA practitioners. The remainder of this book embraces these principles.

### 2.2.1 Having the Right Objectives

If you don't know where you are going, you will wind up somewhere else.

—Yogi Berra

**Focus on Problem Prevention** Preventing problems saves money and improves products. Fixing problems is necessary when they occur, but is substantially more expensive than problem prevention. There is a different mindset in an organization that focuses on problem prevention, and the tools and timing are different. FMEA is a key tool to prevent problems before designs reach testing or processes reach the plant floor, and to improve tests and controls to be sure problems do not reach consumers. The emphasis for this entire book is problem *prevention*.

**Focus on Design and Process Improvements** In order to achieve safe and reliable product and process designs in a timely manner, it is essential for FMEAs to drive design and process *improvements* as the primary objective. Safe and trouble-free designs and stable, capable, and error-proof manufacturing processes must be the primary goal. FMEAs need to drive action strategies that improve designs and processes. Chapter 7 describes many action strategies that can be employed to improve designs and processes, and reduce risk to a very low level.

**Leverage FMEAs to Improve Test Plans and Process Controls** Effective product testing and manufacturing process controls are essential elements of successful product development. Tests and process controls must accurately detect all possible failures and their causes based on the entire range of operating profiles and customers usages. FMEAs can and should improve test plans and process controls. Chapter 6 shows how FMEAs link to design verification and process controls.

**Select FMEA Projects Based on Preliminary Risk Assessment** FMEAs take time and cost money. It is not possible to perform FMEAs on every subsystem and component. A company should use the FMEA tool for projects that present a threshold level of risk based on a preliminary risk assessment. Chapter 4, Section 4.2, explains how to select FMEA projects.

**Keep It Simple** Some FMEA practitioners complicate FMEAs with extraneous and nonvalue information. Columns can be added to FMEAs that may seem like a good idea, but add time without corresponding value. Risk ranking scales can have too many ranking levels and complex criteria that lack clarity. Each and every worksheet column, scale, preparation task, and procedure step must pass this simple test: does it add sufficient value to justify the time that is expended? One of the overriding principles of effective FMEAs is to keep to the essential elements. This book intends to empower FMEA practitioners with knowledge about all aspects of FMEAs so they can make the right choices at each stage and keep the procedure as simple as possible.

### 2.2.2 Having the Right Resources

When every physical and mental resource is focused, one's power to solve a problem multiplies tremendously.

—Norman Vincent Peale

**FMEA Is a Team-Based Activity** To be successful, FMEAs need the right team of subject matter experts. Even the best engineers have blind spots and only a team composed of the right disciplines can provide the necessary input and discussion to ensure all concerns are surfaced and addressed. FMEAs should not be performed by one or two individuals, or with the wrong team composition. Chapter 5, Section 5.3.4, provides guidance in establishing the correct FMEA team and ensuring they are properly trained.

**Fully Understand the Basics of FMEAs** There is no shortcut to understanding the definitions and concepts of FMEAs. Knowing the basics of FMEAs, such as key definitions and concepts, is essential for learning the proper application of FMEAs to achieve safe, reliable, and economical products and processes. FMEA teams need to be well trained on the fundamentals of FMEA and the correct procedures. Chapter 3 covers all of the key definitions, with many real-world examples.

**Provide Skilled FMEA Facilitation and Unleash FMEA Team Creativity** The skill set needed to perform FMEAs is not the same as the skill set needed to facilitate FMEA projects. Good facilitation is crucial for attaining the best results from FMEA teams, shortening FMEA in-meeting time, and maximizing the contributions from subject matter experts. Chapter 10 outlines and explains the unique skills for facilitating successful FMEA projects.

Albert Einstein said, "I am enough of an artist to draw freely upon my imagination. Imagination is more important than knowledge. Knowledge is limited. Imagination encircles the world." When he said that, he certainly did not mean knowledge

is not important. What he meant is that creativity and imagination play significant roles in developing new technology, new products, and new solutions. Many high-risk problems require thinking “outside the box,” and the FMEA team can solve very difficult problems when a skilled facilitator energizes its power of creativity. Chapter 10 covers how to facilitate productive FMEA meetings, unleash creativity, and move the team through the FMEA process to excellent results in a timely manner.

***Benefit from Real-World Lessons Learned*** FMEA has been around for over 50 years and there have been many important lessons learned. Based on the knowledge from thousands of FMEAs and hundreds of companies, certain mistakes are seen to occur repeatedly. FMEA practitioners should not keep repeating these same mistakes. Chapter 9 reveals the most common FMEA mistakes and tells how to translate them into FMEA quality objectives so that results are uniformly exceptional. This chapter also describes an FMEA audit process based upon the FMEA quality objectives.

Another part of lessons learned is the field problems discovered after an FMEA analysis has been completed. No company has ever introduced products with no field problems or failures. An effective process must be in place to capture the test and field failures missed by FMEAs and provide these as input to future FMEA teams.

***Management Plays a Key Role in Establishing and Supporting an Effective FMEA Process*** Individual FMEA practitioners can do their very best to perform FMEAs correctly, but there are certain vital activities that are the proper role of management to implement an effective FMEA process. Without these management-supported steps, FMEAs can flounder and miss the mark. These include establishing the strategy, providing the resources, implementing reviews of high-risk issues, supplier management, FMEA quality audits, integrating FMEAs with other businesses process, and providing the right FMEA software. Chapter 11 outlines the best practices of successful companies in achieving uniformly great results with FMEAs and explains some of the common FMEA implementation mistakes and how to avoid them. Chapter 16 shows how to select the right FMEA software that optimizes FMEA team effectiveness.

***Support the Natural Passion and Energy of Employees to Achieve Trouble-Free Products*** FMEAs have had a reputation for being long, drawn out, and uninteresting. This does not have to be the case and it is hoped that this book will change that reputation where it exists. Every person in a company or organization wants to support safe and trouble-free designs and processes. By following the steps in this book, everyone involved with FMEAs can be part of a dynamic, interesting, and engaging process. Properly done, FMEAs harness the inherent passion and energy that employees have for helping consumers and users receive safe and reliable products.

***Utilize the Wealth of Knowledge in the Fields of Quality and Reliability*** The fields of quality and reliability are fortunate to have professional standards, books, journals, societies, symposiums, and web sites offering a wealth of knowledge and

experience. An effective FMEA process should be infused with the best possible knowledge base. FMEA teams need access to the most credible and effective tools and methods to support each stage of the FMEA. This book provides industry case studies (Chapter 8), examples for each of the key concepts (Chapters 3, 5, and 6), end of chapter problems to challenge the FMEA student (all chapters), a companion web site, and refers to many valuable sources of experience and information.

### 2.2.3 Having the Right Procedures

The desire to know is natural to good men.

—Leonardo da Vinci

**Make It Visible** FMEA is an engineering analysis with conceptual ideas about real parts and processes. Using drawings, diagrams, charts, and real parts to focus the intellect and ideas of the expert team is a necessary element for meaningful discussion and successful outcomes. Making the scope of the project visible will ensure that key elements such as interfaces, integration, key characteristics, functions, and other essential information are not missed. This should be done upfront as part of FMEA preparation and throughout the actual team meetings. Chapter 5, Sections 5.3.2 and 5.3.3 cover how to make the scope of the project visible.

**Ensure FMEAs Are Requirements Driven and Data Driven** Good requirements are a key part of designing for reliability and FMEAs must integrate seamlessly with requirements-driven designs and processes. Likewise, good data are a key element of good product designs and manufacturing processes. Well-organized data from technical specifications, past projects, field history, and other sources drive good FMEAs. Chapter 5 outlines the details of how to integrate FMEAs with requirements and what specific data are needed in preparation for FMEA projects.

**Ensure FMEAs Always Get to Root Cause and Actual Failure Mechanisms for High-Risk Issues** The heart of an FMEA is the *cause*. Well-defined causes provide the opportunity to drive the right behaviors and changes to achieve safe and reliable designs and processes. Essential to defining causes for high-risk issues is to get to the level of the failure mechanism. Chapter 6 describes the correct FMEA procedure, including the “Five Whys” and the basis for arriving at root causes and failure mechanisms that drive effective actions.

**Keep the Focus on Areas of Concern and Risk** In the past, some FMEA teams have been allowed to wander into ever-increasing levels of detail and to spend an inordinate amount of time on low-risk issues. If an FMEA team has lots of spare time and extra budget, performing FMEAs on all subsystems and components and taking up failure modes and causes that are of little or no concern is possible. Most companies are limited in their time, budget, and skilled resources. Therefore, *provided the FMEA team has the correct membership and is led by a skilled facilitator*, it is good practice to limit FMEA entries to areas of genuine concern to one or

more of the team members. Additionally, it serves FMEA teams well to spend more time on areas of higher risk and less time on areas of lower risk. This is further explained in Chapter 10, which covers FMEA facilitation.

**Perform FMEAs Within the Right Time Frame** FMEAs drive design improvements to products and processes and therefore must be done early in the product development process in order to have the greatest impact on product and process designs and support improved test and control methods. Late FMEAs have diminished value. Chapter 4 explains when to do FMEAs to get the best results.

**Fully Execute All Actions to Ensure Risk Reduction to an Acceptable Level** Ignoring FMEA results or not effectively implementing the recommended actions can waste all the work of the FMEA. FMEA issues remain open until each identified risk is reduced to an acceptable level. Chapter 7 shows how to define recommended actions so they are executable, and how to follow up to ensure risk is addressed.

### 2.3 THE ROLE OF FMEA IN DESIGN FOR RELIABILITY

FMEA is an essential tool in Design for Reliability (DFR). DFR is the set of strategies and tools that design-in reliability to products and processes.

Three important statements summarize the reliability philosophy of successful companies:

1. Reliability must be designed-in to products and processes using the best available science-based methods.
2. Knowing how to *calculate* reliability is important, but knowing how to *achieve* reliability is more important.
3. DFR practices must begin early in the design process and must be integrated well into the overall product development cycle.

The overriding philosophy of FMEA supports the Product Development Process and the tools of DFR.

Figure 2.1 shows the relationship of FMEA with DFR.<sup>[1]</sup>

FMEA, driven by requirements and data, supports key design reliability tools, drives design and process improvements, and supports improvements in test regimens and process control methods.

Figure 2.2 shows a “reliability equation.” Consider for a moment, where the majority of the effort should be to improve reliability. The most fruitful effort is on the right side of the equation, by defining, adjusting, and controlling the factors that influence the design, environment, and customer usage. Certainly, it is helpful to calculate or measure reliability; however, focusing on the left side of the equation, while avoiding the right side, does little to improve reliability. FMEAs should attempt to impact the right side of the reliability equation in order to have the greatest impact on achieving reliability objectives.

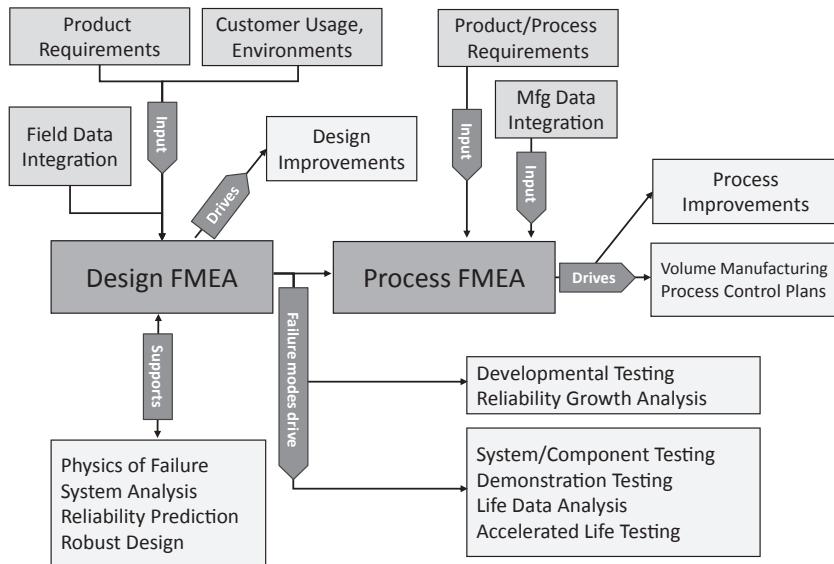


FIGURE 2.1 FMEA relationship with DFR tasks.

$$\text{Reliability} = f \left[ \begin{array}{l} \text{material composition, design parameters,} \\ \text{operating stresses, environmental} \\ \text{conditions, customer usage, system} \\ \text{integration, interfaces between parts, etc.} \end{array} \right]$$

↑  
Measure,  
monitor,  
calculate  
Define, adjust, or control  
the factors that influence  
the design, environment,  
or customer usage

*Question:*

*Where should the focus be to improve reliability?*

*The left or the right side of the equation?*

FIGURE 2.2 Reliability equation.

## 2.4 YOU CAN'T ANTICIPATE EVERYTHING

Prediction is very difficult, especially if it's about the future.

—Niels Bohr

FMEAs are intended to anticipate potential risk and develop actions that will reduce risk to acceptable levels. However, as pointed out in an article written by Daniel Simmons entitled “You Can’t Anticipate Everything,” there is a danger in overconfidence<sup>[2]</sup>:

A standard approach to safety engineering is to try to define all of the potential risks in advance and to design protocols that, if followed precisely, will avoid all of the known hazards. Such safety-by-protocol is great in principle, but it has a critical failing: The illusion of knowledge. The approach assumes that we can know and anticipate all of the potential risks.

In his article, Simmons draws from an experiment in which he shows a video of young people passing basketballs back and forth, and asks the viewer to count the number of times the players in white uniforms pass the ball. Midway through the video, a person in a gorilla costume walks in the middle of the action. It is remarkable that most people who watch the video and focus on counting the passes will entirely miss seeing the gorilla.

In fairness to the participants in this experiment, they were told what to anticipate (i.e., were given blinders, in effect), and so they watched for the passing basketball, and therefore did not see the gorilla walking through. FMEA teams are not given such blinders or limits as to what they may anticipate. Nevertheless, they are vulnerable to not anticipating certain rare or unexpected events, such as the 9.0 Richter scale earthquake and consequent devastating tsunami on March 11, 2011, in Japan.

Simmons continues in his article, “As Nassim Taleb so rightly notes in ‘The Black Swan’, it’s the rare and unexpected events that are the really dangerous ones.”<sup>[2]</sup>

A good FMEA process and skilled facilitator must compensate for this vulnerability and maximize opportunities to anticipate risk.

How can FMEAs *maximize* opportunities to anticipate risk? This book will present many protocols and procedures that will enhance the potential to anticipate high-risk events and minimize the chance of missing them. Readers will learn about brainstorming, divergent-thinking exercises, quality audits, facilitation skills, management reviews, lessons learned, case studies, high severity protocols, correct FMEA team composition, and other topics to help surface both anticipated and previously unanticipated events and occurrences.

No amount of skill will anticipate and prevent every possible problem and risk. However, studying and following the best available procedures brings previously unanticipated events to light and permits properly addressing them.

## 2.5 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

### Problem 2.1

Which of the following statements is true about why FMEAs need to be supported by well-understood and communicated principles? (Select all that apply.)

1. The entire FMEA process needs to be driven by correct philosophy, meaning that the approach is based on proven principles that support achieving high safety and reliability.
2. The essence of “guiding principles” is the specific procedure that the FMEA team follows once the FMEA has begun.

3. If one's approach to doing FMEAs is based on incorrect objectives or wrong principles, then the results will be less than desired.
4. Having the right philosophical approach to doing FMEAs applies to System and Design FMEAs, but not to Process FMEAs.

### Problem 2.2

Which of the following statements about “guiding principles” is correct and why? (Select the correct one.)

1. “Select FMEA projects based on preliminary risk assessment” means that once the project is selected, every item in the bill of material must receive an FMEA.
2. “Keep the focus on areas of concerns and risk” means that if the FMEA team has the correct membership and is led by a skilled facilitator; it is a good practice to limit FMEA entries to areas of genuine concern to one or more of the team members.
3. “Fully execute all actions to ensure risk is reduced to an acceptable level” means that all recommended actions must be reevaluated after execution and the assessed risk is then zero.
4. “Management plays a key role in establishing and supporting an effective FMEA process” means that management must attend all FMEA meetings to ensure they are done properly.

### Problem 2.3

FMEA should align with and support “Design for Reliability.” Which of the following statements embody this relationship? (Select all that are correct.)

1. Knowing how to *calculate* reliability is important, but knowing how to *achieve* reliability is more important.
2. FMEA is a key tool in calculating reliability.
3. Design for Reliability practices must begin early in the design process and be well integrated into the overall product development cycle.
4. Design for Reliability tools precede FMEAs.

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# *Chapter* 3

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## *Understanding the Fundamental Definitions and Concepts of FMEAs*

Intellectuals solve problems, geniuses prevent them.

—Albert Einstein

### **IN THIS CHAPTER**

What exactly is Failure Mode and Effects Analysis (FMEA) and what are its key concepts and definitions? This chapter explains the different types of FMEAs and tells how each is used. The majority of the chapter covers a thorough explanation of the key words and concepts of FMEA, each illustrated with multiple application examples for different types of FMEAs.

#### **3.1 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.

An FMEA is an engineering analysis done by a cross-functional team of subject matter experts that thoroughly analyzes product designs or manufacturing processes

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*Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis*, First Edition. Carl S. Carlson.

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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.

### 3.2 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.

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

FMEA is a vital tool to achieve the above objectives; however, it is important to understand the limitations of FMEA. FMEA does not model the interactions *between* failure modes. When it is necessary to model or understand the interconnected relationship between causes, failure modes, or effects, a Fault Tree Analysis may be the right tool, and can be used to supplement FMEA. Refer to Chapter 14 for information on Fault Tree Analysis. In addition, FMEAs improve reliability but they do not calculate or predict actual reliability. The occurrence ranking of a given failure mode/cause is a relative ranking and, although it may be based on objective failure frequency ranges, it is still a subjective number. If reliability prediction or calculation is needed, other reliability tools do a better job than FMEA. FMEA should be considered as one (albeit essential) tool in the overall reliability plan.

### 3.3 DEFINITION OF FAILURE MODE EFFECTS AND CRITICALITY ANALYSIS

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. Chapter 12 fully explains Criticality Analysis, along with the FMECA procedure. 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.

### 3.4 TYPES OF FMEAs

The three most common types of FMEAs are:

*System FMEA.* This 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 FMEA, the focus is on functions and relationships that are *unique* to the system as a whole (i.e., do not exist at lower levels). The System-level FMEA includes failure modes associated with interfaces and interactions in addition to considering single-point failures (where a single component failure can result in complete failure of the entire system). Some practitioners separate out human interaction and service into their own respective FMEAs.

An example of a System FMEA is a bicycle. The scope of a bicycle System FMEA is the entire bicycle as a system, including the interfaces between the various bicycle subsystems and the integration of the system-level functions. In this example, the purpose is to ensure the bicycle will accomplish its intended functions in a safe and reliable manner as well as to ensure the overall risk of the bicycle system is low. Separate FMEAs cover bicycle subsystems and components, as needed.

*Design FMEA.* This 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 (exceptions covered in Chapter 5, Section 5.3.5).

An example of a Design FMEA at the subsystem level is the hand brake subsystem of a bicycle. The scope of the hand brake Design FMEA is the design of the entire hand brake subsystem, including the interfaces of the various components of the hand brake subsystem. The objective is to ensure the hand brake subsystem accomplishes its intended functions safely and reliably, and the risk due to the subsystem design is low. An example of a Design FMEA at the component level is the bicycle brake pads, with the scope being the design of the brake pads themselves.

*Process FMEA.* This 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 (exceptions covered in Chapter 5, Section 5.3.5).

An example of a Process FMEA is the manufacturing and assembly of a bicycle. In this example, the scope of a bicycle Process FMEA is the entire set of manufacturing and assembly operations of the bicycle. The objective is to ensure that the assembly operations are accomplished as intended in a safe and reliable manner, and ensure the risk due to manufacturing and assembly is low.

Some other types of FMEAs include:

*Concept FMEA.* This is a short version of FMEA to aid in selecting optimum concept alternatives or to determine changes to system design specifications. All potential failure modes and effects of each proposed concept are considered before proceeding with actual design. For example, a bicycle company might be considering three design alternatives. One might be a lightweight design using new material technology, another might be a rugged design with more durable components, and a third could be a hybrid of both. Analyzing the risk of potential failures for each of several bicycle concept alternatives supports determining the most optimum and reliable concept to meet program objectives.

*Reliability-Centered Maintenance (RCM).* This is “an analytical process used to determine preventive maintenance (PM) requirements and identify the need to take other actions that are warranted to ensure safe and cost-effective operations of a system.”<sup>[1]</sup>

The core of an RCM project is an FMEA on selected manufacturing or operational equipment, with additional unique actions that ensure the equipment is safe and reliable in service. An FMEA on a gas turbine to develop the operational maintenance plan or an FMEA on manufacturing equipment, such as a robotic paint application system, to develop the Preventive Maintenance schedule are examples.

*Software FMEA.* This applies to software systems in which software controls the hardware. The focus is on identifying system weaknesses, evaluating the effectiveness of software architecture, validating software safety requirements, and ensuring software specifications can be made comprehensive and unambiguous. The goals are to (1) determine whether the software is fault tolerant with respect to hardware failures and (2) identify missing requirements in the system specification. An example is a Software FMEA on a vehicle antilock brake subsystem (ABS) focusing on how the software works and controls the ABS.

*Hazard Analysis.* This is the process of examining a system throughout its life cycle to identify inherent safety-related risks. The System Hazard Analysis (SHA) focuses on identifying potential hazards associated with the use of a product, estimating and evaluating the risks, controlling the risks, and monitoring the effectiveness of the controls. SHA is required for medical products by U.S. and international regulatory agencies. An example is a Hazard Analysis done on new in vitro medical diagnostic equipment, using the risk assessment approach outlined in International Organization for Standardization (ISO) 14971:2007. Hazard Analysis is used by many other industries as well.

*Human Factors FMEA.* This is a type of system FMEA where the focus is on the interaction between users (humans) and equipment. Sometimes this type of FMEA is integrated with the System FMEA in which the scope of the System FMEA includes human interaction. An example is the human interface to a new missile guidance system, in which the objective is reducing risk associated with interaction between humans and the controllers.

*Service FMEA.* This is a type of system FMEA where the focus is on the installation or service of equipment during operation. Sometimes this type of FMEA is integrated with the System FMEA in which the scope of the System FMEA includes equipment installation and service. An example is servicing an air conditioning system on-site, where the objective is to ensure the installed or serviced air conditioning system operates reliably and safely following service procedures.

*Business Process FMEA.* This focuses on the steps of a business process, and on how to minimize inefficiencies by improving workflow, organizational management, and decision making. It follows a similar format to a Process FMEA, with the exception that the steps of the business process replace the operations of the manufacturing or assembly process. A detailed analysis of the potential failures in a computerized filing system, with the objective of streamlining and improving the system, is an example.

*Failure Modes, Mechanisms, and Effects Analysis (FMMEA).* This “is a systematic methodology to identify potential failure mechanisms and models for all potential failures modes, and to prioritize failure mechanisms. FMMEA enhances the value of the FMEA and FMECA methods by identifying high priority failure mechanisms in order to create an action plan to mitigate their effects. High priority failure mechanisms determine the operational stresses and the environmental and operational parameters that need to be controlled. Models for the failure mechanisms help in the design and development of the product.”<sup>[2]</sup>

*Failure Modes Effects and Diagnostic Analysis (FMEDA).* This is an extension of FMEA with a more systematic way to identify and evaluate the effects of component failure modes. This technique generates failure rates for safety-related effect categories (e.g., failed safe, detected; failed safe, undetected; failed dangerous, detected; failed dangerous, undetected). It is primarily used to develop online diagnostic techniques and as one of the steps to support compliance with International Electrotechnical Commission (IEC) 61508 *Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems.*

### 3.5 FMEA DEFINITIONS AND EXAMPLES

He who loves to practice without theory is like the sailor who boards ship without a rudder and compass and never knows where he may cast.

—Leonardo da Vinci

This section covers the basic definitions of FMEA, along with examples from different types of FMEA applications. Time spent toward understanding the fundamental

Item	Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Design Controls (Prevention)	Current Design Controls (Detection)	Detection	RPN	Recommended Action(s)	Responsible Person	Actions Taken
												Target Completion Date	Effective Completion Date
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(8)	(9)	(10)	(11)		

**FIGURE 3.1** Generic FMEA worksheet. Circled numbers refer to corresponding section numbers in Chapter 3.

concepts and definitions of FMEA 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.

The definitions are presented in the sequence they are normally developed in an FMEA project. In the examples section, where there is one *function* given for an *item*, one *failure mode* for a *function*, or one *cause* for a *failure mode*, it does not mean to imply that there is a one-to-one relationship between these elements. On the contrary, there is a one-to-many relationship between each of the elements of an FMEA, as is further explained in Chapter 6 on the FMEA procedure. Application of the FMEA definitions is also discussed in Chapter 6, along with more thorough examples using the All-Terrain Bicycle project.

FMEA uses a tabular method of presenting data, meaning the content of the analysis is visually displayed in a series of worksheet rows and columns. Figure 3.1 is a generic worksheet with typical FMEA columns (minus revised risk ranking columns, not covered in this chapter). The numbers in each column correlate with the FMEA definitions and examples in this chapter. Note that the Appendix has many more example FMEA worksheets for Design and Process FMEAs.

### 3.5.1 Item

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.

#### Examples of Items for Design FMEAs

- D1. **Item:** Power steering pump
- D2. **Item:** Shaft (part of rock grinding equipment)
- D3. **Item:** Projector lamp
- D4. **Item:** Oven burner assembly
- D5. **Item:** Hydraulic fluid tank
- D6. **Item:** Robotic transfer device

Poorly worded example of **Item:** System

### **Examples of Process Steps for Process FMEAs**

- P1. **Process Step:** Induction harden shafts using induction hardening machine
- P2. **Process Step:** Clamp bicycle upper frame tube in weld fixture
- P3. **Process Step:** Apply lubrication to O-ring using lubricant gun
- P4. **Process Step:** Apply primer to part X using primer paint gun
- P5. **Process Step:** Get part X from part bin and place in fixture
- P6. **Process Step:** Install part A to part B using tool X

Poorly worded example of **Process Step:** Install part A

#### **3.5.2 Function**

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; wording should consider “Do this [operation] to this [the part] with this [the tooling]” along with any needed requirement. There can be many functions for each item or operation. See Chapter 6, Section 6.2.2, which covers the different types of functions, and additional information about application of functions in FMEA procedure.

Functions are typically described in a verb–noun format.

In the FMEA worksheet, the wording of the function and the standard of performance (or requirement) can both be put into the same column (Function) or put into two columns (Function and Requirement).

### **Examples of Functions for Design FMEAs**

- D1. 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 **Function:** Provides hydraulic power

- D2. Item: Shaft (part of rock grinding equipment)

**Function:** Provide mechanical transfer of xx rotational force while maintaining linear and angular stability

- D3. Item: Projector lamp

**Function:** Provide xx lumens of light for image transfer for minimum yy hours of use

- D4. Item: Oven burner assembly

**Function:** Heat the burner plate to 160°F within 60 seconds

- D5. Item: Hydraulic fluid tank

**Function:** Contain the XYZ hydraulic fluid in tank, with no external leakage per specification #456

D6. Item: Robotic transfer device

**Function:** Move the robot arm to desired position, to accuracy of  $\pm 0.1$  mm at each x-y-z coordinate

**Examples of Functions for Process FMEAs**

P1. Process Step: Induction harden shafts using induction hardening machine

**Function:** Induction harden shafts using induction hardening machine ABC, with hardness to specification #123, and case depth /xx/ inches

Poorly worded example of **Function:** Induction harden the shafts

P2. Process Step: Clamp bicycle upper frame tube in weld fixture

**Function:** Securely clamp upper tube in weld fixture, without damaging part and without looseness or movement of part in fixture

P3. Process Step: Apply lubrication to O-ring using lubricant gun

**Function:** Lube O-ring with ABC lubricant, using XYZ specification

P4. Process Step: Apply primer to part X using primer paint gun

**Function:** Apply uniform coat of primer, with thickness and evenness to paint specification #XYZ

P5. Process Step: Get part X from part bin and place in fixture

**Function:** Get part X from bin and place in fixture, to final position x, y, z coordinates

P6. Process Step: Install part A to part B using tool X

**Function:** Install part A to part B with fastener C, and secure using Tool X, to residual torque 25 nm

### 3.5.3 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. Depending on the definition of failure established by the analysis team, failure modes 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.” Combining these two words emphasizes that the failure mode is what presents itself, that is, the *manner* in which the item does not meet the intended function or requirements.

There may be many failure modes for each function. See Chapter 6, Section 6.2.5 for additional information about application of failure modes in FMEA procedure.

**Examples of Failure Modes for Design FMEAs**

D1. 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

**Failure Mode:** Inadequate outlet pressure [less than yy psi]

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

D2. Item: Shaft (part of rock grinding equipment)

Function: Provide mechanical transfer of /xx/ rotational force while maintaining linear and angular stability

**Failure Mode:** Shaft fractured

D3. Item: Projector lamp

Function: Provide xx lumens of light for image transfer for minimum /yy/ hours of use

**Failure Mode:** Lamp shatters

D4. Item: Oven burner assembly

Function: Heat the burner plate to 160°F within 60 seconds

**Failure Mode 1:** Burner plate stays cold

**Failure Mode 2:** Burner plate overheats

**Failure Mode 3:** Burner plate slow heat ramp

D5. Item: Hydraulic fluid tank

Function: Contain the XYZ hydraulic fluid in tank, with no external leakage per specification #456

**Failure Mode 1:** Slow leak

**Failure Mode 2:** Tank rupture

D6. Item: Robotic transfer device

Function: Move the robot arm to desired position, to accuracy of  $\pm 0.1$  mm at each x-y-z coordinate

**Failure Mode 1:** Robot arm does not move when activated

**Failure Mode 2:** Robot arm moves to wrong location

### **Examples of Failure Modes for Process FMEAs**

P1. Process Step: Induction harden 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 **Failure Mode:** Shaft fails

P2. Process Step: Clamp bicycle upper frame tube in weld fixture

Function: Securely clamp upper tube in weld fixture, without damaging part and without looseness or movement of part in fixture

**Failure Mode:** Tube not clamped securely (loose)

P3. Process Step: Apply lubrication to O-ring using lubricant gun

Function: Lube O-ring with ABC lubricant, using XYZ specification

**Failure Mode:** Insufficient lubrication

- P4. Process Step: Apply primer to part X using primer paint gun  
 Function: Apply uniform coat of primer, with thickness and evenness to paint specification #XYZ  
**Failure Mode** 1: No primer  
**Failure Mode** 2: Primer too thick  
**Failure Mode** 3: Primer too thin
- P5. Process Step: Get part X from part bin and place in fixture  
 Function: Get part X from bin and place in fixture, to final position x, y, z coordinates  
**Failure Mode** 1: Wrong part placed in fixture  
**Failure Mode** 2: Part in wrong orientation  
**Failure Mode** 3: Part in wrong position
- P6. Process Step: Install part A to part B using tool X  
 Function: Install part A to part B with fastener C, and secure using Tool X, to residual torque 25 nm  
**Failure Mode** 1: Part A and B loose  
**Failure Mode** 2: Overtorque of Part A and B

An appropriate failure mode description depends on the type of FMEA being performed; in some cases, the cause in a System FMEA will be the failure mode in the Subsystem or Component FMEA. An example will illustrate this concept.

In the Subsystem Design FMEA of a Bicycle Hand Brake Subsystem:

**Failure Mode:** “Insufficient friction delivered between brake pads and wheel rim during heavy rain conditions.”  
**Cause:** “Brake cable breaks”

In the Component Design FMEA for the Brake Cable:

**Failure Mode:** “Brake cable breaks”  
**Causes:** “Wrong cable material” or “Fatigue failure due to overbending”

Therefore, the FMEA team always needs to remain aware at what level of the system hierarchy (system, subsystem, and component) the FMEA is being done. Figure 3.2 shows the progression of failure modes and causes as the FMEA shifts from system to subsystem to component.

**3.5.3.1 Failure Modes at System/Subsystem Level versus Component Level** In order to highlight the difference between failure modes at system or subsystem level compared to component level, more examples follow.

For product designs, a few examples of system-level or subsystem-level failure modes include:

*Unable to Transmit Torque.* If one of the functions of a motor is to transmit torque to some standard of performance, a potential failure mode might be “unable to transmit torque.”

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Potential Cause(s) of Failure
<b>All-Terrain Bicycle System</b>				
The bicycle must provide safe and reliable transportation, including safe stopping distances and safe operation under all customer usage conditions as defined in the All-Terrain technical specification.	Does not stop in required distance	Potential accident or injury to bicycle operator without warning.	10	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions. Brake system misadjusted by bicycle user Underperforming brake system capacity (pads, cables, calipers) Excessive bicycle operator weight
<b>Hand Brake Subsystem</b>				
Provide the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not slow down when the brake lever is pulled, potentially resulting in accident.	10	Cable binds due to inadequate lubrication or poor routing External foreign material reduces friction <b>Cable breaks</b> Brake lever breaks Selected brake pad material does not apply required friction to wheel
<b>Brake Cable</b>				
The brake cable provides adjustable and calibrated movement between the brake lever and brake caliper, under specified conditions of use and operating environment.	<b>Cable breaks</b>	Operator is unable to close brake calipers, wheel does not slow down, possibly resulting in accident.	10	Corrosion of cable wiring due to wrong material selected Fatigue cracks in cable wiring due to inadequate cable thickness

**FIGURE 3.2** Excerpts of bicycle FMEAs showing the progression of Failure Mode and Cause from system to subsystem to component.

**Loss of Structural Support.** If one of the functions of the set of beams in a building is to provide structural support under defined conditions of stress loading, a potential failure mode might be “loss of structural support.”

**Fluid Leak.** If one of the functions of a tank is to contain fluid, without any loss of fluid, a potential failure mode might be “fluid leak.”

**Complete Loss of Electrical Signal.** If one of the functions of a signal generator is to provide a defined electronic output signal to some standard of performance, a potential failure mode might be “complete loss of electrical signal.”

For product designs, a few examples of component-level failure modes include:

**Fatigue Crack.** If one of the functions of a bolt combination is to provide positive clamping force to some defined level, a potential failure mode might be “fatigue crack.” (Note that in a Design FMEA, the concern is the design of the bolt.)

**Ruptured.** If one of the functions of a membrane is to provide physical integrity to an enclosure under defined environmental and stress loads, a potential failure mode might be “ruptured.”

**Seizing.** If one of the functions of a piston is to provide a defined motion within an enclosed channel, a potential failure mode might be “seizing.”

**Lack of Compression.** If one of the functions of a seal is to provide a flexible barrier under defined environments and stresses, a potential failure mode might be “lack of compression.”)

### 3.5.4 Effect

An “effect” is the consequence of the failure on the system or end user. Depending on the ground rules for the analysis, the team may define a single description of the effect on the top-level system and/or end user, or three levels of effects:

*Local Effect.* The consequence of the failure on the item or adjacent items

*Next Higher Level Effect.* The consequence of the failure on the next higher level assembly

*End Effect.* The consequence of the failure on the top-level system and/or end user

For Process FMEAs, the team should consider the effect of the failure at the manufacturing or assembly level, as well as at the system or end user.

There can be more than one effect for each failure mode. However, in most applications the FMEA team will use the most serious of the end effects for the analysis. See Chapter 6, Section 6.2.6, for additional information about application of effects in FMEA procedure.

#### **Examples of Effects for Design FMEAs**

##### D1. 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

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

**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 **Effect**: Unsafe

##### D2. Item: Shaft (part of rock grinding equipment)

Function: Provide mechanical transfer of /xx/ rotational force while maintaining linear and angular stability

Failure Mode: Shaft fractured

**Effect** (Local: Shaft): No torque output (does not transfer energy)

**Effect** (Next level: Grinder Subsystem): Rock grinder teeth do not move

**Effect** (End user): No rocks are pulverized and product order is not filled

##### D3. Item: Projector lamp

Function: Provide xx lumens of light for image transfer for minimum /yy/ hours of use

Failure Mode: Lamp shatters

**Effect**: No light, with potential for operator injury

D4. Item: Oven burner assembly

Function: Heat the burner plate to 160°F within 60 seconds

Failure Mode 1: Burner plate stays cold

**Effect:** No heat to container, with customer dissatisfied

Failure Mode 2: Burner plate overheats

**Effect:** Container overheats, with possible burn injury to user

Failure Mode 3: Burner plate slow heat ramp

**Effect:** Container slow heating, with customer dissatisfied

D5. Item: Hydraulic fluid tank

Function: Contain the XYZ hydraulic fluid in tank, with no external leakage per specification #456

Failure Mode 1: Slow leak

**Effect:** Slow loss of hydraulic fluid, with minor inconvenience to operator

Failure Mode 2: Tank rupture

**Effect:** Rapid loss of hydraulic fluid with potential operator injury

**Examples of Effects for Process FMEAs**

P1. Process Step: Induction harden shafts using induction hardening machine

Function: Induction harden shafts using induction hardening machine ABC, with minimum hardness BHN "X," according to specification #123.

Failure Mode: Shaft hardness less than BHN "X"

**Effect** (In plant): 100% scrap

**Effect** (End user): Potential shaft fracture with complete loss of performance

Poorly worded example of **Effect:** Customer unhappy

P2. Process Step: Clamp bicycle upper frame tube in weld fixture

Function: Securely clamp upper tube in weld fixture, without damaging part and without looseness or movement of part in fixture

Failure Mode: Tube not clamped securely (loose)

**Effect** (In plant): Tube position incorrect, with possible defective welds from tube shifting, and potential for 100% scrap

**Effect** (End user): If upper tubes get out of plant with defective welds, the bicycle frame could collapse, with potential rider injury

P3. Process Step: Apply lubrication to O-ring using lubricant gun

Function: Lube O-ring with ABC lubricant, using XYZ specification

Failure Mode: Insufficient lubrication

**Effect:** Gas leak at fitting, with potential for operator injury; potential hazardous field operation

P4. Process Step: Apply primer to part X using primer paint gun

Function: Apply uniform coat of primer, with thickness and evenness to paint specification #XYZ

Failure Mode 1: No primer

**Effect:** Primer coat operation must be done off-line

Failure Mode 2: Primer too thick

**Effect:** Material must be scrapped

Failure Mode 3: Primer too thin

**Effect:** Primer coat operation must be repaired

### 3.5.5 Severity

“Severity” 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 and is determined without regard to the likelihood of occurrence or detection.

See Figure 3.3 for an example of a severity scale for Design FMEAs and Figure 3.4 for an example of a severity scale for Process FMEAs. These scales are from the Automotive Industry Action Group (AIAG), 4th edition, 2008 Manual, “Potential Failure Mode and Effects Analysis (FMEA).”<sup>[3]</sup>

Suggested DFMEA Severity Evaluation Criteria

Effect	Criteria: Severity of Effect on Product (Customer Effect)	Rank
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	10
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle operable, but comfort/convenience functions inoperable).	6
	Degradation of secondary function (vehicle operable, but comfort/convenience functions at reduced level of performance).	5
Annoyance	Appearance or audible noise, vehicle operable, item does not conform and noticed by most customers (>75%).	4
	Appearance or audible noise, vehicle operable, item does not conform and noticed by many customers (50%).	3
	Appearance or audible noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%).	2
No Effect	No discernible effect.	1

FIGURE 3.3 Example of Design FMEA severity scale.

(Reprinted from “Failure Mode and Effects Analysis (FMEA) 4th Edition,” 2008 Manual, with permission of Chrysler, Ford, and GM Supplier Quality Requirements Task Force.)

### Suggested PFMEA Severity Evaluation Criteria

Effect	Criteria: <b>Severity of Effect on Product (Customer Effect)</b>	Rank	Effect	Criteria: <b>Severity of Effect on Process (Manufacturing/Assembly Effect)</b>
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	10	Failure to Meet Safety and/or Regulatory Requirements	May endanger operator (machine or assembly) without warning.
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9		May endanger operator (machine or assembly) with warning.
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8	Major Disruption	100% of product may have to be scrapped. Line shutdown or stop ship.
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7	Significant Disruption	A portion of the production run may have to be scrapped. Deviation from primary process including decreased line speed or added manpower.
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle operable, but comfort/convenience functions inoperable).	6	Moderate Disruption	100% of production run may have to be reworked off-line and accepted.
	Degradation of secondary function (vehicle operable, but comfort/convenience functions at reduced level of performance).	5		A portion of the production run may have to be reworked offline and accepted.
Annoyance	Appearance or audible noise, vehicle operable, item does not conform and noticed by most customers (>75%).	4	Moderate Disruption	100% of production run may have to be reworked in station before it is processed.
	Appearance or audible noise, vehicle operable, item does not conform and noticed by many customers (50%).	3		A portion of the production run may have to be reworked in station before it is processed.
No Effect	Appearance or audible noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%).	2	Minor Disruption	Slight inconvenience to process, operation, or operator.
	No discernible effect.	1	No Effect	No discernible effect.

**FIGURE 3.4** Example of Process FMEA severity scale.

(Reprinted from "Failure Mode and Effects Analysis (FMEA) 4th Edition," 2008 Manual, with permission of Chrysler, Ford, and GM Supplier Quality Requirements Task Force.)

Note that although these scales use the item “vehicle,” they apply equally well to nonvehicle applications, and are used by hundreds of nonautomotive companies. The categories and criteria for these scales should be reviewed and tailored (as needed) to make sense for individual company applications. Reference Chapter 5, Section 5.2.2 for suggestions on how to establish or modify risk-ranking scales.

### 3.5.6 Cause

A “cause” 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 (or source of variation) that results in the failure mode. In most applications, particularly at the component level, the cause is taken to the level of failure mechanism, which is further explained in Chapter 6, Section 6.2.9. By definition, if a cause occurs, the corresponding failure mode occurs. There can be many causes for each failure mode.

#### ***Examples of Causes for Design FMEA***

##### D1. 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

Failure Mode: Inadequate outlet pressure (less than  $/yy$  psi)

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

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

Poorly worded example of ***Cause:*** Outlet pressure too low

##### D2. Item: Shaft (part of rock grinding equipment)

Function: Provide mechanical transfer of  $/xx$  rotational force while maintaining linear and angular stability

Failure Mode: Shaft fractured

Effect (Local: Shaft): No torque output (does not transfer energy)

Effect (Next level: Grinder Subsystem): Rock grinder teeth do not move

Effect (End user): No rocks are pulverized and product order not filled

***Cause:*** Insufficient shaft strength due to material heat treat incorrectly specified

##### D3. Item: Projector lamp

Function: Provide xx lumens of light for image transfer for minimum  $/yy$  hours of use

Failure Mode: Lamp shatters

Effect: No light, with potential for operator injury

**Cause:** Overpressure due to wrong gas specified

D4. Item: Oven burner assembly

Function: Heat the burner plate to 160°F within 60 seconds

Failure Mode 1: Burner plate stays cold

Effect: No heat to container, with customer dissatisfied

**Cause 1:** Heating coil has open circuit due to wrong wire specification

**Cause 2:** Heating coil to burner plate connector corroded due to moisture intrusion

D5. Item: Hydraulic fluid tank

Function: Contain the XYZ hydraulic fluid in tank, with no external leakage per specification #456

Failure Mode 1: Slow leak

Effect: Slow loss of hydraulic fluid, with minor inconvenience to operator

**Cause 1:** Storage tank has fatigue crack at hose connection due to vibration loads

**Cause 2:** Storage tank wall has pinhole due to corrosion of inner wall

### **Examples of Causes for Process FMEAs**

P1. Process Step: Induction harden shafts using induction hardening machine

Function: Induction harden shafts using induction hardening machine ABC, with minimum hardness BHN "X," according to specification #123.

Failure Mode: Shaft hardness less than BHN "X"

Effect (In plant): 100% scrap

Effect (End user): Potential shaft fracture with complete loss of performance

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

Poorly worded example of **Cause:** Operator error

P2. Process Step: Clamp bicycle upper frame tube in weld fixture

Function: Securely clamp upper tube in weld fixture, without damaging part and without looseness or movement of part in fixture

Failure Mode: Tube not clamped securely (loose)

Effect (In plant): Tube position incorrect, with possible defective welds from tube shifting, and potential for 100% scrap

Effect (End user): If upper tubes get out of plant with defective welds, the bicycle frame could collapse, with potential rider injury

**Cause:** Clamp tooling worn due to lack of scheduled replacement

- P3. Process Step: Apply lubrication to O-ring using lubricant gun  
 Function: Lube O-ring with ABC lubricant, using XYZ specification  
 Failure Mode: Insufficient lubrication  
 Effect: Gas leak at fitting, with potential for operator injury; potential hazardous field operation  
**Cause:** Lubrication gun calibration incorrect due to calibration procedure not followed
- P4. Process Step: Apply primer to part X using primer paint gun  
 Function: Apply uniform coat of primer, with thickness and evenness to paint specification #XYZ  
 Failure Mode 1: No primer  
 Effect: Primer coat operation must be done off-line  
**Cause 1:** Paint gun clogged due to lack of maintenance  
**Cause 2:** No paint in paint holding tank  
 Failure Mode 2: Primer too thick  
 Effect: Material must be scrapped  
**Cause 1:** Shut-off switch does not shut off paint flow due to sensor failure  
**Cause 2:** Paint application equipment not calibrated properly

### 3.5.7 Occurrence

“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, the occurrence ranking considers the likelihood of occurrence during the design life of the product. For Process FMEAs the occurrence ranking considers the likelihood of occurrence during production. It is based on the criteria from the corresponding occurrence scale. The occurrence ranking has a relative meaning rather than an absolute value and is determined without regard to the severity or likelihood of detection.

See Figure 3.5 for an example of an occurrence scale for Design FMEAs and Figure 3.6 for an example of an occurrence scale for Process FMEAs. These scales are from the AIAG, 4th edition, 2008 Manual, “Potential Failure Mode and Effects Analysis (FMEA).”<sup>[3]</sup>

The criteria for these scales should be reviewed and tailored (as needed) to make sense for individual company applications. Reference Chapter 5, Section 5.2.2 for suggestions on how to establish or modify risk-ranking scales.

### 3.5.8 Controls

“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 can be actions to detect a problem during service before it becomes catastrophic. There can be many controls for each cause.

### Suggested DFMEA Occurrence Evaluation Criteria

Likelihood of Failure	Criteria: Occurrence of Cause (Design Life/Reliability of Item/Vehicle)	Criteria: Occurrence of Cause (Incidents per Items/Vehicles)	Rank
Very High	New technology/new design with no history.	$\geq 100$ per thousand $\geq 1$ in 10	10
High	Failure is inevitable with new design, new application, or change in duty cycle/operating conditions.	50 per thousand 1 in 20	9
	Failure is likely with new design, new application, or change in duty cycle/operating conditions.	20 per thousand 1 in 50	8
	Failure is uncertain with new design, new application, or change in duty cycle/operating conditions.	10 per thousand 1 in 100	7
Moderate	Frequent failures associated with similar designs or in design simulation and testing.	2 per thousand 1 in 500	6
	Occasional failures associated with similar designs or in design simulation and testing.	0.5 per thousand 1 in 2000	5
	Isolated failures associated with similar design or in design simulation and testing.	0.1 per thousand 1 in 10,000	4
Low	Only isolated failures associated with almost identical design or in design simulation and testing.	0.01 per thousand 1 in 100,000	3
	No observed failures associated with almost identical design or in design simulation and testing.	$\leq 0.001$ per thousand 1 in 1,000,000	2
Very Low	Failure is eliminated through preventive control.	Failure is eliminated through preventive control.	1

**FIGURE 3.5 Example of Design FMEA occurrence scale.**

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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. Failures managed by system detection, such as tire pressure monitoring, are usually considered prevention-type controls as they reduce the occurrence of the cause. 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. Detection controls are intended to increase the likelihood that the problem will be detected before it reaches the end user.

The idea is to limit controls in the FMEA to what are *currently* planned or that are already in place. See Chapter 6, Sections 6.2.14 and 6.2.15, for additional information about prevention-type controls and detection-type controls in FMEA applications.

### Examples of Controls for Design FMEAs

D1. 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

### Suggested PFMEA Occurrence Evaluation Criteria

Likelihood of Failure	Criteria: Occurrence of Cause—PFMEA (Incidents per Items/Vehicles)	Rank
Very High	≥100 per thousand ≥1 in 10	10
High	50 per thousand 1 in 20	9
	20 per thousand 1 in 50	8
	10 per thousand 1 in 100	7
Moderate	2 per thousand 1 in 500	6
	0.5 per thousand 1 in 2000	5
	0.1 per thousand 1 in 10,000	4
Low	0.01 per thousand 1 in 100,000	3
	≤0.001 per thousand 1 in 1,000,000	2
Very Low	Failure is eliminated through preventive control.	1

**FIGURE 3.6** Example of Process FMEA occurrence scale.

(Reprinted from “Failure Mode and Effects Analysis (FMEA) 4th Edition,” 2008 Manual, with permission of Chrysler, Ford, and GM Supplier Quality Requirements Task Force.)

Failure Mode: Inadequate outlet pressure (less than  $yy$  psi)

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

Cause: Fluid incorrectly specified (viscosity too low)

**Prevention Control:** Design guidelines for hydraulic fluid selection

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

Poorly worded example of **Prevention Control:** Design guide

Poorly worded example of **Detection Control:** Vehicle durability test

D2. Item: Shaft (part of rock grinding equipment)

Function: Provide mechanical transfer of xx rotational force while maintaining linear and angular stability

Failure Mode: Shaft fractured

Effect (Local: Shaft): No torque output (does not transfer energy)

Effect (Next level: Grinder Subsystem): Rock grinder teeth do not move

Effect (End user): No rocks are pulverized, and product order is not filled

Cause: Insufficient shaft strength due to material heat treat incorrectly specified

**Prevention Control:** Heat-treat specification #123

**Detection Control:** Pump pressure shock test, cold start durability test, broken driveshaft test

#### D3. Item: Projector lamp

Function: Provide  $/xx$  lumens of light for image transfer for minimum  $yy$  hours of use

Failure Mode: Lamp shatters

Effect: No light, with potential for operator injury

Cause: Over pressure due to wrong gas specified

**Prevention Control:** Design Guideline for projector lamps including gas properties

**Detection Control:** Lamp pressure test #456

#### D4. Item: Oven burner assembly

Function: Heat the burner plate to 160°F within 60seconds

Failure Mode 1: Burner plate stays cold

Effect: No heat to container, with customer dissatisfied

Cause 1: Heating coil has open circuit due to wrong wire specification

**Prevention Control:** Heating coil wiring specification #456

**Detection Control:** Sneak circuit analysis on heating coil circuitry

Cause 2: Heating coil to burner plate connector corroded due to moisture intrusion

**Prevention Control:** IEEE wiring specification #123

**Detection Control:** Burner-heating test #456

#### D5. Item: Hydraulic fluid tank

Function: Contain the XYZ hydraulic fluid in tank, with no external leakage per specification #456

Failure Mode 1: Slow leak

Effect: Slow loss of hydraulic fluid, with minor inconvenience to operator

Cause 1: Storage tank has fatigue crack at hose connection due to vibration loads

**Prevention Control:** Leak prevention guideline #123

**Detection Control:** Hydraulic fluid tank vibration test #456

Cause 2: Storage tank wall has pinhole due to corrosion of inner wall

**Prevention Control:** None

**Detection Control:** Tank pressure test #ABC (including vibration loading)

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.

### **Examples of Controls for Process FMEAs**

- P1. Process Step: Induction harden shafts using induction hardening machine
- Function: Induction harden shafts using induction hardening machine ABC, with minimum hardness BHN “X,” according to specification #123.
- Failure Mode: Shaft hardness less than BHN “X”
- Effect (In plant): 100% scrap
- Effect (End user): Potential shaft fracture with complete loss of performance
- Cause: Induction machine electrical voltage/current settings incorrect for part number
- Prevention Control:** Shaft hardening setup instructions
- Detection Control:** Audit of shaft hardness
- Poorly worded example of **Prevention Control:** Operator instructions
- Poorly worded example of **Detection Control:** Audit
- P2. Process Step: Clamp bicycle upper frame tube in weld fixture
- Function: Securely clamp upper tube in weld fixture, without damaging part and without looseness or movement of part in fixture
- Failure Mode: Tube not clamped securely (loose)
- Effect (In plant): Tube position incorrect, with possible defective welds from tube shifting, and potential for 100% scrap
- Effect (End user): If upper tubes get out of plant with defective welds, the bicycle frame could collapse, with potential rider injury
- Cause: Clamp tooling worn due to lack of scheduled replacement
- Prevention Control:** Clamp tooling maintenance plan
- Detection Control:** Routine scheduled visual inspection of clamp tool
- P3. Process Step: Apply lubrication to O-ring using lubricant gun
- Function: Lube O-ring with ABC lubricant, using XYZ specification
- Failure Mode: Insufficient lubrication
- Effect: Gas leak at fitting, with potential for operator injury; potential hazardous field operation
- Cause: Lubrication gun calibration incorrect due to calibration procedure not followed
- Prevention Control:** In-plant lube gun calibration procedures
- Detection Control:** End-of-line pressure testing.

### 3.5.9 Detection

“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. The detection ranking considers the likelihood of detection of the failure mode/cause, according to defined criteria. Detection is a relative ranking within the scope of the specific FMEA and is determined without regard to the severity or likelihood of occurrence.

See Figure 3.7 for an example of a detection scale for Design FMEAs and Figure 3.8 for an example of a detection scale for Process FMEAs. These scales are from the AIAG, 4th edition, 2008 Manual, “Potential Failure Mode and Effects Analysis (FMEA).”<sup>[3]</sup>

**Suggested DFMEA Detection Evaluation Criteria**

Opportunity for Detection	Criteria: Likelihood of Detection by Design Control	Rank	Likelihood of Detection
No Detection Opportunity	No current design control; cannot detect or is not analyzed.	10	Almost Impossible
Not Likely to Detect at any Stage	Design analysis/detection controls have a weak detection capability; virtual analysis (e.g., CAE, FEA, etc.) is <u>not correlated</u> to expected actual operating conditions.	9	Very Remote
Postdesign Freeze and Prior to Launch	Product verification/validation after design freeze and prior to launch with <u>pass/fail</u> testing (subsystem or system testing with acceptance criteria such as ride and handling, shipping evaluation, etc.)	8	Remote
	Product verification/validation after design freeze and prior to launch with <u>test to failure</u> testing (subsystem or system testing until failure occurs, testing of system interactions, etc.)	7	Very Low
	Product verification/validation after design freeze and prior to launch with <u>degradation</u> testing (subsystem or system testing after durability test, e.g., function check).	6	Low
Prior to Design Freeze	Product validation (reliability testing, development or validation tests) prior to design freeze using <u>pass/fail</u> testing (e.g., acceptance criteria for performance, function checks, etc.)	5	Moderate
	Product validation (reliability testing, development or validation tests) prior to design freeze using <u>test to failure</u> (e.g., until leaks, yields, cracks, etc.).	4	Moderately High
	Product validation (reliability testing, development or validation tests) prior to design freeze using <u>degradation</u> testing (e.g., data trends, before/after values, etc.)	3	High
Virtual Analysis—Correlated	Design analysis/detection controls have strong detection capability. Virtual analysis (e.g., CAE, FEA, etc.) is <u>highly correlated</u> with actual and/or expected operating conditions prior to design freeze.	2	Very High
Detection Not Applicable; Failure Prevention	Failure cause or failure mode cannot occur because it is fully prevented through design solutions (e.g. proven design standard, best practice or common material, etc.)	1	Almost Certain

**FIGURE 3.7 Example of Design FMEA detection scale.**

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### Suggested PFMEA Detection Evaluation Criteria

Opportunity for Detection	Criteria: Likelihood of Detection by Process Control	Rank	Likelihood of Detection
No Detection Opportunity	No current process control; cannot detect or is not analyzed.	10	Almost Impossible
Not Likely to Detect at any Stage	Failure Mode and/or Error (Cause) is not easily detected (e.g., random audits).	9	Very Remote
Problem Detection Postprocessing	Failure Mode detection postprocessing by operator through visual/tactile/audible means.	8	Remote
Problem Detection at Source	Failure Mode detection in-station by operator through visual/tactile/audible means or postprocessing through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.)	7	Very Low
Problem Detection Postprocessing	Failure Mode detection postprocessing by operator through use of variable gauging or in-station by operator through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.)	6	Low
Problem Detection at Source	Failure Mode or Error (Cause) detection in-station by operator through variable gauging or by automated controls in-station will detect discrepant part and notify operator (light, buzzer, etc.). Gauging performed on setup and first-piece check (for setup causes only)	5	Moderate
Problem Detection Post Processing	Failure Mode detection postprocessing by automated controls that will detect discrepant part and lock part to prevent further processing.	4	Moderately High
Problem Detection at Source	Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing.	3	High
Error Detection and/or Problem Prevention	Error (Cause) detection in-station by automated controls that will detect, error and prevent discrepant part from being made.	2	Very High
Detection Not Applicable; Error Prevention	Error (Cause) prevention as a result of fixture design, machine design, or part design. Discrepant parts cannot be made because item has been error-proofed by process/product design.	1	Almost Certain

**FIGURE 3.8** Example of Process FMEA detection scale.

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The categories and criteria for these scales should be reviewed and tailored (as needed) to make sense for individual company applications. Reference Chapter 5, Section 5.2.2 for suggestions on how to establish or modify risk-ranking scales.

### 3.5.10 Risk Priority Number

Risk Priority Number (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, and likelihood of detection of the cause. Use of RPN is further explained in Chapter 6, Sections 6.2.20 and 6.2.21, including limitations to the use of RPN, and discussion of RPN alternatives.

### 3.5.11 Recommended Actions

“Recommended actions” are the tasks recommended by the FMEA team to reduce or eliminate the risk associated with potential causes of failure. Recommended actions should consider the existing controls, the relative importance (prioritization) of the issue, and the cost and effectiveness of the corrective action. There can be many recommended actions for each cause.

See Chapter 7, Sections 7.2 and 7.3, for information about how to identify effective actions to reduce risk, including action strategies to reduce severity risk, occurrence risk, and detection risk.

#### ***Examples of Recommended Actions for Design FMEAs***

##### D1. 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

Failure Mode: Inadequate outlet pressure (less than  $/yy$  psi)

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

Cause: Fluid incorrectly specified (viscosity too low)

Prevention Control: Design guidelines for hydraulic fluid selection

Detection Control: Vehicle durability testing #123

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

Poorly worded example of ***Recommended Action:*** Change fluid viscosity

##### D2. Item: Shaft (part of rock grinding equipment)

Function: Provide mechanical transfer of xx rotational force while maintaining linear and angular stability

Failure Mode: Shaft fractured

Effect (Local: Shaft): No torque output (does not transfer energy)

Effect (Next level: Grinder Subsystem): Rock grinder teeth do not move

Effect (End user): No rocks are pulverized, and product order is not filled

Cause: Shaft not strong enough due to material heat treat incorrectly specified

Prevention Control: Heat treat specification #123

Detection Control: Pump pressure shock test, cold start durability test, broken driveshaft test

***Recommended Action:*** Increase shaft strength by using more rigorous heat-treat standard #ABC

## D3. Item: Projector lamp

Function: Provide xx lumens of light for image transfer for minimum yy hours of use

Failure Mode: Lamp shatters

Effect: No light, with potential for operator injury

Cause: Over pressure due to wrong gas specified

Prevention Control: Design review including gas properties

Detection Control: Lamp pressure test #456

**Recommended Action:** Reduce gas pressure by changing gas properties to material specification #xyz

### **Examples of Recommended Actions for Process FMEAs**

## P1. Process Step: Induction harden shafts using induction hardening machine

Function: Induction harden shafts using induction hardening machine ABC, with minimum hardness BHN "X," according to specification #123.

Failure Mode: Shaft hardness less than BHN "X"

Effect (In plant): 100% scrap

Effect (End user): Shaft fractures with complete loss of performance

Effect (Assembly): Not noticeable during assembly

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

Prevention Control: Shaft hardening setup instructions

Detection Control: Audit of shaft hardness

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

**Recommended Action:** Implement Statistical Process Control (SPC) charts on machine voltage and current

Poorly worded example of **Recommended Action:** Implement Statistical Process Control

## P2. Process Step: Clamp upper tube in weld fixture

Function: Securely clamp upper tube in weld fixture, without damaging part and without looseness or movement of part in fixture

Failure Mode: Tube not clamped securely (loose)

Effect: (In plant): Tube position incorrect, with possible defective welds from tube shifting, and potential for 100% scrap

Effect: (End user): If upper tubes get out of plant with defective welds, the bicycle frame could collapse, with potential rider injury

Cause: Clamp tooling worn due to lack of scheduled replacement

Prevention Control: Tooling maintenance plan

Detection Control: Routine scheduled visual inspection of clamp tool

**Recommended Action:** Temporarily use daily scheduled visual inspection of clamping tool wear until SPC charts show routine conformance

**Recommended Action:** Use increased hardness clamp tool to reduce wear

### P3. Process Step: Apply lubrication to O-ring using lubricant gun

Function: Lube O-ring with ABC lubricant, using XYZ specification

Failure Mode: Insufficient lubrication

Effect: Gas leak at fitting, with potential for operator injury; system inoperable in field use

Cause: Lubrication gun calibration incorrect due to calibration procedure not followed

Prevention Control: In-plant lube gun calibration procedures

Detection Control: End-of-line pressure testing

**Recommended Action:** Use modified lubrication gun calibration procedure #12345 and update maintenance plan to calibrate every 1000 parts.

Figure 3.9 shows examples of causes, controls, and recommended actions for a Design FMEA for a disk brake system.<sup>[3]</sup>

Figure 3.10 shows examples of causes, controls, and recommended actions for a Process FMEA for a seat-cushion installation operation.<sup>[3]</sup>

Item	Failure Mode	Cause	Prevention Controls	Detection Controls	Recommended Actions
Disk Brake system	Vehicle does not stop	Mechanical linkage break due to environmental corrosion	Designed per material standard MS-845	Environmental stress test 03-9963	Change material to stainless steel.
		Master cylinder vacuum lock	Carry-over design with same duty cycle requirements	Pressure variability testing—system level	None.
		Loss of hydraulic fluid due to back off of connector—hydraulic lines open	Designed per torque requirements—3993	Vibration step-stress test 18-1950	Modify connector from crimp style to quick connect.
		Loss of hydraulic fluid due to hydraulic lines crimped/compressed	Designed per material standard MS-1178	DOE—tube resiliency	Modify hose design from MS-1178 to MS-2025 to increase strength.

**FIGURE 3.9 Examples of causes, controls, and recommended actions for disk brake system.**

(Reprinted from “Failure Mode and Effects Analysis (FMEA) 4th Edition,” 2008 Manual, with permission of Chrysler, Ford, and GM Supplier Quality Requirements Task Force.)

Process Step/Function	Requirement	Failure Mode	Cause	Prevention Controls	Detection Controls	Recommended Actions
Op. 20 (attach seat cushion to track using a torque gun). Select four screws	Four screws	Less than four screws	Too few screws inadvertently installed	Visual aids illustrating correct quantity Operator training	Visual Inspection in station	In-station torque monitoring; line lockout if less than four
	Specified screws	Wrong screw used (larger dia)	Similar screws available at station	Visual aids illustrating correct screw Operator training		
Op. 20 (attach seat cushion to track using a torque gun). Beginning with right front hole, torque each screw to the required torque	Assembly sequence: First screw in right front hole	Screw placed in any other hole	More than one hole available to operator	Visual aids identifying location of first screw	Visual inspection in station	Add position sensor to nut runner, not allowing tool to operate unless runner is aligned with correct hole
				Operator training		

**FIGURE 3.10** Examples of causes, controls, and recommended actions for seat-cushion installation operation.

(Reprinted from “Failure Mode and Effects Analysis (FMEA) 4th Edition,” 2008 Manual, with permission of Chrysler, Ford, and GM Supplier Quality Requirements Task Force.)

### 3.6 IS IT A FAILURE MODE, EFFECT, OR CAUSE?

Things are not always as they seem; the first appearance deceives many.

—Phaedrus

People first learning FMEA definitions and examples often get confused about the difference between failure mode, effect, and cause. A little careful attention to this section, to the definitions given in this book, and a bit of practice, will avoid any such confusion.

Take the example of “leak.” In many cases “leak” is a failure mode, but not always.

**Question:** Can “leak” be a failure mode?

**Answer:** “Yes.”

**Example:** If one function of a storage vessel or tank includes the need to contain fluid to some standard of performance, a “leak” can be a failure mode, which is the manner in which the storage vessel does not perform the containment function.

**Question:** Can “leak” be an effect?

**Answer:** “Yes.”

**Example:** If one function of a vehicle body structure is to provide a safe “crumple zone” during accidents to a given standard of performance, a failure mode can be the structure compresses too quickly, which can result in breach of the vehicle fuel tank integrity and a “leak” of fuel. Thus, “leak” becomes part of the effect description.

**Question:** Can “leak” be a cause?

**Answer:** “Yes.”

**Example:** If one function of a camera flash circuit is to provide the electrical signal for the flash bulb to a given standard of performance, a failure mode can be missing electrical signal and the cause can be capacitor malfunction or “leak.” Note that this is not a *root cause*, as the question still exists why the capacitor leaks. The FMEA team may do an FMEA on the capacitor, or further analyze the cause of the capacitor leakage, in order to arrive at root cause.

A given word or phrase does not itself imply whether it is a failure mode, or an effect, or a cause. Determining whether something is a failure mode, effect, or cause depends on the context in the scenario. There is no substitute for studying and learning many examples for each of the FMEA definitions and concepts, at all different levels of the system hierarchy or the manufacturing operations.

### 3.7 FMEA GLOSSARY

Terms are given in sequence as they occur in an analysis.

*Item* 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* 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; wording should consider “Do this [operation] to this [the part] with this [the tooling]” along with any needed requirement. There may be many functions for each item or operation.

*Failure Mode* The manner in which the item or operation fails to meet or deliver the intended function and its requirements. Depending on the definition of failure established by the analysis team, failure modes 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. There may be many failure modes for each function.

*Effect* The consequence of the failure on the system or end user. For Process FMEAs, the team should consider the effect of the failure at the manufacturing or assembly level, as well as at the system or end user. There can be more than one effect for each failure mode. However, in most applications the FMEA team will use the most serious of the end effects for the analysis.

*Severity* 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 and is determined without regard to the likelihood of occurrence or detection.

*Cause* 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 (or source of variation) that results in the failure mode. In most applications, particularly at the component level, the cause is taken to the level of failure mechanism. By definition, if a cause occurs, the corresponding failure mode occurs. There can be many causes for each failure mode.

**Occurrence** 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, the occurrence ranking considers the likelihood of occurrence during the design life of the product. For Process FMEAs the occurrence ranking considers the likelihood of occurrence during production. It is based on the criteria from the corresponding occurrence scale. The occurrence ranking has a relative meaning rather than an absolute value and is determined without regard to the severity or likelihood of detection.

**Controls** The methods or actions *currently* planned, or that 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 Design Controls** The methods or actions *currently* planned that describe how a cause, failure mode, or effect in the product design is *prevented*. They are intended to reduce the likelihood that the problem will occur, and are used as input to the occurrence ranking.

**Detection-Type Design Controls** The methods or actions *currently* planned that describe how a failure mode or cause in the product design is *detected*, before the product design is released to production. They are used as input to the detection ranking. Detection controls are intended to increase the likelihood that the problem will be detected before it reaches the end user.

**Prevention-Type Process Controls** The methods or actions *currently* planned that describe how a cause, failure mode, or effect in the manufacturing or assembly process is *prevented*. They are intended to reduce the likelihood that the problem will occur, and are used as input to the occurrence ranking.

**Detection-Type Process Controls** The methods or actions *currently* planned that describe how a failure mode or cause in the manufacturing or assembly process is *detected*. They are intended to increase the likelihood that the problem will be detected before the item is shipped from the manufacturing or assembly plant, and are used as an input to the detection ranking.

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

**RPN** RPN is an acronym that stands for “Risk Priority Number.” It 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.

**Recommended Actions** The tasks recommended by the FMEA team that can be performed to reduce or eliminate the risk associated with potential cause of failure. Recommended Actions should consider the existing controls, the relative importance (prioritization) of the issue, and the cost and effectiveness of the corrective action. There can be many recommended actions for each cause.

*Action Taken* The specific action that is implemented to reduce risk to an acceptable level. It should correlate to the recommended action and is assessed as to effectiveness by a revised severity, occurrence, detection ranking, and corresponding revised RPN.

### 3.8 WEB COMPANION TO *EFFECTIVE FMEAs*

More examples of FMEA definitions will be posted on the companion web site to this book. Students and practitioners are encouraged to visit <http://www.wiley.com/go/effectivefmeas>. Additional resources will be posted on this web site as they become available, including more examples of FMEA definitions, case studies, related FMEA material, illustrations, and useful links.

### 3.9 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

#### Problem 3.1

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 3.2

Hypothetical scenario: A hydraulic pump company is developing a new line of hydraulic pumps that has a new material for the pump piston never before used in hydraulic pumps. (Answer True or False for each of the following.)

1. The current hydraulic test procedures should be used. The FMEA should not be used to recommend modifications to pump or piston test procedures. (True/False)
2. The correct sequence is to first test the new pump with the new piston material, and then perform an FMEA to verify the design. (True/False)
3. A Pump System FMEA would include system safety, system integration, and interfaces between the pump subsystems. (True/False)
4. A Piston Design FMEA should be done early in the product development process before the piston design is frozen. (True/False)

**Problem 3.3**

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 3.4**

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 3.5**

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 3.6**

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

1. An “effect” is the specific reason for the failure.
2. An “effect” is the potential consequence or impact of the failure to the system or end user.
3. An “effect” is the manner in which an item does not accomplish its intended functions.
4. None of the above.

**Problem 3.7**

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 3.8**

In an FMEA, which of the following is true about “RPN”? (Select the best answer.)

1. An “RPN” is the sum of Severity, Occurrence, and Detection rankings.
2. An “RPN” is the product of Severity and Occurrence rankings.
3. An “RPN” is the product of Severity, Occurrence, and Detection rankings.
4. None of the above.

**Problem 3.9**

Using the AIAG (4th ed., 2008) severity scales (reference Figures 3.2 and 3.3), select an appropriate severity ranking for the following examples of effects:

**1. 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

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

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

**2. Item: Shaft (part of rock grinding equipment)**

Function: Provide mechanical transfer of /xx/ rotational force while maintaining linear and angular stability

Failure Mode: Shaft fractured

Effect (Local: Shaft): No torque output (does not transport energy)

Effect (Next level: Grinder Subsystem): Rock grinder teeth do not move

Effect (End user): No rocks are pulverized, and product order is not filled

**3. Process Step:** Induction harden shafts using induction hardening machine

Function: Induction harden shafts using induction hardening machine, with hardness to specification #123, and case depth /xx/ inches

Failure Mode: Shaft hardness too soft

Effect (In plant): 100% scrap

Effect (End user): Potential shaft fracture with complete loss of performance

**4. Process Step:** Clamp bicycle upper frame tube in weld fixture

Function: Securely clamp upper tube in weld fixture, without damaging part and without looseness or movement of part in fixture

Failure Mode: Tube not clamped securely (loose)

Effect (In plant): Tube position incorrect, with possible defective welds from tube shifting, and potential for 100% scrap

Effect (End user): If upper tubes get out of plant with defective welds, the bicycle frame could collapse, with potential rider injury

### Problem 3.10

Perform the following steps as part of a hypothetical Design FMEA on an inexpensive wooden pencil:

1. Assuming “pencil system” is the highest level of the system hierarchy, Identify and write down two additional items from the wooden pencil system hierarchy.
2. For the item “Pencil system,” identify and write down two functions of a wooden pencil.
3. Identify and write down two potential failure modes of the first function.
4. Identify and write down the potential effect of the first failure mode.
5. Rank the severity of the effect, using the AIAG 4th edition severity scale. Note that in this scale, “vehicle” can be replaced by “item.”
6. Identify and write down two potential causes of the first failure mode.
7. Identify and write down one prevention-type design control for the first cause.
8. Identify and write down one detection-type design control for the first cause.
9. Assuming either the severity or the RPN is high enough to require action, identify and write down two potential recommended actions to address the risk from the first failure mode/cause.
10. Compare answers to the solutions manual, and restudy the FMEA definitions and examples, as needed.

**REFERENCES**

1. Military, 2001, NAVAIR 00-25-403 Guidelines for the Naval Aviation Reliability-Centered Maintenance Process, Naval Air Systems Command.
2. Pecht, Michael G., Valérie Eveloy, Diganta Das, et al., 2005, Identification and Utilization of Failure Mechanisms to Enhance FMEA and FMECA, in Proceedings of the IEEE Workshop on Accelerated Stress Testing & Reliability (ASTR), IEEE.
3. AIAG, 2008, Potential Failure Mode and Effects Analysis (FMEA) 4th Edition.

# *Chapter* 4

## *Selection and Timing of FMEA Projects*

We can do anything, but we can't do everything . . . at least not at the same time. So think of your priorities not in terms of what activities you do, but when you do them. Timing is everything.

—Dan Millman

### **IN THIS CHAPTER**

This chapter explains the primary selection criteria for FMEA projects and outlines when to do the different types of Failure Mode and Effects Analyses (FMEAs). A technique called Preliminary Risk Assessment is also included, which uses specific selection criteria to identify the most important FMEA projects. The chapter ends by introducing the all-terrain bicycle case study, subsequently used to teach FMEA concepts throughout the book.

#### **4.1 GUIDELINES FOR WHEN TO DO FMEAs**

FMEA projects are often recommended in cases of:

1. New designs or processes, or modifications to existing designs or processes
2. Company policy

3. Customer mandate
4. Other quality and reliability tools

### **New Designs or Processes**

Many companies are in the business of developing new products or processes. An FMEA (or a series of FMEAs) is usually indicated when a new product or process is underway.

New product programs usually begin with a System FMEA. “System” means the highest level configuration that is being developed within the scope of the company. For example, a vehicle manufacturer would consider the entire vehicle the “system” and the entertainment hardware a “subsystem.” However, the entertainment manufacturer might consider the entertainment hardware a “system.” Therefore, the terms “system,” “subsystem,” and “component” are relative to the group that is designing and building the equipment.

New product programs usually require FMEAs beyond the system FMEA, depending on results of the System FMEA, results of the preliminary risk assessment (covered below), company policy, or customer mandates. When subsystem and/or component FMEAs are indicated, they are often called Design FMEAs, which focus on product designs.

Another type of FMEA often done in support of new product programs is a Process FMEA. If the company has responsibility for assembly or manufacturing of the product(s), a Process FMEA may be indicated. Again, the question is degree of change from previous processes. If there is sufficient change to the assembly or manufacturing process, then a Process FMEA should be done.

### **Modifications to Existing Designs or Processes**

If existing designs or processes are changed, FMEAs may be needed to ensure the changes are safe, reliable, and cost-effective. The question to consider is how much change exists between the new product or process and previous products or processes? If a threshold level of risk due to change is identified, an FMEA (or a series of FMEAs) is appropriate. See the section below on “Preliminary Risk Assessment” to help identify the threshold of risk that calls for a new FMEA.

Another technique that may be helpful in identifying changes that require FMEAs is called “Change Point Analysis.” This technique begins with the baseline design and focuses on the *specific changes* to the design. The main idea is to begin with a robust design and to fully understand and document all of the change points to the baseline design. Change points can include changes in design, manufacturing, supplier, supplier design or process, usage environment, interfaces, specifications, performance requirements, or any other changes. Refer to Chapter 13, Section 13.2, for more information on the scope and application of Change Point Analysis.

### **Company Policy**

Some companies have policies that describe when FMEAs should be done. A few companies mandate FMEAs on every product (system, subsystem, and component) and every change to a product. When FMEAs are mandated on every single part,

regardless of potential risk, the result can be a diluted effort by engineering and poor FMEA quality, because the teams do not have time to perform the procedure correctly. It is worthwhile to develop a comprehensive company policy to ensure generation of FMEAs for the right reasons, as discussed in the “Preliminary Risk Assessment” section of this chapter.

### **Customer Mandate**

There are times when FMEAs (or FMECAs) are required by contract. Some original equipment manufacturers (OEMs) require FMEAs for all purchased parts. Some customers (such as the government) require FMEAs (or FMECAs) on selected systems, subsystems, or components as part of the contract to do business. Again, it is worthwhile to ensure the FMEAs are mandated for the right reasons, and if not, to go back to the customer to request a change in contract if necessary.

### **Other Quality and Reliability Tools**

There are many examples in which one quality or reliability tool will recommend an FMEA be done to address a certain risk that has been identified. This is a good use of quality or reliability tools. For example, a System FMEA may identify a need for a subsystem or component FMEA. A Six Sigma team may determine that an FMEA should be done to support the Design for Six Sigma project. A Robust Design project may require an FMEA be done to ensure the primary failure modes are addressed as part of its overall approach. No single quality or reliability tool is all encompassing, and there is synergy between well-done applications.

## **4.2 FMEA PROJECT SELECTION CRITERIA**

FMEAs take time and cost money. They should be done when a certain level of risk can be effectively addressed by the FMEA procedure. From this point, the remainder of the chapter focuses on when to do FMEAs and what kind of FMEAs to do.

Some of the criteria to consider in determining whether to perform an FMEA include:

- Risk identified by System or Concept FMEA
- Potential for safety issues
- New technology
- New applications of existing technology
- History of significant field problems
- Potential for important regulation issues
- Mission-critical applications
- Supplier capability

*Preliminary Risk Assessment* is a procedure that uses these criteria, or other company-determined criteria, to select which FMEAs to do.

### 4.3 PRELIMINARY RISK ASSESSMENT

Short of doing FMEAs on all subsystems and components, which can be very expensive and time consuming, there needs to be a way to prioritize potential FMEA projects, to help identify which FMEAs to do. One way to do this prioritization is Preliminary Risk Assessment. The succeeding paragraphs outline a simple procedure for performing a Preliminary Risk Assessment.

Open up a simple spreadsheet or use FMEA software that supports Preliminary Risk Assessment. In the first column, list the bill of materials or the complete system hierarchy (listing of the subsystems and components). Across the top of the spreadsheet put the risk criteria used to prioritize the risk of the subsystems and components, as described below.

Develop the company-specific risk criteria for use in assessing risk for each item in the bill of materials. For example:

1. Risk identified by System or Concept FMEA (Does the System or Concept FMEA point toward risk in the item?)
2. Potential for safety issues (What is the degree of safety risk associated with the item?)
3. New technology (What is the degree of new technology being introduced with the item?)
4. New applications of existing technology (What is the level of new application for existing technology with the item?)
5. History of significant field problems (What level of field problems has been associated with the item or similar items?)
6. Potential for important regulation issues (What level of government regulation is associated with the item?)
7. Mission-critical applications (To what degree can failures with the item bring about loss of primary mission?)
8. Supplier capability (What is the risk associated with the supplier of the item?)

*Note:* These risk criteria can and should be tailored to the circumstances of an individual company or organization and applied to each item in the Bill of Materials.

The next step is to rank each risk criteria column for each row in the system hierarchy on a scale of risk, such as high, medium, or low, or 1–5. In other words, assess the risk for each item in the Bill of Materials according to the risk criteria.

The final step uses simple arithmetic to multiply the cells in each row to obtain a risk index number for each of the subsystems or components in the system hierarchy. This index can then be used as input to the FMEA selection decision.

Figure 4.1 shows an example of a Preliminary Risk Assessment for an all-terrain bicycle system. In this example, only the subsystems are assessed; however, the same procedure can be used for selection of components. The results of the Preliminary Risk Assessment in this example point toward two subsystems: frame and hand brake.

Preliminary Risk Assessment can be applied equally well to the process hierarchy of a manufacturing or assembly process in order to select the specific operations that will be analyzed with Process FMEA. In many cases, the scope of the Process FMEA will be the entire manufacturing or assembly process; however, the

Subsystem	Risk ID by System FMEA									TOTAL
	Risk ID by System FMEA	Safety Concerns	New Technology	New Applications	Field Problems	Regulatory Risk	Supplier Concerns	Other		
Frame Subsystem	3	2	2	3	1	1	1	1	36	
Front Wheel Subsystem	3	1	1	1	1	1	1	1	3	
Rear Wheel Subsystem	2	1	1	1	1	1	1	1	2	
Sprocket Subsystem	1	1	1	1	1	1	2	1	2	
Chain Subsystem	1	2	1	1	1	1	2	1	4	
Seat Subsystem	2	2	1	1	1	1	1	1	4	
Handlebar Subsystem	1	1	1	1	1	1	1	1	1	
Hand Brake Subsystem	3	2	1	1	3	1	2	1	36	
Suspension Subsystem	1	2	2	2	1	1	1	1	8	

**FIGURE 4.1** Example of preliminary risk assessment for all-terrain bicycle project.

organization may choose to exclude low risk portions of the process. In this case, the Preliminary Risk Assessment criteria will need to be tailored to the manufacturing or assembly application.

#### 4.4 WHEN TO DO DIFFERENT TYPES OF FMEAs

A System FMEA should be done when a new system begins development or when an existing system will be changed sufficiently so that there are concerns about risk. It should be started as soon as system configuration is determined and completed before system configuration freeze date.

Design FMEAs should be done at the subsystem and/or component level when new designs begin development or when existing designs will be changed sufficiently so that there are concerns about risk. *Preliminary Risk Assessment* can be used to prioritize the use of Design FMEAs. They should be started as soon as design concept is determined and completed before design freeze date.

A Process FMEA should be done when a new manufacturing or assembly process is being developed or when an existing manufacturing or assembly process will be changed sufficiently so that there are concerns about risk. It should be started as soon as the manufacturing or assembly process is determined at the concept level, and each section of the Process FMEA should be completed before the corresponding manufacturing or assembly process freeze date, usually called “tooling release.”

Refer to Chapters 5, 6, and 7 for information about preparation, procedure, and execution of System, Design, and Process FMEAs.

A Concept FMEA should be done when concept alternatives are being considered and risk due to failure is part of the concept selection process. It should be

started when the various concepts are identified and completed before the main-stream concept is decided. Refer to the Concept FMEA procedure in Chapter 15, Section 15.3.

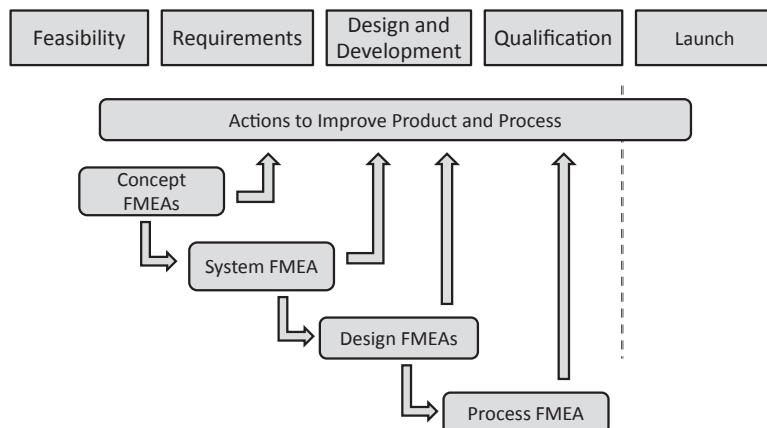
A Software FMEA should be done whenever the product development team considers software issues to be of sufficient risk to justify a separate analysis. The alternative is to include software within the scope of the System and Design FMEAs. Chapter 15, Section 15.4, discusses the procedure for Software FMEAs.

A Maintenance FMEA should be done in support of Reliability-Centered Maintenance (RCM) projects. The FMEA portion of RCM should begin as soon as the maintenance or RCM project is sufficiently mature to identify potential maintenance strategies, and should be completed before the Preventive Maintenance plan is due. The procedure for Maintenance FMEAs as part of RCM projects is detailed in Chapter 15, Section 15.1.

A Hazard Analysis should be done in support of systems, subsystems, or components that are at high risk for safety concerns, or when it is mandated by government regulation. In the case of medical devices, International Organization for Standardization (ISO) 14971:2007 specifies a process for a manufacturer to identify the hazards associated with them. Hazard analysis is usually done when the product development team believes a separate focused analysis is necessary in support of safety concerns. If not mandated, an alternative is to include safety analysis as part of the System and Design FMEA. It should begin upon identification of the system, subsystem, or component concept, and be completed before design freeze dates. The procedure for Hazard Analysis is covered in Chapter 15, Section 15.2.

A FMECA should be done when mandated by government or a customer, or when the organization chooses to add a detailed criticality analysis (CA) to the FMEA procedure. It should be started when design concept is determined and when there is sufficient objective data to perform CA, and be completed before design freeze. FMECA procedure is covered in Chapter 12.

Each of the different types of FMEAs supports the Product Development Process, often called the Stage Gate Process. Figure 4.2 shows this alignment at a high level.



**FIGURE 4.2** The relationship between FMEAs and the stage gate process at a high level.

## 4.5 RESPONSIBILITY FOR FMEAs BETWEEN OEMs AND SUPPLIERS

It is important to establish responsibility for performing the various types of FMEAs. In the majority of systems and projects, there is more than one organization or company involved with the design and manufacturing of products. The question becomes, “Who has the responsibility for performing and executing the FMEAs?”

There are a few simple rules that determine FMEA ownership and responsibility. The organization or company that has responsibility for system design also has responsibility for performing and executing a System FMEA. The organization or company that has responsibility for subsystem or component design also has responsibility for performing and executing the subsystem or component Design FMEAs. The organization or company that has responsibility for manufacturing and assembly also has responsibility for performing and executing the Process FMEA.

What is the rationale for assigning responsibility for performing and executing FMEAs? The organization that has the *expertise* and *body of knowledge* in the product design is in the best position to perform and execute the corresponding System or Design FMEAs. To be successful, Design FMEAs require the focused attention of the subject matter experts in the content and technology of the product design. This also holds true for manufacturing and assembly. The organization or company that manufactures and assembles the system or component usually has the expertise and body of knowledge in product manufacturing, and should be performing and executing the corresponding Process FMEA.

To illustrate these rules, a fictitious example of an appliance manufacturing company will be used. In this example, the management decides to begin a program of FMEAs in order to ensure their appliances are safe and reliable. The appliance company is an OEM and has tier 1 and tier 2 suppliers. The OEM has responsibility for system design and integration. The tier 1 suppliers provide subsystems for the appliance system, and have responsibility for design and manufacturing of the subsystems, with one exception explained below. The tier 2 suppliers provide components for the various subsystems, and have responsibility for design and manufacturing of the components, with one exception also explained below.

The question to be considered is who has responsibility to perform the various types of FMEAs?

In this example, the OEM has responsibility to perform and execute the System FMEA. The tier 1 suppliers have responsibility to perform and execute the Design and Process FMEAs for their respective subsystems. The tier 2 suppliers have responsibility to perform and execute the Design and Process FMEAs for their respective components. Now for the exception: one of the tier 1 suppliers has responsibility for the design of the subsystem, but has outsourced the manufacturing to another supplier. In this case, the tier 1 supplier with design responsibility performs and executes the Design FMEA for the subsystem, and the supplier with manufacturing responsibility performs and executes the Process FMEA for the subsystem. This same division of responsibility can take place at the component level. If a tier 2 supplier has responsibility for component design, they have responsibility to perform and execute the Design FMEA for the component. However, if this same tier 2 supplier uses another company to manufacture the component, then this other company performs and executes the Process FMEA.

The OEM should use Preliminary Risk Assessment to identify which subsystems and components are most critical, and rise to the level of requiring FMEAs. The required subsystem and component Design and Process FMEAs ideally become part of the purchasing contract with the tier 1 and tier 2 suppliers, with OEM reviewing and approving the resulting critical FMEAs before shipment. Refer to Chapter 9 for guidelines of how to review and approve FMEAs against defined quality objectives. Refer to Chapter 11, Section 11.3.3, for more information on conducting supplier FMEA reviews. Refer to Chapter 5, Section 5.3.6, for more information on the relationship between OEMs and suppliers in terms of roles and responsibilities.

Refer to the “End of Chapter Problems” section to explore this topic further.

## 4.6 INTRODUCING THE ALL-TERRAIN BICYCLE CASE STUDY

Demonstrated throughout this book are key methods and approaches to FMEA using a fictional example for a new all-terrain bicycle. Look for the following graphic preceding all bicycle case study entries:



This case study attempts to replicate real-world analysis scenarios; it was prepared for instructional purposes and does not represent an actual product or process.

### All-Terrain Bicycle Case Study Scenario

The Incredible Bike Company designs, develops, manufactures, and sells high performance bicycles, and has been in business for more than 50 years. Their brand is very successful and has a reputation for high performance and durability. The product line for off-road trail bikes is in high demand and requires new technology to meet requirements for lower weight and higher performance.

The all-terrain group will be developing a new lightweight off-road bike, which will accommodate a wider variation in rider weight and height, and, it is hoped, will exceed performance and durability expectations. Because of the high demand, Incredible Bike Company wants to launch its new product quickly; however, it is essential to ensure there are no safety or reliability problems in order to protect the consumer and for the sake of company reputation.

In this case study, the all-terrain development team missed two critical issues. Either one of these issues is significant enough to cause the program to fail. One of the critical issues is design related and the other is manufacturing related. The case study will demonstrate how both of the issues were discovered and resolved by properly done FMEAs and how a high level of reliability was achieved with this product.

### All-Terrain Bicycle Case Study: Design Issue

Unbeknownst to the all-terrain development team, there is a serious problem with the *brake cable*. A new material used in the cable is vulnerable to corrosion and is

prone to breaking under normal usage. If the problem with the brake cable is not discovered before launch of the new All-Terrain Bicycle, it could result in possible injuries, recalls, and lawsuits. The supplier won the brake cable contract primarily due to being a low bidder. The problem is the development team is under pressure to get the new bike to market fast and does not know this issue exists.

### All-Terrain Bicycle Case Study: Manufacturing Issue

Also not known to the all-terrain team is a serious problem with the front wheel subassembly operation that orients and places the wheel spokes into the wheel assembly fixture. Due to the complexity of spoke assembly and the lack of proper fixture configuration, this operation is prone to leave out spokes; however, the bicycle assembly manufacturing team does not yet know this issue. If spokes are left out of the wheel assembly, and if the problem is not caught before the bicycles leave the plant, collapse of the front wheel during severe off-road bicycle maneuvers could result in injuries, recalls, and lawsuits.

### All-Terrain Bicycle Project Information

The following information is available in the Appendix:

All-terrain bicycle schematic

All-terrain bicycle requirements, including operating conditions and customer usage

### How the All-Terrain Case Study Is Used in This Book

The next several chapters comprehensively explain the entire FMEA process from preparation through procedure and execution. To help the reader visualize the whole process from start to finish, the fictional example of the all-terrain bicycle is used through vignettes at the end of each section.

## 4.7 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

### Problem 4.1

Which of the following statements supports the rationale for FMEA selection? (Select all that apply.)

1. In order to reduce risk, FMEAs must be done on every subsystem, component, and part.
2. FMEAs are time intensive and should be done on items that are selected based on defined risk criteria.
3. Top management has the sole discretion of when to do FMEAs.
4. The design or process owner has the sole discretion of when to do FMEAs.

**Problem 4.2**

Which of the following risk criteria should be considered when deciding which FMEAs to do on a given project? (Select all that apply.)

- 1.** The degree of new technology in the design.
- 2.** The cost of the piece part.
- 3.** The degree of field failures on similar parts.
- 4.** The availability of potential FMEA team members to attend meetings.

**Problem 4.3**

Which of the following statements about the timing of Design FMEA projects are true? (Select all that apply.)

- 1.** Design FMEAs should be started before a design concept has been identified and completed before product design has begun.
- 2.** Design FMEAs should be started shortly after a design concept has been determined and completed before design freeze.
- 3.** Design FMEAs should be started shortly after a design concept has been determined and completed sometime after testing and before the product gets into the hands of the consumer.
- 4.** Design FMEAs should be started after the design has been completed and completed before launch of the new product.

**Problem 4.4**

In the example of Preliminary Risk Assessment for the all-terrain bicycle project, one of the risk criteria columns is “Risk identified by System FMEA.” What does this mean?

**Problem 4.5**

The Incredible Bike Company (IBC) has system design, system integration, and system assembly responsibilities for the new all-terrain bicycle. The bicycle seat is made of a new material for comfort and durability, and the seat design is considered critical based on Preliminary Risk Assessment. Company X has responsibility for the seat and does the seat design; however, they outsourced the seat manufacturing to company Y. Company Y ships the seats to company X, who verifies they meet all requirements and ships to IBC for assembly as part of the new all-terrain bicycle. The question is, who has responsibility for the all-terrain System FMEA, all-terrain Process FMEA, seat Design FMEA, and seat Process FMEA, and why?

# *Chapter* 5

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## *How to Perform an FMEA Project: Preparation*

Well begun is half done.

—Greek Proverb

### **IN THIS CHAPTER**

Proper preparation is essential to success in any Failure Mode and Effects Analysis (FMEA) project. This chapter outlines the step-by-step tasks that need to be done *one time* to prepare for future FMEA projects, as well as the tasks that need to be done for *each new* FMEA project. Various preparation checklists are included. Each preparation step is illustrated with an example of how the specific step would be done on a bicycle FMEA project.

Unless otherwise noted, this chapter covers material that is important for *all* FMEA applications, including System FMEA, Design FMEA, and Process FMEA. Topics that are unique to one specific type of FMEA application are clearly indicated in the paragraph title, such as “For System and Design FMEA” or “For Process FMEA.”

### **USE OF THE BICYCLE EXAMPLES IN THE CHAPTER**

In order to highlight the application of various FMEA preparation steps, the all-terrain bicycle case study is used. At the end of each preparation step, a brief example of how the all-terrain bicycle team applied that step in preparing for their

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*Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis*, First Edition. Carl S. Carlson.

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bicycle FMEAs is shown. A bicycle icon precedes these examples. Chapter 8, Section 8.8, has a teaching analysis of the resulting bicycle FMEAs.

## 5.1 THE SUBJECT OF FMEA PREPARATION

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

—William James

In preparation for an FMEA project, some tasks need doing once, but require revisiting from time to time, and there are some tasks that need to be done for each new FMEA. The one-time tasks include selecting FMEA software, selecting or modifying FMEA standards and scales, FMEA team training, meeting logistics, and defining the system hierarchy. The tasks that need to be done for each new FMEA project include determining the scope of the analysis, providing a visual depiction, assembling the correct team of experts, agreeing on the ground rules and assumptions, and gathering the relevant information. All of these steps are discussed more thoroughly below.

The importance of good preparation for the FMEA project cannot be emphasized enough. All of the preparation steps are essential for the FMEA project to be successful and completed in a timely manner. Just as in painting a room in a house, where many tasks are required to properly prepare the walls before the paint is applied, skipping any of the preparation tasks will negatively affect the quality of the result.

## 5.2 PREPARATION TASKS DONE *ONCE* FOR ALL FMEA PROJECTS

The following tasks need to be done *once* for the entire set of FMEA projects, revisiting as needed.

1. FMEA software selection
2. Selecting or modifying FMEA scales and columns
3. Identifying roles and responsibilities
4. FMEA team training
5. Legal guidelines for doing FMEAs
6. Meeting logistics
7. Defining the system hierarchy (for System and Design FMEAs)
8. Defining the process steps (for Process FMEAs)
9. Access to failure information

### 5.2.1 FMEA Software Selection

Having the right FMEA software can greatly improve the quality and timing of FMEA projects. FMEA software needs to be easy to use with an intuitive user interface, allowing the FMEA team to enter information easily, in real time, during FMEA meetings. Some of the characteristics of good FMEA software include a

smooth linkage between system hierarchy, FMEA worksheet, and corresponding test or control plans; capacity for simultaneous users; comprehensive search queries; ability to link all electronic documents; and easily configurable profiles and interfaces.

Chapter 16 covers the characteristics of excellent FMEA software. It is important to use good relational database software so that the team can take advantage of important inputs to the FMEA and streamline reports, updates, queries, and other tasks. A relational database provides access to all FMEAs in one database, which allows the team to build from the lessons of past FMEAs.



### Bicycle Example

The FMEA software used throughout the bicycle FMEA examples is Xfmea version 5, from ReliaSoft Corporation.

#### 5.2.2 Selecting or Modifying FMEA Worksheets and Scales

The company or the FMEA team may have already agreed on the FMEA standard to be followed, the FMEA worksheet columns, and the risk ranking scales. If not, this is the time to do this. If the FMEA standard is not mandated, Automotive Industry Action Group (AIAG) Fourth Edition (2008) or Society of Automotive Engineers (SAE) J1739 (2009) provide a good starting point, with a useful description of the procedure, the worksheet columns, and risk ranking scales. However, it is important to tailor the worksheet columns and risk ranking scales to company-specific applications.

If FMECA is being performed, refer to Chapter 12 for information on FMECA scales and worksheets.

The criteria for the severity scale must be reviewed and agreed upon, clearly showing needed differentiation between safety and regulatory risk, loss or degradation of primary and secondary functions, and lower severity such as annoyance. For Process FMEAs, in addition to the criteria for the effect on the product, the criteria for the effect on the manufacturing process must also be established.

The criteria for the occurrence scale must be reviewed and agreed upon, clearly differentiating the full range of anticipated failure rates, from very low to very high, and where possible identifying ranges of failure frequency for each occurrence level that makes sense for the system, product, or process being analyzed.

The criteria for the detection scale must be reviewed and agreed upon, clearly differentiating the likelihood of detection from very remote to almost certain. For System and Design FMEAs, risk related to detection can also be differentiated based on the timing opportunity for detection and the type of test used for detection, in addition to likelihood of detection. For Process FMEAs, risk related to detection can be further differentiated based on the manufacturing stage or type of operation. Refer to Chapter 6, Section 6.2.17, for more information on detection ranking criteria and analysis of limitations and alternatives to detection scales.

If the risk ranking scales are not mandated and the team has the flexibility to establish their own risk ranking scales, 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 10 ranking levels are needed to adequately differentiate and define the risk, use scales that have 10 ranking levels. It is worthwhile to spend the time needed to define properly the scales with the correct resolution and criteria. Using scales that have too many ranking levels for a given application can result in the FMEA team spending excessive time deciding which level on the scale represents the risk without adding value. Using scales with too few ranking levels can result in the FMEA team missing important risk differentiation.

The planned use of Risk Priority Number (RPN) must be agreed to by the FMEA team. Refer to Chapter 6, Section 6.2.20 for information on RPN, including limitations and alternatives.

Columns of fields can be added or modified to the format of the FMEA standard. Only those columns or fields that bring value to the analysis should be added to keep the FMEA project from growing too long due to excessive unnecessary information. See Appendix B for examples of FMEA worksheets for different applications.

Once agreed upon, the FMEA worksheet configuration and the risk ranking scales should be controlled throughout the company, so that individual FMEA teams maintain a consistent approach to FMEA that supports company objectives.

**Example FMEA Forms** Depending on the FMEA standard selected and individual company policy and needs, there are many different forms available for FMEA applications. Users are encouraged to take the time to study different forms, including the benefits and limitations for each, and then develop the forms/columns that make sense for one's own unique applications. The Appendix has a number of different FMEA forms for both Design FMEAs and Process FMEAs, with an explanation of the uniqueness of the form, and some of the benefits or shortcomings.

**FMEA Header** Part of establishing the content and format of the FMEA worksheet is to agree on the header information that will be associated with each FMEA. The FMEA header typically includes the following information:

- FMEA type (such as system, design, process, etc.)
- FMEA description
- FMEA number
- Start date, finish date, revision date
- Information about the project (such as model year, description of the higher level system, etc.)
- Design or process owner (the person who is responsible for the design or process)
- Primary approval (if applicable)
- Core team/facilitator
- User-defined fields (company-specific information relevant to the FMEA)

**FMEA Item Properties** Each FMEA is performed on an item, which 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. There are properties associated with each item, and the team needs to agree on the properties, such as:

- Item or operation name
- Item or operation description
- Part number or operation number
- Information about the reliability of item or operation
- Any other information that describes the item or operation being analyzed

**FMEA Attachments** In addition, the company or the FMEA team should agree on the specific information that will be electronically attached to the FMEA and easily accessible to the FMEA team. Typical attachments include:

- Ongoing record of meeting attendance with names and dates
- Preliminary Risk Assessment
- Current test plans or Process Control Plans
- Diagrams (such as FMEA Block Diagram, Parameter Diagram [P-Diagram], Functional Block Diagram, FMEA Interface Matrix, Process Flow Diagram [PFD], etc.)
- Ground rules and assumptions
- “Gather information” documents (such as drawings, schematics, engineering specifications, field history, etc.)
- Other documents and information that the company or team believes should be attached and accessible



### Bicycle Example

In the all-terrain bicycle FMEAs, the FMEA teams began with the risk ranking scales (severity, occurrence, and detection) from “Potential Failure Mode and Effects Analysis (FMEA),” 4th edition, 2008, from the Automotive Industry Action Group (AIAG). Refer to Figures 3.2 through 3.7. These scales were modified to be consistent with the design and assembly of bicycles.

#### 5.2.3 Identifying Roles and Responsibilities

Questions often arise as to who is responsible for the various tasks associated with FMEA projects and the nature of the responsibilities.

Who takes the lead in selecting the FMEA projects or performing the Preliminary Risk Assessment?

Who carries out the FMEA preparation tasks?

- Who facilitates the FMEA team meetings?
- Who is ultimately responsible for the FMEA document?
- Who enters the information into the FMEA database?
- Who follows up on the execution of FMEA recommended actions?
- Who communicates the high-risk issues from FMEAs to management?
- Who in management champions the entire FMEA process and sees to the budget, staffing and other needed resources?
- Who trains the FMEA team in the basic FMEA procedure?

For each of these task ownerships, the specific roles and responsibilities need to be defined.

Companies vary widely in how they organize the functions of systems engineering, design engineering, quality, reliability, manufacturing, service, and other departments that will provide representation to FMEA teams. There is no template defining the specific roles and responsibilities for carrying out the FMEA tasks; however, there are certain guidelines. FMEA needs the support of a reliability or quality “homeroom,” where the body of knowledge of FMEA is supported with standards, procedures, training, and facilitation. It is usually a good practice to make the design engineer responsible for accomplishing Design FMEAs and the process engineer responsible for accomplishing Process FMEAs, with the support of the skilled resources from the reliability or quality “homeroom.” It is important to surface the questions in the above paragraph and address them so that everyone knows his or her role and specific duties relating to FMEA.

It is useful for companies to document the various FMEA roles and responsibilities in related job descriptions and work instructions. A great many roles need to come together to make FMEA work efficiently and effectively in any company. It is worth the time and effort to document these roles and the specific duties, as well as generate procedure guidelines. This reduces duplicative efforts and ensures that all team members are working in the same direction. Chapter 10, Section 10.4, suggests roles and responsibilities for the FMEA facilitator in supporting each step of the FMEA process.



### Bicycle Example

For the all-terrain bicycle FMEAs, the FMEA facilitator is the reliability engineer, who also takes the lead in FMEA preparation, administering the FMEA software, and training the FMEA team members. The individual design and manufacturing engineers and other representatives own the assigned FMEA recommendations, including status updates, and follow through on execution of all assigned tasks and recommended actions. The chief engineer of the all-terrain program oversees the FMEA, ensures the team has all the resources it needs, ensures the FMEA is well attended and done properly, sponsors meetings to review status, approves recommended actions, and ensures the FMEA is fully executed.

### 5.2.4 FMEA Team Training

Tell me and I'll forget; show me and I may remember; involve me and I'll understand.

—Marie Curie

FMEA team members need training in the basics of FMEAs before the FMEA team meetings begin. This can either be full team training by an expert in FMEA methods or, at minimum, the team needs a good overview of FMEA fundamentals. If the FMEA team is not familiar with the basics of FMEAs, such as procedure, definitions, examples, and lessons learned, then the meetings will be much longer than necessary and the results will be unsatisfactory.



#### Bicycle Example

The bicycle reliability engineer takes on the role as FMEA team trainer and sees to the proper training of all of the FMEA representatives who participate on FMEA teams for the all-terrain bicycle FMEAs, including the all-terrain System FMEA, the all-terrain Design FMEAs, and the all-terrain Process FMEA.

### 5.2.5 Legal Guidelines for Doing FMEAs

It is important for the FMEA team to understand that FMEAs are legal documents that support the demonstration of due care in product development. As legal documents, they are subject to subpoena for legal proceedings. The FMEA team members should familiarize themselves with and adhere to any relevant company guidelines regarding legal documentation and closely follow advice from company legal representatives. They should also follow common-sense principles, such as:

1. All FMEA database entries should be factual and absent of emotional words or exhortations.
2. All FMEA database entries that state an action will be taken to address a problem should be closed out with a corresponding entry saying what specifically was done, leaving no “open loops.”
3. All FMEA database entries should be detailed and specific enough so that anyone who is not part of the FMEA team can read the entry and understand the meaning and context.
4. The FMEA team should never omit raising an issue or addressing a problem because it does not have an immediate solution or out of concern for legal ramifications. If there are important concerns that are legal in nature, the team should discuss these issues with management and company legal representatives.
5. FMEA teams should continue the FMEA project until an acceptable level of risk is reached.

6. Safety issues are always the highest priority, regardless of likelihood of occurrence. No FMEA is complete unless the FMEA team is satisfied that there are no unaddressed safety-related issues within the scope of the FMEA project.
7. When entering information into the FMEA database, care should be taken to characterize concerns as “potential” or “possible” when appropriate, unless the team is certain the issue will occur. One example is entering an effect that has a possibility of injury. Here it is appropriate to say “with the possibility of injury” rather than saying “will result in injury.”

### 5.2.6 Meeting Logistics

Some forethought about the logistics of the FMEA meetings will aid in the objective of productive meetings. Meeting rooms need to be large enough for the core FMEA team as well as special guest experts invited from time to time. Meeting schedules can be at a set time each week, if the FMEA timing is concurrent with a product development process, or on a more condensed schedule, if timing is critical. This depends on program objectives and availability of subject-matter experts. Meeting rooms should have a projector and screen for sharing the FMEA database/project with the team in real time. An easel and markers are important for brainstorming and for documenting follow-up activities.



#### Bicycle Example

The meetings for the all-terrain System FMEA take place in the main conference room of the all-terrain engineering building between 1:00 P.M. and 4:00 P.M. every Friday afternoon. They continue until the FMEA is completed through the recommended actions. Follow-up FMEA meetings are held to review feedback from management and to ensure full execution of the recommended actions.

The meetings for the all-terrain Process FMEA are held from 1:00 P.M. to 3:00 P.M. every Monday afternoon. They continue until the FMEA is completed through the recommended actions, with follow-up meetings as needed.

### 5.2.7 Defining the System Hierarchy (For System and Design FMEAs)

All product designs, machinery, and equipment of any kind have a system hierarchy sometimes called the *bill of materials*. It is important for the FMEA practitioner to understand the system hierarchy and this begins with a good definition.

The Federal Aviation Administration (FAA) Systems Engineering manual defines “system” as follows<sup>[1]</sup>:

A *system* is an integrated set of constituent parts that are combined in an operational or support environment to accomplish a defined objective. These integrated parts include people, hardware, software, firmware, information, procedures, facilities, services, and other support facets. People from different disciplines and product areas have different perspectives on what makes up a system. For example, software engineers

often refer to an integrated set of computer modules as a system. Electrical engineers might refer to a system as complex integrated circuits or an integrated set of electrical units.

This manual goes on to say:

It is difficult to agree on what comprises a system since it depends entirely on the focus of those who define the objective of the system. If the objective is to print input data, a printer may be defined as the system. Expanding the objective to processing input data and displaying the results yields a computer as the system. If we expand the objective further to include a capability for computing nationwide or worldwide data and merging data/results into a database, then a computing network becomes the system, with the computer and printer(s) as subsystems of the system.

The scope of a system depends on who is defining it. System definition always includes the interfaces between the subsystems.

Further definitions relating to system hierarchy follow.

*Hierarchy* A partitioning scheme that establishes an ordered relationship between the items in a system, where the items are represented as being “above,” “below,” or “at the same level as” one another.

*Subsystem* A system in and of itself (refer to the system definition) contained within a higher level system. The functionality of a subsystem contributes to the overall functionality of the higher level system. The scope of a subsystem’s functionality is less than the scope of functionality contained in the higher level system. Subsystem definition always includes the interfaces between the components.

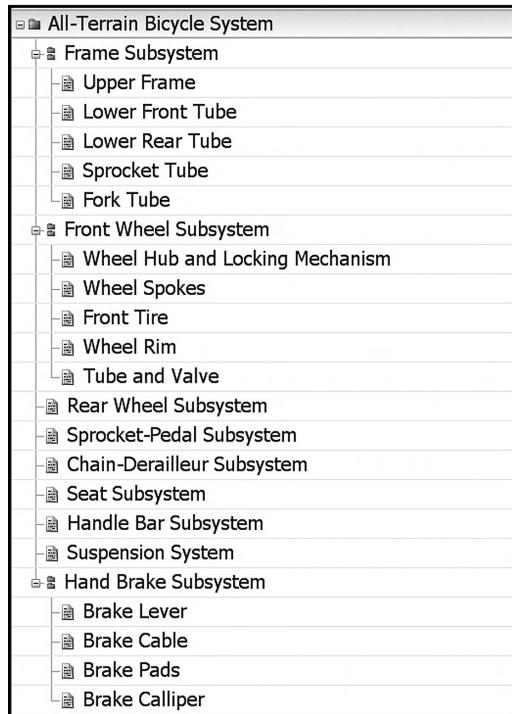
*Component* Composed of multiple parts; a clearly identified subset of the product being designed or produced.

*Part* One, two, or more pieces joined together to make a component; these pieces comprise the lowest level of separately identifiable items within a system and are not normally subject to disassembly without destruction or impairment of its designed use.

Each level of indentation, from system to subsystem, to component, to part, comprises the hierarchy of the system.

When performing a System or Design FMEA, a portion of the system configuration could look like this, with as many subsystems and components as needed:

```
System
  Subsystem A
    Component A.1
    Component A.2
    Etc.
  Subsystem B
    Component B.1
    Component B.2
    Etc.
```



**FIGURE 5.1** Example of system hierarchy for bicycle system.

The FMEA team may choose to perform the analysis at the system, subsystem, and/or component indentation level. The Preliminary Risk Assessment, covered in Chapter 4, Section 4.3, shows how to select which FMEAs will be done from the system hierarchy.



Figure 5.1 is an example of system hierarchy for the all-terrain bicycle (showing three of the subsystems down to components).

### 5.2.8 Defining the Process Steps (for Process FMEAs)

For a Process FMEA, the system hierarchy takes on an entirely different meaning, often called process hierarchy. The Process FMEA team will start by identifying the steps in the process. For example:

Assembly Line  
Station A  
    Operation A.1  
    Operation A.2  
    Etc.

Station B  
 Operation B.1  
 Operation B.2  
 Etc.

In many cases, the scope of the Process FMEA will be the entire manufacturing or assembly process. However, in other situations, the organization may choose to exclude low-risk portions of the process. The Preliminary Risk Assessment, covered in Chapter 4, Section 4.3, shows how to select items from the process hierarchy.

The aspects of the process that go beyond the stations and operations, such as shipping, incoming parts, transporting of materials, storage, conveyors, tool maintenance, and labeling must not be omitted.

Operations are usually accompanied by operation descriptions, which further define the manufacturing operation. Many practitioners who are performing Process FMEAs use the sequence “Do this [operation] to this [part or assembly] with this [tooling]” to properly describe the operation. This operation description is used as input to the description of function(s) in the Process FMEA.



Figure 5.2 is an example of the process hierarchy for the manufacturing-assembly of the all-terrain bicycle (showing the primary assembly stations and the operations for the front wheel subassembly).

Regardless of the type of FMEA project (System FMEA, Design FMEA, Process FMEA, etc.) it is always a good practice to begin with a full depiction of the system hierarchy and/or the process steps.

### 5.2.9 Access to Failure Information

FMEA teams need easy access to information that supports identification of failure modes and causes. This is covered in Section 5.3.7 for the specific FMEA being performed. The following are general sources of information about failure modes and causes that may be useful to FMEA teams.

1. *Past FMEAs.* FMEA teams should have easy access to all past company-generated FMEAs, organized by type or description, so that teams can find past FMEAs that are similar to current FMEA projects. Chapter 16, Section 16.3, describes how a relational database can be used to support this feature.
2. *FMEA “Phrase Libraries.”* FMEA teams should have easy access to all past functions, failure modes, effects, causes, controls, and recommended actions from all previous FMEAs. This greatly aids in the description of current FMEA elements, as often the current failure mode, effect, and so on is similar or the same as a previous failure mode, effect, and so on. Good relational



**FIGURE 5.2** Example of process hierarchy for bicycle front wheel subassembly.

database software supports this feature. (A “phrase library” is a list of pre-defined descriptions that can be used to define any of the text-based record properties in an FMEA.)

3. *General Lists of Failure Modes, Causes, and Failure Mechanisms.* There are publications of generic failure modes, causes, and failure mechanisms that can be helpful to FMEA teams. See the next section for the benefits and limitations of generic lists of failure information.
  - a. Refer to the Appendix for an excerpt from the book *Failure of Materials in Mechanical Design: Analysis, Prediction, Prevention*, by Jack Collins, which lists typical failure mechanisms.
  - b. Alion System Reliability Center offers a publication, *Failure Mode/Mechanism Distributions*, which is a compendium of failure mode and mechanism data, including relative probabilities of occurrence.
  - c. ReliaSoft Corporation offers a series of generic FMEA templates for various physical assets called FMEA Accelerator®.

**Application of Generic Lists of Failure Information** FMEA practitioners should be aware of the benefits and limitations of using generic listings of failure modes, effects, causes, and so on. Generic lists of failure information can be good thought starters for FMEA teams, provide standardized descriptions, and ensure

completeness of analysis. Controlling the description of individual failure modes enables analysis and dissemination of failure information between project teams and the entire organization.

The limitations of using generic failure information include the suitability of generic descriptions to the current project, potential for inclusion of information in current FMEA that is not of concern to FMEA team, and the possibility of stifling the creativity of the FMEA team to “think outside the box” and identify issues not previously seen. This last issue can be addressed by the proper use of brainstorming before exposing the FMEA team to generic failure information. In addition, generic failure data may come from significantly different operating environments and usages than current application.

### 5.3 PREPARATION TASKS FOR EACH NEW FMEA PROJECT

People only see what they are prepared to see.

—Ralph Waldo Emerson

Once the one-time tasks are completed, including defining the system hierarchy (for System and Design FMEAs) or the process steps (for Process FMEAs), the following are the primary preparation tasks that should be done for *each new* FMEA project:

1. Determine the scope of the analysis
2. Make the scope visible (for System and Design FMEAs):
  - FMEA Block Diagram
  - Parameter Diagram (P-Diagram)
  - FMEA Interface Matrix
  - Functional Block Diagram
3. Make the scope visible (for Process FMEAs):
  - Process Flow Diagram (PFD)
  - PFD Worksheet
4. Assemble the correct team
5. Establish the ground rules and assumptions
6. Establish the role of suppliers
7. Gather and review relevant information
  - “Gather Information Checklist” (for System and Design FMEAs)
  - “Gather Information Checklist” (for Process FMEAs)
8. Prepare FMEA software for first team meeting
9. Ready-for-first-meeting checklist

Figure 5.3 is a high-level graphical depiction of the FMEA “road map.” The left portion shows the preparation steps.

In terms of preparation, the high-level steps are the same for all types of FMEAs. However, the specific information will be different between Design FMEAs and

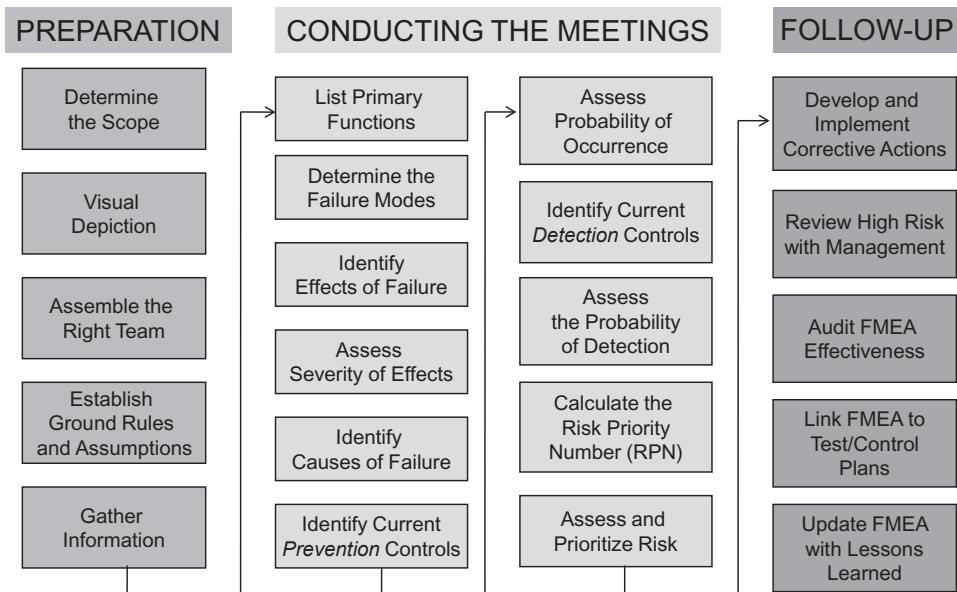


FIGURE 5.3 FMEA roadmap—high level.

Process FMEAs. Figure 5.4 shows the flow of information for Design FMEAs and Figure 5.5 shows the flow of information for Process FMEAs. The “inputs” in these high-level graphics are fully explained in this chapter. The “outputs” in these graphics are fully explained in Chapters 6 and 7.

Sections 5.3.1 through 5.3.9 clearly identify differences between the preparation steps for Design FMEAs and Process FMEAs.

### 5.3.1 Determine the Scope of the Analysis

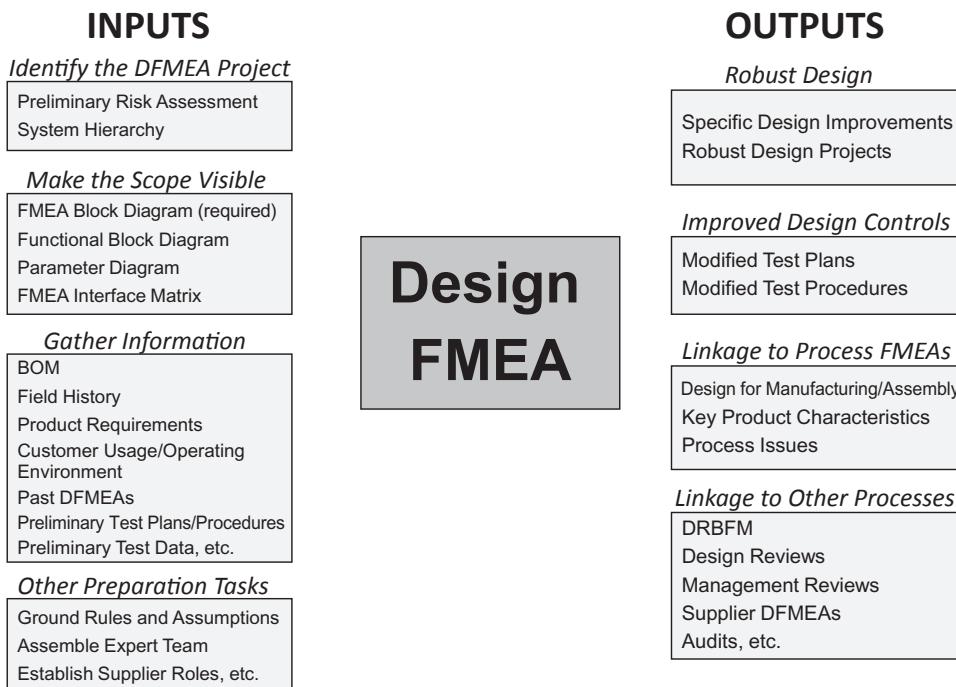
The soul cannot think without a picture.

—Aristotle

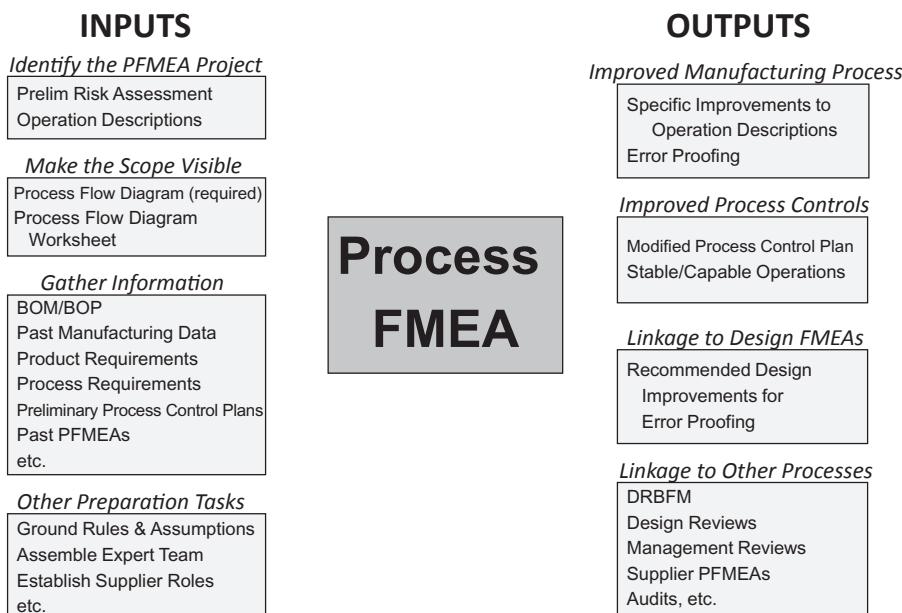
The next step in narrowing down the project focus is determining the specific boundaries or scope of the individual FMEA.

It is important to agree on the scope of the FMEA project before beginning the FMEA itself. Many FMEA projects suffer the effects of “scope creep,” in which the project begins without agreed-upon boundaries and then expands as the meetings go on. If this happens, the team must go back and redo the early work to take into account the larger scope and the project becomes “endless.”

Determining the scope of the analysis is an extremely important step because clearly defined boundaries establish the issues that are to be considered and the approach that the team will take during the analysis. For example, the scope could be identified thus:



**FIGURE 5.4** Design FMEA information flow.  
(BOM, Bill of Materials; DRBFM, Design Review Based on Failure Mode.)



**FIGURE 5.5** Process FMEA information flow.  
(BOP, Bill of Process.)

A high-level analysis focusing generally on the entire system or process, including interfaces and integration

A detailed analysis focusing intensively on a specific aspect of the system or process

In defining the scope of any FMEA project, it is essential to include the *interfaces* between adjacent subsystems or components. This is important because empirical data show that at least 50% of problems occur at the interfaces between subsystems or components. In the case of Process FMEAs, interfaces could include the transfer or movement of material, tools, data, or energy between stations or operations.

For System FMEAs, the scope typically includes system-related deficiencies; 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. The exact scope will need to be determined by the System FMEA team.

For Design FMEAs, the scope typically includes design-related deficiencies, with emphasis on improving the design and ensuring product operation is safe and reliable during the useful life of the item. For subsystem Design FMEAs, the scope includes the subsystem itself, as well as the interfaces between adjacent components. The exact scope will need to be determined by the Design FMEA team.

For Process FMEAs, the scope typically includes manufacturing- or assembly-related deficiencies, as identified in manufacturing and assembly operations, shipping, incoming parts, transporting of materials, storage, conveyors, tool maintenance, and labeling. The exact scope will need to be determined by the Process FMEA team.

The best way to determine and communicate the scope of an FMEA project is use of visual aids.



### Bicycle Example (All-Terrain System FMEA and Hand Brake Design FMEA)

The scope of the all-terrain System FMEA includes system operation, system integration, system safety, subsystem interfaces, interface between bicycle and operator, interactions based on usage and environment, and service issues.

The scope of the all-terrain Hand Brake Design FMEA includes subsystem operation, subsystem integration, subsystem safety, component interfaces, interface and interactions between bicycle and operator for hand brake operation based on usage and environment, and hand brake service issues.

The scope of the all-terrain Process FMEA includes each operation for the manufacturing and assembly of the bicycle, including shipping, incoming parts, transporting of materials, storage, tool maintenance, and labeling.

### 5.3.2 Make the Scope Visible (for System and Design FMEAs)

Refer to Figure 5.4 for the preparation tasks that make the scope visible for System and Design FMEAs. Descriptions with examples are detailed below, along with when to use these tasks.

#### 5.3.2.1 FMEA Block Diagram

*What Is an FMEA Block Diagram?* An FMEA Block Diagram (or FMEA *boundary diagram*) is a visual depiction of the entire system or design to show clearly the boundaries of the FMEA analysis (what is included and not included), the interfaces between the items, and other information that can help to depict the scope of the FMEA. Specifically, the FMEA Block Diagram is a diagram showing the physical and logical relationships between the components in the system or assembly and the boundary of the analysis. It identifies relationships and dependencies between components, such as physical connection, material exchange, energy transfer, and data exchange, and usually shows the inputs and outputs. There should be enough detail in the diagram to visually define the scope of the analysis so the team can maintain the proper scope and not inadvertently expand the project.

In the case of a System FMEA, the FMEA Block Diagram should visually show the interfaces between the various subsystems as well as between the system and its users. For a Subsystem FMEA, the FMEA Block Diagram should visually show the interfaces between the various components.

The FMEA Block Diagram should be attached in an easily retrievable way to the FMEA itself.

*When Is an FMEA Block Diagram Used?* An FMEA Block Diagram is used in preparation for all System or Design FMEAs.

**Examples of FMEA Block Diagram** Figure 5.6 shows an example of an FMEA block (boundary) diagram for a portion of a “flip glass–lift gate” subsystem. In this example, the boundary line encloses flip glass ball studs and hinges, with one-way or two-way connections to environment, manufacturing plant, flip glass gas struts, flip glass, lift gate, and other components of the “flip glass–lift gate” subsystem.<sup>[2]</sup>



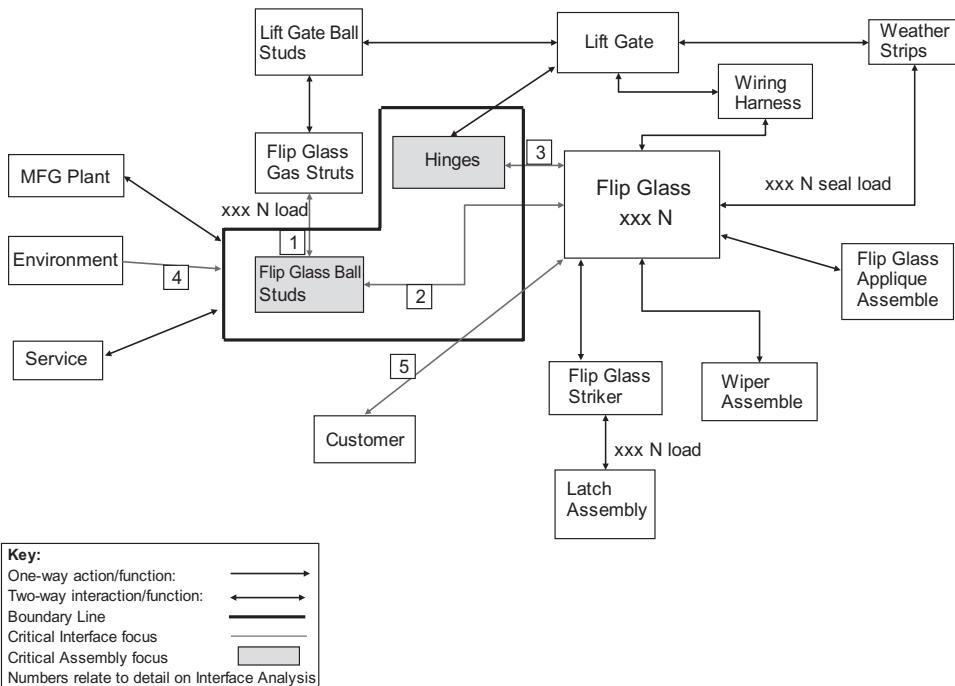
#### Bicycle Example

Figures 5.7 and 5.8 are two examples of FMEA Block Diagrams from the all-terrain bicycle FMEAs. Figure 5.7 is for the all-terrain System FMEA. Figure 5.8 is for a Design FMEA of the all-terrain Hand Brake Subsystem.

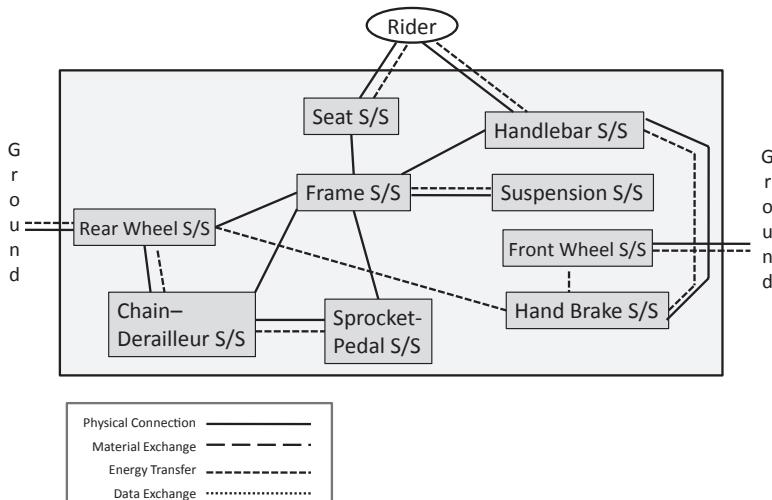
In the first example, there are missing elements to the FMEA Block Diagram at the system level. See the end of chapter problems and corresponding answers to discover the missing elements.

In the second example, the shaded portion of the FMEA Block Diagram is the scope of the Hand Brake Design FMEA, including the interfaces to the subsystems and components outside the shaded area.

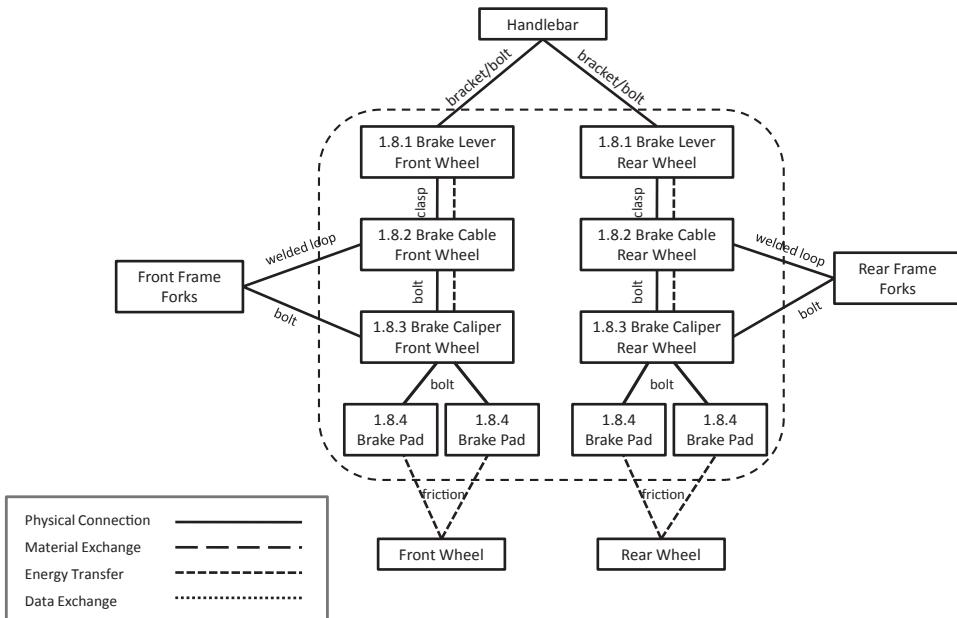
The FMEA team should ensure the FMEA Block Diagram represents exactly what it wants as the scope of the analysis.



**FIGURE 5.6** Example of FMEA block (boundary) diagram for portion of flip glass-lift gate subsystem.  
(Reprinted from “Failure Mode and Effects Analysis (FMEA) 4th Edition,” 2008 Manual, with permission of Chrysler, Ford, and GM Supplier Quality Requirements Task Force.)



**FIGURE 5.7** System FMEA block diagram example—all-terrain bicycle. S/S, subsystem. (Some of the FMEA Block Diagram elements are intentionally missing. Can you determine what they are? See “End of Chapter Problems.”)



**FIGURE 5.8** FMEA block diagram example—hand brake subsystem.

### 5.3.2.2 FMEA Interface Matrix

**What Is an FMEA Interface Matrix?** FMEA interface matrix is a chart with the subsystems and/or components (depending on the scope of the FMEA) on both the vertical and horizontal axes. The chart shows which interfaces must be considered in the analysis and the type of interface.

An interface is the point or surface where two parts or subsystems meet, and it can take various forms. There are four primary types of interfaces: a physical connection, a material exchange, energy transfer, and data exchange. Since interfaces can contain up to 50% or more of the total failure modes, it is essential that any FMEA carefully consider the interfaces between subsystems and components in addition to the content of the subsystems and components themselves.

**When Is an FMEA Interface Matrix Used?** Used for System and Subsystem FMEAs, the FMEA interface matrix is supplemental to the FMEA Block Diagram and is done when the FMEA team wants to ensure that all of the various types of interfaces are included in the analysis, missing none.

**Example of FMEA Interface Matrix** Examples of physical connections include brackets, bolts, clamps, and various types of connectors. Examples of material exchange include pneumatic fluids, hydraulic fluids, or any other fluid or material exchange. Examples of energy transfer include heat transfer, friction, or motion transfer such as chain links or gears. Examples of data exchange include computer inputs or outputs, wiring harnesses, electrical signals, or any other types of information exchange.

### All-Terrain Bicycle System and Hand Brake Subsystem

Bicycle Subsystems	Interface Type:				Functional Necessity:			
	Physical (P)	Material Exchange (M)	Energy Transfer (E)	Data Exchange (D)	Must be present (1)	Must not be present (2)		
1.1 Frame Subsystem	P1	P1	P1		P1	P1	PE1	P1
1.2 Front Wheel Subsystem							E1	
1.3 Rear Wheel Subsystem				PE1			E1	
1.4 Sprocket–Pedal Subsystem				PE1				
1.5 Chain–Derailleur Subsystem								
1.6 Seat Subsystem							P1	P1
1.7 Handlebar Subsystem								
1.8 Suspension System								
1.9 Hand Brake Subsystem								
1.9.1 Brake Lever							PE1	
1.9.2 Brake Cable								PE1
1.9.3 Brake Pads								P1
1.9.4 Brake Caliper								

FIGURE 5.9 FMEA interface matrix example.



### Bicycle Example

Figure 5.9 is an example of FMEA interface matrix for the all-terrain bicycle, showing bicycle subsystems as well as components of the Hand Brake Subsystem.

#### 5.3.2.3 Parameter Diagram (P-Diagram)

**What Is a P-Diagram?** J. M. Juran explains the concept behind P-Diagrams in his book *Quality Planning and Analysis* (3rd Edition, Copyright © The McGraw-Hill Companies, Inc.), in the chapter “Designing for Basic Functional Requirements.” Juran says, “The most basic product feature is performance, that is, the output—the color density of a television set, the turning radius of an automobile. To create such output, engineers use principles to combine inputs of materials, parts, components, assemblies, liquids, etc. For each of these inputs, the engineer identifies parameters and specifies numerical values to achieve the required output of the final product.”<sup>[3]</sup>

“The Parameter Diagram (P-Diagram) takes the inputs from a system/customer and relates those inputs to desired outputs of a design that the engineer is creating, also considering non-controllable outside influences.”<sup>[4]</sup> It is a useful tool in brainstorming and documenting input signals, noise factors, control factors, error states and ideal response, as defined below.

**When Is a P-Diagram Used?** A P-Diagram is an optional step when preparing for a System or Subsystem FMEA. It is most useful when the item under analysis is a complex system with many system interactions, operating conditions, and design parameters, and the team will benefit from seeing these elements visually. It is a time-intensive step, but can provide great value in understanding and controlling the system and identifying input to the FMEA.

### **P-Diagram Definitions**

**Input Signals** These are a description of the energy sources required for fulfilling the system functionality, such as speed, acceleration, input torque, and so on.

**Control Factors** These are typically the system design parameters that the engineering team can change, such as shaft diameter, stiffness, density, hardness, and so on.

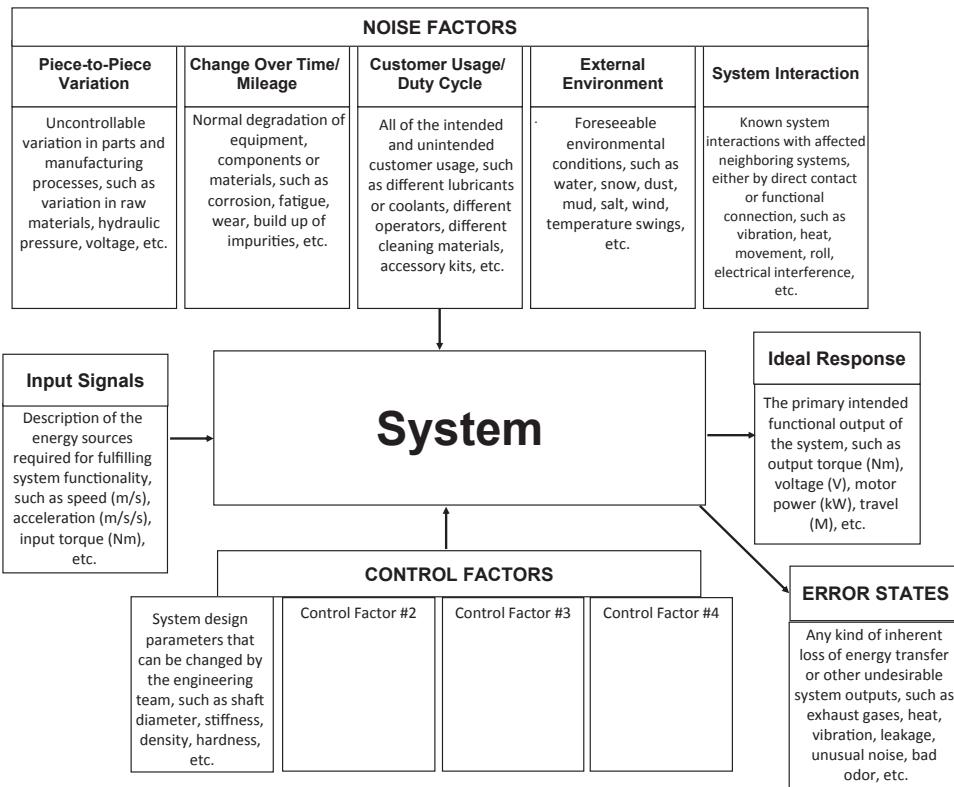
**Error States** These are any kind of inherent loss of energy transfer or other undesirable system outputs, such as exhaust gases, heat, vibration, leakage, unusual noise, or bad odor.

**Noise Factors** These are things that can influence the design but are not under the direct control of the engineer, such as piece-to-piece variation, normal degradation of materials or equipment over time, intended and unintended customer usage, foreseeable environmental conditions, and system interactions. These noise factors, if not protected against, can make the design ineffective; in other words, the design is not robust against the expected noise factors.

**Ideal Response** This is the primary intended functional output of the system, such as output torque, and so on.

**P-Diagram Procedure** The following procedure can be done during the preparation steps of the FMEA, or can be integrated into the procedure steps, once the FMEA team has been formed<sup>[4]</sup>:

1. At the initial design phase or at the beginning of the problem-solving effort, determine the overall objective of the system.
2. Identify the cross-functional team, including members who can provide expertise in the following areas: knowledge of systems approach, measurement and statistical know-how, information as to how the system will be used, knowledge regarding sources of input variability, working knowledge of quality and testing methods, and persons responsible for the design and/or manufacturing of the system being optimized.
3. Review components and their functionality to familiarize all members of the cross-functional team with the system or subsystem.
4. Boundaries of the system must be clearly defined for easier identification of the input and outputs.
5. Determine the Input Signals and the Ideal Response.
6. Determine Control and Noise Factors.
7. Identify the error states, which can be input to failure mode identification in the FMEA, along with other elements of the P-Diagram.
8. Create the graphic P-Diagram showing the relationship between the ideal response, input signals, control factors, noise factors, and error states.



**FIGURE 5.10** Example of Parameter-Diagram.

**Example of P-Diagram** Figure 5.10 is a visual description of a P-Diagram and its various elements, using information about P-Diagrams from an article titled “Using Parameter-Diagrams in Automotive Engineering: Application-Criteria, Guidelines and Best Practice.”<sup>[5]</sup>

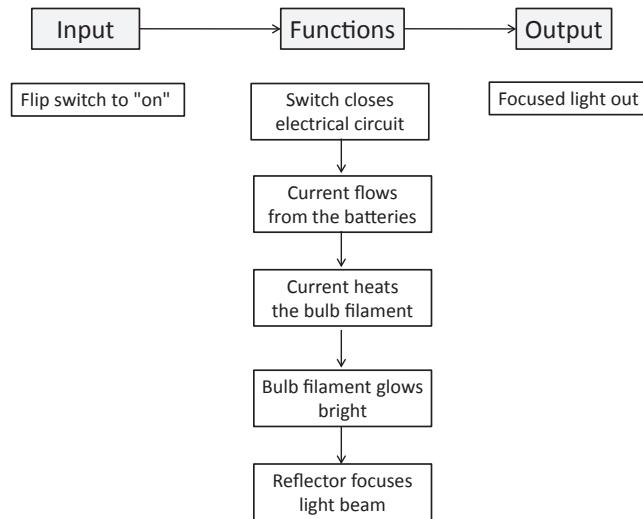
#### 5.3.2.4 Functional Block Diagram

Leadership is the capacity to translate vision into reality.

—Warren G. Bennis

**What Is a Functional Block Diagram?** A Functional Block Diagram is a visual tool to describe the operation, interrelationships, and interdependencies of the functions of a system or equipment. By making the primary functions of the equipment visible, it allows the FMEA team members to agree on how the system works and identify the beginning and end of system or equipment operation. It is usually generated before the formal FMEA team meetings start, and is agreed upon by the FMEA team. Each primary (high-level) function is placed in a “block” and visually laid out in the sequence performed. Inputs and outputs are added for clarity.

**When Is a Functional Block Diagram Used?** Not every item being analyzed will benefit from a Functional Block Diagram. It is best used at a system or subsystem



**FIGURE 5.11** Example of a Functional Block Diagram for a flashlight operation.  
(Reprinted with permission of John Wiley & Sons, Inc.)

level in which there are many functional steps in system operation. Refer to the Section 6.2.2 of Chapter 6 for an explanation of the different types of functions.

**Example of Functional Block Diagram** Figure 5.11 is an example of a Functional Block Diagram for a flashlight operation.<sup>[6]</sup>

### 5.3.3 Make the Scope Visible (for Process FMEAs)

Refer to Figure 5.5 for the preparation tasks that make the scope visible for Process FMEAs. Descriptions with examples are detailed below, along with when to use the tasks.

#### 5.3.3.1 Process Flow Diagram (PFD)

**What Is a PFD?** A PFD is a graphical representation of all of the process operations that result in the manufactured or assembled product, and are within the scope of the Process FMEA project. This is essentially the process hierarchy covered in Section 5.2.8 above, including manufacturing and assembly operations, shipping, incoming parts, transporting of materials, storage, conveyors, tool maintenance, and labeling, and any other steps of the operations that are within the scope of the Process FMEA. Each of the process operations is represented by a symbol representing the type of operation, such as *Fab*, *Move*, *Store*, *Get*, *Inspect*, *Rework*, *Scrap*, or *Contain*, and the symbols are connected in the precise sequence of the operations in the manufacturing or assembly process. Use of such symbols is easily tailored to company needs and policy.

The PFD is a “hierarchy” because the process operations can be at a high level, such as the “front wheel subassembly” station, or at a more detailed operation, such as “Get wheel hub from parts presentation device.”

**When Is a PFD Used?** A PFD is done as part of the preparation for all Process FMEAs. It is either done by itself or in combination with the PFD Worksheet, as shown in the next section.

**PFD Definitions** The following definitions aid in generating the PFD and in ensuring maximum benefit in preparation for the Process FMEA<sup>[7]</sup>:

**Operation Description** This is the detailed description of the manufacturing or assembly process step. Normally, this is in the form of do this (operation), to this (part), with this (tooling). Some PFDs shorten this description and include the detailed Operation Description in the PFD Worksheet as covered in the next section.

**Operation Sequence Number** This is a unique number assigned to each operation step and correlates with the corresponding function in the Process FMEA and the operation in the Process Control Plan.

**Operation Type** This is a category that describes the type of manufacturing or assembly operation, such as *Fab, Move, Store, Get, Inspect, Rework, Scrap, or Contain*.

**Fab** This operation changes the state of the product: assembly, labeling, machining, and so on.

**Move** This operation transports material between stations or stops in a process.

**Store** This operation places material in storage.

**Get** This operation retrieves material from storage.

**Inspect** This operation examines a part to determine whether it conforms to specification. Inspections can be classified by:

A = Automatic, or machine inspected (i.e., leak tester)

M = Manually inspected by the operator (i.e., hand gauge)

V = Visually inspected by the operator

Q = Quality Audit, Process Control Plan check.

**Rework** This operation repairs rejected material, either online or offline.

**Scrap** This operation permanently removes rejected material from the value stream and places it into a scrap container.

**Contain** This operation temporarily holds suspect or rejected material until it can be scrapped or reworked.

**Changeover** This is the action of converting a machine from its state of manufacture for Product A to its required state of manufacture for Product B. In the PFD Worksheet, the individual process steps affected by changeover activities are flagged with one of the Changeover Keys in the Changeover column, which aids in identifying the changeover failure modes and causes in the Process FMEA:

P = Product, material

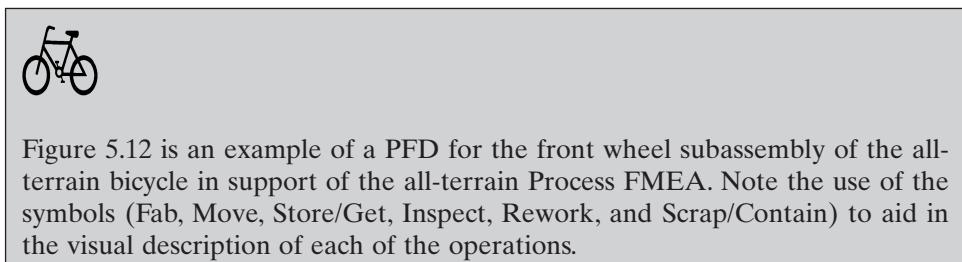
T = Tooling, hard setup changes (adjustments)

S = Software, soft setup (menu, selector switches), job instructions

D = Dunnage, (any material used externally to support or secure products and packages in storage or under transportation in order to protect them from physical damage or to assist in their handling)

L = Labels (in-process labels, product labels, etc.)

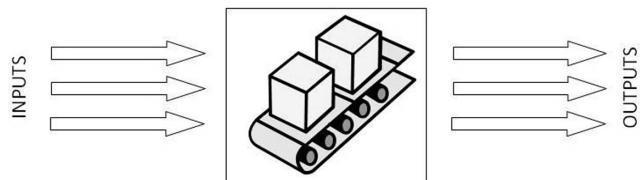
### *Example of PFD*



Op-Seq #		Operation Description							
		Fab	Move	Store/Get	Inspect	Rework	Scrap/Contain	Changeover	
1.2		◊ ○ △ [A] ◊ ○							Front Wheel Subassembly Station
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
1.2.11									Get tire from parts presentation device
1.2.12									Orient and install tire around wheel rim and tire liner
1.2.13									Get tube from parts presentation device
1.2.14									Install tube around tire and rim
1.2.15									Add air to tire to specifications
1.2.16									Mount wheel subassy on wheel balancing device
1.2.17									Add or adjust weights on wheel rim to achieve wheel balance
1.2.18									Visually inspect completed wheel subassy
1.2.19									Place completed wheel subassy on rack for bicycle assembly

**FIGURE 5.12** Process Flow Diagram example—all-terrain front wheel subassembly.

Manufacturing and Assembly Processes have  
Outputs and Inputs



In order to control the outputs of a process, you have to control the inputs

**FIGURE 5.13** Manufacturing process outputs and inputs.

### 5.3.3.2 PFD Worksheet

**What Is a PFD Worksheet?** When doing a PFD, in addition to including symbols and logical sequencing for the entire set of process steps in the manufacturing or assembly process, it is often helpful to provide more information about each of the manufacturing or assembly operations. This includes a detailed description of the process step, called Operation Description, and other information, such as the significant product and process characteristics. With this added information alongside of the graphical PFD, the PFD Worksheet can replace the PFD.

Manufacturing and assembly processes have outputs and inputs. The inputs must be controlled in order to control the outputs. Figure 5.13 is an illustration of the outputs and inputs of a manufacturing process.

Examples of outputs and inputs of an assembly process are:

*Operation.* “Orient and place wheel spokes properly in wheel assembly fixture.”

*Outputs.* Correct number of wheel spokes, correctly oriented spokes properly connected in wheel assembly fixture.

*Inputs.* Correct kit of 36 wheel spokes, error-proofed wheel assembly fixture.

One of the advantages of doing a PFD Worksheet is the mapping of information between the individual process steps and the corresponding columns of the Process FMEA and the Process Control Plan. The following mapping may be useful when doing a Process FMEA:

1. The *Operation Description* from the PFD Worksheet should be considered input to the description of the corresponding *function* of the Process FMEA, and corresponds to the Operation Description in the Process Control Plan.
2. The Significant *Product Characteristics* (outputs) from the PFD Worksheet should be considered input to the description of the corresponding *failure mode* of the Process FMEA.
3. The Significant *Process Characteristics* (inputs) from the PFD Worksheet should be considered input to the description of the corresponding *cause* of the Process FMEA.

4. Key Product Characteristics (KPCs) and Key Control Characteristics (KCCs) identified in the PFD Worksheet flow to the Classification column of the Process FMEA and serve as input to the Process Control Plan.
5. The Operation Sequence Number corresponds one to one with its function in the Process FMEA and operation in the Process Control Plan.

Refer to Chapter 6, Section 6.2.8, for information on the application of product and process characteristics in the FMEA using the Classification column.

**When Is a PFD Worksheet Used?** A PFD Worksheet is used when the FMEA team wants to go beyond the graphical depiction of the manufacturing process (PFD) and include a more complete description of the operations and the significant product and process characteristics that are associated with the operations. This provides a better integration between PFD, Process FMEA, and Process Control Plan.

### **PFD Worksheet Definitions**

**Product Characteristics** These are features, attributes, or properties of a part, component, or assembly. Examples include color, weight, dimensions, surface finish, hardness, appearance, material composition, and so on.

**Process Characteristics** These are process variables and parameters that have a cause-and-effect relationship with the variation found in product characteristics. Examples include mold temperature, cycle time, pressure, flow rate, tool speed, and so on.

**Significant Product Characteristics** These are unique *product*-related characteristics that can affect safety, regulatory compliance, appearance, function, performance, or subsequent product manufacturing. They are the direct *output* of a given manufacturing operation. They may or may not be designated as Key Product Characteristics.

**Key Product Characteristics (KPCs)** These are a subset of the significant product characteristics, and are designated by the company for highlighted attention. They require follow up in the Process Control Plan and usually have their own approval process.

**Significant Process Characteristics** These are unique *process*-related characteristics that can affect the ability of the manufacturing process to meet significant product characteristics. They are *input* to a given manufacturing operation. They may or may not be designated as Key Control Characteristics.

**Key Control Characteristics (KCCs)** These are a subset of the significant process characteristics, and are designated by the company for highlighted attention. They require follow up in the Process Control Plan and usually have their own approval process.

**Class (KPC)** This is a column in the PFD Worksheet used to signify that a significant product characteristic is also designated “KPC.” “Class” refers to “Classification,” which is further explained in Chapter 6, section on Classification.

**Class (KCC)** This is a column in the PFD Worksheet used to signify that a significant process characteristic is also designated “KCC.”

### **Example of PFD Worksheet**



Figure 5.14 is an example of a PFD Worksheet for the front wheel subassembly of the all-terrain bicycle in support of the all-terrain Process FMEA. In this example, the PFD is the left half of the graphic, and the right half includes significant product and process characteristics that are useful in the FMEA.

Regardless of the type of FMEA being performed, a visual depiction of the scope of the FMEA is an essential element of the project in order to ensure the FMEA team agrees on the scope and stays within its limits.

#### **5.3.4 Assemble the Correct Team**

One of the most important steps in preparing for an FMEA is selecting the right team because FMEA is a cross-functional team activity. Doing an FMEA by one person, or with an inadequate or incomplete team, is unacceptable and inevitably results in poor quality. There are three primary reasons for the necessity to have the correct team when doing an FMEA:

1. People have “blind spots.” A well-defined cross-functional team minimizes the errors inherent with “blind spots.”
2. The FMEA analysis requires subject-matter experts from a variety of disciplines to ensure incorporation of all necessary inputs into the exercise, and that the proper expertise is applied to the design or process being analyzed.
3. One of the indispensable values of an FMEA is the cross talk and synergy between subject-matter experts that occurs during the meetings. Well-defined groups can discover things that individuals often miss.

A typical core team for a System or Design FMEA might include representatives from system engineering, design engineering, manufacturing engineering, test engineering, field service, and quality or reliability. Large systems or subsystems may require more than one design representative. Supplier partners may be included for critical parts on a need-to-know basis.

A typical core team for a Process FMEA might include representatives from manufacturing engineering, plant assembly, product engineering, supplier quality, end-of-line test, maintenance, and quality or reliability.

In addition, the FMEA core team can invite other experts for specific topics during FMEA meetings when their topic is being discussed.

The following are suggestions, based on application experience, for selecting the right FMEA team:

1. Each of the FMEA team members should be a subject-matter expert in his/her discipline, not a “stand-in” to attend the meeting.
2. Although there are exceptions, it is usually a good idea to have between four and eight team members. Less than four can result in missed information; more than eight can end up in too much time wasted achieving consensus.

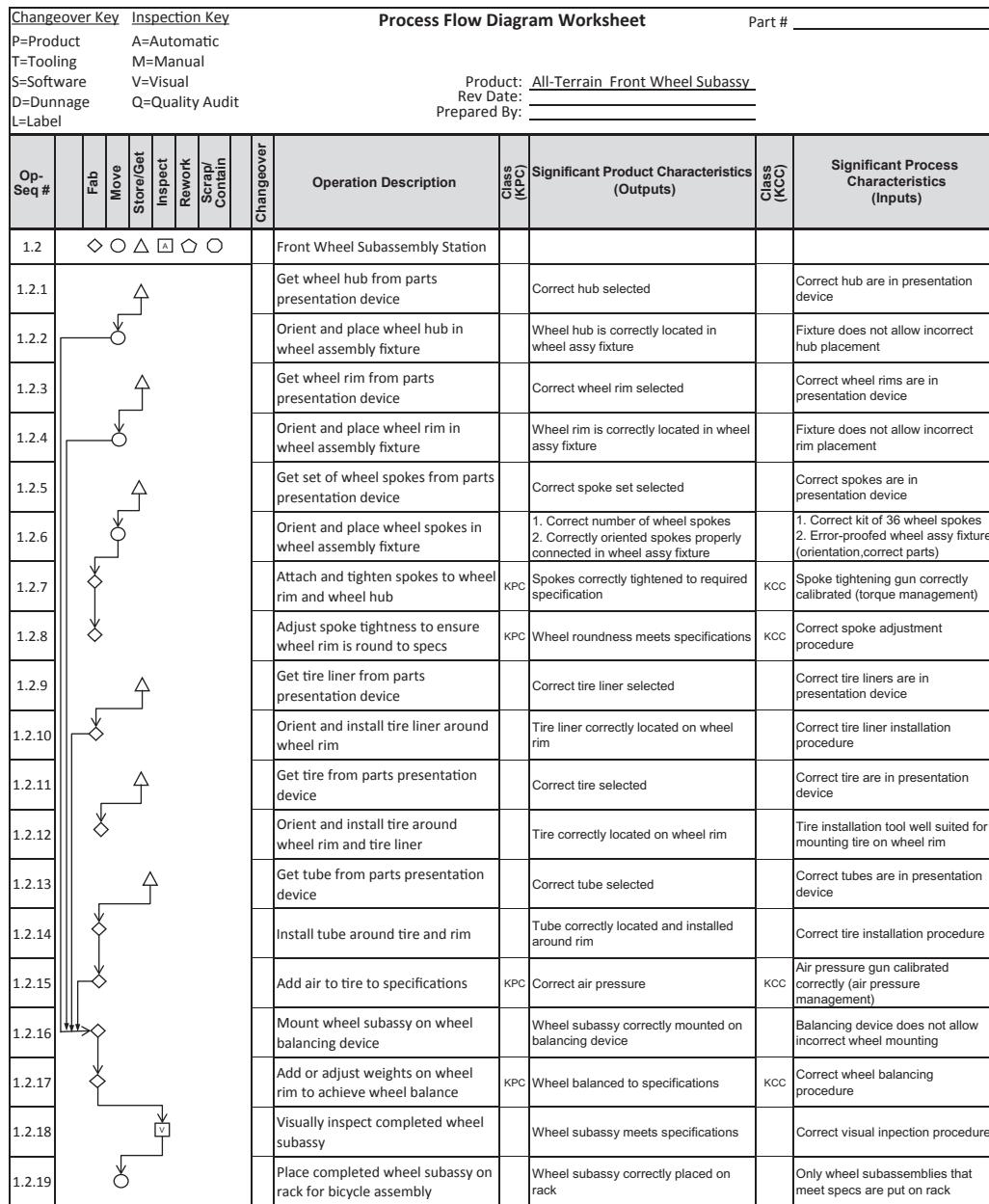


FIGURE 5.14 Process Flow Diagram Worksheet example—all-terrain front wheel subassembly.

3. FMEA team members need to be trained on FMEA procedure and facilitated by someone who is trained in facilitation techniques.
4. Ad hoc team members may be enlisted as needed to cover selected issues. An example of this is an expert in materials, not part of the core team, brought in to discuss a material failure mode.
5. There can be more than one design engineer on the Design FMEA to cover different aspects of the design.
6. There can be more than one process engineer on the Process FMEA to encompass different aspects of the manufacturing or assembly process.
7. Management often has to be involved in empowering FMEA teams to ensure attendance and support. However, a management representative is not usually part of the FMEA team unless he or she is a subject-matter expert and is needed in that capacity.
8. It is a good idea to have individuals on the FMEA team that will be involved with the implementation of recommended changes.
9. It is also a good idea to have team members who either have decision-making authority or can provide access to people with decision-making authority.
10. A supplier representative may participate in an original equipment manufacturer (OEM) Design or Process FMEA, usually on an ad hoc basis to provide supplier-related input.

The whole idea is to get the right people in the room to be able to analyze the entire design or process, come to agreement on root causes, and agree on solutions for high-risk issues.

Someone possessing, or well trained in, team facilitation skills should lead FMEA teams. Chapter 10 covers the unique skills and techniques of excellent FMEA facilitation.



### Bicycle Example

The all-terrain System FMEA team is composed of the following team members: bicycle system design engineer, all-terrain system engineer, bicycle test engineer, bicycle service representative, bicycle assembly representative, and bicycle reliability engineer. In addition, subject-matter experts from the various bicycle subsystems are brought in to the System FMEA meetings as needed when their subsystems are being discussed.

The all-terrain Hand Brake Design FMEA team is composed of the following team members: bicycle system design engineer, bicycle hand brake engineer, bicycle hand brake test engineer, bicycle service representative, bicycle hand brake assembly representative, and bicycle reliability engineer. Subject-matter experts from the various bicycle hand brake components are also invited to attend the Hand Brake Design FMEA meetings as needed when their components are being discussed.

The all-terrain Process FMEA team is composed of the following team members: all-terrain manufacturing engineer, bicycle assembly representative, bicycle system design engineer, bicycle supplier quality, bicycle end-of-line test, bicycle plant maintenance, and bicycle reliability.

### 5.3.5 Establish the Ground Rules and Assumptions

Before beginning the analysis, the team should discuss (and document) the underlying assumptions of the analysis and specific ground rules for how it will be performed. Some of these guidelines may have been determined previously by the department's standard practices for FMEA and some may be specific to the particular analysis project.

A Design FMEA focuses on *design-related* issues emphasizing how the design can be improved to ensure that product-related risk is low during the useful life of the equipment. This includes any potential failure modes and causes that can occur during the manufacturing or assembly process, which are the result of the design. The team may choose to mitigate such failure modes (e.g., error proofing and design for assembly), and these recommendations should be placed in the Recommended Actions column.

A Design FMEA usually assumes the product will be manufactured within engineering specifications. In addition, the Design FMEA team may wish to consider an exception: the part design may include a deficiency that could cause unacceptable variation in the manufacturing or assembly process.

A Process FMEA focuses on *process-related* issues for the manufacturing or assembly process, with emphasis on how the manufacturing process can be improved to ensure that process-related risk is low. The team may identify design opportunities to eliminate or reduce the occurrence of process failure modes, and these should be placed in the Recommended Actions column of the Process FMEA. An example is a design change that eliminates the possibility of operator misassembling a part.

Process FMEAs typically assume the design requirements are correct and incoming parts and materials to an operation meet design intent. In addition, the Process FMEA team may wish to consider an exception when historical data indicate incoming part quality issues: incoming parts or materials may have variation and do not necessarily meet engineering requirements.

The following is an example of some of the ground rules and assumptions the FMEA team may consider before commencing the FMEA project:

1. For Design FMEAs, does the FMEA team assume the product will be manufactured or assembled within engineering specifications?
2. For Design FMEAs, does the FMEA team wish to consider an exception, such as the part design may include a deficiency that could cause unacceptable variation in the manufacturing or assembly process?
3. For Process FMEAs, does the FMEA team assume incoming parts and materials to an operation meet design intent?
4. For Process FMEAs, does the FMEA team wish to consider an exception, such as incoming parts or materials may have variation and do not necessarily meet engineering requirements?
5. What are the assumed environmental conditions?
6. What are the assumed operating profiles?
7. Will the FMEA team assume product abuse by the user? If so, to what levels?
8. What is the definition of failure used in the FMEA?
9. How will the FMEA team use severity rankings and RPNs to prioritize issues for corrective actions?

10. What is the process by which the FMEA team obtains approval for FMEA recommended actions and follow-up for execution?
11. What meeting norms should the team adopt so that meetings run smoothly and efficiently? (See Chapter 10, Section 10.2 for suggested meeting norms.)
12. Who will enter data into the FMEA software during meetings? Will there be a scribe, or will the facilitator enter the data?
13. How will the FMEA team come to decisions on each of the FMEA tasks? (See Chapter 10, Section 10.3, for suggested decision criteria.)
14. If applicable, how will the FMEA team coordinate with suppliers? Will supplier FMEAs be reviewed and approved by the FMEA team for critical parts according to defined FMEA quality objectives? (The FMEA Quality Objectives are covered in Chapter 9, Section 9.1.)
15. How will the organization track the completion of recommended actions and ensure risk reduction to an acceptable level?



### Bicycle Example

Here are the ground rules and assumptions used by the all-terrain System FMEA team and the all-terrain Hand Brake Design FMEA team:

- The all-terrain program FMEA ground rules, as outlined in document #123, are used throughout the analysis.
- The manufacturing and assembly process is assumed to be stable and capable. (Manufacturing and assembly process issues are taken up in the bicycle Process FMEA.)
- The environmental conditions and operating usage are assumed to be as stated in all-terrain Technical specification #ABC.
- The FMEA team considers no other product abuse other than as stated in the above assumptions and the all-terrain technical specifications.
- For the purpose of this FMEA, the definition of failure is any performance or lack of performance that is outside the requirements from the all-terrain technical specifications or the FMEA functions.
- The FMEA team addresses all severity 9's and 10's and the top 20% of RPNs. The FMEA team may agree to address lower RPNs as feasible depending on the resources available.
- The FMEA team presents all high severity and high RPN items including recommended actions to the all-terrain management team at the biweekly meeting; the FMEA team will review and incorporate into the FMEA any management feedback.
- The published FMEA meeting norms are used as outlined in the FMEA technical guidelines.

*(Continued)*

- The all-terrain reliability engineer facilitates the FMEA meetings and is responsible for administering the FMEA database.
- Recommended actions from the FMEA are assigned to the appropriate person in the all-terrain group for execution.
- The entire FMEA team, using consensus and collaboration, should agree on all decisions regarding FMEA content and recommendations. Voting, or majority rule, is not used.
- The FMEA team identifies the most critical supplier parts and requires suppliers to submit Design and Process FMEAs on those critical parts for approval by the FMEA team, according to the FMEA Quality Objectives.
- Monthly status updates of the FMEA progress and key issues are presented at the all-terrain monthly status meeting, and management support is requested for any delinquent tasks.

### 5.3.6 Establish the Role of Suppliers

Part of the preparation for an FMEA project includes determining the role of suppliers. Many of the items in the system hierarchy are supplier designed and/or manufactured. Root causes of important system or subsystem failure modes can have their source within supplier parts. Therefore, the FMEA team must consider how to involve the supplier for critical components in the System or Design FMEA and this may involve different approaches. For example, when the FMEA team is reviewing a subsystem that includes a supplier part they may want to invite the supplier to the FMEA team meeting on a need-to-know basis for the discussion involving that supplied part. Another approach is to conduct an FMEA jointly with a supplier or suppliers of critical parts. A third approach is for a representative from the OEM to review and approve the supplier FMEA for critical parts. However decided, the interaction between OEM/FMEA team and supplier(s) of critical parts is an important preparation concern.

See Chapter 11, Section 11.3.3, Step 6, for more information on how to conduct reviews of supplier FMEAs for critical parts.

### 5.3.7 Gather and Review Relevant Information

One of the most important steps in FMEA preparation is gathering all of the relevant documents and information. If this step is missed or done inadequately the FMEA meetings will be burdened with extra tasks related to missing information, the time of the subject-matter experts will be wasted, and the FMEA results potentially compromised. The following are some of the important categories of information to research and gather prior to the first FMEA meeting.

Access to this information can be either printed matter or electronic, although it is preferred that the information is electronically available. Ideally, whoever is assigned responsibility for FMEA preparation will attach the documents and information to the FMEA project electronically, so the data are easily available to the FMEA team during team meetings.

In general, the following information is important to have available to the FMEA team:

**Bill of Materials** As discussed previously, the bill of materials, also known as the system hierarchy, is a key part of FMEA preparation and documentation.

**Legal and Regulatory** All relevant legal and regulatory issues and documentation need to be available to the FMEA team.

**Past FMEAs** All past FMEAs for similar systems or designs or assemblies should be available to the FMEA team. A relational database best accomplishes this so that the FMEA information is easily accessible to the FMEA team.

**Field History** One of the keys to successful FMEAs is using them to avoid repeating past failures. Every company experiences some field failures. The most successful companies do not *repeat* them. The FMEA team needs to ensure that a summarized list of field failures for similar products is easily available during the FMEA project. This listing of field failures can be “seeded” into the FMEA so the team ensures these failures do not repeat.

To do this, the FMEA team needs access to field service and repair information for similar systems and designs. Field data may be culled for pertinent material, eliminating the irrelevant information, in order to easily identify field failure modes and causes that are useful to the FMEA team.

**Technical Requirements and Specifications** Within the scope of the FMEA project, the FMEA team requires access to all technical requirements and specifications, including functional and performance requirements, customer usage requirements, and operating environments. These help define the functions as well as the operating conditions and profiles for the items under consideration.

**Actual Parts** For System or Design FMEAs, it is important to bring to the FMEA meetings *actual parts* that are as close to the design or process intent as possible. If actual parts are too large to bring to the FMEA meetings, then the FMEA team should arrange to see actual parts on-site. For new projects that are in the early design stage and do not have prototype parts available, similar parts from previous versions suffice for this step. Schematics and drawings can supplement, but nothing can take the place of actual parts to support the “go and see” that is essential for good dialog.

For Process FMEAs, the FMEA team may need to arrange a plant visit to go and see the manufacturing or assembly operations under review. If the manufacturing operations are in the preliminary stage and there are no similar operations to see, then the FMEA team can develop visual aids for the “go and see” that supports good dialog.

Actual parts create a focal point for discussion and allow the FMEA team to see the interfaces and visualize the functionality. This helps the team focus their attention on areas of concern, rather than imagining how the parts function and are connected.

**Test Procedures and Test Plans (for System/Design FMEAs)** The System/Design FMEA teams need access to up-to-date test plans and test procedures in order to be able to assess detection-related risk and recommend appropriate changes.

**Process Control Plans and Procedures (for Process FMEAs)** The Process FMEA teams will need access to up-to-date Process Control Plans and procedures in order to be able to assess detection-related risk and recommend appropriate changes.

**List of Specific Design or Process Changes** In many cases, specific changes to a design or manufacturing process are being considered and will be analyzed by the FMEA team. The nature of the proposed changes must be documented and made available to the FMEA team. This includes changes in design, material, manufacturer, supplier, supplier design or process, usage environment, interfaces, specifications, performance requirements, or any other changes.

**Other** Examples of other preparations include design drawings, assembly drawings, preliminary test results, marketing analysis, and so on. Each company should develop its own list of preparation items for FMEA projects. The whole idea is to get the homework and preparation done in *advance* of the FMEA meetings in order to best utilize the subject-matter experts' time and contributions.

#### **5.3.7.1 “Gather Information Checklist” (for System and Design FMEAs)**

Specifically, for System and Design FMEAs, the following information needs to be readily available to the System or Design FMEA team:

- Bill of Materials
- Past Design FMEAs
- Current System FMEA (if performing a Design FMEA at the subsystem or component level)
- Warranty, recalls, and other field history
- Engineering requirements (functional, performance, operating environments, etc.)
- Drawings and schematics
- Applicable government or safety regulations
- Test procedures
- Preliminary Design Verification Plan
- Preliminary test data (if available)
- FMEA Block Diagram, P-Diagram, FMEA interface matrix, and Functional Block Diagram
- Quality Function Deployment (QFD) (if available)
- Results of design concept selection or trade-off studies
- Actual parts (similar to design intent)
- List of specific design changes
- Other information in addition to field history and test results that will help establish failure frequencies
- Other documents and information that highlight the nature of the design concept

**5.3.7.2 “Gather Information Checklist” (for Process FMEAs)** Specifically, for Process FMEAs, the following information needs to be readily available to the Process FMEA team:

- Bill of Materials
- Bill of Process
- Current and Past Design FMEAs (for the products being analyzed by Process FMEA)
- Past Process FMEAs
- Operator Instructions
- Warranty, recalls, and other field history
- Manufacturing data (plant incidents, etc.)
- Quality performance data (process yield, first time capability, parts per million, process capability indices, etc.)
- Engineering requirements (functional, performance, operating environments, etc.)
- Drawings and schematics
- Applicable government or safety regulations
- Process Control Plan procedures
- Preliminary Process Control Plan
- PFD and PFD Worksheet
- Results of manufacturing concept selection or trade-off studies
- Actual parts (similar to design intent)
- List of specific manufacturing process changes
- A planned visit to “go and see” the manufacturing operations (or other suitable visual aids are provided)
- Other documents and information highlighting the nature of the manufacturing or assembly concept



### Bicycle Example

In the all-terrain bicycle System FMEA example, the team has electronic access to the following material:

- All-terrain Bill of Materials
- System FMEA Block Diagram
- FMEA Interface Matrix and Functional Block Diagram
- All-terrain technical specifications
- All-terrain design schematics

*(Continued)*

- Trade-off studies leading to the current all-terrain concept
- Current bicycle system test plans and procedures
- Preliminary test results
- Field failure data for similar bicycles
- Past all-terrain System FMEAs
- Information about suppliers of critical parts
- All-terrain service manuals
- Applicable government or safety regulations

In the all-terrain bicycle Process FMEA example, the team has electronic access to the following material:

- All-terrain Bill of Materials
- All-terrain Bill of Process
- Past all-terrain Design FMEAs
- Past all-terrain Process FMEAs
- Operator instructions
- Bicycle warranty, recalls, and other field history
- Bicycle manufacturing data (plant incidents, etc.)
- All-terrain engineering requirements
- All-terrain drawings and schematics
- Applicable government or safety regulations
- Current Process Control Plan procedures
- Preliminary Process Control Plan
- All-terrain PFD Worksheet

### 5.3.8 Prepare FMEA Software for First Team Meeting

If not done already, the FMEA software will need to be prepared for the FMEA team meetings. This typically includes the following steps:

- Enter the agreed-upon header information
- Enter the system hierarchy (or process hierarchy), including the specific item being analyzed
- Enter the item properties
- Enter the names of the team members
- Use or modify the worksheet columns, as agreed upon
- Use or modify the risk ranking scales, as agreed upon
- Attach all of the diagrams, ground rules and assumptions, and “gather information” documents, and ensure they are easily accessible to the team during team meetings
- Any other steps to prepare the FMEA software for team meetings, so that in-meeting time is used efficiently

### 5.3.9 Ready-for-First-Meeting Checklist

This checklist helps ensure that all the necessary steps are completed before the first FMEA team meeting.

- The FMEA scales, worksheet, and procedure have been agreed upon and loaded into the FMEA software.
- The FMEA project has been selected based on an identified need or preliminary risk assessment.
- The FMEA team has been identified and notified of the upcoming FMEA.
- The FMEA team is trained in proper FMEA procedure.
- An FMEA facilitator or team leader has been assigned and is trained in how to effectively facilitate FMEAs.
- The proper FMEA procedure is available for use by the FMEA team.
- Management supports the FMEA project and will help to ensure it is done properly with good attendance.
- The scope of the FMEA is well defined and agreed upon.
- For System and Design FMEAs: an FMEA Block Diagram, P-Diagram, FMEA Interface Matrix, and Functional Block Diagram have been done, as needed.
- For Process FMEAs: a PFD and PFD WS have been done, as needed.
- The ground rules and assumptions have been identified and agreed upon.
- All of the relevant information has been gathered in preparation for the upcoming FMEA. (See “Gather Information Checklist” above)
- The FMEA software has been prepared for the first team meeting
- FMEA meeting room has been scheduled and FMEA members have been notified.

## 5.4 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

### Problem 5.1

In an FMEA, which of the following are true statements about the severity, occurrence and detection scales? (Select all that apply.)

1. The scales from the selected FMEA standard must be used exactly as is, without any modification.
2. In using the detection scale, the higher the rating on the scale the lower the detection-related risk.
3. In using the severity scale, severity should be thought of as the severity of the failure mode.
4. In using the occurrence scale, the FMEA team should use objective data, if available, to establish the occurrence rating.

**Problem 5.2**

Which of the following are true statements about FMEA preparations? (Select all that apply.)

1. Past FMEAs should be easily accessible to the FMEA team.
2. Warranty, recalls, and other field history are part of Failure Review and Corrective Action System (FRACAS) but not needed in preparation for FMEAs.
3. Test procedures are needed to provide the functional requirements.
4. An FMEA interface matrix is a chart showing which interfaces must be considered in the analysis and the type of interface.
5. FMEA team meetings with the subject-matter experts should begin as soon as the FMEA team is established, and the various preparation items gathered in between meetings.

**Problem 5.3**

Reference Figure 5.7 “System FMEA block diagram example—all-terrain bicycle.” Name three missing elements from the System FMEA Block Diagram.

**Problem 5.4**

Which of the following would usually be part of a System FMEA team? (Select all that apply.)

1. Design engineer
2. System engineer
3. Manufacturing engineer
4. Reliability or quality representative
5. Director over department of items being analyzed
6. System test engineer
7. Service or field representative

**Problem 5.5**

The purpose of an FMEA Block Diagram is (select all that are true):

1. To document the primary functions of the item.
2. To document the primary failure modes of the item.
3. To visually show the scope of the FMEA, including interfaces.
4. To visually show the timing of the FMEA.

**Problem 5.6**

The FMEA facilitator is trying to determine when to begin holding the FMEA meetings with the subject-matter expert team. (Select all that are true.)

1. Begin holding FMEA meetings as soon as the decision to do the FMEA is made.
2. Begin holding FMEA meetings as soon as all the preparation steps are completed.
3. Begin holding FMEA meetings after the FMEA facilitator has met with each team member separately and received their input.
4. Begin holding FMEA meetings after the FMEA facilitator has filled out the FMEA worksheet.

**Problem 5.7**

Which of the following are important elements of good FMEA preparation? (Select all that apply.)

1. The company organization structure
2. Technical specifications of the item being analyzed with FMEA
3. Schematics of all subsystems outside the scope of the FMEA
4. Field history of similar items to the scope of the FMEA
5. A visual representation of the scope of the FMEA
6. Past FMEAs of similar items to the scope of the FMEA
7. All FMEAs in the company archive

**Problem 5.8**

A Design FMEA will be done on the design of a flashlight. List six examples of information that should be gathered prior to the first meeting with the FMEA team.

**Problem 5.9**

Draw an FMEA Block Diagram for the flashlight. Be sure to include physical connections and energy transfers as well as interfaces.

**Problem 5.10**

A Process FMEA will be done on the assembly of a flashlight. List six examples of information that should be gathered prior to the first meeting with the FMEA team.

### Problem 5.11

**Scenario:** You are preparing to lead a System FMEA on the all-terrain bicycle. Review the section titled “All-Terrain Bicycle Functional/Technical Specifications” in Appendix C, “All-Terrain Bicycle Documents.” Answer these questions:

The Front suspension has a requirement: “Should withstand g-force acceleration to 3g, above which it is considered abusive.” Should this requirement be part of the all-terrain System FMEA, and if so, how would it be used?

The Gears have a requirement: “Ease of pedaling—should be able to move bicycle with 5 Nm torque on first gear.” Should this requirement be part of the all-terrain System FMEA, and if so, how would it be used?

What type of requirement seems to be missing from the section titled “All-Terrain Bicycle Functional/Technical Specifications” of the “All-Terrain Bicycle Documents” in Appendix C?

### Problem 5.12

Refer to the “Operating Conditions” table in Appendix C, “All-Terrain Bicycle Documents.” How should information like this be used in FMEA applications?

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# *Chapter* 6

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## *How to Perform an FMEA Project: Procedure*

The difference between failure and success is doing a thing nearly right and doing a thing exactly right.

—Edward Simmons

### **IN THIS CHAPTER**

As soon as the Failure Mode and Effects Analysis (FMEA) preparation steps are completed, work can begin with the FMEA team on the FMEA procedure. This chapter outlines in detail the basic procedure for doing FMEAs, from items through calculation of Risk Priority Numbers, thoroughly explaining each step in the sequence. The emphasis is on how to apply the FMEA procedure in real-world applications. Sample FMEA forms are included (in the Appendix). The application of each step in the FMEA procedure is further illustrated with the use of the bicycle example for System, Subsystem, Component, and Process FMEAs.

Unless otherwise noted, this chapter covers material that is important for all FMEA applications, including System FMEA, Design FMEA, and Process FMEA. Topics unique to one specific type of FMEA application are clearly noted in the paragraph title, such as “For System and Design FMEA” or “For Process FMEA.”

### **USE OF THE BICYCLE EXAMPLES IN THE CHAPTER**

In order to highlight the application of various FMEA procedure steps, the all-terrain bicycle case study is used. At the end of each procedural step, brief examples

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*Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis*, First Edition. Carl S. Carlson.

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of how the all-terrain bicycle team applied that step in performing its bicycle FMEAs are shown. Note that these examples are shortened excerpts from a longer version of bicycle FMEAs, and therefore do not contain the complete list of functions, failure modes, causes, and so on. A bicycle icon precedes these examples. Chapter 8, Section 8.8, has a teaching analysis of the resulting bicycle FMEAs.

## 6.1 FMEA PROCEDURE SEQUENCE OF STEPS

Once the FMEA team meetings have begun, there are many ways to proceed in doing the FMEA analysis, such as entering each FMEA “column” in sequence (e.g., all the functions, then all the failure modes, and then all the effects) or entering each FMEA “row” in sequence (e.g., one function, one failure mode, one effect, one cause, and one control).

There is no standard method for the sequence of steps; however, many experienced FMEA teams use the following strategy:

1. Enter all the primary functions for the item under analysis.
2. Beginning with the first function, enter all the failure modes and corresponding effects, with severity rankings for the most serious effect of each failure mode.
3. For each failure mode, enter all of the causes, with occurrence rankings for each cause.
4. For each cause, enter prevention-type controls and detection-type controls, with detection rankings for the best detection-type control. (Some practitioners prefer to enter the prevention-type controls before the occurrence rankings as prevention-type controls can influence the value of the occurrence ranking.)
5. Enter the next function and continue until all the functions are analyzed through Risk Priority Numbers (RPNs).
6. Review the high severities and high RPNs, and develop all needed recommended actions that will reduce risk to an acceptable level.
7. Review high-risk FMEA issues, and corresponding recommended actions, with management and proceed to execution steps.

The exact sequence is up to the FMEA team.

### Use of Post-It Notes<sup>TM</sup>

One way to harness the creative energy of the FMEA team is to use Post-It Notes<sup>TM</sup> at the beginning of the FMEA analysis in order to save valuable time spent in meetings. For each item’s function, ask the FMEA team to write Post-It Notes for the primary concerns they have, not emphasizing if the concern is worded as a failure mode, effect, or cause. The writing of Post-It Notes is done concurrently; in other words, all the FMEA team members are writing Post-It Notes at the same time until they have noted all of their primary concerns. The Post-It Notes are placed on a wall easily visible to the FMEA team and organized into similar groupings. The

FMEA team reviews the information on the wall and determines what goes into the FMEA analysis. This technique encourages contribution by all team members, fosters creativity, and saves meeting time.



### Bicycle Example

The all-terrain System FMEA team decides to focus on the single item called “Bicycle System” and takes up the interfaces between the bicycle subsystems at the function level. They begin by entering all the functions of the bicycle system, including interfaces. Next, for each function, they enter all the failure modes and corresponding effects (with severities), causes (with occurrences), controls (with detections), and calculated RPNs. Then, they take up the next function and continue until all the functions are analyzed through RPNs. Next, they review the high severities and high RPNs, and develop all needed recommended actions that will reduce risk to an acceptable level. The high-risk FMEA issues and corresponding recommended actions are reviewed with management.

## 6.2 BASIC FMEA PROCEDURE

Once all of the preparation work is done, and the FMEA team meetings are scheduled, the FMEA procedure follows the steps described in this chapter.

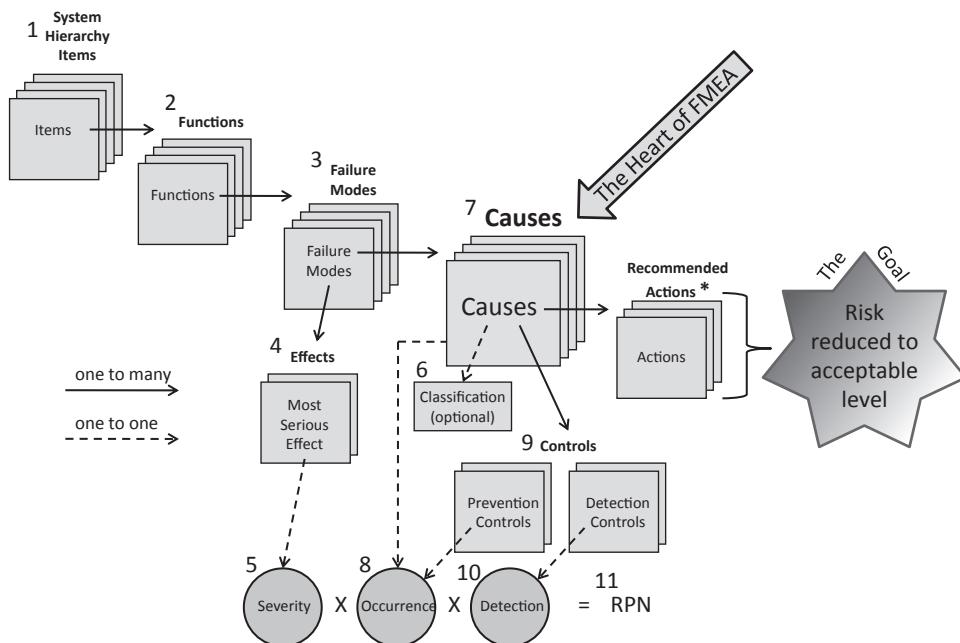
The exact definition of each of the FMEA worksheet elements is provided in Chapter 3, Section 3.5, along with many examples. Each step of the FMEA analysis should be done with enough clarity and detail to proceed to the next step in the analysis. Too much detail and the analysis bogs down and the team gets frustrated. Too little detail and the team will not get to the root causes and proper corrective actions to reduce risk. As the team proceeds, each step, carefully and properly articulated, makes the subsequent step easier for the team to define.

There is a one-to-many relationship between each of these steps. For example, for one item, there may be many functions. For one function, there may be many failure modes. For one failure mode, there may be many causes. For one cause, there may be many controls. In addition, for one cause, there may be many recommended actions.

It is important to understand the logical relationship between the various elements of FMEA. Figure 6.1 shows this logical relationship and illustrates the cause as the “heart” of the FMEA. The circled numbers in this illustration correspond to the elements in the basic FMEA procedure.

### 6.2.1 Items

The FMEA team identifies or confirms the item to be analyzed with FMEA procedure. For System and Design FMEAs, this will be the specific portion of the system hierarchy established during the Preliminary Risk Assessment (as discussed in Chapter 4, Section 4.3), or otherwise determined by the FMEA team. For Process



**FIGURE 6.1** The logical relationship between FMEA elements.

(Illustration numbers correlate to Chapter 6 procedure numbers. \*Recommended Action procedure is covered in Chapter 7.)

FMEAs, this is usually the identified portion of the manufacturing or assembly operations. The item selected for FMEA should be clearly marked or entered into the FMEA database or on the FMEA worksheet.

For System and Design FMEAs, the FMEA team will need to decide how to address interfaces. From the FMEA Block Diagram and the FMEA interface matrix, all of the interfaces that are within the scope of the FMEA project should be clearly identified. There are two ways that the FMEA team can ensure that all the interfaces are properly addressed. The first option is to add the interfaces to the system hierarchy directly underneath the system (for subsystem interfaces) or directly below the subsystem (for component interfaces). The second (and preferred) option is to keep the system hierarchy as it is traditionally defined, but include each interface as a separate function, properly describing the function of the interface.



### Bicycle Example

The item identified by the all-terrain System FMEA team is “Bicycle System.” The item identified by the all-terrain Hand Brake Design FMEA team is “Hand Brake Subsystem.” The item identified by the all-terrain Brake Cable Design FMEA team is “Brake Cable.”

The all-terrain Process FMEA team is performing Process FMEAs on all of the process hierarchy items that comprise the manufacturing and assembly oper-

ations for the bicycle. The item example illustrated in Figure 6.3 is “Orient and place wheel spokes and wheel assembly fixture.”

Note that both the System FMEA team and the Hand Brake Design FMEA team decided to address interfaces as functions in their FMEAs, so the only items identified are the Bicycle System and the Hand Brake Subsystem, respectively.

See Figure 6.2 for an example of item identification by the all-terrain System and Design FMEA teams.

See Figure 6.3 for an example of item identification by the all-terrain Process FMEA team.

## 6.2.2 Functions

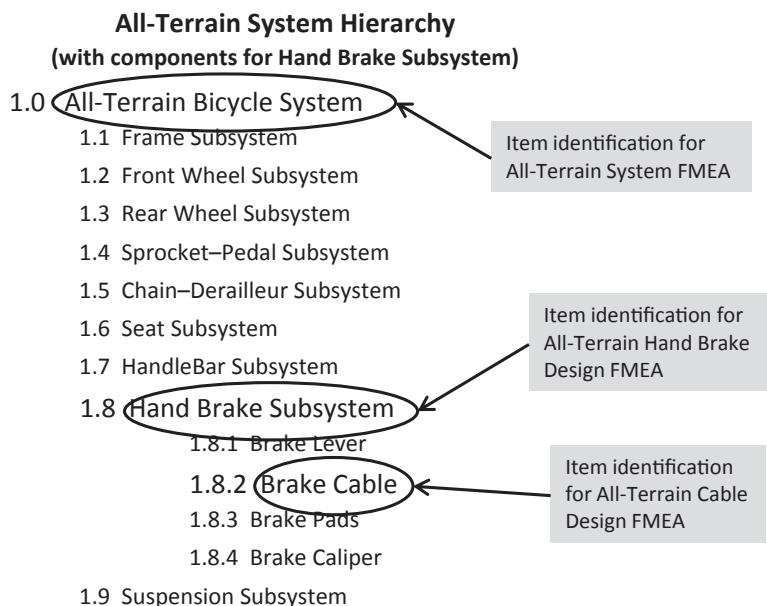
A perfection of means, and confusion of aims, seems to be our main problem.

—Albert Einstein

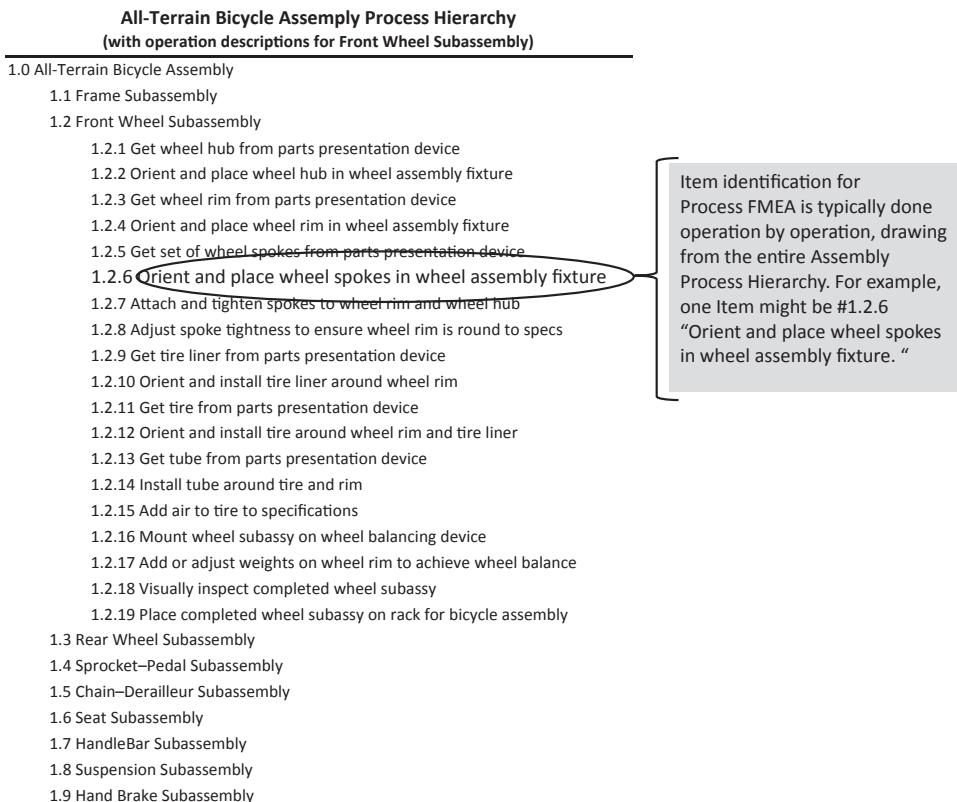
For each item under consideration, the FMEA team identifies the primary functions.

Referencing the definitions in Chapter 3, Section 3.5, 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; wording should consider ‘Do this [operation] to this [the part] with this [the tooling]’ along with any needed requirement.” Refer to this section for a full explanation and useful examples of what constitutes a function.

Some teams list every function separately, while others combine functions into one larger statement. It is a good practice to avoid long lists of functions with narrow



**FIGURE 6.2** Example of item identification for all-terrain System and Design FMEAs.



**FIGURE 6.3** Example of item identification for all-terrain Process FMEA.

differences, as it adds complexity to the analysis without adding value. It is helpful to list functions separately when they are significantly different. The more precise the description of functions, the easier it is to identify potential failure modes for preventive/corrective action. If specific characteristics are required, they should be included quantitatively as part of the functional description. Care should be taken to include interactions and interfaces between parts.

Care should be taken to only include what the team believes to be the *primary* functions, and not include requirements that are too detailed and outside the objectives of the FMEA. For example, one of the requirements in the technical specifications document might be an offering of a particular color. The team may choose to exclude this color requirement in the function column of the System FMEA. The objectives of the FMEA do not include tracing and analyzing every single requirement from the technical specifications documents. Use of FMEAs for this purpose can add considerable length and time to an FMEA and make it more difficult to identify and focus on risk reduction.

For System and Design FMEAs, the FMEA Block Diagram and Functional Block Diagram (if done) are both input to establishing the functions, and make this step considerably easier. For Process FMEAs, the Process Flow Diagram is input to

the functions. See Chapter 5, Sections 5.3.2 and 5.3.3 for information on FMEA Block Diagram, Functional Block Diagram, and Process Flow Diagrams.

**Thought-Starter Questions** When identifying functions for System or Design FMEAs, the team can be asked questions such as:

- “What are the primary purposes of this item?”
- “What is the item supposed to do? What must the item not do?”
- “What is the standard of performance?”
- “What functions occur at the interfaces?”
- “What safety-related functions are important for this item?”
- Any other questions that ensure all of the primary functions are determined (reference Section 6.2.4, “Checklist of Function Types”)

For Process FMEAs, the operation description is input to the function description, often in the form of “Do this [operation] to this [part or assembly] with this [tooling].” There should be a standard of performance or requirement associated with each function description. The team can be asked questions such as:

- “Is the process function described in the form: do this [operation] to this [part or assembly] with this [tooling]?”
- “What is the primary purpose of the operation?”
- “What is the standard of performance of the operation?”
- “What is the operation intended to do? What must the operation not do?”
- Any other questions that ensure all of the primary process functions are determined (reference the section “Checklist of Function Types” below)

**6.2.2.1 Requirements** Remember, for Design FMEAs, the function needs to include the standard of performance or requirements. For Process FMEAs, the function is usually stated in terms of “Do this [operation], to this [part], with this [tooling],” with the addition of applicable standard of performance or requirements.

Requirements are measurable characteristics of a product function or its operation. A separate column may be included in the FMEA worksheet for requirements or they can be included in the function description. Functions may have multiple requirements.

In many situations, an existing document may contain detailed information about the functions that the item or step is intended to perform. For example, Quality Function Deployment (QFD) contains design requirements that should be considered in the Design FMEA; Technical Specifications contain product requirements that describe the performance objectives and functions of product designs; and the Process Flow Diagram worksheet and Operator Instructions contain process operations that should be considered in the Process FMEA.

Properly worded functions, including standard of performance or requirements, will make it easier to identify failure modes.

**6.2.2.2 Checklist of Function Types** There are different *types* of functions. Basic functions fulfill the purpose of a product. Interface functions should be included when they are within the scope of the analysis. Additional functions may be added regarding safety, reliability, product appeal, laws and regulations, product installation, portability, storage, and so on.

Here is a checklist of the various types of functions to help ensure that no primary functions are missed when performing an FMEA. Choose the types of functions that apply to the given analysis.

- Basic functions (the primary purpose of a product, usually obtained from requirements or specification documents)
- Interface functions (from the FMEA Block Diagram or FMEA interface matrix)
- Safety functions (during manufacture or use)
- Reliability functions (life of the product)
- Product appeal functions
- Ergonomic functions
- Human interaction functions
- Legal and regulatory functions
- Functions relating to product installation
- Packaging and shipping functions
- Fluid retention functions
- Service functions
- Storage functions
- Design for manufacturing or assembly functions



### Bicycle Example

A partial list of the *functions* identified by the all-terrain System FMEA team includes:

1. The bicycle must be easy to use by the defined customer profile, including easy mounting, dismounting, steering, and operating, as defined in the all-terrain technical specification.
2. The bicycle must provide safe and reliable transportation throughout the life of the bicycle, including safe stopping distances and safe operation under all customer usage conditions as defined in the all-terrain technical specification. (Note that this function verbiage can be further broken down into more discrete functions, as covered in one of the End of Chapter Problems.)

3. The bicycle must provide comfortable transportation throughout the life of the bicycle, under all operating conditions defined in the all-terrain technical specifications.

(In addition to these functions, the System FMEA would also need to list each subsystem interface function and other functions such as legal and regulatory and appearance)

A partial list of the *functions* identified by the all-terrain Hand Brake Design FMEA team includes:

Provide the correct level of friction between brake pad assembly and wheel rim to stop bicycle safely in the required distance under all operating conditions.

Brake system is easy to adjust and keep in optimal working order.

Bicycle operator is able to provide full braking performance with force of one finger.

(In addition to these functions, the Hand Brake Subsystem Design FMEA also needs to list each component interface function and any other primary functions.)

Figure 6.4 is a truncated excerpt from the all-terrain System FMEA and provides an example of a function for a System FMEA. Note that this example of function is worded very generally, and in practice, it would be advisable to break it down to more discrete functions, which aid in defining failure modes. See the “End of Chapter Problems” section for an exercise related to defining functions.

Figure 6.5 is a truncated excerpt from the all-terrain System FMEA and highlights an example of an interface-type function at the system level.

Figure 6.6 is a truncated excerpt from the all-terrain Hand Brake Subsystem Design FMEA and provides an example of a function for a subsystem Design FMEA.

Figure 6.7 is a truncated excerpt from the all-terrain Brake Cable Design FMEA and provides an example of a function for a component Design FMEA.

For each of these function examples it can be seen that there is an increasing level of detail as one transitions from system to subsystem and ultimately to component. This is further highlighted in the bicycle FMEA examples in Section 6.2.7 of this chapter.

Figure 6.8 is a truncated excerpt from all-terrain Process FMEA, and provides an example of a function for the operation “Orient and place wheel spokes in wheel assembly fixture.”

Item/Function	Potential Failure Mode
<p><b>Bicycle System:</b> The bicycle must provide safe and reliable transportation, including safe stopping distances and safe operation under all customer usage conditions as defined in the All-Terrain technical specification.</p>	<p>Does not stop in required distance</p>

TRUNCATED

TRUNCATED

**FIGURE 6.4** Example of system-level function from all-terrain System FMEA.

Item/Function	Potential Failure Mode
<p><b>Bicycle System:</b> HandleBar S/S interfaces with the Hand Brake S/S to provide a user-adjustable brake lever mechanism that remains fixed in orientation under all operating conditions</p>	<p>Brake lever becomes loose</p> <p>Brake lever cannot be adjusted by user</p>

TRUNCATED

TRUNCATED

**FIGURE 6.5** Example of system-level interface function from all-terrain System FMEA.  
(S/S, subsystem.)

Item/Function	Potential Failure Mode
<p><b>Hand Brake S/S:</b> Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance under all operating conditions.</p>	<p>Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.</p>

TRUNCATED

**FIGURE 6.6** Example of subsystem-level function from all-terrain Hand Brake Design FMEA.

Item/Function	Potential Failure Mode
<p><b>Brake Cable:</b> Provides adjustable and calibrated movement between the brake lever and brake caliper, under specified conditions of use and operating environment.</p>	Cable breaks
	Cable binds

TRUNCATED

**FIGURE 6.7** Example of component-level function from all-terrain Brake Cable Design FMEA.

Process Function	Potential Failure Mode
Orient and place 36 wheel spokes properly in wheel assembly fixture	Too few spokes
	Wheel spokes not in correct orientation

TRUNCATED

**FIGURE 6.8** Example of function from all-terrain Process FMEA (wheel spoke installation).

Focus on function	Description	For the fuel tank shell
Basic function	Function representing the essential work necessary for fulfilling the purpose of a product.	Fuel storage - Capacity 45 L - Input (internal pressure, road surface vibration, road surface interference, flying stones)
Additional functions	Functions added to a product in order to improve its product appeal, or as required by various conditions such as laws and regulations.	Legal compliance - Fuel permeability (2 g/day) - No leakage resulting from rear-end collision
Unit function	Function pertaining to the installation of a product to mating components, portability, or storage.	Mounting to the body
Harm prevention function	Function to prevent a product from causing problems (vibration, noise, odor, etc.) to the user.	Reducing vibration and noise Reducing bad odor
Self-protection function	Function to protect people from harm during use, manufacture, or assembly.	—

**FIGURE 6.9** Example of Function Focal Point Table for fuel tank shell.

**Industry Example of Function Listing** Toyota Motor Corporation uses a “Function Focal Point Table,” which is a “table that is used for listing all the target functions without omissions. The function of the component must be described for all focus points, including the basic function, additional functions, unit functions, harm prevention functions, and self-protection functions.”<sup>[1]</sup>

Figure 6.9 is an example of a Function Focal Point Table for a fuel tank shell.<sup>[1]</sup>

### 6.2.3 Failure Modes

Failure is success if we learn from it.

—Malcolm S. Forbes

For each primary function, the FMEA team identifies the potential failure modes.

Referencing the definitions in Chapter 3, Section 3.5, failure mode is defined as “the manner in which the item or operation potentially fails to meet or deliver the intended function and associated requirements.” Refer to this section for a full explanation and useful examples of what constitutes a failure mode. There can be many failure modes for each function.

In Process FMEAs, the failure mode could be described in terms of how the purpose or function of the manufacturing or assembly operation is not accomplished. It could also be described as the reason a required part characteristic is not manufactured or assembled to engineering specifications. Recall from Chapter 5, Section 5.3.3: “The Significant *Product* Characteristics (outputs) from the PFD Worksheet [Process Flow Diagram Worksheet] should be considered input to the description of the corresponding *failure mode* of the Process FMEA.”

Each potential failure mode in an FMEA is considered independently of any other failure mode. This enables the team to address the unique reasons (causes of failure) for each given failure mode. In the case of failure modes (or causes) that are not independent—in other words, they occur in a dependent relationship—consider using Fault Tree Analysis (FTA) to model the dependency. See Chapter 14 for an introduction to FTA.

Remember, the failure mode is not merely the antithesis of the function. Rather, it is the *manner in which* an item or operation potentially fails to meet or deliver the intended function and associated requirements. The team looks for the *mode* of the failure.

It is a good practice to limit failure modes to those of *concern* to at least one member of a properly constituted FMEA team. It is not an academic listing of every conceivable failure mode (such as the unlikely event of a meteor striking the item) but rather a list of potential failure modes of concern to at least one of the FMEA team members (assuming a properly constituted FMEA team).

Avoid failure mode wording that is too general such as “doesn’t work” for Design FMEAs or “misbuild” for Process FMEAs. Be specific.

**Failure Conditions** The use of failure *conditions* can help identify unique failure modes. Examples of failure conditions include: premature operation, failure to operate at a prescribed time (complete loss of function), intermittent operation, failure to cease operation at a prescribed time, loss of output during operation (reduced performance), degraded operation (loss of performance over time), and/or performing an unintended or undesired function. Each function examined in relation to these failure conditions ensures identification of all relevant failure modes.

**Controlling the Failure Mode Description** The verbiage of individual failure modes can be cataloged and controlled for usage by other FMEA teams. This enables analysis and dissemination of failure information between project teams and the entire organization. Some companies ascribe a failure mode ID number to each unique failure mode. This allows companies to analyze common failure modes across FMEAs and the entire company to develop broad strategies for risk reduction.

**Thought-Starter Questions** When identifying failure modes for System or Design FMEAs, the team can be asked questions, such as:

- “In what way could the item fail to perform its intended function?”
- “In what way could the item perform an unintended function?”
- “What could go wrong with this item?”
- “What could go wrong at the interfaces?”
- “What has gone wrong with this item in the past?”
- “How could the item be abused or misused?”
- “What concerns do you have with this design?”
- Use the “failure conditions” in Section 6.2.3 to be sure no failure modes are missed

When identifying failure modes for Process FMEAs, the team can be asked questions, such as:

- “In what way could the operation fail to perform its intended function?”
- “In what way could the operation perform an unintended function?”
- “What significant product characteristics from the PFD Worksheet can be potential failure modes?”
- “Why would a part be rejected at this operation?”
- “What could go wrong with this operation?”
- “What has gone wrong with this operation in the past?”
- “What concerns do you have with this operation?”
- Use the “failure conditions” in Section 6.2.3 to be sure no failure modes are missed

Properly worded failure modes will help to identify resulting effects and root causes.



### Bicycle Example

Figure 6.10 is a truncated excerpt from the all-terrain System FMEA and provides an example of a failure mode for a System FMEA, specifically the all-terrain Bicycle System.

Figure 6.11 is a truncated excerpt from the all-terrain Hand Brake Subsystem Design FMEA and provides an example of a failure mode for a Subsystem Design FMEA.

Figure 6.12 is a truncated excerpt from the all-terrain Brake Cable Design FMEA and provides an example of a failure mode for a Component Design FMEA.

Figure 6.13 is a truncated excerpt from all-terrain Process FMEA and provides an example of a failure mode for the operation “Orient and place wheel spokes in wheel assembly fixture.”

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	
<b>Bicycle System:</b> The bicycle must provide safe and reliable transportation, including safe stopping distances and safe operation under all customer usage conditions as defined in the All-Terrain technical specification.	<b>Does not stop in required distance</b>	Potential accident or injury to bicycle operator without warning.	TRUNCATED

TRUNCATED

**FIGURE 6.10** Example of system-level failure mode from all-terrain System FMEA.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	
<b>Hand Brake S/S:</b> Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance under all operating conditions.	<b>Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.</b>	Bicycle wheel does not slow down when the brake lever is pulled, potentially resulting in accident.	TRUNCATED

TRUNCATED

**FIGURE 6.11** Example of subsystem-level failure mode from all-terrain Hand Brake Design FMEA.

#### 6.2.4 Effects

Wisdom consists of the anticipation of consequences.

—Norman Cousins

For each of the failure modes, the team lists the effects.

Referencing the definitions in Chapter 3, Section 3.5, an effect is “the consequence of the failure on the system or end user. For Process FMEAs, the team should consider the effect of the failure at the manufacturing or assembly level, as

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure
<b>Brake Cable:</b> Provides adjustable and calibrated movement between the brake lever and brake caliper, under specified conditions of use and operating environment.	<b>Cable breaks</b>	Operator is unable to close brake calipers, wheel does not slow down, possibly resulting in accident.
	<b>Cable binds</b>	Increased friction between cable and sheath, resulting in operator having to use greater effort to close brake calipers.

TRUNCATED

**FIGURE 6.12** Example of component-level failure mode from all-terrain Brake Cable Design FMEA.

Process Function	Potential Failure Mode	Potential Effect(s) of Failure
Orient and place 36 wheel spokes properly in wheel assembly fixture	<b>Too few spokes</b>	<b>Process Effect:</b> wheel not aligned, requiring rework out of station (5) <b>Product Effect:</b> wheel wobble and increasing stress during maneuvers, with potential for wheel collapse and rider injury, with warning (9)
	<b>Wheel spokes not in correct orientation</b>	<b>Process Effect:</b> wheel not aligned, requiring rework out of station (5) <b>Product Effect:</b> wheel wobble with potential for loss of handling during maneuvering and rider injury, with warning (9)

TRUNCATED

**FIGURE 6.13** Example of failure mode from all-terrain Process FMEA (wheel spoke installation).

well as at the system or end user.” Refer to this section for a full explanation and useful examples of what constitutes an effect.

Depending on the FMEA standard used, this may include *local*, *next level*, and *end effect*, or it may include only the *end effect*. If the standard being used by the team only requires end effect, it is still a good idea to include the verbiage in the end effect column tracing the local and next level effects to the end effect. This will

be helpful when the team decides on corrective actions for high severity issues, and shows due care in the analysis. Reference the example below for component-level effect from all-terrain Brake Cable Design FMEA. However done, the team should always arrive at the *end effect* of the failure mode on the user or system. End user effects should reflect what the user might notice or experience. They should clearly state if the effect of a failure mode could potentially affect safety or noncompliance to regulations, when applicable.

For Process FMEAs, the effects can manifest at the next operation, subsequent operations, the dealer or distributor, as well as the end customer.

Recall from Chapter 5, Section 5.2.5: “When entering information into the FMEA database, care should be taken to characterize concerns as ‘potential’ or ‘possible’ when appropriate, unless the team is certain the issue will occur. One example is entering an effect that has a possibility of injury. Here it is appropriate to say ‘with the possibility of injury’ rather than saying ‘will result in injury.’”

**Thought-Starter Questions** When identifying effects for System or Design FMEAs, the team can be asked questions such as:

- “What is the consequence of the failure?”
- “If the item fails, what will be the consequences at the local level? At the next higher level? At the system level? At the end user?”
- “If the item fails, what will the customer see, feel, or experience?”
- “Will the failure cause potential harm to the end users?”
- “Will the failure cause potential violation of regulations?”
- “What would a failure mean to adjacent parts/subsystems?”
- Any other questions that ensure the effects of failure are fully understood at the local level, the next level, and system and/or end user.

When identifying effects for Process FMEAs, the team can be asked questions such as:

- “What is the consequence of the failure?”
- “If the operation fails, what will be the consequences at the local operation? At the next stage of operations? On downstream processing? At the plant level? At the system level? At the end user?”
- “Will the failure cause potential harm to equipment or operators?”
- “Will the failure cause potential violation of regulations?”
- “What would a failure mean to the system or the end user?”
- Any other questions that ensure the effects of failure are fully understood at the manufacturing level and at the system or end user.

Although it is possible to list different effects on separate rows of the FMEA analysis, this is not usually a value-added practice. Take the example of a vehicle engine oil leak: One effect could be engine seizing; another could be a spot of oil on the garage floor. The FMEA team can take up both of these effects separately, but most practitioners believe this does not add value. The FMEA team can save time by only entering the worst-case effect in the analysis.

Avoid wording effects too generally, such as “customer dissatisfaction.” Be specific and describe the effect or consequence on the end user. Even if the FMEA team is only entering end effects, for safety issues it is a good practice to describe the trail of consequences from local, to next level, and to the system or end user. This helps to explain the concern when addressing high-risk issues. See the examples of effects for all-terrain Hand Brake and Brake Cable Design FMEAs to demonstrate this wording.

The verbiage of individual effects can be cataloged and controlled for usage by other FMEA teams. This enables analysis and dissemination of end effects across project teams and the entire organization. For example, an end effect of “patient harm” in a medical device company can show up in many different places in a single FMEA and in a series of FMEAs. Analysis of the contributors can help to mitigate this serious effect, and can be input to a future FTA project.

Properly worded effects will help to identify the correct severity ranking.



## Bicycle Example

Figures 6.14–6.16 are truncated excerpts from the all-terrain System FMEA, Hand Brake Design FMEA, and Brake Cable Design FMEA, respectively, showing examples of an effect. Notice that each effect is taken to the level of the system or end user, regardless of which portion of the system hierarchy is being analyzed.

Figure 6.17 is a truncated excerpt from all-terrain Process FMEA, and provides an example of an effect for the operation “Orient and place wheel spokes in wheel assembly fixture.” In this example, the effect is stated in terms of impact on both the assembly plant and the bicycle system or end user, and the more serious of the two is used for severity ranking.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV
<p><b>Bicycle System:</b></p> <p>The bicycle must provide safe and reliable transportation, including safe stopping distances and safe operation under all customer usage conditions as defined in the All-Terrain technical specification.</p>	<p>Does not stop in required distance</p>	<p><b>Potential accident or injury to bicycle operator without warning.</b></p>	<p>10</p>

**FIGURE 6.14** Example of system-level effect from all-terrain System FMEA.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV
<b>Hand Brake S/S:</b> Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	<b>Bicycle wheel does not slow down when the brake lever is pulled, potentially resulting in accident.</b>	10  TRUNCATED

**FIGURE 6.15** Example of subsystem-level effect from all-terrain Hand Brake Design FMEA.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV
<b>Brake Cable:</b> Provides adjustable and calibrated movement between the brake lever and brake caliper, under specified conditions of use and operating environment.	Cable breaks	<b>Operator is unable to close brake calipers, wheel does not slow down, possibly resulting in accident.</b>	10  TRUNCATED
	Cable binds	<b>Increased friction between cable and sheath, resulting in operator having to use greater effort to close brake calipers.</b>	7

**FIGURE 6.16** Example of component-level effect from all-terrain Brake Cable Design FMEA.

### 6.2.5 Severity Ranking

Having identified the most serious effect for the failure mode, the FMEA team assesses the severity ranking. This is the severity of the *effect* of the failure mode, not the severity of the failure mode itself.

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV
Orient and place 36 wheel spokes properly in wheel assembly fixture	Too few spokes	<b>Process Effect:</b> <b>wheel not aligned, requiring rework out of station (5)</b> <b>Product Effect:</b> <b>wheel wobble and increasing stress during maneuvers, with potential for wheel collapse and rider injury, with warning (9)</b>	9
	Wheel spokes not in correct orientation	<b>Process Effect:</b> <b>wheel not aligned, requiring rework out of station (5)</b> <b>Product Effect:</b> <b>wheel wobble with potential for loss of handling during maneuvering and rider injury, with warning (9)</b>	9

TRUNCATED

**FIGURE 6.17** Example of effect from all-terrain Process FMEA (wheel spoke installation).

Referencing the definitions in Chapter 3, Section 3.5, severity is “a ranking number associated with the most serious effect for a given failure mode, based on the criteria from a severity scale. It is a relative ranking within the scope of the specific FMEA and is determined without regard to the likelihood of occurrence or detection.” Refer to this section for a full explanation and useful examples of how to define severity and use a severity scale.

Using the agreed-upon severity scale, the team carefully reviews the criteria column to make this judgment. If the effect is well defined, the severity is easily established by reviewing the severity scale criteria.

In the case of items that are redundant, and there is no detection or no warning that a redundant item has failed, the severity should be assessed as if all of the redundant items have failed.

Refer to Chapter 3, Section 3.5.5, for an example of Design FMEA and Process FMEA severity scales. As covered in that section, the criteria for these scales should be reviewed and tailored (as needed) to make sense for individual company applications.

Properly assessed severity ranking will help ensure that high severity and high RPN issues are addressed with corrective actions.



### Bicycle Example

Figure 6.18 is a truncated excerpt from the all-terrain System FMEA and provides an example of a severity ranking for a System FMEA, specifically the all-terrain bicycle system.

In this example, based on the severity scale chosen from Automotive Industry Action Group (AIAG) Edition 4 (2008), the ranking criterion that most closely matches this effect is “Potential Failure Mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.” Therefore, the severity is 10.

#### 6.2.6 Classification (Optional)

One of the objectives of FMEA is “to identify significant product of process characteristics.” The classification column can be used to visually display where a significant characteristic is associated with a failure mode or cause. This column can also be used to highlight failure modes or causes for further discussion or for follow-up action.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC
Bicycle System: The bicycle must	Does not stop in	Potential accident or injury to bicycle operator without warning.	10	insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.  Brake system mis-adjusted by bicycle user	5  TRUNCATED

**Suggested DFMEA Severity Evaluation Criteria**

Effect	Criteria: Severity of Effect on Product (Customer Effect)	Rank
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	(10)
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle operable, but comfort/convenience functions inoperable).	6
	Degradation of secondary function (vehicle operable, but comfort/convenience functions at reduced level of performance).	5
Annoyance	Appearance or audible noise, vehicle operable, item does not conform, Defect noticed by most customers (>75%).	4
	Appearance or audible noise, vehicle operable, item does not conform, Defect noticed by many customers (50%).	3
	Appearance or audible noise, vehicle operable, item does not conform, Defect noticed by discriminating customers (<25%).	2
No Effect	No discernible effect.	1

**FIGURE 6.18** Example of severity ranking from all-terrain System FMEA.

Refer to Chapter 5, Section 5.3.3 for information about the application of significant product and process characteristics in Process Flow Diagrams, Process FMEAs, and Process Control Plans. The definitions from that section are repeated here for convenience.

**Product Characteristics** These are features, attributes, or properties of a part, component, or assembly. Examples include color, weight, dimensions, surface finish, hardness, appearance, and material composition.

**Process Characteristics** These are process variables and parameters that have a cause-and-effect relationship with the variation found in product characteristics. Examples include mold temperature, cycle time, pressure, flow rate, and tool speed.

**Significant Product Characteristics** These are unique *product*-related characteristics that can affect safety, regulatory compliance, appearance, function, performance, or subsequent product manufacturing. They are the direct *output* of a given manufacturing operation. They may or may not be designated as Key Product Characteristics.

**Key Product Characteristics (KPCs)** These are a subset of the significant product characteristics, and are designated by the company for highlighted attention. They require follow up in the Process Control Plan (PCP) and usually have their own approval process.

**Significant Process Characteristics** These are unique *process*-related characteristics that can affect the ability of the manufacturing process to meet significant product characteristics. They are *input* to a given manufacturing operation. They may or may not be designated as Key Control Characteristics.

**Key Control Characteristics (KCCs)** These are a subset of the significant process characteristics, and are designated by the company for highlighted attention. They require follow-up in the PCP and usually have their own approval process.

Manufacturing processes have inputs and outputs. Process characteristics define the inputs and product characteristics define the outputs.

In FMEA applications, product or process characteristics are often designated as “critical,” “key,” “significant,” or “other.” However, the definitions and applications of these terms are very company specific, and there are no industry-wide definitions. Some companies use a “critical” designation to refer to product or process characteristics that directly affect safety or compliance with government regulations. In that case, “significant” would refer to all other product or process characteristics whose variation has a significant influence on product performance, appearance, reliability, or manufacturability. Other companies do not use a “critical” designation. They use “significant” to cover safety, regulatory, and all other product or process characteristics whose variation has a significant influence on product outputs. Product or process characteristics are sometimes designated “key” by company-specific guidelines, which specify rigorous follow-up procedures to control the outcomes of manufacturing processes, using PCPs.

Potential significant or key product characteristics identified by the Design FMEA team need to be communicated to the Process FMEA team to be sure

that corresponding significant or key control characteristics can be identified and controlled.

The FMEA team should familiarize themselves with company policy regarding designation of product and process characteristics, and use FMEAs to identify product or process characteristics that require follow up with recommended actions and inclusion in the PCP.

**Application Example of KPCs in Classification Column** An FMEA team is doing a Design FMEA on a shaft and one of the concerns is bending. Computer modeling shows that two characteristics are critical to avoid shaft bending under the required operating stresses—shaft material hardness and shaft diameter. The FMEA team may choose to enter a symbol, such as “KPC,” into the classification column of the Design FMEA, next to the bending failure mode, and follow up in the recommended actions with formal KPC designation and require further controls on both shaft material hardness and shaft diameter in the PCP.

**Application Example of KCCs in Classification Column** The KPCs from the design FMEA may further be developed through a subsequent Process FMEA, or translated directly into KCCs. In this case, the KPC (shaft material hardness) might have two KCCs (temperature of water quench and duration of water quench). The Process FMEA team may choose to enter a symbol, such as KCC, in the classification column of the Process FMEA next to the corresponding failure mode, and follow up in the recommended actions with formal KCC designation and further process controls in the PCP for both water quench temperature and duration.

Use of the classification column can enhance the effectiveness of FMEAs, if done sparingly and correctly, and with proper follow up. In some companies, overuse of “KPC” or “KCC” designation has undermined the effectiveness of the FMEAs and PCPs.

### 6.2.7 Causes and Failure Mechanisms

The effort to get at the truth has to precede all other efforts.

—Albert Einstein

For each failure mode, the FMEA team identifies the causes.

Referencing the definitions in Chapter 3, Section 3.5, a cause 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 (or source of variation) that results in the failure mode.” Refer to this section for a full explanation and useful examples of what constitutes a cause. By definition, if a cause occurs, the corresponding failure mode occurs. There can be many causes for each failure mode.

There can be one or more causes, and the team should identify as many causes as are needed to document their concerns. Causes should be described in sufficient detail to establish the underlying mechanisms of the cause, often called the “root” cause. The only exception to this is for higher levels of analysis, such as System FMEAs, in which the cause may remain at a higher level, such as a component

failure, and not carried all the way down to the reason for the component failure, which the subsequent Design FMEA would analyze for the component. It is vital to understand the primary reasons for the failure. It is often useful to use the phrase “due to” to help get the root cause. For example, in the case of the projector lamp shattering, a possible cause could be “overpressure *due to* wrong gas.”

In Design FMEAs, root causes are often described in terms of product characteristics, such as dimensions, weight, orientation, hardness, and strength. In Process FMEAs, root causes are often described in terms of process characteristics, such as oven temperature, tool wear, part position, weld device current, pressure, and flow rate. These terms are defined in Section 6.2.6 in this chapter.

Recall from Chapter 5, Section 5.3.3: “The Significant *Process* Characteristics (inputs) from the PFD Worksheet should be considered input to the description of the corresponding *cause* of the Process FMEA.”

**Causes Based on Design or Process Assumptions** Recall the assumptions identified during the preparation phase of the FMEA project. Refer to Chapter 5, Section 5.3.5 for examples of assumptions the FMEA team may wish to consider.

Design FMEA assumptions:

1. Assume the part is manufactured or assembled within engineering specifications.

Based on this assumption, failure modes may be caused by design deficiencies.

2. Assume the part design may include a deficiency that could cause unacceptable variation in the manufacturing or assembly process.

Based on this assumption, failure modes may be a result of manufacturing or assembly misbuilds, but the misbuilds are due to design deficiencies.

Process FMEA assumptions:

1. Assume incoming parts or materials to an operation meet design intent.

Based on this assumption, failure modes may be caused by manufacturing or assembly deficiencies.

2. Assume incoming parts or materials may have variation and do not necessarily meet engineering requirements.

Based on this assumption, failure modes may be caused by manufacturing or assembly misbuilds, but the misbuilds are a result of variation in incoming parts that do not necessarily meet engineering requirements.

As is true in identifying failure modes, it is a good practice to limit causes to those of concern to at least one member of a properly constituted FMEA team.

**Cause Categories** If needed, the FMEA team can develop and refer to cause categories as “thought triggers” to help the team brainstorm specific causes to be sure no important causes are missed.

Design-related cause categories include system interactions, time based, operating environment, customer usage, functional performance, and design-for-

manufacturing or assembly. For example, the Design FMEA facilitator might ask the team, “Are there any other system interaction-type causes?”

Process-related cause categories include equipment, methods, material, supplier parts, operator, or environment. For example, the Process FMEA facilitator might ask the team “Are there any other plant environment-type causes?”

Cause categories are only informational, and can be tailored to individual applications. The actual cause will need to be expanded to ensure root cause is identified and described adequately.

**What If Root Cause Is Not Achieved?** It is impossible to overstress the importance of fully analyzing and understanding the cause. A half-analyzed cause has little value, as the cause is the heart and soul of the FMEA. Take the example of a projector lamp shattering. If the FMEA team simply describes the cause as “overpressure” and does not ask why the overpressure, the root cause of “wrong gas” is not established. The team will end up trying to solve “overpressure,” and may miss recommending the correct gas specification. The problem will not be solved.

**Controlling the Cause Description** The verbiage of individual causes can be catalogued and controlled for usage by other FMEA teams. This enables analysis and dissemination of common causes across project teams and the entire organization. For example, a cause of shaft “bending due to incorrect case-hardening specifications” in a metal parts manufacturing company can show up in many different places in a series of FMEAs. Strategies can be developed to prevent this common cause, thus improving the reliability of shafts in different applications.

**Dependent Causes** It is possible for a failure mode to result only when two or more causes occur simultaneously, or in other words, are *dependent* on one another. FMEAs typically assume that causes are independent. There are two alternatives when the FMEA team needs to address dependent causes. The first is to shift to FTA to model the dependent relationships between causes and other events. This method is described in Chapter 14. The second alternative is to list the causes together in one entry in the FMEA worksheet, using the word “and” in between the causes.

#### 6.2.7.1 Failure Mechanisms (for System and Design FMEAs)

Nature never breaks her own laws.

—Leonardo da Vinci

For Design FMEAs at the component level, causes can be further defined and developed by understanding the underlying *failure mechanisms*. Causes are the circumstances that induce or activate a failure mechanism.

Wherever possible, for high-risk issues the FMEA team should define the cause at the *failure mechanism* level. This means for System FMEAs or Subsystem FMEAs, the FMEA team should either proceed with a Component FMEA that can drill down to the precise failure mechanism that explains the failure mode and place it in the cause column, or continue with the “Five Whys” until isolating the cause at the mechanism level. No matter how the FMEA team chooses to proceed, wherever

possible the FMEA team should properly define the cause at the failure mechanism level for high-risk issues.

The FMEA team must include representatives that understand the specific underlying failure mechanisms for the type of items being analyzed.

Failure mechanisms are the physical, chemical, thermodynamic or other processes that result in failure. Failure mechanisms are categorized as either overstress or wear-out mechanisms. Overstress failure arises as a result of a single load (stress) condition, which exceeds a fundamental strength property. Wear-out failure arises as a result of cumulative damage related to loads (stresses) applied over an extended time.<sup>[2]</sup>

It is helpful to emphasize the difference between *failure mode*, *cause*, and *failure mechanism*. A *failure mode* is the manner in which the item or assembly could fail to meet the intended function and its requirements. A *cause* is the specific reason for the failure, an indication of how the failure could occur. A *failure mechanism* is the actual physical phenomenon behind the failure mode or the process of degradation or chain of events leading to and resulting in a particular failure mode. The mechanism should be listed as concisely and completely as possible. For a system, the failure mechanism is the process of error propagation following a component failure that leads to a system failure.

Examples of failure mechanism categories include<sup>[3]</sup>:

Failure mechanism categories relating to *metal structure components* include corrosion, cracking, deformation, embrittlement, fatigue, fracture, friction, yielding, and wear.

Failure mechanism categories relating to *electrical components* include dielectric breakdown, electromigration, induced current, and voltage drop.

Failure mechanism categories relating to *elastomers* include abrasive wear, compression set, extrusion, hardening, shrinking, and swelling.

Many excellent engineering textbooks explain in detail the underlying failure mechanisms for metals, electronics, and elastomers. One such resource is the engineering textbook *Failure of Materials in Mechanical Design: Analysis, Prediction, Prevention* (2nd ed.), by Jack A. Collins.<sup>[4]</sup> An excerpt from this textbook is located in the Appendix, providing a comprehensive list of mechanical and physical failure mechanisms (the author calls them “failure modes”), along with definitions and examples. This is an excellent resource to understand failure mechanisms further, particularly for mechanical designs.

To highlight one approach to this topic of failure mechanisms, a Reliability Engineering group that had responsibility for facilitating FMEAs in a major industrial company held weekly 2-hour workshops to train the reliability engineers and FMEA facilitators in the physics of detailed failure mechanisms. Each week a different enlisted expert taught a particular mechanism of failure.

The failure mechanism and the cause are usually placed in the cause column of the FMEA. An example may help to illustrate:

*Item.* Burner and heating coil subassembly

*Function.* Heat the burner plate to 160°F within 60 seconds

*Failure Mode 1.* Burner plate stays cold

*Effect.* No heat to container, customer dissatisfied

*Cause 1.* Heating coil has voltage drop (failure mechanism) due to wrong wire specification (cause)

*Cause 2.* heating coil-to-burner plate connector corrodes (failure mechanism) due to moisture intrusion (cause)

**Thought-Starter Questions** When identifying causes for System or Design FMEAs, the team can be asked questions such as:

- “How can the failure occur?”
- “What could cause the item to fail in this manner?”
- “What circumstances could cause the item to fail to perform its intended function?”
- “Why could the failure occur?”
- “What is the mechanism of failure?”
- “Are there possible system interactions, degradations, operating environments, customer usages, or design-for-manufacturing/assembly issues that could cause the failure?”
- For each cause identified, ask further “whys” in the direction of isolating root cause.

When identifying causes for Process FMEAs, the team can be asked questions such as:

- “How can the failure occur?”
- “What could cause the operation to fail in this manner?”
- “What significant process characteristics from the PFD Worksheet could be potential causes?”
- “What circumstances could cause the operation to fail to perform its intended function?”
- “Why could the failure occur?”
- “Are there possible equipment, methods, material, supplier parts, operator, or environment issues that could cause the failure?”
- For each cause identified, ask further “whys” in the direction of isolating root cause.

To summarize, failure mechanisms should always be included with the cause entry on high-risk causes at the component level. It is up to the FMEA team if they want to include failure mechanisms for other causes, such as at the subsystem or system levels. Some teams choose to utilize a separate column in the FMEA worksheet for failure mechanisms, although this is not common practice.

Figure 6.19 is an example of a Disk Brake subsystem, showing failure modes with associated failure mechanisms and causes, with the failure mechanisms broken out into a separate column in the FMEA worksheet. Since this example is at the

Failure Mode	Failure Mechanism	Cause
Vehicle does not stop	No transfer of force from pedal to pads	Mechanical linkage break due to inadequate corrosion protection
		Master cylinder vacuum lock due to seal design
		Loss of hydraulic fluid from loose hydraulic line due to incorrect connector torque specification
		Loss of hydraulic fluid due to hydraulic lines crimped/compressed, inappropriate tube material specified
Vehicle stops in excess of yy feet	Reduced transfer of force from pedal to pads	Mechanical linkage joints stiff due to inappropriate lubrication specification
		Mechanical linkage joints corroded due to inadequate corrosion protection
		Partial loss of hydraulic fluid due to hydraulic lines crimped, inappropriate tube material specified
Stops vehicle with more than xx g's of force	Excessive/rapid transfer of force from pedal to pads	Cumulative pressure buildup in master cylinder due to seal design
Activate with no demand; vehicle movement is impeded	Pads do not release	Corrosion or deposit buildup on rails or pad ears due to surface finish not promoting adequate self-cleaning and corrosion protection
Activate with no demand; vehicle cannot move	Hydraulic pressure does not release	Master cylinder vacuum lock due to seal design

**FIGURE 6.19** Example of failure modes with associated failure mechanisms and causes.

(Reprinted from “Failure Mode and Effects Analysis (FMEA) 4th Edition,” 2008 Manual, with permission of Chrysler, Ford, and GM Supplier Quality Requirements Task Force.)

subsystem level, each failure mechanism represents the process of error propagation following a component failure that leads to subsystem failure.<sup>[5]</sup>

Properly worded causes, developed to the failure mechanism level for high-risk issues, will help to assess occurrence ranking and will help in the process of developing effective actions to reduce the risk associated with the failure mode/cause.



### Bicycle Example

Figures 6.20–6.22 are truncated excerpts from the all-terrain System FMEA, Hand Brake Design FMEA, and Brake Cable Design FMEA, respectively, showing examples of a cause. Notice that each cause is developed to the level of detail appropriate for the item being analyzed.

The Subsystem Design FMEA example shown in Figure 6.21 brings up a question. Students of FMEA often ask why “Cable breaks” could be a *cause* for the failure mode “Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions,” as it does not appear to be a *root cause*. This is true; “Cable breaks” is *not* a root cause. At the system and subsystem level, causes often are not described at the root cause level. Instead, for high-risk issues, the usual practice is to continue drilling down to the component level and perform a Design FMEA on the component, in this case Brake

Cable. The *root cause* will be found at the *component* level. At the component level, the subsystem level cause “Cable breaks” becomes the failure mode for the item “Brake Cable,” and the causes become “corrosion of cable wiring due to wrong material selected” and “fatigue cracks in cable wiring due to inadequate cable thickness.” It is always necessary to get to root cause for higher risk issues, and the best way is with the progression from system to subsystem to component. This concept is illustrated in Chapter 3, Section 3.5.3, Figure 3.2.

Figure 6.22 shows the component failure mode “Cable breaks” taken to root cause.

Figure 6.23 is a truncated excerpt from all-terrain Process FMEA, and provides an example of a cause for the operation “Orient and place wheel spokes in wheel assembly fixture.”

Again, to emphasize the importance of this concept: The FMEA team should always ask “why” to each cause until it is satisfied the root cause has been determined. It is usually helpful to use the phrase “due to” in showing this progression, such as “insufficient shaft strength *due to* material heat treatment incorrectly specified.” Another way to test to see if root cause has been achieved is to ask the question, “If the cause is corrected, will the issue be resolved permanently?” If the answer is “yes,” root cause has most likely been achieved.

Be specific when describing causes. For Design FMEAs (especially at the component level), avoid using cause wordings that are too general, such as “fails” or “doesn’t work.” When doing Process FMEAs, avoid using cause wordings that are too general, such as “operator error.” Instead, be specific with the precise error that is the cause of the failure mode, such as “wrong drill gun selected.”

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC
<b>Bicycle System:</b> The bicycle must provide safe and reliable transportation, including safe stopping distances and safe operation under all customer usage conditions as defined in the All-Terrain technical specification.	Does not stop in required distance	Potential accident or injury to bicycle operator without warning.	10	<b>Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.</b>	5
				<b>Brake system mis-adjusted by bicycle user</b>	3

TRUNCATED

TRUNCATED

**FIGURE 6.20** Example of system-level cause from all-terrain System FMEA.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC
<b>Hand Brake S/S:</b> Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not slow down when the brake lever is pulled, potentially resulting in accident.	10	<b>Cable Binds due to inadequate lubrication or poor routing</b>	4
				<b>External foreign material reduces friction</b>	2
				<b>Cable breaks</b>	6

TRUNCATED

**FIGURE 6.21** Example of subsystem-level cause from all-terrain Hand Brake Design FMEA.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC
<b>Brake Cable:</b> Provides adjustable and calibrated movement between the brake lever and brake caliper, under specified conditions of use and operating environment.	Cable breaks	Operator is unable to close brake calipers, wheel does not slow down, possibly resulting in accident.	10	<b>Corrosion of cable wiring due to wrong material selected</b>	5
				<b>Fatigue cracks in cable wiring due to inadequate cable thickness</b>	2
	Cable binds	Increased friction between cable and sheath, resulting in operator having to use greater effort to close brake calipers.	7	<b>Bend or kink in cable due to misrouting</b>	3
				<b>Inadequate or wrong lubrication between cable and sheath</b>	5

TRUNCATED

**FIGURE 6.22** Example of component-level cause from all-terrain Brake Cable Design FMEA.

### 6.2.7.2 Five Whys

The important thing is not to stop questioning.

—Albert Einstein

Many practitioners use repeated questioning of the FMEA team to ensure that the basic “why” is determined as the cause of a failure mode. This technique, called the

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC
Orient and place 36 wheel spokes properly in wheel assembly fixture	Too few spokes	<b>Process Effect:</b> wheel not aligned, requiring rework out of station (5) <b>Product Effect:</b> wheel wobble and increasing stress during maneuvers, with potential for wheel collapse and rider injury, with warning (9)	9	<b>Lack of organized wheel spoke kit</b>	3
	Wheel spokes not in correct orientation	<b>Process Effect:</b> wheel not aligned, requiring rework out of station (5) <b>Product Effect:</b> wheel wobble with potential for loss of handling during maneuvering and rider injury, with warning (9)	9	<b>Fixture is not error proofed to prevent incorrect orientation</b>	6

TRUNCATED

**FIGURE 6.23** Example of cause from all-terrain Process FMEA (wheel spoke installation).

*Five Whys*, can be very helpful, especially when the root cause is not forthcoming. The *Five Whys* is a technique developed by Taiichi Ohno, originator of the Toyota Production System. It means that by asking “why” five times, the team will be able to discover the progression of cause-and-effect relationships behind a problem and the root cause that is below the surface.

### Five Whys Example

1. Why does the cable break?  
Why #1: Because the stress from the most extreme in-use operating conditions exceeds the strength of the cable.
2. Why does the stress from the most extreme in-use operating conditions exceed the strength of the cable?  
Why #2: Because the strength of the current cable material can degrade under certain extreme environmental operating conditions.
3. Why can the strength of the current cable material degrade under certain extreme environmental operating conditions?  
Why #3: Because the current cable material corrodes when exposed to extreme hot and moist environments.
4. Why does the current cable material corrode when exposed to extreme hot and moist operating environments?  
Why #4: Because the current cable material is not suitable for the most extreme operation conditions for the all-terrain bicycle.

5. Why is the current cable material not suitable for the most extreme operation conditions for the all-terrain bicycle?  
Why #5: Because the cable supplier selected the wrong material for the brake cable.

### 6.2.8 Occurrence Ranking

For each cause, the FMEA team assesses the occurrence ranking. This is the likelihood of occurrence of the cause of the failure mode.

Refer to Chapter 3, Section 3.5 for a full explanation and useful examples of how to define occurrence and use an occurrence scale: “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 within the design life. For System and Design FMEAs, the occurrence ranking considers the likelihood of occurrence during the design life of the product. For Process FMEAs the occurrence ranking considers the likelihood of occurrence during production. Based on the criteria from the corresponding occurrence scale, the occurrence ranking has a relative meaning rather than an absolute value and is determined without regard to the severity or likelihood of detection.”

Using the agreed-upon occurrence scale, the team carefully reviews the criteria column to make this judgment. This assessment of occurrence ranking should be as objective as possible, using past field history of similar items, previous test results, experience with similar systems, and other sources of information. There will always be a subjective element to this ranking, as the FMEA is done on new designs, design changes, and/or new applications. However, the FMEA team should endeavor to be as objective as possible, using the criteria from the occurrence scale to help determine the appropriate rank. If the assessment of occurrence ranking falls between discreet occurrence numbers on the scale (such as between 4 and 5), the team should use the higher number.

If tables of generic component failure rates are used to support the assessment of occurrence ranking, care should be taken to understand limitations. Generic failure rates are based on historical data, with assumptions that may or may not be applicable to the current item being analyzed. Current applications may have significantly different operating environments, materials, technology, operating profiles, and interfaces. It is necessary for the FMEA expert team to discuss and agree on the occurrence ranking, and not to automatically use any one source of information.

Refer to Chapter 3, Section 3.5.7, for an example of Design FMEA and Process FMEA occurrence scales. As covered in that section, the criteria for these scales should be reviewed and tailored (as needed) to make sense for individual company applications.

Note that *prevention*-type controls are considered input to the occurrence ranking, as covered in Section 6.2.9 below.

Properly assessed occurrence ranking will help ensure that risk due to frequency of occurrence is addressed with corrective actions, along with other high severity and high RPN issues.



### Bicycle Example

Figure 6.24 is a truncated excerpt from the all-terrain System FMEA and provides an example of an occurrence ranking for a System FMEA, specifically the all-terrain bicycle system.

In this example, based on the occurrence scale chosen from AIAG Edition 4 (2008), the ranking criterion that most closely matches the first cause is “Occasional failures associated with similar designs or in design simulation and testing,” and the second cause is “Only isolated failure associated with almost identical design or in design simulation testing.” Therefore, the occurrence is 5 and 3, respectively.

	Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) Failure	Occ
	Bicycle System: The bicycle must provide safe and reliable	Does not stop in required distance	Potential accident or injury to bicycle	10	insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	5
<b>Suggested DFMEA Occurrence Evaluation Criteria</b>						
Likelihood of Failure	Criteria: Occurrence of Cause (Design Life/Reliability of Item/Vehicle)	Rank				
Very High	New technology/new design with no history.	10				
	Failure is inevitable with new design, new application, or change in duty cycle/operating conditions.	9				
High	Failure is likely with new design, new application, or change in duty cycle/operating conditions.	8				
	Failure is uncertain with new design, new application, or change in duty cycle/operating conditions.	7				
Moderate	Frequent failures associated with similar designs or in design simulation and testing.	6				
	Occasional failures associated with similar designs or in design simulation and testing.	5				
	Isolated failures associated with similar design or in design simulation and testing.	4				
Low	Only isolated failures associated with almost identical design or in design simulation and testing.	3				
	No observed failures associated with almost identical design or in design simulation and testing.	2				
Very Low	Failures is eliminated through preventative control.	1				

**FIGURE 6.24** Example of occurrence ranking from all-terrain system FMEA.

**Potential Misapplication of Occurrence Ranking** Some practitioners attempt to use the occurrence ranking to reflect the likelihood of the *effect*, instead of the likelihood of the *cause*. This is an incorrect application, and the confusion may be due to a misunderstanding between FMEA and FMECA. One of the elements in the Criticality Analysis for FMECA includes “Probability of Loss,” which is also called “Failure Effect Probability” in Military Standard (MIL-STD) 1629A. Chapter 12 provides the proper procedure for FMECA. Occurrence is the likelihood of the cause, not the likelihood of the effect.

It is possible to calculate the likelihood of the effect, and the correct tool to do this is FTA. Refer to Chapter 14 for instruction for how to do this modeling and calculation.

### 6.2.9 Controls

For each cause, the FMEA team identifies the design or process controls. When doing System or Design FMEAs, these are called Design Controls. When doing Process FMEAs, these are called Process Controls.

Referencing the definitions in Chapter 3, Section 3.5, controls are “the methods or actions *currently planned* or already in place to reduce or eliminate risk. Controls can be the methods to prevent or detect the cause during product development, or can be actions to detect a problem during service before it becomes catastrophic.” Refer to this section for a full explanation and useful examples of what constitutes controls.

Realize that these are the *currently planned* controls, not controls that have yet to be established or that will be changed. The idea is to list the controls that are in place or will be used *if no changes are made to current program plans*. If the FMEA team wishes to add, modify, or delete design or process controls, they should use the recommended action column. Most FMEA standards require two types of controls be identified (i.e., prevention and detection). A few FMEA standards require only controls to be identified, with the option of tagging them as prevention or detection. Either way, the list of currently planned controls is entered in the analysis. Best practice is to identify clearly prevention-type controls separate from detection-type controls, as they are used differently in establishing risk rankings in the FMEA.

**6.2.9.1 Design Controls for System or Design FMEAs** The definitions and usages for design and process controls from Chapter 3 are repeated here for convenience. 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. 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. Detection controls are intended to increase the likelihood that the problem will be detected before it reaches the end user.

Examples of prevention-type design controls include use of design guidelines, use of design standards, and use of field lessons learned. Failures managed by system

detection during operation, such as tire pressure monitoring, are usually considered prevention-type controls as they reduce the occurrence of the cause.

Examples of detection-type design controls include all types of analytical or physical methods to detect problems before launch, such as Finite Element Analysis (FEA), verification testing, validation testing, and tolerance analysis.

**6.2.9.2 Process Controls for Process FMEAs** 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.

Examples of prevention-type process controls include product design error proofing, process error proofing, operator instructions, equipment controls, and preventive maintenance. Statistical Process Controls may be considered prevention-type controls for specific causes whose trends are identifiable in advance of an actual nonconformance, such as tool wear.

Examples of detection-type process controls include operator inspections, in-station error detection, end-of-line testing, and measuring or gauging tasks.

**Use of Controls in the FMEA** If the FMEA team believes that prevention or detection controls need enhancement or modification in any way, the enhancements or modifications are identified in the recommended actions column of the FMEA.

If no prevention or detection controls are applicable for a given failure mode or cause, the FMEA team should leave the corresponding column blank.

Properly defined prevention controls are considered input to the occurrence ranking, and will help to determine the type of recommend actions that may be needed to reduce the risk associated with frequency of *occurrence*. Just as prevention controls are input to the occurrence ranking, so are properly defined detection controls considered input to the detection ranking, and will help to determine the type of recommend actions that may be needed to reduce risk associated with *detection*.

Be specific when identifying design or process controls. Avoid using general terms such as “reliability testing” for design controls or “process monitoring” for process controls. Instead, use specific descriptions such as “Reliability Test Procedure XYZ” for design controls, or “hole size error detection in Operation Guide #15-A,” for process controls.

**Thought-Starter Questions** When identifying prevention-type design controls for System or Design FMEAs, the team can be asked questions such as:

- “What is already in place that could possibly prevent the cause?”
- “What is not in place yet but is currently planned that could possibly prevent the cause?”
- “What design guidelines, design standards, use of field lessons learned, or other prevention-type tasks are planned or already in place that could prevent the cause?”

When identifying detection-type design controls for System or Design FMEAs, the team can be asked questions such as:

- “What is already in place that could possibly detect the cause?”
- “What is not in place yet but is currently planned that could possibly detect the cause?”
- “What tests, analyses, or other analytical or physical tasks are already in place or currently planned that could detect the cause before launch?”

When identifying prevention-type process controls for Process FMEAs, the team can be asked questions such as:

- “What is already in place that could possibly prevent the cause?”
- “What is not in place yet but is currently planned that could possibly prevent the cause?”
- “What design error proofing, process error proofing, operator instructions, equipment controls, preventive maintenance, or other prevention-type tasks are planned or already in place that could prevent the cause?”

When identifying detection-type process controls for Process FMEAs, the team can be asked questions such as:

- “What is already in place that could possibly detect the cause?”
- “What is not in place yet but is currently planned that could possibly detect the cause?”
- “What operator inspections, in-station error detection, end-of-line testing, measuring, gauging or other detection-type tasks are already in place or currently planned that could detect the cause before the product leaves the plant?”

**6.2.9.3 Use of Early Warning Devices and Mitigating Controls** Proper warnings are important to alert users to unsafe operating conditions and to ensure satisfactory system status before commencing operations. Examples include audible or visual warning mechanisms such as a low oil pressure warning light on the vehicle information display, an alarm inside a manufacturing plant warning operators that carbon monoxide has been detected, or a pressure indicator on a residential fire extinguisher where the dial pointing in the “red” range warns the user that replacement is needed. As covered above, failures managed by system detection during operation are usually considered prevention-type controls as they can reduce the occurrence of system failure.

System-level controls that detect and react to faults during operation are considered “mitigating controls.” Mitigating controls utilize two design strategies: “fail-safe,” where in the event of failure, the system responds in a way that will cause minimal harm to other devices or danger to personnel, and “fault-tolerance,” where a system continues operation, possibly at a reduced level, rather than failing completely. An example of mitigating controls using a fail-safe strategy is air brakes on a truck, which are held in the “off” position by air pressure created in the brake

system. Should a brake line split, the air pressure will be lost and the brakes applied. It is impossible to drive a train or truck with a serious leak in the air brake system. An example of mitigating controls using a fault-tolerant strategy is a hospital electrical backup system. If an electrical outage occurs, backup generators kick in, allowing vital functions to continue, although at a reduced level of performance. Mitigating controls do not change the likelihood of failure; however, if a failure does occur, they can reduce the severity of the effect of the failure.

Early warning devices and mitigating controls are not typically part of the detection ranking assessment. An exception is covered in Section 6.2.10, under the heading “Detection Scale for Assessing Risk Related to In-Service Detection Systems.”



### Bicycle Example

Figures 6.25–6.27 are truncated excerpts from the all-terrain System FMEA, Hand Brake Design FMEA, and Brake Cable Design FMEA, respectively, showing examples of prevention- and detection-type design controls.

Some FMEA practitioners use “Design Review” as a prevention-type design control. The placement of Design Review in prevention-type design control column of the FMEA worksheet has been argued both ways, as to whether it should be a prevention-type or a detection-type design control. Since a Design Review is typically composed of subject-matter experts gathering around the design schematics and drawings to bring up issues and concerns, most practitioners show Design Review as a detection-type design control.

Figure 6.28 is a truncated excerpt from all-terrain Process FMEA, and provides an example of prevention- and detection-type process controls for the operation “Orient and place wheel spokes in wheel assembly fixture.”

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET
<b>Bicycle System:</b> The bicycle must provide safe and reliable transportation, including safe stopping distances and safe operation under all customer usage conditions as defined in the All-Terrain technical specification.	Does not stop in required distance	Potential accident or injury to bicycle operator without warning.	10	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	5	All-Terrain braking system design guide (document #123)	All-Terrain bicycle stopping test #ABC	5
				Brake system mis-adjusted by bicycle user.	3	None	1. Bicycle system durability test #789 2. Bicycle system performance testing to design requirements	9

TRUNCATED

**FIGURE 6.25** Example of system-level design controls from all-terrain System FMEA.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET
<b>Hand Brake S/S:</b> Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not slow down when the brake lever is pulled, potentially resulting in accident.	10	Cable Binds due to inadequate lubrication or poor routing	4	Hand Brake Design Guide #123	Bicycle system durability test #789	2
				External foreign material reduces friction	2			3
				Cable breaks	6	Cable material selection based on ANSI #ABC.	Bicycle system durability test #789	4

TRUNCATED

**FIGURE 6.26** Example of subsystem-level design controls from all-terrain Hand Brake Design FMEA.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET
<b>Brake Cable:</b> Provides adjustable and calibrated movement between the brake lever and brake caliper, under specified conditions of use and operating environment.	Cable breaks	Operator is unable to close brake calipers, wheel does not slow down, possibly resulting in accident.	10	Corrosion of cable wiring due to wrong material selected	5	Cable material selection based on ANSI Standard #ABC.	Cable strength test #456	4
				Fatigue cracks in cable wiring due to inadequate cable thickness	2	Finite Element Analysis of all new cable material	Laboratory analysis for fatigue cracks at regular intervals per test regimen #456	2
	Cable binds	Increased friction between cable and sheath, resulting in operator having to use greater effort to close brake calipers.	7	Bend or kink in cable due to misrouting	3		Design Review at prototype build	2
				Inadequate or wrong lubrication between cable and sheath	5	Cable lubrication selection based on ANSI Standard #XYZ.	Bicycle durability test #123	4

TRUNCATED

**FIGURE 6.27** Example of component-level design controls from all-terrain Brake Cable Design FMEA. (ANSI, American National Standards Institute.)

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	Current Process Controls (Prevention)	Current Process Controls (Detection)	DET
Orient and place 36 wheel spokes properly in wheel assembly fixture	Too few spokes	<b>Process Effect:</b> wheel not aligned, requiring rework out of station (5) <b>Product Effect:</b> wheel wobble and increasing stress during maneuvers, with potential for wheel collapse and rider injury, with warning (9)	9	Lack of organized wheel spoke kit	3	Wheel spoke installation work instructions	Visual check of wheel assembly by operator	5
	Wheel spokes not in correct orientation	<b>Process Effect:</b> wheel not aligned, requiring rework out of station (5) <b>Product Effect:</b> wheel wobble with potential for loss of handling during maneuvering and rider injury, with warning (9)	9	Fixture is not error proofed to prevent incorrect orientation	6	Wheel spoke installation work instructions	In-station test for wheel alignment/truing	7

TRUNCATED

**FIGURE 6.28** Example of process controls from all-terrain Process FMEA (wheel spoke installation).

### 6.2.10 Detection Ranking

For each cause, The FMEA team assesses the detection ranking. This is the likelihood that the current detection-type controls will be able to detect the cause of the failure mode.

Referencing the definitions in Chapter 3, Section 3.5, 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. The detection ranking considers the likelihood of detection of the failure mode/cause, according to defined criteria. Detection is a relative ranking within the scope of the specific FMEA and is determined without regard to the severity or likelihood of occurrence.” Refer to this section for a full explanation and useful examples of how to define detection and use a detection scale.

For Design FMEAs, detection is the ranking number corresponding to the likelihood that the current detection-type Design Controls will detect the failure mode/cause, typically in a time frame before the product design is released for production. For Process FMEAs, detection is the ranking number corresponding to the likelihood that the current detection-type Process Controls will detect the failure mode/cause, typically in a time frame before the part or assembly leaves the manufacturing or assembly plant. Section 6.2.10 discusses an exception to this definition for application in industries where the emphasis needs to be on detecting failures once the customer takes ownership (or the system is in operation).

Using the agreed-upon detection scale, the team carefully reviews the criteria column to make this judgment. Although it is possible to analyze each control separately, this is not necessary in most applications.

Refer to Chapter 3, Section 3.5.9, for an example of Design FMEA and Process FMEA detection scales. As covered in that section, the criteria for these scales should be reviewed and tailored (as needed) to make sense for individual company applications.

A suggested approach is assuming the failure has occurred and then assessing the capability of the detection-type design or process control to detect the failure mode or cause. If there is no detection-type control for a given failure mode/cause, the detection ranking should be set to the highest level.

Although most FMEA standards define detection as the ranking associated with the best control from the list of detection controls, an alternative is to consider the likelihood of detection based on the aggregate set of controls for a given cause. For example, if there are two different controls and each one has a likelihood of detection of a given cause of 50%, then both of the controls together would have a likelihood of detection of the same cause of 75%. If the rule of using the “best” control were applied, the likelihood of detection would be only 50%. Therefore, it may be more accurate to take into consideration the aggregate set of controls than merely the “best” control. Quality or reliability engineers should be able to help in this modeling, using reliability analysis for series-parallel systems, if the team wishes to use the aggregate set of controls in estimating detection ranking.

Properly assessed detection ranking will help ensure that risk due to detection is addressed with corrective actions, along with other high severity and high RPN issues.



### Bicycle Example

Figure 6.29 provides an example of a detection ranking for the all-terrain bicycle System.

In this example, based on the detection scale chosen from AIAG Edition 4 (2008), the ranking criterion (*Likelihood of Detection by Design Control*) that most closely matches the first cause and control is “Product validation (reliability testing, development, or validation tests) prior to design freeze using pass/fail testing.” Therefore, the detection ranking is 5.

#### 6.2.10.1 Detection Scale for Assessing Risk Related to In-Service Detection Systems

A unique application of detection scale is used in industries where the emphasis needs to be on detecting failures once the customer takes ownership (or the system is in operation), and less focus on detecting failures during product development. One example is an oil rig, in which the emphasis is on detecting and mitigating failures during operation of the oil rig system. Another example is a warning system in a nuclear power plant in which sensors detect an emerging

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of failure	OCC	Current Design Controls (Prevention)	Current Design Controls (Prevention)	DET
Bicycle System: The bicycle must provide safe and reliable transportation, including safe	Does not stop in required distance	Potential accident or injury to bicycle operator without	10	insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain	5	All-Terrain braking system design guide (document #123)	All-Terrain bicycle stopping test #ABC	5

**Suggested DFMEA Severity Evaluation Criteria**

Opportunity for Detection	Criteria: (Likelihood of Detection by Design Control)	Rank	Likelihood of Detection	
No Detection Opportunity	No current design control; cannot detect or is not analyzed.	10	Absolute Uncertainty	
No Likely to Detect at any Stage	Design analysis/detection controls have a weak detection capability; virtual analysis (e.g., CAE, FEA, etc.) is <b>not correlated</b> to expected actual operating conditions.	9	Very Remote	
Postdesign Freeze and Prior to Launch	Product verification/validation after design freeze and prior to launch with <b>pass/fail</b> testing (subsystem or system testing with acceptance criteria, e.g., ride and handling, shipping evaluation, etc.)	8	Remote	
	Product verification/validation after design freeze and prior to launch with <b>test to failure</b> testing (subsystem or system testing until failure occurs, testing of system interactions, etc.)	7	Very Low	
	Product verification/validation after design freeze and prior to launch with <b>degradation</b> testing (subsystem or system testing after durability test, e.g., function check).	6	Low	
Prior to Design Freeze	Product validation (reliability testing, development, or validation tests) prior to design freeze using <b>pass/fail</b> testing (e.g. acceptance criteria for performance, function checks, etc.)	5	Moderately	1. Bicycle system durability test #789 2. Bicycle system performance testing to design requirements
	Product validation (reliability testing, development, or validation tests) prior to design freeze using <b>test to failure</b> (e.g. until leaks, yields, cracks, etc.)	4	Moderately High	
	Product validation (reliability testing, development, or validation tests) prior to design freeze using <b>degradation</b> testing (e.g. data trends, before/after values, etc.)	3	High	

**FIGURE 6.29** Example of detection ranking from all-terrain System FMEA.

(CAE, computer-aided engineering; FEA, finite element analysis.)

Rank	Likelihood of Detection	Criteria: Likelihood of In-Service Detection by Design Control
10	Almost Impossible	Failure mode/cause are not detectable in service
9	Very Remote	Failure mode/cause is possibly detected during offline unplanned testing or inspection
8	Remote	Failure mode/cause is most likely detected during offline unplanned testing or inspection
7	Very Low	Failure mode/cause is possibly detected by offline planned periodic testing or monitoring
6	Low	Failure mode/cause is most likely detected by offline planned periodic testing or monitoring
5	Moderate	Failure mode/cause is possibly detected by online planned periodic testing or monitoring
4	Moderately High	Failure mode/cause is most likely detected by online planned periodic testing or monitoring
3	High	Failure mode/cause is possibly detected by online automatic continuous testing or monitoring
2	Very High	Failure mode/cause is most likely detected by online automatic continuous testing or monitoring
1	Almost Certain	Failure mode/cause is detected by online automatic continuous testing or monitoring

**FIGURE 6.30** Example of in-service detection scale.

problem, alerting personnel who can then prevent the problem or avert it before an accident or serious consequence occurs. The scale assesses the likelihood of the monitoring-type control to detect the problem during system operation. The nature of the application should determine the specific criteria of this unique detection scale.

Figure 6.30 is an example of an in-service detection scale. This scale should be tailored to individual company applications.

**6.2.10.2 Limitations and Alternatives to Using Detection Ranking** The detection ranking scale is the most controversial of the three risk ranking scales (severity, occurrence, and detection). Some of the concerns are the result of

misunderstanding of the detection scale itself. Other concerns represent valid experiences and opinions of skilled practitioners.

The most common misunderstanding or misapplication of the detection scale is to confuse or commingle the three types of detection risk:

1. Likelihood of detection by the identified controls—specifically, what is the likelihood that the current detection-type control will be able to discover the failure mode or its cause (remote, low, moderate, high, etc.)?
2. Timing of the opportunity for detection—specifically, what is the timing of the current detection-type control (prior to design freeze, post design freeze, in service, etc.)?
3. Type of test used to detect the cause of the problem—what is the quality of test method used to detect the failure mode or its cause (degradation test, test to failure, pass/fail test, etc.)?

The detection scale must clearly identify which of the three types of detection risk is being assessed by the individual criteria of the scale.

Some detection scales, such as the Design FMEA detection scale in Society of Automotive Engineers (SAE) J1739 (January 2009) and AIAG Edition 4 (2008), attempt to integrate the three types of detection risk together in one scale, bringing together likelihood of detection risk, timing risk, and test type risk into one criteria column. This is a noble attempt and a good start. However, a problem occurs when the timing and test type risk criteria point to one detection ranking number and the likelihood of detection risk points to a completely different detection ranking number. If the detection scale the team uses integrates the three types of detection risk, the FMEA team will need to establish how to resolve the above issue. One way to do this is to take the worst case (highest detection ranking) when there are conflicting criteria.

Figure 6.31 is an example of a Design FMEA detection scale that attempts to integrate the three types of detection risk without the pitfalls outlined above.

Some practitioners avoid the detection scale entirely because of concerns about the validity of this type of risk. Instead, they focus on severity and occurrence. If an FMEA team chooses to use an FMEA standard that does not incorporate detection ranking, or otherwise chooses to avoid use of any detection ranking scale, *it must still address the risk associated with detection of the failure modes and their associated causes*. One potential way to do this is to require a separate task to review the controls and ensure they are adequate and sufficient, and then to take action to remedy deficiencies.

Regardless of what the FMEA team chooses to do regarding detection ranking, there is risk associated with detection of the failure modes and their associated causes, and this risk must be addressed.

### 6.2.11 Risk Priority Number (RPN)

The perfect is the enemy of the good.

—Voltaire

Referencing the definitions in Chapter 3, Section 3.5, RPN is “a numerical ranking of the risk of each potential failure mode/cause, made up of the arithmetic product

Rank	Likelihood of Detection by Design Control*	Criteria: Timing of Design Control*	Criteria: Type of Design Control*
<b>10 Almost Impossible</b>	No current Design Control, or current Design Control cannot detect potential cause and subsequent failure mode.	No current Design Control, or current Design Control cannot detect potential cause and subsequent failure mode.	No current Design Control, or current Design Control cannot detect potential cause and subsequent failure mode.
<b>9 Very Remote</b>	Very remote chance that current Design Control will detect potential cause and subsequent failure mode.	Design Control is most likely to occur during operation of product after launch	Design Control is entirely uncorrelated to expected actual environmental or operating conditions.
<b>8 Remote</b>	Remote chance that current Design Control will detect potential cause and subsequent failure mode.	Design Control is most likely to occur during operation of product after launch	Design Control is only partially correlated to expected actual environmental or operating conditions.
<b>7 Very low</b>	Very low chance that current Design Control will detect potential cause and subsequent failure mode.	Design Control is most likely to occur after design verification/validation prior to launch	Design Control is comprised of pass/fail type of test procedure
<b>6 Low</b>	Very low chance that current Design Control will detect potential cause and subsequent failure mode.	Design Control is most likely to occur after design verification/validation prior to launch	Design Control is comprised of pass/fail type of test procedure
<b>5 Moderate</b>	Moderate chance that current Design Control will detect potential cause and subsequent failure mode.	Design Control is most likely to occur during design verification/validation prior to launch	Design Control is comprised of test-to-failure type of procedure
<b>4 Moderately high</b>	Moderately high chance that current Design Control will detect potential cause and subsequent failure mode.	Design Control is most likely to occur during design verification/validation prior to launch	Design Control is comprised of test-to-failure type of procedure
<b>3 High</b>	High chance that current Design Control will detect potential cause and subsequent failure mode.	Design Control is most likely to occur prior to design freeze and design verification/validation	Design Control is comprised of degradation type of test procedure
<b>2 Very high</b>	Very high chance that current Design Control will detect potential cause and subsequent failure mode.	Design Control is most likely to occur prior to design freeze and design verification/validation	Design Control is comprised of degradation type of test procedure
<b>1 Almost Certain</b>	Design Control will almost certainly detect potential cause and subsequent failure mode.	Design Control is most likely to occur prior to well before design freeze	Design Control is comprised of properly correlated virtual analysis

**FIGURE 6.31** Example of Design FMEA detection scale (integrating three types of detection risk).

(\*FMEA Team assesses risk based on likelihood of detection by Design Control (first column), timing opportunity for Design Control (second column), and test type of Design Control (third column). The worst case becomes the Detection ranking.)

of the three elements: severity of the effect, likelihood of occurrence of the cause, and likelihood of detection of the cause.”

RPN is not a perfect measure of risk. It has proven useful to a majority of practitioners, and others have decided to use alternatives. This book will introduce RPN, explain how it is used, and discuss limitations and alternatives.

RPN is the product of each of the three rating scales: severity, occurrence and detection. If the scales for severity, occurrence, and detection each range from 1 to 10, then the RPN (in theory) can range from 1 to 1000.

In the author’s experience, only one example of an RPN of 1000 has been seen. It was an early version of a plastic fuel tank, and the FMEA team was convinced it would fail (tank rupture), with potentially catastrophic effect, and (at the time) there was no agreed-upon way to detect the failure mode or its cause. Of course, the design was changed to a robust design, and proper testing was developed.

#### **Example (scales ranging from 1 to 10)**

Severity	8
Occurrence	4
Detection	3
RPN	96 (product of $8 \times 4 \times 3$ )

#### **Example (scales ranging from 1 to 5)**

Severity	4
Occurrence	2
Detection	3
RPN	24 (product of $4 \times 2 \times 3$ )

The entire purpose of the RPN value is to help the FMEA team prioritize issues for corrective action within the scope of the specific FMEA project. In application, it is always necessary to separately review and address all high severities as well as high RPNs. The reason is that high severity, but low RPN, has the potential to result in high risk to end users and to the company.

##### **6.2.11.1 Limitations and Alternatives to Using RPN**

Good things do not come easy. The road is lined with pitfalls.

—Desi Arnaz

There are certain limitations to using RPNs, and FMEA teams need to understand these limitations. Here are the primary ones:

1. *Subjectivity of RPN.* Since the components of RPN (severity [S], occurrence [O], detection [D]) are each subjective ratings, the RPN value is subjective in nature. It only has application in helping the FMEA team prioritize issues for corrective action within a given FMEA, and cannot be used to assess risk across different FMEAs. The FMEA team must understand the limitations of RPN due to its subjectivity and other limitations.
2. *Limitations of Detection.* The detection scale is controversial for some companies and practitioners, and as a result, some have chosen not to use detection

ranking at all. A minority of companies and corresponding applications use the severity and occurrence scale (without detection) and then prioritize issues by the product of  $S \times O$ . If the FMEA team chooses to use  $S \times O$  instead of RPN, then the team needs to consider how to address the risk associated with detection.

3. *Holes in the Scale.* “Although the RPN is an integer scale, it is not continuous. Many of the numbers in the range of 1 to 1000 cannot be formed from the product of S, O, and D. This creates ‘holes’ in the scale. These holes are the cause of the most serious problems in interpreting the RPN.”<sup>[6]</sup> This is true particularly if the FMEA team expects higher RPNs to represent higher risk in a manner that is continuous and proportional.
4. *Duplicate RPN Numbers.* “All possible products of S, O, and D include many duplicate numbers . . . It is difficult to accept that failures whose severities range from 1 (not noticeable except by the most discerning customer) to 8 (inoperable with loss of primary function) can be evaluated as having the same importance.”<sup>[6]</sup> For example, a severity of 1, occurrence of 8, and detection of 8 has the same RPN value as a severity of 8, occurrence of 4, and detection of 2. Clearly, there is very different risk associated between these two examples.
5. *RPN Thresholds.* It is enticing for management to use thresholds for RPN values and require defined action if the RPN value exceeds the given threshold. In most cases, this is a flawed approach, as it can easily become a numbers game. If management exerts sufficient pressure, through excessive consequences for RPN values exceeding thresholds, the FMEA teams or suppliers can bias the RPN components (S, O, and D) to lower the resulting RPN below the threshold. If RPN thresholds are used at all, they should only trigger a heightened level of review, not specifically mandated action.
6. *High Severity by Itself.* High severity is high risk, regardless of the RPN. Therefore, it is *always* necessary to address high severity in addition to high RPN.

There is no perfect risk priority system. RPN is one way for the FMEA team to take into account the three types of risks, namely risk due to the severity of the effect of the failure mode, risk due to the frequency of occurrence of the cause of the failure mode, and risk due to the ability to detect the failure mode and its cause. However, the FMEA team needs to be aware of the limitations of RPN, and always remember to address the severity risk separately.

Whatever risk system the FMEA team uses, an understanding of the advantages and disadvantages of the risk system is essential to prioritize correctly issues for corrective action.

**Alternatives to RPN** Listed here are some of the alternatives to RPN, with an explanation of each.

**$S \times O$**  The product of  $S \times O$  gives a numerical rating of the combined risk of severity and occurrence, sometimes called a Criticality Number. In FMECAs, this is the subjective risk ranking system. Using  $S \times O$  avoids trying to integrate three types of risk into one number (RPN). However, it is still necessary to address

severity by itself. If the FMEA team chooses to use  $S \times O$  instead of RPN, then the team needs to consider how to address the risk associated with detection.

**S-O-D** Some companies use the numerical value of S-O-D. If severity is 7, occurrence is 3, and detection is 5, then S-O-D is 735. This avoids the “holes” in RPN (covered above), but severity by itself must still be addressed. In addition, the numerical values of S-O-D do not necessarily show increasing risk. For example, severity 6, occurrence 8, detection 8 (688) compared to severity 7, occurrence 1, detection 2 (712). Clearly, the first value (688) represents more inherent risk, because of frequency, than the second value (712), even though the number is lower.

**S-O-D Matrix** Another interesting approach is to make a three-dimensional chart based on the individual rankings for severity, occurrence, and detection. Liken this to an xyz chart, with severity on the x-axis, occurrence on the y-axis, and detection on the z-axis. For each potential value of S, O, and D, the company has guidelines for prioritization of action. Some use a red–yellow–green coloration to show the risk associated with the corresponding values of S, O, and D. This approach takes into account and prioritizes for risk every combination of S, O, and D.

**RPN Application** Each company needs to decide how to characterize risk. Severity by itself is an essential risk characterization metric. RPN can be useful to complement severity with the risk due to occurrence and detection as long as limitations are understood. Alternatives to RPN can be used as long as risk due to detection is addressed and not ignored. The three types of risk (severity, occurrence, and detection) all must be taken into consideration and are essential elements to properly characterizing risk and prioritizing corrective actions. When statistician and experimentation expert George Box said, “All models are wrong, but some are useful,” he might as well been referring to RPN.

## 6.3 FMEA LINKAGES

### 6.3.1 System or Design FMEA Linkage to Design Verification Plan

A Design Verification Plan (DVP) documents the strategy that will be used to verify and ensure that a product or system meets its design specifications and other requirements. Each of the product requirements are listed in the DVP along with the physical test or analytical method that will determine if the requirement is met.

The System or Design FMEA is a key contributor to the effectiveness of the DVP. The linkage between the FMEA and the DVP plan goes two ways. In the first, the FMEA team includes representation from the testing department in order to ensure that the team considers all needed input from testing as part of the analysis. In the second, the FMEA team ensures that the DVP is impacted by the results of the FMEA. Specifically, when the FMEA team identifies failure modes and associated causes that are not currently well detected in test plans or procedures, the test plans and procedures should be updated and improved so all failure modes of concern are detected during testing. Any changes to test procedures or test plans should be identified as FMEA recommended actions.



### Bicycle Example

In the all-terrain Hand Brake Design FMEA, the test engineer is able to provide input to the FMEA team about how the hand brake subsystem does not apply the needed friction between brake pads and wheel rims, such as “Cable breaks.” The FMEA team should consider this potential cause as part of its analysis.

The FMEA team should also consider how to lower the detection ranking for “Cable breaks” from its current level of 4. In order to do this, the team recommended adding a cable strength test to the DVP and placed it in the FMEA recommended actions column.

Figure 6.32 is an example of a DVP for Hand Brake Subsystem. The current design controls are transferred from the Design FMEA to the “Test/Specification Method” column of the DVP. The Test/Verification team filled out the rest of the DVP. Note, in this example, that in addition to transferring the design controls to the DVP, the Design FMEA recommended actions that relate to test improvements are also added to the DVP.

### 6.3.2 Process FMEA Linkage to Process Control Plans

“The Process Control Plan provides a documented ‘summary description’ of the methods used to minimize process and product variation. It provides a structured approach for the design, selection and implementation of value added control methods. It is not intended to replace the detailed information contained in operator work instructions.”<sup>[7]</sup> It is also used to control product and process characteristics and requirements, and to react to problems with the manufacturing and assembly operations when they do occur.

The Process Control Plan (PCP) receives input from both the Process Flow Diagram and the Process FMEA. There is an organized flow of information from Process Flow Diagram Worksheet to Process FMEA to PCP. The mapping of operation descriptions and key characteristics is covered in Chapter 5, Section 5.3.3, on Process Flow Diagram Worksheet.

In addition to the flow of information from the PFD Worksheet to Process FMEA, the causes from the Process FMEA become process characteristics in the PCP and the Process Controls from the Process FMEA become control methods in the PCP.

The Process FMEA is a key contributor to the effectiveness of the PCP. This linkage between the Process FMEA and the PCP goes two ways:

The Process FMEA team includes representation from the manufacturing controls area in order to ensure that the team considers all needed input from process controls as part of the analysis.

When the Process FMEA team identifies failure modes and associated causes that are not currently detected or controlled in PCPs or associated procedures, the PCP and procedures can be updated and improved, so all failure modes of concern are detected and controlled during manufacturing or assembly. Any changes to PCPs or procedures should be included in the FMEA recommended actions.

All-Terrain Hand Brake Design Verification Plan						
Part Number	Supplier Name			Page		
Part Name	Supplier Code			Date		
Application	DVP Number			Test Engr		
Plan Date	Report Date			Design Engr		
VERIFICATION PLAN						
Test Number	Test Name	Test/Specification Method	Acceptance Criteria	Responsibility	Sample Size	Sample Type
1	Bicycle Durability Test	Bicycle system durability test #789	Per test #789	Joe S.	3	Prototype
2	Cable Strength Test	Cable strength test #456	Per test #456	Mary B.	6	Prototype
3	Design Review	Design review of brake system	Peer review acceptance	Bill R.	n/a	Prototype
4	Laboratory Analysis	All cable testing samples undergo laboratory analysis for fatigue cracks at regular intervals per test regimen #456	No cracks at end of testing	Mary B.	All samples	Prototype
5	Recommended Action	Modify bicycle durability testing to include periodic brake cable checks for binding	Test modified	Joe S.	n/a	n/a
6	Recommended Action	Based on results of Cable DFMEA, develop cable strength test and modify cable design to improve strength	DFMEA done, test modified	Mary B.	n/a	n/a
7	Recommended Action	Revise the bicycle durability test regimen to periodically check for brake cable misadjustment	Test modified	Joe S.	n/a	n/a

FIGURE 6.32 Example of Design Verification Plan for hand brake subsystem.



Figure 6.33 is an example of a PCP for the all-terrain bicycle wheel spoke installation. The process characteristic controlled in this example is “correct number of wheel spokes.” The current process controls from the Process FMEA were transferred to the Control Method column of the PCP. The manufacturing team filled out the rest of the PCP.

In this example, the correct number of wheel spokes is a key characteristic. In the Process FMEA example shown in Figure 6.28, the Process FMEA team assessed the capability of the current visual controls with detection rankings of 3 and 6. This reveals a weakness in the visual controls, and as later shown in the recommended actions for the wheel spoke installation example (Chapter 7, Section 7.4), the team recommends upgrading to an in-station vision system. When the new controls (upgraded in-station vision system) are implemented, the PCP will be modified to reflect the improved controls, and will be better able to monitor and control the number of wheel spokes.

### 6.3.3 Design FMEA Linkage to Process FMEA

There is both a physical linkage and a conceptual linkage between Design FMEA and Process FMEA.

From a physical linkage standpoint, the Design FMEA can directly provide important input to the Process FMEA. The FMEA team may wish to transfer relevant information in the following manner: causes in the Design FMEA can become failures in the Process FMEA; failures in the Design FMEA can become effects in the Process FMEA.

**Example:** If the Design FMEA indicates that Part X will leak if the diameter of the hole is too wide, then the Process FMEA should consider aspects of the manufacturing process that may cause this.

*Design FMEA.* Failure = Leak; Cause = Hole too wide.

*Process FMEA.* Failure = Hole too wide; Effect = Leak

Of course, once this transfer has taken place, the Process FMEA team should review the transfer items to be sure they make sense based on the scope and content of the Process FMEA. It will also need to add the other relevant information in order to complete the Process FMEA. At best, transferring information from Design FMEA to Process FMEA is only a beginning.

Another linkage between Design FMEAs and Process FMEAs is key characteristics. As covered earlier in this chapter, Design FMEAs can identify KPCs. An example is the diameter of a shaft and/or the material composition of a shaft. The Process FMEA team can then take these KPCs as input and develop the corresponding Key Control Characteristics (KCCs) that must be controlled with the PCP.

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**FIGURE 6.33** Example of Process Control Plan for wheel spoke installation.

In the shaft example, with a KPC of the shaft diameter, the corresponding KCC in the manufacturing process might be the *xyz* coordinates of the cutting tool.

From a conceptual linkage standpoint, product designs must be able to be manufactured and assembled. This can be accomplished by ensuring that a manufacturing representative is always on the Design FMEA. The manufacturing team member helps to ensure that the design can easily be manufactured without failures. One technique to reduce manufacturing failures in design is called “mistake proofing” or “error proofing,” in which the design is modified to make it difficult to assemble incorrectly.

There will be times when performing a Design FMEA that the team identifies a potential weakness in the manufacturing or assembly process. If the identified weakness is outside the scope of the Design FMEA, the information needs to be forwarded to the Process FMEA team. Similarly, if the Process FMEA team identifies a potential weakness in the product design that is outside the scope of the Process FMEA, the information should be passed to the Design FMEA team.

#### **6.3.4 Relationship between System, Subsystem, and Component FMEAs**

As covered in Chapter 6, Section 6.2.1, FMEAs are done at specific levels of the system hierarchy (for System and Design FMEAs). These different levels of FMEAs are linked through relationships between cause, failure mode, and effect of failure.

Regarding the FMEA linkage from higher levels to lower levels of the design hierarchy, as covered earlier in this chapter, causes at the system level can become failure modes at the subsystem level, and causes at the subsystem level can become failure modes at the component level. This follows the trail of physics of failure, as the FMEA teams delve deeper from system to subsystem to component in search of the root causes and underlying failure mechanisms for high-risk items.

The FMEA linkage from lower levels to higher levels is different. The local effect of a failure mode at a given level can be a failure mode at the next higher level. The bicycle example directly below will illustrate.



#### **Bicycle Example**

*Component.* Bicycle wheel rim

*Function.* Provide radially balanced structural support for spokes and tires

*Failure Mode.* Wheel rim bent

*Effect.* Wheel wobbles (local effect), bicycle can become unstable, with potential for rider injury

*Subsystem.* Front wheel subassembly

*Function.* Provide friction with road to enable safe maneuvering and for safe stopping and travel

*Failure Mode.* Wheel wobbles

*(Continued)*

*Effect.* Bicycle handling becomes unstable (local effect), with potential for rider injury

*System.* Bicycle

*Function.* The bicycle must provide safe and reliable transportation, including safe stopping distances and safe operation under all customer usage conditions as defined in the all-terrain technical specifications.

*Failure Mode.* Bicycle handling becomes unstable

*Effect.* Bicycle rider can lose control, with potential for rider injury

The “bottom-up” approach to multiple levels of Design FMEAs, with corresponding linkage from lower levels to higher levels, can become problematic. Since FMEAs are not done on all items and all levels of the hierarchy due to risk prioritization and cost considerations, there is usually not a realistic opportunity to link FMEAs from lower levels to each subsequent higher level.

## 6.4 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

### Problem 6.1

**Hypothetical Scenario:** A System FMEA is planned for the all-terrain bicycle. Which of the following should be included within the scope of the all-terrain System FMEA? (Select all that apply.)

1. The interfaces between the bicycle subsystems
2. The interactions between the bicycle and the rider
3. The components of the bicycle
4. The all-terrain bicycle assembly process

### Problem 6.2

Which of the following is an example of an effect in the Hand Brake Subsystem Design FMEA? (Select all that apply.)

1. Bicycle wheel does not slow down when the brake lever is pulled, potentially resulting in accident.
2. Cable binds due to inadequate lubrication or poor routing.
3. Provide the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.
4. Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.

**Problem 6.3**

FMEA teams sometimes get confused between failure mode, effect, and cause in an FMEA. Which of the following are true statements about a failure mode, effect, and cause in an FMEA? (Select all that apply.)

1. The “cause” is the cause of the effect.
2. The “cause” is the cause of the failure mode.
3. The “effect” is related to the cause.
4. The “effect” is related to the failure mode.

**Problem 6.4**

Which of the following apply to prevention-type design controls? (Select all that apply.)

1. Prevention-type design controls are part of the basis for determining the detection ranking.
2. Prevention-type design controls describe how a cause or failure mode can be prevented based on newly recommended actions.
3. Prevention-type design controls describe how a cause or failure mode can be prevented based on current or planned actions.
4. Prevention-type design controls are part of the basis for determining the occurrence ranking.

**Problem 6.5**

Which of the following statements are true about failure mechanisms? (Select all that apply.)

1. Understanding the underlying failure mechanism will help to generate effective recommendations to resolve the problem and improve the design.
2. Understanding the underlying failure mechanism does not help to ensure proper tests are developed to detect the failure mode and its cause.
3. Failure mechanisms are the physical, chemical, thermodynamic, or other processes that result in failure.
4. An example of a failure mechanism is electrical wiring.
5. An example of a failure mechanism is metal fatigue.

**Problem 6.6**

It is important to identify the primary functions in the Function column of an FMEA. There are a number of different *types* of functions. List three function types.

**Problem 6.7**

Interfaces must be covered in the scope of an FMEA. One way to do this is to include interfaces in the FMEA Function column. Chapter 6 includes an example of an interface-type function for the interface between the all-terrain handlebar subsystem and hand brake subsystem.

What document contains the interface information?

Identify two other subsystem interfaces for the all-terrain bicycle that should be included in the scope of the all-terrain System FMEA.

**Problem 6.8**

An FMEA is being done on a projector lamp, with a function “Provide reliable light for image transfer at a minimum of 1000 lumens for 2000 hours of operation.”

One possible failure mode is “lamp burns out prematurely.” Brainstorm one other possible failure mode.

For the failure mode “lamp burns out prematurely,” brainstorm two possible causes. Try to include at least one underlying failure mechanism.

**Problem 6.9**

Hypothetical scenario: a manufacturer of air conditioning (AC) systems is concerned about potential failures introduced during installation of the AC system at commercial or residential sites. From an FMEA standpoint, how can this concern be addressed?

**Problem 6.10**

A Process FMEA is being done on a pump assembly station. Widget ‘A’ is a supplier part that is assembled into the pump. One of the operations being analyzed is “inspect the length of widget ‘A’ to print dimension 123.” The Process FMEA team has identified the primary function of this operation as “verify the length of widget ‘A’ meets the print dimension 123, using measuring device #456.” One of the failure modes identified by the team is “length of widget ‘A’ is less than dimension 123.” Describe what is wrong with that failure mode.

**Problem 6.11**

**Scenario:** In 2011, a vehicle manufacturer announced a recall of certain models for improper routing of the vehicle’s power steering hose, which could lead to melting of the hose due to its close proximity to the catalytic converter. The safety concern was that the melted hose could drip power steering fluid onto the vehicle’s catalytic converter and potentially ignite the flammable hydraulic steering fluid. From an FMEA viewpoint, which type of FMEA should address this issue within the scope of the FMEA and why?

### Problem 6.12

An example of a function from the System FMEA of the all-terrain bicycle stated, “The bicycle must provide safe and reliable transportation, including safe stopping distances and safe operation under all customer usage conditions as defined in the all-terrain technical specification.” As noted in Section 6.2.2, this example of function is worded quite generally, and in practice, it may be advisable to break it down to more discrete functions, which aid in defining failure modes.

Refer to Appendix C, “All-Terrain Bicycle Documents,” and the “Checklist of function types” in Section 6.2.2 of this chapter. Brainstorm three additional primary functions of the all-terrain bicycle.

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# *Chapter* 7

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## *How to Develop and Execute Effective Risk Reduction Actions*

I have been impressed with the urgency of doing. Knowing is not enough; we must apply. Being willing is not enough; we must do.

—Leonardo da Vinci

### **IN THIS CHAPTER**

Once the Failure Mode and Effects Analysis (FMEA) team has performed the analysis up through Risk Priority Number (RPN) calculation, the important work of defining and executing effective actions can begin. This chapter explains how to prioritize issues for corrective action, outlines how to identify and implement the most effective action strategies, and provides key enablers for removing roadblocks to successful execution of FMEAs objectives.

### **USE OF THE BICYCLE EXAMPLES IN THE CHAPTER**

In order to highlight the application of various FMEA action strategies, the all-terrain bicycle case study is used. Also shown at the end of selected sections are brief examples of how the all-terrain bicycle team applies that step in performing their bicycle FMEAs. Note that these examples are shortened excerpts from a longer version of bicycle FMEAs, and therefore do not show the complete list of recommended actions. A bicycle icon precedes these examples. Chapter 8, Section 8.8, has a teaching analysis of the resulting bicycle FMEAs.

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*Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis*, First Edition. Carl S. Carlson.

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## 7.1 PRIORITY ISSUES FOR CORRECTIVE ACTION

Hope for the best, but prepare for the worst.

—English Proverb

This is the point at which the FMEA team must decide which issues to address in the FMEA. It is best to complete the FMEA up through RPNs before prioritizing issues for corrective action so that the team can address the highest risk issues first. There are two tasks involved in this. Good FMEA software can make this part of the FMEA project very easy.

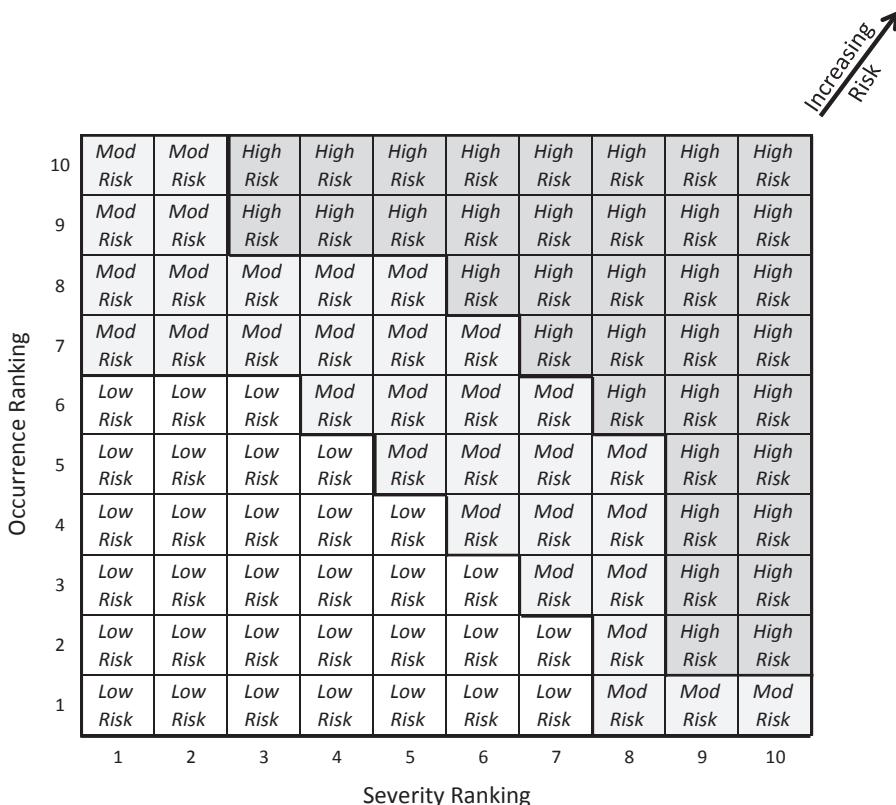
*Risk Prioritization Task One:* The FMEA team must adequately address *all high severity problems*. If the team is using a severity scale of 1–10, this means addressing all 9s and 10s at minimum. The FMEA team must review and fully understand all the high severity issues so as to address them in its recommended actions to ensure those issues do not occur within the life of the product or manufacturing process. The intention is to ensure the FMEA team takes positive and effective action to ensure high severity issues are fully resolved.

For System FMEAs, part of the task of addressing high severity problems is to understand and identify “single-point failures.” A “single-point failure” occurs where failure of a single component results in complete failure of the entire system. On a severity scale of 1–10, this would include severity 8 (complete loss of performance), as well as severity 9 and 10.

*Risk Prioritization Task Two:* In addition to addressing all high severities, the FMEA team needs to *review and prioritize the high RPNs*. There are different ways to do this. One prioritization approach is the use of RPN thresholds. This approach has significant pitfalls, and is not recommended. Another approach is to begin with the highest RPN and work down the list. In this approach, the FMEA team continues addressing lower and lower RPNs given available resources and program goals. A third approach is to rank the RPNs and then address an agreed-upon percentage of total issues. This percent threshold may be 20%, 30%, or another number the FMEA team believes will reduce risk to an acceptable level. In this approach, the FMEA team will address all RPNs above that percent.

If the FMEA team has chosen to use severity and occurrence, and not RPN, they may want to plot the severity and occurrence rankings on a risk matrix to graphically show risk prioritization. Figure 7.1 shows a severity–occurrence risk matrix with “High Risk,” “Moderate (Mod) Risk,” and “Low Risk” for each combination of severity and occurrence. Companies can tailor the risk categorization to their specific needs.

Another and successful approach (combining the above methods) is used by some FMEA teams focusing on severity, occurrence, and detection rankings within the context of a three-dimensional matrix. In this case, the FMEA team, or the company, has published guidelines for each combination of severity, occurrence, and detection, and the team takes appropriate action based on those guidelines.

**FIGURE 7.1** Example of severity–occurrence risk matrix.

When assessing the degree of risk using the FMEA ranking scales, it is not appropriate to compare the ratings of one team's FMEA with the ratings from another team. Even if the product or process appears to be similar, each application is unique in terms of operating environment, customer usage, and specific technical content. The risk ranking scales, including RPN, are designed as a means to prioritize issues for corrective actions within the scope of individual FMEAs.

Regardless of which approach the FMEA team decides to use, it is crucial to address all high severities and all high RPNs until the level of risk is acceptable.

### **7.1.1 Is Action Always Required on High Severity Issues?**

What if severity is high (9 or 10 on a severity scale of 1–10), and the occurrence and detection rankings are both very low? Is action still required? If severity is 9 or 10, the team must first attempt to lower the severity ranking, such as by design change. If lowering the severity ranking is not possible or feasible, the FMEA team must confirm and verify that the occurrence and detection rankings are as low as possible (preferably 1), or must take all action necessary to achieve lowest possible occurrence and detection rankings, and then obtain management's concurrence and support before determining that no further action is required. *Both management*

and the FMEA team must agree that everything possible has been done to prevent safety problems within the design life of the product or during the manufacturing process.



### Bicycle Example

Refer to Problem 7.1 at the “End of Chapter Problems” section to see an excerpt from the Brake Cable Design FMEA, with the recommended actions omitted. Study the FMEA, including severities and RPNS, and prioritize issues for corrective action. Answers will be in the *Solutions Manual*.

## 7.2 DEVELOP EFFECTIVE RECOMMENDED ACTIONS

The FMEA team reviews each of the high severities and each of the high RPNs, and develops the recommended actions that, when executed will reduce risk to an acceptable level. There is often more than one action needed to address risk associated with each of the failure modes and causes. The FMEA team should take care to recommend feasible and effective actions that will fully address the risk associated with each failure mode/cause. Whatever action the FMEA team believes needs to be done to address risk must show up in the recommended action column.

In identifying recommended actions, the FMEA team should consider existing controls, the relative importance (prioritization) of the issues, as well as the cost and effectiveness of corrective actions.

For each recommended action, the FMEA team should assign the person responsible, the due date, and other typical project management type of information in order to be able to execute the actions efficiently.

FMEA recommended actions should be effective, detailed, and executable. They should have management agreement and drive design or manufacturing process improvements. FMEA teams should consider the full range of quality and reliability tools. There are many excellent resources describing the quality and reliability tools that are available to an FMEA team to help formulate effective recommended actions.

In addition to identifying recommended actions to improve designs and reduce risk, the team should review the corresponding engineering or manufacturing requirements. The question needs to be asked, “Do the engineering or manufacturing requirements need to be changed to reflect the design or process improvement?” If the answer to this question is “yes,” the team needs to add recommended actions to improve the requirements. This is important because it is ultimately the engineering or manufacturing requirements that drive product designs, product testing, manufacturing processes, and process control plans.

The Design FMEA team should not rely on process controls to overcome design weaknesses. On the contrary, the focus of the Design FMEA team should be on making the design more robust so that special process controls are not required to resolve design deficiencies. Similarly, the Process FMEA team should not rely on design controls to overcome process weaknesses.

Remember, reduce risk from high severity first, followed by risk from high RPNs. The most effective actions mitigate the effect to a lower severity through design changes and improve the design to make it more robust.

### **7.2.1 Quality and Reliability Resources to Help Formulate FMEA Recommended Actions**

The following is a short list of quality and reliability resources available to FMEA teams to support research in development of effective FMEA recommendations.

- Applied Reliability Symposium, <http://www.arsymposium.org/>
- Reliability and Maintainability Symposium, <http://rams.org/>
- The Center for Advanced Life Cycle Engineering (CALCE), University of Maryland, <http://www.calce.umd.edu/>
- Reliability Engineering Resource web site, <http://www.weibull.com/>
- Society of Automotive Engineers (SAE) JA1000/1 *Reliability Program Standard Implementation Guide*, 1999
- *Assurance Technologies Principles and Practices: A Product, Process and System Safety Perspective*, 2nd edition, by Dev G. Raheja and Michael Allococo, Wiley-Interscience, 2006
- *Practical Reliability Engineering*, 5th edition, by Patrick O'Connor and Andre Kleyner, Wiley, 2012
- *Improving Product Reliability: Strategies and Implementation*, by Mark A. Levin and Ted T. Kalal, Wiley, 2003
- *Accelerated Reliability Engineering: HALT and HASS*, 1st edition, by Gregg Hobbs, John Wiley & Sons, 2000
- *Product Reliability, Maintainability, and Supportability Handbook*, 2nd edition, by Michael Pecht, CRC Press, 2009
- *Design for Six Sigma: A Roadmap for Product Development*, 2nd edition, by Kai Yang and Basem EI-Haik, McGraw-Hill, 2008
- *Design for Reliability* (Quality and Reliability Series), 1st edition, by Dev G. Raheja, Wiley, 2012

There are also many excellent web sites of professional organizations, such as American Society of Quality (ASQ), Society of Automotive Engineers (SAE), Institute of Environmental Sciences and Technology (IEST), Institute of Electrical and Electronics Engineers (IEEE), International System Safety Society (ISSS), Society of Reliability Engineers (SRE), and many others.

In summary, there is a wealth of methods and tools available in the fields of quality and reliability. They should be made available to FMEA teams in their search for answers, and should be used to broaden the tools available to FMEA team members in resolving high-risk issues.

## **7.3 ACTION STRATEGIES TO REDUCE RISK**

Strategy without tactics is the slowest route to victory. Tactics without strategy is the noise before defeat.

—Sun Tzu

FMEA teams can use a multitude of proven strategies to address risk associated with high severity, high occurrence, and/or high detection. The following sections are some of these strategies.

### 7.3.1 Action Strategies to Reduce Severity Risk

**Design for Fail-Safe** A *fail-safe* design is one that, in the event of failure, responds in a way that will cause minimal harm to other devices or danger to personnel. Fail-safe does not mean that failure is improbable; rather, that a system's design mitigates any unsafe consequences of failure. In FMEA language, fail-safe reduces the severity of the effect to a level that is safe.

**Example:** Laminated safety glass for windshields prevents injury from glass shards.

**Example:** Lawnmowers or snow blowers require a hand-closed lever to operate, which prevents injury from moving blades if the operator falls or the device turns over.

**Design for Fault-Tolerance** A *fault-tolerant* design is a design that enables a system to continue operation, possibly at a reduced level (also known as graceful degradation), rather than failing completely when some part of the system fails. In FMEA language, fault-tolerance reduces the severity of the effect to a level that is consistent with performance degradation.

**Example:** A passenger car can have “run-flat” tires, each of which contain a solid rubber core, allowing their use even if a tire is punctured. The punctured “run-flat” tire is effective for a limited time at a reduced speed.

**Design for Redundancy** A *redundant* design provides for the duplication of critical components of a system with the intention of increasing reliability of the system, usually in the case of a backup or fail-safe. This means having backup components that automatically “kick in” should one component fail. In FMEA language, redundant design can reduce the occurrence of *system* failure and reduce system severity to a safe level. This strategy can be employed to address single-point failures.

**Example:** Large cargo trucks can lose a tire without major consequences. They have many tires, and no one tire is critical (with the exception of the front tires, which are involved in steering).

**Provide Early Warning** Failures that occur without warning are more dangerous than failures with warning. Catastrophic effects can be avoided by adding a warning device to system design. In FMEA language, adding early warning reduces the severity of the effect, potentially reduces the occurrence of system failure, and increases likelihood of detection of failure mode/cause during in-service usage.

**Example:** A vehicle manufacturer uses a passenger side air bag to prevent injuries to the passenger. Severe injury is possible to a passenger if the air bag fails to activate during an accident. The FMEA team recommends a warning light on the driver display to alert the driver if there is a malfunction of the air bag system.

**Example:** A tire manufacturer adds a tire pressure monitor to alert the driver to unsafe tire pressure.

**Example:** Manufacturers of battery-operated residential smoke and fire alarms add a loud audible signal to alert consumers when the alarm battery is low.

### 7.3.2 Action Strategies to Reduce Occurrence Risk

As noted above, *redundant design* can reduce the occurrence of *system* failure.

Also noted above, an *early warning* device can reduce the occurrence of *system* failure.

**Change the Design to Eliminate the Failure Mode or Cause** It is possible to eliminate the failure mode or cause by changing the design of the product or the process. In FMEA language, eliminating the failure mode or cause will reduce the likelihood of occurrence to the lowest possible level.

**Example:** A robot arm uses a hydraulic lifting mechanism prone to “oil leaks.” The FMEA team recommends an electronic robot arm using solenoids and motors. The failure mode “oil leak” is no longer possible. Of course, the new electronic system will have its own set of failure modes requiring consideration.

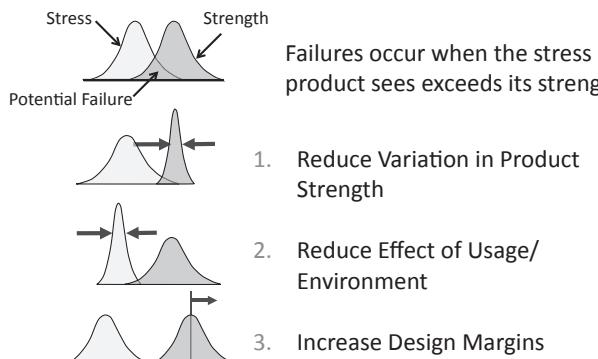
**Example:** A metal bracket can break because of fatigue cracking due to corrosion. The FMEA team recommends changing the bracket material to a composite that does not experience corrosion. The cause “fatigue cracking due to corrosion” is no longer possible.

**Example:** During the conversion from leaded to unleaded fuel, there was a concern about consumers putting leaded fuel into a vehicle designed for unleaded fuel. This concern was resolved by making the gas tank opening too small for the leaded gas nozzle.

**Design for Robustness and Other Design Optimization Techniques** The objective of *Robust Design* is to optimize design parameters to make the product design less sensitive to the effects of variation that is present in the system’s input variables and parameters. *Taguchi methods* are statistical methods using analysis of variance with the objective of identifying design factors responsible for degradation of performance. *Design of Experiments* is a technique for studying the factors that may affect a product or process in order to identify significant factors and optimize designs. All of these techniques are powerful strategies to improve the quality and reliability of products and processes. In FMEA language, Robust Design and other design optimization techniques improve performance and can significantly reduce the frequency of the cause of failure.

**Example:** A sport utility vehicle (SUV) has a removable rear seat feature. Early prototypes show high efforts are required to unlatch the release mechanism due to variation in the linkage system. A Robust Design project modeled the linkage system and optimized the linkage dimensions and tolerances to minimize the efforts required to unlatch. The unlatching problem was resolved.

**Example:** A plastic emblem is attached to the side of an appliance using an adhesive process during manufacturing. Some of the emblems were falling off after customer delivery. A Design of Experiments project was done to identify the primary control factors (adhesive composition, temperature, time, etc.) to ensure the emblem remained attached to the appliance throughout the customer usage period. The emblem falling off problem was resolved.



**FIGURE 7.2** Three stress–strength strategies to reduce failures.

**Reduce Stress–Strength Interference** When product stress exceeds product strength (a condition called *stress–strength interference*), failures occur. There is *variation* in both the strength of a product and the stress that a product experiences during customer usage. Reducing variation in product strength, reducing variation in stress (how a product is used and the environment it experiences), and increasing the design margin between stress and strength will all reduce the stress–strength interference and the frequency of failure. In FMEA language, these strategies reduce the frequency of the cause of the failure mode. See the “Factor of Safety” section directly below for more information on increasing design margins as an FMEA action strategy.

Figure 7.2 shows three strategies to reduce failures that relate to product stress and strength.

**Example:** A plastic door handle on a microwave appliance has been breaking during use by customers. The following are three stress–strength strategies to address this problem.

*Reduce the Variation in Strength of the Plastic Door Handle.* The FMEA team recommends controlling the door handle cross section to tight tolerance. They also recommend controlling the material composition. The result is less variation in the strength of the handle and fewer failures.

*Reduce the Variation in the Stresses that the Plastic Handle Sees in Operation.* The FMEA team recommends a physical stop limit on the handle travel so that the handle experiences less force when operated. The result is less stress on the handle and fewer failures.

*Increase the Design Margin between Stress and Strength.* The FMEA team recommends a new composite-type plastic that has a much higher nominal strength for the same geometry. The result is the handle strength increases well beyond the stress that the handle sees in operation and fewer failures.

**Use Physics-of-Failure Modeling of Failure Mechanisms** Higher risk failure mechanisms can be analytically modeled to reduce failures and obtain an accurate

advanced warning of impending failures. Chapter 15, Section 15.5, covers a type of FMEA called Failure Mode, Mechanisms, and Effects Analysis that prioritizes failure mechanisms for physics-of-failure modeling.

**Example:** Electrical interconnects sometimes fail due to temperature cycling or random vibration, with an underlying failure mechanism of fatigue. This mechanism can be modeled to reduce the likelihood of interconnect-fatigue failures or predict when they will occur.

**Use a Factor-of-Safety** One of the most effective action strategies to prevent failures is to design in a factor-of-safety. For structural applications, this is the ratio of the maximum stress that a structural part or other piece of material can withstand to the maximum stress it is anticipated to experience in the use for which it is designed. Essentially, how much stronger the system is than it usually needs to be for an intended load. The greater the factor-of-safety, the lower the likelihood of structural failure. In FMEA language, increasing the factor-of-safety reduces the frequency of the cause of the failure mode.

**Historical example:** Designed and built in the 1870s, the Brooklyn Bridge was widely acclaimed to be an engineering marvel. The suspension bridge structure used four large wire ropes, each rope containing 5434 wires, each wire more than 3500 miles long. The span of the suspension bridge was 50% longer than any previous suspension bridge and the application of steel cables in suspension bridges had never been tried previously. “The cables had been designed to have a margin of safety of six, that is, they were six times as strong as they had to be.”<sup>[1]</sup> This factor of safety proved to be more than adequate to address manufacturing and supplier variables.

Many companies use safety factor guidelines, ranging from four or higher, to as little as 1.1. Typically, the higher the severity risk, the higher the factor-of-safety, as modified by weight, cost, and other factors.

A similar approach, often applied to electrical parts, is called *derating*:

Derating is a technique usually employed in electrical power and electronic devices, wherein devices are operated at less than their rated maximum power dissipation, taking into account the case/body temperature, the ambient temperature and the type of cooling mechanism used. Derating increases the margin of safety between part design limits and applied stresses, thereby providing extra protection for the part. By applying derating in an electrical or electronic component, its degradation rate is reduced. The reliability and life expectancy are improved.<sup>[2]</sup>

**Change the Design to Reduce the Likelihood of Occurrence of the Cause**  
The FMEA team can recommend changes to the design of the product or the process in order to reduce the likelihood of occurrence of the cause.

**Example:** A computer company uses a motherboard capacitor that has a high frequency of leaking due to overheating. The FMEA team recommends a different capacitor that is less likely to leak due to overheating.

**Example:** A medical device company has a line of diagnostic equipment. A robot system moves samples from one location to the next and has a problem with intermittent sticking. The FMEA team recommends a different lubricant for the robot arm, which reduces the frequency of the sticking problem.

**Change the Way the Product or Process Interacts with the Environment**

The FMEA team can recommend changes in the way the product or process interacts with the environment, which can reduce the frequency of the cause of failure.

**Example:** A line of amplifiers has increasing problems when the user ambient temperature exceeds 90°F. The FMEA team recommends a fan that activates before the temperature reaches 90°.

**Change the Way the User Interacts with the Product or Process** The FMEA team can recommend changes to the way the user or operator interacts with the product or process, which can reduce the frequency of the cause of failure.

**Example:** A company that designs and manufactures treadmills is concerned about potential injury to users if they fall off the treadmill and get tangled up in the equipment. The FMEA team recommends a device that senses if the user is no longer on the treadmill so that the equipment automatically shuts down.

**Error Proof a Product Design** It is possible to change the product design so that errors in manufacturing or assembly processing are reduced or eliminated.

**Example:** A wiring connector is designed so that it can only be assembled in the correct orientation.

**Example:** A fuel pump shaft has a key that makes it impossible to install in wrong position.

**Error Proof the Manufacturing Process** The manufacturing or assembly process can be changed so that processing errors are reduced or eliminated. In FMEA language, error proofing a product design or a manufacturing process reduces the frequency of the cause of the failure mode.

**Example:** Wires that are assembled in a wiring harness are color coded to ensure the correct wires are assembled.

**Example:** A manual adhesive operation is replaced by a robotic system to avoid human error in the adhesive application.

**Error Proof the Product Use** The operation of products or equipment can be designed so that unsafe operation is not possible.

**Example:** An automatic transmission shifter must be in “park” in order to start the vehicle engine or, in the case of a manual transmission, the clutch pedal must be depressed.

**Example:** In order to activate a metal stamping machine, two buttons (separated by at least 3 feet) must be simultaneously pushed.

**Example:** A kerosene space heater is designed to immediately turn off if it falls over.

**Use Statistical Process Control to Monitor and Control Manufacturing Processes** Statistical Process Control (SPC) is the application of statistical methods to measure and analyze the variation in manufacturing (or other) processes, with the objective of getting and keeping processes under control and producing conforming products. SPC will not improve a poorly designed product's reliability, but

can be used to maintain the consistency of how the product is made. Properly used, SPC can significantly reduce defects in the manufacturing process.

**Example:** A magnetic film gauge is used to nondestructively measure the thickness of a nonmagnetic coating of a manufactured product. The output of the gauge is plotted with SPC software and the operator is alerted before the process goes out of control, so that action can be taken to avoid defects.

**Example:** A manufacturing process using a cylinder boring machine requires the inside diameter of the cylinder to be held to tight tolerances. SPC is used to analyze the variation in cylinder diameter measurements in order to keep the boring process under control.

### 7.3.3 Action Strategies to Reduce *Detection Risk*

As noted above, adding an *early warning* device can increase the likelihood of detection of a failure mode/cause during in-service usage.

**Utilize Existing Detection-Type Controls to Increase the Likelihood of Detection of the Cause** The FMEA team may decide to utilize detection-type controls that already exist but were not currently used to detect the failure mode or cause being analyzed. If selected properly, the detection-type controls can increase the likelihood of detection of the cause of failure.

**Example:** A lawn mower manufacturing company has a potential problem with fuel leakage at the fuel connector hose that is not well detected by current durability testing. An existing fuel integrity test can be added to the test regimen, which has a higher likelihood of detecting fuel leaks.

**Modify Existing Detection-Type Controls to Increase the Likelihood of Detection of the Cause** The FMEA team can recommend changes to the existing detection-type controls to increase the likelihood of detection of the cause.

**Example:** A manufacturer of irrigation valves experiences a field problem of valve sticking due to foreign material. Yet, the valve meets all current testing requirements. The FMEA team recommends changing the valve test regimen to include foreign material intrusion.

**Develop New Detection-Type Controls to Increase the Likelihood of Detection of the Cause** The FMEA team may decide to develop new detection-type controls that do not currently exist. In FMEA language, by adding the newly developed detection-type controls, the likelihood of detecting the cause of the failure can be increased.

**Example:** A metal parts manufacturing plant has a problem with corrosion due to inadequate thickness of galvanizing coating. The FMEA team recommends a new inline control that measures the precise thickness of the coating surface to ensure adequacy.

**Use Improved Test Strategies, Such as Degradation Testing, Accelerated Testing, and/or Test-To-Failure** The risk due to inadequate design controls can be reduced by changing the type of test. Traditional pass-fail testing introduces risk

by not detecting or understanding the cause of failure. Where possible, it is important to test to failure and use degradation testing to understand the progression of failure. Strategies such as Highly Accelerated Life Testing (HALT), Accelerated Life Testing (ALT), and degradation testing can markedly improve detection risk.

**Example:** An aircraft navigation controller undergoes pass-fail testing, which provides little failure information or understanding of actual design margins. ALT along with test-to-failure regimens can greatly speed up the test results and provide root-cause failure data to improve controller design.

The above action strategies are only a few of the wealth of quality and reliability strategies that exist. FMEA teams should take the time to consider and recommend the right actions that can reduce risk due to high severity, occurrence, or detection.

**Thought-Starter Questions** When identifying recommended actions for System or Design FMEAs, the team can be asked questions such as:

- “What can be done to reduce severity to a safe level by modifying the design?”
- “Which of the ‘Action Strategies to Reduce *Severity* Risk’ should be recommended?”
- “How can the current design be made safer?”
- “If the product fails, how can the user be protected from potential harm or injury?”
- “What can be done to reduce likelihood of occurrence to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Occurrence* Risk’ should be recommended?”
- “How can the current design be made more robust?”
- “What can be done to reduce likelihood of detection to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Detection* Risk’ should be recommended?”
- “What tests or evaluation techniques need to be added or modified to improve detection capability?”
- “Are there any other actions that are needed to reduce risk to an acceptable level?”
- “If the recommended actions are implemented, will that be sufficient to address all high severity and high RPN risk?”

When identifying recommended actions for Process FMEAs, the team can be asked questions such as:

- “What can be done to reduce severity to a safe level by modifying the process?”
- “Which of the ‘Action Strategies to Reduce *Severity* Risk’ should be recommended?”
- “How can the current process be made safer?”
- “If the manufacturing or assembly operation fails, how can the operator be protected from potential harm or injury?”

- “What can be done to reduce likelihood of occurrence to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Occurrence* Risk’ should be recommended?”
- “How can the current operation be made more successful?”
- “What can be done to reduce likelihood of detection to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Detection* Risk’ should be recommended?”
- “What process controls need to be added or modified to improve detection capability?”
- “Are there any other actions that are needed to reduce risk to an acceptable level?”
- “If the recommended actions are implemented, will that be sufficient to address all high severity and high RPN risk?”

In summary, essential to effective FMEAs is to generate effective actions that reduce risk. In most cases, particularly for high severity or high RPN issues, more than one recommended action is needed. As covered above, the most effective actions mitigate the effect to a lower severity through design changes and improve the design to make it more robust.

#### **7.3.4 Common Action Strategy Mistakes to Avoid**

Knowing how to identify effective action strategies to reduce risk is important, but it is also essential to avoid the most common mistakes. The succeeding sections provide some of the more common mistakes that FMEA practitioners make when recommending actions to reduce risk.

***Using a Single Action to Address High Risk When Multiple Actions Are Needed*** In most cases, when addressing high risk, the FMEA team will need to identify more than one action strategy. The mistake is to rely on a single recommended action when trying to address high risk. This is applicable when the team is targeting one category of risk, such as frequency of occurrence; and it is certainly applicable when addressing multiple levels of risk (severity, occurrence, and/or detection.) The key is to use multiple effective actions when addressing high risk.

***“Hobby Horsing” One Particular Action Strategy*** Some practitioners or teams have a favorite strategy (called a “hobby horse”) that is recommended more often than appropriate. Even if this favorite strategy is very effective when applied to the right set of circumstances, it is not useful to apply it broadly as a solution when selection criteria are not met. Avoid “hobby horsing” a single action strategy.

***Focusing on Only One Type of Risk*** Some teams tend to focus on only one of the three types of risk, such as detection risk. They end up recommending many changes to testing regimens, for example, but miss the opportunity to reduce severity or occurrence risk, and make designs more robust. FMEA teams should review the

actions being recommended and ensure they are reducing all three types of risk, as needed.

**Actions That Are Unspecific** FMEA teams can develop the right action strategy during team meetings and yet document the recommended action verbiage too generally. They may have the right concept in mind, yet fail to identify the specific actions to implement the concept. Refer to Section 7.5 for guidelines on writing effective actions.

**Tampering** Variation is present in all natural systems. The challenge is to differentiate between variations due to “common causes” versus “special causes.” The differentiation requires knowledge of SPCs and control charts, which is why it is essential to have a quality or reliability expert as part of the FMEA team. Dr. W. Edwards Deming cautioned against tampering with systems that are “in control,” which increases variation.

The field of quality control teaches the correct use of control charts in achieving stable and capable manufacturing processes. Process FMEA teams should familiarize themselves with quality control resources and ensure they recommend effective strategies to improve manufacturing process and avoid tampering.

**Using the FMEA Recommended Actions to Execute the Current Design Verification Plan** A Design Verification Plan (DVP) is a separate method from FMEA. The relationship between the two analyses is covered in Chapter 6, Section 6.3.1.

Some companies want to use the FMEA recommended actions tracking mechanism to implement design controls or tests in the DVP.

As stated in Chapter 3, Section 3.2:

*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.

A secondary purpose of an FMEA is to improve test and verification plans (in the case of System or Design FMEAs) or to improve Process Control Plans (in the case of Process FMEAs).

DVPs should have rigorous execution mechanisms in place to ensure all of the tests and evaluations are properly executed on time. FMEA recommended actions should be used to add or modify specific tests in the DVP in order to address detection-type risk identified in the FMEA. It is a misuse of the FMEA recommended actions to track the execution of the corresponding DVP tests and evaluations, and amounts to double tracking, which is a waste of resources. The exception would be if the FMEA team is concerned about the efficacy of the DVP process and consciously decides to use the mechanism of FMEA recommended action tracking to also track the execution of a highly critical test. In this exception, management should be apprised of the inadequacy of the DVP process so that remedial action can be taken.

## 7.4 EXAMPLES OF RECOMMENDED ACTIONS



### Bicycle Example

Figure 7.3 is an excerpt from the all-terrain System FMEA providing examples of recommended actions.

Figure 7.4 is an excerpt from the all-terrain Hand Brake Design FMEA providing examples of recommended actions.

Figure 7.5 is an excerpt from the all-terrain Brake Cable Design FMEA providing examples of recommended actions.

Figure 7.6 is an excerpt from the all-terrain Process FMEA, providing examples of recommended actions for the operation “Orient and place wheel spokes in wheel assembly fixture.”

## 7.5 FMEA EXECUTION ENABLERS

There is only one way to get anybody to do anything. And that is by making the other person want to do it.

—Dale Carnegie

Once all of the FMEA recommended actions are identified, the FMEA team should be confident that they have identified all of the necessary tasks and actions to reduce risk to an acceptable level, that is, design-related risk in a System or Design FMEA or manufacturing-related risk in a Process FMEA. The importance of timely execution of these recommended actions cannot be overstressed. There is little benefit to the FMEA without full execution of the recommended actions.

The following are key elements for ensuring timely execution of FMEA recommended actions:

1. *Recommended Actions Are Well Defined.* Each recommended action should be thoroughly defined so that the end result is clear and so that someone who is not involved in the FMEA can understand what is being recommended.
2. *Recommended Actions Include Specific Information:*
  - *Responsible Person* (the primary person who is responsible for seeing to the execution of the action item)
  - *Action Category* (the type of action, such as testing, design, etc., so the actions can be followed up by the associated department)
  - *Target Completion Date* (the date the action must be completed)
  - *Review and Approved by . . .* (If a review and approval process for each FMEA recommended action is implemented, the name of the company manager or other representative should be included.)

The *responsible person* for executing the action item should be the person who has the closest responsibility for the issue being addressed, such as the Design Engineer for design issues, the Process Engineer for process issues, the System Engineer for system Engineers, and the Test Engineer for test issues.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) of Failure	SEV	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	RPN	Recommended Actions
<b>Bicycle System:</b> The bicycle must provide safe and reliable transportation, including safe stopping distances and safe operation under all customer usage conditions as defined in the All-Terrain technical specification.	Does not stop in required distance	Potential accident or injury to bicycle operator without warning.	10 Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	5	All-Terrain braking system design guide (document #123)	All-Terrain bicycle stopping test #ABC	5	250	Perform Design FMEA on All-Terrain Hand Brake subsystem	TRUNCATED
						Develop analytical model to simulate the All-Terrain braking system and use the model to optimize the hand brake design				
						Improve All-Terrain bicycle stopping test by including all weather conditions.				
						Add rigorous tire durability testing to tire test regimen				
							Perform design sensitivity analysis on brake adjustment system to improve the adjustment feature under varying geometry and usage stresses	9	270	Offer free safety clinics to all bicycle users, covering proper brake adjustment and other safety features
							Require all bicycle sellers to instruct customers on how to adjust brakes before delivery to customer			TRUNCATED

**FIGURE 7.3** Example of recommended actions for all-terrain System FMEA.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	Occ	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	RPN	Recommended Actions
<b>Hand Brake S/S:</b> Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	10 Bicycle wheel does not slow down when the brake lever is pulled, potentially resulting in accident.	4 Cable Binds due to inadequate lubrication or poor routing	4 Hand Brake Design Guide #123	Bicycle system durability test #789	2	80 Redesign hand brake Cable Routing to reduce friction and make system insensitive to lubrication degradation			
				3 External foreign material reduces friction		3	60 Modify bicycle durability testing to include periodic brake cable checks for binding			
				6 Cable breaks	Cable material selection based on ANSI #ABC.	4	240 Require cable DFMEA/PFMEA from cable supplier approved by All-Terrain FMEA team.			
				1 Brake lever breaks	Hand Brake Design Guide #123	1	10 Based on results of Cable DFMEA, develop cable strength test and modify cable design to improve strength			
				2 Selected brake pad material does not apply required friction to wheel		2	40 TRUNCATED			

**FIGURE 7.4** Example of recommended actions for all-terrain Hand Brake Design FMEA.

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) of Failure	SEV	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	RPN	Recommended Actions
<b>Brake Cable:</b> Provides adjustable and calibrated movement between the brake lever and brake caliper, under specified conditions of use and operating environment.	Cable breaks	Operator is unable to close brake calipers, wheel does not slow down, possibly resulting in accident.	Corrosion of cable wiring due to wrong material selected	10	5	Cable material selection based on ANSI Standard #ABC.	Cable strength test #456	4	200	Perform a thorough review of cable material alternatives, including corrosion resistance.  Conduct Design of Experiments to optimize cable material and geometry for maximum corrosion resistance.
			Fatigue cracks in cable wing due to inadequate cable thickness	2	2	Finite Element Analysis of all new cable material	Laboratory analysis for fatigue cracks at regular intervals per test regimen #456	2	40	
			Cable binds	7	3	Bend or kink in cable due to mis- routing	Design Review at prototype build	2	42	Select new cable lubrication for improved performance under all operating conditions.  Add brake cable lube check at regular intervals during bicycle durability testing.

**FIGURE 7.5** Example of recommended actions for all-terrain Brake Cable Design FMEA.

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of failure	Current Process Controls (Prevention)	Current Process Controls (Detection)	DFT	RPN	Recommended Action(s)
TRUNCATED									
Orient and place 36 wheel spokes properly in wheel assembly fixture	Too few spokes	<b>Process Effect:</b> wheel not aligned, requiring rework out of station (5) <b>Product Effect:</b> wheel wobble and increasing stress during maneuvers, with potential for wheel collapse and rider injury, with warning (9)	9	Lack of organized wheel spoke kit	3	Wheel spoke installation work instructions	Visual check of wheel assembly by operator	5	Kit the spokes into quantities of 36
Wheel spokes not in correct orientation		<b>Process Effect:</b> wheel not aligned, requiring rework out of station (5) <b>Product Effect:</b> wheel wobble with potential for loss of handling during maneuvering and rider injury, with warning (9)	9	Fixture is not error proofed to prevent incorrect orientation	6	Wheel spoke installation work instructions	In-station test for wheel alignment/truing	7	Develop and implement error-proofed wheel installation fixture to prevent incorrect orientation
TRUNCATED									

**FIGURE 7.6** Example of recommended actions from all-terrain Process FMEA (wheel spoke installation).

It is incorrect to assign the FMEA facilitator automatically as the person responsible for action execution.

If the FMEA recommended actions are defined well as to responsibilities for execution, follow up and implementation are made much easier. Without this definition, FMEAs can languish and go unexecuted, without reduction in risk.

3. *Recommended Actions Are Energetically Followed Up.* A process needs to be in place to follow up with the responsible person and assess status and inform management if there are execution problems. Status is reported back to the FMEA team who enters it into the FMEA database. When completed, Actions Taken are recorded in the FMEA worksheet and the team must ensure those actions reduce risk to an acceptable level.

Once FMEA Actions are assigned properly, the people who are charged with seeing to the execution of the Action Items should carry out the assignment. However, as anyone who has worked in business or government knows, there can be myriad distractions and roadblocks to implementation. Priorities change, roles and responsibilities change, and people get reassigned or promoted. The FMEA team needs to stay engaged and connected to the process of execution to maintain the focus and ensure the actions are fully implemented.

4. *Execution Problems Are Quickly Identified and Resolved.* It is important for the responsible person to communicate problems in execution quickly to the FMEA team as well as to management. The FMEA team may be able to resolve these by redefining the action or reassigning the action item. If not, the FMEA team must elevate execution problems quickly to management.

Companies have differing dynamics when it comes to how problems are communicated. Some managers do not like to hear bad news. It is important that the “messenger” not be deterred when it comes to issues with implementation. FMEA teams are encouraged to be assertive, not passive, when it comes to FMEA execution. Nothing is more important to any company than achieving products that are safe and reliable.

5. *Management Reviews All High Severity and High RPN Issues.* It is essential that management regularly review the status of FMEA action items for both high severities and high RPNs. These reviews may be part of other problem review meetings or ongoing program review meetings. The *responsible person* should present the status and raise any issues with execution. Management provides approval and support for the FMEA corrective actions, as well as positive steps to resolve execution issues. Feedback from management goes back to FMEA teams for review and incorporation.

In Chapter 11, Section 11.3.3, the nature and content of management reviews are discussed further. This is a key step to ensure the high-risk issues from FMEAs get the attention they require and that management is fully engaged in supporting the FMEA from beginning to end.

6. *The FMEA Team Remains Actively Involved until All FMEA Recommended Actions Have Been Executed.* The FMEA team should meet regularly, or on an ad hoc basis, to review the status of all FMEA recommended actions. These postanalysis meetings have the purpose of documenting actions taken, ensuring proper execution, recommending “workarounds” if issues with execution arise, bringing execution problems to the attention of management, and ensuring risk is reduced to an acceptable level.

Too often omitted, this follow-up activity by the FMEA team is critical in successful application of FMEA. In many companies, the FMEA team ceases to meet and is dissolved once the recommended actions are developed. The manner in which the team stays engaged can vary and depends on the roles and responsibilities of the FMEA team members. The important thing is for the team to stay vigilant and active all the way through full implementation of the actions, particularly on the high-risk issues.

For difficult issues, do not be afraid to use *conditional* tasks, such as investigations or studies, followed by execution tasks based on the results of the investigations or studies.

## 7.6 THE ESSENCE OF EXECUTION

The following is an excerpt from an article entitled “Promise-Based Management: The Essence of Execution”<sup>[3]</sup>:

Critical initiatives stall for a variety of reasons—employee disengagement, a lack of coordination between functions, complex organizational structures that obscure accountability, and so on. To overcome such obstacles, managers must fundamentally rethink how work gets done. Most of the challenges stem from broken or poorly crafted commitments. That’s because every company is, at its heart, a dynamic network of promises made between employees and colleagues, customers, outsourcing partners, or other stakeholders. Executives can overcome many problems in the short term and foster productive, reliable workforces for the long term by practicing what the authors call “promise-based management,” which involves cultivating and coordinating commitments in a systematic way. Good promises share five qualities: They are public, active, voluntary, explicit, and mission based. To develop and execute an effective promise, the “provider” and the “customer” in the deal should go through three phases of conversation. The first, achieving a meeting of minds, entails exploring the fundamental questions of coordinated effort: What do you mean? Do you understand what I mean? What should I do? What will you do? Who else should we talk to? In the next phase, making it happen, the provider executes on the promise. In the final phase, closing the loop, the customer publicly declares that the provider has either delivered the goods or failed to do so. Leaders must weave and manage their webs of promises with great care—encouraging iterative conversation and making sure commitments are fulfilled reliably. If they do, they can enhance coordination and cooperation among colleagues, build the organizational agility required to seize new business opportunities, and tap employees’ entrepreneurial energies.

In this article, the authors clearly show the value of three phases of execution: achieving a meeting of the minds, making it happen, and closing the loop. All three are essential in accomplishing effective FMEA execution.

There is much more information on how to implement an effective FMEA process and that is the subject of Chapter 11.

## 7.7 DOCUMENTING ACTIONS TAKEN

The FMEA team documents the specific actions taken to implement the recommended actions. Care should be taken to ensure that the correct actions were implemented and that the risk is reduced to an acceptable level.

The great civil engineer, John Roebling, famous for his wire rope suspension bridge designs including the Brooklyn Bridge, said to his employees, “If one plan won’t do, then another must.”

If the risk is not sufficiently reduced, the FMEA team will need to generate new and more effective recommended actions. FMEA teams often miss this step.

## 7.8 ENSURING RISK IS REDUCED TO AN ACCEPTABLE LEVEL

It ain’t over till it’s over.

—Yogi Berra

Once the FMEA recommended actions are implemented and the actions taken documented in the FMEA worksheet, the FMEA team must reassess each of the risk rankings for severity, occurrence, and detection. This risk reassessment is very important because it shows how well the risk associated with each failure mode and associated cause is reduced as a result of the specific actions from the FMEA. The FMEA team should review the revised severities and RPNS to be sure they are acceptable. The essence of this step is to ensure that risk is reduced to an acceptable level. The FMEA team must inform management, and take positive action to remedy, if unacceptable risk is determined.

## 7.9 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

### Problem 7.1

Figure 7.7 is an excerpt from the Brake Cable Design FMEA, with the recommended actions omitted. Study the FMEA, including severities and RPNS, and prioritize issues for corrective action. Use the Causes numbers (1, 2, 3, 4) to identify the priority sequence.

### Problem 7.2

Which of the following is important input to prioritization of corrective actions? (Select all that apply.)

1. All high RPN issues, regardless of whether severity is high or low
2. All high severity issues, regardless of whether RPN is high or low
3. All low severity issues
4. All low RPN issues

### Problem 7.3

Which of the following are action strategies to reduce the severity risk? (Select all that apply.)

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	occ	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	RPN	Recommended Actions
<b>Brake Cable:</b> Provides adjustable and calibrated movement between the brake lever and brake caliper, under specified conditions of use and operating environment.	Cable breaks	Operator is unable to close brake calipers, wheel does not slow down, possibly resulting in accident.	10	1. Corrosion of cable wiring due to wrong material selected  2. Fatigue cracks in cable wiring due to inadequate cable thickness	5	Cable material selection based on ANSI Standard #ABC.	Cable strength test #456	4	200	What priority?
	Cable binds	Increased friction between cable and sheath, resulting in operator having to use greater effort to close brake calipers.	7	3. Bend or kink in cable due to mis- routing  4. Inadequate or wrong lubrication between cable and sheath	3		Laboratory analysis for fatigue cracks at regular intervals per test regimen #456	2	40	What priority?
							Design Review at prototype build	2	42	What priority?

**FIGURE 7.7** What is the priority sequence for addressing issues in this FMEA excerpt?

1. Make the design fault tolerant.
2. Introduce redundancy to the design.
3. Reduce stress–strength interference.
4. Increase the design margin.

### Problem 7.4

Which of the following are action strategies to reduce the occurrence risk? (Select all that apply.)

1. Make the design fault tolerant.
2. Introduce redundancy to the design.
3. Reduce stress–strength interference.
4. Increase the design margin.

### Problem 7.5

Which of the following are characteristics of well-written FMEA recommended actions? (Select all that apply.)

1. The name of the person on the FMEA team who recommended the action.
2. The name of the person who is responsible for execution of the recommended action.
3. A brief description (no longer than three or four words in length) of what action is to be done.
4. The date the recommended action was first established.
5. The date the recommended action needs to be completed.

### Problem 7.6

Which of the following are true statements about management's role in ensuring the execution of FMEA recommended actions? (Select all that apply.)

1. Management needs to stay directly involved in the approval, status, and execution of all FMEA recommended actions for high severity and high RPN issues.
2. The responsibility for execution of FMEA recommended actions should be delegated to the quality or reliability engineer.
3. The primary role of management in FMEA execution is to ensure financial budgets are maintained.
4. One of the primary roles of management in FMEAs is to help to eliminate roadblocks to execution of FMEA action items.

### Problem 7.7

An FMEA team is considering how to address a high severity and high occurrence issue. Some of the team members want to reduce the severity risk with action

strategies such as fail-safe and early warning. Other team members want to significantly reduce the occurrence risk using a robust design strategy. What is the best approach for this team?

### Problem 7.8

What are “single-point failures?” How can an FMEA team identify and address single-point failures?

### Problem 7.9

Refer to the following example of a Process FMEA recommended action from Chapter 3:

Process Step: Apply lubrication to O-ring using lubricant gun

Function: Lube O-ring with ABC lubricant, using XYZ specification

Failure Mode: Insufficient lubrication

Effect: Gas leak at fitting, with potential for operator injury; system inoperable in field use

Cause: Lubrication gun calibration incorrect due to calibration procedure not followed

Prevention Control: In-plant lube gun calibration procedures

Detection Control: End-of-line pressure testing

**Recommended Action:** Use modified lubrication-gun calibration procedure #12345 and update maintenance plan to calibrate every 1000 parts.

The effect of the example failure mode says, “Gas leak at fitting, with potential for operator injury; system inoperable in field use.” Since there is potential for operator injury, the severity would be a 10, on a scale of 1–10. Which of the three types of risk (severity, occurrence, and detection) does the example recommended action address? What might be a recommended action to reduce the severity of the effect? Is it possible to eliminate the failure mode due to the cause (Lubrication gun calibration incorrect)?

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2. Derating for electrical components. *Reliability HotWire: The eMagazine for the Reliability Professional*. ReliaSoft Corporation, October 2008. Issue 92. Available at <http://www.weibull.com/hotwire/issue92/relbasics92.htm>
3. Sull, Donald and Charles Spinosa, Promise-based management: The essence of execution. *Harvard Business Review*. April 1, 2007. Product # R0704E-HCB-ENG.

# *Chapter* 8

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## *Case Studies*

It is easier to produce ten volumes of philosophical writing than to put one principle into practice.

—Leo Nikolayevich Tolstoy

### **IN THIS CHAPTER**

This chapter presents a series of case studies on the application of Failure Mode and Effects Analysis (FMEA) in a variety of industries and applications. Five of the case studies are from actual industry applications. Two of the case studies draw from catastrophic events and are included for teaching analysis. The remaining three case studies are fictional examples that provide insight into FMEA application for teaching purposes. Each case study is further evaluated with end of chapter problems.

The purpose of these case studies is to share insight into how FMEA can be applied to a variety of industries and applications. Case studies are not perfect examples of the techniques and methods. They are meant to be glimpses into how others apply the techniques for instructional purposes. Students and industry practitioners are encouraged to read these case studies from the viewpoint of learning and improving, and to question how the information in the case study could be applied to one's own department or area of interest. The "End of Chapter Problems" section provides student exercises for each case study with teaching analysis in the Appendix.

## 8.1 CASE STUDY: SHOCK ABSORBER ASSEMBLY

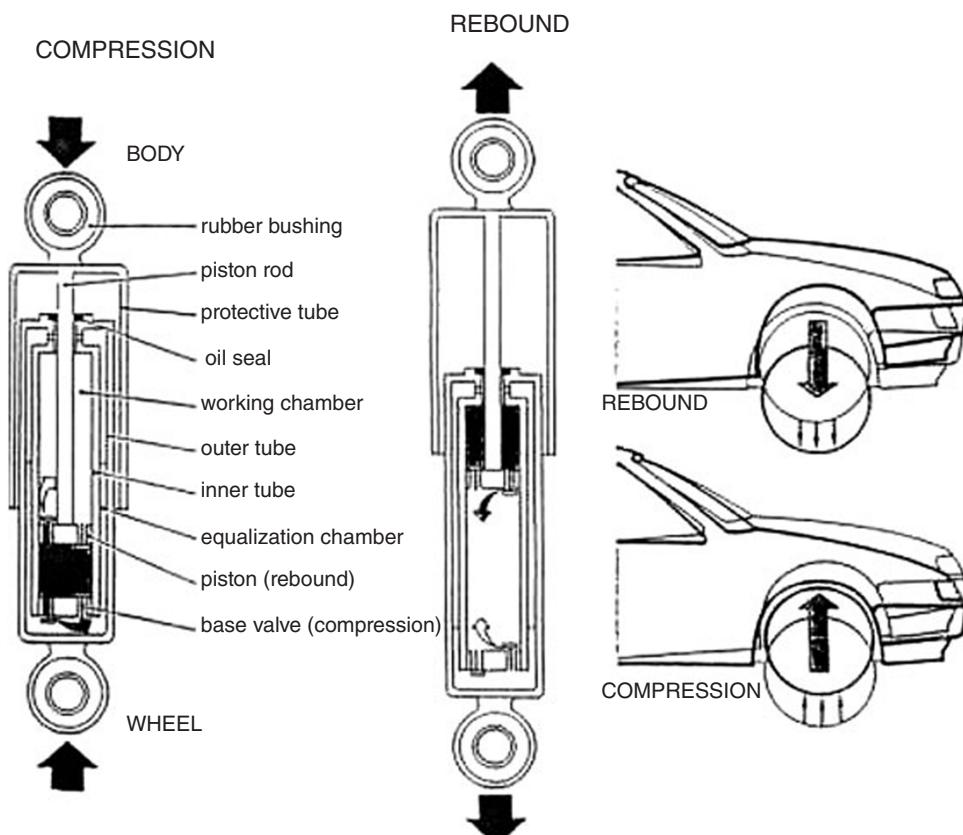
**Reference article:** Gulsen Aydin Keskin and Coskun Ozkan, "An alternative evaluation of FMEA: Fuzzy ART algorithm," *Quality and Reliability Engineering International*, 2009, Vol. 25, pp. 647–661.<sup>[1]</sup>

### Introduction

This case study is about introducing a new mathematical algorithm in an attempt to improve the application of Risk Priority Number (RPN) and using FMEA to evaluate the benefit of the algorithm. The highlighted FMEA is on a vehicle shock absorber. The case study is included here not to evaluate the algorithm, but rather to highlight the Process FMEA that was introduced.

### Use of FMEA

A Process FMEA was conducted on each of the process operations involved with shock absorber assembly. Figure 8.1 shows the structure of a common shock absorber and Figure 8.2 shows the Process FMEA for the vehicle shock absorber.<sup>[1]</sup>



**FIGURE 8.1** The structure of a common shock absorber and its direction of motion.

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Part name	Process function	Potential failure mode	Potential causes of failure	Current controls	Recommended actions and status			Actions taken	S	O	D	RPN	Possible activity		
					S	O	D								
Subassembly group	Cleaning subassembly group with air brush	Burr on metal	Burrs remaining at subassembly group damaged the shock absorber by moving into the parts of the valve	Insufficient air brush system	9	8	7	504	Changing the brushes	Brushes are changed	9	3	7	189 Method and product development	
Pressure pipe	Pressure pipe calibration	Scratching interior surface of the pressure pipe	Performance changes in time between ball and pressure tube because of unsuitable environment conditions	Penetrating foreign substance between ball and pressure tube	None	5	6	180	Preventing entrance of burr spreading from pah kirma mill next to gauge mill to oily environment where gauge is made	Placing a disk to provide safety between calibration bench and chamber bench	5	4	6	120 Management	
Suction valve	Suction valve to shaft assembly	Suction valve to shaft assembly is skipped	Performance of shock absorber changes	Operator fault	Performance test	5	5	125	Job enrichment by relocating the operators	Decided to relocate the operators by 2-hour periods	5	4	4	80 Method and product development	
Lubricant retainer seal	Lubricant retainer seal to shaft assembly	Reverse fixing lubricant retainer seal to shaft	Oil leakage	Operator fault	9	3	7	189	Job enrichment by relocating the operators	Decided to relocate the operators by 2-hour periods	9	2	7	126 Method and product development	
Pressure pipe	Filling grease in pressure pipe	Filling insufficient amount of grease in pressure pipe	Shock absorber may not work	Operator fault	8	2	5	80			8	2	5	80	
Serration disc	Serration disc assembly	Assembly of serration disc is skipped	Unstable performance	Operator fault	Performance test	2	8	3	48			2	8	3	48
Valve spring	Valve spring assembly	Valve spring assembly is skipped	Shock absorber does not work	Operator fault	10	1	1	10			10	1	1	10	
Ring-type shim	Ring-type shim assembly	Ring-type shim assembly is skipped	Unstable performance	Operator fault	Performance test	8	3	5	120	Job enrichment by relocating the operators	Decided to relocate the operators by 2-hour periods	8	1	5	40 Method and product development
Valve body	Valve body assembly	Valve body assembly is skipped	Shock absorber does not work	Operator fault	Valve assembly	8	1	5	40			8	1	5	40
Split ring	Split ring to shaft assembly	Split ring to shaft assembly is skipped	Performance failure	Operator fault	Performance test	7	3	5	105	Job enrichment by relocating the operators	Decided to relocate the operators by 2-hour periods	7	1	5	35 Method and product development
Torque ring-type shim	Torque ring-type shim assembly	Assembly of torque ring-type shim is skipped	Not a problem	Operator fault	Control instruction	4	4	3	48			4	4	3	48

**FIGURE 8.2** Excerpt from shock absorber process FMEA.

(S, severity; O, occurrence; D, detection. Reprinted with permission of John Wiley & Sons, Inc.)

## Conclusion

As mentioned in the introduction to this case study, the purpose of including it here is not to evaluate the efficacy of the algorithm. If readers are interested in the use of an algorithm as an alternative to RPN, the referenced paper can be located at the Wiley Online Library.

Evaluation of the Shock Absorber Process FMEA shows 13 failure modes/causes with initial RPN values greater than 100, yet six of these RPNs are still above 100 even after action taken. There are five failure modes/causes with severity 9 or 10 and initial RPN greater than 100, yet all five of them still have RPNs above 100 after action taken.

## Student Exercise

Students are encouraged to review this Process FMEA from an evaluation standpoint and consider what further action could have been taken by the Process FMEA team to further reduce risk. See Section 8.13, “End of Chapter Problems,” Problem 8.1, for the evaluation exercise.

## 8.2 CASE STUDY: STRUDEL PASTRY MANUFACTURING

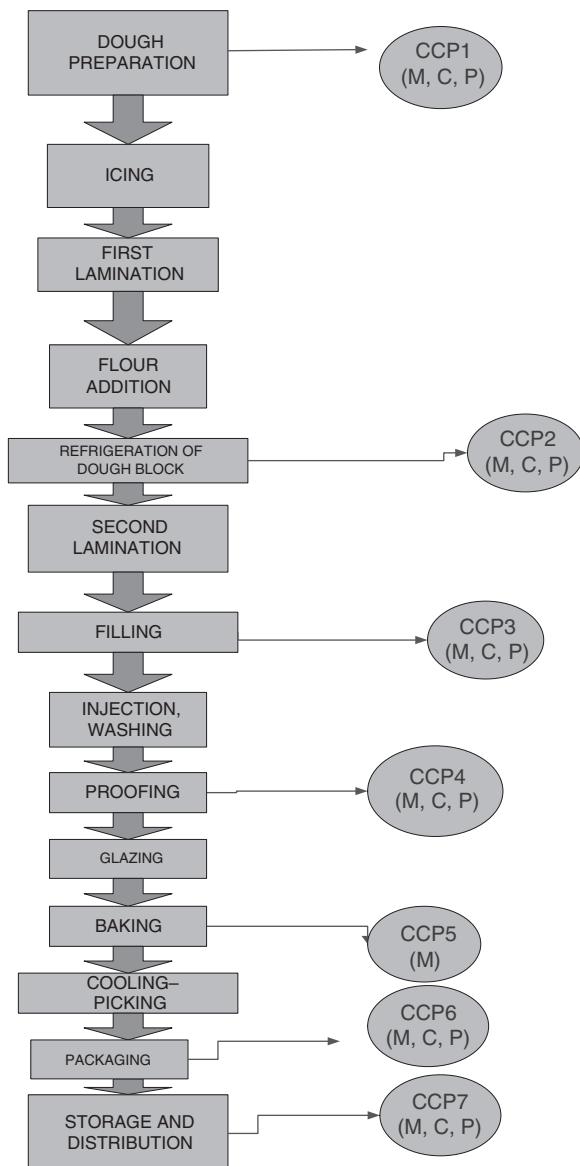
**Reference article:** Ioannis S. Arvanitoyannis and Theodoros H. Varzakas, “A conjoint study of quantitative and semi-quantitative assessment of failure in a strudel manufacturing plant by means of FMEA and HACCP, Cause and Effect and Pareto diagram,” *International Journal of Food Science and Technology*, 2007, Vol. 42, pp. 1156–1176.<sup>[2]</sup>

### Introduction

This case study is about improving the manufacturing of strudel. Strudel is a puff pastry product derived from wheat flour. The authors point out that “wheat flour could be the focal point of bacterial and fungal growth. Hence, meticulous handling should be carried out by personnel at all stages of production from harvesting, processing, maintenance, packaging until reaching the consumers.”<sup>[2]</sup>

### Use of FMEA and Hazard Analysis

In this case study, Hazard Analysis Critical Control Point (HACCP) “refers to physical, chemical, and microbiological hazards occurring in raw material/process over the food production.”<sup>[2]</sup> The conjoint study began with a Process Flow Diagram of the strudel processing steps, and Critical Control Points (CCPs) were identified. A *cause and effect diagram* (also known as Ishikawa, tree diagram, and fishbone diagram) was made for each CCP, identifying biological, chemical, and physical hazards for each step in the strudel processing. A formal Hazard Analysis, conducted on the strudel processing steps, identified and quantified the risk associated with the hazards, and corrective actions to reduce risk were determined. The results were then organized in an FMEA format and actions tracked to closure and risk

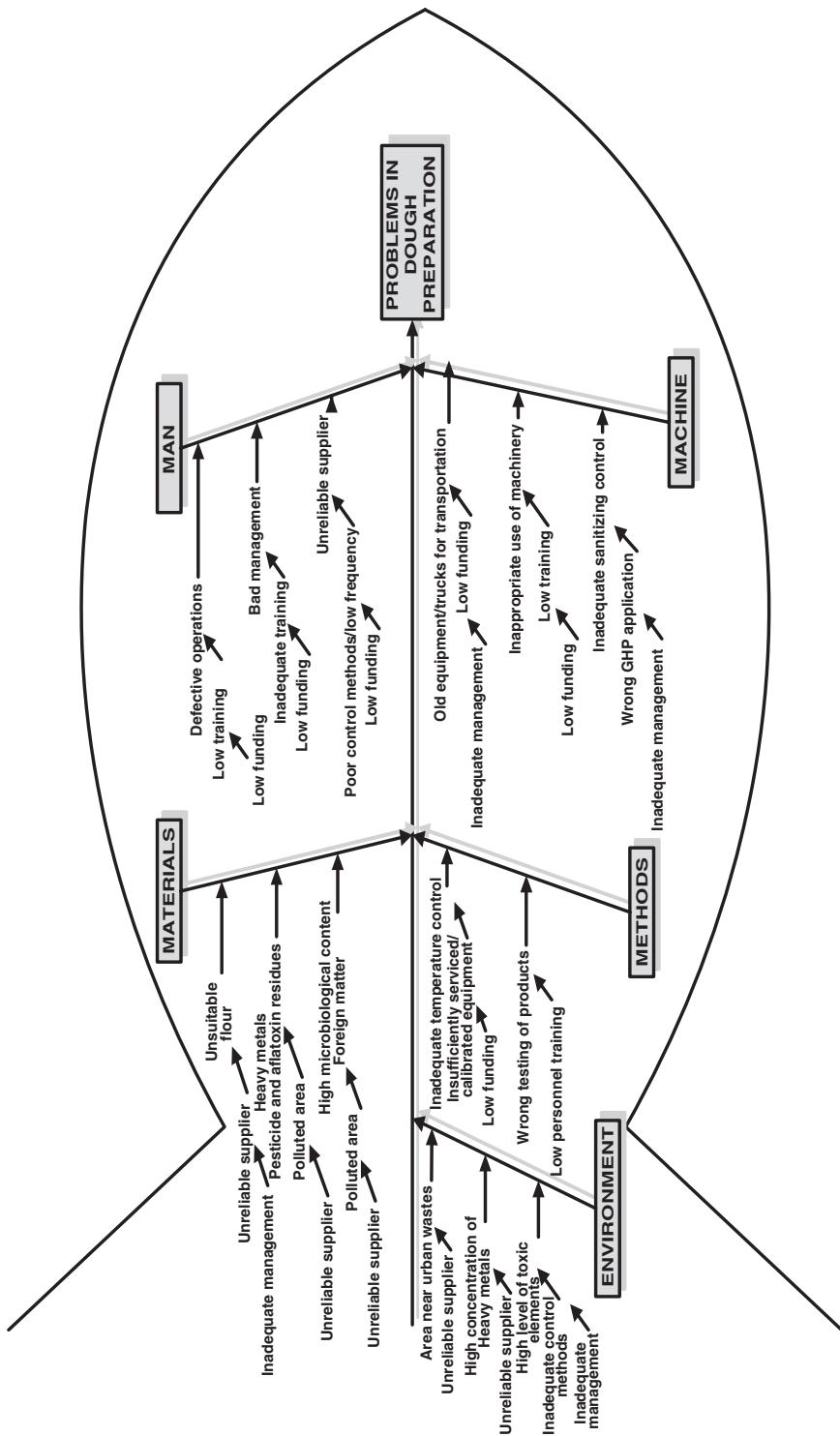


**FIGURE 8.3** Process Flow Diagram for strudel processing with Critical Control Points (CCP). (M, microbiological; C, chemical; P, physical. Reprinted with permission of John Wiley & Sons, Inc.)

reassessed to ensure proper risk reduction. Pareto diagrams were employed in an attempt to optimize the detection potential of FMEA.

Figure 8.3 shows the Process Flow Diagram for strudel processing. In this illustration, the CCPs are further described as M (microbiological), C (chemical), and/or P (physical).<sup>[2]</sup>

Figure 8.4 shows the Ishikawa diagram (also called fishbone diagram) for one of the CCPs, “Problems in dough preparation.”<sup>[2]</sup>



**FIGURE 8.4** Example of the use of Ishikawa diagram (fishbone diagram) for understanding critical control points (CCPs).  
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Figure 8.5 shows the process to determine CCPs, and the specific “yes” or “no” questions that are asked.<sup>[2]</sup>

Figure 8.6 shows the list of biological, chemical, and physical hazards plotted against each of the strudel processing steps.<sup>[2]</sup>

Figure 8.7 shows the use of FMEA to capture the hazards and the resulting risk assessments.<sup>[2]</sup>

## Conclusion

As the authors of this case study point out, HACCP and FMEA have a similar aim, which is to assure the safety and quality of the product. The authors believe one of the advantages of the cause and effect diagram is in visually presenting the factors that can cause the problem in a way that is easily understood. However, they point out that “it is not likely to identify and elaborate accurately all possible problems in strudel processing in a diagram.” In their opinion, the best solution is the combination of CCPs with the cause and effect diagram, along with a Hazard Analysis on the processing steps, and an FMEA to organize and assess risk and track actions to closure.

Packaging, storage and distribution, refrigeration, baking, and filling were the processes identified as the ones with the highest RPN (225, 225, 225, 180, and 180, respectively) and corrective actions were undertaken. Following the application of corrective actions, a second calculation of RPN values was carried out, leading to considerably lower values. Therefore, the authors conclude “the incorporation of FMEA analysis within the HACCP system of a strudel industry is considered both fruitful and imperative.”<sup>[2]</sup>

Refer to Chapter 15, Section 15.2, for description and procedure for Hazard Analysis.

## Student Exercise

Students are encouraged to analyze the results of this Hazard Analysis, FMEA, and risk assessment, and consider ways to improve the risk reduction. See Section 8.13, “End of Chapter Problems,” Problem 8.2, for the evaluation exercise.

### 8.3 CASE STUDY: MOTOROLA SOLUTIONS “PRESS-TO-TALK” FEATURE

**Reference presentation:** Shri Gupta, “Application of DFMEA and FTA in subscriber radio product engineering for reliability improvement,” Applied Reliability Symposium, 2010. <sup>[3]</sup>

#### Project Description

Motorola Solutions has a line of mobile two-way radios used in public safety. They are complex units with mechanical, electrical, and software components in them. Motorola introduces a new generation of radios with enhanced capabilities and new features every few years. The challenge is to prevent failures during development and

Procedure step	Q1 Do preventative control measures exist? (Yes/No)	Q2 Is the step specifically designed to eliminate or reduce the likely occurrence of hazard to an acceptable level? (Yes/No)		Q3 Could contamination with identified hazard(s) occur or could this increase to unacceptable levels? (Yes/No)	Q4 Will a subsequent step eliminate identified hazard(s) or reduce likely occurrence to acceptable levels? (Yes/No)	Is this step a critical control point? (Yes/No)
		Y	N			
Dough preparation	Y	N	Y	Y	CCP1 (M, C, P)	
Icing	Y	N	Y	Y		
First lamination	Y	N	Y	Y		
Flour addition	Y	N	N	—		
Refrigeration of dough block	Y	N	Y	—		
Second lamination	Y	N	Y	Y	CCP2 (M, C, P)	
Filling	Y	N	Y	Y	CCP3 (M, C, P)	
Injection	Y	N	Y	Y	CCP4 (M, C, P)	
Washing	Y	N	Y	Y	CCP5 (M)	
Proofing	Y	N	Y	Y	CP1 (M, P)	
Glazing	Y	N	Y	Y	CCP6 (M, C, P)	
Baking	Y	N	Y	Y	CP2 (C, P)	
Cooling tower	Y	N	Y	Y	CCP7 (M, C, P)	
Picking	Y	N	Y	Y		
Packaging	Y	N	Y	Y		
Metal detection	Y	N	Y	Y		
Palletizing	Y	N	Y	Y		
Storage and Distribution	Y	N	Y	Y		

**FIGURE 8.5** Process for identifying Critical Control Points in strudel processing.  
(CCP, Critical Control Point; CP, control point; M, microbiological; C, chemical; P, physical. Reprinted with permission of John Wiley & Sons, Inc.)

Procedure step	Biological hazards	Chemical hazards	Physical hazards
Dough preparation	<i>Clostridium botulinum, Listeria Monocytogenes, toxins, Salmonella sp., Staphylococcus aureus, Shigella spp., Shigella spp. Coliform, Parasites, GMO wheat, Bacillus cereus, Bacillus mesentericus, yeasts, and molds.</i> All these could be found in flour, yeast, water, pasteurized eggs, butter, sugar, fat, fillings, milk powders, whey powders	Heavy metals, pesticide and insecticide residues in flour, germ residues, aflatoxin residues in flour, cross contamination by preservatives	Foreign matter in flour (lice), foreign matter in water, sugar, salt, preservative
Icing	Microorganisms in water	Heavy metals and pesticide residues in water	Foreign matter in water
First lamination	Contamination	Lubricant leakage from motor	Foreign matter
Flour addition	As mentioned earlier	As mentioned earlier	As mentioned earlier
Refrigeration of dough block	Growth of microorganisms	Not common	Foreign matter
Second lamination	Contamination	Lubricant leakage from motor	Foreign matter
Filling	Microorganisms	Pesticide and aflatoxin residues	Unlikely
Injection	Growth of pathogens	Not common	Foreign matter
Washing	Growth of pathogens	Detergent residues	Foreign matter
Proofing	Growth of yeasts and molds due to inappropriate temperature, bad humidity conditions, or wrong proofing time	Not common	Foreign matter
Glazing	Growth of pathogens due to inappropriate temperature	Not common	Foreign matter
Baking	Growth of pathogens due to inappropriate temperature	Not common	Foreign matter
Cooling tower	Growth of pathogens due to inappropriate cooling	Unlikely	Foreign matter
Pickling	Unlikely	Unlikely	Unlikely
Packaging	Growth of pathogens due to temperature abuse or problematic packaging materials	Excessive alcohol addition	Foreign matter
Metal detection	Unlikely	Unlikely	Foreign matter
Palletizing	Unlikely	Unlikely	Foreign matter
Storage and distribution	Growth of pathogens and toxin production mainly due to temperature abuse	Not common	Foreign matter

**FIGURE 8.6** Hazard Identification in strudel processing.

(GMO, genetically modified organism. Reprinted with permission of John Wiley &amp; Sons, Inc.)

above all to prevent failures once the product is in the hands of the customers. In order to accomplish this objective, they flush out the maximum number of failure modes during development. Motorola uses both FMEA and Fault Tree Analysis (FTA) to help preempt failures early in the design cycle, as well as help in root cause analysis of major failures seen during the development life cycle of a product. They perform FMEAs on critical parameters identified early in program development. Failure events identified early in the design cycle can be prevented from occurring.

In order to narrow the focus of FMEA or FTA, the Motorola Solutions team uses a process they call Critical Parameter Management. First, they identify critical parameters for the mobile radio project, using criteria such as *new, unique, or difficult*. Next, they obtain input from subject-matter experts. Finally, they rank the parameters and choose the parameters that will benefit from FMEA or FTA.

Figure 8.8 is a graphic representation of a typical two-way radio, similar to the one in this case study. This case study will focus on the PTT (press-to-talk) feature.<sup>[3]</sup>

Figure 8.9 shows the Critical Parameter Management process used by Motorola Solutions to select the most important parameters for the radio project. Teams were set up for each of the Critical Parameters very early in the program to perform DFMEAs.<sup>[3]</sup>

Defective products										Estimated result after corrective actions			
Production step	Hazards	Causes	S	O	D	RPN	Corrective actions			S	O	D	RPN
Dough preparation	Pathogens, parasites, heavy metals, toxins	Unsuitable raw materials	9	4	5	180 <sup>a</sup>	Supplier must be reliable (archives confirming handling conditions)			9	2	2	36
Icing	Heavy metals, pesticide residues	Processing	5	3	4	60	Foreign matter control			—	—	—	—
First lamination	Foreign matter	Wrong handling by personnel	5	3	4	60	Foreign matter control			—	—	—	—
Flour addition	Pathogens, pesticide, and aflatoxin residues	Unsuitable flour	9	4	5	180 <sup>a</sup>	Check supplier			9	2	2	36
Refrigeration of dough block	Contamination from wrong temperature or time remaining at the fridge	Improper control of refrigerator	9	5	5	225 <sup>a</sup>	Check refrigerator			9	2	2	36
Second lamination	Contamination from foreign matter	Improper sanitation	6	2	3	36	Not required			—	—	—	—
Filling	Contamination from equipment	Improper sanitation	9	4	5	180 <sup>a</sup>	Proper sanitation			9	2	2	36
Injection	Humidity not recorded accurately	Humidity meter not working effectively	4	4	4	64	Not required			—	—	—	—
Washing		Inadequate functioning of temperature and time in the fryer	9	4	4	144 <sup>a</sup>	Adequate control of temperature and time			9	3	3	81
Proofing	Growth of pathogens due to inadequate time and temperature conditions	Improper sanitation	9	4	4	144 <sup>a</sup>	Proper sanitation			9	3	3	81
Glazing	Contamination from equipment	Improper sanitation	6	2	3	36	Not required			—	—	—	—
Baking	Contamination from wrong temperature	Improper oven functioning	9	4	5	180 <sup>a</sup>	Oven control			9	2	2	36
Cooling tower	Inappropriate cooling or foreign matter	Proper sanitation	5	3	4	60	Not required			—	—	—	—
Picking	Unlikely	—	—	—	—	—	Not required			—	—	—	—
Packaging	Growth of pathogens and fungi	Packaging temperature and packaging materials	9	5	5	225 <sup>a</sup>	Certified packaging materials			9	2	2	36
Storage	Growth of pathogens, toxin production, and fungi	Storage temperature	9	5	5	225 <sup>a</sup>	Extra control of storage temperature; storage place should be separated from the rest of the production line			9	2	2	36
Distribution	Growth of pathogens, toxin production, and fungi	Temperature abuse during distribution	9	4	4	144 <sup>a</sup>	Adequate equipment for distribution			9	2	2	36

**FIGURE 8.7** Failure Mode and Effects Analysis table of hazardous processing methods for strudel processing.

(<sup>a</sup> When RPN is above 130, corrective actions are required. RPN, Risk Priority Number; S, severity; O, occurrence; D, detection. Reprinted with permission of John Wiley & Sons, Inc.)

### Typical 2-Way Portable Radios

- Can talk through:
  - Base station
  - Radio to radio
- Clear or secure modes
- PTT (Press to talk button)
- Channel Select knob
- Volume knob
- Antenna
- Keypad
- Soft keys
- Charger contacts
- Display
- Emergency button



**FIGURE 8.8** Typical two-way portable radios.

(MOTOROLA and the Stylized M logo are registered in the U.S. Patent & Trademark Office. All other product or service names are the property of their respective owners. ©Motorola, Inc. 2010.)

Parameter	Voc	Eng: EE	Eng: SW	Eng: ME	Eng: MOL	Eng: Quality	Overall Rank
Audio Quality	144	9	9	9	9	9	1296
Size	186	3	3	9	9	9	1228
F2	171	9	3	1	1	3	581
Display	91	3	3	9	3	1	346
Battery Life	63	3	9	1	3	9	315
Mil Specs	102	3	1	9	1	1	306
OTAP	66	NA	1	NA	3	9	286
Range	96	3	3	1	3	3	250
Camera	61	1	3	9	NA	1	214
Mobility	53	3	3	1	3	9	201
GPS	70	3	1	3	1	1	126
Multiple Band Capability	72	NA	1	1	1	3	108
PTT	17	3	1	3	1	9	58
Core Processor Usage	7	9	9	NA	NA	3	49
Weight	30	NA	NA	1	1	1	30

**FIGURE 8.9** Sample new product critical parameters.

(MOTOROLA and the Stylized M logo are registered in the U.S. Patent & Trademark Office. All other product or service names are the property of their respective owners. ©Motorola, Inc. 2010. OTAP, over the air programming; GPS, global positioning system; VOC, voice of the customer; EE, SE, ME, and MOL refer to engineering groups.)

Having selected the parameters, an introductory session was held to bring everyone up to speed to the DFMEA process, followed by a brainstorming session to qualitatively capture the failure modes with their effects and causes. RPNs were captured next with associated actions and owners. Tracking the execution and closure of recommended actions facilitated reduction in RPNs.

One example, an issue concerning difficulty activating the PTT feature on two-way radios while the user was wearing thick gloves, was taken up and addressed as shown in the illustrations here.

Figure 8.10 is an excerpt highlighting one line of the PTT portion of the Design FMEA done on the item "Subscriber radio." The function "PTT" refers to the "press-to-talk" button on the side of the radio.<sup>[3]</sup>

Notice the significant reduction in both occurrence and detection rankings due to the increased activation force, improved textured area, addition of tactile locator ramps, and the updated usability study.

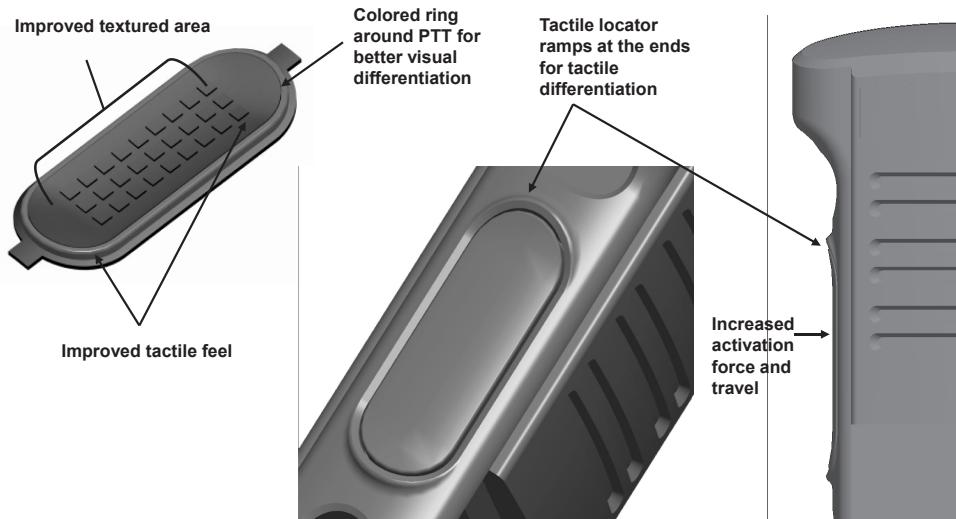
Figure 8.11 is an illustration of the improvements made to the Subscriber Radio to address the "difficult to press" issue.<sup>[3]</sup>

As part of their FMEA process, Motorola Solutions also uses a proactive FMEA action–closure process to track open failures modes, RPN reduction, and delinquent actions. They believe that management needs to be actively involved in the FMEA process all the way through 100% closure of all FMEA actions. Figure 8.12 is a chart showing the type of FMEA closure information tracked by management. In this PTT case study, Parameter Number 6 represents the PTT feature. Note that this chart is a snapshot of the status of failure mode closure at one point in time. Since making this chart, all of the open failure mode items have been closed.<sup>[3]</sup>

Item	Function(s)	Potential Failure Mode	Potential Effects of Failure	Potential Cause(s) of Failure	Severity	Occurrence	Current Design Controls (Prevention)	Current Design Controls (Detection)	RPN	Recommended Action(s)	Revised Rankings			
											Severity	Occurrence	Detection	RPN
PTT	Press-to-talk functionality	Difficult to press	Unable to transmit	7	Use of thick gloves	6	(Not documented)	Initial usability baseline studies	9	378	Perform updated usability study for improvement.	7	3	2
								Study performed. Both activation force and travel on PTT were improved.						42

Design FMEA excerpt truncated after this line

**FIGURE 8.10** Single-line excerpt of PTT Design FMEA.  
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**FIGURE 8.11** Example of PTT improvements.

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Parameter Number	Failure Modes			Expected Closure Date	Delinquent Closure
	Quantity	Open	% Closed		
1	47	20	57%	7/1/2008	None
2	23	2	91%	4/4/2008	None
3	45	16	64%	3/29/2008	None
4	16	3	81%	4/30/2008	None
5	18	3	83%	3/29/2008	None
6	10	4	60%	3/31/2008	None
7	9	2	78%	3/28/2008	None
8	9	6	33%	3/31/2008	None
9	7	4	43%	3/1/2008	None
10	7	6	14%	7/1/2008	None
Total	191	66	65%	7/1/2008	None

PTT feature included in Parameter # 6

**FIGURE 8.12** Snapshot of FMEA closure tracking.

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## Project Results

In this portion of the FMEA, a significant problem (*difficult to press*) was surfaced and resolved by the FMEA team before the new Subscriber Radio went into production. Both the PTT activation force and travel improved, with corresponding improvements in customer satisfaction. The associated RPN with the “difficult to press” problem declined from 378 to 42.

The reliability of the Subscriber Radio has benefited from the use of a rigorous approach to critical parameter selection, FMEA performance, and implementation.

### Student Exercise

See Section 8.13, “End of Chapter Problems,” Problem 8.3, for an evaluation exercise relating to this case study.

## 8.4 CASE STUDY: FLASHLIGHT

**Reference book:** Mark Levin and Ted Kalal, *Improving Product Reliability: Strategies and Implementation*, John Wiley & Sons, 2003, chapter 7.<sup>[4]</sup>

In the “FMEA Process” section of the “Reliability Toolbox” chapter, the authors use a flashlight to demonstrate the use of FMEA and Fault Tree Analysis (FTA). Included in this case study is a Functional Block Diagram of the flashlight operation, an FTA of the unwanted event “Intermittent Light Output,” and an FMEA excerpt for the failure mode “Switch doesn’t close circuit.”

Figure 8.13 shows a schematic of the flashlight that is analyzed in this case study. Figure 8.14 is an example of the Functional Block Diagram for the operation of the flashlight. Figure 8.15 shows the Fault Tree Diagram for the top event “Intermittent Light Output.” Figure 8.16 shows the flow of information between the flashlight Functional Block Diagram, FTA, and the corresponding FMEA.<sup>[4]</sup>

### Conclusion

FTA can augment FMEA when used to further analyze a top-level event, such as “Intermittent Light Output.” This case study shows the relationship and flow of information between FTA and FMEA.

### Student Exercise

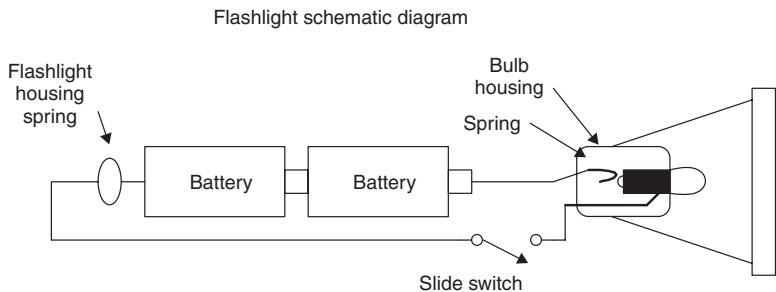
Students are encouraged to analyze the results of this FTA/FMEA combination, and consider ways to improve the FMEA in Figure 8.16. See Section 8.13, “End of Chapter Problems,” Problem 8.4, for the evaluation exercise.

## 8.5 CASE STUDY: DC-10 CARGO DOOR FAILURE

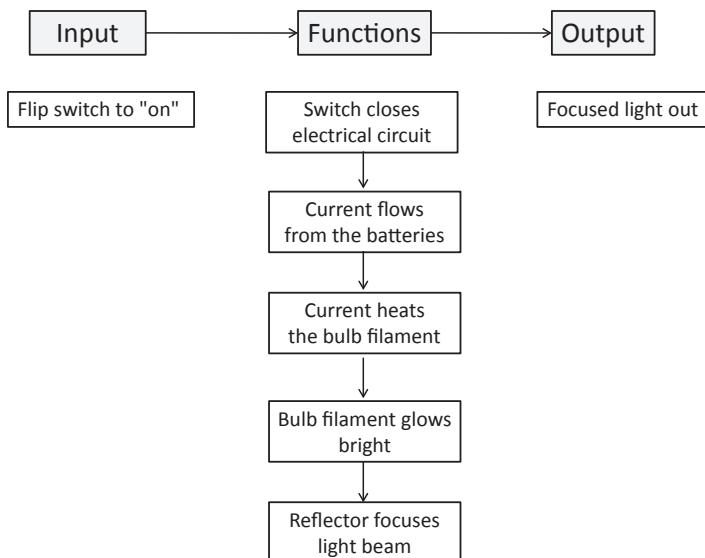
**Reference book:** James Chiles, *Inviting Disasters: Lessons from the Edge of Technology*, HarperBusiness, 2002.

The following is an excerpt from the book *Inviting Disaster*, by James Chiles<sup>[5]</sup>:

Climbing on autopilot through an altitude of twelve thousand feet with sixty seven people aboard, American Airlines Flight 96 was near Windsor, Ontario, when things went crazy on the flight deck. The crew members heard a bang from the rear of the plane, and a jolt sent pilot Bryce McCormick slamming back in his seat. The left rudder pedal jammed to the floor, and the engine throttles flew back to idle. McCormick’s right leg came up, and his knee hit him in the chest as a blast of dust, grit and rivets blew into his face, knocking his headset off. The emergency trim handle broke off in his hands.



**FIGURE 8.13** Schematic diagram of a flashlight.  
(Reprinted with permission of John Wiley & Sons, Inc.)

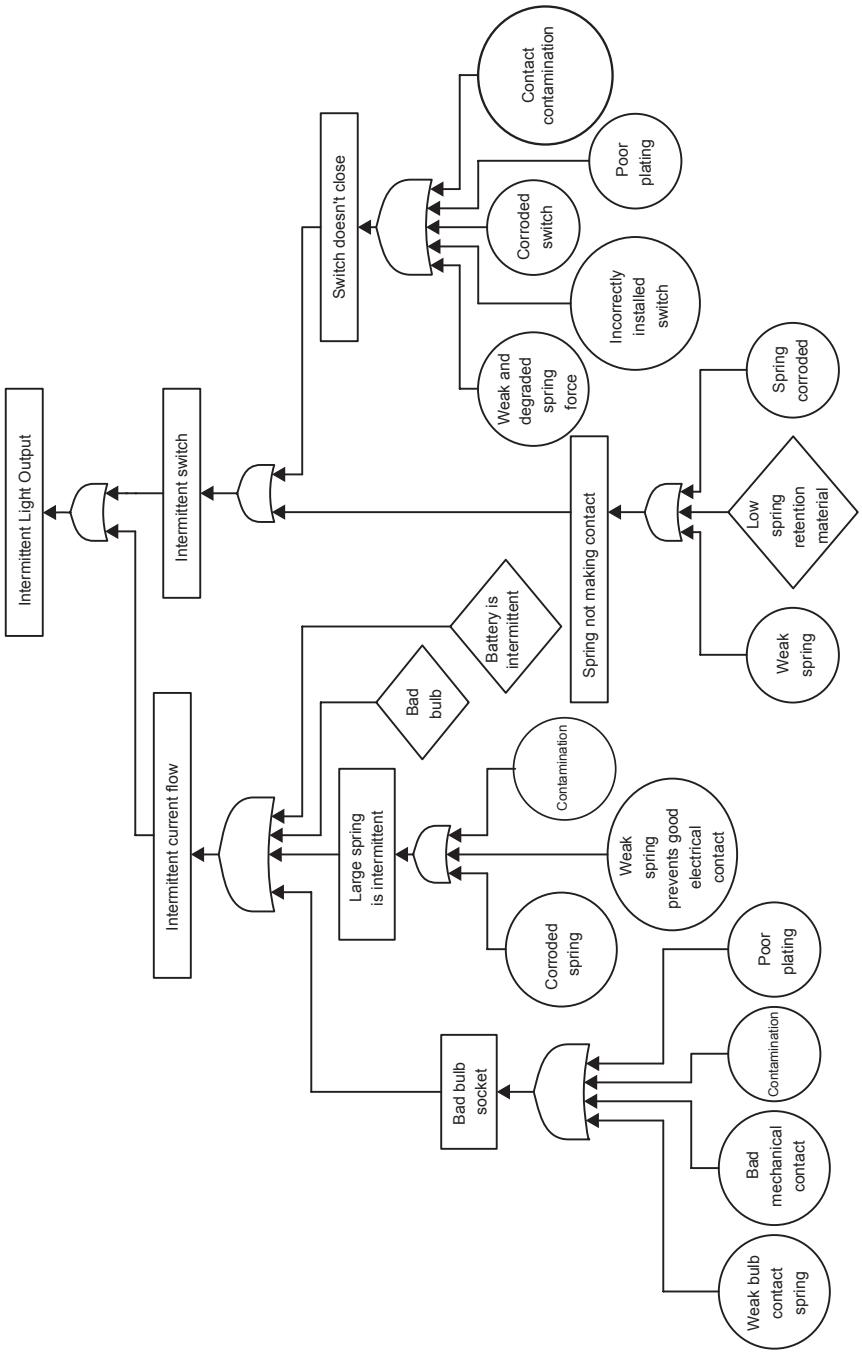


**FIGURE 8.14** Example of a Functional Block Diagram for a flashlight operation.  
(Reprinted with permission of John Wiley & Sons, Inc.)

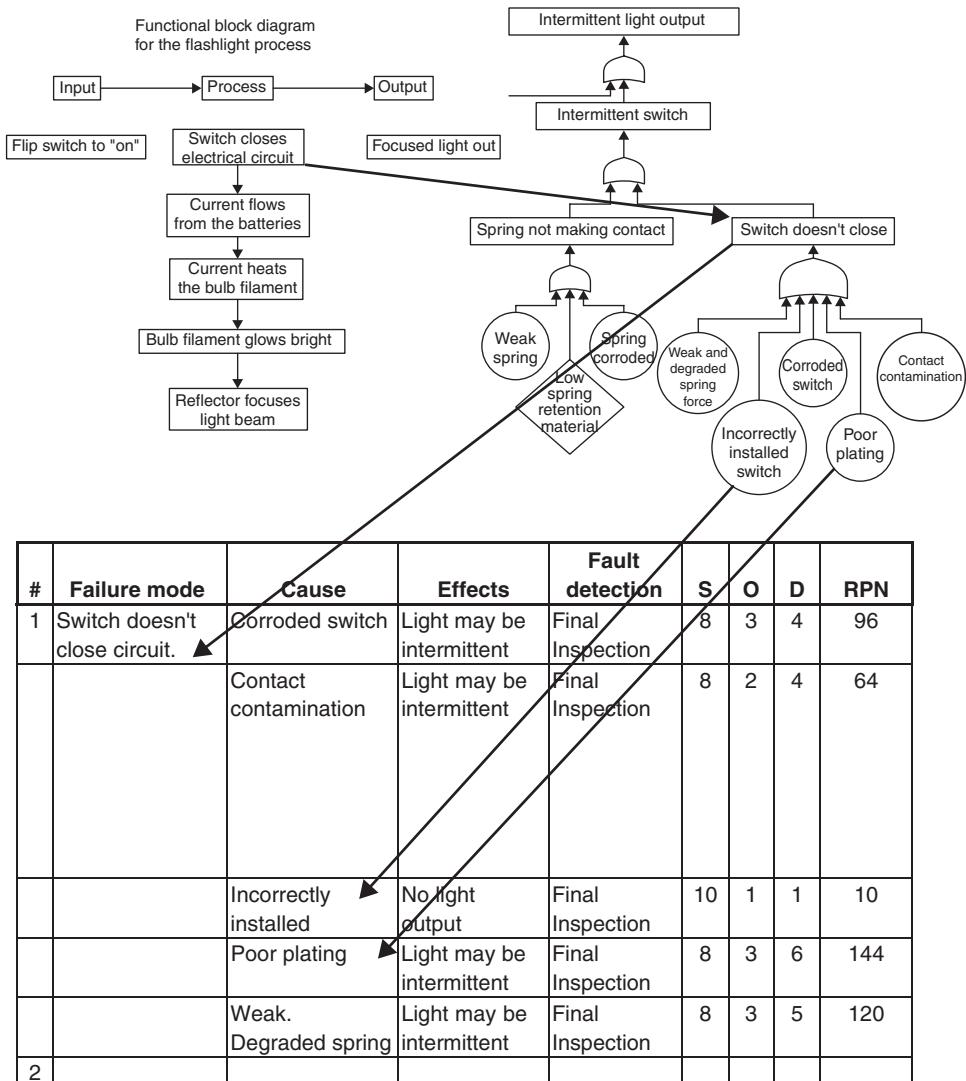
McCormick tried moving the control column back in order to level out the airplane, but the elevator controls were so damaged that he could budge the column only with great difficulty. The airplane went into a right hand turn and began nosing into a dive that if not stopped would be its last. Cockpit warning lamps flared up from one side of the panel to the other, telling of an engine fire and dangerously low air speed, among many other problems. The only thing McCormick could think of as the cause was either a midair collision or a bomb explosion.

Miraculously, the pilot brought the airplane under control and, on that afternoon of July 1972, maneuvered a skilled crash landing. Thankfully, there were no fatalities.

What were the series of events that brought about this catastrophic airplane failure, and what might have prevented the disaster? This is what has since been learned.



**FIGURE 8.15** Flashlight fault tree logic diagram.  
(Reprinted with permission of John Wiley & Sons, Inc.)



**FIGURE 8.16** Example of flow of information between Functional Block Diagram, FTA, and FMEA.  
(Reprinted with permission of John Wiley & Sons, Inc.)

McDonnell Douglas learned from cabin pressure testing that an improperly closed cargo door could burst open due to loss of cabin pressure, potentially resulting in the floor of the passenger compartment crashing down into the cargo compartment. The temporary solution was to put a vent flap in the door that would close by the same linkage that shut the cargo door, which would keep the airliner from holding pressure unless the cargo door was safely latched, thereby alerting the pilot to the problem. However, a bit of excessive force by a baggage handler shutting the door could make the vent flap close even though the cargo door was not fully latched. The DC-10 with the cargo door vent flap was put back in service. On a brief layover before the Flight 96 leg to Detroit, a cargo handler had trouble shutting the

rear cargo door, but managed to get it shut with a little extra force. Since the door latch signaled “closed,” the warning light in the cockpit did not show a problem. However, the force the cargo handler used to shut the door bent a metal linkage on the inside of the door so that the door was not properly closed. The air pressure during ascent generated too much force on the bent door linkage and it sheared off the pins releasing the door. The cabin near the door collapsed and jammed the control cables to the tail. The rest is tragic history.

### **What Is the Probable Failure Sequence of the DC-10 Cargo Door?**

1. Airline cargo handler uses extra force to close rear door, bending door pin. Door does not securely close.
2. The door vent flap does not trigger the electronic alarm, and the pilot is not notified the cargo door failed to lock securely.
3. The air pressure outside the cargo door drops during ascent, until pressure on the door from the inside causes the door latch pin to shear. The cargo door blows out.
4. High-pressure air inside the cabin collapses the floor, resulting in hydraulic lines and cables becoming nonfunctional.

### **Student Exercise**

See Problem 8.5 in Section 8.13, “End of Chapter Problems,” for student exercises for the DC-10 cargo door case study.

## **8.6 CASE STUDY: SPACE SHUTTLE CHALLENGER O-RING FAILURE**

**Reference book:** James Chiles, *Inviting Disasters: Lessons from the Edge of Technology*, HarperBusiness, 2002.

The following is an excerpt from the book *Inviting Disaster*, by James Chiles:<sup>[5]</sup>

When the “ice team” made its last checks during a two-hour hold in the countdown, the temperature of the left booster was 33 degrees F, and the right booster was fourteen degrees colder. But with all the contractors signing their approval for launch, this otherwise alarming development became nothing more than a notation in the preflight logbook. The countdown resumed and ignition took place at 11:38 AM.

The gas from the boosters entered the exhaust nozzles at 5,700 degrees F and left at four thousand miles an hour. A booster was the ultimate cutting torch, so hot that a steel plate near the support posts needed replacement every three or four flights because so much metal boiled away.

At fifty-eight seconds after the booster ignitions, ground-based telescope cameras caught a glow from the right booster.

Most everyone will remember where he was when the tragic news aired about the space shuttle *Challenger* disaster. There have been many investigations and books

written about the events leading up to the catastrophe. As to how this tragedy may have been prevented, there has been intense speculation.

### What Can We Say about the Failure History?

- An O-ring seal in the space shuttle's right solid rocket booster (SRB) failed during liftoff.
- The O-ring failure resulted in a breach in the SRB joint it sealed, allowing pressurized hot gas from within the solid rocket motor to reach the outside and impinge upon the adjacent SRB attachment hardware and external fuel tank.
- This led to the separation of the right-hand SRB's aft attachment and the structural failure of the external tank.
- Aerodynamic forces immediately broke up the orbiter.

### What Is an O-Ring Seal and What Is Its Role in the Shuttle Configuration?

An O-ring is a small loop of material called “elastomer,” which has many of the same properties as rubber. In sealing applications, it is surprisingly strong, often able to seal objects against extremely high pressure. In the space shuttle *Challenger*, the O-ring seal was designed to provide a flexible joint for the SRB that molded to the changing joint configuration during liftoff and kept hot gases from escaping. It was intended to retain its flexibility under specified temperature extremes.

### Why Did the O-Ring Seal Fail?

A warm compressed O-ring returns to its original shape more quickly than a cold O-ring when compression is relieved. In the space shuttle configuration, an O-ring is designed to follow the opening in the SRB joint; however, a cold one may not. If the ambient air temperature were too cold at launch, the O-ring would be very slow in returning to its normal rounded shape, and would not follow the gap, thus allowing hot gases to escape.

### What Is the Probable Failure Sequence?

1. Prelaunch cold ambient temperatures reduce the sealing ability of O-rings inside SRB joints.
2. The cold O-ring seal does not mold properly to the changing joint configuration of the right-hand SRB.
3. Pressurized hot gases escape from the SRB and impinge on the attachment hardware.
4. The strut fails and the external fuel tank ruptures.
5. The space shuttle breaks up, and crew compartment falls away.

**Student Exercise**

See Problem 8.6 in Section 8.13, “End of Chapter Problems,” for student exercises for the space shuttle *Challenger* O-ring case study.

**8.7 CASE STUDY: PROJECTOR LAMP**

**Reference:** Fictional example of projector lamp Design FMEA.

A fictional Design FMEA was performed on a projector lamp assembly to improve the reliability and safety of the device. According to specifications, the lamp is rated at 1000 lumens, which is the brightness required as received. The lamp must operate for 2000 hours, which represents the number of hours before the lamp is at half of its original brightness. Usage of the lamp is up to 5 hours per day in a clean, relatively dust-free environment. It is expected that the customer will clean the air filter every 3 months to avoid projector overheating. Customers are expected to avoid causing physical “shocks” to the projector or the lamp, although the exact shock load is not defined.

Figure 8.17 is an excerpt from the fictional Projector Lamp Design FMEA. It has missing or incorrect elements for teaching purposes.

**Student Exercise**

See Problem 8.7 in Section 8.13, “End of Chapter Problems,” for a student exercise for the Projector Lamp Design FMEA.

**8.8 CASE STUDY: ALL-TERRAIN BICYCLE**

See Chapter 4, Section 4.6, for a description of this fictional case study. As described in this section, the all-terrain bicycle is used in this book as a case study to teach the application of FMEA, specifically in the preparation, procedure, and execution chapters of the book. There are four separate examples that are part of the all-terrain bicycle FMEA case study: all-terrain System FMEA, Hand Brake Subsystem Design FMEA, Brake Cable Design FMEA, and a single manufacturing operation (wheel spoke installation) from the all-terrain Process FMEA. Excerpts from each of these four examples are included in this section, with errors introduced for teaching purposes.

**8.8.1 All-Terrain Bicycle System FMEA**

Figure 8.18 is an excerpt from the all-terrain System FMEA.

**Student Exercise**

See Problem 8.8 in Section 8.13, “End of Chapter Problems,” for a student exercise for the all-terrain System FMEA.

Function	Potential Failure Mode	Potential Effects(s) of Failure	SEV Class	Potential Cause(s)	Occ	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	RPN	Recommended Action(s)
Provide reliable light for image transfer at a minimum of 1000 lumens for 2000 hours of operation	Lamp burns out prematurely	No light on image, customer dissatisfied	8	Hot spots on glass due to over touching	5	ANSI Guideline for incandescent bulbs	Lamp environmental test #123	3	120	Implement new glass coating to minimize impact of touching on bulb durability Revise Lamp environmental test #123 to include periodic touching of glass
		Gas leak at base of glass due to overheating	2				Lamp environmental test #123	1	16	
		Inadequate voltage to lamp due to corrosion of base	8	Sneak circuit analysis on projector system			Lamp durability test #456	7	448	Change lamp base to material ABC in order to be less corrosive. Revise Lamp durability test #456 to add corrosion inducement and checking.
										Revise the interface between bulb base and electrical connection to ensure positive connection, with increased connection force.
										Install additional plastic shield on projector to ensure no injury to user if glass shatters.
										Modify projector lamp Design Guide #ABC to include correct bulb gas.
										Conduct Design of Experiments on projector bulb gas to determine the optimum gas specification to desensitize bulb pressure to gas variation.
										Modify Lamp durability test #456 to include induced gas pressure build up.
Low light output	User may have difficulty viewing image	6		Lamp filament has low resistance due to wrong filament material	3	Projector lamp design guide #ABC		2	36	
				Slow gas leak due to customer abuse during installation	6					Lamp durability test #456
										Modify Lamp durability test #456 to include moderate customer abuse during installation process.

**FIGURE 8.17** Excerpt from Projector Lamp Design FMEA (with missing or incorrect elements for teaching purposes).

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) of Failure	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	RPN	Recommended Actions	Responsible Person	Target Completion Date	Action Taken	SEV	OCCR	DETR	RPNr
Bicycle System: The bicycle must provide safe and reliable transportation, including safe stopping distances and safe operation under all customer usage conditions as defined in the All-Terrain technical specification.	Does not stop in required distance	Potential accident or injury to bicycle operator without warning.	10 Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	5 All-Terrain braking system bicycle stopping test #ABC	5 All-Terrain braking system design guide (document #123)	250	Perform Design FMEA on All-Terrain Hand Brake subsystem	Mary	6/1/XXXX	Design FMEA completed on Hand Brake subsystem; reference FMEA #123		10	2	2	40
								Develop analytical model to simulate the All-Terrain braking system and use the model to optimize the Hand Brake design	Bill	7/1/XXXX	Braking system analytical model completed and hand brake system revised to Rev 2				
								Improve All-Terrain bicycle stopping test by including all weather conditions.	Susan	8/1/XXXX	All weather conditions added to bicycle stopping test #ABC				
								Add rigorous tire durability testing to tire test regimen	Joe	9/1/XXXX	Tire durability testing added to tire test regimen #456				
								1. Bicycle system durability test #789 2. Bicycle system performance testing to design requirements	Mary	6/1/XXXX	Brake adjustment sensitivity analysis completed and brake adjustment feature modified to Rev 2				
								Require all bicycle sellers to instruct customers on how to adjust brakes, before delivery to customer	Bill	7/1/XXXX	Bicycle distributors required to confirm brake adjustment procedure shown to customer				
								Offer free safety clinics to all bicycle users, covering proper brake adjustment, and other safety features	Susan	8/1/XXXX	Letter sent to all current and past customers announcing safety clinics				

TRUNCATED

**FIGURE 8.18** Excerpt from all-terrain System FMEA (with missing or incorrect elements for teaching purposes).

### 8.8.2 All-Terrain Hand Brake Design FMEA

Figure 8.19 is an excerpt from the all-terrain Hand Brake Design FMEA.

#### Student Exercise

See Problem 8.8 in Section 8.13, “End of Chapter Problems,” for a student exercise for the all-terrain Hand Brake Design FMEA.

### 8.8.3 All-Terrain Brake Cable Design FMEA

Figure 8.20 is an excerpt from the all-terrain Brake Cable Design FMEA.

#### All-Terrain Bicycle Case Study: Design Issue

In Chapter 4, Section 4.6, the all-terrain bicycle case study scenario was introduced, presenting one of the problems as a faulty brake cable, a potentially serious problem. The brake cables were made of a new material that was vulnerable to corrosion and prone to breaking under normal usage. If the problem with the brake cable went undiscovered until launch of the new all-terrain bicycle, it could have resulted in injuries. The team discovered the problem through their FMEA process. The all-terrain System FMEA recommended an FMEA on the Hand Brake Subsystem, and the Hand Brake Design FMEA recommended an FMEA on the brake cable. The brake cable corrosion problem was analyzed in the Brake Cable FMEA and the FMEA team resolved and prevented the problem before launch by recommending new, highly corrosion-resistant material, and increasing the cable cross-section geometry.

#### Student Exercise

See Problem 8.8 in Section 8.13, “End of Chapter Problems,” for a student exercise for the all-terrain Brake Cable Design FMEA.

### 8.8.4 All-Terrain Process FMEA (Wheel Spoke Installation)

Figure 8.21 is an excerpt from a single operation (wheel spoke installation) from the all-terrain Process FMEA.

#### All-Terrain Bicycle Case Study: Manufacturing Issue

Also not known to the all-terrain team at the time was a serious problem with the bicycle assembly operation that orients and places the wheel spokes into the wheel assembly fixture. If spokes were left out of the wheel assembly, and if the problem was not caught before the bicycles left the plant, the front wheel could collapse during severe off-road bicycle maneuvers, resulting in possible injuries. The all-terrain Process FMEA analyzed each of the process steps of the bicycle assembly process. In the PFMEA on the wheel spoke installation, the problem of missing spokes was uncovered and solved by kitting the spokes into quantities of 36 and

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) of Failure	SEV	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	RPN	Recommended Actions	Responsible Person	Target Completion Date	Action Taken	SEVr	OCCR	DETr	RPNr
<b>Hand Brake S/S:</b> Provides the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance under all operating conditions.	Bicycle wheel does not slow down when the brake lever is pulled, potentially resulting in accident.	10 Cable binds due to inadequate lubrication or poor routing	4 Hand Brake Design Guide #123	Bicycle system durability test #789	2	80 Redesign hand brake cable routing to reduce friction and make system insensitive to lubrication degradation		Mary	6/1/XXXX	Brake cable routing was redesigned to reduce bending; lubrication changed to #12345	10	2	1	20			
	External foreign material reduces friction	2					Modify bicycle durability testing to include periodic brake cable checks for binding	Bill	7/1/XXXX	Four brake cable binding checks added to bicycle durability test #789							
	Cable breaks	6 Cable material selection based on ANSI #ABC.		Bicycle system durability test #789	4	240 Require cable DFMEA/PFMEA from cable supplier approved by All-Terrain FMEA team.		Joe	9/1/XXXX	Cable supplier completed DFMEA/PFMEA and approved by All-Terrain team			2	1	20		
	Brake lever breaks	1 Hand Brake Design Guide #123		Bicycle system durability test #789	1	10 Based on results of Cable DFMEA, develop cable strength test and modify cable design to improve strength		Mary	6/1/XXXX	Cable strength test #789 was developed and cable geometry cross section revised (Rev 3)							
	Selected brake pad material does not apply required friction to wheel	2			2	40		Bill	7/1/XXXX	No action taken			1	1	10		
								Susan	8/1/XXXX	No action taken			2	2	40		

**FIGURE 8.19** Excerpt from all-terrain Hand Brake Design FMEA (with missing or incorrect elements for teaching purposes).  
(S/S, subsystem; DFMEA, Design FMEA; PFMEA, Process FMEA.)

TRUNCATED

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) of Failure	SEV	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	RPN	Recommended Actions	Responsible Person	Target Completion Date	Action Taken	SEVr	OCCR	DET	RPNr
<b>Brake Cable:</b> Provides adjustable and calibrated movement between the brake lever and brake caliper, under specified conditions of use and operating environment.	Cable breaks	Operator is unable to close brake calipers, wheel does not slow down, possibly resulting in accident.	Corrosion of cable wiring due to wrong material selected	10	Cable material selection based on ANSI Standard #ABC.	Cable strength test #456	4	200	Perform a thorough review of cable material alternatives including corrosion resistance.	Mary	6/1/XXXX	Cable materials reviewed; new material selected that is highly corrosion resistant	10	1	4	40
									Conduct Design of Experiments to optimize cable material and geometry for maximum corrosion resistance.	Bill	7/1/XXXX	DOE completed and cable geometry cross section increased (Rev 3)				
			Fatigue cracks in cable wiring due to inadequate cable thickness	2	Finite Element Analysis of all new cable material	Laboratory analysis for fatigue cracks at regular intervals per test regimen #456	2	40		Susan	8/1/XXXX	No action taken		2	2	40
Cable binds	Increased friction	Bend or kink in cable due to misrouting	7	Design Review at prototype build			2	42		Joe	9/1/XXXX	No action taken	7	3	2	42
		Inadequate or wrong lubrication between cable and sheath	5	Bicycle durability test #123	Cable lubrication selection based on ANSI Standard #XYZ.		4	140	Select new cable lubrication for improved performance under all operating conditions.	Mary	6/1/XXXX	New cable lubrication selected #12345, and tested successfully		2	1	14
									Add brake cable lube check at regular intervals during bicycle durability testing.	Bill	7/1/XXXX	Four brake cable lube checks added to bicycle durability test #423				

TRUNCATED

**FIGURE 8.20** Excerpt from all-terrain Brake Cable Design FMEA (with missing or incorrect elements for teaching purposes).

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCC	Current Process Controls (Prevention)	Current Process Controls (Detection)	DET	RPN	Recommended Action(s)	Responsible Person	Target Completion Date	Action Taken	SEvr	OCCR	DETT	RPNr
Orient and place 36-wheel spokes properly in wheel assembly fixture	Process Effect: wheel not aligned, requiring rework out of station (5)  Product Effect: wheel wobble and increasing stress during maneuvers, with potential for wheel collapse and rider injury, with warning (9)	9	Lack of organized spoke kit	3	Wheel spoke installation work instructions	Visual check of wheel assembly by operator	5	135	Kit the spokes into quantities of 36	Mary	6/1/XXXX	Changed wheel spoke purchase system to buy kit of 36; added supplier quality audit	9	1	2	18	
	Process Effect: wheel not aligned, requiring rework out of station (5)  Product Effect: wheel wobble with potential for loss of handling during maneuvering and rider injury, with warning (9)	9	Fixture is not error proofed to prevent incorrect orientation	6	Wheel spoke installation work instructions	In-station vision system to detect missing wheel spokes	7	378	Develop and implement in-station vision system to detect missing wheel spokes	Bill	7/1/XXXX	In-station vision system added to detect both missing or mis-oriented spoke installation					
	Process Effect: wheel not aligned, requiring rework out of station (5)  Product Effect: wheel wobble with potential for loss of handling during maneuvering and rider injury, with warning (9)	9	Fixture is not error proofed to prevent incorrect orientation	6	Wheel spoke installation work instructions	In-station test for wheel alignment/truing	7	378	Develop and implement error-proofed wheel installation fixture to prevent incorrect orientation	Susan	8/1/XXXX	Wheel installation fixture has been error proofed to prevent incorrect orientation of spokes	9	1	2	18	
TRUNCATED																	

**FIGURE 8.21** Excerpt from wheel-spoke installation operation all-terrain Process FMEA (with missing or incorrect elements for teaching purposes).

implementing an in-station vision system to detect automatically missing or misoriented spokes. This prevented the problem before launch.

### **Student Exercise**

See Problem 8.8 in Section 8.13, “End of Chapter Problems,” for a student exercise for the all-terrain Process FMEA (wheel spoke installation.)

## **8.9 CASE STUDY: RESIN LEVER**

**Reference article:** Shigeto Kano and Hirokazu Shimizu, “A Guide to GD<sup>3</sup> Activities and DRBFM Technique to Prevent Trouble” (Version 5.0), by Vehicle Technology Dept No. 1, Toyota Motor Corporation.<sup>[6]</sup>

### **Introduction**

This case study examines the use of resin for a lever to be used in an engine compartment. The reference paper is a guide to Design Review Based on Failure Mode (DRBFM), and the resin lever is one of the examples used to show the progression from FMEA to DRBFM.

### **Use of FMEA and DRBFM**

Figure 8.22 shows what the authors consider a typical FMEA worksheet of a resin part (excerpt). In this first FMEA example, they note that the FMEA worksheet does not specify problems peculiar to that particular component; rather, it lists universal factors common to all resin parts. Figure 8.23 shows a more specific FMEA (excerpt) that reveals considerably more detail in the causes that are specific to the resin application being analyzed. As the authors note, this greatly aids in establishing corrective actions, and will allow the team to transfer the information directly to the DRBFM worksheet. In the paper, this FMEA is called “creative FMEA (DRBFM), which forms the basis for debate at the DRBFM.”<sup>[6]</sup> Figure 8.24 is the DRBFM worksheet (excerpt), with information transferred from the properly done FMEA.<sup>[6]</sup>

### **Conclusion**

A well-done FMEA is an important precursor to a DRBFM project. This paper shows how a poorly done FMEA adds little value and cannot be used in support of DRBFM. The paper also shows the value of a detailed FMEA with root causes and specific recommended actions. The DRBFM can expand the value by adding good discussion and countermeasures that are more effective.

### **Student Exercise**

See Problem 8.9 in Section 8.13, “End of Chapter Problems,” for a student exercise for the resin lever case study.

No.	Region	Component's function	Failure mode	Cause of failure (initial, deterioration over time)	Effect of disorder		Corrective action	
					Effect on assembly	Vehicle or EGI	Design action	Check method and result
1	Resin lever ( PA66 )	Spring retention	1. Rupture of the boss that fixes the spring hook	1. Defective material 2. Defective molding 3. Defective dimension 4. Thermal deterioration of material 5. Selection of the wrong material 6. Internal residual stress	Unable to open	Unable to travel	1 3 1 3 1 3	<ul style="list-style-type: none"> <li>• Selection of a material that allows for deterioration</li> </ul>
				1. Defective material 2. Defective molding 3. Defective dimension 4. Thermal deterioration of material 5. Selection of the wrong material 6. Spring resonance	3. Wear of the boss that fixes the spring hook		<ul style="list-style-type: none"> <li>• A shape design conducted, allowing for residual stresses</li> </ul>	<ul style="list-style-type: none"> <li>• Durability tests conducted: No problems revealed</li> </ul>

**FIGURE 8.22** Excerpt from typical FMEA worksheet for a resin part.

No.	Component (region)	Change and nature of change	Component's function	Functional disorder and unmarketability due to the change (failure mode)	Effect of disorder System Vehicle	Symptom as a factor	Cause of failure	Factors leading to functional disorders and unmarketability			Corrective action		
								Importance	Frequency	Severity	Reflection on the design (design actions)	Severity	
1	Resin lever	Metal to PA	1. Spring retention	1. Damage to the boss that fixes the spring hook	Unable to open	Deterioration over time	- Static strength declined and damage resulted due to resin deterioration. * Thermal deterioration * Grease deterioration * Deterioration due to moisture * Deterioration due to calcium chloride and LC - Fatigue strength declined and damage resulted due to resin deterioration.	A	A	A	- Perform strength calculations allowing for the causes of deterioration. * Determine the safety factor. * Perform calculations based on the characteristics after deterioration due to heat and grease. - Survey the attackable solvents (such as EG oil, fuel and LC).	Relative necessity	Relative frequency
				2. Deformation of the boss that fixes the spring hook	Overload	Impact	- Damage due to spring impact	B	A	A	- Perform a durability test after deterioration. * Durability test after deterioration due to heat and grease * 100°C x 500 hns - Perform a composite deterioration durability test. Cold and heat: coat with calcium chloride (-35 to 100°C, 95% RH) - Perform a test at the top limit spring force.	Relative necessity	Relative frequency
						Fatigue	- Cracks resulted from a boss having too small an outside diameter and the repeated reaction of the spring. - A boss bottom with a small radius of curvature resulted in stress concentrations, which then resulted in cracks. - A high GF fill-up ratio resulted in repeated loading, which then resulted in fatigue cracks in the boss bottom. - Dispersions in the molding conditions resulted in welds in the boss bottom, which then resulted in cracks. - Forcible releasing of the mold resulted in cracks in the boss bottom.	B	B	B	- Conduct an approximate quote on impact strength. - Conduct a quote on fatigue strength. * Conduct an estimate based on S-N chart of stresses generated and PA.	Relative necessity	Relative frequency
							- Boss radius of curvature: 0.5 or more indicated in the drawings	B	A	A	- Conduct a durability test after deterioration.	Relative necessity	Relative frequency
							C	C	C	C	- Check the dimensions of the sample.	Relative necessity	Relative frequency
							- Consider the optimal fill-up ratio of glass fiber. * Consider static strength, fatigue, and impact strength.				- Perform an impact test (at low and high temperatures).	Relative necessity	Relative frequency
							- Control the molding conditions thoroughly. * Specify in the QC process chart: resin temperature, mold temperature, injection pressure, injection speed, etc.	A	A	A	- Perform a durability test on a worst-scenario sample with welds.	Relative necessity	Relative frequency
							- Give instructions to check the boss for cracks in an inspection instruction sheet.	B	A	A	- Check for deformation in a hot atmosphere. - Perform a deformation test after deterioration (due to heat, grease, and temperature).	Relative necessity	Relative frequency
							- Perform deformation calculations based on a material characteristics chart after deterioration. (A stress-strain curve.) * Consider the outside diameter and height of the boss. * Give instructions about the tolerance of the spring force.				- Perform a deformation test on a sample under the worst molding conditions.	Relative necessity	Relative frequency
							- Make sure that the instructions are followed in installing the spring.	B	B	B	- Check the orientation of the glass fibers. (Consider optimizing the molding conditions.)	Relative necessity	Relative frequency

FIGURE 8.23 Excerpt from improved FMEA worksheet for a resin part.

Component (region)	Change and nature of change	Concerns over the change (failure mode)		Concerns in what case?		Effects on customers	What design was made to eliminate the concern? (such as design requirements, design standards, and check sheets)	Recommended actions (DRBFM results)		Activity performed as a result of the actions
		Loss of function	Any other concerns? (DRBFM)	Any other Cause/factor	Considered? (DRBFM)			Priority rating	Progress deadline	
Resin lever	Metal to PA	1. Spring retention	- Static strength declined and damage * Thermal deterioration * Grease deterioration * Deterioration due to E/G oil, fuel, and LLC * Deterioration due to moisture * Deterioration due to calcium chloride - Fatigue strength declined and damaged resulted due to resin deterioration.	Unable to travel	A	* Automatic PA adopted in view of thermal deterioration and deterioration due to moisture.	Importance A	<ul style="list-style-type: none"> <li>- Perform a durability test after deterioration.</li> <li>- Determine the safety factor.</li> <li>- Perform calculations based on the characteristics after deterioration due to heat and grease.</li> <li>- Survey the sticky solvents (such as E/G oil, fuel and LLC).</li> <li>- Cold and heat coat with calcium chloride (&lt;35 to 100 C, 85%).</li> <li>- Perform a test at the top limit spring force.</li> </ul>	Part A, Mar. Part B, Jun.	Test in progress (scheduled to be finished in June)
		Impact	Low	High	A	* Safety factor of static strength >3.0	C	<ul style="list-style-type: none"> <li>- Conduct an approximate quote on impact strength.</li> <li>- Perform an impact test (at low and high temperatures).</li> </ul>	Part A, May. Part B, Jun.	Completed
		Fall/guge	Medium	Medium	A	* Boss radius of curvature to small radius of curvature resulted in stress concentration, which then resulted in cracks.	A	<ul style="list-style-type: none"> <li>- Conduct a quote on fatigue strength.</li> <li>- Conduct an estimate based on an S-N chart of stresses generated and P.A.</li> </ul>	Part A, Mar. Part B, Apr.	Test in progress (scheduled to be finished in June)
					B	- Boss radius of curvature to 0.5 or more indicated in the drawings	A	<ul style="list-style-type: none"> <li>- Check the dimensions of the sample.</li> </ul>	Part A, Feb. Part B, Apr.	Boundary samples to be used to make sure that all workers observe the requirements.
					B	- Consider the optimal fill-up ratio of glass fiber. * Consider static strength, fatigue, and impact strength.	A	<ul style="list-style-type: none"> <li>- Items of acceptance inspection of molding materials to be determined and observed by all personnel</li> </ul>	Part A, Mar. Part B, Apr.	Boundary samples to be used to make sure that all workers observe the requirements.
					A	- A high GF fill-up ratio resulted in repeated loading, which then resulted in fatigue cracks in the boss bottom.	A	<ul style="list-style-type: none"> <li>- A 3-point gate to be used to prevent welds and increase resin fluidity</li> <li>- Perform a durability test on a worst-case scenario sample with welds.</li> </ul>	Part C, Sep. Part C, Sep.	Molding conditions to be controlled thoroughly * Specifically in the QC process that the resin temperature, mold temperature, injection pressure, and injection speed.

**FIGURE 8.24** Excerpt from DRBFM worksheet for a resin part.

## 8.10 CASE STUDY: POWER STEERING

**Reference:** SAE J1739 JAN2009 Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA)<sup>[7]</sup>

### Introduction

SAE J1739 (Appendix G) includes three brief Design FMEA excerpts: vehicle steering system, power steering pump subsystem, and a driveshaft component. The excerpts are included in the standard for informational purposes to support the content of the standard. Each Design FMEA excerpt begins with the description “excerpts for example purposes, not all requirements are shown or analyzed here.”

### Use of FMEA

The referenced System and Design FMEA excerpts are replicated in Figure 8.25. They show the progression of FMEA from system to subsystem to component.<sup>[7]</sup>

### Student Exercise

Students are encouraged to analyze these Design FMEA excerpts. See Problem 8.10 in Section 8.13, “End of Chapter Problems,” for an evaluation exercise relating to these FMEA excerpts.

## 8.11 OTHER CASE STUDIES AND EXAMPLES

There are other case studies and examples in different chapters of this book.

Chapter 1, Section 1.4 contains five brief FMEA case studies from various industries.

Chapter 12, Sections 12.5, 12.6, and 12.7 include examples of Quantitative Criticality Analysis, Qualitative Criticality Analysis, and Criticality Matrix on a bicycle brake pad.

Chapter 13, Section 13.6 has a DRBFM example for an electronic power steering system rack boot subassembly and a fictional example of Change Point Analysis and DRBFM for a wooden catapult structure.

Chapter 14, Section 14.6, includes an example of FTA of the event: unwanted acceleration.

The “Reliability-Centered Maintenance” section of Chapter 15 includes an RCM case study involving a circuit breaker that is part of a gas insulated switchgear system.

The “Hazard Analysis” section of Chapter 15 includes an example of Preliminary Hazard Analysis on a pressure cooker and an example excerpt of Hazard Analysis for a fuel control subsystem.

The “Concept FMEA” section of Chapter 15 includes an example excerpt of a Concept FMEA on a bicycle brake cable with new nylon material.

## DESIGN FAILURE MODES AND EFFECTS ANALYSIS (DFMEA)

System Name: Steering System Example										DFMEA Number: D453301021					
Model Year / Program(s): Starting 2012 / New Power Pump Family										Revision Date: 17JN2008					
DFMEA Owner (Design Resp.): Patrick Schreiner (DE), Paul Baird (DE), John Paris (DE)										Key Date: 08JN2008					
Core Team / Facilitator: Mike Down (VE), Bill Haughey (PE) / Rhonda Brender (Facilitator)										Original Completion Date: 14FE2008					
Support Team: Bernd von Regius (Customer DE), Hisham Younis (SE), Glen Vallance (ME), John Feghali (QE)										Design Eng (DE), Validation Eng (VE), Systems Eng (SE), Manuf Eng (ME), Process Eng (FE), Quality Eng (QE)					
Item / Function / Requirement	Potential Failure Mode	Potential Effect(s) of Failure	S Classifications	P Potential Cause(s) of Failure	O C	C Potential Cause(s) of Failure	V	Current Design Controls (Prevention)	Current Design Controls (Detection)	D E	R P	T N	Recommended Action	Responsibility & Target Completion Date	Action Results
<b>System (Vehicle level excerpts for example purposes, not all requirements are shown or analyzed here.)</b>															
Steering System / Direct front vehicle wheels based on driver steering input / turning degrees, turning efforts	Steering effort too low (light steering feel)	End user: Minor driver actions cause excessive wheel movement	7	Power steering pump has excessive flow	Steering guideline	7 system design	Vehicle testing and validation	5	Conduct virtual steering system flow rates	Von Regius, Bernd	Virtual analysis completed; confirmed flow rates within operating parameters is acceptable, ref. file no. VA2380, Jan. 2007	7	2	28	
Steering System / Direct front vehicle wheels based on driver steering input / turning degrees, turning efforts	Steering efforts too high (periods of difficult steering or pump catch)	End user: Driver has difficulty turning or parking	7	Power steering pump inadequate flow	Steering guideline	7 system design	Vehicle testing and validation	5	Conduct virtual steering system minimum flow capability	Von Regius, Bernd	Virtual analysis completed; confirmed flow rates within operating parameters is acceptable, ref. file no. VA2380, Jan. 2007	7	2	28	

**FIGURE 8.25** Example Design FMEA excerpts—steering system, power steering pump subsystem, and driveshaft.

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## DESIGN FAILURE MODES AND EFFECTS ANALYSIS (DFMEA)

Subsystem Name: Steering Pump Subsystem Example										DFMEA Number: D453301021
Model Year / Program(s): Starting 2012 / New Power Pump Family										Revision Date: 17 JN2008
DFMEA Owner (Design Resp.): Patrick Schreiner (DE), Paul Baird (DE), John Paris (DE)										Key Date: 08 JN2008
Core Team / Facilitator: Mike Down (VE), Bill Haughey (PE) / Rhonda Brender (Facilitator)										Original Completion Date: 14FE2008
Item / Function / Requirement	Potential Failure Mode	Potential Effect(s) of Failure	S Classification	Potential Causes(s) of Failure	O C	Current Design Controls	Current Design Controls	D E P	R T N	Responsibility & Target Completion Date
<b>Sub-system (Assembly) level excerpts for example purposes, not all requirements are shown or analyzed here.)</b>										Action Results
Power steering pump / Transforms rotational speed and torque at the shaft into oil flow and pressure / pressure (xx psi), flow rate (xx lpm)	End user: Steering efforts drop (less effort at higher tie rod end loads), loss of hydraulic assist Steering System: Excess pressure to gear and hoses Pump: Fluid leakage, fractured housing, pump inoperable	Excessive pressure (more than xx psi)	8	Pressure relief incorrectly specified on drawing	7	Pressure relief valve design guidelines	Bench rig test for function (5)	5	280	Review results of function test to confirm successful pressure and flow rates achieved
Power steering pump / Transforms rotational speed and torque at the shaft into oil flow and pressure / pressure (xx psi), flow rate (xx lpm)	Inadequate flow (less than xx lpm)	End user: Increased steering effort when turning quickly Steering system: Steering gear piston unable to travel at required minimum speed Pump: Pump catch	5	Fluid incorrectly specified (viscosity too low resulting in limited internal leakage)	5	Design guidelines for fluid	Vehicle durability testing (6)	6	150	Obtain and evaluate results of OEM durability testing
Power steering pump / Transforms rotational speed and torque at the shaft into oil flow and pressure / pressure (xx psi), flow rate (xx lpm)	Inadequate flow (less than xx lpm)	Pump: Pump catch Steering system: Steering gear piston unable to travel at required minimum speed Vehicle: Increased steering effort when turning quickly	5	Clearances between components incorrectly called out on drawing (gaps too large resulting in large internal leakage)	3	Design standards for clearances	Engineering calculations (2), validation function test (5)	2	30	Characterize development sample unit for performance (tolerance analysis and stacks)
Power steering pump / Transforms rotational speed and torque at the shaft into oil flow and pressure / pressure (xx psi), flow rate (xx lpm)	No flow	End user: Loss of hydraulic assist (manual steer only) Steering system: Loss of oil flow and pressure Pump: Inoperable	8	Fractured shaft	7	Standard shaft design	Pump pressure shock test, cold start, durability test, broken drive shaft test	5	280	1. Conduct DRBTR tear down review 2. Update drive shaft component DFMEA
12-Aug-2007										Validation completed and passed, DRBTR showed no evidence (buds) of problems exist on shaft, ref. test plan VT3741, Aug 2008

**FIGURE 8.25** (Continued)

## DESIGN FAILURE MODES AND EFFECTS ANALYSIS (DFMEA)

Component Name: Driveshaft Component Example											
Model Year / Program(s): Starting 2012 / New Power Pump Family		DFMEA Number: D453301021		Revision Date: 17JN2008		Key Date: 08JN2008		Original Completion Date: 14FE2008			
DFMEA Owner (Design Resp.): Patrick Schreiner (DE), Paul Baird (DE), John Paris (DE)		Core Team / Facilitator: Mike Down (VE), Bill Haughey (PE), Rhonda Brender (Facilitator)		Support Team: Bernd von Regius (Customer DE), Hisham Younis (SE), Glen Vallance (ME), John Feghali (							
Design Eng (DE), Validation Eng (VE), Systems Eng (SE), Manuf Eng (ME), Process Eng (PE), Quality Eng (QE)											
Item / Function / Requirement	Potential Failure Mode	Potential Effect(s) of Failure	S	O	C	Current Design Controls Prevention	D	R	Action Results		
			Classification	Failure Cause(s)	Failure Type	Current Design Controls Prevention	Design Eng (DE)	Review (PE)	Actions Taken & Effective Date		
Shaft / Withstand rotational forces / forces of xx	Shaft fractured	End user: Loss of hydraulic assist (manual steer only) Pump: No flow output (does not transform energy)	8 R	Shaft not strong enough due to material heat treat (does not transform energy)	1 Heat treat specification incorrectly specified	Pump pressure shock test, cold start durability test, broken drive shaft test	1	8	None		
Shaft / Withstand rotational forces / forces of xx	Shaft fractured	End user: Loss of hydraulic assist (manual steer only) Pump: No flow output (does not transform energy)	8	Shaft stressed due to new step design feature	Engineering calculations (2), pressure shock test, broken drive shaft test, high ambient heavy belt load test (5), durability vehicle test (6)	1. Conduct Finite Element Analysis 2. Convert to constant diameter drive shaft if necessary	2	112	FEA completed; confirmed shaft strength is adequate, ref. file no. FEA1950 step design approved, March 2007		

**FIGURE 8.25** (Continued)

The “Software FMEA” section of Chapter 15 includes the following example excerpts of Software FMEA: Function-Level Software FMEA on a hospital X-ray system, Logic-Level Software FMEA, and a Code-Level Software FMEA on a ventilator system for hospital arrhythmia patients.

The “Failure Mode Mechanisms and Effects Analysis” section of Chapter 15 includes an example excerpt of an FMMEA for a printed circuit board assembly that is mounted in an automotive underhood environment.

## 8.12 WEB COMPANION TO *EFFECTIVE FMEAs*

More FMEA case studies will be posted on the companion web site to this book. Students and practitioners are encouraged to visit <http://www.wiley.com/go/effectivefmeas>. Additional resources will be posted on this web site as they become available, including more examples of FMEA definitions, case studies, related FMEA material, illustrations, and useful links.

## 8.13 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

### Case Study Problem 8.1

#### **Shock Absorber Assembly (Use of Process FMEA)**

Review the Shock Absorber case study in Section 8.1 and the Process FMEA in Figure 8.2. Suggest three improvements that can made to this PFMEA.

### Case Study Problem 8.2

#### **Strudel Pastry Manufacturing (Use of Hazard Analysis and FMEA)**

Review the Strudel Pastry Manufacturing case study in Section 8.2 and the FMEA/Hazard Analysis table in Figure 8.7. Suggest two improvements that can made to this FMEA/Hazard Analysis.

### Case Study Problem 8.3

#### **Motorola Solutions “Press-to-Talk” Feature (Use of Design FMEA)**

Review the Motorola Solutions “Press-to-Talk” case study in Section 8.3 and the FMEA single-line excerpt in Figure 8.10. For teaching purposes, brainstorm two other hypothetical failure modes for the PTT functionality.

### Case Study Problem 8.4

#### **Flashlight (Use of Design FMEA with FTA)**

Review the Flashlight case study in Section 8.4 and the flow of information from FTA to FMEA in Figure 8.16. Although this FMEA is a truncated excerpt to show

the transfer of information from FTA to FMEA, it can be used as a teaching example. Suggest two improvements that can be made to the FMEA in Figure 8.16.

### Case Study Problem 8.5

#### DC-10 Cargo Door Failure (Use of FMEA to Study Cargo Door Failure)

Review the DC-10 Cargo Door Failure case study in Section 8.5. Use the door latch pin failure on DC cargo door latching subsystem as an example to practice identifying function, failure mode, effect, cause, and controls based on the cargo door latch pin failure history. Try answering the following questions.

##### **Identify a function**

Write down on a memo pad a possible *function* of the door latch pin of the DC-10 cargo door.

##### **Identify a failure mode**

Write down on a memo pad a possible *failure mode* of door latch pin of the DC-10 cargo door.

##### **Identify an effect**

Write down on a memo pad a possible *effect* of the door latch pin failure mode.

##### **Identify a severity**

Write down on a memo pad the *severity* of the effect of the door latch pin failure mode. Refer to Chapter 3, Section 3.5 for an example of a severity scale.

##### **Identify a cause**

Write down on a memo pad a possible *cause* of the door latch pin failure mode.

##### **Identify a control (prevention type)**

Write down on a memo pad a possible *prevention-type control* for the cause of the door latch pin failure mode.

##### **Identify a control (detection type)**

Write down on a memo pad a possible *detection-type control* for the cause of the door latch pin failure mode.

##### **Identify a recommended action**

Write down on a memo pad a possible *recommended action* for the cause of the door latch pin failure mode.

### Case Study Problem 8.6

#### Space Shuttle Challenger O-Ring Failure (Use of FMEA to Study O-Ring Failure)

Review the Space Shuttle Challenger O-Ring Failure case study in Section 8.6. Use the O-ring failure on the space shuttle *Challenger* as an example to practice identifying function, failure mode, effect, cause, and controls based on the O-ring failure history. Try the following exercises.

##### **Identify a function**

Write down on a memo pad a possible *function* of the O-ring in SRB of the space shuttle *Challenger*.

**Identify a failure mode**

Write down on a memo pad a possible *failure mode* of the O-ring.

**Identify an effect**

Write down on a memo pad a possible *effect* of the O-ring failure mode on the SRB and the crew of the space shuttle *Challenger*.

**Identify a severity**

Write down on a memo pad the *severity* of the effect of the O-ring failure mode on the SRB and the crew of the space shuttle *Challenger*. Refer to Chapter 3, Section 3.5 for an example of a severity scale.

**Identify a cause**

Write down on a memo pad a possible *cause* of the O-ring failure mode.

**Identify a control (prevention type)**

Write down on a memo pad a possible *prevention-type control* for the cause of the O-ring failure mode.

**Identify a control (detection type)**

Write down on a memo pad a possible *detection-type control* for the cause of the O-ring failure mode.

**Identify a recommended action**

Write down on a memo pad a possible *recommended action* for the cause of the O-ring failure mode.

**Case Study Problem 8.7****Projector Lamp (Use of Design FMEA)**

Study the Projector Lamp FMEA in Figure 8.17 of Section 8.7. Analyze the FMEA in terms of quality, completeness, and adequacy. Note three specific deficiencies and suggest improvements. Compare results to the teaching analysis.

**Case Study Problem 8.8****All-Terrain Bicycle (Use of System, Design, and Process FMEA)***All-Terrain Bicycle System FMEA*

Study the all-terrain System FMEA in Figure 8.18. Analyze the FMEA in terms of quality, completeness, and adequacy. Since this is an excerpt of an FMEA, there will be missing functions, failure modes, and causes, so those topics are excluded from the analysis. Note specific deficiencies and suggest improvements. Compare results to the teaching analysis.

*All-Terrain Hand Brake Design FMEA*

Study the all-terrain Hand Brake Design FMEA in Figure 8.19. Analyze the FMEA in terms of quality, completeness, and adequacy. Since this is an excerpt of an FMEA, there will be missing functions, failure modes, and causes so those topics are excluded from the analysis. Note specific deficiencies and suggest improvements. Compare results to the teaching analysis.

### All-Terrain Brake Cable Design FMEA

Study the all-terrain Brake Cable Design FMEA in Figure 8.20. Analyze the FMEA in terms of quality, completeness, and adequacy. Since this is an excerpt of an FMEA, there will be missing functions, failure modes, and causes, so those topics are excluded from the analysis. Note specific deficiencies and suggest improvements. Compare results to the teaching analysis.

### All-Terrain Wheel-Spoke Installation Process FMEA

Study the all-terrain wheel spoke installation Process FMEA in Figure 8.21. Analyze the FMEA in terms of quality, completeness, and adequacy. Since this is an excerpt of an FMEA, there will be missing functions, failure modes and causes, so those topics are excluded from the analysis. Note specific deficiencies and suggest improvements. Compare results to the teaching analysis.

### Case Study Problem 8.9

#### **Resin Lever (Use of FMEA and DRBFM)**

Review the Resin Lever case study in Section 8.9 and the improved FMEA in Figure 8.23. Identify two positive attributes in this FMEA.

### Case Study Problem 8.10

#### **Power Steering (Use of Design FMEA at System, Subsystem, and Component Levels)**

Review the three Design FMEA excerpts from Figure 8.25 of Section 8.10. Although these three FMEAs are example excerpts only, with sanitized data and recommendations, they can be used as teaching examples. Answer the questions below and compare to the teaching analysis.

1. Read the recommended actions for the three FMEA excerpts. Referring to the primary objective of an FMEA from Chapter 3, Section 3.2, what *type* of recommended action is not well represented in these excerpts and why is this important?
2. Read the first line of the power steering pump FMEA excerpt. The failure mode is “excessive pressure (more than xx psi)” and the cause is “pressure relief incorrectly specified on drawing.” Does the recommended action address this cause? What other possible recommended actions might be considered?
3. The first line of the driveshaft FMEA excerpt has “DR” in the Classification column, which stands for “documentation required.” Discuss how this special characteristic might be used in other analyses.

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# *Chapter* 9

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## *Lessons Learned for Effective FMEAs*

Experience is the name everyone gives to their mistakes.

—Oscar Wilde

### **IN THIS CHAPTER**

Much is learned by observing the mistakes companies have made in doing Failure Mode and Effects Analyses (FMEAs). Based on the experience of over 2000 FMEAs and working with many companies in a wide variety of applications, certain common mistakes show up repeatedly. This chapter outlines the most common FMEA mistakes and describes how to avoid them. FMEA Quality Objectives are described, along with an effective FMEA audit procedure.

#### **9.1 THE MOST COMMON FMEA MISTAKES: HOW TO AVOID THEM AND AUDIT THEM**

Good judgment comes from experience and experience comes from poor judgment.  
—Will Rogers

Below are the most common FMEA mistakes and their corresponding quality objectives, including examples for each mistake, and guidelines on *how to audit* each FMEA Quality Objective. The FMEA team should review these Quality Objectives as needed to ensure they are met before the FMEA is considered complete.

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*Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis*, First Edition. Carl S. Carlson.  
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What are the primary ways that FMEAs can be done wrongly (mistakes made), and what are the leading factors that make for effective FMEAs (quality objectives)?

### Mistake #1

Based on empirical review of many FMEAs, some FMEAs do not recommend any action at all. Some FMEAs recommend mostly testing while others recommend ineffective action. It is important for FMEA teams to recommend actions that effectively and actively drive improvements to the design of the product or content of the manufacturing processes. The mistake is:

*Failure of the FMEA to drive design or process improvements.*

### Quality Objective #1

*The FMEA drives product design or process improvements as the primary objective.*

**Application Note** Quality and Reliability engineering have a multitude of tools to choose from in driving design or process improvements. It is important to use the FMEA “Recommended Actions” field to identify and execute best practice tools that can optimize designs. This is one of the reasons reliability or quality engineers need to participate in FMEAs. Chapter 7, Section 7.3 outlines many effective action strategies using the tools of quality and reliability.

**Example** A company that developed products under government regulation requested assistance in reviewing their FMEA process in order to improve the quality of the results. A review of actual FMEAs showed there were few recommended actions. When asked why so few recommended actions were included in the FMEAs, the answer was high Risk Priority Numbers (RPNs) and corresponding recommended actions often triggered negative responses from the government, and they needed to pass regulations. The company was informed the way they were doing FMEAs was a waste of time. The company changed the process to perform proper FMEAs with the objective to *improve* the safety and design of the equipment. Then, a document was prepared to *verify* that the equipment was fully safe and reliable, and to satisfy government regulatory requirements.

**How to Audit** Look at the recommended actions and observe whether or not most of them drive design improvements (in the case of a System or Design FMEA) or process improvements (in the case of a Process FMEA). Talk with the team to ensure focus was on improvements to design or process.

### Mistake #2

There are various methods the FMEA team can use to identify which failure modes and which causes require follow-up action. Some companies set predetermined risk criteria; others review RPNs or Criticality using methods such as Pareto-type

techniques. Whichever method used, failure to address *all* high-risk failure modes (including high severity) can result in potentially catastrophic problems or lower customer satisfaction. The mistake is:

*Failure of the FMEA to address all high-risk failure modes.*

### **Quality Objective #2**

*The FMEA addresses all high-risk failure modes with effective and executable action plans.*

**Application Note** The emphasis on this Quality Objective ensures that all of the high-risk failure modes/causes are adequately addressed with effective actions, including both high severity and high RPN issues. The key is *effective* actions that reduce or eliminate the risk.

**Example** A company that uses glass in a complex system was developing a new device with new application of existing technology. The FMEA was nearly done, and upon review, the facilitator asked if all of the major concerns had been identified. There was one concern, omitted from the FMEA, relating to gas bubbles in the fabrication of the glass that the subject-matter experts knew would be present and that was high risk. The reason for the omission was that even though they knew it would occur, no one had a solution. Fortunately, the FMEA facilitator did the right thing and got the team to include the high-risk failure mode in the FMEA, and the team subsequently generated a series of recommended actions, including enlisting outside technical support.

**How to Audit** Review high severity and high RPN issues to see if the corresponding recommended actions are adequate to reduce risk to an acceptable level. Talk with the team to ensure they are satisfied all high risk is addressed and no important concerns are left unaddressed. One way to do this is to ask the subject-matter experts for their two or three biggest concerns on the project, and then to verify that these concerns are adequately addressed in the body of the FMEA.

### **Mistake #3**

Some companies miss the opportunity to improve Design Verification Plans (DVPs) or Process Control Plans (PCPs) based on the failure modes/causes from the FMEA. Some FMEA teams do not include knowledgeable representatives from the test or analysis departments. The result is inadequate design verification testing or PCPs. The mistake is:

*Failure of the FMEA to improve Test/Control Plans.*

### **Quality Objective #3**

*The Design Verification Plan (DVP) or the Process Control Plan (PCP) considers the failure modes from the FMEA.*

**Application Note** The FMEA team will often discover failure modes/causes not adequately addressed in the test plans/procedures or included in the PCPs. The key is to ensure the DVP or the PCP is impacted by the results of the FMEA. This is best accomplished by including test/control membership on the FMEA team and through well-written actions.

**Example** A test laboratory in a large original equipment manufacturer (OEM) conducted testing on subsystem X that passed each year. Yet, there continued to be field problems with subsystem X. The test group was part of the engineering department and the warranty group was in an entirely different department. Neither one talked to the other year after year. One day, the engineering department began doing FMEAs and the FMEA team for subsystem X asked why the current tests always passed in spite of field failures. The test procedures were revised to detect the causes from the FMEAs so that subsystem X tests began to fail, revealing needed design changes that ended up greatly reducing warranty.

**How to Audit** Review the recommended actions to see if there are improvements to the Design Verification Plans or procedures, or the Process Control Plans, based on risk associated with current detection controls. Talk with the team to determine if they had adequate representation from testing and if the FMEA benefited from the testing experience, and to learn whether the test regimens were improved if the current detection controls were not adequate.

#### Mistake #4

Empirical data show that at least 50% of field problems can occur at interfaces or integration with the system. Some companies focus on part or subsystem failures and miss the interfaces. The mistake is:

*Not including interfaces or integration in FMEA.*

#### Quality Objective #4

*The FMEA scope includes integration and interface failure modes in both block diagram and analysis.*

**Application Note** Interfaces can be included as part of the system hierarchy (Subsystem A, Subsystem B, Interface Subsystem A-B, etc.) or as separate functions in the function listing (Function A, Function B, Function A-B, etc.) The FMEA Block Diagram must clearly show the interfaces that are part of the FMEA scope.

**Example** A generator in an automobile was noisy by actual noise measurements in vehicle testing. A previous FMEA on the generator revealed no issue with noise. Pulling the generator and thoroughly testing and analyzing it showed no noise problems. It was revealed the bracket that secured the generator to the engine frame was faulty. The bracket was an interface between the generator and the engine frame. It is essential that interfaces be included in FMEA analyses.

**How to Audit** Review items, functions, failure modes, and other portions of the FMEA to ensure that interface and integration issues were taken up and addressed within the scope of the FMEA. Look at the FMEA Block Diagram to verify. Talk with the team, inquire how they ensured no interface issues were missed.

### Mistake #5

Fool me once, shame on you. Fool me twice, shame on me.

—English Proverb

Some companies provide no linkage between FMEAs and field data. It takes concerted effort to integrate problem resolution databases with FMEA. Otherwise, serious problems can repeat. The mistake is:

*Disconnect between FMEA and information from the field.*

### Quality Objective #5

*The FMEA considers all major “lessons learned” (such as high warranty and campaigns) as input to failure mode identification.*

**Application Note** Field failure data can be brought into generic FMEAs on a regular basis. As covered in Chapter 11, Section 11.3.2, generic FMEAs contain both *historical* (empirical) and *potential* failure modes, causes, controls, and so on. They are done at the generic level of the system, subsystem, or component, not at the program-specific level. New project FMEAs can begin with the generic FMEA information, thus benefiting from the field failure data, and proceed with appropriate changes and modifications to complete the FMEA. If generic FMEAs are not used, new FMEAs should be seeded with potential field problems and be required to show how they will not repeat in the new design/process. It is vital to hold the FMEA team responsible to ensure that major field problems do not repeat. One other application point: field data can be “noisy,” in that the data often do not provide actual failure mode or cause verbiage. The reason is field warranty systems are usually set up to provide warranty reimbursement for dealers and not identify root causes of failures. It takes conscious effort by the engineering team to turn noisy field data into useable input for FMEAs.

**Example** In one automotive company, in the 1980s, there was a major hood secondary latch bracket recall costing millions of dollars. The root cause was fatigue cracking of the bracket. The problem was resolved with an improved bracket design. However, this problem and its solution were never recorded in a field problem database from which future program design engineers could easily retrieve and use the information. A few years later, the same problem occurred on a hood secondary latch on a different vehicle program, and a second, more expensive recall occurred. At this point, the company decided to use FMEAs as the mechanism to prevent field problem recurrences. All future FMEAs were required to include past field problems as failure modes/causes on FMEAs for similar designs, with the FMEA team held accountable to ensure that problems did not recur.

**How to Audit** Review failure modes and causes to ensure that they contain supplemental field failure data. Preferably, there is a visual way to see which failure modes are from field information and how they are addressed. Talk with the FMEA team to ensure that the FMEA benefited from field lessons learned and that high-risk issues from the field will not be repeated.

### Mistake #6

Size isn't everything. The whale is endangered, while the ant continues to do just fine.  
—Bill Vaughan

Some FMEAs go into too much detail in the analysis, which makes it difficult to focus on areas of higher risk, “missing the forest for the trees.” Some FMEAs go into too little detail, which makes it difficult to determine root cause and effective corrective actions. The mistake is:

*Wrong level of detail in the analysis.*

### Quality Objective #6

*The FMEA provides the correct level of detail in order to get to root causes and effective actions.*

**Application Note** Good FMEA facilitation keeps the team focused on areas of risk that lead to root causes and effective corrective actions. FMEA discussion should be limited to areas of concern by the team members and avoid lengthy discussions on low-risk issues. In other words, the higher the risk the more important and in depth should be the discussion. Lower risk issues should receive less, but appropriate discussion.

**Example** A vehicle integrator was developing a new transmission with new technology and new applications of existing technology. They requested help with their reliability program. Even though product launch was only a few months away, the System FMEA was only a third completed, and was already over 400 pages long. This company had used automated FMEA software that generated functions from requirements and failure modes from functions. There are three problems with this approach: (1) lack of adequate subject-matter expert involvement, (2) functions included that are trivial to the primary performance objectives of the system, and (3) failure modes generated that are of no concern to the FMEA team. This approach to FMEA is a waste of time and money.

**How to Audit** Verify that the level of detail on higher risk issues is adequate to fully understand root causes and develop effective corrective actions. Review the different columns of the FMEA to see if the overall level of detail is proper and adequate. Too much detail shows up as endless pages of FMEA material, including areas that no one on the FMEA team is concerned about; too little detail shows up as underdefined functions, failure modes, effects, causes or controls, or as areas of unaddressed concern from one or more FMEA team members. Talk with the FMEA

team to determine how they addressed the level of detail and ensured all concerns were included in the scope of the FMEA project.

### Mistake #7

Many companies are late to perform FMEAs, reducing their effectiveness. FMEAs should be completed by design or process freeze dates, concurrent with the design process. This very common problem greatly reduces the effectiveness of the FMEAs. The mistake is:

*Performing FMEAs late.*

### Quality Objective #7

*The FMEA is completed during the “window of opportunity,” from where it can most effectively influence the product or process design.*

**Application Note** Crucial to getting FMEAs done on time is to start the FMEAs on time, that is, as soon as the design or process concept has been determined. The exception is FMEAs done in support of concept alternative studies—these should, of course, be started earlier.

**Example** An executive in a computer manufacturing company heard about FMEA and wanted to use this tool on a new line of computers almost ready to launch. Because the equipment had already been designed and was mostly tested, the objective of this FMEA was to find any unnoticed major problems. The resulting value of the FMEA was much lower than if it had been done before the design and testing were completed, as the FMEA team was by that time hesitant to recommend design changes or test improvements.

**How to Audit** Review the timing of the FMEA project against the product development process timing gates. Verify the FMEA was started and completed in the proper time frame for ensuring maximum value.

### Mistake #8

Some FMEA teams do not have the right experts on the core team. Some FMEA teams do not have good attendance. Some FMEA team members just sit in their chairs not contributing to team synergy. The mistake is:

*FMEAs with inadequate team composition and lack of participation.*

### Quality Objective #8

*The right people, adequately trained in the procedure, participate in the FMEA team throughout the analysis.*

**Application Note** Based on an actual survey, design engineers believe FMEAs are too important not to do, but too time consuming to participate in. The FMEA

facilitator must value the time of team members and not waste it. FMEAs must be done by properly constituted teams. There are many reasons for this. One is that individual people have blind spots, and because of this can miss seeing important faults or design deficiencies. Formation of teams helps overcome blind spots by contributions of team members through their different viewpoints, allowing more thorough examination of the data. Another is that the information necessary to fully understand failure modes and their respective causes cross many disciplines. It is key to encourage the people who are knowledgeable and experienced in potential failures and their resolutions to actually arrive at the meetings. Attendance often takes management support. Team size is best between four and eight people. If the team gets too large, consider breaking into additional smaller FMEAs.

**Example** A common practice at one military supplier was to have the reliability engineer do the FMEAs by sitting in front of each system or design engineer separately, one by one, and fill out the form. Even if the reliability engineer talked individually with *all* of the correct FMEA team members (which was not done in this example), the quality of the FMEA would still be lacking. One of the leading values of an FMEA is the synergy and cross talk by the various team members, to be certain that all of the right information is included, and nothing is missed.

**How to Audit** Review the FMEA team membership roster to ensure that there was adequate representation from the various disciplines needed based on the type of FMEA and the scope of the project. Check FMEA team meeting records to ensure attendance was adequate at each meeting. Talk with the individual team members to see if their input was elicited in the decisions.

### Mistake #9

There are hundreds of ways to do FMEAs incorrectly. Some companies do not encourage or control proper FMEA procedure. Training, coaching, and reviews are all necessary to success. The mistake is:

*FMEAs with improper procedure.*

### Quality Objective #9

*The FMEA document is completed “by the book,” including “Action Taken” and final risk assessment.*

**Application Note** The FMEA team must have a solid understanding of the basics of FMEAs, including the definitions and applications. One common problem is not getting to the root cause of failure modes. Expert input is necessary. Follow-up actions based on poorly defined causes will not effectively resolve the problem and the FMEA will not be successful. Another common problem is lack of follow-up to ensure execution of the FMEA recommended actions and that risk is reduced to an acceptable level. This is a broad quality objective to ensure that the entire FMEA worksheet is done completely and properly.

**Example** A vehicle manufacturing company did FMEAs up to recommended actions, and then filed them. In this instance, it was thought the primary purpose was to fill out the FMEA form. This is the wrong purpose for conducting FMEAs and provides little or no real value. The value of the FMEA is in the open dialog by subject-matter experts leading to specific changes in design, evaluation and/or manufacturing process, and the *execution* of the recommendations. If the recommended changes are done but are not recorded, the company may be legally vulnerable. If the recommended changes are not done, risk is not reduced to an acceptable level.

**How to Audit** Look at the FMEA to see if the various columns were properly filled out and that FMEA best practice procedure was followed. Talk with the FMEA team to ensure they rigorously followed FMEA guidelines and practices.

### Mistake #10

Some companies mandate FMEAs and then do not ensure that the time is well spent. Preparation work must be completed, meetings must be well run, and there must be efficient follow-up of high-risk issues. Ask the FMEA team if its time has been well spent and take action to address shortcomings. The mistake is:

*Inefficient use of time.*

### Quality Objective #10

*Time spent by the FMEA team is an effective and efficient use of time with a value-added result.*

**Application Note** If this Quality Objective is met, future FMEA meetings will be well attended and supported by subject-matter experts and management. Conversely, if subject-matter expert time is wasted, it will be very difficult to get attendance at future meetings.

**Example** In an FMEA audit, the auditor asked the FMEA team members what they thought of the value of doing that particular FMEA. The FMEA had looked reasonably good in terms of completion, but the auditor wanted to find out if the individual team members thought their time was well spent in terms of what was learned from the FMEA exercise. The answer from some team members revealed they thought their time was wasted. The auditor found that the FMEA facilitator did not do the FMEA preparation steps very well and the FMEA team members had to wait more than once for information to be gathered that should have been prepared before the meetings began. These team members thought they had little reason to show up for the next FMEA.

**How to Audit** Talk with the FMEA team to see if each member believes his time was well spent and a value-added result was achieved. If any issues arise, find out why.

## 9.2 SUMMARY OF FMEA QUALITY OBJECTIVES

The above 10 common FMEA mistakes and corresponding quality objectives resulted from years of experience with hundreds of companies and have since been taught in FMEA tutorials and seminars for many years. Summarized, they are:

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 and campaigns) as input to failure mode identification.
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” from where 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.

The FMEA Quality Objectives should be integrated into FMEA team training and reviewed at each stage of FMEA project completion. It is suggested that FMEAs not be considered completed until all of the quality objectives have been met. They are an essential part of quality audits.

## 9.3 FMEA QUALITY AUDIT PROCEDURE

The FMEA quality audit procedure is an essential part of ensuring good quality FMEAs. FMEA quality audits are in-person audits of completed (or nearly completed) FMEAs, done with the FMEA facilitator and the FMEA core team present. The audit can be done on a prescheduled or random basis. Someone who is skilled and experienced with the content and quality of good FMEAs performs the audit, from either management or an FMEA subject matter-expert. Here is the procedure.

Each of the 10 FMEA Quality Objectives have a corresponding “How to audit” recommendation. In a nutshell, an FMEA subject-matter expert or management person reviews the FMEA results with the FMEA team against each of the FMEA Quality Objectives, one by one, using the “How to audit” recommendation. Each

quality objective is evaluated for how well it is achieved. This evaluation can be done on a yes/no basis or a variable evaluation, such as high, medium, or low. The estimated time is 1 hour for this audit, about 5 minutes per FMEA Quality Objective. The results of the audit provide valuable feedback to improve future FMEAs. The focus is on improving the FMEA process, not on the person or team doing the FMEA. The auditor is looking for specific process-related issues that underlie deficiencies in achieving the quality objectives, such as lack of training, procedure, facilitation skills, standards, resources, and support. Action items from the FMEA quality audit should be documented and pursued to improve the overall FMEA process. Do not expect to achieve all 10 FMEA quality objectives instantly. Rather, work to maintain steady improvement.

#### 9.4 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

##### **Practice Audit 9.1**

###### **Evaluating the Quality of the Bicycle Brake Cable Case Study**

Figure 9.1, showing the All-Terrain Brake Cable Design FMEA, includes errors that are specifically for instructional purposes. Study this FMEA and evaluate it against the first three FMEA Quality Objectives.

*Student Exercise*

**FMEA Quality Objective #1:** “The FMEA drives product or process design improvements as the primary objective.”

Student reviews the All-Terrain Brake Cable Design FMEA against the first quality objective and determines how well it is met and why.

*Student Exercise*

**FMEA Quality Objective #2:** “The FMEA addresses all high severity and high RPN failure modes and their causes, as identified by the FMEA team, with executable action plans.”

Student reviews the All-Terrain Brake Cable Design FMEA against the second quality objective and determines how well it is met and why.

*Student Exercise*

**FMEA Quality Objective #3:** “The Test Plan or the PCP considers the failure modes from the FMEA.”

Student reviews the All-Terrain Brake Cable Design FMEA against the third quality objective and determines how well it is met and why.

##### **Practice Audit 9.2**

###### **Evaluating the Quality of the Bicycle Hand Brake Case Study**

Figure 9.2 is a Design FMEA on a Bicycle Hand Brake Subsystem. It has been selectively modified with errors for evaluation of the ten FMEA Quality Objectives. The FMEA team is made up of a bicycle design engineer and a bicycle test engineer,

**Item: Bicycle Brake Cable**

Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) of Failure	OCC	Current Design Controls (Prevention)	Current Design Controls (Detection)	DET	RPN	Recommended Actions
The brake cable provides adjustable and calibrated movement between the brake lever and brake caliper under specified conditions of use and operating environment.	Cable breaks	Operator is unable to close brake calipers, wheel does not slow down, possibly resulting in accident.	Corrosion of cable wiring due to wrong material selected	5	Cable material selection based on ANSI Standard #ABC.	Cable strength test #456	4	200	Perform a thorough review of cable material alternatives, including corrosion resistance.
			Fatigue cracks in cable wiring due to inadequate cable thickness	2	Finite Element Analysis of all new cable material	All testing samples undergo laboratory analysis for fatigue cracks at regular intervals per test regimen #456	2	40	Conduct Design of Experiments to optimize cable material and cross section for maximum corrosion resistance.

TRUNCATED

**FIGURE 9.1** Excerpt from All-Terrain Brake Cable Design FMEA—for instructional purposes (with errors introduced for FMEA Quality Objectives evaluation).

### Item: Bicycle Hand Brake Subsystem

Item/Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Classification	Potential Cause(s) of Failure	occ	Current Design Controls (Prevention)			Current Design Controls (Detection)			DET RPN	Recommended Actions	Responsibility and Target Completion Date	Action Results			
							Actions Taken and Effective Date		SEV	OCC	DET	RPN				Actions Taken and Effective Date	SEV	OCC	DET RPN
Provide the correct level of friction between brake pad assembly and wheel rim to safely stop bicycle in the required distance, under all operating conditions.	Insufficient friction delivered by hand brake subsystem between brake pads and wheels during heavy rain conditions.	Bicycle wheel does not slow down when the brake lever is pulled potentially resulting in accident.	10	Cable Binds due to inadequate lubrication or poor routing	4	Design review of brake system	Bicycle system durability test # 789	2	80	Modify bicycle durability testing to include periodic brake cable checks for binding									
		External foreign material reduces friction	2							3	60	Modify bicycle durability testing to include foreign material (dust, leaves, etc.) at interface of brake pad and wheel rim							
		Cable breaks	6	Cable material selection based on ANSI #ABC.			Bicycle material durability test # 789			4	240	1. Require cable DFMEA and PFMEA from cable supplier approved by All-Terrain FMEA team. 2. Based on results of Cable DFMEA, develop cable strength test							
		Brake Lever breaks	1	Design review of brake system			Bicycle system durability test # 789			1	10								
		Selected brake pad material does not apply required friction to wheel	2							2	40	Add bench test to evaluate adequate brake pad friction							
		Brake system does not stop bicycle in required distance or is erratic, potentially resulting in accident.	10	Brake cable mis-adjusted by user	6					5	300	1. Develop new brake cable adjustment test that identifies mis-adjustment problems 2. Revise bicycle durability test regimen to periodically check for brake cable, pad, and lever misadjustment							
		Brake becomes mis-adjusted due to failure of interaction/interface between brake cable assy., brake pad assy. and/or wheel assy.					Brake pad mis-adjusted by user	1	Design review of brake system durability test # 789		1	10							
							Brake lever mis-adjusted by user	1	Design review of brake system durability test # 789		2	20							

TRUNCATED

**FIGURE 9.2** Excerpt from Hand Brake Subsystem Design FMEA—for instructional purposes (with errors introduced for FMEA Quality Objectives evaluation).

in support of a new all-terrain bicycle due to be launched soon. The FMEA was completed 4 weeks after design freeze, after testing had begun. For each of the 10 exercises, note how well the quality objective was achieved in the FMEA and why.

*Student Exercise: Quality Objective #1*

Review Figure 9.2 to assess how well it achieves the FMEA Quality Objective #1: *The FMEA drives product design or process improvements as the primary objective.* Make note of how well this objective was achieved. Explain.

*Student Exercise: Quality Objective #2*

Review Figure 9.2 to assess how well it achieves the FMEA Quality Objective #2: *The FMEA addresses all high-risk failure modes with effective and executable action plans.* Make note of how well this objective was achieved. Explain.

*Student Exercise: Quality Objective #3*

Review Figure 9.2 to assess how well it achieves the FMEA Quality Objective #3: *The Design Verification Plan (DVP) or the Process Control Plan (PCP) considers the failure modes from the FMEA.* Make note of how well this objective was achieved. Explain.

*Student Exercise: Quality Objective #4*

Review Figure 9.2 to assess how well it achieves the FMEA Quality Objective #4: *The FMEA scope includes integration and interface failure modes in both block diagram and analysis.* Make note of how well this objective was achieved. Explain.

*Student Exercise: Quality Objective #5*

Review Figure 9.2 to assess how well it achieves the FMEA Quality Objective #5: *The FMEA considers all major “lessons learned” (such as high warranty and campaigns) as input to failure mode identification.* Make note of how well this objective was achieved. Explain.

*Student Exercise: Quality Objective #6*

Review Figure 9.2 to assess how well it achieves the FMEA Quality Objective #6: *The FMEA provides the correct level of detail in order to get to root causes and effective actions.* Make note of how well this objective was achieved. Explain.

*Student Exercise: Quality Objective #7*

Review Figure 9.2 to assess how well it achieves the FMEA Quality Objective #7: *The FMEA is completed during the “window of opportunity” from where it can most effectively influence the product or process design.* Make note of how well this objective was achieved. Explain.

*Student Exercise: Quality Objective #8*

Review Figure 9.2 to assess how well it achieves the FMEA Quality Objective #8: *The right people are adequately trained in the procedure and participate on the*

*FMEA team throughout the analysis.* Make note of how well this objective was achieved. Explain.

*Student Exercise: Quality Objective #9*

Review Figure 9.2 to assess how well it achieves the FMEA Quality Objective #9: *The FMEA document is completely filled out “by the book,” including “Action Taken” and final risk assessment.* Make note of how well this objective was achieved. Explain.

*Student Exercise: Quality Objective #10*

Review Figure 9.2 to assess how well it achieves the FMEA Quality Objective #10: *The time spent by the FMEA team is an effective and efficient use of time with a value-added result.* Make note of how this objective can be evaluated.

# *Chapter* 10

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## *How to Facilitate Successful FMEA Projects*

The way a team plays as a whole determines its success. You may have the greatest bunch of individual stars in the world, but if they don't play together, the club won't be worth a dime.

—Babe Ruth

### **IN THIS CHAPTER**

Failure Mode and Effects Analysis (FMEA) teams need the leadership of someone who is skilled in team leadership and facilitation. This chapter outlines the primary FMEA facilitation skills that ensure success in FMEA applications as well as the central elements for conducting effective meetings. Included in this chapter are techniques to resolve difficult facilitation problems and maximize team creativity. The chapter also outlines the unique roles and responsibilities of the FMEA facilitator in performing each of the steps of the FMEA procedure.

#### **10.1 FMEA FACILITATION**

One of the main factors for successful application of FMEAs is proper facilitation of the FMEA process, including FMEA team meetings. The skills associated with excellent facilitation are different from the skills associated with participating in FMEAs as a team member. This chapter is divided into two sections. The first section

teaches the primary skills associated with excellent facilitation. The second section outlines the specific roles and responsibilities of an FMEA facilitator.

Before discussing general facilitation skills, the terms *facilitator* and *FMEA facilitator* need defining.

A *facilitator* is “one who contributes structure and process to interactions so groups are able to function effectively and make high quality decisions; a helper and enabler whose goal is to support others as they achieve exceptional performance.”<sup>[1]</sup> In order to do this, a facilitator needs to support team members to do their best thinking. The facilitator also helps team members come to useful decisions and sort the insignificant input from those inputs that affect customer expectations, experience, and/or safety. Overall, the role of the facilitator is to move the team through the process and achieve a value-added result.

An *FMEA facilitator* is a person trained in both FMEA procedures and facilitation techniques, who leads an FMEA team to successful completion of FMEA project, with associated risk reduced to an acceptable level.

Why is FMEA facilitation Important? The simple fact is most FMEA teams will not achieve a high-quality result without expert facilitation.

The facilitator is not a passive position but a proactive role also encompassing general leadership skills. Some companies have tried introducing FMEA facilitators in a passive or “neutral” role, not offering their own expertise or opinions concerning the content of the FMEA. Best practice is the FMEA team led by a trained and experienced facilitator who *also* brings his or her own subject-matter expertise to the meetings. For example, the FMEA facilitator might be a reliability or quality engineer; in addition to facilitating the FMEA process and the team meetings, this person also brings reliability or quality expertise to the meetings and has opinions to offer on the content of the FMEA. In order to perform these dual roles, the facilitator must be well skilled in facilitation techniques.

## 10.2 EFFECTIVE MEETINGS

FMEA facilitators must be able to run effective meetings. Some of the characteristics of well-run meetings include<sup>[1]</sup>:

1. Starting and ending meetings on time
2. Publishing and sticking to agendas
3. Developing and getting agreement on meeting “Norms”
4. Always maintaining focus on the meeting objectives
5. Summarizing results and follow-up actions at end of meeting
6. Preparing required documents, visuals, network access, software, and so on
7. Ensuring decision-making options are clear (see Section 10.3.6, “Making Decisions”)
8. Encouraging healthy member behaviors (see Section 10.3.7, “Conflict Management”)
9. Providing periodic process checks
10. Implementing a process to create true closure
11. Providing detailed minutes and specific follow-up plans

Meeting “Norms” are agreed-upon behaviors by meeting participants. They need to be developed by the team or the company. The FMEA team can use predetermined templates and develop company-specific guidelines. Below is an example of what comprises a set of meeting “Norms.”

It is expected that each meeting participant:

1. Arrives to meetings promptly as scheduled
2. Respects others’ opinions
3. Debates differences of opinion calmly
4. Takes responsibility for assigned actions
5. Listens carefully to all ideas
6. Avoids doing e-mails, using cell phones, or other personal devices during meeting time
7. Maintains focus on the agenda
8. Uses “Parking Lot” if a topic is off agenda\*
9. Provides constructive feedback
10. Maintains equal opportunity for participation by all team members
11. Engages in no “war stories” or side conversations

### **10.3 PRIMARY FMEA FACILITATION SKILLS**

Interdependent people combine their own efforts with the efforts of others to achieve their greatest success.

—Stephen Covey

There are specific facilitation skills for any aspiring facilitator to learn. The following are some of the primary facilitation skills he or she should master in order to effectively facilitate FMEA meetings to the desired results.

#### **10.3.1 Brainstorming**

The mere formulation of a problem is far more essential than its solution, which may be merely a matter of mathematical or experimental skills. To raise new questions, new possibilities, to regard old problems from a new angle, requires creative imagination and marks real advances in science.

—Albert Einstein

Brainstorming is a technique for getting a flow of ideas on the table before making decisions. This technique is most useful when a decision or solution is not easily forthcoming. The purpose of brainstorming is to allow people to “put ideas on the table without fear of being corrected or challenged. It separates the creation of ideas

\* “Parking Lot” refers to a list of issues maintained by the facilitator that are not directly concerned with the agenda, but should be pursued in another venue.

from the evaluation activity.”<sup>[1]</sup> The outcome of brainstorming is a list of creative ideas involving the entire team.

The rules of brainstorming include<sup>[1]</sup>:

1. Let ideas flow freely.
2. Defer evaluation of ideas until later.
3. Build on ideas of others.
4. Nurture creativity.
5. Defer debates.
6. Everyone participates.
7. Think “out of the box.”
8. Keep discussions moving.

Here is an example of the power of brainstorming. General Motors (GM), in the late 1980s, held in their large auditorium a lunchtime demonstration of *Odyssey of the Mind*, a science and creativity program for school-age children sponsored in part by National Aeronautics and Space Administration. At the front of the auditorium were two tables with video-mounted cameras above the tables and presented on large screens. At one of the tables was a small group of high school students from a local chapter of *Odyssey of the Mind*. At the other table was a group of experienced (20 years or more) engineers from GM. Each team had 8 minutes to solve a creativity problem and demonstrate the solution on the table for the audience to see. The details of the problem were not important. What was important was that the students *creatively* solved the problem faster and better than the experienced engineers did. Before beginning the actual work on the task, the students brainstormed ideas to arrive at the best solution. The experienced engineers did not brainstorm, but immediately began working on the task.

When properly used, brainstorming can infuse creativity into the FMEA process and support high-quality results.

### **10.3.2 Asking Probing Questions**

He who asks a question is a fool for five minutes; he who does not ask a question remains a fool forever.

—Chinese Proverb

Effective questioning is a key facilitation technique. The FMEA facilitator can direct questions to an individual (expert) or the group to stimulate thinking. This facilitation technique is used to open up discussion and to bring it to a deeper level. Avoid “yes” or “no” questions which serve to close off the discussion rather than opening to more creative ideas. Here are a few examples of probing questions.

1. How would you describe the current situation regarding . . .?
2. What has been done in the past regarding . . .?
3. What has worked/not worked regarding . . .?
4. What would have to happen for this problem to be completely solved?
5. What do you (a team member) think of (another team member’s) idea?

### 10.3.3 Encouraging Participation

If a man does not keep pace with his companions, perhaps it is because he hears a different drummer. Let him step to the music he hears, however measured or far away.

—Henry David Thoreau

The facilitator must create the environment that encourages *all* of the team members to express their thoughts, ideas, and experiences. Assuming the FMEA team is made up of the correct team members who represent the needed disciplines, the most important tool in successful facilitation is gaining a balanced involvement and participation from each and every team member. In order to encourage participation from the entire FMEA team, it is helpful for the facilitator to understand personality types. There are many different personality types but two of the most common types are extroverts and introverts. Extroverts are more likely to talk in team meetings than introverts are, but their contributions are no more important. Introverts tend to do less talking in team meetings, but their contributions are no less important.

When there is an imbalance in participation, it may be necessary for the FMEA facilitator to moderate the input from team participants who tend to be extroverted if they begin to dominate the dialog. This needs to be done in a respectful way, without discouraging their input. While moderating the input from extroverts, it may be necessary for the FMEA facilitator to draw out the input from team participants who tend to be introverts if they are not contributing sufficiently. Again, this must be done in a respectful manner. It is the challenge of the FMEA facilitator to encourage and elicit equal participation from every team member, regardless of personality type.

### 10.3.4 Active Listening

Seek first to understand, then to be understood.

—Stephen Covey

A good listener tries to understand thoroughly what the other person is saying. In the end, the listener may disagree sharply, but before voicing disagreement, the active listener wants to know exactly what the other person is saying and why. Active, effective listening is a habit, as well as the foundation of effective communication. A good listener is able to repeat in his own words what another person has said, satisfying the person that he was understood. This does not mean agreeing with what the other person is saying. Ask clarifying questions in order to ensure full understanding of the other person's intention. Management consultant Peter Drucker says, "The most important thing in communication is hearing what isn't said."

### 10.3.5 Controlling Discussion

It was impossible to get a conversation going, everybody was talking too much.

—Yogi Berra

A facilitator must know how to encourage discussion, how to limit discussion, and when to switch gears. Some facilitators use time limits. Some set benchmarks for

the level of detail. Learn to gauge when discussion is fruitful and when it has gone on too long.

A common problem in meetings is participants going off topic into their personal “war stories.” A “war story” is a colloquial term that refers to personal anecdotes that may be interesting or entertaining but are not essential to the meeting topic. They distract the team, lengthen the meetings, and should be discouraged.

Side conversations—two or more meeting participants engaging in conversation not intended for the entire group—must be controlled. One technique is for the facilitator to ask the person if the conversation is relevant to the meeting topic and if so, to share it with the group. If it is not, and the behavior continues, the facilitator should refer to the meeting “norms.”

In some groups, one or two members tend to dominate the discussion. The reason for this could be an extroverted talkative member or someone with an agenda to influence the meeting outcome. The facilitator must not allow a small portion of the group to dominate the discussion, but should refer the person to the meeting “norms” in order to ensure balanced participation by all group members.

It is essential to keep the team focused on the tasks and refer the team to meeting norms whenever discussion is off topic or distracting, or when someone is dominating the meeting.

### 10.3.6 Making Decisions

A genuine leader is not a searcher for consensus but a molder of consensus.

—Martin Luther King

Teams can come together and make important decisions in many different ways. The most common decision making techniques are covered below.<sup>[1]</sup>

*Spontaneous agreement* means the team comes together quickly and without a need for lengthy discussion. If this happens, it is perfectly fine as long as there are no disagreements or concerns by any of the team members and care is taken to ensure nothing is left uncovered.

*One person deciding* is autocratic, which has no place in FMEA team meetings.

*Compromise* means listening and understanding differing ideas, and then making modifications to find a middle ground. Each side makes concessions. It is one of the more popular methods for reaching team agreement, but this practice has many pitfalls when applied to FMEA teams. Compromise can result in a substandard result. For example, if there are two good (but different) ideas under discussion for an FMEA recommended action, a compromise may end up diluting both ideas into a solution that does not work very well. Another example is a good proposal and one that is ineffective. Compromise can render the good proposal unworkable.

*Majority voting* is when the team votes, for example, on a risk ranking or a particular solution, and chooses the solution with the most team votes. This is not a good technique for effective FMEAs because the FMEA team is composed of subject matter experts, each of whom has viewpoints and opinions that are essential to the proper outcome of the FMEA. One person may have critical (and valid) views on a topic being discussed, and can be easily overruled by the majority of other team members, with suboptimum results.

*Consensus building* is the best practice for all of the FMEA team decisions. This means the FMEA team takes the time to understand all sides of an issue and finds a solution or determines a course of action that is supported by all team members. Facilitating is a consensual activity. The hallmarks of a good consensus process include<sup>[1]</sup>:

1. Many ideas are shared.
2. Discussion is based on facts.
3. Everyone is heard.
4. There is active listening, clarification, building of ideas.
5. No one pushes a predetermined solution.
6. Team is satisfied with final solution.

This question embodies the key to good team decisions: “Have we gotten to a well-thought-out solution that we all concur is the best possible and that everyone on the team can commit to implement?”

### 10.3.7 Conflict Management

Honest disagreement is often a good sign of progress.

—Gandhi

Conflicts are bound to arise from time to time. They can actually be positive and beneficial. An absence of any expressions of disagreement or conflict may indicate a problem in adequacy or quality of facilitation. Facilitators should not be afraid of conflict, but should learn the value of disagreements and how to manage them. Understanding the difference between healthy debates and dysfunctional arguments is critical to good facilitation.

Healthy debates consist of these elements<sup>[1]</sup>:

1. Be open to hearing ideas from other people.
2. Listen and respond to ideas.
3. Understand other person’s point of view.
4. Stay objective and focused on facts.
5. Use a systematic approach in debating ideas.

Facilitators should use these elements to encourage healthy debates<sup>[1]</sup>:

1. Point out differences.
2. Assertively require that participants listen.
3. Use rules politely.
4. Focus on facts.
5. Invite feedback.
6. Control conversation.

Conflict Management Technique	Explanation
Avoiding conflict	Not dealing with conflict at all
Win/lose	Using force to make points
Compromising	Finding a middle ground
Collaborating	Working together to find the best possible solution

**FIGURE 10.1** Conflict management techniques.

There are effective and ineffective ways to manage conflict. Some facilitators use “Avoiding”—not dealing with conflict at all. It should rarely be used and only when situations are extreme and cannot be resolved during the meeting. Some facilitators use “Win/Lose”—using force to make points. This rarely works. Others use “Compromising”—finding a middle ground. This usually ends up with less than optimum solutions and should only be used when faced with polarizing and unworkable choices. The best method is “Collaborating”—people working together to find the best solution. Skilled facilitators prefer this approach.<sup>[1]</sup>

Figure 10.1 shows various conflict management techniques, along with a brief explanation and common results.

A good facilitator views conflicting opinions as a healthy way to bring out all sides of an issue. It is important for each team member to have a chance to discuss his/her viewpoints on any contentious issues. Here, the facilitator uses a combination of skills, such as probing questions, active listening, and consensus building. Firmly disallowing rude behavior or comments that demean character or personality is essential. If any behavior occurs that is not conducive to healthy discussions, the facilitator must immediately refer the offending person or the entire group to the meeting norms and insist adherence.

### 10.3.8 Facilitator Interventions

There are times when the facilitator should intervene in the flow of a meeting and reinforce good meeting etiquette. The following are examples<sup>[1]</sup>:

1. When someone is preoccupied, or not paying attention, the facilitator should tactfully engage the person in the meeting topics.
2. When two people are having a side conversation, the facilitator should respectfully request any side conversations cease.
3. When a team member is being rude or otherwise disrespectful to another team member, the facilitator must end the rude or disrespectful behavior, even if that means taking a break in the meeting.
4. When the meeting discussion is getting off track, the facilitator skillfully brings it back on track.
5. When people are violating any of the meeting norms, the facilitator should refer the offenders to the published (and agreed-upon) meeting norms and enforce them.

### 10.3.9 Managing Time

Is what I'm doing or about to do getting us closer to our objective?

—Robert Townsend

There are certain proven and essential elements of time management from an FMEA facilitator standpoint. These include:

1. Having agreed-upon objectives
2. Developing and adhering to a clear agenda
3. Keeping the meeting focused on *risk*
4. Avoiding discussion on topics or issues no one in the meeting is concerned about
5. Maintaining group “norms” of behavior
6. Managing the level of detail
7. Controlling discussions
8. Keeping the meeting moving forward

When all of these are applied to FMEA meetings, the FMEA team will accomplish its objectives more quickly and with a more effective result. Refer to Section 10.6 for ideas on how to reduce FMEA in-meeting time.

The facilitation skills covered above take time and practice to master. Leading and controlling teams does not come naturally to some people. Yet through diligence and willingness to step outside one's personal “comfort zone,” anyone can master these skills and successfully facilitate FMEAs to excellent results.

### 10.3.10 Common Facilitation Problems

Sometimes, in spite of the best intentions and training, facilitators run into difficulty getting the team on the right track. A few of the more troubling facilitation problems follow, with advice on how to remedy them. There are countless books and articles on facilitation skills, so this is by necessity an abbreviated summarization.

***The Team Has Difficulty Coming to Consensus*** As covered in the “Making Decisions” section above, team facilitation is a consensual activity, meaning that the team comes to a well-thought-out solution that all concur is the best possible under the circumstances, and that everyone on the team can commit to implement. If a facilitator is having difficulty bringing the team to consensus or the discussion is taking excessive time, refer to Section 10.7 for remedies.

***Someone Dominates the Meetings*** In spite of the best efforts of a team facilitator, sometimes there is one person who continues to dominate discussion. Of course, the facilitator should use the techniques covered above to limit discussion of an overly verbose team member and refer to the meeting norms. If the problem persists, here are a few possible remedies.

1. Ensure that every effort has been made to balance discussion according to the advices in the sections on encouraging participation and controlling discussion above and referring to meeting norms.

2. As facilitator, make sure that you understand the most recent point made by the person who is dominating the meeting discussion. Tell this person that you understand the point they are making and ask them to listen while other team members can provide their input to the discussion. If this does not remedy, take a break and talk over the problem with the person. Make sure they understand the need for balanced input from all meeting participants.
3. If all else fails, the person dominating the discussion will need to be replaced. The success of the FMEA depends on balanced input from all team members.

**No Effective Solution Is Forthcoming for a High-Risk Problem** As covered in Chapter 7, higher risk issues usually need more than one effective action to resolve and reduce risk. The facilitator must not allow the team to move onto another issue if the corrective actions for a high-risk issue are inadequate. Merely having a “solution” in the recommended actions column of the FMEA does not mean the team has done its job. For high-risk issues, the set of recommended actions must reduce the risk to an acceptable level. What, then, does the facilitator do if the team cannot find or develop solutions that are adequate to the task?

1. Be certain that the root cause for the high-risk issue has been correctly determined. Having a wrong or inadequately defined cause can obscure correct solutions.
2. Next, the facilitator needs to ensure the team agrees on the level of risk and the necessity for effective solutions. Merely placing ineffective verbiage in the recommended action column of the FMEA does not address the risk.
3. Begin using brainstorming techniques, as covered above, to find creative solutions to the problem being discussed.
4. Review the action strategies outlined in Chapter 7, Section 7.3, “Action Strategies to Reduce Risk,” with the FMEA team. Discuss which ones might be effective.
5. Review the resources from Chapter 7, Section 7.2.1, “Quality and Reliability Resources to Help Formulate FMEA Recommended Actions,” with the FMEA team. Discuss if any of these resources provide techniques or strategies that might be useful or effective.
6. If there are still no effective solutions to a high-risk issue, it is time to recognize the solution may not be in the room. The issue should be opened to subject-matter experts outside of the FMEA team, and possibly entirely outside the company. Consider academic or industry resources that specialize in specific failure mechanisms.
7. Bring the issue to management. Ensure they are engaged and understand the unresolved risk and the status of potential solutions.

**Ineffective or Weak Facilitation** Learning facilitation skills requires a combination of learning the various facilitation techniques in this book and learning how to lead groups of people. Group Leadership skills can be learned; however, the path for someone who has difficulty being assertive in front of a group of people is more challenging. Assertiveness and leadership skills take time to develop. Where facilitation students learn the facilitation techniques in this book and still have difficulty

leading FMEA teams, the following are suggestions to enhance their group leadership skills.

1. Review the facilitation techniques covered in this book to be sure they are well internalized and can be applied in theory.
2. Request help from fellow students or practitioners to role-play each of the facilitation techniques. The facilitation student needs to practice leading groups with various scenarios role-played by colleagues.
3. Identify which scenarios are most challenging to the facilitation student and which of those specific techniques should be further drilled and practiced.
4. Assign an experienced FMEA facilitator to team up with the facilitation student to colead a series of FMEA projects. Feedback will be important to identify areas of weakness for further practice.
5. Continue this process until the facilitation student gains confidence and is able to assertively and successfully lead FMEA teams and apply each of the facilitation techniques without difficulty.

### 10.3.11 Attitude

Attitude is a little thing that makes a big difference.

—Winston Churchill

Learning and applying facilitation skills can be greatly enhanced by having the right attitude. Attitude is “a predisposition or a tendency to respond positively or negatively towards a certain idea, object, person, or situation. Attitude influences an individual’s choice of action, and responses to challenges, incentives, and rewards.”<sup>[2]</sup> Being a good facilitator is a lot like being a good coach. In the sports analogy, if the team believes they can win, they will put forth greater effort and energy, and are more likely to be successful. When facilitating a team, the leader should direct the team in a positive and encouraging manner. For example, a team member might say, “We’ve always had that problem and we always will.” The facilitator (using active listening and showing the right attitude) can answer, “I understand it is a difficult problem. Let’s focus the team on solving this problem once and for all. Now, what can be done differently to solve the problem?” This is not to say that the facilitator does not recognize when a situation or problem is difficult or perceived to be intractable. Having the right attitude means the facilitator and the team know that every problem can be taken to root cause and solved, provided the correct resources and imaginative ideas are applied to the problem.

Part of having the right attitude is keeping the team energized. Even the best teams can have difficulty maintaining a positive focus on the difficult tasks inherent in FMEAs. The German philosopher Georg Hegel said, “Nothing great in the world has ever been accomplished without passion.” Passion, enthusiasm, humor, and commitment will help the team focus their energies and become more successful.

FMEA teams with the right attitude will more easily find root causes and develop effective actions in the shortest possible time, and the facilitator is the key person to make this happen.

## 10.4 UNLEASHING TEAM CREATIVITY

Creativity is an ability to respond adaptively to the needs for new approaches and new products.

—Frank Barron

There are many times in an FMEA project when it becomes essential to muster the creative forces of FMEA team members. Creativity is a developed talent, not a God-given talent, and a good facilitator can bring out the best creative thinking of the team to help face the most difficult and seemingly intractable problems.

What is creativity and how can an FMEA facilitator harness the power of creativity to solve seemingly unsolvable problems?

In her book, *Your Creative Brain: Seven Steps to Maximize Imagination, Productivity, and Innovation in Your Life*, Shelly Carson, Ph.D., talks about the important elements in the definition of creativity<sup>[3]</sup>:

Though philosophers and writers have come up with a number of definitions for *creative*, there are two elements to the definition that virtually all of us who study creativity agree need to be present in the creative idea or product. First, the creative idea or product needs to be *novel* or *original*, and second, it has to be *useful* or *adaptive* to at least a segment of the population. Note, for example, that the scribblings of a toddler who has just learned to hold a crayon are novel...but, as a product, they are not considered *useful* or *adaptive*.

The author goes on to say:

We are all creative. Creativity is the hallmark human capacity that has allowed us to survive thus far. Our brains are wired to be creative, and the only thing stopping you from expressing the creativity that is your birthright is your belief that there are creative people and uncreative people and that you fall in the second category.

The FMEA facilitator's job is to unleash the innate creativity of the FMEA team and focus it on the issues being analyzed.

There are two types of creative reasoning used in the creative problem-solving process. One is “divergent thinking” and the other is “convergent thinking”:

Divergent and convergent thinking skills are both important aspects of intelligence, problem solving and critical thinking. Bringing facts and data together from various sources and then applying logic and knowledge to solve problems, achieve objectives or make decisions is known as convergent-type thinking.

Divergent thinking is thinking outwards instead of inward. It is the ability to develop original and unique ideas and then come up with a problem solution or achieve an objective. Einstein was a strong divergent thinker. He asked simple questions and then did mental exercises to solve problems. For example, as a young man Einstein asked himself what it would be like to ride on a beam of light. It took him many years of thought experiments, however the answer helped him develop the special theory of relativity.<sup>[4]</sup>

Most problem solving uses convergent reasoning, and the FMEA procedure is well suited to utilize this form of team thinking. However, effective facilitation must also

use divergent reasoning to be successful in coming up with the most creative and innovative ideas and solutions.

“The goal of divergent thinking is to generate many different ideas about a topic in a short period of time. Divergent thinking typically occurs in a spontaneous, free-flowing manner, such that the ideas are generated in a random, unorganized fashion. Following divergent thinking, the ideas and information will be organized using convergent thinking; that is, putting the various ideas back together in some organized, structured way.”<sup>[5]</sup>

Both divergent and convergent thinking are necessary to harness the full creative potential of the FMEA team to solve difficult or persistent problems. The key is to use divergent thinking separately from convergent thinking. “Make lists of options first, judge them later.”<sup>[6]</sup>

### Divergent Thinking Guidelines

“Done correctly, divergent thinking is done without immediate judgment. Ideas are going to be judged, make no mistake. But not yet. . . . When you think divergently, follow these guidelines for best results.”<sup>[6]</sup> Figure 10.2 shares guidelines for thinking divergently.<sup>[6]</sup>

### Convergent Thinking Guidelines

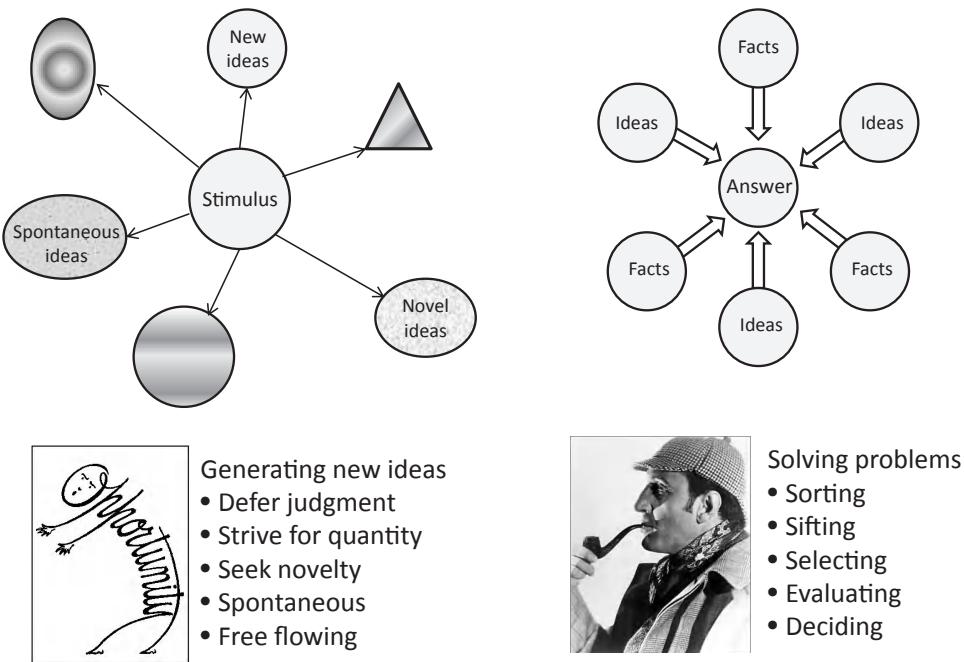
“Convergent thinking is sorting, sifting, selecting, evaluating, and deciding. . . . When you think convergently, follow these guidelines for best results.”<sup>[6]</sup> Figure 10.3 shares guidelines for thinking convergently.<sup>[6]</sup>

Defer judgment	This can be difficult, but try to resist your inclination to decide now whether an idea is good or not. Just record it.
Strive for quantity	The first ideas will likely be commonplace. Record them and keep going. Later ideas will tend to be more novel.
Seek novelty	If you are after creative solutions, you need to allow novel ideas to come out. Most will not work. That's OK.
Build and connect	Take ideas and build on them. Elaborate and extend. Connect the unconnected together.
Allow for incubation	Provide time to step away from the problem. Your mind will work on it without you, often to great benefit.

**FIGURE 10.2** Divergent thinking guidelines.

Apply affirmative judgment	Consider the good aspects of ideas, rather than finding only faults. Good ideas often get lost due to faults that could have been overcome.
Keep novelty alive	If you truly want creative solutions, don't immediately kill the novel ideas. Consider them carefully. Expand and improve them. Nurture them. Be brave.
Check the objectives	Return to the original objective (the goal, the question, etc.) to be certain that the answers you are considering do in fact address the question at hand.
Improve ideas	Rather than dismiss ideas that are close but not perfect, allow time to see if they can be made to work.
Allow for incubation	Provide time to step away from the problem. Your mind will work on it without you, often to great benefit.

**FIGURE 10.3** Convergent thinking guidelines.



**FIGURE 10.4** Divergent and convergent thinking—both are needed.

Figure 10.4 illustrates the inward-to-outward divergent-thinking process and compares it to the outward-to-inward convergent-thinking process. One follows the other.

#### 10.4.1 Techniques to Stimulate Divergent Thinking

The creative processes of divergent thinking can be supported by techniques that are easily learned. The FMEA facilitator should draw from these techniques when needed to help the team think creatively and to address the most difficult problems that have resisted resolution.

Brainstorming is one technique that uses divergent thinking, which is already covered in Section 10.3.1. Other techniques follow.

**SCAMPER** SCAMPER is a technique to stimulate thinking and new ideas by the use of focused questions. The facilitator uses the acronym SCAMPER (Substitute, Combine, Adapt, Modify, Put, Eliminate, Rearrange) in the form of questions to the team.<sup>[7]</sup>

- **Substitute:** What are alternatives to materials, processes, and methods already being used?
- **Combine:** How can seemingly disparate ideas be combined?
- **Adapt:** How can something already being used or done be adapted for a project?
- **Modify:** What materials, processes, and methods can be modified to solve a problem?
- **Put to other use:** Can a material, process, or method be put to another use?

- **Eliminate:** What can be done to eliminate problems and inefficiencies? What materials, methods, and steps can be eliminated?
- **Rearrange:** How can materials, method steps, and processes be moved around to solve a problem?

**Brainwriting** With brainwriting, “groups of people who are brainstorming do not have to speak to each other, at least initially. Ideas are written down (e.g., on sticky notes or index cards) and shared later. This encourages all voices to be heard and prevents people from forgetting their ideas as they wait for an opportunity to speak. Building on ideas occurs after ideas are shared. In a variation of this technique, one participant writes down three ideas on a piece of paper in response to a problem statement and passes it on to the next participant who writes down three different ideas and then passes it on to the next participant who continues the process.”<sup>[7]</sup>

**Finding the Rationale** Current ways of thinking and patterns of behavior may have been useful at one time, but can easily become old and outmoded. Yet if old and outmoded ideas are not questioned, they tend to persist. Within the topic being discussed, the facilitator asks the team what patterns of behavior or ways of doing things have been in place for a long time, and then directly questions the reason behind those behaviors or methods. The object is to find the *rationale* behind the current ways of doing things. The rationale may be perfectly fine; however, old patterns sometimes outlive their usefulness and need to be questioned. When outmoded patterns of behavior are surfaced and examined, it can clear the way to new and innovative ideas.

**Forced or Visual Connections** The techniques of forced or visual connections can be used when brainstorming or brainwriting do not generate sufficient ideas, or when the team is stuck in coming up with new ideas concerning a difficult problem.

With forced connection, the idea is to “force novel thinking by selecting an object unrelated to the problem, then asking: ‘When you look at this (object), what ideas do you get for solving this problem?’”<sup>[6]</sup>

With visual connection, the idea is to “make connections from an unrelated image to the current problem. Write down words suggested by an image, then make a direct connection from the words to the problem.”<sup>[6]</sup>

### **Mind or Subject Mapping**

Mind or subject mapping involves putting brainstormed ideas in the form of a visual map or picture that shows the relationships among these ideas. One starts with a central idea or topic, and then draws branches off the main topic, which represent different parts or aspects of the main topic. This creates a visual image or “map” of the topic, which the writer can use to develop the topic further. For example, a topic may have four different branches (sub-topics), and each of those four branches may have two branches of its own (sub-topics of the sub-topic) Mind or subject mapping includes both divergent and convergent thinking.<sup>[5]</sup>

## **10.5 FMEA FACILITATION ROLES AND RESPONSIBILITIES**

In earlier chapters, the fundamentals of FMEA were covered from the viewpoint of FMEA team members. In this section, the fundamentals of FMEA are outlined

from the viewpoint of the roles and responsibilities of an FMEA *facilitator*. In each of these steps, the FMEA facilitator either does the work, or sees to it that the work is done. The following are the primary roles and responsibilities of an FMEA facilitator.

1. Determine the scope and timing of the project.
2. Establish and train the FMEA team.
3. Ensure all prework is done before first meeting (including ground rules and assumptions, and gather information).
4. Perform FMEA analysis up through recommended actions.
5. Review FMEA recommended actions with management for all high severities and high Risk Priority Numbers (RPN)s.
6. Execute recommended actions.
7. Provide linkage with other processes such as Test Plans and Process Control Plans (PCPs).
8. Verify FMEA Quality Objectives.
9. Review and approve critical supplier FMEAs.
10. Verify risk reduction has been achieved.

The FMEA facilitator should be a person who is willing and able to lead the FMEA team through the project to a successful conclusion. He/she must be trained and experienced in the fundamentals of FMEA and the skills of facilitation.

### **Step 1. Determine the Scope and Timing of the Project**

Chapter 4, Sections 4.3 and 4.4, discuss the importance of using Preliminary Risk Assessment to determine which FMEA projects should be done and the timing of FMEA projects. Chapter 5, Sections 5.1 through 5.3, discuss how to properly establish the scope of the FMEA project on the selected items. The FMEA facilitator's role in Step 1 is to:

1. Lead the Preliminary Risk Assessment or ensure the list of needed FMEAs is identified and agreed upon by management.
2. Determine the system configuration for the assigned project, including proper levels of indentation.
3. For System or Design FMEAs, develop or see to the development of:
  - a. FMEA Block Diagram to visually show the scope and boundaries of the project
  - b. Functional Block Diagram (if needed) to identify the primary functions for the system being analyzed
  - c. Parameter Diagram (if needed) to support the inputs and outputs for FMEA
  - d. FMEA Interface Matrix (if needed) to ensure that all interfaces are covered
4. For Process FMEAs, develop or see to the development of:

- a. Process Flow Diagram to show the process operations visually and their logical sequence
- b. Process Flow Diagram worksheet to identify significant product and process characteristics that will flow to the Process FMEA
5. Establish the timing needs of the project, specifically review needed start and finish dates with management in order to ensure FMEAs are completed within the window of opportunity to maximize the most value to company.

*Note:* If the FMEA facilitator sees that FMEA project timing or quality is jeopardized, it needs to be brought to management's attention so that action can be taken.

### **Step 2. Establish and Train the FMEA Team**

Chapter 5, Section 5.3.4, discusses the proper composition of FMEA teams for various types of FMEA projects. The FMEA facilitator's role in Step 2 is to:

1. Ensure the team composition is correct or take action to remedy.
2. Ensure all the team members are properly trained in FMEA procedure by either training the team or arranging outside training.
  - a. Frequent FMEA team members should be trained on fundamentals of FMEA.
  - b. Infrequent FMEA team members should be taught an overview of FMEA procedure, preferably just before FMEA meetings.
3. Assemble the FMEA team and schedule the first meeting after all prework is done.

The FMEA facilitator needs to be sure the team fully understands each of the FMEA definitions. One of the most time-wasting problems with FMEA teams occurs when the team flounders between functions, failure modes, effects, causes and controls, misunderstanding, and misplacing the terms. Refer to Chapter 3, Section 3.5, for examples of these terms from different types of FMEA applications.

### **Step 3. Ensure All Prework Is Done before the First FMEA Meeting**

Chapter 5, Sections 5.3.5 through 5.3.9, discuss how to prepare properly for FMEAs, including ground rules and assumptions, and gathering information. The FMEA facilitator's role in Step 3 is to:

1. Ensure all FMEA resources are agreed upon and readily accessible, such as the FMEA software, FMEA scales, FMEA procedure, and FMEA standard. Refer to Chapter 5, Section 5.2.
2. Determine the ground rules and assumptions to be used in the assigned project, as well as the role of suppliers. Refer to Chapter 5, Section 5.3.5 and 5.3.6.
3. Gather together all the needed FMEA prework information before the first meeting, including past FMEAs, product requirements, technical specifications,

schematics, field history, test procedures, and test plans. Refer to Chapter 5, Section 5.3.7.

4. Understand why the FMEA project is being done so that the team can be guided to address the risk.

*Note:* There are usually specific circumstances that trigger or launch an FMEA project, such as new technology, troublesome field history, new applications, safety concerns, and so on. It is incumbent on the FMEA Facilitator to understand the nature of the risk being addressed so that the team can stay focused on risk reduction.

#### **Step 4. Perform FMEA Analysis (up through Recommended Actions)**

Chapter 3, Section 3.5, discusses the basic definitions of FMEAs. Chapters 6 and 7 discuss how to conduct the FMEA procedure and how to develop effective recommended actions. The FMEA facilitator's role in Step 4 is to:

1. Work with FMEA team to perform the basic FMEA procedure exactly according to the FMEA training materials.
2. Use the primary FMEA facilitation skills throughout each meeting to ensure excellent results in a timely manner.
3. Review all high severity and high RPN issues with the FMEA team and ensure there are effective recommended actions developed that improve the design and reduce risk to an acceptable level. Draw from the "Action Strategies to Reduce Risk" Section 7.3 of Chapter 7, as needed.
4. Ensure the FMEA Quality Objectives are met.

**Use of Post-It Notes™** As mentioned in Chapter 6, Section 6.1, one way to harness the creative energy of the FMEA team is to use Post-It Notes™ at the beginning of the FMEA analysis in order to save valuable time spent in meetings. For each item's function, ask the FMEA team to write Post-It Notes for the primary concerns they have, not emphasizing if the concern is worded as a failure mode, effect, or cause. The writing of Post-It Notes is done concurrently; in other words, all the FMEA team members are writing Post-It Notes at the same time until they have noted all of their primary concerns. The Post-It Notes are placed on a wall easily visible to the FMEA team and organized into similar groupings. The FMEA team reviews the information on the wall and determines what goes into the FMEA analysis. This technique encourages contribution by all team members, fosters creativity, and saves meeting time.

**Use of Thought-Starter Questions** As an aid for the FMEA facilitator, "thought-starter" questions have been summarized and added to Appendix D.4. The FMEA facilitator should review these questions and tailor them for use in FMEA meetings to be sure that the best possible information is solicited from the FMEA team and included in the FMEA project. These questions are only thought starters and are not meant to limit in any way the skill of the FMEA facilitator and team in establishing the content of the FMEA.

### **Step 5. Review FMEA Recommended Actions with Management for All High Severities and High RPNs**

Chapter 11, Section 11.3.3, shows how regular management reviews of the high severities and high RPNs from FMEAs are an essential part of an effective FMEA process. The FMEA facilitator's role in Step 5 is to:

1. Ensure the FMEA team understands the review process with management.
2. Generate the list of high severities and high RPNs from the FMEA. This includes corresponding causes, controls, and recommended actions.
3. Ensure all high severities and high RPNs from FMEA are reviewed with management for feedback and concurrence on a regular basis.
4. Review results from the management review with FMEA team and integrate back into FMEA. If management turns down a particular recommended action, the FMEA team will need to either resubmit with additional substantiating information or find alternative solutions to reduce risk.

There may already be a process in place to review failures that need to be addressed from field experiences or testing results. Most companies “piggyback” the review of FMEA high-risk issues with the review of field or test failures.

Review only high severity and high RPN failure modes and their causes. Have the “natural owner” of the failure mode present the problem/solution to management. Close the loop with the FMEA team to ensure overall risk is reduced to an acceptable level.

### **Step 6. Execute Recommended Actions**

Chapter 7, Sections 7.5 through 7.8, discuss the importance of executing all of the recommended actions from the FMEA—the FMEA has little value unless the recommended actions are fully executed. The FMEA facilitator's role in Step 6 is to:

1. Work with management to ensure a process is in place for execution of FMEA actions, and that support is provided for this important task.
2. Pursue each recommended action to ensure completion to satisfaction of FMEA team and risk is eliminated or is mitigated to acceptable level.
3. Bring problems with execution back to management.
4. Update Action Taken and Revised RPNs in FMEA database.

### **Step 7. Provide Linkage with Other Processes**

Chapter 6, Section 6.3, discusses the linkages between FMEA and other quality and reliability processes such as Design Verification Plan (DVP), Process Control Plan (PCP), and many others. The FMEA facilitator's role in Step 7 is to:

1. Ensure Design FMEA properly links to and improves the DVP.
2. Ensure Process FMEA properly links to and improves the PCP.

3. Ensure Design FMEAs properly link with Process FMEAs.
4. Ensure FMEAs link to other quality and reliability processes such as Design Reviews.

### **Step 8. Verify FMEA Quality Objectives**

Chapter 9, Section 9.1, discusses the 10 most common mistakes that are made in conducting FMEAs and how to convert them into quality objectives. The FMEA facilitator's role in Step 8 is to:

1. Ensure the FMEA team understands the FMEA Quality Objectives.
2. Review FMEA Quality Objectives frequently during meetings and take positive action to verify they are met.
3. Request support from management to perform regular FMEA audits against the Quality Objectives.

### **Step 9. Review and Approve Critical Supplier FMEAs**

Chapter 11, Section 11.3.3, discusses how potential system or subsystem level failures with high severities or high RPNs can have their root cause in supplier components, and how suppliers of critical parts should submit completed FMEAs for review and approval, prior to part shipment. The FMEA facilitator's role in Step 9 is to:

1. Work with management to identify suppliers who provide parts that potentially involve high risk and ensure appropriate Design and/or Process FMEAs are assigned.
2. Ensure that the assigned supplier FMEAs are reviewed against the FMEA Quality Objectives and continued until they meet the objectives.

Supplier FMEA reviews of critical parts can be done at the supplier site, original equipment manufacturer (OEM) site, or by Web conference. The reviewing company does not retain copies or control of the supplier FMEAs.

### **Step 10. Verify Risk Reduction Is Achieved**

Chapter 7, Section 7.8, discusses the importance of continuing FMEAs until risk is reduced to an acceptable level. The FMEA facilitator's role in Step 10 is to:

1. Work with the FMEA team, reassess RPNs after execution of recommended actions, and take further action until risk is reduced to an acceptable level within the scope of the original FMEA.
2. Communicate the accomplishment of this objective to management, including the originators of the FMEA project.
3. Maintain all FMEA records in the FMEA database for use on future FMEA projects.

## 10.6 HOW TO REDUCE FMEA IN-MEETING TIME

One of the common complaints about FMEAs is that the meetings drag out and take too long. Good facilitation will solve this issue, as will following the recommendations throughout this book. Here are some tips to keep FMEA in-meeting time as short as possible without reducing the quality of results, including where these topics are covered in this book.

1. Make sure the FMEA team *fully* understands the definitions and concepts of FMEAs (Chapter 3, Section 3.5).
2. Improve FMEA facilitation skills (Chapter 10, Section 10.3).
3. Use relational database software (Chapter 16, Section 16.3).
4. Consider use of “Generic” FMEAs (Chapter 11, Section 11.3.2).
5. Limit in-meeting discussion to areas of concern (Chapter 2, Section 2.2.3).
6. Make good use of past FMEAs and field data (Chapter 5, Section 5.3.7 and Chapter 11, Section 11.3.4).
7. Do a thorough job of premeeting preparation. (Chapter 5, Section 5.3)
8. Control in-meeting discussion (Chapter 10, Section 10.3.5).
9. Use Post-It Notes when brainstorming for new ideas (Chapter 6, Section 6.1).
10. Prevent “scope creep” by making the scope visible and well defined (Chapter 5, Sections 5.3.2 and 5.3.3).

## 10.7 DIFFICULTY GETTING CONSENSUS ON COMPETING IDEAS

There will be times when an FMEA facilitator has difficulty arriving at consensus with the FMEA team. This most often happens when there are two or more competing ideas or solutions and members of the team feel strongly about their personal idea or solution.

It will be important for the facilitator to ensure the differing positions are clearly identified. Probing questions and active listening should be used to provide clarity to the differing ideas.

Team members who oppose certain ideas can be asked questions (in a nonthreatening manner), such as:

“What are your specific objections?”

“What changes would allow you to support this idea?”

The FMEA facilitator should use the full arsenal of skills, including brainstorming, encouraging discussion, probing questions, active listening, and controlling discussion. Often times a “win-win” solution can be creatively brought forward and agreed to.

One tool that is useful in achieving team consensus with competing ideas is called a Pugh analysis, invented by Stuart Pugh, at the University of Strathclyde, in Glasgow, Scotland. A Pugh analysis is a decision matrix where alternatives or solutions are listed on one axis, and evaluation criteria are listed on the other axis. The objective

is to evaluate and prioritize the alternatives or solutions. The team first establishes and weights the evaluation criteria and then evaluates each option against those criteria.

The steps of a Pugh analysis are:

1. Document the short list of ideas or alternatives that are being evaluated.
2. Develop the list of criteria that will be used to evaluate alternatives.
3. Assign a relative weight to each criterion based on how important that criterion is to the subject being evaluated.
4. Using a simple matrix, list the evaluation criteria on the left and the alternatives across the top.
5. Establish a baseline, which may be one of the alternatives or some other solution or alternative the team agrees is a baseline.
6. For each of the criteria, evaluate each of the alternatives against the baseline, using scores of worse (-1), same (0), or better (+1). Multiply each rating by the criterion weighting. Sum the results and identify the alternative with the highest score.
7. If one of the alternatives has not emerged as the clear best idea with team consensus, look for a hybrid idea that captures the best features of the competing alternatives and rescore.

Figure 10.5 is an example of the use of Pugh analysis to determine the best solution for an FMEA decision. The example is taken from the Design FMEA for an all-terrain bicycle brake cable. In this example, the failure mode is “cable binds” and the cause is “inadequate or wrong lubrication between cable and sheath.” Since the severity = 7 and the RPN = 140, the team has placed a high priority on finding the best solution (recommended action). The team has narrowed down to two possible lubricants. The first alternative is a lubricant gel that is lower cost, easier to maintain, but has less performance over temperature and humidity extremes, provides slightly less friction reduction, and the supplier has an excellent record of quality. The second alternative is a high performance liquid lubricant that provides better friction reduction over a wide variety of operating extremes, but is harder to apply, costlier, and the supplier has a spotty quality record. For the purposes of the Pugh analysis, the current lubricant is called “baseline.” As can be seen from the decision

Evaluation Criteria	Weight Factor	Baseline Lubricant		Alternative Lubricants					
				Gel		Liquid		Hybrid	
				Rating	Weighted	Rating	Weighted	Rating	Weighted
Environmental performance	3	0	0	-1	-3	1	3	1	3
Friction performance	4	0	0	-1	-4	1	4	1	4
Cost	3	0	0	1	3	-1	-3	-1	-3
Supplier quality	3	0	0	1	3	-1	-3	1	3
Ease of maintenance	2	0	0	1	2	-1	-2	0	0
Score		0	0		1		-1		7

**FIGURE 10.5** Example of Pugh analysis to evaluate alternative lubricants for bicycle cable.

matrix, the gel lubricant slightly outperformed the liquid lubricant. The team looked for a hybrid solution and found a supplier for the liquid lubricant with a better quality record that was easier to apply. The hybrid column shows the results and the decision was made.

## 10.8 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

### Problem 10.1

A facilitator is one who . . . (Select all that apply.)

1. Contributes structure and process to groups.
2. Effectively solves the problems brought forward by the group.
3. Supports the group to achieve exceptional performance.
4. Acts as a tiebreaker when the group cannot come to a decision.

### Problem 10.2

**Scenario:** you are facilitating an FMEA meeting and two attendees are having a side conversation. You should . . . (Select all that apply.)

1. Out of courtesy, allow the side conversation to continue until the two attendees have finished their conversation.
2. Interrupt the two people who are having a side conversation and tell them to leave the meeting.
3. Refer the two attendees to the meeting “norms” and ask them to hold off any side conversations.
4. Ask the two attendees if they are discussing something they want to share with the group that is consistent with the meeting agenda.

### Problem 10.3

**Scenario:** You are facilitating an FMEA meeting and the group is having trouble developing effective recommended actions for a known cause. The best facilitation tool to address this scenario is . . . (Select all that apply.)

1. Use conflict management techniques to find and address the obvious conflict that is holding up the group.
2. Use active listening to try to understand better what the group is saying.
3. Use brainstorming to open up the flow of ideas.
4. Use probing questions to solicit more participation from everyone in the group.

**Problem 10.4**

**Scenario:** Two people in the group you are facilitating begin shouting at one another and generally acting rude. You should . . . (Select all that apply.)

1. Use your active listening skills as you know that conflict is good and there may be important ideas being communicated, even if rudely.
2. Intervene in the conflict by telling the two people to stop shouting and refer them to the meeting “norms” that do not allow rude behavior. If they cannot cease, take a break from the meeting to allow things to cool down and ensure the two people can act with courtesy.
3. Intervene in the conflict on the side of the person who you believe is correct.
4. Tell the two people to stop shouting and ask the group to vote on which of the two has the best ideas.

**Problem 10.5**

**Scenario:** The FMEA team is having trouble understanding the difference between a failure mode and a cause. The meeting is dragging on and on. You should . . . (Select all that apply.)

1. Refer to the FMEA training material and review the definitions of failure mode and cause with the team. Proceed when you are certain they understand the concepts.
2. Move on to the next column so that the team can keep progressing. Come back to the issue later.
3. Have the team vote on which is the right definition and proceed.
4. End the meeting and reschedule for the next day. The break will probably refresh people’s memories on the definitions.

**Problem 10.6**

The hallmarks of a good *consensus* process include . . . (Select all answers that apply.)

1. One person who disagrees cannot hold up the team.
2. Many ideas are shared.
3. No one pushes a predetermined solution.
4. The team compromises to get agreement.

**Problem 10.7**

The FMEA team has a few members who are not contributing during a discussion about potential recommended actions for a high-risk issue. What are three probing

questions that the nonparticipating team members can be asked to solicit their input?

### Problem 10.8

**Scenario:** You are assigned to facilitate a Design FMEA; however, due to heavy workload and unavailability of subject-matter experts, you have been told to do the FMEA with the design engineer. What should you do?

### Problem 10.9

When should brainstorming be used in an FMEA? List two examples showing which elements of an FMEA that could receive benefit from brainstorming and the circumstances that would generate the brainstorming technique for both examples.

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# *Chapter* 11

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## *Implementing an Effective Company-Wide FMEA Process*

One gets a good rating for fighting a fire. The result is visible; can be quantified. If you do it right the first time, you are invisible. You satisfied the requirements. That is your job. Mess it up, and correct it later, you become a hero.

—Dr. W. Edwards Deming

### **IN THIS CHAPTER**

Failure Mode and Effects Analysis (FMEA) teams require vigorous support by management with specific strategies and reviews. This chapter outlines a company-wide FMEA process that will result in effective implementation of FMEA projects. The specific roles and responsibilities of management are explained, along with lessons learned from successful and unsuccessful FMEA implementations.

#### **11.1 WHAT IS A COMPANY-WIDE FMEA PROCESS AND WHY IS IT IMPORTANT?**

In order to be fully effective, FMEAs require an infrastructure and coordinated approach from many different departments and organizational functions. 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.

### **Primary Reasons for Ineffective FMEAs (based on practical experience)**

1. Insufficient strategic or resource planning
2. Doing FMEAs improperly or too late
3. Lack of management sponsorship and support
4. Failure to execute recommended actions for high-risk issues
5. Not meeting FMEA Quality Objectives
6. Failure to address supplier issues
7. Failure to incorporate lessons learned from past FMEAs or test and field data
8. Failure to integrate FMEAs with other key processes

The FMEA Process addresses these issues and ensures successful FMEA application.

### **A Comment on Corporate Culture**

When Sir Isaac Newton said, “Every body remains in a state of constant velocity unless acted upon by an external unbalanced force,” he was talking about the laws of motion. However, he might as well have been talking about the nature of human beings. People will continue to do what they normally do unless there is some external force that changes their activities. People continue to operate in their personal comfort zone. Old tools that are not necessarily value added will tend to continue. It takes strong action from both management and employees to implement new tools and cease the use of old tools.

## **11.2 MANAGEMENT ROLES AND RESPONSIBILITIES**

Leadership is the capacity to translate vision into reality.

—Warren G. Bennis

The importance of broad support from management in implementing an Effective FMEA process cannot be overstated. Here is a short list of key management responsibilities.

1. Champion the subject of FMEA with management and employees.
2. Provide agreement on FMEA strategy and support needed resources.
3. Implement an effective FMEA training program.
4. Vigorously implement each of the steps of the FMEA process, as covered in this chapter.
5. Define roles and responsibilities for all FMEA participants, and integrate with employee work instructions.
6. Assist in integrating FMEA with other business processes, including Design Reviews, Design Verification Plans, Process Control Plans, and others.
7. Provide effective reviews of high-risk failure modes and recommended actions.
8. Support attendance of expert FMEA team members.

9. Help ensure FMEAs are fully executed.
10. Establish an FMEA audit process to continuously improve the quality of FMEAs.

It is understood that implementing an effective FMEA process will run up against difficulties and roadblocks. Change is not easy in any company. Part of the roles of FMEA “champion” is to stay focused on the positive results and celebrate victories along the way. As mentioned in Chapter 2, FMEAs have had a reputation for being long, drawn out, and uninteresting. This does not have to be the case and it is hoped that this book will change that reputation where it exists. Every person in a company or organization wants to support safe and trouble-free designs and processes. By following the steps in this book, everyone involved with FMEAs can be part of a dynamic, interesting, and engaging process. Properly done, FMEAs harness the inherent passion and energy that employees have for helping consumers and users receive safe and reliable products.

### 11.3 EFFECTIVE FMEA PROCESS

The best practice for implementing FMEAs in any company includes the following key steps:

#### **Planning Stage**

- Step 1A: Develop and execute an FMEA strategic plan
- Step 1B: Develop and execute an FMEA resource plan

#### **Performing FMEAs Stage**

- Step 2: Develop generic FMEAs (optional)
- Step 3: Develop program-specific FMEAs

#### **Review Stage**

- Step 4: Conduct management reviews of high-risk FMEA issues
- Step 5: Conduct FMEA quality audits
- Step 6: Review supplier FMEAs

#### **Implementation Stage**

- Step 7: Execute actions to reduce or eliminate risk
- Step 8: Link FMEAs to Other Processes
- Step 9: Incorporate test and field failures
- Step 10: Support FMEA Process with fully integrated software

Figure 11.1 is a graphic illustration of an Effective FMEA Process used throughout this chapter to show how the various stages of the process come together.

#### **11.3.1 Planning Stage**

Good things only happen when planned; bad things happen on their own.

—Philip B. Crosby

## EFFECTIVE COMPANY-WIDE FMEA PROCESS

*How an entire company works together to support FMEAs that get results*

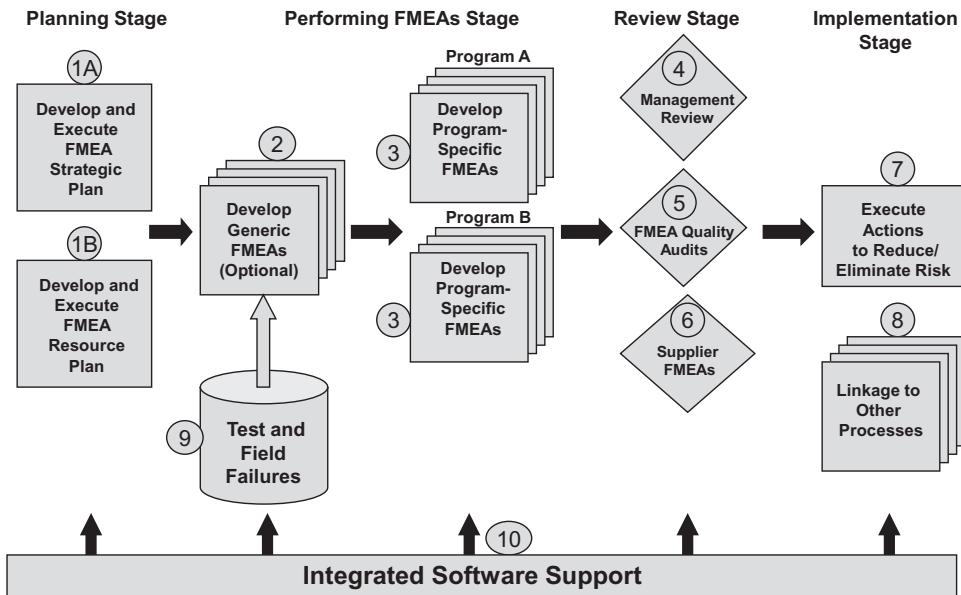


FIGURE 11.1 Effective FMEA process.

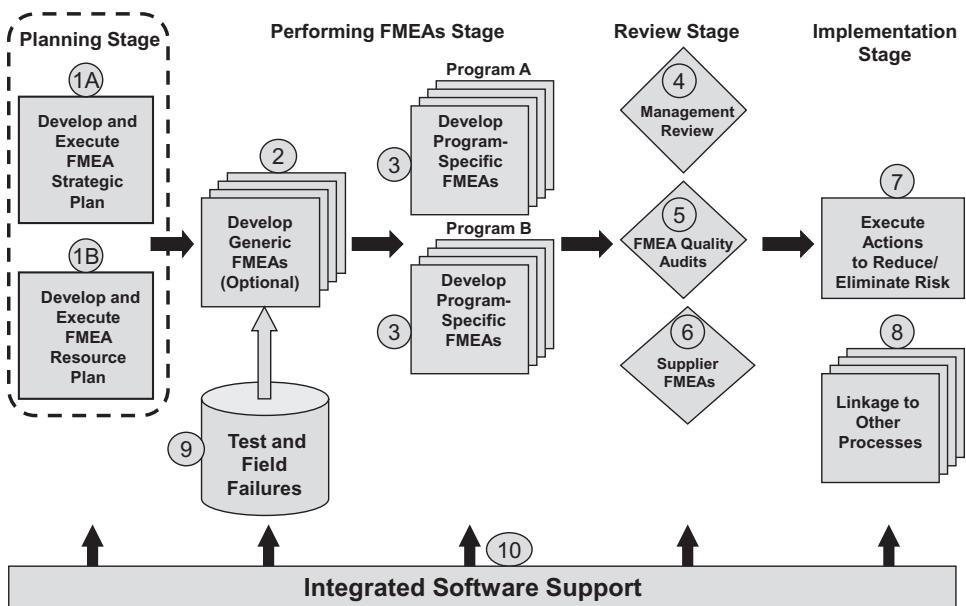
Management should discuss and decide what strategic and resource tasks are needed before beginning actual FMEA projects. Figure 11.2 shows the FMEA Process tasks that are usually done during the planning stage of an Effective FMEA Process.

**Step 1A: Develop and Execute an FMEA Strategic Plan** Management needs to make the following strategic decisions:

1. What types of FMEAs will be done? (System, Design, Process, Hazard Analysis, Maintenance, Software, etc.)
2. What selection criteria will be used to identify new FMEAs? (Preliminary Risk Assessment, new designs, new processes, etc.)
3. What is appropriate FMEA timing? (For example: prior to design freeze, during the time when designs or processes are being developed)
4. What level of security is needed for the different types of FMEA projects, and how will security be implemented and controlled?
5. What FMEA standard will be used? (Society of Automotive Engineers [SAE] J1739, Automotive Industry Action Group [AIAG] 4, etc.)
6. What generic FMEAs will be developed? By whom?
7. What program-specific FMEAs will be developed? By whom?
8. What level of detail is needed for Generic or Program-Specific FMEAs? (System, Subsystem, Component, etc.)

## EFFECTIVE COMPANY-WIDE FMEA PROCESS

*How an entire company works together to support FMEAs that get results*



**FIGURE 11.2** Tasks done during the Planning Stage of an Effective FMEA Process.

9. How will quality audits be implemented for ongoing improvements to FMEA process?
10. How will FMEA projects be tracked, including closure of all recommended actions?
11. How will FMEA postanalysis lessons learned be captured?
12. How will FMEAs be stored for easy retrieval?
13. What linkages are needed to other processes (Failure Review and Corrective Action System, Design Verification Plan, Design Reviews, Process Control Plans, etc.)?
14. How will supplier FMEAs be handled? Who will review and approve FMEAs for critical parts?

FMEAs need to be done during the “window of opportunity” to best impact design of the product or process. For Design FMEAs, too early means before design concept is established; too late means after design freeze. The ideal timing is while design of the product is being developed. For Process FMEAs, too early means before manufacturing or assembly concept is established; too late is after manufacturing or assembly process is finalized. The ideal timing is while design of the manufacturing or assembly process is being developed.

When deciding the scope of FMEA, keep in mind that the size of FMEA team should be about four to eight members for an effective core team focus and

efficiency. Too few participants can result in absence of important expert input. Too many can result in unmanageable FMEA team meetings and wasted time. Assign as many FMEA projects as necessary to address risk, and still keep teams to a manageable size.

Refer to Chapter 4, Section 4.3, for information on how to perform Preliminary Risk Assessment, a technique to determine which FMEAs should be done to support new product designs or processes, or changes to current product designs or processes.

**Step 1B: Develop and Execute an FMEA Resource Plan** Management must make the following resource decisions:

1. What software is needed? (such as Xfmea [from ReliaSoft Corporation] or other relational-database software)
2. Where will the FMEA homeroom (center for FMEA expertise) reside? (FMEA body of knowledge, FMEA facilitators, etc.)
3. Who will perform FMEA facilitation and administration?
4. What is the FMEA training plan for facilitators, teams, and management?
5. What will be the specific FMEA procedure used by all FMEA teams, and how will it be documented, maintained, and adhered to?
6. What should be the composition of the core FMEA team?
7. How will management support be provided?
  - a. What will be the content and frequency of management reviews?
  - b. What approval system should be required for FMEA recommended actions?
  - c. What FMEA reports does management need and when?

An FMEA homeroom is important to support FMEA process and execution. The roles and responsibilities include providing expert FMEA facilitation, FMEA training, FMEA common process and standards, FMEA software, FMEA methodology expertise, and FMEA quality audits. Without an effective FMEA homeroom, the results of FMEA can vary and become less effective.

**FMEA Training** FMEA team member training should include the basics of FMEA procedure as covered in this book and as provided through expert FMEA training.

FMEA Facilitator training should include the basics of FMEA procedure, the roles and responsibilities of facilitator in leading the FMEA process, and training in general facilitation skills.

Management training on the subject of FMEAs should include the elements of an Effective FMEA process from the viewpoint of management, and the roles and responsibilities needed to support effective FMEAs.

Refer to Chapter 3 for the fundamental concepts and definitions of FMEA, Chapter 5 for FMEA preparation steps, Chapter 6 for FMEA procedure, and Chapter 7 for defining and executing effective actions to reduce risk.

## EFFECTIVE COMPANY-WIDE FMEA PROCESS

*How an entire company works together to support FMEAs that get results*

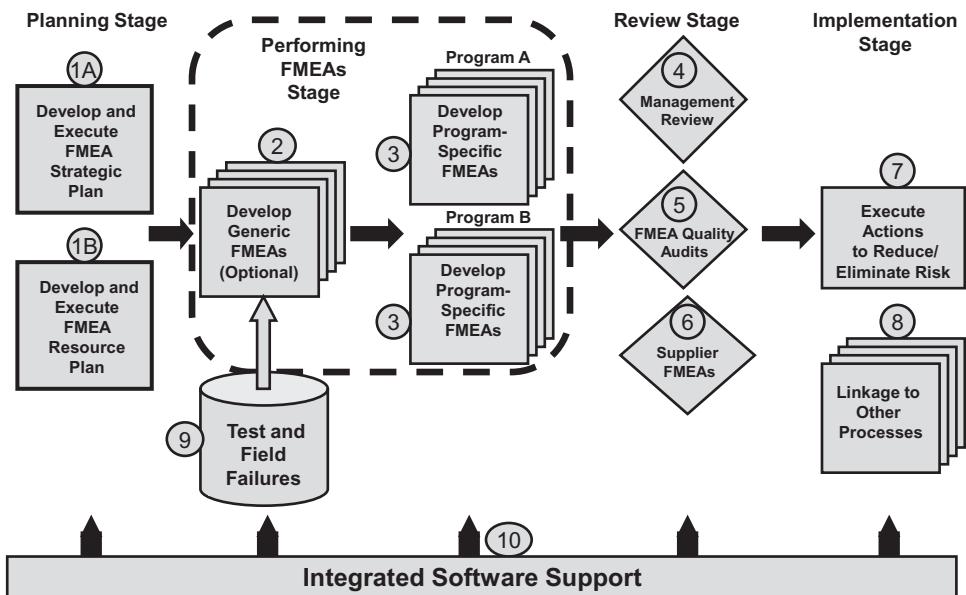


FIGURE 11.3 Tasks done during the Performing Stage of an Effective FMEA Process.

### 11.3.2 Performing FMEAs Stage

Once the planning steps have been done, actual FMEA projects can begin. Chapter 4, Sections 4.2 and 4.3, describe the process for selecting FMEA projects. Figure 11.3 shows the FMEA Process tasks that are typically done during the performing stage of an Effective FMEA Process.

**Step 2: Develop Generic FMEAs** Generic FMEAs are FMEAs that contain both *historical* (empirical) and *potential* failure modes, causes, controls, and so on. They are done at the generic level of the system, subsystem, or component, not at the program-specific level. Most often, they are done once, and then they are updated when needed from test and field data and/or new technology. The purpose is to support a learning organization, retain the lessons learned from test and field, and make it easier to generate program-specific FMEAs in the future.

Management needs to decide whether to use generic FMEAs, and if so, which ones, what content, what standard, and the level of detail to be included.

#### For Each Generic FMEA, Complete These Steps

1. Assign generic FMEA facilitator and team.
2. Establish generic FMEA timing and scope.

3. Gather past relevant FMEA(s), and all needed prework documents and information, including field history.
4. Perform FMEA analysis (according to FMEA standard) up through design or process controls.

Generic FMEAs can be used for concept trade-off studies or as input to program-specific FMEAs. They are optional and require up-front commitment. The payoff is not immediate. They are most useful if the product line is relatively stable over time. By actual experience, generic FMEAs can reduce the time to perform program-specific FMEAs by as much as half.

Refer to Chapter 5 for FMEA preparation and Chapter 6 for FMEA procedure, both of which apply to generic FMEAs.

**Step 3: Develop Program-Specific FMEAs** Program-specific FMEAs are FMEAs that focus on specific applications or projects. They are tailored from generic FMEAs or are done newly. They are completed through the entire FMEA worksheet and must meet the FMEA Quality Objectives.

Management needs to decide which programs will get FMEAs, what FMEAs to do for each program, what types of FMEAs, and the timing of them. Management also needs to decide what FMEA standard to use, how to handle suppliers, how management review and approval of FMEA recommendations will be achieved, and how program-specific FMEAs will be tracked to assure timely and successful completion with risk reduced to an acceptable level. Preliminary Risk Assessment, covered in Chapter 4, Section 4.3, is the best technique for selection of which FMEAs to do on a given program.

#### **For Each Program-Specific FMEA, Complete These 10 Steps**

1. Assign FMEA facilitator and team and ensure they are properly trained.
2. Establish FMEA timing and scope.
3. Establish ground rules and assumptions, gather relevant documentation, and perform other FMEA preparation steps.
4. Perform FMEA analysis (according to FMEA procedure) up through recommended actions.
5. Provide input to Design Verification Plans or Process Control Plans.
6. Review risk and recommended actions with management.
7. Update FMEA project tracking.
8. Execute recommended actions and update risk assessment.
9. Review and approve all critical supplier FMEAs.
10. Ensure risk is reduced to an acceptable level and FMEA is completed “by the book.”

A note on implementing FMEAs in a company with an FMEA history: Past FMEAs may have had varying degrees of success, particularly if previous FMEAs were improperly conducted. Before implementing a new round of FMEAs, it is helpful to review what has worked in the past as well as what has not worked. Employees

## EFFECTIVE COMPANY-WIDE FMEA PROCESS

*How an entire company works together to support FMEAs that get results*

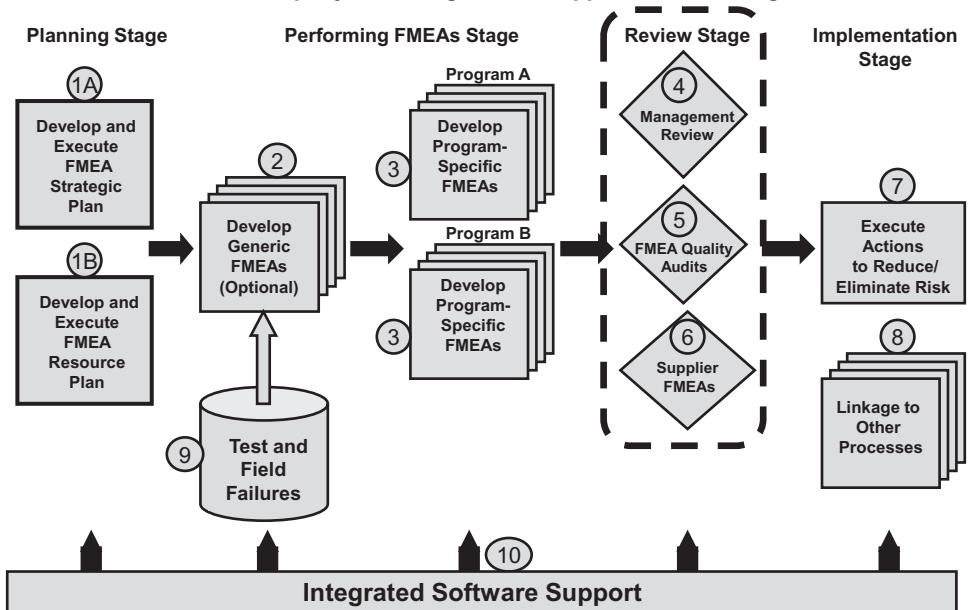


FIGURE 11.4 Tasks done during the Review Stage of an Effective FMEA Process.

need to know that management understands the lessons from the past, so the new implementation strategies are not met with resistance relating to past unsatisfactory results. It is good to “clear the air” and begin a fresh start with “best practice.” See the *Harvard Business Review* article “Promise-Based Management,” excerpted in the Chapter 7, Section 7.6.

Refer to Chapter 5 for FMEA preparation, Chapter 6 for FMEA procedure, and Chapter 7 for FMEA execution, all of which apply to program-specific FMEAs.

### 11.3.3 Review Stage

Once FMEAs are completed up through recommended actions, there are three types of reviews that should be done. Figure 11.4 shows the FMEA Process tasks that are done during the review stage of an Effective FMEA Process.

**Step 4: Conduct Management Reviews of High-Risk FMEA Issues** Until the FMEA is fully implemented, with risk reduced to an acceptable level, management must regularly review the high-risk issues and recommended actions from FMEAs. This is essential to ensure understanding, agreement, support, and adequacy. The FMEA facilitator can generate FMEA reports and charts in whatever format and summarized content best support this objective. Feedback from management goes back to FMEA teams for review and incorporation in the FMEA. There may already be a process in place to review failure modes from the field or from tests. Most companies combine, or “piggyback,” the review of FMEA high-risk issues with the review of field or test failures.

As covered in Chapter 10, Section 10.5, the management review of FMEA issues should only be on the high severity and high Risk Priority Number (RPN) failure modes and their causes. The “natural owner” of the issue should present the problem and the solution to management, and seek discussion and agreement. The essence of this presentation needs to be concise, containing pertinent, accurate data, followed by good listening to management’s feedback. Close the loop with the FMEA team.

It is incumbent on management to ensure that all high severity issues are properly addressed within the scope of the FMEA, regardless of RPN value. The reason for this is high severity/low RPN issues have the potential to cause harm to customers and result in considerable legal and public relations problems for the company. In addition, all high RPN items must also be addressed.

If the FMEA recommended actions for a high-risk issue are not approved, management should provide clear and timely feedback to the FMEA team representative. The FMEA team will need to decide whether they resubmit their proposal with more thorough substantiation or generate alternative solutions. It is essential for management to work with the FMEA team to find ways to reduce risk to an acceptable level.

**Step 5: Conduct FMEA Quality Audits** FMEA quality audits are in-person audits of completed (or nearly completed) FMEAs, done with the FMEA facilitator and the FMEA core team present. Someone—usually from management—who is experienced with the content and quality of good FMEAs performs these quality audits. Done in an interview format, on a prescheduled or random basis, they are based on the 10 FMEA Quality Objectives as covered in Chapter 9, Section 9.1, which also details how to audit each objective. FMEA quality audits take about 1 hour per audit, or about 5 minutes per individual quality objective. They provide valuable feedback to improve future FMEAs. It is important for the auditor not to single out and criticize the FMEA team, but rather develop action items for follow-up to improve the FMEA process.

Management audits demonstrate commitment. J. M. Juran, renowned quality management consultant, always insisted that quality should not be delegated.

**Use of Quality Surveys** A survey of each FMEA team (as well as internal customer of FMEA) for FMEA effectiveness is an optional step (Reference Figure 11.5). The purpose of the survey is to assess the quality of current FMEAs in order to improve the quality of future FMEAs. These surveys, based on 10 FMEA Quality Objectives, can be in writing or online. The idea is to ask how well the FMEA team did in achieving each of the ten FMEA Quality Objectives, usually on a scale of 1–3 or 1–5. Individual survey content should be confidential to facilitate candid responses. The surveys identify action items for follow-up to improve the FMEA process. Tracking results of such surveys over time will show FMEA quality improvement.

When using FMEA surveys or audits, the focus should be improving the FMEA process. Do not expect to achieve all 10 objectives instantly, but work to maintain steady improvement.

**Step 6: Review Supplier FMEAs** As covered in Chapter 5, Section 5.3.6, potential high-risk system- or subsystem-level failures might have their root causes in

## FMEA Quality Survey

FMEA Number \_\_\_\_\_ FMEA Description \_\_\_\_\_ FMEA Date \_\_\_\_\_

FMEA Team \_\_\_\_\_

Survey Respondent Name \_\_\_\_\_ Survey Date \_\_\_\_\_ Department/Program \_\_\_\_\_

Please answer honestly how well the above FMEA achieved each of the following 10 quality objectives . Answer on a scale of 1–5, where 1 is the lowest score (quality objective not achieved at all) and 5 is the highest score (quality objective fully achieved). Answers will be kept confidential.

- The FMEA drives product design or process improvements as the primary objective
- The FMEA addresses all high-risk failure modes with effective and executable action plans
- The Design Verification Plan & Report (DVP&R) or the Process Control Plan (PCP) considers the failure modes from the FMEA
- The FMEA scope includes integration and interface failure modes in both block diagram and analysis
- The FMEA considers all major "lessons learned" (such as high warranty, campaigns, etc.) as input to failure mode identification
- The FMEA provides the correct level of detail in order to get to root causes and effective actions
- The FMEA is completed during the "window of opportunity" where it can most effectively impact the product or process design
- The right people participate on the FMEA team throughout the analysis and are adequately trained in the procedure
- The FMEA document is completely filled out "by the book," including "Action Taken" and final risk assessment
- The time spent by the FMEA team is an effective and efficient use of time with a value added result

Average score \_\_\_\_\_ (completed by survey coordinator)

Please add any comments on how the FMEA process can be improved in the future \_\_\_\_\_

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**FIGURE 11.5** FMEA quality survey form.

supplier components. FMEA strategic planning should determine how to address supplier FMEAs, and how to identify which suppliers require FMEA review. The FMEA team can, and should as appropriate, invite suppliers to participate on FMEAs; usually, this is on a need-to-know basis.

It is a good reliability management practice to ensure all suppliers demonstrate due care in their product designs and manufacturing processes. For suppliers of

critical parts, they should be required to submit completed FMEAs for review *and approval*, prior to part shipment. Reviews based on the FMEA Quality Objectives should be conducted either by the FMEA team or by a qualified representative. The supplier continues working on their FMEAs until they meet all quality objectives.

It takes time to bring about the right relationship with suppliers on FMEAs and other reliability tasks. Suppliers must aspire to develop subsystems and parts that are failure free during useful life. Purchasing contracts, supplier selection, specifications, and follow-up activity should all support this, working in the direction of achieving excellent supplier FMEAs.

Some suppliers may resist at first when being required to do FMEAs and to have them reviewed for meeting quality standards. In order to ensure FMEA Quality Objectives are met for critical parts, the original equipment manufacturer (OEM) may have to help suppliers with training or participate as needed in certain FMEA team meetings. Since the content of supplier FMEAs is proprietary, the OEM should not retain copies of FMEAs, and, of course, nondisclosure agreements must be in place. With these provisions, most suppliers willingly cooperate in the FMEA quality assurance process, as it is in their best interest to do so.

#### 11.3.4 Implementation Stage

All of the work to plan and implement FMEAs is wasted if the FMEA recommendations are not fully implemented. This is essentially project management and it is in everyone's best interest that it be energetically supported. Figure 11.6 shows the

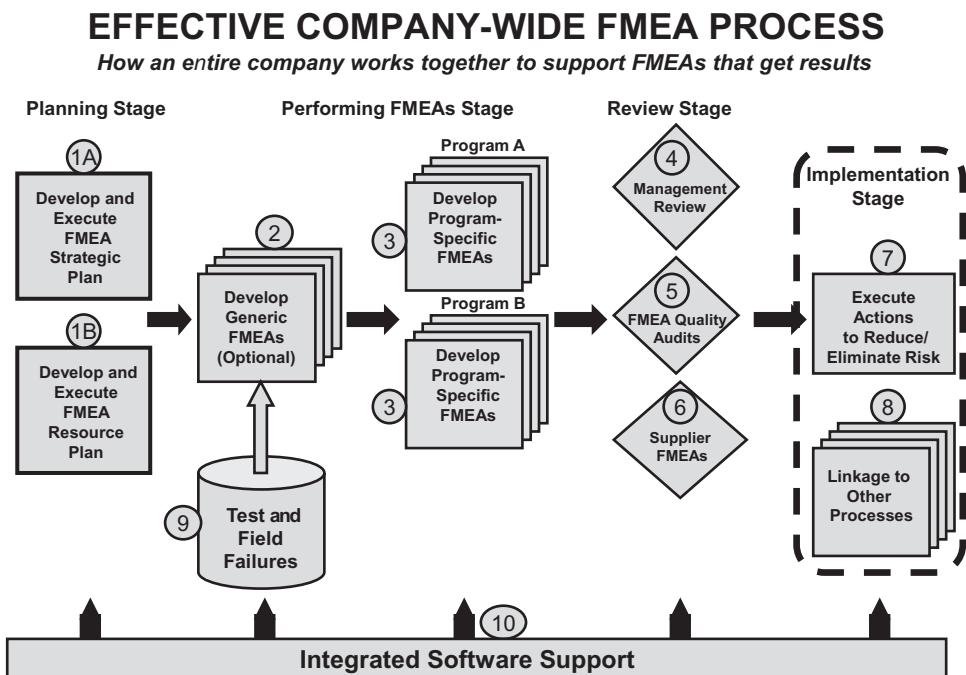


FIGURE 11.6 Tasks done during the Implementation Stage of an Effective FMEA Process.

FMEA Process tasks that are most often done during the implementation stage of an Effective FMEA Process.

**Step 7: Execution of FMEA Recommended Actions** FMEA has little value unless the recommended actions are fully executed. It is vital to follow up each recommended action to ensure completion to the satisfaction of the FMEA team so that risk is eliminated or mitigated to an acceptable level. The FMEA team must bring problems with execution back to management.

Some companies make the mistake of filing their FMEAs as soon as actions are identified. Some companies fail to follow up on recommended actions with a rigorous execution process. Some companies fail to close the loop to assure proper risk reduction. Executing FMEA recommended actions shows due care in assuring the safety, quality, and reliability of systems, subsystems, and components. Undone FMEA recommendations are also “open loops” with potential negative legal ramifications.

Successful FMEA recommended actions should be effective, detailed, and executable. They must have management support and their primary focus should drive design improvements. FMEA teams should use the full range of reliability tools. For additional information on how to develop and execute effective FMEA recommended actions, refer to Chapter 7, Sections 7.2 through 7.6.

**Step 8: Linkages to Other Processes** There are many important quality, reliability, design, and manufacturing processes seamlessly linkable to FMEAs, greatly leveraging their value and usefulness. Examples of these include developing test plans and test procedures, developing manufacturing Process Control Plans, conducting Design Reviews, and the problem tracking and solving process. Many of these processes are detailed in the Advanced Product Quality Planning (APQP) guidelines. Consider this when seeking out software that integrates all of these processes in order to maximize the value of FMEAs.

It is vital that the FMEA Process be integrated with the overall Product Development Process (PDP) and supported with work instructions that define specific procedures and roles and responsibilities for each of the PDP tasks.

It is true that FMEA can be implemented as a stand-alone process and make significant product design or manufacturing process improvements. However, linking FMEAs to other processes results in numerous improved efficiencies also making the linked processes more effective. Refer to Chapter 6, Section 6.3, for specific FMEA linkages to other processes.

### **Step 9: Incorporate Test and Field Failures**

An organization’s ability to learn, and translate that learning into action rapidly, is the ultimate competitive advantage.

—Jack Welch

One of the most important elements of a successful FMEA program is to ensure FMEAs include test and field history. By so doing, the FMEA team can ensure problems that have occurred in the past do not show up in new or modified products. Unfortunately, it is quite common that many of the product issues that result in expensive recalls and warranty payments have occurred before.

There needs to be a separate process and database to capture all test and field failure data. This is the subject of the Failure Review and Corrective Action System. Test and field failure data are critical input to all FMEAs. FMEA teams must carefully review the failure history of similar products or processes and make this information easily accessible. Using this feedback process with test and field data brought into FMEAs, the FMEA team can clearly show which of the failure modes have been seen before and provide assurance to management that they will not be repeated within the scope of the project.

Many companies use generic FMEAs as the repository for test and field issues. In this way, future FMEA projects can benefit from these lessons and ensure that previously seen failures do not repeat. Care must be taken to avoid inaccurate data from the warranty system, which is often “noisy” due to focus on dealer costs and reimbursements, not failure modes and causes.

**Step 10: Support the FMEA Process with Fully Integrated Software** There are many good reasons to use relational database software when doing FMEAs. These include:

- accessibility for all FMEA projects,
- configurability of FMEA standards to organization needs,
- maintenance of generic and program-specific FMEAs,
- ability to easily import and export FMEA data and attach files,
- seamless linkage to other processes,
- easy tracking of FMEA execution of risk reduction actions,
- easy generation of plots and reports for management reviews, and
- allowing users simultaneous access to FMEA database.

All past FMEAs must be easily accessible to current FMEA teams. Chapter 16 covers in detail the selection of good FMEA software. Xfmea software from ReliaSoft Corporation is one such relational database that has been effective in accomplishing all of the above objectives.

## 11.4 LESSONS LEARNED IN IMPLEMENTING A COMPANY-WIDE FMEA PROCESS

### Implementation Case Study 1

#### Company: Large Manufacturer of Vehicle Systems

This company began energetically implementing an FMEA process around 1990 for System, Design, and Process FMEAs. An executive “champion” who oversaw the FMEA process development led the effort and supported the resources needed to be successful. Over the next 5 years, an effective FMEA process was established with trained FMEA core teams and facilitators, including preparation checklists, worksheets, and scales. FMEAs were selected based on preliminary risk assessments and included integrated field histories, supplier FMEA reviews and approvals, and focused on improving designs through a common FMEA process, all the way through to action closure tracking and quality audits.

A noticeable reduction in warranty accrual was observed because of the FMEA implementation efforts on two targeted programs. However, in the early 2000s, the executive “champion” was transferred. Without energetic support from management, budget and headcount reductions forced the transfer of many of the skilled FMEA resources. In many cases, the design and manufacturing engineers were left on their own to do (or not do) FMEAs. Much of the FMEA implementation progress over this 10-year period was lost.

**Lesson:** A successful FMEA process needs the consistent support of an executive “champion” and will falter if support is withdrawn.

### Implementation Case Study 2

#### Company: Equipment OEM

This company required all suppliers to follow the Production Part Approval Process (PPAP) for incoming parts. PPAP requires a Design FMEA if the supplier is responsible for the product design and a Process FMEA if the supplier has manufacturing responsibility. Although the supplier quality department monitored the quality of supplier parts, little effort was put forth to review or audit the *quality* of supplier FMEAs. For the most part the only control was whether an FMEA was done. The company had a policy for RPN “thresholds” in which the supplier was required to submit additional documentation for any RPNs with values over 100. A random review of supplier FMEAs showed mostly poor quality, and not surprisingly, there were few RPNs over 100. For the most part, the supplier FMEAs had little value.

**Lesson:** Companies need to be careful about the use of RPN “thresholds.” Supplier FMEAs need a quality audit process, particularly for critical parts.

### Implementation Case Study 3

#### Company: Small Device Manufacturer

This company developed and manufactured devices that were strictly regulated by the Food and Drug Administration (FDA). They were required to perform FMEAs and use a “red,” “yellow,” and “green” system to highlight risk. The FDA, with significant extra paperwork and meetings, closely monitored all “yellow” and “red” issues. The company worked through all of the “red” and “yellow” issues outside of the FMEA and used the FMEA worksheet to show how the risk was entirely “green.” There were very few recommended actions on the FMEA because there were no “unresolved” issues. The FMEA process was being used as a regulation compliance process, and as a result, it had almost no value in terms of engineering development.

**Lesson:** Using FMEAs *only* to show compliance to a regulatory body wastes valuable time and denies the company a valuable tool to improve product designs.

### Implementation Case Study 4

#### Company: Large Equipment Manufacturer

This company had a moderate quality of FMEAs when they began a process to standardize FMEAs across all of its operations and to improve overall FMEA

quality. The corporate strategy was to establish an “FMEA common process team,” task them to develop and implement a common process, and select and roll out FMEA software. They hoped to gain efficiencies and effectiveness through global standardization and use of common FMEA software. The company maintained dozens of decentralized engineering and manufacturing operations around the globe, which presented a significant challenge to the FMEA common process team. As a result, the corporate strategy to standardize the FMEA process stalled and 5 years later, there was little progress. Missing was strong leadership at the corporate level to require the decentralized business units to make the hard choices needed to achieve standardized processes.

**Lesson:** Potentially great efficiencies are obtainable with company-wide common FMEA processes. However, it requires strong and persistent leadership to achieve this goal.

### Implementation Case Study 5

#### Company: Military Contractor

This company was under contract with the military to design, test, and build a certain type of weapons system. Part of the contract was to perform Failure Mode Effects and Criticality Analysis (FMECA). The FMECA task was delegated to the responsible engineer with no further support from management. The FMECA had to be completed by a certain date and submitted to the government. Without management support, the assigned engineer set up one-on-one meetings with various systems and design engineers to fill out the FMECA form. Much of the Criticality Assessment information was extracted from Military Handbook (MIL-HDBK) 217 or other libraries of data that had only partial relevance to the actual parts being designed. The result was a FMECA worksheet with little or no value.

**Lesson:** Management cannot delegate the entire responsibility for FMEA or FMECA. There are specific roles and responsibilities that management must follow for the FMEA or FMECA to be successful.

## 11.5 COMPANY CLIMATE FOR SHARING FAILURE INFORMATION

Drive out fear, so that everyone may work effectively for the company.

—Dr. W. Edwards Deming

Any organization or company desiring to achieve the highest quality for its products or services, and function at its best, must engender an environment in which personnel feel free and safe to expose discovered weaknesses wherever they are found without fear of reprisal. FMEA, by its very nature, discovers and exposes weaknesses for the sole purpose of correcting them in order to improve the product or service that keeps the company in business. When the focus is on criticism of the “messenger,” instead of the company’s quality and reliability objectives, participation is discouraged. As the company’s success depends upon willing and open participation, it is the responsibility of top management to create the climate for sharing failure information.

## 11.6 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

### Problem 11.1

Management has many important roles in the successful implementation of FMEAs in their company. Which of the following are key roles for management in implementing a successful FMEA process? (Select all that apply.)

1. Provides agreement on FMEA strategy and supports needed resources.
2. Attends individual FMEA meetings to offer management input and support.
3. Assists in integrating FMEA with other business processes.
4. Personally gathers FMEA preliminary information (prework).
5. Provides effective reviews of high severity and high RPN failure modes, causes, and recommended actions.
6. Personally facilitates FMEA meetings according to FMEA procedure.
7. Supports the attendance of expert FMEA team members.
8. Ensures that specific FMEA-related duties of employees are integrated into employee's work instructions.

### Problem 11.2

The following are statements about management reviewing FMEA issues. (Select all that are true.)

1. It is important for management to review all failure modes, causes, and recommendations on a regular basis.
2. Management should review the high-risk issues from FMEAs on a regular basis.
3. When management reviews FMEAs they should offer feedback as to whether or not they support the recommendations from the FMEA team and why.
4. It is only necessary to review the high-risk issues from FMEAs once.

### Problem 11.3

**Scenario:** An FMEA audit is under way. The FMEA team has omitted recommended actions for several high-risk issues in the FMEA. The FMEA auditor should . . . (Select all that apply.)

1. Make note of the omission, recommend the team develop effective actions for the high-risk issues, and recommend remedial FMEA training.
2. Complete the FMEA properly as soon as the audit session is completed.

3. Note the names of the FMEA team members and let their managers know that they are underperforming.
4. Ignore this issue, as it is not the auditors' role to judge the quality of the FMEA.

### Problem 11.4

The following are statements relating to the question how to deal with supplier parts. (Select all that are true.)

1. All supplier FMEAs should be reviewed and approved by the FMEA team according to the FMEA Quality Objectives.
2. Suppliers of critical parts (deemed high risk by the project team) should be required to do FMEAs and warrant that they followed existing standards.
3. Suppliers of critical parts (deemed high risk by the project team) should be required to do FMEAs, and the quality of these selected supplier FMEAs should be reviewed and approved by the FMEA team.
4. If the FMEA team reviewing a supplier FMEA determines that it does not meet the quality objectives, they should return the analysis to the supplier for corrections and resubmission.

### Problem 11.5

This is the same scenario as an End of Chapter problem in Chapter 4, with a different question at the end.

The Incredible Bike Company (IBC) has system design, system integration, and system assembly responsibilities for the new all-terrain bicycle. They decide to use FMEAs to ensure the safety and reliability of the next generation of all-terrain bicycles. The bicycle seat is made of a new material for comfort and durability, and the seat design is considered critical based on Preliminary Risk Assessment. Company X has responsibility for the seat and does the seat design; however, they outsourced the seat manufacturing to company Y. Company Y ships the seats to company X, who verifies they meet all requirements and ships to IBC for assembly as part of the new all-terrain bicycle. The question is, who approves the seat Design and Process FMEAs and why?

### Problem 11.6

FMEAs can be linked to other quality and reliability tools to increase their value. Which of the following statements are true about the linkage of FMEAs to other tools? (Select all that apply.)

- 1.** Design FMEAs may identify shortcomings in the manufacturing Process Control Plans.
- 2.** Process FMEAs can be used to correct shortcomings in the manufacturing Process Control Plans.
- 3.** Design FMEAs identify shortcomings in the Design Verification Plans.
- 4.** FMEA-related tasks should be integrated into the company's Product Development Process.

# *Chapter* 12

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## *Failure Mode Effects and Criticality Analysis (FMECA)*

Measure twice, cut once.

—English Proverb

### **IN THIS CHAPTER**

Some companies choose to add or are mandated to add a Criticality Analysis to the Failure Mode and Effects Analysis (FMEA) procedure, according to specific procedures. This chapter introduces Failure Mode Effects and Criticality Analysis (FMECA) and explains how it is different from FMEA. The Criticality Analysis is detailed here, including both Quantitative and Qualitative Criticality Analysis. Also included are an outline of FMECA history and specific FMECA scales, standards, and examples.

#### **12.1 INTRODUCTION TO FMECA**

Failure Mode Effects and Criticality Analysis (FMECA) is similar to FMEA, with a few exceptions: it uses a different standard, a different set of scales, and it adds a calculation or assessment of *criticality* to the analysis.

The theory and definitions of FMEA and FMECA are similar. Therefore, this chapter does not repeat the concepts, the definitions, and their examples as given in Chapter 3, Section 3.5. The material covered in Chapter 5, Chapter 6, and Chapter

7 on FMEA preparation, procedure, and execution applies quite well to FMECA, and likewise, is not repeated. This chapter focuses on the unique aspects of FMECA, such as the standard, scales, and criticality procedure. Practitioners who will be performing FMECA should study the above referenced chapters on FMEA as well as this chapter on FMECA.

Two analyses comprise the FMECA: FMEA and a separate Criticality Analysis. The FMEA portion analyzes different failure modes and their effects on the system, using specific standards. The Criticality Analysis portion is an objective procedure by which “each potential failure mode is ranked according to the combined influence of its severity and probability of occurrence, and each item has an assigned criticality number.”<sup>[1]</sup>

## 12.2 WHEN TO USE FMECA

There are two common reasons that drive an organization to use FMECA instead of FMEA. The most common reason occurs when government or a customer mandates a FMECA. When mandated, it is usually required to use one of the standards such as Military Standard (MIL-STD) 1629A or Society of Automotive Engineers (SAE) ARP5580 as the standard for application. A second reason is the organization may wish to benefit from the more detailed risk-ranking information from the Criticality Analysis, provided there is sufficient objective failure data and time available to perform the more rigorous calculations.

## 12.3 BRIEF HISTORY OF FMECA

The following excerpt is from a 2006 Department of Army manual describing the history of FMECA<sup>[2]</sup>:

The FMECA was originally developed by the National Aeronautics and Space Administration (NASA) to improve and verify the reliability of space program hardware. The cancelled MIL-STD-785B, entitled *Reliability Program for System and Equipment Development and Production*, Task 204, *Failure Mode, Effects and Criticality Analysis* calls out the procedures for performing a FMECA on equipment or systems. The cancelled MIL-STD-1629A is the military standard that establishes requirements and procedures for performing a FMECA, to evaluate and document, by failure mode analysis, the potential impact of each functional or hardware failure on mission success, personnel and system safety, maintainability and system performance. Each potential failure is ranked by the severity of its effect so that corrective actions may be taken to eliminate or control design risk. High-risk items are those items whose failure would jeopardize the mission or endanger personnel. The techniques presented in this standard may be applied to any electrical or mechanical equipment or system. Although MIL-STD-1629A has been cancelled, its concepts should be applied during the development phases of all critical systems and equipment whether it is military, commercial or industrial systems/products.

The original FMECA military standard was Military Procedure (MIL-P)-1629, written in 1949. It has undergone a number of revisions since then, culminating in the MIL-STD 1629A, entitled “Procedures for Performing a Failure Mode Effects and Criticality Analysis,” published in 1980. Partially revised in 1984, the 1980

version of MIL-STD 1629A was cancelled on August 4, 1998 by issue of the Department of Defense. The 1998 Notice of Cancellation is brief and states, “MIL-STD-1629A, dated 24 November 1980, is hereby canceled. Users may consult various national and international documents for information regarding failure mode, effects, and criticality analysis.”<sup>[3]</sup>

The foreword in SAE ARP5580 *Recommended Failure Mode and Effects Analysis (FMEA) Practices for Non-Automotive Applications* provides a historical record of the transition from MIL-STD-1629 to a new FMEA procedure<sup>[4]</sup>:

In June of 1994, then Secretary of Defense William Perry issued a memorandum titled “Specifications and Standards – A New Way of Doing Business,” which directed the Department of Defense to increase their reliance on commercial products and practices. As a result of “the Perry Memo,” many US military standardization documents, including MIL-STD-1629, were cited for cancellation. Around the same time, the Defense Standards Improvement Council (DSIC) was chartered to oversee the standardization reform process. DSIC coordinated its position on MIL-STD-1629 with the Society of Automotive Engineers, which through its G-11, Reliability, Maintainability, Supportability and Logistics (RMSL) Division had already chartered a subcommittee to create a new FMEA procedure updating MIL-STD-1629. The subcommittee was composed of representatives from industry, government and academia. In response to that charter, this recommended best practice was developed.

## 12.4 TYPES OF FMECA

There are two primary types of FMECA. One is *Quantitative FMECA*, and the other is *Qualitative FMECA*. Both types of FMECA use a defined criticality analysis. They are similar in procedure, with the exception that the *Quantitative FMECA* uses a *Quantitative Criticality Analysis* and the *Qualitative FMECA* uses a *Qualitative Criticality Analysis*. Each type of analysis is described below.

MIL-STD 1629A discusses two *approaches* for accomplishing an FMEA. One is the “hardware approach,” which lists individual hardware items and analyzes their possible failure modes. According to MIL-STD 1629A, the hardware approach is normally utilized in a part level up (bottom-up) approach. The other is the “functional approach,” which recognizes that every item is designed to perform a number of functions that can be classified as outputs. The standard goes on to describe the application differences between these two approaches. Care should be exercised when interpreting hardware versus functional approaches to avoid potential misapplications. *All* FMEAs require identifying and understanding the *functions* of each item being analyzed, regardless of whether the item is a system, subsystem, component, or part. In addition, great care must be taken to address all *interfaces* between parts, components, subsystems, and users, which usually account for more than half of the potential failure modes.

## 12.5 QUANTITATIVE CRITICALITY ANALYSIS

Quantitative Criticality Analysis is a series of calculations to rank items and failure modes according to a formula covered below. To use Quantitative Criticality Analysis to evaluate risk and prioritize corrective actions:

1. *Calculate the Expected Failures for Each Item.* This is the number of failures estimated to occur based on the reliability/unreliability of the item at a given time. Reliability is the probability that an item will perform a required function without failure under stated conditions for a stated period of time. Unreliability is one minus reliability. The “time” for the calculation is most often the target or useful life of the item. With an exponential distribution, *expected failures* is calculated by multiplying the failure rate by the time ( $\lambda t$ ), but it is estimated differently for other distributions.

Care must be taken to ensure calculations for reliability/unreliability and expected failures are based on correct failure distributions. Some practitioners assume an exponential distribution (constant failure rate); however, this assumption is not always valid. It is wise to solicit the support of a reliability engineer or other practitioner who is well experienced in these types of calculations.

2. *Identify the Mode Ratio of Unreliability for Each Potential Failure Mode.* This is the portion of the item’s unreliability (in terms of expected failures) attributable to each potential failure mode. In other words, this represents the percentage of all failures for the item that will be due to the failure mode under consideration. The total percentage assigned to all modes must be equal to 100%.

The failure mode ratio of unreliability can be based on reliability growth testing data for the current design, field data and/or test data from a similar design, engineering judgment (“best guess”), or apportionment libraries such as MIL-HDBK-338B. Exercise care if engineering judgment is used because the intent of a criticality calculation is an objective number, not a “best guess” number. Apportionment libraries are often only rough approximations, and should only be used if one is confident of their validity for the given application.

3. *Rate the Probability of Loss That Will Result from Each Failure Mode That Will Occur.* This is the probability that a failure of the item under analysis will cause a system failure. The following are guidelines from MIL-STD 1629A for establishing the probability of loss for the criticality calculation<sup>[1]</sup>:

Actual Loss: 100%

Probable Loss: from >10% to <100%

Possible Loss: from >0% to <10%

None: 0

4. *Calculate the Mode Criticality for Each Potential Failure Mode.* This is the product of the three factors:

$$\text{Mode Criticality} = \text{Expected Failures (for the item)} \times$$

$$\text{Mode Ratio of Unreliability (for the failure mode)} \times$$

$$\text{Probability of Loss (for the failure mode)}$$

5. *Calculate the Item Criticality for Each Item.* This is the sum of the mode criticalities for each failure mode identified for the item.

$$\text{Item Criticality} = \text{SUM of Mode Criticalities}$$

### **Example: Quantitative Criticality Analysis on Bicycle Brake Pad**

In this example, shown in Figure 12.1, a bicycle brake pad is analyzed using *Quantitative Criticality Analysis*. The values in this example for reliability, unreliability, failure mode apportionment, and probability of loss are fictional.

Item: bicycle brake pad

Assumptions for this example: time frame = 5 years; customer usage for high end user = 3 h/day or 5475 hours over the life of the brake pad. Assumed failure rate = 0.0001 failures/hour.

1. Calculate the *expected failures* for the brake pad at 5 years. Based on assumptions, the number of failures at 5 years is 0.548 (5475 hours multiplied by 0.0001 failures/hour)
2. Identify the portion of the item's unreliability (in terms of expected failures) attributed to each potential failure mode. In this example, there are two failure modes: excessive wear (85%) and cracking (15%).
3. Rate the probability of loss (or severity) that will result from each failure mode that will occur. In this example, the probability of loss of the system due to excessive wear is 75% and due to cracking is 15%.
4. Calculate the criticality for each potential failure mode by obtaining the product of the three factors:

$$\text{Mode Criticality for excessive wear} = 0.548 \times 0.85 \times 0.75 = 0.349,$$

$$\text{Mode Criticality for cracking} = 0.548 \times 0.15 \times 0.15 = 0.012.$$

5. Calculate the criticality for each item by obtaining the sum of the criticalities for each failure mode identified for the item:

$$\text{Item Criticality for the brake pad} = 0.349 + 0.012 = 0.361.$$

Figure 12.1 shows an example of Quantitative Criticality Analysis in worksheet form along with associated FMEA information.

## **12.6 QUALITATIVE CRITICALITY ANALYSIS**

Qualitative Criticality Analysis does not involve the same rigorous calculations as Quantitative Criticality Analysis. To use Qualitative Criticality Analysis to evaluate risk and prioritize corrective actions:

1. Rate the severity of the potential effects of failure. The severity ranking is determined using the unique severity scale for FMECA.
2. Rate the likelihood of occurrence for each potential failure mode. The occurrence ranking is determined using the unique occurrence scale for FMECA.
3. Compare failure modes using a criticality matrix. The criticality matrix identifies severity on the horizontal axis and occurrence on the vertical axis.

ITEMS	OPERATING TIME (hours)	EXPECTED FAILURES	FUNCTIONS	FAILURES AND CAUSES	RATIO OF UNRELIABILITY	PROBABILITY OF LOSS	MODE CRITICALITY	ITEM CRITICALITY
Brake Pad	5475	0.548	The brake pads provide the primary means of friction between the force of the brake caliper against the front and rear wheel in order to bring the wheel to a controlled stop. The pads needs to be adjustable on the brake caliper by bicycle operator and durable in all operating conditions for the life of the bicycle.	Excessive wear of pad material - Wrong pad material selected	0.85	0.75	0.349	0.361
				Pad material cracks - Pad material cured at incorrect temperature	0.15	0.15	0.012	0.012

TRUNCATED

**FIGURE 12.1** Example of Quantitative Criticality Analysis on a bicycle brake pad.

The scale utilized to assign severity classification from MIL-STD 1629A follows<sup>[1]</sup>:

**Category I: Catastrophic**

Criteria: A failure that may cause death or system loss

**Category II: Critical**

Criteria: A failure that may cause severe injury, major property damage, or major system damage which will result in mission loss

**Category III: Marginal**

Criteria: A failure that may cause minor injury, minor property damage, or minor system damage which will result in delay or loss of availability or mission degradation

**Category IV: Minor**

Criteria: A failure that is not serious enough to cause injury, property damage, or system damage, but will result in unscheduled maintenance or repair

The scale utilized to assign failure probability from MIL-STD 1629A follows<sup>[1]</sup>:

**Level A: Frequent**

A high probability of occurrence during the item operating time interval. *Frequent* may be defined as a single failure mode probability greater than 0.20 of the overall probability of failure during the item operating time interval.

**Level B: Reasonably Probable**

A moderate probability of occurrence during the item operating time interval. *Reasonably probable* may be defined as a single failure mode probability of occurrence which is more than 0.10 but less than 0.20 of the overall probability of failure during the item operating time.

**Level C: Occasional**

An occasional probability of occurrence during item operating time interval. *Occasional probability* may be defined as a single failure mode probability of occurrence which is more than 0.01 but less than 0.10 of the overall probability of failure during the item operating time.

**Level D: Remote**

An unlikely probability of occurrence during item operating time interval. *Remote probability* may be defined as a single failure mode probability of occurrence which is more than 0.001 but less than 0.01 of the overall probability of failure during the item operating time.

**Level E: Extremely Unlikely**

A failure whose probability of occurrence is essentially zero during item operating time interval. *Extremely unlikely* may be defined as a single failure mode probability of occurrence which is less than 0.001 of the overall probability of failure during the item operating time.

### Example: Qualitative Criticality Analysis on Bicycle Brake Pad

In this example, a bicycle brake pad is being analyzed using *Qualitative* Criticality Analysis. Figure 12.2 shows the Qualitative Criticality Analysis in worksheet format.

## 12.7 FMECA CRITICALITY MATRIX

It can be useful to graphically display the risk associated with severity and occurrence. This graphical depiction is called a criticality matrix. The criticality matrix identifies severity on the horizontal axis and occurrence on the vertical axis. Figure 12.3 shows a criticality matrix for the bicycle brake pad.

Criticality matrix can also be used in Quantitative Criticality Analysis in order to graphically plot item criticality versus severity. In that use of criticality matrix, item criticality substitutes for occurrence on the vertical axis.

## 12.8 FMECA WORKSHEET

The preparation steps outlined for FMEA in Chapter 5 are similar for FMECA. Of course, the scales will be different and, if *Quantitative* Criticality Analysis is used, the “gather information” step needs to include item reliability and failure mode apportionment data.

Figure 12.4 is an example of a FMECA worksheet, not including the Criticality Analysis.<sup>[1]</sup>

## 12.9 SUMMARY OUTPUT OF FMECA

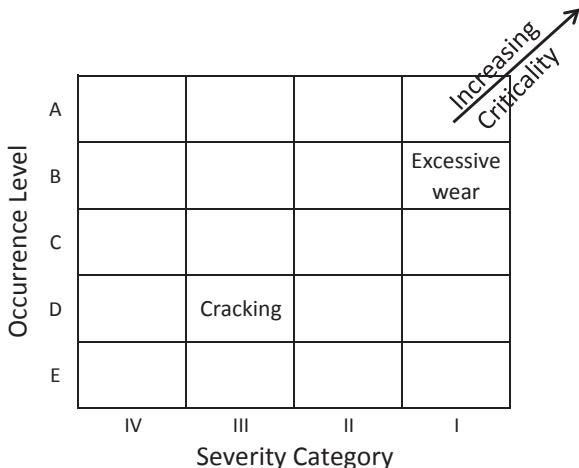
As required by MIL-STD 1629A, the following is a list of the summary output items from a completed FMECA project<sup>[1]</sup>:

1. Reliability critical item list
  - a. Description of design features which minimize the occurrence of failure for each item
  - b. Description of tests accomplished that verify design features and tests planned that would detect the failure mode
  - c. Description of planned inspections to ensure hardware is being built to design requirements
  - d. Statement relating to history of design
  - e. Description of method by which operator will detect the failure mode
  - f. Rationale for not eliminating the related failure modes
2. Category I and II failure mode list, with same information as reliability critical list
3. Single failure points list, with the same information as reliability critical list, including the criticality classification for each single failure point

ITEM	FUNCTION	FAILURE MODES AND CAUSES	LOCAL EFFECTS	FAILURE EFFECTS	SEVERITY CLASS	FAILURE DETECTION METHOD	COMPENSATING PROVISIONS
			NEXT HIGHER LEVEL	END EFFECTS			
Brake Pads	The brake pads provide the primary means of friction between the force of the brake caliper against front and rear wheel in order to bring the wheel to a controlled stop. The pads need to be adjustable on the brake caliper by bicycle operator and durable in all operating conditions for the life of the bicycle.	Excessive wear of pad material Wrong pad material selected	The brake pad does not provide adequate and controlled friction to the wheel.	Wheel does not slow adequately down when brake lever pulled	Category I - Catastrophic	Bicycle brake testing procedure #1234	1. Add new brake pad durability test 2. Select new brake material with better durability
		Pad material cracks	Pad provides erratic friction	Wheel motion chugs during stopping maneuver	Bicycle operator dissatisfied with bicycle operation	Category III - Marginal	No detection provided until owner discovers problem
		Pad material cured at incorrect temperature					1. Revise pad material curing procedure to ensure no cracking

TRUNCATED

**FIGURE 12.2** Example of Qualitative Criticality Analysis on a bicycle brake pad.



**FIGURE 12.3** Example of FMECA Criticality Matrix on a bicycle brake pad.

A “single failure point” is defined as “the failure of an item which would result in failure of the system and is not compensated for by redundancy or an alternative operational procedure.”<sup>[1]</sup>

## 12.10 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

### Problem 12.1

The following are statements about FMECAs (select all that are true):

1. FMECA adds a Criticality Analysis to FMEA, along with a different set of scales.
2. There is no difference between an FMEA and a FMECA.
3. FMECA is no longer used by companies as the original standard has been canceled.
4. The “C” in FMECA stands for “Cause.”

### Problem 12.2

When doing a Criticality Analysis for a FMECA, keep in mind the following (select all that apply):

1. A Criticality Analysis is the same as a Risk Priority Number (RPN) calculation in FMEA procedure.

**FIGURE 12.4** Example of FMECA worksheet not including criticality analysis.

2. Quantitative Criticality Analysis calculation uses the *mode ratio of unreliability* for each potential failure mode as part of its calculation.
3. Qualitative Criticality Analysis uses severity and detection risk rankings.
4. A criticality matrix can be used to graphically plot criticality versus severity.

### Problem 12.3

Mode Criticality is the product of which three factors? (Select the correct answer.)

1. Severity, probability of occurrence, and probability of loss
2. Expected failures, mode ratio of unreliability, and item criticality
3. Failure probability, mode ratio of reliability, and expected failures
4. Expected failures, mode ratio of unreliability, and probability of loss

### Problem 12.4

Perform quantitative criticality analysis on a bicycle brake lever.

Input data:

The brake lever has an expected life of 5 years. The bicycle reliability engineer says the brake lever will have an estimated 0.5 failures in 5 years based on failure distributions, and so on.

There are two failure modes: cracking and bending. Cracking makes up 30% of the failures; bending makes up the other 70% of the failures. The probability of system loss for cracking is 60%, and for bending, is 10%.

Calculate the criticality for each potential failure mode and the overall criticality of the brake lever.

## REFERENCES

1. Military, United States, 1980, MIL-STD-1629A: Procedures for Performing a Failure Mode Effects and Criticality Analysis, Department of Defense.
2. Military, United States, 2006, Failure Modes, Effects and Criticality Analysis (FMECA) for Command, Control, Communications, Computer, Intelligence, Surveillance, and Reconnaissance (C4ISR) Facilities, Headquarters, Department of Army.
3. Military, United States, 1998, Notice of Cancellation: Procedures for Performing a Failure Mode Effects and Criticality Analysis, Defense, Editor.
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# *Chapter* 13

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## *Introduction to Design Review Based on Failure Mode (DRBFM)*

The whole of science is nothing more than the refinement of thinking.

—Albert Einstein

### **IN THIS CHAPTER**

Many companies are incorporating Design Review Based on Failure Mode (DRBFM) along with Failure Mode and Effects Analysis (FMEA). This chapter introduces the DRBFM methodology, explains how it is different from FMEA, when it should be used, and how it is done. Also covered is a brief history of DRBFM, the DRBFM procedure, DRBFM case studies, available DRBFM references and a section on Design Review Based on Test Results (DRBTR).

#### **13.1 WHAT IS DRBFM?**

Design Review Based on Failure Mode (DRBFM) is a method developed by Tatsuhiko Yoshimura, a quality expert with extensive experience in academia and industry. Yoshimura says that design problems occur when changes are made without the proper level of supporting documentation. Using the philosophy of Preventive Measures (Mizenboushi), he created his own philosophy of DRBFM. The Philosophy of DRBFM centers on three concepts: Good Design, Good Discussion, and Good Dissection. These three concepts are called GD<sup>3</sup>.

Figure 13.1 shows the conceptual relationship between the elements of GD<sup>3</sup>.<sup>[1]</sup>

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*Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis*, First Edition. Carl S. Carlson.

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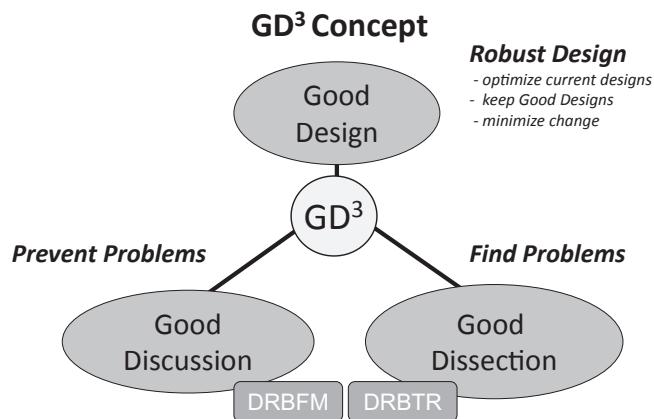


FIGURE 13.1 Good design, good discussion, good dissection.

The practice of GD<sup>3</sup> directs attention to *change*, as change creates “buds of problems,” meaning the early manifestation of problems that can grow and cause trouble if not discovered and eliminated. It directs attention to interfaces, as most defects occur at the interfaces. In addition, it directs people to visualize and to find, as *seeing* and *finding* are the proactive characteristics of DRBFM. “For this reason, DRBFM has been developed to perform a Design Review based on FMEA in order to ‘discover and solve problems,’ while focusing specifically on ‘intentional and incidental changes.’”<sup>[2]</sup>

### Good Design

The first GD (Good Design) is a robust design, one that is safe, reliable, insensitive to anticipated variations in environment and applications, and has successfully been used in service. The essence of Good Design is to begin with a proven and reliable design. It is well known to reliability experts that changes in design can result in reliability problems. If a design changes, the change should occur in small increments. Design problems often result when implementing changes affecting the interfaces between parts. The design should not be changed in two different places simultaneously, because making too many changes too fast has the potential to result in failures faster than the capacity to resolve them.

Good Design is intended to accomplish a trouble-free design using all reliability techniques possible. Tatsuhiko Yoshimura stresses utilizing engineering knowledge to uncover hidden problems within new designs and foresee problems with change points that are intentional and incidental. Starting with the foundation of known (good) design is a fundamental step in DRBFM.<sup>[1]</sup>

### Good Discussion

The second GD (Good Discussion) helps find problems through a forum of open discussion with a cross-functional team. The essence of Good Discussion is to identify and eliminate risk, and one of the keys to this is making changes visible. It does this by comparing the differences between the current design and the “Good

Design.” The real gains are in taking steps to prevent problems prior to their occurrence. The intent of DRBFM is early identification of any problems hidden within new designs and design modifications. DRBFM is a method of uncovering problems and addressing them by developing countermeasures and action plans (design, validation, and manufacturing).<sup>[1]</sup>

Discussions should focus on the proposed changes to a design. If a proven good design is applied to future products, then the risk of failure is lower; however, if changes are made to the existing design, then the probability of failure is increased. DRBFM teams should work to understand the changes and afford them their due importance. Validation testing can help to identify design weaknesses; however, good discussions held at preliminary design reviews can achieve the same result. Mr. Yoshimura recommends using the Design FMEA format if a good FMEA process is already in place. A comprehensive, well-done FMEA can be considered a prerequisite for a DRBFM; the DRBFM can be implemented when design changes occur. The intent of the DRBFM is to make the changes visible by discussing them at length, as well as every possible concern for failure that may potentially occur.

### **Good Dissection**

The third GD (Good Dissection) focuses on a review of products that have completed validation testing. The essence of Good Dissection is to examine the results of validation testing, making all mistakes visible. This examination involves applying DRBFM to another concept, Design Review Based on Test Results (DRBTR). When applying DRBTR, wherever possible the actual test failure must be observed. DRBFM encourages the designer to discuss potential design problems or weaknesses from a cross-functional multiperspective approach, and to share this information. DRBTR involves the designer observing actual test pieces and discussing test results in open discussions during design reviews. Furthermore, when dissecting test results, one should also determine if the test regimen was the most effective means for finding problems.

The product may have passed the test to requirements; however, it is important to understand if something is about to happen (a bud of a problem). This step will document these observations. Parts need to be closely examined after testing and it is very helpful to examine the parts while comparing to a reference part that was not tested to determine if there is a change in the ideal state.<sup>[1]</sup>

DRBFM thoroughly evaluates proposed changes to an existing design. It is now widely used by many companies. It combines Design Review and FMEA, with combined discussion of concerns, such as:

- Design concerns
- Validation and verification concerns
- Process concerns
- Manufacturing concerns
- Supplier concerns
- Customer expectations
- Cost and delivery concerns
- Maintenance concerns

In summary, Good Design begins with stable and robust design, preferably with a good FMEA. Good Discussion identifies the intentional and incidental changes, thoroughly discusses the changes with a team of subject-matter experts focusing on weak points in the design, and identifies countermeasures in the design, evaluation, and manufacturing process. Good Dissection examines the results of evaluation testing, making all mistakes visible.

## 13.2 CHANGE POINT ANALYSIS

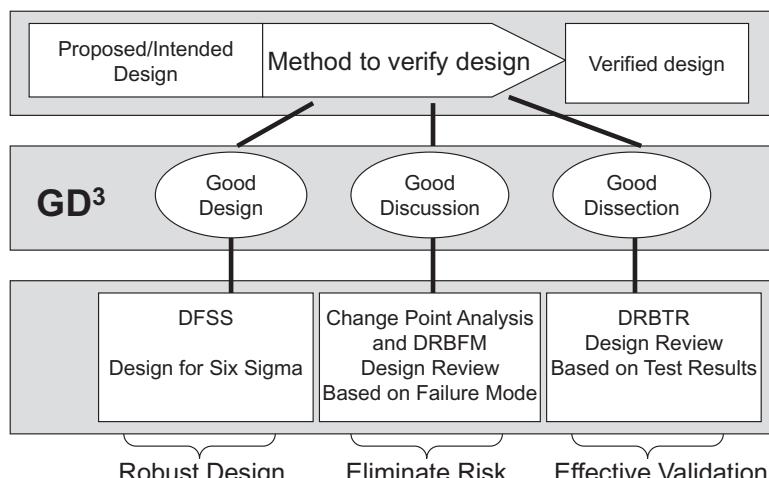
Nothing endures but change.

—Heraclitus

A DRBFM project always builds from the success of a Good Design. Once the Good Design is established, the next step in a DRBFM project is called “Change Point Analysis.” It begins with the baseline design and focuses on the *specific changes* to the design. It is the initial step in Good Discussion. The main idea is to begin with a robust design and to fully understand and document all of the change points to the baseline design. Change points can include changes in design, manufacturing, supplier, supplier design or process, usage environment, interfaces, specifications, performance requirements, or any other changes.<sup>[3]</sup>

Figure 13.2 is an example from one company of the entire GD<sup>3</sup> method for problem prevention, including how point Change Point Analysis fits into the process.<sup>[3]</sup>

Figure 13.3 is an example of a table that can be helpful to make the changes visible. The “Change Category” column can be tailored to company applications. The idea is to list all specific changes and compare them to the baseline. In this



**FIGURE 13.2** GD<sup>3</sup> method for problem prevention.  
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Change Category	Description of Intentional or Incidental Change		Initial Concerns	Risk Priority (high, med, low)	Priority Reason
	Old	New			
Specifications					
Functions					
Environment					
Temperature					
Temp ramp					
Humidity					
Stress loads					
EMI					
Dust					
Light					
Water					
Etc.					
Interfaces					
Size					
Shape					
Electrical inputs					
Material					
Lubrication					
Supplier					
Manufacturing process					
Assembly process					
Etc.					

**FIGURE 13.3** Example of change point table.

(EMI, electromagnetic interference.)

example, “Initial Concerns” and “Risk Priority” columns are added to the table and will be helpful when performing the DRBFM analysis.

Some companies also use a Change Point–Function matrix to help make changes even more visible. Changes become rows in the matrix and Functions are columns. Initial concerns are entered in the appropriate cells of the matrix. The more visible the changes the less likely any will be missed.

The following is an excerpt from a paper titled “Reliability Problem Prevention Method for Automotive Components,” authored by Hirokazu Shimizu and Toshiyuki Imagawa from Toyota Motor Corporation and Hiroshi Noguchi from Kyushu University. It discusses the importance of clarifying changes.<sup>[4]</sup>

Before discussing problems, it is important to clarify changes that are intentional (involving an engineering change) and changes that are incidental (change in environment or load conditions). Discussion of these two types of changes is the most important process: it helps discover the “buds of problems” hidden in the new designs. If the changes become clear, it is likely that potential problems will present themselves as well, possibly from a viewpoint different from that of the original designer. To encourage this, a change list is made...before holding discussion for the Part DRBFM. The priority for removing or modifying an element, even a small part, is determined by the potential effect on part functionality and not by the scale of the change.

An example of Change Point Analysis is shown in DRBFM Case Study 2, in Section 13.6.

### 13.3 CONDUCTING DRBFM PROJECTS

Similar to FMEA, DRBFM projects require thorough preparation, defined procedure, and energetic execution of recommendations. A brief description of these steps follows.

#### **DRBFM Preparation**

DRBFM preparation begins by identifying the changes that need to be analyzed with DRBFM. See Section 13.2, “Change Point Analysis” in this chapter, which outlines the process to make changes visible. The identified changes define the scope of the DRBFM project. Refer also to Chapter 4, Section 4.3, for information on “Preliminary Risk Assessment,” which can be applied to DRBFM project selection.

Once a DRBFM project is selected and the changes made visible, the project leader needs to gather documents and information in preparation for the DRBFM meetings. Within the scope of the DRBFM project, preparation includes:

- Parts and interfaces that are changing
- Description of the changes (Change Point Analysis)
- Understanding of the interactions and interfaces for the parts under consideration
- Customer usages and operating environments
- Requirements and specifications
- Previous FMEAs, FTAs, and testing results
- Engineering drawings and sample parts
- Current test plans and procedures
- Function Focal Point Table (reference Chapter 6, Section 6.2)

Some companies use a stress-malfunction worksheet to increase awareness of potential causes and their relationship to the myriad of stresses. The categories of stress are listed in the left column, the specific stresses in the middle column, and potential malfunction examples in the right column. This worksheet can be tailored to the unique system being analyzed. The purpose is to generate discussion during the engineering discussion portion of the DRBFM project.

Refer to Chapter 5, which has information that can be helpful in preparing for a DRBFM project.

#### **DRBFM Procedure: Portion Completed by Design Representative**

Once the change points are determined and the DRBFM preparation material is gathered, the DRBFM analysis is usually done in two separate steps. In the first step, the responsible engineer completes the first portion of the DRBFM worksheet, including intentional and incidental changes, functions, initial concerns, initial causes, and a description of how the current design avoids concerns, and provides a draft to the team prior to the review. A comprehensive listing of all functions is a necessary part of the DRBFM analysis. Refer to the “Checklist of Function Types” and the example of “Function Focal Point Table” in Chapter 6, Section 6.2.2, for information on how to ensure all primary functions are identified.

## DRBFM Procedure: Engineering Discussion by Expert Team

The second step is an *engineering discussion* regarding the areas of change and interfaces. Experts from the required disciplines participate to make sure the responsible engineer missed nothing. The responsible engineer explains the changes to the DRBFM team and reviews whatever analyses have been completed to date. The expert team identifies additional points of concern, effects to customer, detailed causes, and recommended actions (design related, evaluation related, and manufacturing/supplier related) to eliminate the concerns.

“With a focus on *intentional* and *incidental* changes, concerns (failure modes) are considered from the customer’s point of view, for each component subject to discussion. The discussion clarifies potential causes behind concerns, which are systematically organized using the DRBFM worksheet.”<sup>[4]</sup>

The essence of the engineering discussion is on *openness* and *depth* of discussion. The value of the DRBFM is in the synergy and dialog between the expert team members.

Section 13.5 includes an example of a DRBFM worksheet, which shows the columns that are filled out by the design representative (first step) and the columns that are part of the engineering discussion (second step).

Emphasis should be on using the “Five Whys” to be sure that root causes are identified for all concerns. (Refer to the section on “Five Whys” in Chapter 6, Section 6.2.7).

The expert team identifies actions to address the root causes of each concern, focusing on items to reflect in design, evaluation, manufacturing, and/or with supplier. Refer to Chapter 7, Sections 7.2 and 7.3, for information on how to develop effective action strategies to address risk in design, validation, or manufacturing.

However it is done, it is essential for the expert team to ensure that all concerns are identified, with root causes for each concern, and effective actions recommended that mitigate or eliminate risk.

## DRBFM Closure

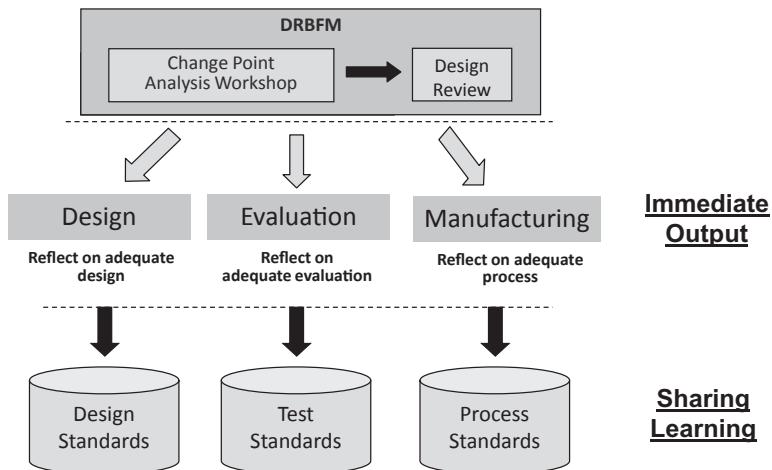
Each of the recommended actions that address concerns related to design, evaluation, and manufacturing need to be implemented. Refer to Chapter 7, Section 7.5, for suggestions on how to ensure recommended actions are properly executed.

In order to verify that each identified cause has been thoroughly addressed, the following DRBFM actions are reviewed and documented:

- All design-related actions
- All validation/verification testing
- All manufacturing-, assembly-, and supplier-related actions

If the above actions effectively address all of the concerns identified by the DRBFM team, the proposed change (the subject of the DRBFM) is accepted and implemented. If the above actions are implemented and the concerns are not resolved, the proposed change should be rejected.

Figure 13.4 illustrates the immediate output of a DRBFM project, as well as the concept of shared learning.<sup>[3]</sup>



**FIGURE 13.4** Output of a DRBFM project.

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### 13.4 HOW DRBFM INTEGRATES WITH FMEA

Ideally, a well-done baseline FMEA should precede a DRBFM project. Properly done, an FMEA is an essential part of design for reliability and Good Design. Subsequent changes to the design or the process can be evaluated by proper DRBFM procedure to ensure all concerns are surfaced and addressed. Many of the elements of FMEA provide input to the DRBFM analysis, and good FMEA software should support this integration between DRBFM and FMEA. Emphasis must be on a *well-done* FMEA, including proper preparation, correct cross-functional team of experts, correct procedure, identification of true root causes, and development and execution of effective actions to reduce risk. An improper FMEA is not a baseline to a DRBFM project.

Refer to Chapters 5, 6, and 7 for information on the preparation, procedure, and execution of effective FMEAs.

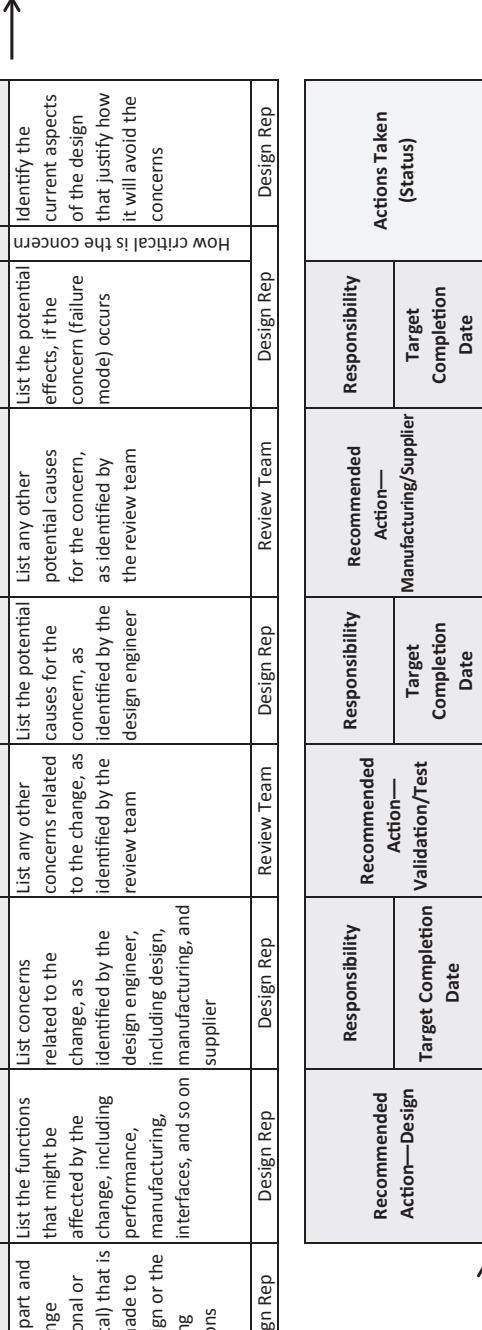
### 13.5 DRBFM WORKSHEET

Figure 13.5 is an example of a DRBFM worksheet, with explanations for each column. The column headings are an integration of the DRBFM references noted later in this chapter. As of the publication date for this book, there is no standard worksheet for DRBFM. Individual practitioners can tailor the column headings for their unique application, paying attention to ensure the flow of information is consistent with good DRBFM techniques.

### 13.6 DRBFM EXAMPLES AND CASE STUDIES

#### 13.6.1 DRBFM Case Study 1

In their paper titled “Design review based on failure mode to visualize reliability problems in the development stage of mechanical products,”<sup>[5]</sup> the authors highlight a system DRBFM case study on the Electric Power Steering (EPS) system. The EPS



Part/Intentional or Incidental Change	Function	Concerns Related to Change (Failure Mode)	Any Other Concerns (Review)	Causes/Root Cause	Any Other Causes (Review)	Potential Effects of Concern	How Current Design Avoids Concerns
List the part and the change (intentional or incidental) that is being made to the design or the operating conditions	List the functions that might be affected by the change, including performance, manufacturing, interfaces, and so on	List concerns related to the change, as identified by the design engineer, including design, manufacturing, and supplier	List any other concerns related to the change, as identified by the review team	List the potential causes for the concern, as identified by the design engineer	List any other potential causes for the concern, as identified by the review team	List the potential effects, if the concern (failure mode) occurs	Identify the current aspects of the design that justify how it will avoid the concerns How critical is the concern
Design Rep	Design Rep	Design Rep	Review Team	Design Rep	Review Team	Design Rep	Design Rep

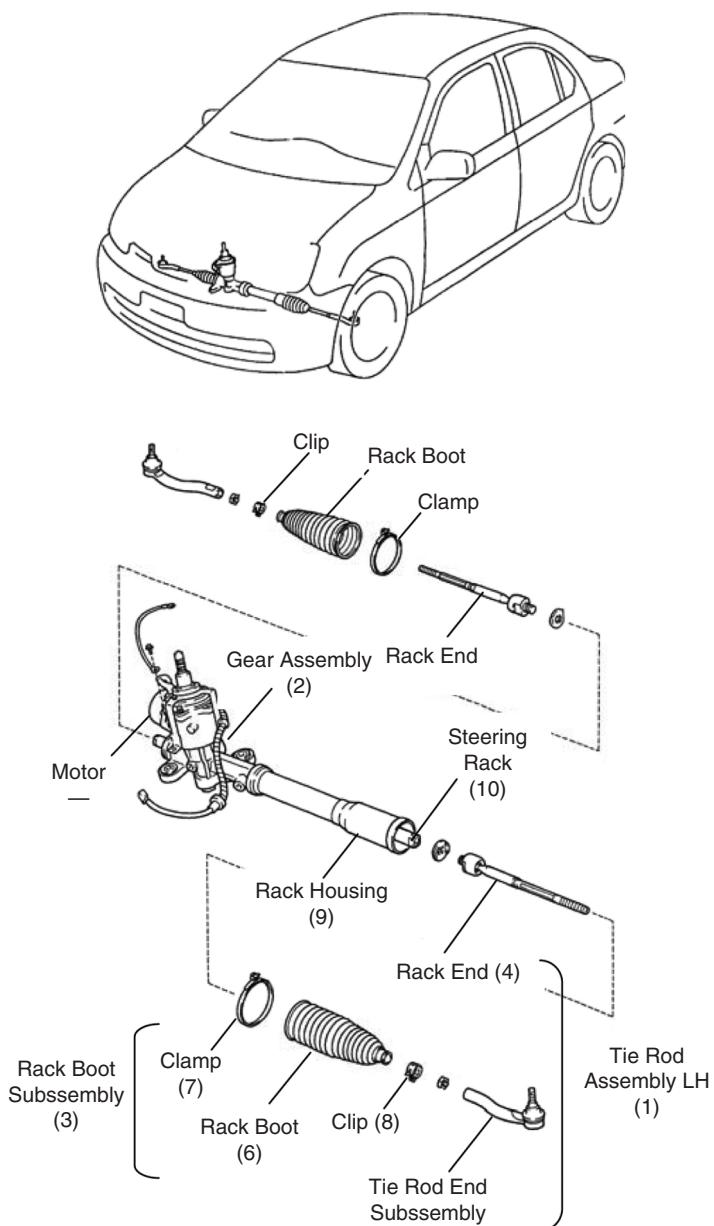
  

Recommended Action—Design	Responsibility	Recommended Action—Validation/Test	Responsibility	Recommended Action—Manufacturing/Supplier	Responsibility	Target Completion Date	Actions Taken (Status)
List the design-related actions that could be taken to reduce the risk associated with the concerns	The name of the person who has responsibility for each action	List the testing-related actions that could be taken to reduce the risk associated with the concerns	The name of the person who has responsibility for each action	List the manufacturing-related actions that could be taken to reduce the risk associated with the concerns	The name of the person who has responsibility for each action	The actions taken (or result) for each action	
Review Team	Review Team	Review Team	Review Team	Review Team	Review Team	Review Team	Review Team

**FIGURE 13.5** Example of DRBFM worksheet.

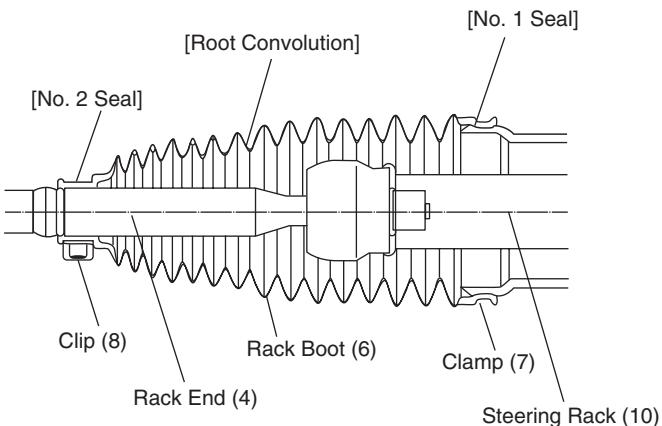
includes both a mechanical system and electronic control system, with DRBFM participants from those respective disciplines. In this case study, design changes to the Rack Boot Subassembly (component of the Tie Rod Assembly) were targeted for the DRBFM process. The DRBFM team documented the specific design and material changes to the Rack Boot Subassembly, called a Modified Item List, and this was a key input to the system DRBFM.<sup>[5]</sup>

Figure 13.6 is a graphic representation of the EPS system. Figure 13.7 shows a sectional view of the Rack Boot Subassembly.<sup>[5]</sup>



**FIGURE 13.6** Target of system DRBFM—electronic power steering system.

(The numbers in parentheses refer to the EPS system hierarchy designation. Reprinted with kind permission from InderScience Enterprises Limited.)



**FIGURE 13.7** Rack boot subassembly sectional view.

(The numbers in parentheses refer to the EPS system hierarchy designation. Reprinted with kind permission from InderScience Enterprises Limited.)

Figure 13.8 shows an excerpt from the results of the EPS DRBFM in the DRBFM worksheet format. The discussion first focused on the impact of the planned hardness increase of the Rack Boot (from 50 to 95 Hs) and corresponding countermeasures. Similar discussions took place about changes to other elements of the Rack Boot Subassembly, with appropriate countermeasures.<sup>[5]</sup>

### Student Exercise

Students are encouraged to analyze this case study, including the DRBFM worksheet on rack boot subassembly. See Problem 13.8 in Section 13.10, “End of Chapter Problems,” for the evaluation exercise.

#### 13.6.2 DRBFM Case Study 2

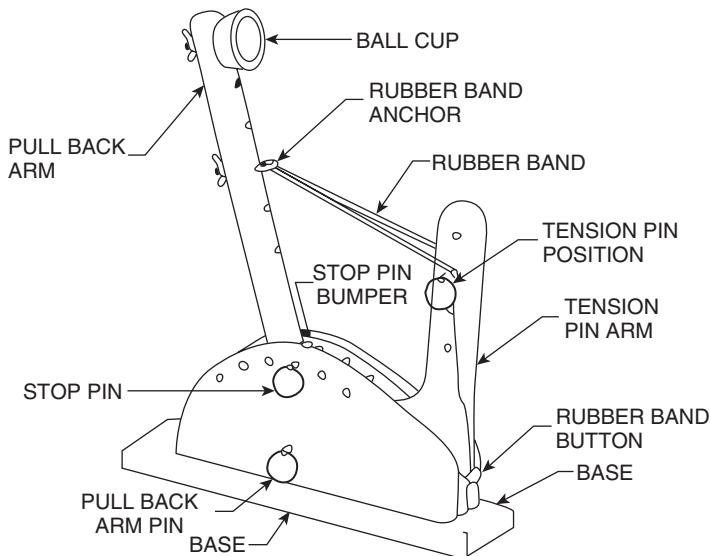
This fictional case study of a catapult is excerpted from a paper presented at the 2008 Applied Reliability Symposium entitled “Change Point Analysis and DRBFM: A Winning Combination,” presented by Lisa Allan. The catapult arm material was to be changed from oak to pine, and specific changes were analyzed in the Change Point Analysis, followed by a DRBFM project. Figure 13.9 is a schematic of the catapult. Figure 13.10 shows the Change Point Analysis on the proposed catapult design change. Figure 13.11 shows the DRBFM worksheet and the results of the DRBFM analysis.<sup>[3]</sup>

#### 13.6.3 DRBFM Case Study 3

Refer to Chapter 8, Section 8.9, for a case study based on a paper written by two DRBFM experts from Toyota Motor Corporation. This case study shows the progression from FMEA to DRBFM by examining the application of resin for a lever to be used in an engine compartment.

		Concerns regarding change (Failure mode)			When and how concern points appear		Effect to customer (System)		Current design steps to avoid concerns (inc. design rules, design standard & check items)		Recommended actions (Results of DRBFM)	
Item name/Change points	Function	Potential failure mode due to change	(DRBFM)	Root cause/ Dominant cause	(DRBFM)	Importance	Items to reflect in "Design"	Items to reflect in "Evaluation"	Items to reflect in "Production"			
Rack boot sub-assy 1. Rack Boot 1) Convolution membrane	Recipro-cating motion		(*) • TPO hardness increased (50HS⇒95HS)		Poor steering feeling	A		Investigation for increasing resistance due to hardness change		Measuring reciprocating resistance		
2) Root convolution [Modified point] • CR⇒TPO • Configuration	Protect for rack end	Fracture		• Cracking by flying gravel • Bending fatigue cracking at bellows section (PS oil, high temp. & heat age) • Convolute deformation due to heat or uneven thickness (interference with B/J)	Steering operation will not work	A	TPO material (TPO has the advantage of high impact resistance) FEM analysis (Max. strain ≤ □ %)	Safety convolute membrane ratio ≥ □ % Addition ribs at large & small convolute sections	Glavelo meter impact test at -40°C Durability test after heat age (100°C-500hrs)	Thickness Control during blow molding		
3) No.1 Seal	Sealing	Stress relaxation		• Stress relaxation due to radiant heat of exhaust pipe	Steering operation will not	A	Cramping at plastic region		Sealing test after durability test	Thickness dimension inspection		
4)	No.2 Seal	Sealing	Crack	• Cracking during clamping process	due to	A		Round shape at clamp end				
	2.Clamp											
	3.Clip											

**FIGURE 13.8** DRBFM worksheet of rack boot subassembly.  
(TPO, thermoplastic elastomer; CR, chloroprene rubber; PS, power steering. Reprinted with kind permission from Inderscience Enterprises Limited.)



**FIGURE 13.9** Schematic of fictional catapult.  
 (© Copyright Delphi Corporation 2003–2008. All rights reserved.)

Comparison Category/Potential Design Object	Description of Intentional/Unintentional Change Points		Concerns/Impacts	Risk Priority (High/Low)	Priority Reason	Risk Reduction Strategy (for High-Priority Items)
	Old (Specify Baseline)	New (Specify New)				
Catapult arm	Material: Oak	Material: Pine	Lighter, softer material Greater pin hole wear on arm Less stability of arm Lower cost Higher burn rate - safety! Better material availability	High	1. Highest packaging cost risk - amount of material required 2. Greatest effect on repeatable results - most pin holes, subject to user variation	DRBFM
Pin length	2.5 in.	3.5 in.	Difficult to assemble by user Less packaging space Bent pins May damage other parts Heavier, higher cost	Low		

**FIGURE 13.10** Example of catapult change point analysis.  
 (© Copyright Delphi Corporation 2003–2008. All rights reserved.)

### 13.7 DESIGN REVIEW BASED ON TEST RESULTS

Design Review Based on Test Results (DRBTR) refers to the third element of GD<sup>3</sup> (Good Dissection). Recall from the Good Dissection section above that the essence of Good Dissection is to examine the results of validation testing, making all mistakes visible. During validation and verification testing, it is important to go and see problems and thoroughly understand the test results.

DRBTR can be done during the test, after the test, after teardown, or during “autopsy” of parts. An evaluation team compares the actual test results to past

Parts/Change Points	Functions of the Object	Concerns about the Changed Points		Cause Factors	Any Other Factors to be Considered	To Prevent the Concerns	Effect for Customers
		Malfunction Related to Changes	Any Other Concerns				
Catapult arm material changing from oak to pine	1. Ball picked up material changing 2. Ball projected from oak to pine	Deforms/dents easily around the pin hole when there is tension at the anchor pin	Sappy wood may be messy to work	When user pulls back angle greater than 60 degrees, deformation is induced due to the low hardness value for this soft wood (white pine density is approx 23 lbs per cu ft)		White pine was chosen as it is readily available in the usage area, as well as the lowest cost	Reduced accuracy in hitting the target over time

Proposed Design Countermeasures	Responsibility	Proposed Evaluation Countermeasures	Target Completion Date	Product Engr	Proposed Manufacturing Countermeasures	Responsibility	Target Completion Date	Mfg Engr	Action Results/ Actions Taken
1. Evaluate suitable foam plastic washers to absorb the stress against the soft wood. Contact SMEs to perform pugh matrix on concepts.	19-Jul		1-Oct						Document results. Can also be used for management control.
2. Homogeneity concept - Evaluate also using pine for the anchor pin. Look at FEA.	6-Sep								

**FIGURE 13.11** Example of catapult DRBFM worksheet.

(© Copyright Delphi Corporation 2003–2008. All rights reserved. SME, subject matter expert; FEA, finite element analysis.)

lessons from similar tests. The team reviews probable causes and other observations and makes suggestions to address issues found. Its recommendations are followed up to closure. Discussion and actions are documented in a report. Issues and buds of problems are summarized and documented.

It is helpful to examine the parts while comparing to a reference part that was not tested. According to Tatsuhiko Yoshimura, “any meeting in which there are no parts to look at is a waste of time.”<sup>[6]</sup> Yoshimura used the term *genchi genbutsu*, which can be interpreted as “actual place, actual thing.” He wanted “everyone on the team to see the test properties and have a good discussion around them.”<sup>[6]</sup>

### 13.8 DRBFM GLOSSARY

The following definitions begin with general DRBFM terms, followed by the primary column headings of a DRBFM analysis.

**DRBFM** This is the abbreviation for Design Review Based on Failure Mode. It is a combination of FMEA and Design Review, with the focus on intentional and incidental changes. Its purpose is to stimulate discussion, leading to the proactive prevention of problems.

**Design Review** A technique that examines the current technical features and characteristics of a design at an appropriate stage of development. The review involves the participation of representatives from all the departments associated with the design stage to be analyzed. A record of the discussion and results should be kept.

**DRBFM Worksheet** This worksheet documents the DRBFM discussion. It has two areas: The design engineer usually fills in the first and includes intentional and incidental changes, functions, concerns, causes, and a description of how the current design avoids concerns. The second area of the worksheet documents the discussion by an expert review team of any additional concerns and causes, and recommended actions to address the concern points (design, evaluation, and production process).

**GD<sup>3</sup> Activity** GD<sup>3</sup> stands for Good Design, Good Discussion, and Good Dissection. “These are the three elements that are applied to the proactive prevention of problems by ‘getting back to basics.’ Together, they are called GD<sup>3</sup>.<sup>[2]</sup>

**Change Point Analysis** Change Point Analysis begins with the baseline design and focuses on the *specific changes* to the design. It is the initial step in Good Discussion. Change points can include changes in design, manufacturing, supplier, supplier design or process, usage environment, interfaces, specifications, performance requirements, or any other changes.<sup>[3]</sup>

**Intentional Changes** Intentional changes are the complete list of modifications that are being proposed to the current design. “In DRBFM, it is first necessary to clarify the intentional changes, in order to conduct DRBFM in an effective manner.”<sup>[2]</sup>

**Incidental Changes** Incidental changes are due to the differences in the usage environment conditions, such as increased or decreased ambient temperatures, or changes in the shape, material, or lubricants used in the interfacing components.

Also included are variables associated with the loads or environmental conditions that act on the component.

*Functions* A function is what the item or process is intended to do, usually to a given standard of performance or requirement. Care must be taken to list all of the functions in the DRBFM worksheet. Refer to the “Checklist of Function Types” and “Function Focal Point Table,” in Chapter 6, Section 6.2.2.

*Concerns Related to Change* Concerns are the issues raised by the design engineer or the review team resulting from the intentional or incidental changes under discussion. The concern points are described in detail with regard to what happens and when.

*Causes/Root Cause* A cause is the specific reason for the failure, preferably found by asking “why” until the root cause is determined. After concerns are discussed and documented, the true causes can be brought to light by asking “why” repeatedly as described in “Five Whys” from Chapter 6, Section 6.2.7.

*How Current Design Avoids Concerns* These are the specific aspects of the design intended to address the concerns. This is what is currently in place, before the review team discusses modifications and solutions to concerns.

*Items to Be Reflected in Design* These are specific and detailed *design*-related solutions for the causes or concerns that have been raised in the DRBFM, and are part of the results section of the DRBFM.

*Items to Be Reflected in Evaluation* These are specific and detailed *evaluation*-related solutions for the causes or concerns raised in the DRBFM, and are part of the results section of the DRBFM. Evaluation includes the tests or analyses that verify the design measures taken to address the causes or concerns raised.

*Items to Be Reflected in Production Process* These are specific and detailed *production process*-related solutions for the causes or concerns raised in the DRBFM, and are part of the results section of the DRBFM. Production process includes assembly methods, component fabrication methods, and manufacturing operations. Also included are solutions related to process controls.

### 13.9 DRBFM RESOURCES FOR FURTHER STUDY

- Yoshimura, Tatsuhiko, *Toyota Quality Prevention Method GD<sup>3</sup>*, JUSE Press 2002
- Hirokazu Shimizu, Yuichi Otsuka, Hiroshi Noguchi, “Design review based on failure mode to visualize reliability problems in the development stage of mechanical products,” International Journal of Vehicle Design, 2010, pp. 149–165
- Quality Magazine article: “Quality Software & Analysis: APQP Revisited,” by Lou Ann Lathrop, January 29, 2010
- SAE 2003-01-2877, JSAE 20037158, “Reliability Problem Prevention Method for Automotive Components,” by Hirokazu Shimizu and Toshijuki Imagawa, Toyota Motor Corporation, Hiroshi Noguchi, Kyushu University, 2003
- *Reliability Edge* Volume 9, Issue 2, “Change Point Analysis and DRBFM: A Winning Combination,” by Lisa Allan, Delphi Thermal Systems, 2009

- Yoshimura, Tatsuhiko, *Toyota Style Mizenboushi (Preventive Measures) Method GD<sup>3</sup>, How to Prevent a Problem Before It Occurs*, JUSE Press Ltd., 2002
- Haughey, Bill, *DRBFM and DRBTR Process Guide and Workbook*, to be published through SAE

### **13.10 END OF CHAPTER PROBLEMS**

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

#### **Problem 13.1**

Which of the following statements are true about DRBFM? (Select all that apply.)

1. DRBFM uses same set of risk ranking scales as FMEA, for severity, occurrence, and detection.
2. The DRBFM worksheet is identical to an FMEA worksheet, without the risk ranking scales.
3. After preparation for a DRBFM project, the responsible engineer completes the first portion of the DRBFM worksheet and provides a draft to the team prior to the review.
4. The discussion portion of DRBFM is focused on the areas of the design that have not changed.

#### **Problem 13.2**

Which of the following are good practices when doing a DRBFM project? (Select all that apply.)

1. Ideally, the DRBFM project is based on a well-done FMEA, with the focus on changes and interfaces.
2. The DRBFM should look at actual physical parts when discussing the changes to the parts.
3. The discussion should be limited to areas of concern to the team.
4. A DRBFM project should be done before beginning an FMEA.

#### **Problem 13.3**

In DRBFM, the essence of Good Design is . . . (Select one.)

1. To properly prepare for the DRBFM project.
2. To examine the results of testing.
3. To begin with a proven and reliable design.
4. To identify and eliminate risk due to changes in design.

**Problem 13.4**

The following changes should be considered when doing Change Point Analysis. (Select all that apply.)

1. Changes to the supplier process
2. Changes to the usage environment
3. Changes to the DRBFM review team
4. Changes to component interfaces

**Problem 13.5**

Intentional and incidental changes need to be considered when performing DRBFM. Which of the following are within the scope of incidental changes? (Select all that apply.)

1. The list of modifications that are being proposed to the current design
2. Differences in the usage environment conditions
3. Changes in the shape of interfacing components
4. Proposed changes to test regimens

**Problem 13.6**

The analysis portion of DRBFM procedure calls for two separate steps, with the first step being performed by the responsible engineer and the second step by the expert team. Which specific columns are filled out by the responsible engineer and which portion of the DRBFM procedure is done by the expert team?

**Problem 13.7**

The three elements of GD<sup>3</sup> are Good Design, Good Discussion, and Good Dissection. What is Change Point Analysis and where does it fit into the GD<sup>3</sup> process?

**Problem 13.8**

Review Case Study 1 and Figure 13.8, “DRBFM worksheet of rack boot subassembly,” in Section 13.6. One of the concerns being discussed by the DRBFM team was the hardness of the Rack Boot (with the thermoplastic elastomer) increasing from 50 to 95 Hs. The authors said, “Participants noticed the problem of the increasing reciprocate resistance due to the change.” Discuss how the Recommended Actions address the concern relating to TPO hardness increase.

## REFERENCES

1. Haughey, Bill, Reliatrain, DRBFM-related documents and material, based on training and coaching from Tatsuhiko Yoshimura.
2. SQC Study Committee and TQM Promotion Committee of the Toyota Group, 2005, Beginners' Guide to DRBFM (Proactive Prevention based on Creative Thinking, dated September 30, 2005, 1st edition (Ver. 1.0)).
3. Allan, Lisa, 2008, Change Point Analysis and DRBFM, in Applied Reliability Symposium.
4. Shimizu, Hirokazu and Toshiyuki Imagawa, 2003, SAE 2003-01-2877 Reliability Problem Prevention Method for Automotive Components.
5. Shimizu, Hirokazu, Yuichi Otsuka, and Hiroshi Noguchi, 2010, Design review based on failure mode to visualize reliability problems in the development stage of mechanical products. International Journal of Vehicle Design, Vol. 53, No. 3, pp. 149–165.
6. Lathrop, Lou A., Quality software & analysis: APQP revisited. *Quality Magazine*, 2010, Available at <http://www.qualitymag.com/> (search on article title).

# *Chapter* 14

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## *Introduction to Fault Tree Analysis (FTA)*

Those things that hurt, instruct.

—Benjamin Franklin

### **IN THIS CHAPTER**

There are times when it is essential to avoid an undesirable event or other high-risk situation that has numerous and complex potential contributors. This chapter is a brief overview of Fault Tree Analysis (FTA) and how it relates to Failure Mode and Effects Analysis (FMEA), including its history, procedures, and examples. Practitioners who will be doing FTA projects are encouraged to do further study or training on FTA.

#### **14.1 WHAT IS FAULT TREE ANALYSIS?**

The following is an excerpt from the *Fault Tree Handbook* published by the U.S. Nuclear Regulatory Commission<sup>[1]</sup>:

A Fault Tree Analysis can be simply described as an analytical technique, whereby an undesired state of the system is specified (usually a state that is critical from a safety standpoint), and the system is then analyzed in the context of its environment and operation to find all credible ways in which the undesired event can occur. The fault tree itself is a graphical model of the various parallel and sequential combinations of faults that will result in the occurrence of the predefined undesired event. The faults

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*Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis*, First Edition. Carl S. Carlson.

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can be events that are associated with component hardware failures, human errors, or any other pertinent events that can lead to the undesired event. A fault tree thus depicts the logical interrelations of basic events that lead to the undesired event – which is the top event of the fault tree.

Fault Tree Analysis (FTA) is a type of failure analysis in which an undesired state of a system is analyzed using Boolean logic to combine a series of lower level events. This analysis method is used mainly to quantitatively determine the probability of a complex safety hazard in order to develop actions to mitigate or eliminate the hazard. It is a top-down graphical model of the pathways and unique relationships within a system that can lead to an unwanted top-level event. The pathways connect contributory events and conditions using standard logic symbols. The unwanted event can be a failure, undesired event, or unintended event. FTA is best applied when there is a large threat of loss, or other high-risk situation, with numerous potential contributors to the event.

## 14.2 FTA AND FMEA

The primary differences between FTA and FMEA include:

1. FTA is a graphical representation of the complex relationships in the system leading to the unwanted event, whereas FMEA is worksheet based.
2. FTA considers the interactions between unwanted events and multiple contributors, such as two or more contributors that each must be present in order for the unwanted event to manifest. FMEA usually considers each contributor separately.
3. FTA has the capability of incorporating the probabilities for each of the contributors and the complex interactions and interrelationships with the top-level unwanted event. FMEA does not usually support the probability calculation of a top-level unwanted event.

### 14.2.1 When Should FTA Be Used in Addition to FMEA?

When it is necessary to model or understand the interconnected relationship between causes, failure modes, or effects, an FTA may be the right tool. The unwanted event can be either a failure mode or an effect.

In the context of FMEA projects, FTA can be a useful additional analysis whenever one or more of the following circumstances arise.

1. The FMEA team is analyzing a complex failure mode with many causes and would like a visual tool that graphically shows the complex set of causes.
2. Two or more causes of a given failure mode are not unique, but rather occur in tandem (AND gates); and in order to account for the logic of these pathways, an FTA would be useful.
3. The FMEA team would like to understand the probability of a high-level unwanted event occurring.

### 14.3 BRIEF HISTORY OF FTA

H. A. Watson of Bell Laboratories developed the concept of FTA for the U.S. Air Force in 1961 for use on the Minuteman system. Later, the Boeing Company adopted it and extensively applied it. The first technical papers on FTA were presented at the 1965 System Safety Conference in Seattle, Washington. During the latter half of the 1960s, FTA was adopted more broadly by the aerospace industry in the development of aircraft and weapon systems. In the 1970s, FTA was used by the nuclear power industry and later in the software (safety) community. Today, it is used in a wide variety of industries and applications as part of system safety and reliability improvement.<sup>[2]</sup>

### 14.4 MODELS

Essentially, all models are wrong, but some are useful.

—George Box<sup>[3]</sup>

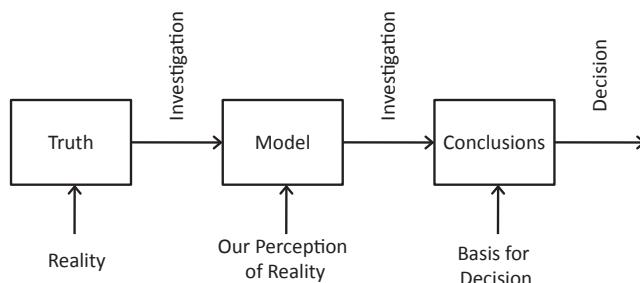
FTA is a graphical model, and therefore the applications and limitations of models are important to understand. The *Oxford Concise English Dictionary* defines *model* as “a simplified description, especially a mathematical one, of a system or process, to assist calculations and predictions.” A model is a representation containing the essential structure of some process or event in the real world.

One of the uses of models is to aid in the decision-making process. Figure 14.1 shows the relationship between reality, system model, and decision process.<sup>[4]</sup>

### 14.5 EVENTS AND GATES

Events and gates are symbols that represent the logic of the analysis. They do not always correlate to component parts of the system being analyzed.

An *event* is a graphical and mathematical representation of a fault or other unwanted occurrence. There are many types of events used in FTA, the most common being top-level event, intermediate event, and basic event. Less common but useful events include undeveloped event, conditioning event, and external event



**FIGURE 14.1** Relationship between reality, system model, and decision process.

(refer to the section “FTA Glossary” below). An event in a fault tree can be associated with a probability of occurrence (or a distribution function). Fault trees also use several graphical symbols to represent different types of events. For example, a circle typically represents a basic initiating event in a fault tree diagram. All events are treated the same from an analytical perspective.

A *gate* is a logic symbol that interconnects contributory events and conditions in a fault tree diagram. The most common gates are the AND gate, in which the output fault occurs if all of the input faults occur, and the OR gate, in which the output fault occurs if at least one of the input faults occurs. Fault trees can also logically connect events with other gates, such as the voting OR gate, in which the output event occurs if a certain number of the input events occur (i.e., k-out-of-n redundancy), and the sequence-enforcing gate, in which the output event occurs if all events occur in a specific sequence, and so on. (Refer to FTA definitions below.)

Figures 14.2 and 14.3 show example FTA symbols for events and gates. Although the symbols for events and gates are described in various FTA publications, there is no universally standardized set of symbols.<sup>[4, 5]</sup>

## 14.6 FTA EXAMPLE

Figure 14.4 shows a fictional example of an FTA depicting an undesired event: “Bicycle doesn’t stop in required distance.” For the objective of simplicity, only AND gates or OR gates are used in this example.

Fault Tree Event Symbols		
Primary Event Block	Classic FTA Symbol	Description
Basic Event		A basic initiating fault (or failure event).
Intermediate Event		A fault event that occurs because of one or more antecedent causes.
External Event (House Event)		External events can be set to occur or not occur, that is, they have a fixed probability of 0 or 1.
Undeveloped Event		An event which is not further developed. It is a basic event that does not need further resolution.
Conditioning Event		A specific condition or restriction that can apply to any gate.
Transfer		Indicates a transfer continuation to a subtree.

FIGURE 14.2 Fault tree event symbols.

Fault Tree Gate Symbols		
Name of Gate	Classic FTA Symbol	Description
AND		The output event occurs if all input events occur.
OR		The output event occurs if at least one of the input events occurs.
Voting OR (k-out-of-n)		The output event occurs if k or more of the input events occur.
Inhibit		The input event occurs if all input events occur and an additional conditional event occurs.
Priority AND		The output event occurs if all input events occur in a specific sequence.
Exclusive OR		The output event occurs if exactly one input event occurs.

FIGURE 14.3 Fault tree gate symbols.

### Student Exercise

Students are encouraged to analyze this FTA example to understand the logical relationship between the events and the gates. See Problem 14.3 in Section 14.12, “End of Chapter Problems,” for an evaluation exercise related to this example.

For another example of FTA, refer to Chapter 8, Section 8.4, for an example of a flashlight FTA and the flow of information from Functional Block Diagram to FTA to Design FMEA.

### 14.7 FTA GLOSSARY

The following definitions may be useful for application of Fault Tree Analysis.<sup>[4,5]</sup>

**AND Gate** An AND gate output fault occurs if all of the input faults occur.

**Basic Event** An initiating fault that requires no further development.

**Conditioning Event** A specific condition or restriction that can apply to any gate.

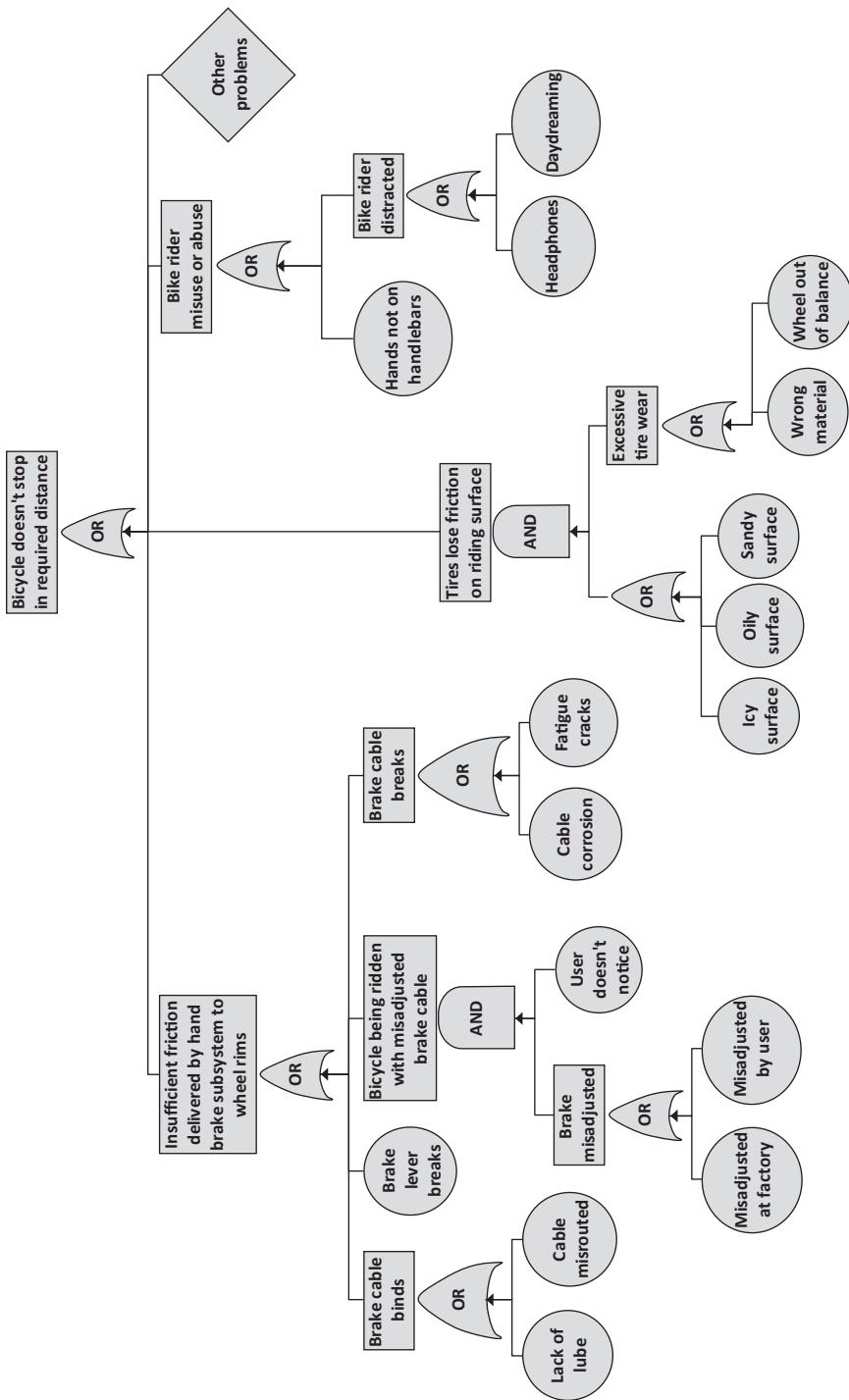


FIGURE 14.4 FTA example for top event (bicycle doesn't stop in required distance).

**Cut Set** A set of basic events whose occurrence ensures that the top event occurs. A cut set is said to be minimal if the set cannot be reduced without losing its status as a cut set.

**Event** A graphical and mathematical representation of a fault or other unwanted occurrence. There are many types of events that are used in FTA, the most common being top-level event, intermediate event, and basic event. Less common but useful events include undeveloped event, conditioning event, and external event.

**External Event** An event that is normally expected either to occur or not to occur. In general, these events have a fixed probability of 0 or 1.

**Failure** The inability of an item to perform its required function within previously specified limits.

**Fault** An anomaly in the functional operation of an equipment or system.

**Fault Tree Analysis** A graphic “model” of the pathways within a system that can lead to a foreseeable, undesirable loss event.

**Gate** Logic symbol used in FTA that represents the relationship between fault inputs and outputs. There are many types of gates that are used in FTA, the most common being AND gates and OR gates. Less common but useful gates include exclusive OR gate, priority AND gate, and inhibit gate.

**Inhibit Gate** An inhibit gate output fault occurs if all input events occur and an additional event occurs.

**Intermediate Event** A fault that occurs because of one or more antecedent causes acting through logic gates.

**OR Gate** An OR gate output fault occurs if at least one of the input faults occurs.

**Path Set** A set of basic events whose nonoccurrence (simultaneously) ensures that the top event does not occur. A path set is said to be minimal if the set cannot be reduced without losing its status as a path set.

**Priority AND Gate** A priority AND gate output fault occurs if all input events occur in a specific sequence.

**Top-Level Event** The highest-level focus of the FTA. It is the unwanted occurrence that represents the outcome of the entire graphical model of the FTA. All of the other gates and subevents lead up to the top-level event.

**Undeveloped Event** An event that is not further developed or does not need further resolution.

**Voting OR Gate** A voting OR gate output fault occurs if a certain number of the input events occur.

## Fault versus Failure

FTA makes a distinction between “failure” and “fault.” The *U.S. Nuclear Regulatory Commission Fault Tree Handbook* describes this difference<sup>[1]</sup>:

We first make the distinction between the rather specific word “failure” and the more general word “fault.” Consider a relay. If the relay closes properly when a voltage is impressed across its terminals, we call this a relay “success.” If, however, the relay fails to close under these circumstances, we call this a relay “failure.” Another possibility is that

the relay closes at the wrong time due to improper functioning of some upstream component. This is clearly not a relay failure; however, untimely relay operation may well cause the entire circuit to enter an unsatisfactory state. We shall call an occurrence like this a “fault” so that, generally speaking, all failures are faults but not all faults are failures. Failures are basic abnormal occurrences, whereas faults are “higher order” events.

## 14.8 FTA PROCEDURE

The general procedure for doing FTA follows these five steps:

### 1. Define the undesired event to study

An FTA always begins with an already identified unwanted event in which there is a large threat of loss or other high-risk situation and numerous potential contributors to the event.

“Careful choice of the top event is important to the success of the analysis. If it is too general, the analysis becomes unmanageable; if it is too specific, the analysis does not provide a sufficiently broad view of the system. Fault tree analysis can be an expensive and time-consuming exercise and its cost must be measured against the cost associated with the occurrence of the relevant undesired event.”<sup>[1]</sup>

### 2. Obtain an understanding of the system

Once the undesired event is defined, the next step is to identify the underlying contributors and causes. For complex systems, this may have to be done in layers, with each subsequent layer going deeper into the system. If the probabilities of various contributors are known at this point, they should be noted. The appropriate subject-matter experts need to be consulted in order to fully understand the overall system that affects the event under consideration.

### 3. Construct the fault tree

After identifying the top-level undesired event and having analyzed the system so that all the primary contributors and causes are known, including their probabilities, the fault tree can be constructed. The contributors and causes of the event are logically connected through the various gates and subevents according to FTA procedure. This construction process goes deeper and deeper into subevents until root causes are documented. Good FTA software will facilitate construction of the FTA and help with connecting proper and logical pathways.

### 4. Evaluate the fault tree

Once constructed properly for a specific undesired event, the fault tree can be evaluated and analyzed to discover the overall probability of the top event. Various “what if” scenarios can be developed and analyzed for system improvement. Good FTA software is essential in order to analyze mathematically the fault tree with all of its Boolean logic and numerous pathways.

### 5. Control the risks identified

The FTA should be used to support the identification and execution of specific strategies to reduce the probability and associated risk of an unwanted event. Changes to the system configuration can be reviewed and analyzed, along with associated cost and effectiveness.

One of the potential pitfalls in proper FTA application is the problem of interfaces. Many failure modes or their causes occur at the interfaces between subsystems or components. If the construction of the FTA does not properly include interfaces, then the results will be inaccurate and misleading. Interfaces must be clearly included in the analysis.

Another potential pitfall in proper FTA application is accurate mathematical representation of the contributors. This is where many practitioners can make mistakes. Probabilities and failure rates often vary with time, and proper distributions are essential to correct modeling of the system. The FTA practitioner must either understand the subject of life data analysis and system reliability analysis, or obtain this important technical support.

## 14.9 FTA HANDBOOKS AND STANDARDS

- NASA *Fault Tree Handbook with Aerospace Applications*, version 1.1, Prepared for NASA Office of Safety and Mission Assurance, NASA Headquarters Washington, DC 20546, published August 2002
- U.S. Nuclear Regulatory Commission *Fault Tree Handbook*, NUREG-0492, published January 1981
- IEC International Standard *Fault Tree Analysis (FTA)*, IEC 61025 Edition 2.0 2006-12
- FAA System Safety Handbook, Chapter 9: Analysis Techniques, Dec 30, 2000

## 14.10 USE OF FTA ON SOFTWARE

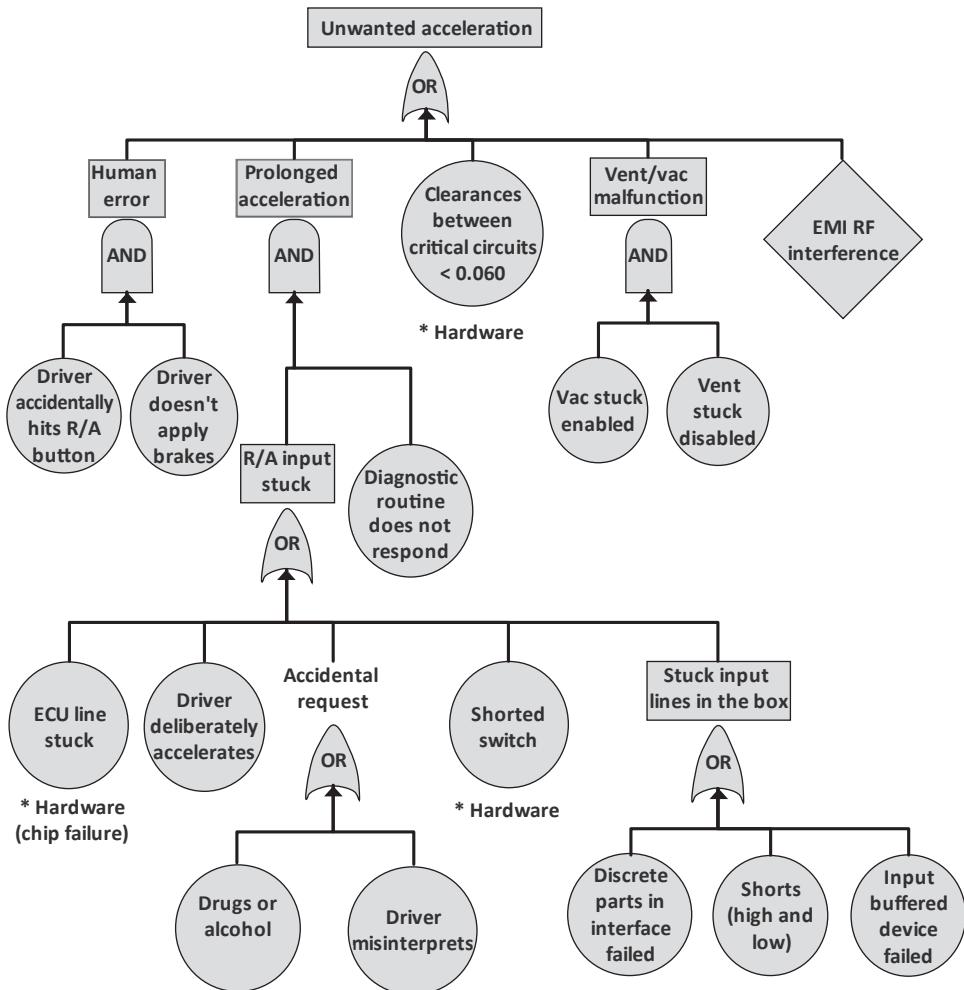
FTA can also be a useful tool in analyzing software contributions to a high-level unwanted event. However, most practitioners agree that FTA should be applied to both hardware and software as components of one system.

Figure 14.5 is an example that shows a fault tree for a hardware–software–human system. All three elements are analyzed in the same tree. “For a safe and fault-tolerant design, the criterion is that the failure of the system should not be a result of a single-point failure. Therefore, the top-level should always have an AND gate. In the system of [Figure 14.5], AND gates were designed into the product at the second level because the AND gate at the top level was not viable. When this criterion is used, many faults at lower level can be tolerated. . . . Designs using this criterion have been safe and efficient and result in lower life-cycle costs.”<sup>[6]</sup>

## 14.11 FTA BENEFITS AND LIMITATIONS

Properly done, FTA will provide the following benefits:

1. Graphically and mathematically, show the risk of an unwanted event, along with the complex relationships of primary contributors.
2. Identify the set of basic events whose occurrence will bring about the unwanted top event.



**FIGURE 14.5** Example of fault tree for software–hardware–human interface.

(EMI, electromagnetic interference; RF, radio frequency; R/A, resume/accelerate; ECU, electronic control unit.)

3. Serve as evidence of “due care” in the development of products or processes.
4. Provide input to various related activities, for example, test procedures, troubleshooting manuals, and maintenance procedures.

FTA has certain limitations to keep in mind. FTA is a labor-intensive activity, and therefore the time taken to do the analysis must be balanced with the benefits derived from the activity. There is a high level of expertise needed to perform the analysis. In addition, since probability data are based on estimations and predictions of the frequency of faults and failures, care must be taken to interpret the results with respect to any potential errors in the input data.

## 14.12 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

### Problem 14.1

In describing FTA, which of the following are true? (Select all that apply.)

1. FTA begins with an already identified unwanted event.
2. An event is a logic symbol used in FTA that represents the relationship between fault inputs and outputs.
3. The top level of the FTA is the root cause of the unwanted event.
4. The best application for FTA is having all of the events connected by OR gates.
5. A gate is a logic symbol used in FTA that represents the relationship between fault inputs and outputs.

### Problem 14.2

FTA should be used . . . (Select all that apply.)

1. Instead of FMEA when the team has limited time.
2. When the FMEA team is analyzing a complex failure mode with many causes and would like a visual tool to show graphically the complex set of causes.
3. When the FMEA team would like to understand the probability of a high-level unwanted event occurring.
4. When failure rate data are not available.

### Problem 14.3

Review the FTA in Figure 14.4, “Bicycle does not stop in time,” and answer the following questions.

#### ***Question 1***

On the left side of the FTA there is an intermediate event “Bicycle being ridden with misadjusted brake cable.” If the brake cable was misadjusted at factory and the user notices the problem (and takes the proper corrective action), what happens to the event “Bicycle being ridden with misadjusted brake cable”?

#### ***Question 2***

Based on the logic in the FTA, if the “Brake cable breaks” is a fault and the “Tires lose friction on riding surface” is not a fault, what happens to the top event “Bicycle doesn’t stop in time”?

**Question 3**

The intermediate event “Insufficient friction delivered by hand brake subsystem to wheel rims” event has four contributory events. Is this complete, or are there other possible contributory events? Where would one look in the Hand Brake Design FMEA for additional information?

**REFERENCES**

1. U.S. Nuclear Regulatory Commission, *NUREG-0492—Fault Tree Handbook*. U.S. Nuclear Regulatory Commission, 1981.
2. Ericson, Clif, 1999, *Fault Tree Analysis—A History*, International System Safety Conference.
3. Box, George and Norman Draper, *Empirical Model-Building and Response Surfaces*. Wiley, 1987.
4. NASA, 2002, Fault Tree Handbook with Aerospace Applications, NASA Office of Safety and Mission Assurance.
5. *Fault Tree Analysis: An Overview of Basic Concepts*. ReliaSoft Corporation. Reliability Engineering Resources. Available at <http://www.weibull.com/basics/fault-tree/index.htm>.
6. Rajeja, Dev, *Assurance Technologies: Principles and Practices*. Engineering and Technology Management Series, ed. M. Badawy. McGraw Hill, 1991.

# *Chapter* 15

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## *Other FMEA Applications*

The secret of success is to do the common things uncommonly well.

—John D. Rockefeller

### **IN THIS CHAPTER**

Many variants of Failure Mode and Effects Analysis (FMEA) build on the basic FMEA principles for unique applications. This chapter discusses Reliability-Centered Maintenance, Hazard Analysis, Concept FMEA, Software FMEA, a focused type of FMEA called Failure Modes, Mechanisms, and Effects Analysis (FMMEA), and a type of FMEA used to develop online diagnostic techniques called Failure Modes Effects and Diagnostic Analysis (FMEDA). Each section includes the basic definitions, a brief history, and a short summary of the fundamental concepts, procedures, and examples.

#### **15.1 RELIABILITY-CENTERED MAINTENANCE**

Understanding the laws of nature does not mean that we are immune to their operations.

—David Gerrold

This section is a brief overview of Reliability-Centered Maintenance (RCM). Practitioners who will be doing RCM projects are encouraged to read the RCM standards that apply to their projects and obtain further training on RCM.

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*Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis*, First Edition. Carl S. Carlson.

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“Reliability-Centered Maintenance (RCM) is an analytical process used to determine preventive maintenance (PM) requirements and identify the need to take other actions that are warranted to ensure safe and cost-effective operations of a system.”<sup>[1]</sup>

### 15.1.1 RCM and FMEA

A well-done equipment FMEA or series of equipment FMEAs is at the core of an RCM analysis. The chapters in this book that apply to FMEAs apply to RCM projects as well, with some adjustments as covered below. Refer to Chapter 3 for the fundamental concepts and definitions of FMEA, Chapter 4 for FMEA project selection and timing, and Chapters 5–7 for the material on FMEA preparation, procedure, and execution. All of this material is applicable to performing RCM projects properly, and should be integrated into the preparation and procedure steps covered below. In addition to the core FMEA, an RCM project has certain unique elements, including selection of the specific equipment items, a unique worksheet, a set of failure effect categorization logic diagrams, and maintenance task selection logic charts to help select the tasks for the PM plan. Section 15.1.4 on RCM Procedure covers these differences.

**Mapping of Definitions between RCM and FMEA** There are different definitions for some of the terms used to do an RCM analysis compared to an FMEA analysis. RCM definitions are not always consistent between the various RCM standards. See Figure 15.1 for an analysis of RCM definitions.<sup>[1–4]</sup>

Many practitioners of both RCM and FMEA map them as follows:

- “Function” for FMEA maps to “Function” for RCM
- “Failure Mode” for FMEA maps to “Functional Failure” for RCM
- “Effect” for FMEA maps to “Effect” for RCM
- “Cause” for FMEA maps to “Failure Mode (Cause)” for RCM

This mapping is not perfect, but provides a starting point for understanding the differences between RCM and FMEA in terms of definitions. The key is to place the maintenance actionable item in the RCM failure mode (cause) column. By doing so, the RCM method will support development of good maintenance strategies.

### 15.1.2 RCM: The Seven Basic Questions

Many RCM books and standards suggest asking seven basic questions about the asset or system under review. At a high level, these seven questions form the basis for the RCM procedure.<sup>[4]</sup>

1. What are the functions and associated performance standards of the asset in its present operating context?
2. In what ways does it fail to fulfill its functions?
3. What causes each functional failure?
4. What happens when each failure occurs?

RCM Definitions by Publication				FMEA Definitions
	ATA MSG-3	NAVAIR	SAE JA1012	Moubray
<b>Function</b>	"The normal characteristic actions of an item."	"An intended purpose of an item as described by a required standard of performance."	"What the owner or user of a physical asset or system wants it to do."	A "Function" is what the item is intended to do, usually to a given standard of performance.
<b>Functional Failure</b>	"Failure of an item to perform its intended function within specified limits."	"The inability of an item to perform a specific function within the specified limits."	"A state in which a physical asset or system is unable to perform a specific function to a desired level of performance."	"A functional failure is defined as the inability of any asset to fulfil a function to standard of performance which is acceptable to the user."
<b>Failure Mode</b>	Failure Mode is not defined. "Failure - the inability of an item to perform within previously specified limits."	"A specific physical condition that causes a functional failure. The failure mode statement should include a description of the failure mechanism (e.g., fatigue) whenever possible."	"A failure mode is any event which causes a functional failure."	"A "Failure Mode" is the manner in which the item or assembly could fail to meet the intended function and its requirements."
<b>Failure Effect</b>	"What is the result of a functional failure."	"The result of a functional failure on surrounding items, the functional capability of the end item, and hazards to personnel and the environment."	"What happens when a failure mode occurs."	"An "Effect" is the consequence of the failure on the system or end user."
<b>Cause</b>	"Failure cause - why the functional failure occurs."	See above. "The failure mode statement should include a description of the failure mechanism (e.g., fatigue) whenever possible."	"Identify failure modes at a level of causation that makes it possible to identify an appropriate failure management policy."	"A "Cause" is the specific reason for the failure, preferably found by asking "why" until the root cause is determined."

**FIGURE 15.1** Analysis of RCM definitions.

5. In what way does each failure matter?
6. What can be done to predict or prevent each failure?
7. What should be done if a suitable proactive task cannot be found?

As can be seen, these seven questions align with many of the steps in the FMEA process, with certain differences covered in Section 15.1.4 on RCM procedure.

### 15.1.3 RCM Decision Logic Diagrams

When you come to a fork in the road, take it.

—Yogi Berra

There are published RCM decision logic diagrams that help to determine which maintenance strategies are appropriate to either eliminate or lessen the consequences of functional failures for a given set of circumstances. “Every functional failure has one or more failure modes, any of which, if allowed to occur, will result in a loss of function. Each of these failure modes must be processed through the Decision Logic to determine whether a PM task should be developed, or if some other action might be warranted. The goal here is to determine the best alternative for either preventing the functional failure altogether, or mitigating its consequences to an acceptable level if it does occur.”<sup>[1]</sup>

The decision logic requires that the following be considered for each failure mode being analyzed<sup>[1]</sup>:

- Consequences of failure (safety, environmental, operational, economical)
- Whether the functional failure is evident or hidden to the operating crews
- Evidence of reduced resistance to failure
- Age-reliability characteristics of each item
- Trade-off analyses comparing various maintenance tasks for optimum handling of a failure mode

Maintenance tasks are selected that minimize risk and provide the desired level of availability for the minimum cost.

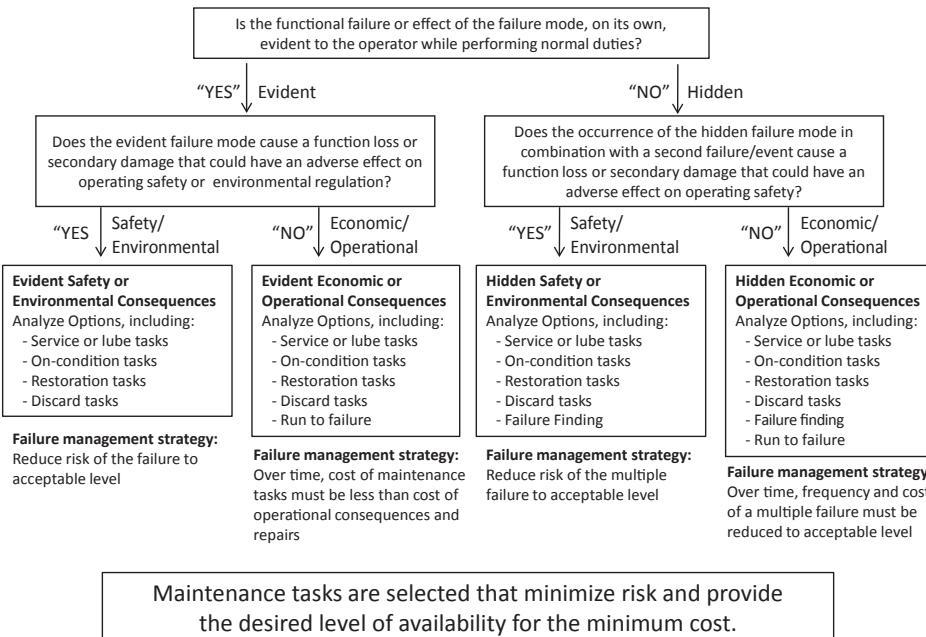
Figure 15.2 shows an example of RCM decision logic diagram. In this example, the functional failures and effects for each Maintenance Significant Item (MSI) are evaluated according to the decision logic, and appropriate maintenance tasks are selected based on the outcome.<sup>[1]</sup>

It is essential to study the appropriate publications and standards in order to correctly apply the RCM decision logic diagram.

### 15.1.4 RCM Procedure

It is important for the RCM analysis team to agree on the standard that it will be using and to understand the definitions and applications of the various columns, including function, functional failure, and failure mode.

There are five key steps to an RCM procedure, unique to RCM.



**FIGURE 15.2** Example of an RCM decision logic diagram.

1. *Identify Maintenance Significant Items (MSIs).* This step determines the most significant equipment items from a risk standpoint that will need to be followed up with the seven questions and the rest of the RCM procedure. The usual approach to obtaining MSIs includes either asking a series of “yes” or “no” questions based on selection criteria or otherwise using selection criteria to subjectively assess and rate candidate MSIs. The “RCM Publications and Standards” section below has excellent references that describe in detail how to select MSIs and perform the other tasks in RCM. This step is similar to the Preliminary Risk Assessment (Chapter 4, Section 4.3) used to select items from the system hierarchy that will receive FMEAs.
  2. *Identify the Functions, Functional Failures, Failure Modes (Causes), and Effects for Each MSI.* Section 15.1.1, “Mapping of Definitions between RCM and FMEA,” maps the FMEA definitions for functions, failure modes, effects, and causes to the RCM definitions for functions, functional failures, failure modes (causes), and effects.
- This step is essentially the equipment FMEA that makes up the core of any RCM project, using the RCM worksheet and definitions. Best practice is first to do a thorough preparation for the RCM project similar to FMEA preparation, including ground rules and assumptions, gathering relevant information, and agreeing on the exact scope of the project. The procedure for doing FMEAs applies to the FMEA portion of the RCM project. Refer to Chapter 5 on FMEA preparation and Chapter 6 on FMEA procedure.
3. *Identify and Evaluate (Categorize) the Effects of Failure Using Unique Logic Diagrams.* This step goes well beyond the traditional FMEA evaluation of

effects using a severity scale. Most RCM references contain a logic diagram to evaluate and categorize the effects of failure, called failure effect categorization. The purpose of the logic diagram is to identify whether or not the effect has safety, environmental, or operational consequences, and whether the effect is evident or hidden. The results of the diagram are important input to the selection of maintenance strategies. Refer to Figure 15.2, “Example of decision logic diagram,” the portion up to “Analyze Options.”

4. *Select the Appropriate Maintenance Tasks to Address Potential Causes of Failure.* The RCM analysis team can recommend various maintenance strategies based on the results of the FMEA, the failure effect categorization, and using a decision logic diagram such as the one in Figure 15.2 (the portion beginning with “Analyze Options”).

These strategies include:

*Scheduled Preventive Maintenance.* This can include servicing, lubrication, restoration, repairing, or replacing equipment on a scheduled basis.

*Scheduled Inspections.* Equipment is inspected on a scheduled basis or monitored on an ongoing basis to discover hidden or imminent failures, and citing appropriate corrective maintenance. Also called on-condition tasks.

*Run-to-Failure.* Equipment is run without any scheduled maintenance actions until it fails, at which point it is fixed or replaced.

*Design Change.* Equipment can be redesigned or some type of one-time change can be made to improve the reliability or availability.

The selection of specific maintenance strategies requires knowledge and expertise in the various maintenance strategies and which ones are appropriate for the different failure effect categories (evident safety/environmental, evident economic/operational, hidden safety/environmental, and hidden economic/operational). The references in Section 15.1.8 provide further information on maintenance strategies and their application to failure effect categories.

5. *Implement the Recommended Maintenance Strategies.* The selected maintenance tasks need to be implemented, either by organizing them into a maintenance task list, such as a PM plan, or by directly implementing the task. Management must approve maintenance task lists or PM plans. Refer to Chapter 7, Sections 7.5 through 7.8, for information and strategies on executing tasks.

**Level of Detail** Similar to FMEAs, the level of detail in an RCM analysis must be carefully managed. John Moubray, in his book *Reliability-Centered Maintenance*, says this about the level of detail in an RCM analysis<sup>[4]</sup>:

Excessive detail can cause the process to take two or three times longer than necessary (a phenomenon known as *analysis paralysis*). . . . Too little detail and/or too few failure modes lead to superficial and sometimes dangerous analyses. . . . Failure modes should be defined in enough detail for it to be possible to select a suitable failure management policy. . . . Failure effects should be described in a way that enables the team doing the RCM analysis to decide whether the failure will become evident to the operating crew under normal circumstances.<sup>[4]</sup>

**ASSET: Hydraulic Pumping System**

<b>Function</b>	<b>Functional Failure (Loss of Function)</b>	<b>Failure Mode (Cause of Failure)</b>
Transfer oil from tank X to tank Y at not less than 15 gallons per minute	Unable to transfer any oil at all	Pump bearing seizes Pump motor burns out Piston connecting rod comes loose Cylinder block cracks Inlet valve jams closed Piston seizes in cylinder chamber Etc.
	Transfers less than 15 gallons per minute	Piston head worn Partially blocked inlet line Etc.

**FIGURE 15.3** Example of hydraulic pump failure modes in RCM project.

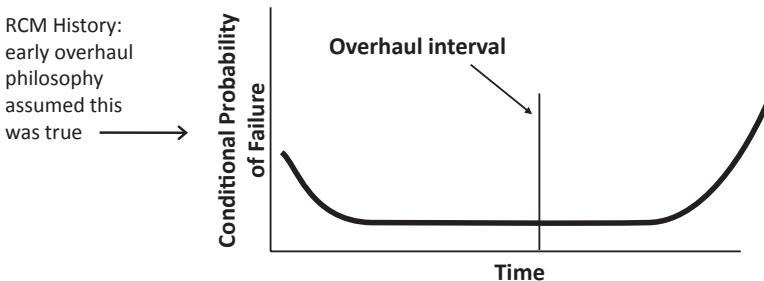
Figure 15.3 shows an example of the function, functional failure (loss of function), and failure mode (causes of failure) for a hydraulic pumping system.

### 15.1.5 History of RCM

The following is a brief history of RCM excerpted from a Naval Air Systems Command (NAVAIR) presentation called “Introduction to RCM.”<sup>[5]</sup>

Early PM programs were based on the concept that periodic overhauls ensured reliability and, therefore, safety. Overhaul meant the tearing down and rebuilding of components. The introduction of Boeing 747, McDonnell Douglas DC-10, and Lockheed L-1011 in the 1960s led airlines to conclude that current PM philosophies were unsustainable. The Federal Aviation Administration (FAA) and commercial aviation industry formed a group to study PM. The conclusion: overhauls had little or no effect on overall reliability or safety in many cases. Figure 15.4 shows the problem. Up until the study, the overhaul philosophy assumed that the overhaul interval could be set just before wear out or failure. The airlines discovered through statistical analysis that, in most cases, there was no change in safety or reliability when overhaul limits were changed. The facts about overhauls show that many failure modes do not support an overhaul philosophy at a predefined interval. In other words, many failure modes have no “right” overhaul time. In addition, the process of overhauling reintroduces “infant mortality” failures. Airlines failure data plotted against time showed that the vast majority of cases did not benefit from overhauls.<sup>[5]</sup>

An alternative was needed for the overhaul approach, and that became the mission of RCM. The early alternatives included use of inspections to look for “potential failure” conditions. This allowed assets to stay in service for more of their useful life, and promoted product and process improvement. Another alternative was called “run to failure,” which was useful when the consequences were tolerable, but not an option for safety consequences. RCM applies the most appropriate maintenance philosophy to each failure mode.<sup>[5]</sup>



What the airlines discovered

- Statistical analysis showed, in most cases, no change in safety or reliability when overhaul limits changed.
- Initial overhaul limits were not analytically based.
- High repair costs for little or no benefits.

Facts about overhauls

- Many failure modes do not support overhaul philosophy—have no 'right' overhaul time.
- Lose considerable component life.
- Overhauls can reintroduce infant mortality failures.

**FIGURE 15.4** Early overhaul philosophy was proven wrong.

### 15.1.6 RCM Definitions

The following definitions may be useful for application of Reliability-Centered Maintenance.<sup>[1,4]</sup>

*Failure Consequences* The adverse impact that a functional failure has on safety, environment, operations, and economics.

*Failure Effects* The result of a functional failure on surrounding items, the functional capability of the end item, and hazards to personnel and the environment.

*Failure Finding Task* A preventive maintenance task performed at a specified interval to determine whether a hidden failure has occurred.

*Failure Mode* A specific physical condition that causes a particular functional failure.

*Function* An intended purpose of an item as described by a required standard of performance.

*Functional Failure* The inability of any asset to fulfill a function to a standard of performance that is acceptable to the user.

*Hidden Failure* A failure with effects that will not become evident to the operating crew under normal circumstances if the failure mode occurs on its own.

*On-Condition Task* A scheduled inspection designed to detect a potential failure condition.

*Potential Failure* A definable and detectable condition that indicates that a functional failure is in the process of occurring.

**Predictive Maintenance (PdM)** Those tasks that involve continuous or periodic monitoring and diagnosis in order to predict component degradations so that planned maintenance can be performed prior to equipment failure.

**Preventive Maintenance (PM)** Actions performed periodically to maximize the probability that an item will achieve the desired level of safety and reliability.

**Reliability-Centered Maintenance** A process used to determine what must be done to ensure that any physical asset continues to do what its users want it to do in its present operating context.

**Servicing Task** The replenishment of consumable materials depleted during normal operations.

### 15.1.7 RCM Case Study

**Reference paper:** Sornchai Buakaew, “Reliability Centered Maintenance for Gas Insulated Switchgear Maintenance,” presented at the 18th annual Conference of Electric Power Supply Industry, 2010.<sup>[6]</sup>

This case study targets the circuit breaker of a gas insulated switchgear system, which is filled with sulfur hexafluoride ( $SF_6$ ) underneath its enclosures. The circuit breaker is used to open or close the circuit during normal operation, and it is expected to interrupt the circuit during fault conditions.

Figure 15.5 shows the FMEA portion of the RCM project, specifically on the circuit breaker.<sup>[6]</sup> Note that the use of “Low,” “Medium,” and “High” in the Severity, Frequency, and Criticality columns are unique to this case study.

Important function	Function failures	Failure modes (Causes of failure)	Failure effects	Severity	Frequency	Criticality ranking
Close circuit during normal condition	Fail to close circuit during normal condition	<ul style="list-style-type: none"> <li>• Main contact damage</li> <li>• CB mechanism damage</li> <li>• Closing coil failure</li> </ul>	Outage problem and Inconvenient switching	Medium	Low	Low
Open circuit during normal condition	Fail to open circuit during normal condition	<ul style="list-style-type: none"> <li>• Main contact damage</li> <li>• CB mechanism damage</li> <li>• Tripping coil failure</li> </ul>	Inconvenient switching	Medium	Low	Low
Interrupt fault during fault condition	Fail to interrupt fault during fault condition	<ul style="list-style-type: none"> <li>• Main contact of CB damage</li> <li>• Arcing contact of CB damage</li> <li>• CB mechanism damage</li> <li>• Tripping coil failure</li> <li>• Accumulated Fault very high</li> <li>• <math>SF_6</math> gas contamination</li> </ul>	Safety problem and Outage problem	High	Low	Medium

FIGURE 15.5 FMEA portion of circuit breaker (CB) RCM project.

Figure 15.6 shows the RCM decision diagram used in the case study that determines the failure consequences and provides input to the maintenance task selection.<sup>[6]</sup>

Figure 15.7 summarizes the failure consequences from the RCM decision diagram and identifies cost-effective maintenance tasks for each of the failure modes (causes of failure).<sup>[6]</sup>

Figure 15.8 is an overview of the RCM recommendations from the case study and the resulting PM program.<sup>[6]</sup>

**Student Exercise** Students are encouraged to analyze this case study, including the RCM recommendations and the PM program, and consider specific improvements to the recommendations and final PM program. See Problem 15.3 in Section 15.7, “End of Chapter Problems,” for the evaluation exercise.

### 15.1.8 RCM Publications and Standards

- *Reliability-Centered Maintenance* by F. Stanley Nowlan and Howard F. Heap of United Airlines, issued in December 1978.
- Air Transport Association (ATA) MSG-3 *Operator/Manufacturer Scheduled Maintenance Development*, updated in March 2003.
- NAVAIR 00-25-403 *Guidelines for the Naval Aviation Reliability-Centered Maintenance Process*, issued in February 2001.
- Society of Automotive Engineers (SAE) JA1011 *Evaluation Criteria for Reliability-Centered Maintenance (RCM) Processes*, issued in August 1999.
- SAE JA1012 *A Guide to the Reliability-Centered Maintenance (RCM) Standard*, issued in January 2002.
- *Reliability-Centered Maintenance*, 2nd edition by John Moubray, published in 1997.
- *Reliability-Centered Maintenance: Gateway to World Class Maintenance* by Anthony M. Smith, published in 1993.
- *Practical Application of Reliability-Centered Maintenance* by the Reliability Analysis Center, issued in 2003.
- Military Standard (MIL-STD)-2173(AS) *Reliability-Centered Maintenance Requirements for Naval Aircraft, Weapons Systems and Support Equipment*, issued in January 1986.
- NASA *Reliability Centered Maintenance Guide for Facilities and Collateral Equipment*, issued in February 2000.
- International Electrotechnical Commission (IEC) 60300-3-11 *Dependability management—Part 3-11: Application guide—Reliability Centered Maintenance*, issued January 2003

### 15.1.9 RCM Benefits

When done well, RCM will have many benefits. It is a proven technique for developing effective PM plans, and can result in lower maintenance costs and higher

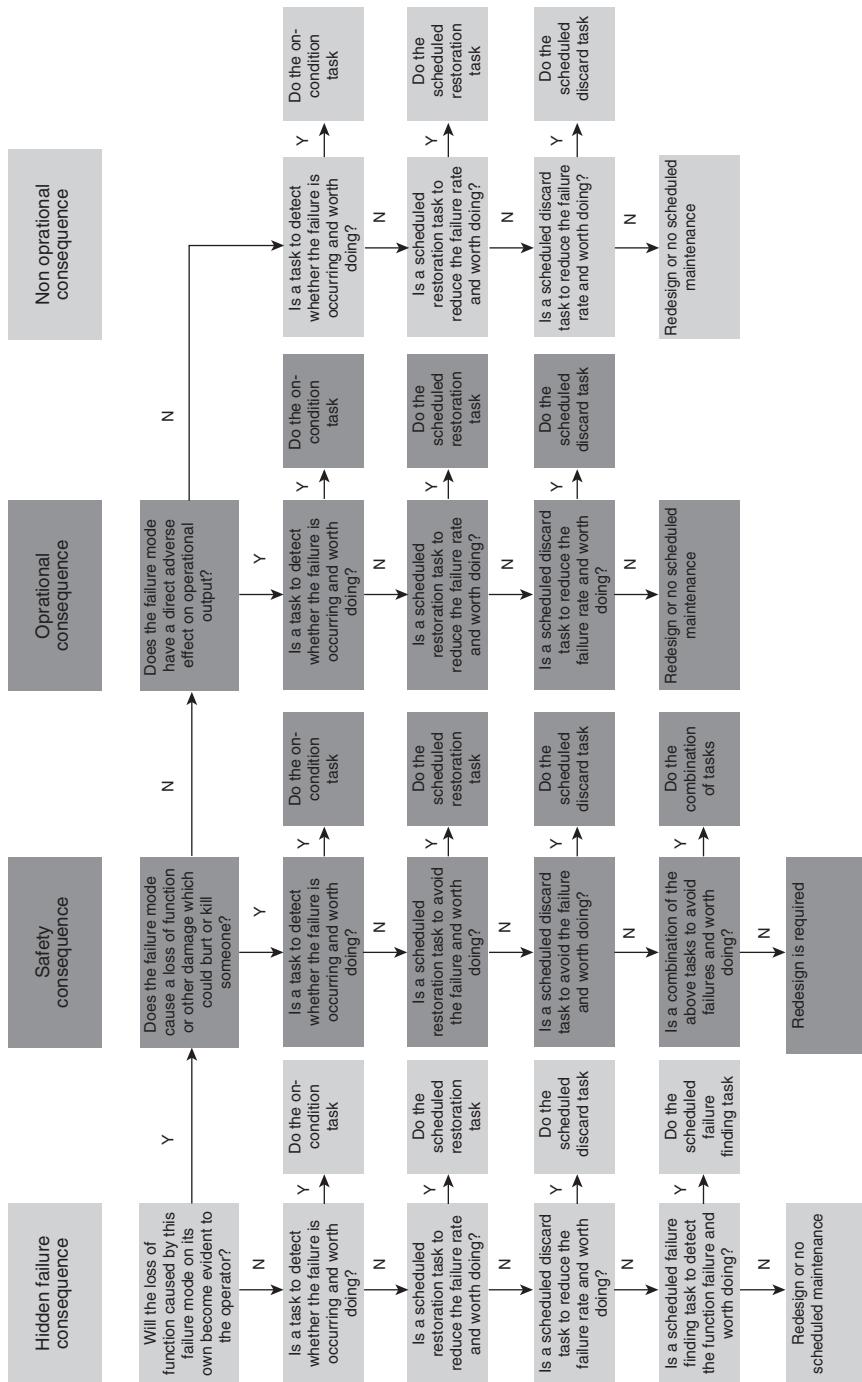


FIGURE 15.6 RCM Decision Diagram for circuit breaker RCM project.

Critical function failure	Failure modes (Causes of failure)	Failure consequences				Cost-effective maintenance task
		Hidden failure	Safety	Operation	Non-operation	
Fail to interrupt fault	Main contact damage	No	Yes	No	No	Contact resistance measurement
	Arcing contact Damage	No	Yes	No	No	Dynamic resistance measurement
	CB mechanism damage	No	No	Yes	No	CB timing measurement Motion measurement Lubricate mechanism
	Tripping coil failure	No	No	Yes	No	Tripping coil circuit supervision, Tripping coil current and resistance measurement
	Accumulated Fault very high	No	Yes	No	No	Record number of CB operation or interrupt fault
	SF <sub>6</sub> gas contamination	No	Yes	No	No	SF <sub>6</sub> gas moisture measurement SF <sub>6</sub> gas percentage measurement

**FIGURE 15.7** Failure consequences and maintenance tasks selection for circuit breaker RCM project.

RCM recommendation	The current preventive maintenance program	The final preventive maintenance program
<p>Every year</p> <ul style="list-style-type: none"> <li>▪ Visual inspection for Tripping coil circuit supervision</li> <li>▪ Record number of CB operation or interrupt fault.</li> </ul> <p>Every 5 years</p> <ul style="list-style-type: none"> <li>▪ Contact resistance measurement</li> <li>▪ SF<sub>6</sub> gas moisture measurement</li> <li>▪ SF<sub>6</sub> gas percentage measurement</li> <li>▪ CB Timing measurement</li> <li>▪ Tripping coil current and resistance measurement</li> <li>▪ Motion measurement</li> <li>▪ Dynamic resistance measurement</li> <li>▪ Lubrication mechanism</li> </ul>	<p>Every year</p> <ul style="list-style-type: none"> <li>▪ Cleanliness and Visual inspection</li> </ul> <p>Every 5 years</p> <ul style="list-style-type: none"> <li>▪ Measure Moisture and Percentage SF<sub>6</sub> Gas</li> <li>▪ Measure Contact Resistance</li> <li>▪ Measure CB Timing</li> <li>▪ Motion measurement</li> <li>▪ Mechanism inspection and Lubrication</li> </ul>	<p>Every year</p> <ul style="list-style-type: none"> <li>▪ Cleanliness and Visual inspection for SF<sub>6</sub> gas pressure</li> <li>▪ Visual inspection for Tripping coil circuit supervision</li> <li>▪ Record number of CB operation or interrupt fault.</li> </ul> <p>Every 5 years</p> <ul style="list-style-type: none"> <li>▪ Contact resistance measurement</li> <li>▪ SF<sub>6</sub> gas moisture measurement</li> <li>▪ SF<sub>6</sub> gas percentage measurement</li> <li>▪ CB Timing measurement</li> <li>▪ Tripping coil current and resistance measurement</li> <li>▪ Motion measurement</li> <li>▪ Dynamic resistance measurement</li> <li>▪ Inspection and Lubrication mechanism</li> </ul>

**FIGURE 15.8** Overview of PM program for circuit breaker RCM project.

reliability and safety for fielded equipment, especially when maintenance or inspections are difficult to perform due to location or complexity. RCM provides an audit trail such that any further review can identify how tasks were justified in the past. It will increase the safety and reliability of equipment in plants and in field operations.

### 15.1.10 RCM Limitations

RCM has limitations. For one thing, it can be labor intensive. In addition, since RCM uses FMEA to perform its work, the FMEA must be tailored for RCM. Further, RCM provides maintenance tasks for a specific operating context so that if the context changes significantly, the tasks may no longer be suitable. In order for RCM to be fully effective, precise distributions of failure patterns are advisable, and often these data are not readily available in the required format. The benefits of RCM will need to be weighed against the costs and limitations for the specific project under consideration to determine the value in carrying out the exercise.

## 15.2 HAZARD ANALYSIS

Be wary then; best safety lies in fear.

—William Shakespeare

This section is a brief overview of Hazard Analysis. Practitioners who will be performing Hazard Analysis projects, in addition to applying the material on FMEA preparation and procedures in this book, are encouraged to study the standards and publications that apply to their specific Hazard Analysis application (reference Section 15.2.5).

“Hazard analysis is the process of examining a system throughout its life cycle to identify inherent safety related risks.”<sup>[7]</sup>

A hazard is defined by the Department of Defense in MIL-STD 882D as “Any real or potential condition that can cause injury, illness, or death to personnel; damage to or loss of a system, equipment or property; or damage to the environment.”<sup>[8]</sup> The FAA’s broader definition for hazard is a “condition, event, or circumstance that could lead to or contribute to an unplanned or undesirable event.”<sup>[9]</sup>

System Hazard Analysis (SHA) is used by many industries, including aviation, military, medical, food processing and chemical processing. The SHA identifies potential hazards associated with the use of a product, estimates and evaluates the risks, controls the risks, and monitors the effectiveness of the controls.

SHA is specifically required for medical products by U.S. and other international regulatory agencies. Medical products are required to perform risk management in compliance with International Organization for Standardization (ISO) 14971:2007. This ISO standard specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. The requirements of ISO 14971:2007 are applicable to all stages of the life cycle of a medical device.<sup>[10]</sup>

Hazard Analysis and Critical Control Point (HACCP) is a management system, endorsed by the U.S. Food and Drug Administration, in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement, and handling, to manufacturing, distribution, and consumption of the finished product. Refer to Chapter 8, Section 8.2 to see a case study on strudel processing that uses HACCP.

### 15.2.1 Hazard Analysis and FMEA

There are many similarities between a Hazard Analysis and an FMEA, and the chapters in this book that apply to FMEA apply equally to Hazard Analysis. Refer to Chapter 3 for the fundamental concepts and definitions of FMEA, Chapter 4 for FMEA project selection and timing, and Chapters 5–7 for the material on FMEA preparation, procedure, and execution. All of this material is essential to performing Hazard Analysis properly. Both FMEA and Hazard Analysis examine functions, failures modes, effects and causes. The primary difference with a Hazard Analysis is that it focuses entirely on *safety hazards*, whereas the scope of an FMEA covers safety as well as performance, quality, and reliability. There are other procedural and worksheet differences, as covered below.

Since the scope of Hazard Analysis is safety hazards, project teams will need to perform Design FMEA in addition to Hazard Analysis in order to improve the product design and Process FMEA in order to improve the manufacturing process.

### 15.2.2 Hazard Analysis Procedure

Before beginning a Hazard Analysis project, the team will need to agree on the standard, worksheet columns, and scales. See Section 15.2.5 for Hazard Analysis references and standards. Similar to FMEA, unless specifically mandated, the team should tailor the worksheet columns and scales to their unique industry application. Section 15.2.3 gives some examples of Hazard Analysis scales and worksheet columns; however, there is considerable difference from standard to standard, depending on industry and application.

The following is a general overview of Hazard Analysis procedure:

1. Prepare for the Hazard Analysis with similar steps to FMEA preparation, as covered in Chapter 5. It is important to focus on safety hazard-related information. Determine and agree on the standard, scales, and worksheet unique to Hazard Analysis.
2. Identify all hazards of concern. This includes hardware hazards, material hazards, software hazards, procedural hazards, human factors, environmental hazards, and interface hazards.
3. Follow the agreed-upon standard and worksheet. Develop the analysis from the beginning through recommended actions, including function, hazard description, hazard cause, and risk assessment. Refer to Chapter 6 for procedure advice.
4. Control the identified hazards based on risk priority and in the following order of precedence.<sup>[11]</sup> Refer to Chapter 7, Section 7.3, for action strategy suggestions.
  - a. *Design the hazard out* of the product. If the hazard cannot be eliminated, minimize the residual risk.
  - b. *Design for fail-safe default mode* by incorporating safety devices or fault-tolerant features.
  - c. *Provide early warning* through measuring devices, software, or other means. The warning should be clear and should attract the attention of the responsible operator.

### Suggested Mishap Severity Categories

Description	Category	Environmental, Safety, and Health Result Criteria
Catastrophic	I	Could result in death, permanent total disability, loss exceeding \$1M, or irreversible severe environmental damage that violates law or regulation.
Critical	II	Could result in permanent partial disability, injuries or occupational illness that may result in hospitalization of at least three personnel, loss exceeding \$200K but less than \$1M, or reversible environmental damage causing a violation of law or regulation.
Marginal	III	Could result in injury or occupational illness resulting in one or more lost work day(s), loss exceeding \$10K but less than \$200K, or mitigatable environmental damage without violation of law or regulation where restoration activities can be accomplished.
Negligible	IV	Could result in injury or illness not resulting in a lost work day, loss exceeding \$2K but less than \$10K, or minimal environmental damage not violating law or regulation.

**FIGURE 15.9** Suggested mishap severity categories.

(Excerpt from MIL-STD 882D, Standard Practice for System Safety, February 10, 2008, p. 18.)

- d. *Implement special procedures and training* when the above means are unable to eliminate the hazard.
- 5. Implement the identified controls, summarize the Hazard Analysis, and share the report with appropriate subject-matter experts and management. Refer to Chapter 7, Sections 7.5 through 7.7, for action execution enablers.

#### 15.2.3 Hazard Analysis Tables and Examples

As noted above, there are many references for the procedure, scales, and worksheets for performing a Hazard Analysis. One of the standards (MIL-STD 882D) has been selected to provide an example of severity and probability scales. Figure 15.9 shows the severity criteria that are used to assess the severity of the hazard risk. Figure 15.10 shows criteria for the probability levels that are useful in evaluating hazards.<sup>[8]</sup>

As with FMEA, Hazard Analysis recommends actions to reduce risk to an acceptable level. Figure 15.11 illustrates possible corrective actions for the hazard “Failure to extend landing gear prior to landing an aircraft,” based on safety precedence.<sup>[7]</sup>

As noted above, the specific worksheet columns used in a Hazard Analysis depend on the standard being used and the industry application. Typical columns include:

- Item/Part Name
- Function
- Hazard Description
- Cause of Hazard (or Trigger Mechanism)
- Effect of Hazard
- Category (Severity) of the Risk
- Probability of the Risk
- Recommended Corrective Action(s)

### Suggested Mishap Probability Levels

Description*	Level	Specific Individual Item	Fleet or Inventory**
Frequent	A	Likely to occur often in the life of an item, with a probability of occurrence greater than $10^{-1}$ in that life.	Continuously experienced.
Probable	B	Will occur several times in the life of an item, with a probability of occurrence less than $10^{-1}$ but greater than $10^{-2}$ in that life.	Will occur frequently.
Occasional	C	Likely to occur some time in the life of an item, with a probability of occurrence less than $10^{-2}$ but greater than $10^{-3}$ in that life.	Will occur several times.
Remote	D	Unlikely but possible to occur in the life of an item, with a probability of occurrence less than $10^{-3}$ but greater than $10^{-6}$ in that life.	Unlikely, but can reasonably be expected to occur.
Improbable	E	So unlikely, it can be assumed occurrence may not be experienced, with a probability of occurrence less than $10^{-6}$ in that life.	Unlikely to occur, but possible.

**FIGURE 15.10** Suggested mishap probability levels.

(Excerpt from MIL-STD 882D, Standard Practice for System Safety, February 10, 2008, p. 19 \*Definitions of descriptive words may have to be modified based on quantity of items involved. \*\*The expected size of the fleet or inventory should be defined prior to accomplishing an assessment of the system.)

### HAZARD: Failure to extend landing gear prior to landing an aircraft

Resolution Method	Example
Change design to eliminate hazard.	Use fixed (nonretractable) landing gear.
Use safety devices	Have landing gear extend automatically when certain parameters exist (e.g., airspeed, altitude)
Use warning devices	Provide a warning light, horn, or voice if the landing gear is not down when certain parameters are met (as in above).
Use special training and procedures	Instruct pilot to extend the gear prior to landing. Incorporate in flight simulators. Place procedural step "Landing Gear Down" in the flight manual.

**FIGURE 15.11** Safety precedence hazard resolution example.

**Hazard Analysis Example 1** The following example of Preliminary Hazard Analysis (PHA) comes from the mechanical engineering department of the University of Utah. It is a PHA done on a pressure cooker.<sup>[12]</sup>

The example begins with a Preliminary Hazard Matrix, which is a thought starter to help the team identify the entire list of hazard concerns. The Preliminary Hazard

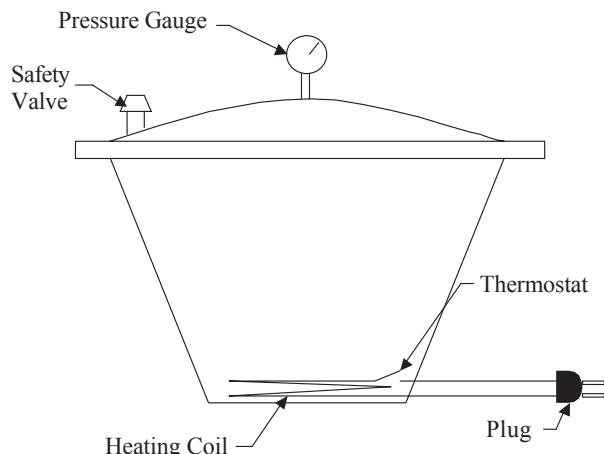
Matrix identifies the hazard category in the left column (such as collision, corrosion, electric shock, fire, and radiation), and the potential areas for failure from left to right on the grid (such as structural, electrical, pressure, and leakage).

The pressure cooker PHA follows these steps.<sup>[12]</sup>

1. Identify known hazards.
2. Determine the cause(s) of the hazards.
3. Determine the effects of the hazards.
4. Determine the probability that an accident will be caused by a hazard.
5. Establish initial design and procedural requirements to eliminate or control hazards.

Figure 15.12 is a schematic of a pressure cooker, with the current safety features. Figure 15.13 is a worksheet of the Pressure Cooker PHA.<sup>[12]</sup>

**Student Exercise** Students are encouraged to analyze this case study, including the PHA on the pressure cooker. See Problem 15.5 in Section 15.7, “End of Chapter Problems,” for the evaluation exercise.



#### Pressure Cooker Safety Features

1. Safety valve relieves pressure before it reaches dangerous levels.
2. Thermostat opens circuit through heating coil when the temperature rises above 250°C.
3. Pressure Gauge is divided into green and red sections. “Danger” is indicated when the pointer is in the red section.

**FIGURE 15.12** Pressure cooker schematic with current safety features.

Hazard	Cause	Effect	Probability of Accident due to Hazard	Corrective or Preventive Measures
Shock	Faulty wire insulation creates circuit to ground through operator when operator touches cord.	Mild shock to electrocution depending on the overall resistance to current flow through the person's body. The overall resistance would depend on factors such as the resistance of the person's shoes, whether or not his or her fingers were wet, and the condition of the insulation.	Remote	Use insulation that is very resistant to deterioration.  Use a grounded cord (three-pronged plug).  Only plug the pressure cooker into outlets that are equipped with a ground-fault circuit interrupter.
Fire	Sparks are generated near a flammable material when current passes from the cord to another object at a point where the insulation is faulty.	Significant damage to system and surroundings.	Extremely remote (A fault must be present in the insulation, sparks must be generated, and a flammable material must be located very close to the cord. The probability that all of these conditions will exist simultaneously is very low.)	Same three used for shock.  Keep flammable materials away from system.
Burn	Person touches hot pressure cooker surface or hot materials inside pressure cooker.  Steam from safety valve burns person.	First- or second-degree burns depending on how long the person's skin is in contact with the hot surface or material.	Reasonably probable	Use hot pads if the pressure cooker must be touched.  Keep pressure cooker out of the reach of children.  Put a cover on the safety valve to spread the steam out so that it is not concentrated enough to burn the skin
Explosion	Thermostat and safety valve fail, and no one notices that the pressure gauge indicates "danger."	Sever injuries or fatalities.  Loss of system.  Damage to surroundings.	Remote	Use only high-quality thermostats and safety valves.  Use more redundancies. (Example: Two safety valves)

**FIGURE 15.13** Example of Preliminary Hazard Analysis on a pressure cooker.

**Hazard Analysis Example 2** Figure 15.14 is an example of a Hazard Analysis of a fuel control subsystem.<sup>[11]</sup> It comes from the book *Assurance Technologies: Principles and Practices* by Dev Raheja.

**Hazard Analysis Example 3** Refer to Chapter 8, Section 8.2 to see a case study on strudel processing that uses a combined FMEA and Hazard Analysis.

Subsystem Hazard Analysis				Date: _____	Analyst: _____
System: "X" vehicle					
Part Name	Hazard Description	Accident (Trigger Event)	Criticality	Recommended Controls	Revised Criticality
Fuel Tank	Tank rupture	Differential in pressure between the inside and outside of tank	IB	Qualify tank for 20-year ability to withstand rupture forces. Use ductile material.	IIIE
	Failure of tank seal	Any kind of flame or spark	IB	Provide double seal.	IIC
Fuel Pump	Fire	Spark in the area	IIA	Mount fuel pump inside tank.	IIIE
Fuel Line	Fuel line rupture	Corrosion sufficient to penetrate through the wall thickness	IIC	Use stainless steel lines or corrosion-resistant material.	IIIE
Filter	Dirty or clogged filter	High buildup of pressure	IC	Design for pressure relief. In addition, design filter for twice the current life.	IIIB
Carburetor	Fuel leakage	Vehicle rollover	IID	Use electronic fuel injection.	IIID

**FIGURE 15.14** Example of Hazard Analysis on fuel control subsystem.

#### 15.2.4 Hazard Analysis Definitions

Definitions are from “MIL-STD-882D Standard Practice for System Safety.”<sup>[8]</sup>

**Fail-Safe** A design feature that ensures the system remains safe or, in the event of a failure, causes the system to revert to a state that will not cause a mishap.

**Hazard** Any real or potential condition that can cause injury, illness, or death to personnel; damage to, or loss of a system, equipment, or property; or damage to the environment.

**Health Hazard Assessment** The application of biomedical knowledge and principles to identify and eliminate or control health hazards associated with systems in direct support of the life-cycle management of materiel items.

**Mishap** An unplanned event or series of events resulting in death, injury, occupational illness, damage to, or loss of equipment or property, or damage to the environment.

**Mishap Probability** The aggregate probability of occurrence of the individual events/hazards that might create a specific mishap.

**Mishap Probability Levels** An arbitrary categorization that provides a qualitative measure of the most reasonable likelihood of occurrence of a mishap resulting from personnel error, environmental conditions, design inadequacies, procedural deficiencies, or system, subsystem, or component failure or malfunction.

**Mishap Risk Assessment** The process of characterizing hazards within risk areas and critical technical processes, analyzing them for their potential mishap severity and probabilities of occurrence, and prioritizing them for risk mitigation actions.

**Mishap Risk Categories** An arbitrary categorization of mishap risk assessment values often used to generate specific action such as mandatory reporting of certain hazards to management for action, or formal acceptance of the associated mishap risk.

**Mishap Severity** An assessment of the consequences of the most reasonable credible mishap that could be caused by a specific hazard.

*Mishap Severity Category* An arbitrary categorization that provides a qualitative measure of the most reasonable credible mishap resulting from personnel error, environmental conditions, design inadequacies, procedural deficiencies, or system, subsystem, or component failure or malfunction.

*Safety Critical* A term applied to any condition, event, operation, process, or item whose proper recognition, control, performance, or tolerance is essential to safe system operation and support (e.g., safety critical function, safety critical path, or safety critical component).

### 15.2.5 Hazard Analysis References and Standards

- American National Standards Institute (ANSI)/Government Electronics and Information Technology Association Standard (GEIA-STD)-0010-2009, *Standard Best Practices for System Safety Program Development and Execution*
- FAA System Safety Handbook, chapter 7: *Integrated System Hazard Analysis*, December 30, 2010
- FAA System Safety Handbook, chapter 8: *Safety Analysis/Hazard Analysis Tasks*, December 30, 2010
- Institute of Electrical and Electronics Engineers Standard (IEEE STD)-1228-1994 *Standard for Software Safety Plans*
- ISO 14971:2007, *Medical devices—Application of risk management to medical devices*
- SAE ARP4761, *Guidelines and Methods for Conducting the Safety Assessment Process on Civil Airborne Systems and Equipment*, 1996-12-01
- MIL-STD 882D, *Standard Practice for System Safety*, 10 Feb 2000
- U.S. Food and Drug Administration, *Hazard Analysis and Critical Control Point Principles and Application Guidelines*, adopted August 14, 1997, National Advisory Committee on Microbiological Criteria for Foods

## 15.3 CONCEPT FMEA

Most product development processes have an early stage in which the various design concepts are reviewed against program criteria and the most optimum design concept is selected. This stage is sometimes called Feasibility Studies or Concept Alternative Selection. It is important to include risk assessment from the standpoint of safety and reliability as part of the concept selection criteria for all product or process concepts that are being considered. One of the best ways to do this is through a Concept FMEA.

A *Concept FMEA* is a short version of FMEA to aid in selecting optimum concept alternatives or to determine changes to system design specifications. It increases the likelihood that potential failure modes and resulting effects of a proposed concept are considered before the final concept is determined and actual design work proceeds. An example of this is analyzing the risk of failures of each of the new all-terrain bicycle concept alternatives, in support of the decision

to select the optimum concept that is most reliable and will meet program objectives. The Concept FMEA also identifies system-level testing requirements and helps to determine if hardware system redundancy may be required within a design proposal.

The timing of a Concept FMEA is important. It should be done as soon as various concepts are identified and before the final concept is selected.

The Concept FMEA includes the following elements from a traditional FMEA.

- Item(s)
- Function(s)
- Failure mode(s)
- Effect(s)
- Severity ranking of the most serious effect
- Cause(s)
- Occurrence ranking of primary cause(s)
- Design control(s)

The Concept FMEA is performed for each of the design alternatives under consideration. In order to shorten the time needed to do Concept FMEAs, most practitioners limit the exercise to the primary functions only, failure modes of most concern, worst-case effects, and causes of most concern. This is not intended to be a thorough FMEA—it is intended to provide safety and reliability input to the concept selection decision.

Later, after the design concept selection, a thorough FMEA can be performed according to the chapters on how to perform an FMEA, as covered earlier in this book. The Concept FMEA should be done using the same worksheets and software that are used for formal FMEAs in order to facilitate the eventual transfer of information to the subsequent System and Design FMEAs.

The material in this book on FMEA preparation and procedure (Chapters 5 and 6) applies to Concept FMEA, as modified by the unique elements and objectives of Concept FMEA.

Figure 15.15 shows an example of a Concept FMEA on a bicycle brake cable with new nylon material. Notice the “concerns” that are generated by the abbreviated FMEA. These concerns should be compared to other concepts that are being considered, and are input to the concept selection process.

## 15.4 SOFTWARE FMEA

My software never has bugs. It just develops random features.

—Anonymous

This section is a brief overview of software FMEA. Practitioners who will be doing software FMEA projects are encouraged to read the software FMEA publications that apply to their specific application (reference Section 15.4.3), in addition to reviewing the applicable FMEA material. Refer to Chapter 3 for the fundamental concepts and definitions of FMEA, Chapter 4 for FMEA project selection and

Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s)/Mechanism(s) of Failure	Sev	Occ	Current Design Controls (Prevention)	Current Design Controls (Detection)	Det	RPN	Concerns
The brake cable provides adjustable and calibrated movement between the brake lever and brake caliper, under specified conditions of use and operating environment.	Cable breaks	Operator is unable to close brake calipers, wheel does not slow down, possibly resulting in accident.	Abrasive wear of nylon cable due to wrong material selected	10	3	Cable material selection based on ANSI Standard #ABC.	Cable strength test# 456	2	60	Strength of new nylon cable material is less than steel for similar diameter
	Cable binds	Increased friction between cable and sheath, resulting in operator having to use greater effort to close brake calipers.	Inadequate or wrong lubrication between cable and sheath	7	5	Nylon cable material design guide #123	Finite Element Analysis of all new cable material	2	70	Added controls will be needed in plant cable assembly
	Cable slips (at brake caliper or brake lever pulled, resulting in inadequate friction between brake pads and wheel, with possibility of accident.)	Brake caliper does not close properly when brake lever is pulled, resulting in inadequate friction between brake pads and wheel, with possibility of accident.	Brake cable diameter too small to maintain secure position when locking nut is engaged	10	5	Tolerance study of cable locking mechanism	Brake calibration test #567	1	7	Redesign of cable locking mechanism will be needed

TRUNCATED

**FIGURE 15.15** Example of Concept FMEA on Bicycle Brake Cable—with new nylon material.

timing, and Chapters 5–7 for the material on FMEA preparation, procedure, and execution. All of this material is essential to performing software FMEAs properly, and should be integrated into the preparation and procedure steps covered below.

Many mechanical and electrical systems include software integration. The FMEA methodology applies very well to software as well as hardware. It is possible to include software functionality in the System FMEA as part of the functional descriptions. However, especially for complex software functionality such as embedded control systems, it may be useful to perform a separate software FMEA.

“Software FMEA assesses the ability of the system design, as expressed through its software design, to react in a predictable manner to ensure system safety.”<sup>[13]</sup>

Software FMEA can be applied at the system functional level, the detailed design (logic level), or at the code level. For critical applications, it should be done at all three levels. Other applications include developing requirements for diagnostics and prognostics.

Dev Raheja, in his book *Assurance Technologies: Principles and Practices*, writes this about software FMEAs performed at the system functional level<sup>[11]</sup>:

Software System Failure Mode and Effects Analysis (SSFMEA) applies to software systems where software controls the hardware. Most technical products belong in this category, such as aircraft, power plants, refineries and complex systems. In SSFMEA, the focus is on identifying system weaknesses through software flow charts so that software specifications can be made complete, clear, comprehensive, and unambiguous. The goal is 1) to determine whether the software is fault-tolerant with respect to hardware failures and 2) to identify missing requirements in the system specification.

If the system is highly complex, one can use data flow diagrams to support the software FMEA and to help discover latent failure modes. A data flow diagram is a graphical representation of how data flow between processes in a system, visually showing what kinds of data will be input to and output from the system.

The second level is software FMEA performed at the *detail* or logic level. Detailed software FMEA is used to verify that the software design achieves the specified software requirements and provides all needed system safety protection. Detailed software FMEA “is lengthy and labor intensive . . . mostly appropriate for critical systems with minimal or no hardware protection of memory, processing results, or communications.”<sup>[13]</sup>

Reference Chapter 4, Section 4.3, for information on “Preliminary Risk Assessment,” which can be used to identify critical systems for detailed software FMEA. The risk criteria should be tailored to software application.

The third level is software FMEA performed at the *code* level. Software inputs and outputs are analyzed to determine what can go wrong, and anomalies are identified. The objective is to ensure inputs and outputs are acceptable and processed correctly, and if failure occurs, the product fails in a fail-safe mode. Similar to software FMEAs performed at the detail level, code-level software FMEA is most appropriate for critical systems.

As is true in all types of FMEAs, it is important to define what constitutes a failure. “Software failure can be the result of errors in software design being expressed due to the specific environmental exposure of the software or of transient or permanent hardware failures.”<sup>[13]</sup>

Different organizations and practitioners use software FMEA for various objectives. Here are some possible objectives for software FMEA:

- Identifying missing software requirements
- Analyzing output variables
- Analyzing a system's behavior as it responds to a request that originates from outside of that system
- Identifying (and mitigating) single-point failures that can result in catastrophic failures
- Analyzing interfaces in addition to functions
- Identifying software response to hardware anomalies

There is no universally agreed-upon standard for performing software FMEAs, although it is the subject of various standards committees. Section 15.4.3 of this chapter lists a variety of references for Software FMEAs. Practitioners who will be performing software FMEA projects are encouraged to read the software standards and articles that apply to their projects. In addition, it is essential for any software FMEA team to have a subject-matter expert in the specific software systems that are being analyzed.

Peter Goddard, in a paper entitled “Software FMEA Techniques” presented at the 2000 Reliability and Maintainability Symposium, suggests performing a Software Hazard Analysis before beginning a software FMEA<sup>[13]</sup>:

Unlike hardware and system FMEAs, a software FMEA cannot easily be used to identify system level hazards. Since software is a logical construct, instead of a physical entity, hazards must be identified and translated into software terms prior to the analysis. Prior to beginning the development of a software FMEA, a system preliminary hazard analysis (PHA) for the system should exist. The PHA needs to include all the hazards, which can have software as a potential cause.

A software hazard analysis is an extension of the System Hazard Analysis as covered in Section 15.2 of this chapter. The first step is to identify each hazard from the System Hazard Analysis. For each potential hazard and hazard cause, which could be the result of software failures, an appropriate set of software input and output variable values is identified. The values associated with each hazard cause is then identified as a potential software hazard, which becomes input to the software FMEA.

#### **15.4.1 General Procedure for Software FMEAs**

The following are the preparation and general procedure steps for conducting software FMEAs.

**Software FMEA Preparation Steps** Refer to Chapter 5, Section 5.3, for complete FMEA preparation steps, many of which apply directly to Software FMEA. The steps for software FMEA preparation are summarized below:

1. Graphically depict the scope of the analysis either by modifying the FMEA Block Diagram or by separately providing a chart showing how software

functions integrate with hardware. For complex systems, data flow diagrams can be used.

2. Ensure software requirements are well defined before beginning the Software FMEA.\*
3. Gather all information needed to begin the analysis.
4. Agree on ground rules, assumptions, and limitations.
5. Assemble the correct software FMEA team, ensuring it includes subject-matter experts from software development, hardware design, systems engineering, testing, manufacturing, and service.
6. Agree on ranking scales appropriate for software analysis.
7. Agree on the level of analysis, that is, system functional level, logic level and/or code level.

**Software FMEA Procedure Steps** The material in Chapters 6 and 7 on FMEA procedure and developing effective action strategies is applicable to software FMEAs. Once the preparation steps are done, the following are the general procedural steps for a software FMEA at the system level. This procedure aligns closely with a paper written by Dev Raheja, “Software FMEA: A Missing Link in Design for Robustness.”<sup>[14]</sup>

Similar to System FMEAs, software system FMEAs should be performed early in the design process as soon as the software design team has determined initial software architecture and transferred the functional requirements to the software design. Software FMEAs at the detail level are typically done later in the software design process, when detailed design description and preliminary code exists.

1. Define the primary functions of the software–hardware integrated system. The software should always go to the desired state no matter what causes the software to malfunction. If a desired state is not identified in the specification, the software should always go into fail-safe state. A *fail-safe* state is one that, in the event of failure, responds in a way that will cause minimal harm to other devices or danger to personnel.
2. As in traditional FMEAs, each function is analyzed for what can go wrong with the function. Use the definition of “failure” that applies to software. The following are examples of possible software failures from Dev Raheja’s paper<sup>[14]</sup>:
  - a. Failure to perform a function reliably
  - b. Failure to perform a function safely
  - c. Failure to perform a function when needed

\* Software requirements—Peter Goddard, in “Software FMEA Techniques,” provides these comments about software requirements:

One of the crucial elements of any safety program for a software intensive system is the development of software requirements to guide the design team in the creation of a software architecture and implementation which includes all the features needed to support safety critical processing. The existence and understanding of these requirements by both the safety and software design groups is crucial to achieving a system design which is adequate for the intended application and to allow the software design group to understand the results of and recommendations from the software FMEA.<sup>[13]</sup>

- d. Performing a function when not needed, such as deploying an air bag in a car when there is no accident
  - e. Performing functions that are not in the specification
  - f. Failure to stop a task at the right time
  - g. Loss of input or output
  - h. Failure to execute a function or a task
  - i. Intermittent behavior
  - j. Corrupted performance by an operating environment
  - k. Failure from an incorrect request by a user
  - l. Incomplete execution
  - m. Inability to execute critical interruptions
  - n. Degraded capability
3. Identify the effects of failures, as with traditional FMEAs. For system-level software FMEAs, the effect of each failure mode on the software outputs is compared to the results of the software hazard analysis (if available) to identify hazardous outcomes. For detailed-level software FMEAs, the effects for each postulated failure mode are traced “through the code and to the output signals. The resultant software state is then compared to the defined software hazards to allow identification of potentially hazardous failures.”<sup>[13]</sup>
4. Rank the severity of the failure effects using the agreed-upon scale.
5. Identify the causes of failure. It can be helpful to agree on the *types* of causes that are within the boundaries of the analysis. Some examples of possible software cause types include:<sup>[14]</sup>
- a. EMI/RFI (electromagnetic interference and radio frequency interference)
  - b. Coding or logic errors
  - c. Input/output errors
  - d. Data handling
  - e. Definition of variables
  - f. Interface failure
  - g. Failed hardware
  - h. Communication failure
  - i. Power outage
  - j. Omissions in the specification
  - k. Insufficient or corrupted memory
  - l. Operational environment
  - m. Loose wires and cables
  - n. Inaccurate inputs such as from sensors
- (The above are examples of cause types. In actual Software FMEA applications, causes need to be taken to root cause level. Refer to Chapter 6, Section 6.2.7.1, “Five Whys.”)
6. Rank the occurrence and detection using the agreed-upon scales.
7. Identify the current controls, similar to traditional FMEA.
8. Use the following precedence guidelines for solutions to software problems:

- a. Design out the failure mode
  - b. Use redundancy to achieve fault tolerance
  - c. Go into fail-safe mode (e.g., the ability to “limp home”)
  - d. Implement early prognostic warning
  - e. Implement training to reduce risk for human error
9. Recommended actions should use the above precedence suggestions and ensure the software is fail-safe and accomplishes its functions, with heightened focus on potential hazardous outcomes. Special attention should be paid to identify any need for new or modified software requirements. Refer to Chapter 7, Section 7.3, for advice on developing effective action strategies.
10. Implement recommended actions and ensure software–hardware risk is reduced to an acceptable level. Refer to Chapter 7, Sections 7.5 through 7.7 for advice on FMEA execution.

#### 15.4.2 Software FMEA Examples

The following sections present three examples of brief excerpts from software FMEAs at the function level, logic level, and code level. They are provided by Dev Raheja.<sup>[15]</sup>

**Software FMEA Example: Function Level** Figure 15.16 is an example excerpt from a *function-level* software FMEA. Software system functions are analyzed for their failure modes, causes, effects, and criticality. Only the top-level functions are analyzed in the function-level FMEA. This should be done once the software requirements are available. The *Robust Controls* column includes identifying new requirements, changing the design to prevent the failure mode, adding fault tolerance, ensuring the product fails in a fail-safe mode, and adding warnings.<sup>[15]</sup>

**Software FMEA Example: Logic Level** Figure 15.17 is an example excerpt from a *logic-level* software FMEA. The focus is at the detailed software design prior to coding. It is best done after all associated information is available. Each logic task

Spec. Ref.	Function	Failure Modes	Causes	Effects	Criticality	Robust Controls	Interface Effects
1001	Provide required levels of radiation	Radiation level too high for the required intervention.	Technician did not set the radiation at right level.	Overradiation to patients.	I D	Develop algorithm to reset to normal levels after imaging each patient.	Impact from hardware failures, electrical noise.
		Radiation at lower level than required.	Software does not respond to hardware mechanical setting.	Patient fails to receive enough radiation.	III C	Include failure detection in software. Include visual/audio alarm in the code.	Needs easy service interface. Improve recovery protocol.
1002	Protect patients from unexpected high radiation.	Higher radiation than required.	Sneak paths in software.	Radiation burns	II C	Shut the system if radiation level does not match the inputs.	Revisit traceability matrix.

**FIGURE 15.16** Example excerpt of software FMEA at the function level. Product: X-ray system for a hospital.

(Criticality nomenclature: Severity scale (highest to lowest) in this example is I, II, III, IV, V. Probability levels (highest to lowest) are A, B, C, D, E. This guideline is used widely in aerospace and defense contracts based on MIL-STD 882. Courtesy of Dev Raheja, President of Raheja Consulting, Inc., Laurel, Maryland, 2011.)

Task#	Description	Failure Modes	Causes	Effects	Criticality	Robust Controls	Interface effects
406	Nurse chooses desired breathing rate.	Unreasonable breathing rate requested.	Nurse inadvertently uses the volume control knob instead of breath control.	Insufficient breathing initiated.	II B	Add redundant built-in verification to assure the breathing rate matches patient need.	Need to warn caregiver. Ventilator and the patient output interface should correlate to the selection.

**FIGURE 15.17** Example excerpt of software FMEA at the logic level. Product: Ventilator for arrhythmia patients.

(Criticality nomenclature: Severity scale (highest to lowest) in this example is I, II, III, IV, V. Probability levels (highest to lowest) are A, B, C, D, E. Courtesy of Dev Raheja, President of Raheja Consulting, Inc., Laurel, Maryland, 2011.)

Item#	Input/Output	Failure Modes	Causes	Effects	Criticality	Robust Controls	System Behavior
151	Alarm must be active when patient condition worsens.	Alarm gives false positive.	Signal-to-noise ratio inadequate.	Nurses distracted from attending to other patients unnecessarily.	III C	Develop new algorithm to correlate signal-to-noise ratio and the actual need for the alarm.	Under no condition should the alarm give false warning. Include redundant algorithm to verify authenticity of the alarm.

**FIGURE 15.18** Example excerpt of software FMEA at the code level. Product: Ventilator for arrhythmia patients.

(Criticality nomenclature: Severity scale (highest to lowest) in this example is I, II, III, IV, V. Probability levels (highest to lowest) are A, B, C, D, E. Courtesy of Dev Raheja, President of Raheja Consulting, Inc., Laurel, Maryland, 2011.)

is analyzed to determine what can go wrong, and missing logic is shown in the *Robust Controls* column.<sup>[15]</sup>

**Software FMEA Example: Code Level** Figure 15.18 is an example excerpt from a *code-level* software FMEA. Software inputs and outputs are analyzed to determine what can go wrong, and anomalies are identified. The *Robust Controls* column is used to ensure inputs and outputs are acceptable and processed correctly, and if failure occurs, the product fails in a fail-safe mode<sup>[15]</sup>.

#### 15.4.3 Software FMEA References and Standards

- IEC 61508, *Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems*, 2005
- NIST (National Institute of Standards and Technology), Planning Report 02-3, *The Economic Impact of Inadequate Infrastructure for Software Testing*, May 2003
- SAE JA 1002, *Software Reliability Program Standard*, January 2004
- Raheja, Dev, *Assurance Technologies: Principles and Practices*, McGraw-Hill, 1991
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- John B. Bowles, Chi Wan, “Software Failure Modes and Effects Analysis for a Small Embedded Control System,” Proceedings of the Annual Reliability and Maintainability Symposium, January 2001
- NIST (National Institute of Standards and Technology), Planning Report 02-3, *The Economic Impact of Inadequate Infrastructure for Software Testing*, May 2003.

## 15.5 FAILURE MODES, MECHANISMS, AND EFFECTS ANALYSIS

In a paper entitled “Identification and Utilization of Failure Mechanisms to Enhance FMEA and FMECA,” presented at the 2005 IEEE Workshop on Accelerated Stress Testing & Reliability, the authors state that one of the shortcomings of FMEA or FMECA as it is applied in many industries today is lack of establishing the underlying failure mechanisms that bring about the failure modes. This “limits their applicability to provide a meaningful input to critical procedures such as virtual qualification, root cause analysis, accelerated test programs, and to remaining life assessment.” Failure Modes, Mechanisms, and Effects Analysis (FMMEA) “enhances the value of FMEA and FMECA by identifying high-priority failure mechanisms and failure models.”<sup>[16]</sup>

The authors of this paper go on to say:

FMMEA is a systematic methodology to identify potential failure mechanisms and models for all potential failures modes, and to prioritize failure mechanisms. FMMEA enhances the value of the FMEA and FMECA methods by identifying high-priority failure mechanisms in order to create an action plan to mitigate their effects. High-priority failure mechanisms determine the operational stresses and the environmental and operational parameters that need to be controlled. Models for the failure mechanisms help in the design and development of the product.<sup>[16]</sup>

Additionally, knowledge of the ranked failure mechanisms will help in selecting appropriate precursor parameters and stress and damage models to obtain an accurate advanced warning of the impending failure, thus enhancing prognostics planning and implementation.

As covered in Chapter 6, Section 6.2.7, “Failure mechanisms are the physical, chemical, thermodynamic or other processes that result in failure. Failure mechanisms are categorized as either overstress or wear-out mechanisms. Overstress failure arises as a result of a single load (stress) condition, which exceeds a fundamental strength property. Wear-out failure arises as a result of cumulative damage related to loads (stresses) applied over an extended time.”<sup>[17]</sup>

### Physics of Failure

One of the uses of FMMEA is to prioritize failure mechanisms for modeling and simulation, and one of the more useful failure mechanism models is called “Physics of Failure” (PoF).

The following PoF description comes from the Army Material Systems Analysis Activity (AMSA) web site<sup>[18]</sup>:

Physics of Failure (PoF) is a science-based approach to reliability that uses modeling and simulation to design-in-reliability. It helps to understand system performance and reduce decision risk during design and after the equipment is fielded. This approach models the root causes of failure such as fatigue, fracture, wear, and corrosion. Computer-Aided Design (CAD) tools have been developed to address various failure mechanisms and sites. An example of a failure mechanism is the fatigue cracking of electronic solder joints. PoF saves time, money, and improves reliability.<sup>[18]</sup>

Physics of Failure modeling has great benefits; however, it must be done based on correct selection criteria and with the support of trained and skilled resources.

## When to Use FMMEA

The following selection criteria will help identify potential FMMEA projects.

- When there is a need to identify potential failure mechanisms and models for all potential failures modes and to prioritize failure mechanisms for use in creating an action plan to mitigate their effects.
- When knowledge of the ranked failure mechanisms will help in selecting appropriate precursor parameters and stress and damage models to obtain an accurate advanced warning of impending failure.
- When it is advantageous to support Design for Reliability by internalizing failure mechanisms at each step of the decision-making process.

Practitioners who wish to use FMMEA are encouraged to study the referenced papers and other material on PoF, including papers published by IEEE and as researched and published by the Center for Advanced Life Cycle Engineering (CALCE) Electronic Products and Systems Center at the University of Maryland.

The chapters in this book that apply to FMEAs apply equally to FMMEAs. Refer to Chapter 3 for the fundamental concepts and definitions of FMEA, Chapter 4 for FMEA project selection and timing, and Chapters 5–7 for the material on FMEA preparation, procedure, and execution. All of this material is important to performing FMMEAs properly. FMMEA does not replace the need to do FMEAs. Rather, it is the unique focus and application of FMMEA that sets it apart.

## FMMEA Procedure Steps

Procedure steps are from Pecht et al.<sup>[16]</sup>

1. Define the system and identify elements and functions to be analyzed
2. Identify potential failure modes
3. Identify potential failure causes (input is life-cycle environmental and operating conditions)
4. Identify potential failure mechanisms
5. Identify failure models
6. Prioritize failure mechanisms
7. Document the process (including the corrective actions considered and implemented)

### FMMEA Example

Figure 15.19 is an example of an FMMEA worksheet for a printed circuit board (PCB) assembly that is mounted in an automotive underhood environment.<sup>[16]</sup>

To understand this worksheet, the following description is provided: The assembly consisted of a PCB with copper metallization, plated-through holes (PTH), and eight surface-mounted inductors that were soldered onto the PCB pads. This assembly was mounted in the engine compartment of a 1997 Toyota 4Runner, and was mechanically connected to the compartment at its four PCB corners. Assembly failure was defined as one that would result in breakdown, or no current passage in the event-detector circuit. To detect failure, the PTHs were solder filled and an event-detector circuit was connected in series with all inductors through the PTHs. The assembly was powered independently from the automobile electrical system using a 3 V battery source. The bracketed numbers in the “failure model” column and the legend of the worksheet refer to references identified in the source paper.<sup>[16]</sup>

The outputs of an FMMEA project include a prioritized listing of failure mechanisms for use in development of models and the selection of appropriate precursor parameters and stress and damage models to obtain accurate advanced warning of impending failures. Therefore, it is essential that FMMEA projects include well-defined recommended actions in order to ensure the results are executed.

## 15.6 FAILURE MODES, EFFECTS, AND DIAGNOSTIC ANALYSIS

Failure Modes, Effects, and Diagnostic Analysis (FMEDA) is an extension of FMEA with a more systematic way to identify and evaluate the effects of component failure modes. This technique generates failure rates for safety-related effect categories (e.g., failed safe, detected; failed safe, undetected; failed dangerous, detected; failed dangerous, undetected). It is primarily used to develop online diagnostic techniques and as one of the steps to support compliance with IEC61508, *Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems*.

The following comes from a paper titled “FMEDA – Accurate Product Failure Metrics,” written by John C. Grebe and Dr. William M. Goble<sup>[19]</sup>:

The Failure Modes, Effects and Diagnostic Analysis, FMEDA, technique was developed in the late 1980’s based in part on a paper in the 1984 RAMS Symposium. The FMEDA added two additional pieces of information to the FMEA analysis process. The first piece of information added in an FMEDA is the quantitative failure data (failure rates and the distribution of failure modes) for all components being analyzed. The second piece of information added to an FMEDA is the ability of the system or subsystem to detect internal failures via automatic on-line diagnostics.

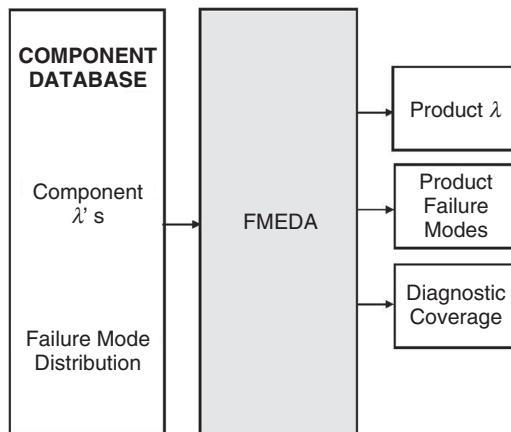
The FMEDA technique considers<sup>[19]</sup>:

- All components of a design,
- The functionality of each component,
- The failure modes of each component,

Element	Potential failure mode	Potential failure cause	Potential failure mechanism	Mechanism type	Failure model	Failure susceptibility	Occurrence	Severity	Risk
PTH	Electrical open in PTH	Temperature cycling	Fatigue	Wearout	CALCE PTH barrel thermal fatigue [25]	>10 years	Remote	Very low	Low
Metallization	High temperature	Electromigration	Wearout	Wearout	Black [26]	>10 years	Remote	Very high	Moderate
	High relative humidity	Corrosion	Wearout	Wearout	Howard [27]	>10 years	Remote	Very high	Moderate
	Ionic contamination					---			
Component (Inductor)	Electrical short/open between windings and core	High temperature	Wearout of winding insulation	Wearout	No Model	---	Remote*	Very high	Moderate
	Temperature cycling	Fatigue	Wearout	Wearout	Coffin-Manson [20]	1/70 days	Frequent	Very high	High
	Random vibration								
Interconnect	Sudden impact	Shock	Oversress	Oversress	Steinberg [28]	No failure	Extremely unlikely	Very high	Moderate
	Electrical short between PTHs	High relative humidity	CFF	Wearout	Rudra and Pecht [29]	4.6 years	Occasional	Very low	Low
	Crack/fracture	Random vibration	Fatigue	Wearout	Basquin [28]	>10 years	Remote	Very high	Moderate
PCB	Sudden impact	Shock	Oversress	Oversress	Steinberg [28]	No failure	Extremely unlikely	Very high	Moderate
	Loss of polymer strength	High temperature	Glass transition	Oversress	No model	No failure	Extremely unlikely	Very high	Moderate
	Open	Discharge of high voltage through dielectric material	EOS/ESD	Oversress	No model		Eliminated in first level prioritization		Low
Excessive noise	Proximity to high current or magnetic source	EMI	Oversress	No model		Eliminated in first level prioritization		Low	
	Temperature cycling/random vibration	Fatigue	Wearout	No Model	---	Remote	Very high	Moderate	
Pad	Lift/crack	Sudden impact	Shock	Oversress	---	Extremely unlikely	Very high	Moderate	

**FIGURE 15.19** FMEA worksheet for a PCB assembly mounted in an automotive under-hood environment.

(© 2005 IEEE. \*Based on failure rate data for inductors from Telcordia<sup>®</sup>. EOS, electrical overstress; ESD, electrostatic discharge; CFF, conductive filament formation.)

**FIGURE 15.20** FMEDA inputs and outputs.

- The impact of each component failure mode on the product functionality,
- The ability of any automatic diagnostics to detect the failure,
- The design strength (derating, safety factors), and
- The operational profile (environmental stress factors).

The authors of “FMEDA – Accurate Product Failure Metrics” go on to say<sup>[19]</sup>:

IEC61508 use of the FMEDA is focused on determination of two safety integrity measurements; the dangerous undetected failure rate and a metric known as the Safe Failure Fraction (SFF). The SFF represents the percentage of failures that are not dangerous and are detected.... IEC61508 Part 4 (1998) defines a dangerous failure as a failure which “has the potential to put the safety-related system in a hazardous or fail-to-function state.”

Figure 15.20 shows the high-level inputs and outputs for a FMEDA project.<sup>[19]</sup>

As with any application based on FMEA, the chapters in this book that apply to FMEAs also apply to FMEDA projects. Refer to Chapter 3 for the fundamental concepts and definitions of FMEA, Chapter 4 for FMEA project selection and timing, and Chapters 5–7 for the material on FMEA preparation, procedure, and execution. This material is applicable to performing FMEDA projects properly, and should be integrated into the preparation and procedure steps. In addition, FMEDA requires unique techniques for assessing safety-related effects and generating corresponding failure rates, as well as assessing the capability of online diagnostics techniques. Practitioners who will be performing FMEDA projects need to study the references and ensure the differences between FMEA and FMEDA are well understood.

To be successful, a FMEDA project requires accurate component failure rates and failure distributions. In addition, since FMEDA is more time consuming than FMEA, project selection should be carefully considered.

### References for FMEDA Information

- IEC 61508, *Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems*, edition 2.0, 2010
- <http://www.exida.com>
- John C. Grebe and Dr. William M. Goble, “FMEDA—Accurate Product Failure Metrics,” available on <http://www.exida.com>
- John Peter Rooney, *IEC61508: An Opportunity for Reliability*, RAMS 2001

## 15.7 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

### Problem 15.1

One of the primary purposes of RCM is . . . (Select one.)

1. To determine the reliability of equipment.
2. To determine PM requirements and other actions needed to ensure safe and cost-effective operations of a system.
3. To improve the manufacturing process.
4. To develop highly reliable equipment that will not need any maintenance during the expected life.

### Problem 15.2

Identify which of the following statements about RCM are true or false.

1. A well-done equipment FMEA or series of equipment FMEAs is at the core of an RCM analysis.
2. The output of an RCM project is input to an FMEA project.
3. Run to failure is a valid RCM strategy in which equipment is allowed to run without any scheduled maintenance actions until it fails, at which point it is fixed or replaced.
4. RCM uses the same effect scale as FMEA.

### Problem 15.3

Review the gas insulated switchgear RCM project covered in Section 15.1.7. One of the concerns from the FMEA was SF<sub>6</sub> gas contamination. What failure effect consequence was identified from the decision diagram? What tasks were proposed in the PM program to address this concern?

**Problem 15.4**

A Hazard Analysis is . . . (Select one.)

1. In reality, the same as a System FMEA.
2. A Design FMEA that focuses only on high severity and high occurrence.
3. A type of FMEA that focuses on safety and has its own set of scales.
4. A type of FMEA that focuses on safety and uses the same scales as other types of FMEAs.

**Problem 15.5**

Review Hazard Analysis example 1 on a pressure cooker (Section 15.2.3), including the PHA worksheet. Answer the following questions.

1. What column is missing in the PHA worksheet?
2. What additional corrective or preventive measures might be considered to address the burn hazard, caused by “person touches hot pressure cooker surface or hot materials inside pressure cooker”?

**Problem 15.6**

Review the section on “All-Terrain Bicycle Trade-off Analysis” in Appendix C. What concept FMEAs could be done and how would these concept FMEAs help with the concept trade-off decision for the all-terrain bicycle?

**Problem 15.7**

Some of the possible objectives for software FMEA include . . . (Select all that apply.)

1. Identifying missing software requirements.
2. Writing the software code.
3. Analyzing a system’s behavior as it responds to a request that originates from outside of that system.
4. Replacing the need to do Design or Process FMEAs.

**Problem 15.8**

Identify which of the following statements are true about software FMEAs. (Select all that apply.)

1. Many of the preparation steps for software FMEA are similar to regular FMEAs.

2. As in traditional FMEAs, each function is analyzed for what can go wrong with the function.
3. Software FMEAs should be done only at the function level, not at the logic or code level.
4. Unlike traditional FMEAs, Software FMEAs do not need to have recommended actions.

### Problem 15.9

When defining the functions in a software FMEA, the procedure says the software should always go to the “desired state” no matter what causes the software to malfunction, and further says if a desired state is not identified in the specification, the software should always go into fail-safe state. From a software standpoint, what does it mean to “go into fail-safe state”? Give one example.

### Problem 15.10

Software FMEA procedure advises the use of precedence guidelines for solutions to software problems: (1) design out the failure mode, (2) use redundancy to achieve fault tolerance, (3) go into fail-safe mode (e.g., the ability to “limp home”), (4) implement early prognostic warning, and (5) implement training to reduce risk for human error. Refer to the example of software FMEA at the function level (Figure 15.16) in Section 15.4.2, specifically the “Robust Controls” column. Determine which precedence (1–5 above) was used for each of the four entries.

### Problem 15.11

FMMEA is different from traditional FMEA in the following ways. (Select all that apply.)

1. FMMEA requires each failure mode be analyzed for the underlying failure mechanism.
2. FMMEA can be used to prioritize failure mechanisms for PoF models.
3. FMMEA has the same output as a traditional FMEA.
4. FMMEA can use the same risk ranking scales as traditional FMEA.

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# *Chapter* 16

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## *Selecting the Right FMEA Software*

Things should be made as simple as possible, but not any simpler.

—Albert Einstein

### **IN THIS CHAPTER**

Using good relational database software is an essential element for an effective Failure Mode and Effects Analysis (FMEA) program in any company. In this chapter, the important characteristics for selection of the best FMEA software are outlined and discussed.

#### **16.1 CHARACTERISTICS OF EXCELLENT FMEA SOFTWARE**

There are many characteristics to review in the selection of FMEA software. The following are important characteristics to consider:

1. Basic FMEA functionality
2. Time savings
3. Easily generated reports and charts
4. Import functionality

5. All major standards supported
6. Seamless linkage to other processes
7. Simultaneous access for multiple users
8. Security
9. Technical support and upgrades
10. Relational database

### **Basic FMEA Functionality**

First-time practitioners should be able to boot up the software and begin entering FMEA information easily, real-time in FMEA meetings, and without tutorials or training. The menus and dialog boxes should be intuitive and simple to find and use.

Users should look for certain basic functionality, including an easy-to-use interface, easy sorting of information, clear and configurable report generation, basic spreadsheet functionality, and easy copy/paste.

The user should be able to add, subtract, activate, or modify FMEA columns and profiles with one or two clicks. This feature should be restricted to an administrator if the company wants to control profiles and standards. Modified profiles should be easy to export to the company library.

### **Time Savings**

Good FMEA software can reduce overall FMEA time, both in meeting and out of meeting. It can accomplish this by providing instant retrieval of past FMEAs, easy access to a library of failure modes and other FMEA information, transfer of FMEA data to and from other applications, and simple entry screens that aid in real-time data entry during FMEA meetings.

Other ways that FMEA software can save time include:

- Electronic attachment of all information related to the FMEA,
- Ability to instantly search and access past failures and causes during FMEA meetings,
- Use of generic FMEAs to populate the beginning of program-specific FMEAs, and
- Access to all past FMEA data that can be brought into each FMEA column with a single click rather than retying the words.

### **Easily Generated Reports and Charts**

The FMEA database must be able to generate a variety of reports and charts in order to provide a means to communicate status of FMEA projects and show the FMEA in a traditional format. FMEA software should include a broad variety of preloaded plots and reports that can be configured to meet company-specific requirements. In addition, it is important to be able to summarize reports and charts across a selected combination of FMEAs, or across the entire FMEA database.

## Import Functionality

When doing FMEA projects, it is important to be able to access the entire set of past FMEAs and information that supports the FMEA project. FMEA software should accommodate easy importing of past FMEA projects and related FMEA information from any spreadsheet format into the FMEA database. In addition, FMEA software should easily import system hierarchies (Bill of Materials) or process operations (Bill of Process) in order to avoid unnecessary data entry.

## All Major Standards Supported

FMEA software should support a wide variety of FMEA standards, and should be easily configurable to provide FMEA teams with a library of FMEA worksheets meeting their needs. Companies should tailor the selected FMEA standard to their unique needs and circumstances, and make the agreed-upon standard easily available to each FMEA team. FMEA software should promote consistency in the way FMEAs are performed, with all users following the same format/standard/profile, if required, and having access to phrase libraries to promote consistent use of language.

## Seamless Linkage to Other Processes

FMEAs can benefit from and positively affect many other quality and reliability processes. FMEA software should support these linkages in a seamless and user-friendly manner. Potential linkage to reliability tools includes Reliability Block Diagram, Fault Tree Analysis, Design Verification Testing, Process Control Plans, Design Review Based on Failure Mode (DRBFM), Reliability-Centered Maintenance, Failure Review and Corrective Action System, and Life Data Analysis. Many of the linkages to quality and reliability documents are accomplished through transfer functions whereby selected FMEA information is transferred to the other documents by synchronization. Examples of FMEA software transfer functions include Design FMEAs transfer to Process FMEAs, Design FMEAs synchronization to DRBFM, Design FMEAs synchronization to Design Verification Plans, and Process FMEAs synchronization to Process Control Plans and Process Flow Diagrams.

## Simultaneous Access for Multiple Users

Good FMEA software can accommodate simultaneous access from multiple FMEA practitioners and subject matter experts. Without this feature, some FMEA users will be waiting to access the database, wasting their time. An alternative is for all input to the FMEA database to be channeled through an administrator; however, this is highly inefficient and denies the FMEA users access to the wealth of information that should be available. When working in a company with multiple FMEA users, the database should be easily accessible to different users simultaneously.

## Security

FMEAs contain confidential information and need to be secure. Security of documents can range from simple login security to complex levels of secure access. Most

FMEA software users should have full FMEA development and modification capabilities. However, it may be appropriate to restrict some users to read-only access. A small number of FMEA software users should have the capability of setting up and modifying profiles and libraries. FMEA databases must support the degree of security and access levels that is appropriate for company applications.

### Technical Support and Upgrades

The best FMEA software has excellent technical support and provides regular upgrades in an easily downloadable manner. Things to look for include live access to knowledgeable tech support staff, version control and upgrades, and a well-written technical manual.

## 16.2 WHY NOT JUST USE SPREADSHEET SOFTWARE?

Experienced spreadsheet users talk about familiarity, functionality, and simplicity of use, and some find that this keeps them in their personal “comfort zone.” However, spreadsheets are “two dimensional,” with limited and inefficient ability to access other information. The companies with the best FMEA programs require immediate and efficient access to all past FMEAs, as well as a database of field failures, test regimens, Process Control Plans, and many other sources of information. Even spreadsheet macros cannot come close the power of a *relational* database.

Good FMEA software should not only utilize a relational database, but also have the ability to provide user interfaces with an FMEA worksheet that looks and acts similar to spreadsheet software. That is the best of both worlds, and should be required.

## 16.3 ADVANTAGES OF RELATIONAL DATABASE

The technical definition of *relational database* is:

[A] computer database in which all data is stored in *relations*, which (to the user) are tables with rows and columns. Each table is composed of records and each record is identified by a field (attribute) containing a unique value. Every table shares at least one field with another table in ‘one-to-one,’ ‘one-to-many,’ or ‘many-to-many’ relationships. These relationships allow the database user to access the data in almost an unlimited number of ways, and to combine the tables as building blocks to create complex and very large databases.<sup>[1]</sup>

Some of the more important reasons to use a relational database include:

- All FMEAs are stored and easily accessed in one database.
- Users have the capability for comprehensive query functions across all FMEAs.
- Information is easily stored and retrieved across the entire set of FMEAs.
- Users have easy access to libraries of profiles and failure data.

- FMEAs can be easily imported from or exported to common spreadsheet software.
- Information from FMEAs can be easily transferred to and from other FMEA projects.
- Multiuser environment with login security and multiple levels of access is available.
- Recommended actions and status updates can be automatically e-mailed to responsible persons.
- FMEA software is scalable and can grow with user needs, from a few single users to begin with, to large groups, all the way to the complete enterprise.

#### 16.4 USING THE CRITERIA FOR SELECTING RELATIONAL DATABASE SOFTWARE

There are many FMEA software products on the market. Users are encouraged to do their own evaluation against the characteristics of good FMEA software outlined in this chapter. FMEA software should be based on a relational database. Of all the FMEA software packages currently being marketed, only a few use a relational database, and fewer still meet the characteristics of good FMEA software.

FMEA software should be supported by excellent technical support, preferably live and knowledgeable. There should be good version control and easily accessible software upgrades. A well-written manual without overly technical “geek speak” is a plus.

This author is most familiar with an FMEA software package called *Xfmea*, developed by ReliaSoft Corporation. It meets the above criteria for excellent FMEA software and utilizes a user-friendly relational database. Regardless of the software selected for FMEAs, users should evaluate the FMEA software from a rational set of criteria, and base the selection on their own unique needs.

#### 16.5 END OF CHAPTER PROBLEMS

Solutions to these problems can be found in the Solutions Manual; ordering information is located at the end of the Introduction to this book.

##### Problem 16.1

A relational database is a type of database that (indicate true or false):

1. Is the same as Microsoft Excel®.
2. Stores data in “relations” which (to the end user) are in tables with rows and columns.
3. Allows data to be easily accessed from other projects that are in the same database.
4. Allows only single-user access at one time.

**Problem 16.2**

The reasons to move from use of spreadsheet-based FMEA software to a relational database include (select all that apply):

1. Comprehensive query functions across FMEAs.
2. The FMEA team will save in meeting and administrative time when doing multiple FMEAs.
3. Multiuser environment with login security.
4. Spreadsheet macros can accomplish the same functions as a relational database.

**Problem 16.3**

When selecting software for doing FMEAs, it is important to consider (select all that apply):

1. Ease of performing basic FMEA functionality.
2. Ability to access all FMEAs in the database.
3. Linkage to other quality and reliability processes.
4. Users' familiarity with spreadsheet-based software.

**REFERENCE**

1. *Relational Database Definition*. [Online] 2010 [cited 2010]. Available at <http://www.businessdictionary.com/definition/relational-database.html>, BusinessDictionary.com.

# Appendices

## APPENDIX A FMEA SCALES

The following scales are from the Automotive Industry Action Group (AIAG), 4th edition, 2008 manual, “Potential Failure Mode and Effects Analysis (FMEA).”<sup>[1]</sup> These are example scales and will need to be tailored to individual company applications. Reference Chapter 5, Section 5.2.2, for information on how to select or modify FMEA worksheets and columns.

**Suggested DFMEA Severity Evaluation Criteria**

Effect	Criteria: Severity of Effect on Product (Customer Effect)	Rank
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	10
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle operable, but comfort/convenience functions inoperable).	6
	Degradation of secondary function (vehicle operable, but comfort/convenience functions at reduced level of performance).	5
Annoyance	Appearance or audible noise, vehicle operable, item does not conform and noticed by most customers (>75%).	4
	Appearance or audible noise, vehicle operable, item does not conform and noticed by many customers (50%).	3
	Appearance or audible noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%).	2
No Effect	No discernible effect.	1

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*Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis*, First Edition. Carl S. Carlson.

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### Suggested PFMEA Severity Evaluation Criteria

Effect	Criteria: <b>Severity of Effect on Product (Customer Effect)</b>	Rank	Effect	Criteria: <b>Severity of Effect on Process (Manufacturing/Assembly Effect)</b>
<b>Failure to Meet Safety and/or Regulatory Requirements</b>	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	10	<b>Failure to Meet Safety and/or Regulatory Requirements</b>	May endanger operator (machine or assembly) without warning.
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9		May endanger operator (machine or assembly) with warning.
<b>Loss or Degradation of Primary Function</b>	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8	<b>Major Disruption</b>	100% of product may have to be scrapped. Line shutdown or stop ship.
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7	<b>Significant Disruption</b>	A portion of the production run may have to be scrapped. Deviation from primary process including decreased speed or added manpower.
<b>Loss or Degradation of Secondary Function</b>	Loss of secondary function (vehicle operable, but comfort/convenience functions inoperable).	6	<b>Moderate Disruption</b>	100% of production run may have to be reworked off-line and accepted.
	Degradation of secondary function (vehicle operable, but comfort/convenience functions at reduced level of performance).	5		A portion of the production run may have to be reworked off-line and accepted.
<b>Annoyance</b>	Appearance or audible noise, vehicle operable, item does not conform and noticed by most customers (>75%).	4	<b>Moderate Disruption</b>	100% of production run may have to be reworked in station before it is processed.
	Appearance or audible noise, vehicle operable, item does not conform and noticed by many customers (50%).	3		A portion of the production run may have to be reworked in station before it is processed.
	Appearance or audible noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%).	2	<b>Minor Disruption</b>	Slight inconvenience to process, operation, or operator.
<b>No Effect</b>	No discernible effect.	1	<b>No Effect</b>	No discernible effect.

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### Suggested DFMEA Occurrence Evaluation Criteria

Likelihood of Failure	Criteria: Occurrence of Cause (Design Life/Reliability of Item/Vehicle)	Criteria: Occurrence of Cause (Incidents per Items/Vehicles)	Rank
Very High	New technology/new design with no history.	≥100 per thousand ≥1 in 10	10
High	Failure is inevitable with new design, new application, or change in duty cycle/operating conditions.	50 per thousand 1 in 20	9
	Failure is likely with new design, new application, or change in duty cycle/operating conditions.	20 per thousand 1 in 50	8
	Failure is uncertain with new design, new application, or change in duty cycle/operating conditions.	10 per thousand 1 in 100	7
Moderate	Frequent failures associated with similar designs or in design simulation and testing.	2 per thousand 1 in 500	6
	Occasional failures associated with similar designs or in design simulation and testing.	0.5 per thousand 1 in 2000	5
	Isolated failures associated with similar design or in design simulation and testing.	0.1 per thousand 1 in 10,000	4
Low	Only isolated failures associated with almost identical design or in design simulation and testing.	0.01 per thousand 1 in 100,000	3
	No observed failures associated with almost identical design or in design simulation and testing.	≤0.001 per thousand 1 in 1,000,000	2
Very Low	Failure is eliminated through preventive control.	Failure is eliminated through preventive control.	1

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### Suggested PFMEA Occurrence Evaluation Criteria

Likelihood of Failure	Criteria: Occurrence of Cause—PFMEA (Incidents per Items/Vehicles)	Rank
Very High	≥100 per thousand ≥1 in 10	10
High	50 per thousand 1 in 20	9
	20 per thousand 1 in 50	8
	10 per thousand 1 in 100	7
Moderate	2 per thousand 1 in 500	6
	0.5 per thousand 1 in 2000	5
	0.1 per thousand 1 in 10,000	4
Low	0.01 per thousand 1 in 100,000	3
	≤0.001 per thousand 1 in 1,000,000	2
Very Low	Failure is eliminated through preventive control.	1

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### Suggested DFMEA Detection Evaluation Criteria

Opportunity for Detection	Criteria: Likelihood of Detection by Design Control	Rank	Likelihood of Detection
<b>No Detection Opportunity</b>	No current design control; cannot detect or is not analyzed.	10	Almost Impossible
<b>Not Likely to Detect at any Stage</b>	Design analysis/detection controls have a weak detection capability; virtual analysis (e.g., CAE, FEA, etc.) is <u>not correlated</u> to expected actual operating conditions.	9	Very Remote
<b>Postdesign Freeze and Prior to Launch</b>	Product verification/validation after design freeze and prior to launch with <u>pass/fail</u> testing (subsystem or system testing with acceptance criteria such as ride and handling, shipping evaluation, etc.)	8	Remote
	Product verification/validation after design freeze and prior to launch with <u>test to failure</u> testing (subsystem or system testing until failure occurs, testing of system interactions, etc.)	7	Very Low
	Product verification/validation after design freeze and prior to launch with <u>degradation</u> testing (subsystem or system testing after durability test, e.g., function check).	6	Low
<b>Prior to Design Freeze</b>	Product validation (reliability testing, development or validation tests) prior to design freeze using <u>pass/fail</u> testing (e.g., acceptance criteria for performance, function checks, etc.)	5	Moderate
	Product validation (reliability testing, development or validation tests) prior to design freeze using <u>test to failure</u> (e.g., until leaks, yields, cracks, etc.).	4	Moderately High
	Product validation (reliability testing, development or validation tests) prior to design freeze using <u>degradation</u> testing (e.g., data trends, before/after values, etc.)	3	High
<b>Virtual Analysis—Correlated</b>	Design analysis/detection controls have strong detection capability. Virtual analysis (e.g., CAE, FEA, etc.) is <u>highly correlated</u> with actual and/or expected operating conditions prior to design freeze.	2	Very High
<b>Detection Not Applicable; Failure Prevention</b>	Failure cause or failure mode cannot occur because it is fully prevented through design solutions (e.g. proven design standard, best practice or common material, etc.)	1	Almost Certain

CAE, computer-aided engineering; FEA, finite element analysis.

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### Suggested PFMEA Detection Evaluation Criteria

Opportunity for Detection	Criteria: Likelihood of Detection by Process Control	Rank	Likelihood of Detection
No Detection Opportunity	No current process control; cannot detect or is not analyzed.	10	Almost Impossible
Not Likely to Detect at any Stage	Failure Mode and/or Error (Cause) is not easily detected (e.g., random audits).	9	Very Remote
Problem Detection Postprocessing	Failure Mode detection postprocessing by operator through visual/tactile/audible means.	8	Remote
Problem Detection at Source	Failure Mode detection in-station by operator through visual/tactile/audible means or postprocessing through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.)	7	Very Low
Problem Detection Postprocessing	Failure Mode detection postprocessing by operator through use of variable gauging or in-station by operator through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.)	6	Low
Problem Detection at Source	Failure Mode or Error (Cause) detection in-station by operator through variable gauging or by automated controls in-station will detect discrepant part and notify operator (light, buzzer, etc.). Gauging performed on setup and first-piece check (for setup causes only)	5	Moderate
Problem Detection Post Processing	Failure Mode detection postprocessing by automated controls that will detect discrepant part and lock part to prevent further processing.	4	Moderately High
Problem Detection at Source	Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing.	3	High
Error Detection and/or Problem Prevention	Error (Cause) detection in-station by automated controls that will detect, error and prevent discrepant part from being made.	2	Very High
Detection Not Applicable; Error Prevention	Error (Cause) prevention as a result of fixture design, machine design, or part design. Discrepant parts cannot be made because item has been error-proofed by process/product design.	1	Almost Certain

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### APPENDIX B FMEA WORKSHEET FORMS

The following FMEA worksheet forms are examples from a variety of industry applications. They include forms for Design FMEAs and Process FMEAs. They do not follow any given FMEA standard, and can be tailored to the unique industry application. Each individual form gives a brief explanation of the rationale for the form.

## B.1 Design FMEA Worksheet Forms

Design FMEA Form A

This is a basic Design FMEA form, with the Prevention-type Design Controls in the same column as the Detection-type Design Controls. If this form is used, it is recommended to note next to each Design Control what type it is ("P" or "D"). Note that it is recommended to place each "Item" in a separate column from the corresponding "Function(s)." RPN, Risk Priority Number.

Design FMEA Form B

This is a basic Design FMEA form, with the Prevention-type Design Controls in a separate column from the Detection-type Design Controls, which is preferred for visual clarity. Note that it is recommended to place each "Item" in a separate column from the corresponding "Function(s)."

Design FMEA Form C

Item	Function(s)	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Occurrence	Current Design Controls (Prevention)	Current Design Controls (Detection)	PZ Detection	PZ Occurrence	Recommended Action(s)	Responsible Person	Actions Taken	Revised Rankings				
															Severity	Occurrence	Detection	PZ	Revised
1	System A	R1	F1	E1	High	Critical	Low	Medium	Medium	Medium	Medium	Medium	Medium	John Doe	Completed	1	1	1	1
2	System B	R2	F2	E2	Medium	Major	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Jane Smith	In Progress	2	2	2	2
3	System C	R3	F3	E3	Low	Minor	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Mike Johnson	Planned	3	3	3	3
4	System D	R4	F4	E4	Very Low	Trivial	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Sarah Lee	Monitored	4	4	4	4
5	System E	R5	F5	E5	Very Low	Trivial	Medium	Medium	Medium	Medium	Medium	Medium	Medium	David White	Monitored	5	5	5	5
6	System F	R6	F6	E6	Very Low	Trivial	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Emily Green	Monitored	6	6	6	6
7	System G	R7	F7	E7	Very Low	Trivial	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Alex Brown	Monitored	7	7	7	7
8	System H	R8	F8	E8	Very Low	Trivial	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Olivia Wilson	Monitored	8	8	8	8
9	System I	R9	F9	E9	Very Low	Trivial	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Benjamin Clark	Monitored	9	9	9	9
10	System J	R10	F10	E10	Very Low	Trivial	Medium	Medium	Medium	Medium	Medium	Medium	Medium	Charlotte Davis	Monitored	10	10	10	10

This is a simple Design FMEA form, with the added “Requirements” column. This added column aids in identifying the “standard of performance” for each Function. Note that it is recommended to place each “Item” in a separate column from the corresponding “Function(s).”

Design FMEA Form D

Item	Function(s)	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Current Design Controls (Prevention)	Current Design Controls (Detection)	RPN	Revised Rankings					
										Responsible Person	Actions Taken	Effective Completion Date	Severity	Difference	RPN
1	Function A	Req A1	Mode 1A	Effect 1A	Low	Critical	Preventive	Detective	10	John Doe	Completed	2024-01-15	Low	0	10
2	Function B	Req B1	Mode 2B	Effect 2B	Medium	Major	Preventive	Detective	20	Jane Smith	In Progress	2024-02-15	Medium	10	20
3	Function C	Req C1	Mode 3C	Effect 3C	High	Minor	Preventive	Detective	30	Mike Johnson	Pending Review	2024-03-15	High	20	30
4	Function D	Req D1	Mode 4D	Effect 4D	Very High	Major	Preventive	Detective	40	Sarah Lee	On Hold	2024-04-15	Very High	30	40
5	Function E	Req E1	Mode 5E	Effect 5E	Medium	Major	Preventive	Detective	50	David White	Planned	2024-05-15	Medium	40	50
6	Function F	Req F1	Mode 6F	Effect 6F	Low	Minor	Preventive	Detective	60	Emily Green	Completed	2024-06-15	Low	50	60
7	Function G	Req G1	Mode 7G	Effect 7G	Medium	Major	Preventive	Detective	70	Alex Brown	In Progress	2024-07-15	Medium	60	70
8	Function H	Req H1	Mode 8H	Effect 8H	High	Minor	Preventive	Detective	80	Olivia Wilson	Pending Review	2024-08-15	High	70	80
9	Function I	Req I1	Mode 9I	Effect 9I	Very High	Major	Preventive	Detective	90	Henry Parker	On Hold	2024-09-15	Very High	80	90
10	Function J	Req J1	Mode 10J	Effect 10J	Medium	Minor	Preventive	Detective	100	Grace Parker	Planned	2024-10-15	Medium	90	100

In this Design FMEA form, the Prevention-type Design Controls are shifted to just before the Occurrence column in order to aid in Occurrence ranking.

Design FMEA Form E

In this Design FMEA form, the "Responsible Person" is separated from the "Target Completion Date," and the "Actions Taken" is separated from the "Effective Completion Date."

### **B.2 Process FMEA Worksheet Forms**

Process FMEA Form A

This is a basic Process FMEA form, with the Prevention-type Process Controls in the same column as the Detection-type Process Controls. If this form is used, it is recommended to note next to each Process Control what type it is ("P" or "D"). Note that it is recommended to place each "Process Step" in a separate column from the corresponding "Function(s)."

Process FMEA Form B

This is a basic Process FMEA form, with the Prevention-type Process Controls in a separate column from the Detection-type Process Controls, which is preferred for visual clarity. Note that it is recommended to place each "Process Step" in a separate column from the corresponding "Function(s)."

**Process FMEA Form C**

Process Step	Function(s)	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Occurrence	Current Process Controls (Prevention)	Current Process Controls (Detection)	PPZ Detection	Recommended Action(s)	Target Completion Date	Effective Completion Date	RPN	Occurrence	Severity	Revised Rankings	

This is a simple Process FMEA form, with the added "Requirements" column. This added column aids in identifying the "standard of performance" for each Process Function. Note that it is recommended to place each "Process Step" in a separate column from the corresponding "Function(s)."

Process FMEA Form D

In this Process FMEA form, the Prevention-type Process Controls are shifted to just before the Occurrence column in order to aid in Occurrence ranking.

Process FMEA Form E

In this Process FMEA form, the "Responsible Person" is separated from the "Target Completion Date," and the "Actions Taken" is separated from the "Effective Completion Date."

Process FMEA Form F

In this Process FMEA form, the "Requirements" column is further broken down into two separate columns, one for the Product Requirements and one for the Process Requirements. These added columns aid in identifying the "standard of performance" for each Process Function. Note that it is recommended to place each "Process Step" in a separate column from the corresponding "Function(s)."

## APPENDIX C ALL-TERRAIN BICYCLE DOCUMENTS

The following documents support the All-Terrain Bicycle examples in Chapters 5–7, as well as the All-Terrain Bicycle Case Study in Chapter 8, Section 8.8.

[This is a fictitious technical specification for the all-terrain bicycle. It is intended to support the exercises in the book and has some errors or deficiencies for training purposes.]

### All-Terrain Bicycle Performance Requirements

The Incredible Bike Company designs, develops, manufactures, and sells high performance bicycles. The All-Terrain group is developing a new lighter weight off-road bike, which will accommodate a wider variation of rider weight and height, and will hopefully exceed performance and durability expectations. However, it is important to get the new bike to market quickly for marketing reasons. It is also important to launch the bike without any safety or reliability problems, as the company reputation is at stake.

This document includes:

- *All-Terrain Bicycle Customer Requirements.* An overview of basic customer requirements, which drive the design choices for the all-terrain bike.
- *All-Terrain Bicycle Trade-off Analysis.* Alternative designs that were considered during the Concept Stage
- *All-Terrain Bicycle Functional/Technical Specifications.* Detailed technical requirements for the all-terrain bike.
- *All-Terrain Bicycle Test Plans.* Specific test regimens that were used in previous versions of all-terrain bikes.

### All-Terrain Bicycle Customer Requirements

*Rider Weight* The bicycle needs to support a rider of up to 270 pounds or up to 250 pounds when composite materials are used in seat posts, handlebar stems, or handlebars.

*Product Life* The bicycle frame structure needs to provide 8 years of useful life, free of cracks, deformation, corrosion, and paint peeling. Specified subsystems such as the gear/pedal and the wheel should be preventively maintained at predefined intervals.

*Normal Usage* This bicycle is intended to be used predominantly in trails for recreational mountain biking. This bicycle is not intended for competitive downhill biking, trick riding, ramp riding, jumping higher than 2 feet, and similar forms of aggressive riding. Riding in severe climates or riding with heavy loads is not considered normal usage.

*Storage Environment* All parts need to be corrosion free for 8 years. The assumption is that the bicycle will be stored outdoors and will be exposed to rain, sun, snow, dirt, and so on.

*Operating Conditions* The following table shows the expected operating environments of the bicycle throughout its life cycle:

Environment/Event	Percentage of Operation in Environment	Expected Range or Level
High temperature	10%	50°C
Low temperature	2%	-15°C
Thermal cycling	5%	10°C/min
Humidity/moisture	100%	0–100% relative humidity (RH), condensing, mean = 60%, standard deviation = 10%
Rain	10%	
Immersion	1%	
Hail/sleet/freezing rain	5%	
Frost/ice/icing	5%	
Snow	5%	
Sand/dust/mud	70%	
Solar load (sunlight)	80%	

*Monthly Usage* The monthly usage for all-terrain bicycle riders is 50 miles per month for 95th percentile riders.

#### *Percentage of Usage in Various Terrains*

Street	Dirt Road	Trail	Sand	Rock	Snow
30%	10%	55%	2%	2%	1%

*Percentage of Downhill/Uphill Activity* Uphill and downhill are defined as 20 degrees incline or higher

Level	Uphill	Downhill
50%	25%	25%

### All-Terrain Bicycle Trade-off Analysis

Three alternative designs were considered during the concept stage for the all-terrain bicycle.

**Design for Speed** This design emphasizes a lightweight structure. The aluminum frame and the absence of a rear suspension system, the narrower tires, and the double-walled 26-inch alloy rims contribute to reduction of weight down to 25 pounds. The absence of the rear suspension system also supports higher speeds since less energy is lost during pedaling. Since this bike is designed with speed in mind, the cassette chosen was the ABC nine-speed, instead of the more powerful yet slower XYZ 10-speed. The chainrings choices were with higher diameter for easier acceleration.

**Design for Durability** This design provides robustness and durability for advanced level all-terrain biking and superior downhill performance. The alloy frame tubes are significantly wider and enforced welding technology is used to assure maximum reliability in the joint regions. The rear suspension with advanced fading technology and adjustable rebound provides maximum bump compliance. The wider wheels are sturdy, with bladed spokes and a stiff, oversized axle to hold up to the rough terrain.

**Design for Comfort** The focus of this design is on user comfort. The absence of the rear suspension guarantees pedaling efficiency and yet the frame is specifically designed to absorb more shock and not transfer it to the rider. Special attention has been put in the choice of the front suspension, which is softer and provides a smoother absorption of shock forces. The bike is designed for a more upright natural stance, which does not put strain on the rider's back. The longer wheelbase (the horizontal distance between the centers of the front and rear wheels) has a major influence on the longitudinal stability of the bike, providing a more comfortable and stable ride that allows for extended hours of use.

**Final Choice** Based on the identified customer needs for the all-terrain bicycle (see previous section), it was determined that the focus of the new all-terrain bicycle should be on speed. With that in mind, the first design was chosen.

## All-Terrain Bicycle Functional/Technical Specifications

*Front Suspension* The front suspension should be able to absorb forces up to 1000 N without reaching the end of the travel distance. It uses a 75 mm travel coil-sprung fork with hydraulic damping for greater adjustability and control. It should also withstand g-force acceleration to 3 g, above which it is considered abusive usage. The fork shock absorber should have adjustable spring rates and damping. The damper should be oil filled (not air compressed).

*Color Offerings* Colors are grey-black or silver-red with scratch-resistant coating.

*Frame Strength* The bicycle frame should be able to withstand twice the 95th percentile rider (in terms of weight) on the top part, plus 2000 N of force on points of contact with rear and front wheel, and 1500 N on point of contact with handlebars.

*Frame Weight* The frame weight should be less than 25 pounds (maximum).

*Frame Material* The frame material should be B1457 premium aluminum. No visible corrosion on frame for 8 years.

*Frame Diameter* The maximum diameter of the frame is 2 inches at down tube, 1 inch at top tube, 0.75 inch at seat tube, and up to 0.5 inches for the rest of the tubes.

*Frame Welding* The frame uses Tungsten Inert Gas (TIG) welding.

*Gears* The gears should be ABC nine speed.

*Ease of Pedaling* The rider should be able to move the bicycle with 5 Nm torque on the first gear.

*Rims* The double-walled 26-inch alloy rims should be able to withstand twice the rider's weight, plus 3 g-force deceleration impact on solid surfaces such as rocks. Each rim should weigh no more than 10% of bicycle's total weight.

*Tubes* These should be designed for nominal pressure of 40 psi (2.8 bars), but should be able to withstand temporary increase of 50% in pressure.

***Braking*** The rider should be able to apply full force with one finger. The braking system should be effective to fully stop the bicycle within 5 meters when a 95th percentile rider (size and weight) travels in a horizontal asphalt road at a speed of 35 miles per hour.

***Steering Axis Angle*** The steering axis angle should be 74 degrees for balance of stability and maneuverability.

***Handlebar*** The handlebar should be able to withstand 600 Nm of torque on each side when assembled in the stem.

***Stem*** The stem should be able to withstand 1000 Nm of torque.

***Safety Features*** The bicycle should have reflective lights. Step-in pedals should have adjustable auto releasing, but should never exceed 5 pounds of force required.

***Time to Remove Wheels*** The time to remove the front wheel (average user) should be less than 10 seconds. The time to remove the rear wheel (average user) should be less than 30 seconds.

## **Test Plans from Previous Design**

### **System Tests**

***System Reliability Growth Test*** This is a test at the system level using lab equipment to simulate normal usage of the bicycle with usage acceleration (continuous testing). The automation includes accumulating mileage by pedaling, braking, and shifting gears. Load that simulates the rider's weight is placed at the seat post, handlebars, and pedals. The whole test is conducted on vibration tables so that it simulates an average trail.

***Beta Field Testing*** The prototype bicycles will be distributed to selected customers for beta testing.

### **Subsystem Tests**

***Braking System*** A life test is conducted on the braking system (front and rear are identical).

***Gear–Pedaling System*** A life test is conducted on the gear–pedaling system with variable loads that simulates the rider's applied force during uphill, downhill, and level activity.

***Frame Subsystem (without Suspension Fork)*** A force profile is applied on the frame subsystem to simulate usage conditions.

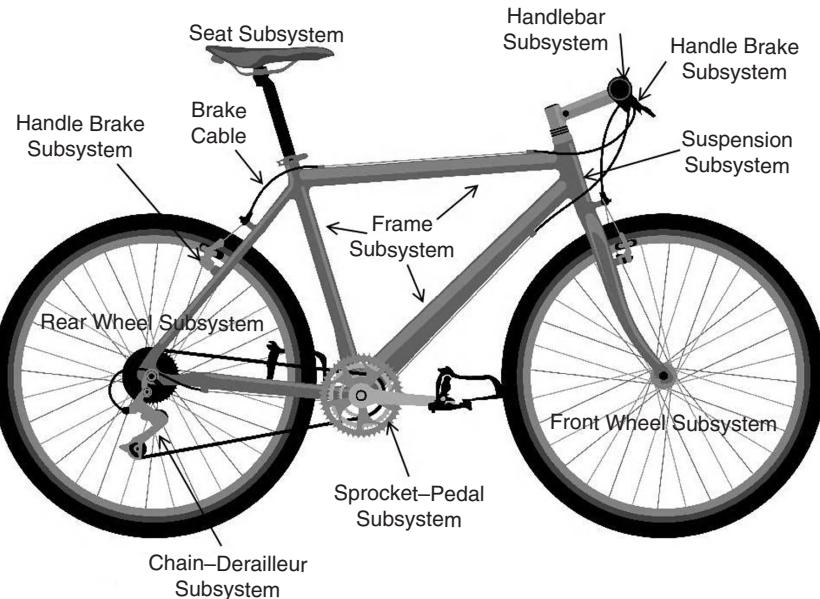
### **Component Tests**

***Suspension Fork*** A quantitative accelerated life test is conducted on the suspension fork, with the force applied on the fork (cyclical every 3 seconds) to project to normal usage conditions.

***Handlebars*** A fatigue test using a cyclic stress is conducted with the stress applied at the points of contact with the rider and the stem.

**Mechanical Disk** A quantitative accelerated degradation test is conducted on the mechanical disk (front and rear are identical). The acceleration factor is the level of force applied from the calipers to the mechanical disk.

### All-Terrain Bicycle Schematic



## APPENDIX D LISTS AND CHECKLISTS

The following lists and checklists are taken from the book. They are duplicated in the appendix as an aid for FMEA teams.

### D.1 FMEA Preparation Checklists

Chapter 5 covers how to prepare for FMEA projects. The following checklists help with FMEA preparation.

#### D.1.1 Checklist for FMEA Preparation

##### Preparation Tasks Done Once for All FMEA Projects

- FMEA Software Selection
- Selecting or Modifying FMEA Scales and Columns
- Identifying Roles and Responsibilities
- FMEA Team Training
- Legal Guidelines for Doing FMEAs
- Meeting Logistics
- Defining the System Hierarchy (for System and Design FMEAs)

- Defining the Process Steps (for Process FMEAs)
- Access to Failure Information

### **Preparation Tasks for *Each New FMEA Project***

- Determine the Scope of the Analysis
- Make the Scope Visible (for System and Design FMEAs):
  - FMEA Block Diagram
  - Parameter Diagram (P-Diagram)
  - FMEA Interface Matrix
  - Functional Block Diagram
- Make the Scope Visible (for Process FMEAs):
  - Process Flow Diagram (PFD)
  - Process Flow Diagram Worksheet (PFD Worksheet)
- Assemble the Correct Team
- Establish the Ground Rules and Assumptions
- Establish the Role of Suppliers
- Gather and Review Relevant Information
  - “Gather Information Checklist” (for System and Design FMEAs)
  - “Gather Information Checklist” (for Process FMEAs)
- Prepare FMEA Software for First Team Meeting
- “Ready-for-First-Meeting Checklist”

**D.1.2 *Ground Rules and Assumptions Checklist*** The following is an example of some of the ground rules and assumptions the FMEA team may consider before commencing the FMEA project:

1. For Design FMEAs, does the FMEA team assume the product will be manufactured or assembled within engineering specifications?
2. For Design FMEAs, does the FMEA team wish to consider an exception, such as the part design may include a deficiency that could cause unacceptable variation in the manufacturing or assembly process?
3. For Process FMEAs, does the FMEA team assume incoming parts and materials to an operation meet design intent?
4. For Process FMEAs, does the FMEA team wish to consider an exception, such as incoming parts or materials may have variation and do not necessarily meet engineering requirements?
5. What are the assumed environmental conditions?
6. What are the assumed operating profiles?
7. Will the FMEA team assume product abuse by the user? If so, to what levels?
8. What is the definition of failure used in the FMEA?
9. How will the FMEA team use severity rankings and RPNs to prioritize issues for corrective actions?

10. What is the process by which the FMEA team obtains approval for FMEA recommended actions and follow-up for execution?
11. What meeting norms should the team adopt so that meetings run smoothly and efficiently? (See Chapter 10, Section 10.2 for suggested meeting norms.)
12. Who will enter data into the FMEA software during meetings? Will there be a scribe, or will the facilitator enter the data?
13. How will the FMEA team come to decisions on each of the FMEA tasks? (See Chapter 10, Section 10.3.6, for suggested decision criteria.)
14. If applicable, how will the FMEA team coordinate with suppliers? Will supplier FMEAs be reviewed and approved by the FMEA team for critical parts according to defined FMEA quality objectives? (The FMEA Quality Objectives are covered in Chapter 9, Section 9.1.)
15. How will the organization track the completion of recommended actions and ensure risk reduction to an acceptable level?

**D.1.3 Gather Information Checklist (for System and Design FMEAs)** For System and Design FMEAs, the following information needs to be readily available to the System or Design FMEA team.

- Bill of Materials
- Past Design FMEAs
- Current System FMEA (if performing a Design FMEA at the subsystem or component level)
- Warranty, recalls, and other field history
- Engineering requirements (functional, performance, operating environments, etc.)
- Drawings and schematics
- Applicable government or safety regulations
- Test procedures
- Preliminary Design Verification Plan
- Preliminary test data (if available)
- FMEA Block Diagram, P-Diagram, FMEA interface matrix, and Functional Block Diagram
- Quality Function Deployment (QFD) (if available)
- Results of design concept selection or trade-off studies
- Actual parts (similar to design intent)
- List of specific design changes
- Other information in addition to field history and test results that will help establish failure frequencies
- Other documents and information that highlight the nature of the design concept

**D.1.4 Gather Information Checklist (for Process FMEAs)** For Process FMEAs, the following information needs to be readily available to the Process FMEA team.

- Bill of Materials
- Bill of Process
- Current and Past Design FMEAs (for the products being analyzed by Process FMEA)
- Past Process FMEAs
- Operator Instructions
- Warranty, recalls, and other field history
- Manufacturing data (plant incidents, etc.)
- Quality performance data (process yield, first time capability, parts per million, process capability indices, etc.)
- Engineering requirements (functional, performance, operating environments, etc.)
- Drawings and schematics
- Applicable government or safety regulations
- Process Control Plan (PCP) procedures
- Preliminary PCP
- PFD and PFD Worksheet
- Results of manufacturing concept selection or trade-off studies
- Actual parts (similar to design intent)
- List of specific manufacturing process changes
- A planned visit to “go and see” the manufacturing operations (or other suitable visual aids are provided)
- Other documents and information highlighting the nature of the manufacturing or assembly concept

**D.1.5 Ready-for-First-Meeting Checklist** This checklist helps ensure that all the necessary steps are completed before the first FMEA team meeting.

- The FMEA scales, worksheet, and procedure have been agreed upon and loaded into the FMEA software.
- The FMEA project has been selected based on an identified need or preliminary risk assessment.
- The FMEA team has been identified and notified of the upcoming FMEA.
- The FMEA team is trained in proper FMEA procedure.
- An FMEA facilitator or team leader has been assigned and is trained in how to effectively facilitate FMEAs.
- The proper FMEA procedure is available for use by the FMEA team.

- Management supports the FMEA project and will help to ensure it is done properly with good attendance.
- The scope of the FMEA is well defined and agreed upon.
- For System and Design FMEAs: an FMEA Block Diagram, P-Diagram, FMEA Interface Matrix, and Functional Block Diagram have been done, as needed.
- For Process FMEAs: a PFD and PFD Worksheet have been done, as needed.
- The ground rules and assumptions have been identified and agreed upon.
- All of the relevant information has been gathered in preparation for the upcoming FMEA. (See “Gather Information Checklist” above.)
- The FMEA software has been prepared for the first team meeting
- FMEA meeting room has been scheduled and FMEA members have been notified.

## D.2 Lists of Failure Mechanisms (excerpts from book)

Chapter 6, Section 6.2.7, establishes the role of failure mechanisms in FMEAs. Many FMEA practitioners find it helpful to see example listings of failure mechanisms. The succeeding sections 2.1 and 2.2 is an excerpt from the book *Failure of Materials in Mechanical Design: Analysis, Prediction, Prevention* by Jack Collins (John Wiley & Sons. Inc., 1993).<sup>[2]</sup> Note that in this book the author refers to failure mechanisms as “failure modes.”

### 2.1 DEFINITION OF FAILURE MODE

In the first chapter it was suggested that mechanical failure might be defined as any change in the size, shape, or material properties of a structure, machine, or machine part that renders it incapable of satisfactorily performing its intended function. With this definition in mind, one might define *failure mode* as the physical process or processes that take place or combine their effects to produce failure.

It has been suggested that a systematic classification might be devised by which all possible failure modes could be predicted. Such a classification is based on defining three categories: (1) manifestations of failure, (2) failure-inducing agents, and (3) locations of failure. These categories are specifically defined in the text that follows. Each specific failure mode is then identified as a combination of one or more manifestations of failure together with one or more failure-inducing agents and a failure location. Literally hundreds of combinations can be systematically listed. To explain the system in more detail, we may develop the three categories in more detail, as follows.

The four *manifestations of failure*, some with subcategories, are:

1. Elastic deformation
2. Plastic deformation
3. Rupture or fracture
4. Material change

- A. Metallurgical
- B. Chemical
- C. Nuclear

The four *failure-inducing* agents, each with subcategories, are:

1. Force
  - A. Steady
  - B. Transient
  - C. Cyclic
  - D. Random
2. Time
  - A. Very short
  - B. Short
  - C. Long
3. Temperature
  - A. Low
  - B. Room
  - C. Elevated
  - D. Steady
  - E. Transient
  - F. Cyclic
  - G. Random
4. Reactive environment
  - A. Chemical
  - B. Nuclear

The two *failure locations* are:

1. Body type
2. Surface type

To be precise in describing a specific mode of failure, it is necessary to select appropriate categories from those just listed without omitting any of the three major categories. For example, one might select *plastic deformation* from the first category, *steady force* and *room temperature* from the second category, and *body type* from the third category. Thus, the failure mode selected could be properly described as body-type plastic deformation under *steady force* at room temperature. This failure mode is commonly called *yielding*. Note, however, that the term *yielding* does not imply all of these restrictions; it is more general than that.

Many other failure modes of special interest have been defined that refer to general patterns of the three categories listed. To be useful, these terms require additional description and elaboration, but the terms are commonly used and very useful because of the importance of the failure phenomena that they represent. Twenty-three such specific failure modes are listed in Section 2.2. Later in the text, entire chapters are devoted to some of the more important failure modes.

## 2.2 FAILURE MODES OBSERVED IN PRACTICE

The following list of failure modes includes those most commonly observed in practice. In reviewing the list, it may be noted that certain failure modes are unilateral phenomena, whereas others are combined phenomena. For example, corrosion is listed as a failure mode, fatigue is listed as a failure mode, and corrosion-fatigue is listed as still another failure mode. Such combinations are included because they are commonly observed, important, and usually synergistic. That is, in the case of corrosion-fatigue, for example, the presence of active corrosion *aggravates* the fatigue process, and at the same time the presence of fluctuating fatigue loads aggravates the corrosion process. The following list is not presented in any special order, but it includes all commonly observed modes of mechanical failure.

1. Force and/or temperature-induced elastic deformation
2. Yielding
3. Brinnelling
4. Ductile rupture
5. Brittle fracture
6. Fatigue
  - A. High-cycle fatigue
  - B. Low-cycle fatigue
  - C. Thermal fatigue
  - D. Surface fatigue
  - E. Impact fatigue
  - F. Corrosion fatigue
  - G. Fretting fatigue
7. Corrosion
  - A. Direct chemical attack
  - B. Galvanic corrosion
  - C. Crevice corrosion
  - D. Pitting corrosion
  - E. Intergranular corrosion
  - F. Selective leaching
  - G. Erosion corrosion
  - H. Cavitation corrosion
  - I. Hydrogen damage
  - J. Biological corrosion
  - K. Stress corrosion
8. Wear
  - A. Adhesive wear
  - B. Abrasive wear
  - C. Corrosive wear
  - D. Surface fatigue wear
  - E. Deformation wear
  - F. Impact wear
  - G. Fretting wear

9. Impact
  - A. Impact fracture
  - B. Impact deformation
  - C. Impact wear
  - D. Impact fretting
  - E. Impact fatigue
10. Fretting
  - A. Fretting fatigue
  - B. Fretting wear
  - C. Fretting corrosion
11. Creep
12. Thermal relaxation
13. Stress rupture
14. Thermal shock
15. Galling and seizure
16. Spalling
17. Radiation damage
18. Buckling
19. Creep buckling
20. Stress corrosion
21. Corrosion wear
22. Corrosion fatigue
23. Combined creep and fatigue

### **D.3 FMEA Quality Objectives**

Chapter 9 describes the most common FMEA mistakes and the corresponding quality objectives. The next section presents the summary list of FMEA 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.
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” from where it can most effectively influence the product or process design.
8. *Team.* The right people are adequately trained in the procedure and participate in 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.

#### D.4 FMEA Facilitation Checklists

Chapter 10 covers how to lead successful FMEA projects, with Section 10.2 describing how to lead effective meetings, and Section 10.3 outlining the primary facilitation skills. The following checklists support FMEA facilitation.

##### D.4.1 Checklist for Effective Meetings

FMEA facilitators must be able to run effective meetings. Some of the characteristics of well-run meetings include:

1. Starting and ending meetings on time
2. Publishing and sticking to agendas
3. Developing and getting agreement on meeting “Norms”
4. Always maintaining focus on the meeting objectives
5. Summarizing results and follow-up actions at end of meeting
6. Preparing required documents, visuals, network access, software, and so on
7. Ensuring decision-making options are clear
8. Encouraging healthy member behaviors
9. Providing periodic process checks
10. Implementing a process to create true closure
11. Providing detailed minutes and specific follow-up plans

Meeting “Norms” are agreed-upon behaviors by meeting participants. They need to be developed by the team or the company. The FMEA team can use predetermined templates and develop company-specific guidelines. Below is an example of what comprises a set of Meeting “Norms.”

It is expected that each meeting participant:

1. Arrives to meetings promptly as scheduled
2. Respects others’ opinions
3. Debates differences of opinion calmly
4. Takes responsibility for assigned actions
5. Listens carefully to all ideas

6. Avoids doing e-mails, using cell phones, or other personal devices during meeting time
7. Maintains focus on the agenda
8. Uses “Parking Lot” if a topic is off agenda\*
9. Provides constructive feedback
10. Maintains equal opportunity for participation by all team members
11. Engages in no “war stories” or side conversations.

**D.4.2 FMEA Facilitator “Thought-Starter” Questions** As an aid for the FMEA facilitator, the following are possible questions to ask as part of the FMEA procedure. These questions are only thought starters and are not meant to limit in any way the skill of the FMEA facilitator and team in establishing the content of the FMEA.

**Functions** When identifying functions for System or Design FMEAs, the team can be asked questions such as:

- “What are the primary purposes of this item?”
- “What is the item supposed to do? What must the item not do?”
- “What is the standard of performance?”
- “What functions occur at the interfaces?”
- “What safety-related functions are important for this item?”
- Any other questions that ensure all of the primary functions are determined (reference Chapter 6, Section 6.2.2, “Checklist of Function Types”).

When identifying functions for Process FMEAs, the team can be asked questions such as:

- “Is the process function described in the form: do this [operation] to this [part or assembly] with this [tooling]?”
- “What is the primary purpose of the operation?”
- “What is the standard of performance of the operation?”
- “What is the operation intended to do? What must the operation not do?”
- Any other questions that ensure all of the primary process functions are determined (reference Chapter 6, Section 6.2.2, “Checklist of Function Types”).

**Failure Modes** When identifying failures modes for System or Design FMEAs, the team can be asked questions such as:

- “In what way could the item fail to perform its intended function?”
- “In what way could the item perform an unintended function?”
- “What could go wrong with this item?”

\* “Parking Lot” refers to a list of issues maintained by the facilitator that are not directly concerned with the agenda, but should be pursued in another venue.

- “What could go wrong at the interfaces?”
- “What has gone wrong with this item in the past?”
- “How could the item be abused or misused?”
- “What concerns do you have with this design?”
- Use the “failure conditions” in Chapter 6, Section 6.2.3 to be sure no failure modes are missed.

When identifying failure modes for Process FMEAs, the team can be asked questions such as:

- “In what way could the operation fail to perform its intended function?”
- “In what way could the operation perform an unintended function?”
- “What significant product characteristics from the PFD Worksheet can be potential failure modes?”
- “Why would a part be rejected at this operation?”
- “What could go wrong with this operation?”
- “What has gone wrong with this operation in the past?”
- “What concerns do you have with this operation?”
- Use the “failure conditions” in Chapter 6, Section 6.2.3 to be sure no failure modes are missed.

**Effects** When identifying effects for System or Design FMEAs, the team can be asked questions such as:

- “What is the consequence of the failure?”
- “If the item fails, what will be the consequences at the local level? At the next higher level? At the system level? At the end user?”
- “If the item fails, what will the customer see, feel, or experience?”
- “Will the failure cause potential harm to the end users?”
- “Will the failure cause potential violation of regulations?”
- “What would a failure mean to adjacent parts/subsystems?”
- Any other questions that ensure the effects of failure are fully understood at the local level, the next level, and system and/or end user.

When identifying effects for Process FMEAs, the team can be asked questions such as:

- “What is the consequence of the failure?”
- “If the operation fails, what will be the consequences at the local operation? At the next stage of operations? On downstream processing? At the plant level? At the system level? At the end user?”
- “Will the failure cause potential harm to equipment or operators?”
- “Will the failure cause potential violation of regulations?”
- “What would a failure mean to the system or the end user?”
- Any other questions that ensure the effects of failure are fully understood at the manufacturing level and at the system or end user.

**Causes** When identifying causes for System or Design FMEAs, the team can be asked questions such as:

- “How can the failure occur?”
- “What could cause the item to fail in this manner?”
- “What circumstances could cause the item to fail to perform its intended function?”
- “Why could the failure occur?”
- “What is the mechanism of failure?”
- “Are there possible system interactions, degradations, operating environments, customer usages, or design-for-manufacturing/assembly issues that could cause the failure?”
- For each cause identified, ask further “whys” in the direction of isolating root cause.

When identifying causes for Process FMEAs, the team can be asked questions such as:

- “How can the failure occur?”
- “What could cause the operation to fail in this manner?”
- “What significant process characteristics from the PFD worksheet could be potential causes?”
- “What circumstances could cause the operation to fail to perform its intended function?”
- “Why could the failure occur?”
- “Are there possible equipment, methods, material, supplier parts, operator, or environment issues that could cause the failure?”
- For each cause identified, ask further “whys” in the direction of isolating root cause.

**Controls** When identifying prevention-type design controls for System or Design FMEAs, the team can be asked questions such as:

- “What is already in place that could possibly prevent the cause?”
- “What is not in place yet but is currently planned that could possibly prevent the cause?”
- “What design guidelines, design standards, use of field lessons learned, or other prevention-type tasks are planned or already in place that could prevent the cause?”

When identifying detection-type design controls for System or Design FMEAs, the team can be asked questions such as:

- “What is already in place that could possibly detect the cause?”
- “What is not in place yet but is currently planned that could possibly detect the cause?”
- “What tests, analyses, or other analytical or physical tasks are already in place or currently planned that could detect the cause before launch?”

When identifying prevention-type process controls for Process FMEAs, the team can be asked questions such as:

- “What is already in place that could possibly prevent the cause?”
- “What is not in place yet but is currently planned that could possibly prevent the cause?”
- “What design error proofing, process error proofing, operator instructions, equipment controls, preventive maintenance (PM), or other prevention-type tasks are planned or already in place that could prevent the cause?”

When identifying detection-type process controls for Process FMEAs, the team can be asked questions such as:

- “What is already in place that could possibly detect the cause?”
- “What is not in place yet but is currently planned that could possibly detect the cause?”
- “What operator inspections, in-station error detection, end-of-line testing, measuring, gauging, or other detection-type tasks are already in place or currently planned that could detect the cause before the product leaves the plant?”

**Recommended Actions** When identifying recommended actions for System or Design FMEAs, the team can be asked questions such as:

- “What can be done to reduce severity to a safe level by modifying the design?”
- “Which of the ‘Action Strategies to Reduce *Severity Risk*’ should be recommended?”
- “How can the current design be made safer?”
- “If the product fails, how can the user be protected from potential harm or injury?”
- “What can be done to reduce likelihood of occurrence to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Occurrence Risk*’ should be recommended?”
- “How can the current design be made more robust?”
- “What can be done to reduce likelihood of detection to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Detection Risk*’ should be recommended?”
- “What tests or evaluation techniques need to be added or modified to improve detection capability?”
- “Are there any other actions that are needed to reduce risk to an acceptable level?”
- “If the recommended actions are implemented, will that be sufficient to address all high-severity and high-RPN risk?”

When identifying recommended actions for Process FMEAs, the team can be asked questions such as:

- “What can be done to reduce severity to a safe level by modifying the process?”
- “Which of the ‘Action Strategies to Reduce *Severity* Risk’ should be recommended?”
- “How can the current process be made safer?”
- “If the manufacturing or assembly operation fails, how can the operator be protected from potential harm or injury?”
- “What can be done to reduce likelihood of occurrence to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Occurrence* Risk’ should be recommended?”
- “How can the current operation be made more successful?”
- “What can be done to reduce likelihood of detection to a very low level?”
- “Which of the ‘Action Strategies to Reduce *Detection* Risk’ should be recommended?”
- “What process controls need to be added or modified to improve detection capability?”
- “Are there any other actions that are needed to reduce risk to an acceptable level?”
- “If the recommended actions are implemented, will that be sufficient to address all high-severity and high-RPN risk?”

## **D.5 FMEA Action Strategy Checklist**

Chapter 7, Section 7.3 describes action strategies to reduce risk. The succeeding sections are a summary of potential actions strategies that can be considered by FMEA teams.

### ***Summary of Action Strategies to Reduce Risk***

#### *Action Strategies to Reduce Severity Risk*

**DESIGN FOR FAIL-SAFE** A *fail-safe* design is one that, in the event of failure, responds in a way that will cause minimal harm to other devices or danger to personnel. Fail-safe does not mean that failure is improbable; rather, that a system’s design mitigates any unsafe consequences of failure. In FMEA language, fail-safe reduces the severity of the effect to a level that is safe.

**DESIGN FOR FAULT-TOLERANCE** A *fault-tolerant* design is a design that enables a system to continue operation, possibly at a reduced level (also known as “graceful degradation”), rather than failing completely, when some part of the system fails. In FMEA language, fault-tolerance reduces the severity of the effect to a level that is consistent with performance degradation.

**DESIGN FOR REDUNDANCY** A *redundant* design provides for the duplication of critical components of a system with the intention of increasing reliability of the system, usually in the case of a backup or fail-safe. This means having backup components that automatically “kick in” should one component fail. In FMEA language, redundant design can reduce the occurrence of *system* failure and reduce system severity to a safe level.

**PROVIDE EARLY WARNING** Failures that occur without warning are more dangerous than failures with warning. Catastrophic effects can be avoided by adding a warning device to system design. In FMEA language, adding early warning reduces the severity of the effect, potentially reduces the occurrence of system failure, and increases likelihood of detection of failure mode/cause during in-service usage.

#### Action Strategies to Reduce Occurrence Risk

As noted above, *redundant design* can reduce the occurrence of *system* failure.

Also noted above, an *early warning* device can reduce the occurrence of *system* failure.

**CHANGE THE DESIGN TO ELIMINATE THE FAILURE MODE OR CAUSE** It is possible to eliminate the failure mode or cause by changing the design of the product or the process. In FMEA language, eliminating the failure mode or cause will reduce the likelihood of occurrence to the lowest possible level.

**DESIGN FOR ROBUSTNESS AND OTHER DESIGN OPTIMIZATION TECHNIQUES** The objective of *Robust Design* is to optimize design parameters to make the product design less sensitive to the effects of variation that is present in the system's input variables and parameters. *Taguchi methods* are statistical methods using analysis of variance with the objective of identifying design factors responsible for degradation of performance. *Design of Experiments* is a technique for studying the factors that may affect a product or process in order to identify significant factors and optimize designs. All of these techniques are powerful strategies to improve the quality and reliability of products and processes. In FMEA language, Robust Design and other design optimization techniques improve performance and can significantly reduce the frequency of the cause of failure.

**REDUCE STRESS-STRENGTH INTERFERENCE** When product stress exceeds product strength (a condition called *stress-strength interference*), failures occur. There is *variation* in both the strength of a product and the stress that a product experiences during customer usage. Reducing variation in product strength, reducing variation in stress (how a product is used and the environment it experiences), and increasing the design margin between stress and strength will all reduce the stress-strength interference and the frequency of failure. In FMEA language, these strategies reduce the frequency of the cause of the failure mode. See the “Use a Factor of Safety” section directly below for more information on increasing design margins as an FMEA action strategy.

**USE PHYSICS-OF-FAILURE MODELING OF FAILURE MECHANISMS** Higher risk failure mechanisms can be analytically modeled to reduce failures and obtain an accurate advanced warning of impending failures. Chapter 15, Section 15.5, covers a type of FMEA called Failure Mode, Mechanism, and Effects Analysis (FMMEA) that prioritizes failure mechanisms for physics-of-failure modeling.

**USE A FACTOR OF SAFETY** One of the most effective action strategies to prevent failures is to design in a safety factor, also known as factor of safety. For structural applications, this is the ratio of the maximum stress that a structural part or other

piece of material can withstand to the maximum stress it is anticipated to experience in the use for which it is designed. Essentially, how much stronger the system is than it usually needs to be for an intended load. The greater the safety factor, the lower the likelihood of structural failure. In FMEA language, increasing the factor of safety reduces the frequency of the cause of the failure mode.

A similar approach, often applied to electrical parts, is called *derating*. Derating is a technique wherein devices are operated at less than their rated maximum power dissipation, taking into account the case/body temperature, the ambient temperature, and the type of cooling mechanism used. Derating increases the margin of safety between part design limits and applied stresses, thereby providing extra protection for the part. By applying derating in an electrical or electronic component, its degradation rate is reduced. The reliability and life expectancy are improved.

**CHANGE THE DESIGN TO REDUCE THE LIKELIHOOD OF OCCURRENCE OF THE CAUSE** The FMEA team can recommend changes to the design of the product or the process in order to reduce the likelihood of occurrence of the cause.

**CHANGE THE WAY THE PRODUCT OR PROCESS INTERACTS WITH THE ENVIRONMENT** The FMEA team can recommend changes in the way the product or process interacts with the environment, which can reduce the frequency of the cause of failure.

**CHANGE THE WAY THE USER INTERACTS WITH THE PRODUCT OR PROCESS** The FMEA team can recommend changes to the way the user or operator interacts with the product or process, which can reduce the frequency of the cause of failure.

**ERROR PROOF A PRODUCT DESIGN** It is possible to change the product design so that errors in manufacturing or assembly processing are reduced or eliminated.

**ERROR PROOF THE MANUFACTURING PROCESS** The manufacturing or assembly process can be changed so that processing errors are reduced or eliminated. In FMEA language, error proofing a product design or a manufacturing process reduces the frequency of the cause of the failure mode.

**ERROR PROOF THE PRODUCT USE** The operation of products or equipment can be designed so that unsafe operation is not possible.

**USE STATISTICAL PROCESS CONTROL TO MONITOR AND CONTROL MANUFACTURING PROCESSES** Statistical process control (SPC) is the application of statistical methods to measure and analyze the variation in manufacturing (or other) processes, with the objective of getting and keeping processes under control and producing conforming products. SPC will not improve a poorly designed product's reliability, but can be used to maintain the consistency of how the product is made. Properly used, SPC can significantly reduce defects in the manufacturing process.

### *Action Strategies to Reduce Detection Risk*

As noted above, adding an *early warning* device can increase the likelihood of detection of a failure mode/cause during in-service usage.

UTILIZE EXISTING DETECTION-TYPE CONTROLS TO INCREASE THE LIKELIHOOD OF DETECTION OF THE CAUSE The FMEA team may decide to utilize detection-type controls that already exist but were not currently used to detect the failure mode or cause being analyzed. If selected properly, the detection-type controls can increase the likelihood of detection of the cause of failure.

MODIFY EXISTING DETECTION-TYPE CONTROLS TO INCREASE THE LIKELIHOOD OF DETECTION OF THE CAUSE The FMEA team can recommend changes to the existing detection-type controls to increase the likelihood of detection of the cause.

DEVELOP NEW DETECTION-TYPE CONTROLS TO INCREASE THE LIKELIHOOD OF DETECTION OF THE CAUSE The FMEA team may decide to develop new detection-type controls that do not currently exist. In FMEA language, by adding the newly developed detection-type controls, the likelihood of detecting the cause of the failure can be increased.

USE IMPROVED TEST STRATEGIES, SUCH AS DEGRADATION TESTING, ACCELERATED TESTING, AND/OR TEST-TO-FAILURE The risk due to inadequate design controls can be reduced by changing the type of test. Traditional pass-fail testing introduces risk by not detecting or understanding the cause of failure. Where possible, it is important to test to failure and use degradation testing to understand the progression of failure. Strategies such as Highly Accelerated Life Testing (HALT), Accelerated Life Testing (ALT), and degradation testing can markedly improve detection risk.

#### *Common Action Strategy Mistakes to Avoid*

Knowing how to identify effective action strategies to reduce risk is important, but it is also essential to avoid the most common mistakes. Here are some of the more common mistakes that FMEA practitioners make when recommending actions to reduce risk.

USING A SINGLE ACTION TO ADDRESS HIGH RISK WHEN MULTIPLE ACTIONS ARE NEEDED In most cases, when addressing high risk, the FMEA team will need to identify more than one action strategy. The mistake is to rely on a single recommended action when trying to address high risk. This is applicable when the team is targeting one category of risk, such as frequency of occurrence, and it is certainly applicable when addressing multiple levels of risk (severity, occurrence, and/or detection.) The key is to use multiple effective actions when addressing high risk.

“HOBBY HORsing” ONE PARTICULAR ACTION STRATEGY Some practitioners or teams have a favorite strategy (called a “hobby horse”) that is recommended more often than appropriate. Even if this favorite strategy is very effective when applied to the right set of circumstances, it is not useful to apply it broadly as a solution when selection criteria are not met. Avoid “hobby horsing” a single action strategy.

FOCUSING ON ONLY ONE TYPE OF RISK Some teams tend to focus on only one of the three types of risk, such as detection risk. They end up recommending many changes to testing regimens, for example, but miss the opportunity to reduce severity or occurrence risk, and make designs more robust. FMEA teams should review the

actions being recommended and ensure they are reducing all three types of risk, as needed.

**ACTIONS THAT ARE UNSPECIFIC** FMEA teams can develop the right action strategy during team meetings and yet document the recommended action verbiage too generally. They may have the right concept in mind, yet fail to identify the specific actions to implement the concept. Refer to Section 7.5 for guidelines on writing effective actions.

**TAMPERING** Variation is present in all natural systems. The challenge is to differentiate between variations due to “common causes” versus “special causes.” The differentiation requires knowledge of SPCs and control charts, which is why it is essential to have a quality or reliability expert as part of the FMEA team. Dr. W. Edwards Deming cautioned against tampering with systems that are “in control,” which increases variation.

The field of quality control teaches the correct use of control charts in achieving stable and capable manufacturing processes. Process FMEA teams should familiarize themselves with quality control resources and ensure they recommend effective strategies to improve manufacturing process and avoid tampering.

## D.6 FMEA Quality Audit Procedure

Chapter 9, Section 9.1, outlines the 10 most common FMEA mistakes and the corresponding quality objectives, along with how to audit each quality objective. The next section summarizes the FMEA quality audit procedure.

**FMEA Quality Audit Procedure** The FMEA quality audit procedure is an essential part of ensuring good quality FMEAs. FMEA quality audits are in-person audits of completed (or nearly completed) FMEAs, done with the FMEA facilitator and the FMEA core team present. The audit can be done on a prescheduled or random basis. Someone who is skilled and experienced with the content and quality of good FMEAs performs the audit, from either management or an FMEA subject-matter expert. Here is the procedure.

Each of the 10 FMEA Quality Objectives have a corresponding “How to Audit” recommendation. In a nutshell, an FMEA subject-matter expert or management person reviews the FMEA results with the FMEA team against each of the FMEA Quality Objectives, one by one, using the “How to Audit” recommendation. Each quality objective is evaluated for how well it is achieved. This evaluation can be done on a yes/no basis or a variable evaluation, such as high, medium, or low. The estimated time is 1 hour for this audit, about 5 minutes per FMEA Quality Objective. The results of the audit provide valuable feedback to improve future FMEAs. The focus is on improving the FMEA process, not on the person or team doing the FMEA. The auditor is looking for specific process-related issues that underlie deficiencies in achieving the quality objectives, such as lack of training, procedure, facilitation skills, standards, resources, support, and so on. Action items from the FMEA quality audit should be documented and pursued to improve the overall FMEA process. Do not expect to achieve all 10 FMEA quality objectives instantly. Rather, work to maintain steady improvement.

## FMEA 10 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.
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” from where it can most effectively impact the product or process design.
8. *Team.* The right people are adequately trained in the procedure and participate in 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.

### Mistake #1

*Failure of the FMEA to drive design or process improvements.*

### Quality Objective #1

*The FMEA drives product design or process improvements as the primary objective*

*How to Audit:* Look at the recommended actions and observe whether or not most of them drive design improvements (in the case of a System or Design FMEA) or process improvements (in the case of a Process FMEA). Talk with the team to ensure focus was on improvements to design or process.

### Mistake #2

*Failure of the FMEA to address all high-risk failure modes.*

### Quality Objective #2

*The FMEA addresses all high-risk failure modes with effective and executable action plans.*

*How to Audit:* Review high severity and high RPN issues to see if the corresponding recommended actions are adequate to reduce risk to an acceptable level. Talk with the team to ensure they are satisfied all high risk is addressed and no important concerns are left unaddressed. One way to do this is to ask the subject-matter experts for their two or three biggest concerns on the project, and then to verify that these concerns are adequately addressed in the body of the FMEA.

**Mistake #3**

*Failure of the FMEA to improve Test/Control Plans.*

**Quality Objective #3**

*The Design Verification Plan (DVP) or the Process Control Plan (PCP) consider the failure modes from the FMEA.*

*How to Audit:* Review the recommended actions to see if there are improvements to the Design Verification Plans or procedures, or the Process Control Plans, based on risk associated with current detection controls. Talk with the team to determine if they had adequate representation from testing and if the FMEA benefited from the testing experience, and to learn whether the test regimens were improved if the current detection controls were not adequate.

**Mistake #4**

*Not including interfaces or integration in FMEA.*

**Quality Objective #4**

*The FMEA scope includes integration and interface failure modes in both block diagram and analysis.*

*How to Audit:* Review items, functions, failure modes, and other portions of the FMEA to ensure that interface and integration issues were taken up and addressed within the scope of the FMEA. Look at the FMEA Block Diagram to verify. Talk with the team inquiring how they ensured no interface issues were missed.

**Mistake #5**

*Disconnect between FMEA and information from the field.*

**Quality Objective #5**

*The FMEA considers all major “lessons learned” (such as high warranty, campaigns, etc.) as input to Failure Mode identification.*

*How to Audit:* Review failure modes and causes to ensure that they contain supplemental field failure data. Preferably, there is a visual way to see which failure modes are from field information and how they are addressed. Talk with the FMEA team to ensure that the FMEA benefited from field lessons learned and that high-risk issues from the field will not be repeated.

**Mistake #6**

*Wrong level of detail in the analysis.*

**Quality Objective #6**

*The FMEA provides the correct level of detail in order to get to root causes and effective actions.*

*How to Audit:* Verify that the level of detail on higher risk issues is adequate to fully understand root causes and develop effective corrective actions. Review the different columns of the FMEA to see if the overall level of detail is proper and adequate. Too much detail shows up as endless pages of FMEA material, including areas that no one on the FMEA team is concerned about; too little detail shows up as underdefined functions, failure modes, effects, causes or controls, or

as areas of unaddressed concern from one or more FMEA team members. Talk with the FMEA team to determine how they addressed the level of detail and ensured all concerns were included in the scope of the FMEA project.

### **Mistake #7**

*Performing FMEAs late.*

### **Quality Objective #7**

*The FMEA is completed during the “window of opportunity” from where it can most effectively impact the product or process design.*

*How to Audit:* Review the timing of the FMEA project against the product development process timing gates. Verify the FMEA was started and completed in the proper time frame for ensuring maximum value.

### **Mistake #8**

*FMEAs with inadequate team composition and lack of participation.*

### **Quality Objective #8**

*The right people, adequately trained in the procedure, participate in the FMEA team throughout the analysis.*

*How to Audit:* Review the FMEA team membership roster to ensure that there was adequate representation from the various disciplines needed based on the type of FMEA and the scope of the project. Check FMEA team meeting records to ensure attendance was adequate at each meeting. Talk with the individual team members to see if their input was elicited in the decisions.

### **Mistake #9**

*FMEAs with improper procedure.*

### **Quality Objective #9**

*The FMEA document is completed “by the book,” including “Action Taken” and final risk assessment.*

*How to Audit:* Look at the FMEA to see if the various columns were properly filled out and that FMEA best practice procedure was followed. Talk with the FMEA team to ensure they rigorously followed FMEA guidelines and practices.

### **Mistake #10**

*Inefficient use of time.*

### **Quality Objective #10**

*Time spent by the FMEA team is an effective and efficient use of time with a value-added result.*

*How to Audit:* Talk with the FMEA team to see if each member believes his time was well spent and a value-added result was achieved. If any issues arise, find out why.

## D.7 FMEA Quality Survey Form

Chapter 11, Section 11.3.3, describes an FMEA quality survey that can be used to assess the quality of current FMEAs in order to improve the quality of future FMEAs. The succeeding section presents the FMEA Quality Survey Form.

### FMEA Quality Survey Form

FMEA Number \_\_\_\_\_ FMEA Description \_\_\_\_\_ FMEA Date \_\_\_\_\_

FMEA Team \_\_\_\_\_

Survey Respondent Name \_\_\_\_\_ Survey Date \_\_\_\_ Department/Program \_\_\_\_\_

Please answer honestly how well the above FMEA achieved each of the following 10 quality objectives. Answer on a scale of 1–5, where 1 is the lowest score (quality objective not achieved at all) and 5 is the highest score (quality objective fully achieved). Answers will be kept confidential.

- The FMEA drives product design or process improvements as the primary objective
- The FMEA addresses all high-risk failure modes with effective and executable action plans
- The Design Verification Plan (DVP) or the Process Control Plan (PCP) considers the failure modes from the FMEA
- The FMEA scope includes integration and interface failure modes in both block diagram and analysis
- The FMEA considers all major “lessons learned” (such as high warranty, campaigns, etc.) as input to failure mode identification
- The FMEA provides the correct level of detail in order to get to root causes and effective actions
- The FMEA is completed during the “window of opportunity” where it can most effectively impact the product or process design
- The right people participate on the FMEA team throughout the analysis and are adequately trained in the procedure
- The FMEA document is completely filled out “by the book,” including “Action Taken” and final risk assessment
- The time spent by the FMEA team is an effective and efficient use of time with a value added result

Average score \_\_\_\_\_ (completed by survey coordinator)

Please add any comments on how the FMEA process can be improved in the future \_\_\_\_\_

---

## APPENDIX E FMEA GLOSSARY

Every effort has been made to define technical terms as they arise in each chapter. In addition, some of the chapters have a glossary of terms relating to the chapter topics. Chapter 3, Section 3.7, has a glossary of basic FMEA terms. Chapter 13, Section 13.8, has a glossary of DRBFM terms. Chapter 14, Section 14.7, has a glossary of Fault Tree Analysis terms. Chapter 15, Section 15.1.6, has a glossary of RCM terms. Finally, Chapter 15, Section 15.2.4 has a glossary of Hazard Analysis terms. As an aid to FMEA teams, this section is a reprint of the basic FMEA terms from Chapter 3.

### FMEA Glossary of Terms

#### **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.

#### **FMECA**

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. Chapter 12 fully explains Criticality Analysis, along with the FMECA procedure. 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.

#### **Types of FMEAs**

The three most common types of FMEAs are:

*System FMEA* This 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 FMEA, the focus is on functions and relationships that are *unique* to the system as a whole (i.e., do not exist at lower levels). The System-level FMEA includes failure modes associated with interfaces and interactions in addition to considering single-point failures. Some practitioners separate out human interaction and service into their own respective FMEAs.

*Design FMEA* This 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* This 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.

Some other types of FMEAs include:

*Concept FMEA* This is a short version of FMEA to aid in selecting optimum concept alternatives or to determine changes to system design specifications. All potential failure modes and effects of each proposed concept are considered before proceeding with actual design.

*Reliability-Centered Maintenance (RCM)* This is an analytical process used to determine Preventive Maintenance (PM) requirements and identify the need to take other actions that are warranted to ensure safe and cost-effective operations of a system. The core of an RCM project is an FMEA on selected manufacturing or operational equipment, with additional unique actions that ensure the equipment is safe and reliable in service.

*Software FMEA* This applies to software systems in which software controls the hardware. In Software FMEA, the focus is on identifying system weaknesses through software flow charts so that software specifications can be made comprehensive and unambiguous. The goals are to (1) determine whether the software is fault tolerant with respect to hardware failures and (2) identify missing requirements in the system specification.

*Hazard Analysis* This is the process of examining a system throughout its life cycle to identify inherent safety-related risks. The System Hazard Analysis focuses on identifying potential hazards associated with the use of a product, estimating and evaluating the risks, controlling the risks, and monitoring the effectiveness of the controls.

*Human Factors FMEA* This is a type of system FMEA where the focus is on the interaction between users (humans) and equipment. Sometimes this type of FMEA is integrated with the System FMEA in which the scope of the System FMEA includes human interaction.

*Service FMEA* This is a type of system FMEA where the focus is on the installation or service of equipment during operation. Sometimes this type of FMEA is integrated with the System FMEA in which the scope of the System FMEA includes equipment installation and service.

*Business Process FMEA* This focuses on the steps of a business process and on how to minimize inefficiencies by improving workflow, organizational management, and decision making. It follows a similar format to a Process FMEA, with the exception that the steps of the business process replace the operations of the manufacturing or assembly process.

*Failure Modes, Mechanisms, and Effects Analysis* (FMMEA) FMMEA is a systematic methodology to identify potential failure mechanisms and models for all potential failures modes, and to prioritize failure mechanisms. FMMEA enhances the value of the FMEA and FMECA methods by identifying high priority failure mechanisms in order to create an action plan to mitigate their effects.

*Failure Modes, Effects and Diagnostic Analysis* (FMEDA). This is an extension of FMEA with a more systematic way to identify and evaluate the effects of component failure modes. This technique generates failure rates for safety-related effect categories (e.g., failed safe, detected; failed safe, undetected; failed dangerous, detected; failed dangerous, undetected).

### FMEA Worksheet Definitions

The definitions are presented in sequence of their position in FMEA Worksheets.

*Item* 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* 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; wording should consider “Do this [operation] to this [the part] with this [the tooling]” along with any needed requirement. There may be many functions for each item or operation.

*Failure Mode* The manner in which the item or operation fails to meet or deliver the intended function and its requirements. Depending on the definition of failure established by the analysis team, failure modes 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. There may be many failure modes for each function.

*Effect* The consequence of the failure on the system or end user. For Process FMEAs, the team should consider the effect of the failure at the manufacturing or assembly level, as well as at the system or end user. There can be more than one effect for each failure mode. However, in most applications the FMEA team will use the most serious of the end effects for the analysis.

*Severity* 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 and is determined without regard to the likelihood of occurrence or detection.

*Cause* 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 (or source of variation) that results

in the failure mode. In most applications, particularly at the component level, the cause is taken to the level of failure mechanism. By definition, if a cause occurs, the corresponding failure mode occurs. There can be many causes for each failure mode.

**Occurrence** 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, the occurrence ranking considers the likelihood of occurrence during the design life of the product. For Process FMEAs the occurrence ranking considers the likelihood of occurrence during production. It is based on the criteria from the corresponding occurrence scale. The occurrence ranking has a relative meaning rather than an absolute value and is determined without regard to the severity or likelihood of detection.

**Controls** The methods or actions *currently* planned, or that 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 Design Controls** The methods or actions *currently* planned that describe how a cause, failure mode, or effect in the product design is *prevented*. They are intended to reduce the likelihood that the problem will occur, and are used as input to the occurrence ranking.

**Detection-Type Design Controls** The methods or actions *currently* planned that describe how a failure mode or cause in the product design is *detected*, before the product design is released to production. They are used as input to the detection ranking. Detection controls are intended to increase the likelihood that the problem will be detected before it reaches the end user.

**Prevention-Type Process Controls** The methods or actions *currently* planned that describe how a cause, failure mode, or effect in the manufacturing or assembly process is *prevented*. They are intended to reduce the likelihood that the problem will occur, and are used as input to the occurrence ranking.

**Detection-Type Process Controls** The methods or actions *currently* planned that describe how a failure mode or cause in the manufacturing or assembly process is *detected*. They are intended to increase the likelihood that the problem will be detected before the item is shipped from the manufacturing or assembly plant, and are used as an input to the detection ranking.

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

**RPN** RPN is an acronym that stands for “Risk Priority Number.” It 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.

**Recommended Actions** The tasks recommended by the FMEA team that can be performed to reduce or eliminate the risk associated with potential cause

of failure. Recommended Actions should consider the existing controls, the relative importance (prioritization) of the issue, and the cost and effectiveness of the corrective action. There can be many recommended actions for each cause.

*Action Taken* The specific action that is implemented to reduce risk to an acceptable level. It should correlate to the recommended action and is assessed as to effectiveness by a revised severity, occurrence, detection ranking, and corresponding revised RPN.

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