Chapter 1

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.[1]

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

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.[2]

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.[3]

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.[4]

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.[5]

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

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.

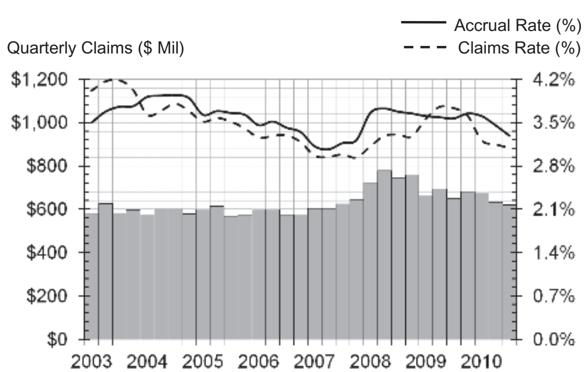

***FIGURE 1.1** Hewlett-Packard warranty claims and accruals 2003–2010.*
(Source: Warranty Week from SEC data.)

		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%
	TOTAL	**$15,688**	

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.[7]

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.[8]

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.[9]

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.[10]

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 organizations 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."[11]

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

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.[13, 14]

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.[15]

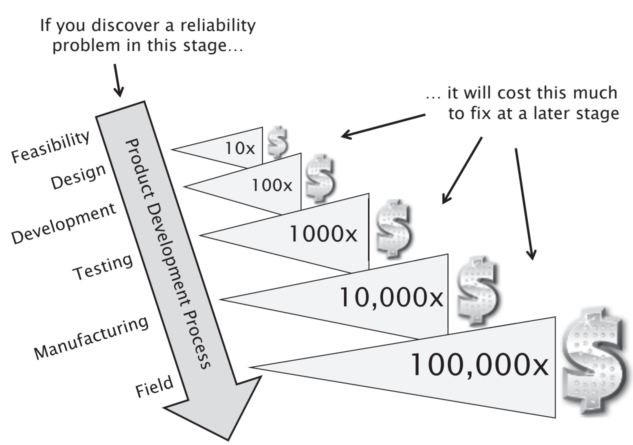

FIGURE 1.3 *Factor of 10 rule.*

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

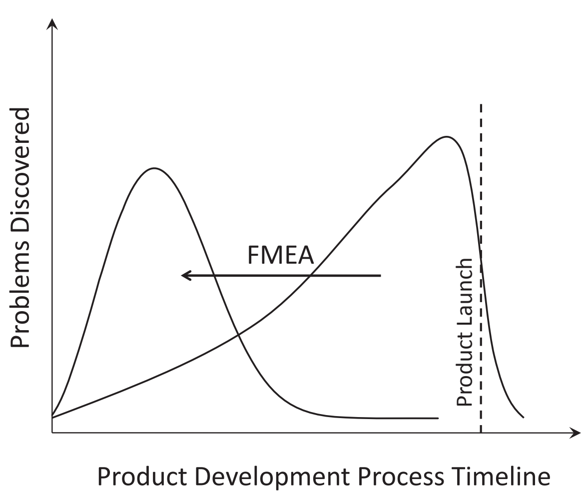

FIGURE 1.4 *FMEA shifts problem discovery earlier in the product development process.*

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."[16] 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."[17]

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.

REFERENCES

1. Fried, Ina. *Microsoft to Extend Xbox 360 Warranty, Take 1$ Billion Hit* [Online] 2007. Available at http://news.cnet.com/Microsoft-to-extend-Xbox-360-warranty%2C-take-1-billion-hit/2100-1014_3-6195058.html?tag=contentMain;contentBody;1n, Article date July 5, 2007 CNET News.
2. *PC Notebook Computer Batteries Recalled Due to Fire and Burn Hazard*. Available at http://www.cpsc.gov/cpscpub/prerel/prhtml09/09035.html, Bulletin date October 30, 2008; Release #09-035, U.S. Consumer Product Safety Commission.
3. *Firestone Tires Recalled*. [Online] 2000. Available at http://money.cnn.com/2000/08/09/news/firestone_recall/, Article date August 9, 2000, CNN Money.
4. *Yamaha Recalls Snowmobiles Due to Loss of Steering Control*. Available at http://www.cpsc.gov/cpscpub/prerel/prhtml10/10719.html, Bulletin date January 27, 2010; Alert #10-719, U.S. Consumer Product Safety Commission.
5. *Computer Warranty Claims and Accruals*. Product Warranty Series [Online] 2010. Available at http://www.warrantyweek.com/archive/ww20100916.html, Warranty Week, based on SEC data.
6. *Warranty Claims & Accruals in Financial Statements.* [Online] 2011. Available at http://www.warrantyweek.com/, Warranty Week, based on SEC data.
7. Carlson, Carl, Georgios Sarakakis, David Groebel, and Adamantios Mettas, 2010, Best Practices for Effective Reliability Program Plans, in Reliability and Maintainability Symposium.
8. ASQ. *Six Sigma Black Belt Certification* Certification [Online] 2011 [cited 2011]. Available at http://asq.org/certification/six-sigma/bok.html.
9. ISO, 2009, ISO/TS 16949 Quality Management Systems—Particular Requirements for the Application of ISO 9001:2008 for Automotive Production and Relevant Service Part Organizations.
10. AIAG, 2008, Advanced Product Quality Planning and Control Plan (APQP), AIAG.
11. JCR, *Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction*, 3rd ed. Joint Commission Resources, 2010.
12. ISO, 2007, ISO 14791 Medical devices—Application of Risk Management to Medical Devices.
13. Military, United States, 1980, MIL-STD-1629A: Procedures for Performing A Failure Mode Effects And Criticality Analysis, Department of Defense.
14. SAE, 2001, SAE ARP5580: Recommended Failure Mode and Effects Analysis (FMEA) Practices for Non-Automotive Applications, copyright 2001 SAE International.
15. DFR Fundamentals: An Introduction to Design for Reliability. 2007. ReliaSoft Corporation.RS 560 DFR Fundamentals, Copyright ReliaSoft Corporation.
16. Military, United States, 1949, Mil-P 1629 Procedures for Performing a Failure Mode Effect and Criticality Analysis.
17. Fadlovich, Erik. *Performing Failure Mode and Effect Analysis* [Online] 2007 [cited 2010]. Available at http://www.embeddedtechmag.com/component/content/article/6134, Embedded Technology.